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Good Practice in Legislation and Regulations for TB Control: An Indicator of Political Will

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I. SCOPE AND PURPOSE OF THE MODEL FOR GOOD PRACTICE

Recognising that the Tuberculosis (TB) epidemic was out of control in many parts of the world, in 1993, WHO declared a global emergency and pointed to the need to take prompt action to strengthen TB programmes globally. Following intensive research by several agencies and institutions in many countries, in 1997 WHO packaged the most effective and internationally accepted treatment strategy for TB and promoted it as the DOTS strategy which has been field tested by WHO and the IUATLD, and proven to be the most successful approach for tackling TB.

Dr Gro Harlem Brundtland, the Director General of WHO, invited in 1998 participation in a new Stop TB Initiative to catalyse a global coalition of partners from all sectors of society, to address the problem of TB and encourage the use of DOTS more widely. The Stop TB Initiative marks a crossroads in TB control and we must use all the tools that we have.

Health legislation is an effective tool to implement public health goals. A focus of the Stop TB Initiative is to address ways to strengthen health legislation and regulation in order to better support the vital efforts to strengthen tuberculosis prevention and control. A crucial expression of political will is to have in place up-to-date legislation on communicable diseases control and, on the basis of that legislation, to adopt regulations which apply the principles and provisions of that legislation to TB control. The legislation and regulations together serve to support and sustain a dedicated public health strategy for TB control, exemplified by DOTS.

The overriding aim of legislative measures is to prevent the transmission of TB infection and the development of the disease following infection. But legislation and regulation must protect public health and as well safeguard the legal rights of individuals. This document offers guidance, based on current best practice, in the drafting of such legislation and regulations, placing them in the context of a comprehensive strategy of the political, health and social actions needed to strengthen TB prevention and control. The purpose is to encourage and facilitate the updating of legislation and regulations, particularly in countries with a high incidence of TB.

The document has been prepared on the basis that its main messages are relevant to all countries. Of course not all the provisions proposed will have the same importance or indeed applicability for all countries. It is for each country to interpret the document in the light of its unique circumstances.

A ‘good practice’ model for legislation and regulation is presented. The model respects, protects and fulfils international human rights principles and focuses on the components of TB prevention and control that are amenable to legislation and regulation. The full version of a Communicable Disease Control Act and the related TB Control Regulation are given in an Appendix to this document.

The model has been developed with an awareness of two factors:

First, countries not only have different health systems through which they implement policies, but they also have diverse legal traditions, resources and experience. Member States need flexibility to choose a legal strategy for a particular communicable disease, appropriate to their particular needs and circumstances.

Secondly, it is highly desirable to have a single set of legislative provisions which address all communicable diseases and then to draft regulations based on that legislation and which are specific to a given disease, in this case tuberculosis.

Member States are urged to consider how they can make use of this guidance, when reviewing and, if necessary, updating their own legislative and regulatory frameworks.

II. THE NEED AND OPPORTUNITY FOR TUBERCULOSIS CONTROL

Need and opportunity

Worldwide, TB is still the leading cause of adult death due to a single infectious agent. High mortality and morbidity are often the result of inadequate measures and neglect that have allowed TB control systems to deteriorate or even disappear in many parts of the world. Incorrectly conceptualized and poorly supervised programmes have contributed to an increase in the burden of the disease, as well as to the emergence of multi-drug resistant TB (MDR-TB).

If current control efforts are not dramatically improved and expanded about eight million new cases will emerge annually during the next few years. The majority of new cases will be in the 20-44 age group, those who are in their most productive years. Nearly two million of them will die annually, unless there is a radically improved response to the global problem. No country can afford to ignore the threat of the current TB epidemic to the health of its population and socio-economic development.

Even industrialised countries, especially those facing economic recession and socio-economic problems, have experienced alarming increases in TB. They have also found that treatment of MDR-TB cases is not only difficult and expensive but often fails. It is in the interest of industrialised countries to address the global problems and invest resources and expertise to provide support to TB control programmes in high prevalence countries

These past two decades the HIV epidemic has aggravated the problem; there has been an explosion of TB cases in HIV-endemic areas. HIV, by virtue of its immuno-suppressive nature, favours reactivation of latent TB infection in individuals, accelerating the breakdown from infection to disease. The ability of HIV to accelerate the onset of acute MDR-TB has serious implications for humanity.

The number of refugees and displaced persons in the world has increased nine fold in twenty years, inevitably contributing to the growth of TB. Tuberculosis thrives in conditions of poverty, mass migration, civil unrest, environmental degradation where large number of people are exposed to infectious diseases with little in the way of the most basic health care.

Inequality between rich and poor countries and rich and poor communities within countries; malnutrition, poor sanitation, homelessness; the living conditions that exist in many poor communities, overcrowded shelters and prisons; all these stand as acute reminders of social failures and contribute to the growth of TB.

Reversing the epidemic

Despite the gravity of the global problem, it is now within our grasp to contain and reverse the epidemic and ultimately to make it a near certainty that every TB patient treated will be cured. In 1997, WHO was able to announce the results of field tests of the DOTS strategy. Those results showed that the strategy could be used everywhere and could produce cure rates of 85% and more. According to a World Bank analysis, DOTS is one of the most cost effective disease control interventions, costing as little as US$ 10-15 per patient. However, with MRD-TB treatment the cost shoots upwards to US$ 2000. It is cheaper to treat patients right the first time; TB strains that are resistant to two or more of the most common drugs are hundred times more expensive to treat and often cannot be cured.

Regrettably, at this time, only 21% of all the estimated cases of infectious TB are treated under DOTS. But if sufficient human, financial and other resources are made available on a sustainable basis, and the implementation capacity to build up and maintain the control programme is put in place in each country, universal coverage of the populations of the "high burden" countries (which carry 80 % of the global TB burden) within five years is feasible. The majority of death and much of the suffering can be avoided at an affordable cost, taking priority steps, mobilising political support and using effective tools. Health legislation is one of them.

DOTS: Five critical elements

The success of the DOTS strategy depends on the implementation of a five-point package. These five critical elements work together to produce high cure rates and break the transmission cycle of the disease. These are:

- Government commitment to ensuring sustained, comprehensive tuberculosis control activities.
- Case detection by sputum smear microscopy among symptomatic patients self-reporting to health services.
- Standardised short-course chemotherapy using regimens of six to eight months, for at least all confirmed smear positive cases. Good case management includes directly observed therapy during the intensive phase for all new sputum smear-positive cases, the continuation phase of rifampicin-containing regimens and the whole re-treatment regimen.
- A regular, uninterrupted supply of all essential anti-tuberculosis drugs.
- A standardized recording and reporting system that allows assessment of case-finding and treatment results for each patient and of the tuberculosis contol programme's performance overall.

This strategy is an effective case management system that helps ensure that patients take quality anti-tuberculosis drugs, at the right dosage, for the appropriate length of time. It also minimizes the development of resistance by preventing treatment failure. The strategy can be integrated successfully within general health services to achieve widespread coverage.

DOTS does not require hospitalization or isolation, patients can remain in their homes and return to work in a few weeks.

III. THE ROLE OF LEGISLATION, REGULATION AND GUIDELINES IN TB CONTROL

Legislation expresses and formulates health policy

The purpose of every country's public policy is to secure and enhance the well-being of its citizens. In the field of health policy, the purpose can be expressed as to protect and promote the health of the population. One principal means of pursuing this purpose is the enactment of legislation and regulations.

Health legislation deals with healthy people as well as with sick people, with social interests as well as with individual concerns. Health legislation expresses and formulates health policy and provides a framework for its implementation. Health legislation is mainly determined by health policy and not the other way round.

Exactly how the process is carried forward depends on the circumstances of a particular country. When drawing up legislation the whole context of a country should be taken into account: its cultural and religious dimensions, social climate, educational level, financial resources, legal tradition and political philosophy. These country specific factors need to be understood in the context of basic human rights as these have been adopted by the international community and what are understood and accepted fundamental social values.

It may be unrealistic to expect the same form of legislative support throughout the world. In all countries, however, the basic goals are the same: to protect and advance the health of the population as a whole, while at the same time protecting basic human rights and social values.

Legislation supports the implementation of public health goals

Health legislation is a proven, effective tool in implementing public health goals. It is a statement of the importance society places on national health development goals which include the control of communicable diseases. Health legislation, health policy and public health programmes are interlocking elements of national health development.

Legislation sets the foundation for executive action

Health legislation provides the administrative basis for the development and management of health systems and programmes; it clarifies definitions, boundaries, responsibilities, eligibility, standards and other guidelines for action. Legislation and regulations made pursuant to the law give clear definition of duties and responsibilities at all levels and make provision for the human, technical and financial resources that are needed. There are necessary measures to support or make operational the various components of a TB control strategy.

Legislation also formulates rights and duties

Legislation intervenes to balance public interest and rights of the individual, to balance the interests of various groups in society, and to settle conflicts of interest between these groups. Health legislation has contributed much to the growing awareness that health and human rights are closely inter-linked. It serves to safeguard human rights in health care and in particular to protect the individual against social discrimination on the grounds of health status.

Good practice in legislation and regulation for tuberculosis control.

Considering the above role, a first and crucial expression of political will should be to have in place up-to-date legislation on communicable diseases control and, on the basis of that legislation, to adopt regulations which apply the principles and provisions of that legislation to TB control. The legislation and regulations together serve to support and sustain a dedicated public health strategy for TB control exemplified by DOTS. The scope and purpose can be defined as follows:

Scope and purpose of communicable diseases legislation

The scope of the Act should cover all communicable diseases and a distinction should be made between communicable diseases which are hazardous to public health and other infections.

Its purpose should be:

-To protect the population from communicable diseases by preventing their occurrence or spread;

-To ensure that health authorities and other authorities implement the measures necessary to control communicable diseases and to coordinate their efforts;

-To safeguard the rights of individuals who are affected by measures to control communicable diseases pursuant to the legislation.

The legislation should provide the legal basis for the implementation of the various measures proven to be of value in combating communicable diseases, and for the continuous and systematic prevention and control of outbreaks. These measures must be:

- Necessary to prevent the transmission of a disease;

- Justifiable from a medical point of view, and must not cause needless or unreasonable harm to those affected.

The voluntary participation of affected citizens should always be sought. Participation can be made compulsory if this is needed to prevent the spread of a communicable disease that is hazardous to public health. In extreme situations measures may be made compulsory. Such compulsory measures should be limitatively enumerated in the law, and provisions must be made for such decisions to be appealed in court.

Scope and purpose of tuberculosis control regulations

Within the overall objective of the TB control strategy, which is to reduce mortality and morbidity and transmission of the disease until it no longer poses a threat to public health, the purpose of the regulations is to prevent the transmission of infection and the development of disease following infection. TB Control Regulations include measures intended:

-To protect uninfected persons against TB infection;

-To detect cases of infectious TB as early as possible after the onset of symptoms and to initiate treatment

-To ensure that persons with active TB are given adequate treatment;

-To notify and report cases of TB;

-To perform screening to detect TB infection and disease among close contacts of index cases;

-To prevent the development of disseminated disease in children by offering BCG vaccination;

-To prevent the development of the disease by offering prophylactic treatment to certain groups of infected persons.

Regulation and the autonomy of the physician

Where legislation or regulations specify actions required of a physician during, or as a consequence of, their treatment of a patient or medical examination of an individual, these duties are imposed on grounds of protecting public health or ensuring public order.

Except where such duties are proposed, neither the principles for formulating legislation and regulations presented in this document, nor the models set out in the Appendices should be construed as intended to dictate a physician's clinical practice (i.e. the exercise of professional judgement in the treatment of an individual patient). Matters determining the nature of professional autonomy and any constraints on it will be covered by specific legislation and regulations governing the medical profession and the conduct of individual licensed practitioners in the country.

The significance of guidelines

Guidelines must be drawn up to be consistent with the legislation and regulations, and to facilitate their proper application to the intended benefit of individual patients and (in so far as they improve population protection against the disease) the general public.

Guidelines for good practice may be divided into two categories, mandatory and non-mandatory. Those which are formulated under regulations pursuant to a Communicable Disease Control Act are mandatory on the authorities responsible for TB control and, as

appropriate, on physicians and other healthcare providers. These are justified on grounds of public health and public order. The regulations also give a health ministry (or other designated competent body) authority to vary the guidelines to ensure that they reflect the up-to-date good practice and current knowledge.

These mandatory guidelines, drawn up and promulgated through legislation and regulation, need to be clearly distinguished from other, non-mandatory guidelines, whose primary purpose is to draw physicians' attention to methods of prevention and treatment which are of proven clinical efficacy and cost effectiveness. They are used to encourage physicians to apply the principles articulated in the guidelines when exercising their professional judgement in the interest of their patients

Relationships between public health officials and physicians practising in the private sector

In many countries the health care system has a pluralistic form with public, private and voluntary sector institutions providing services often side by side. Physicians may be employed in the public sector or work independently as self employed private practitioners.

It is in the nature of communicable diseases control programmes that statutory responsibilities are placed on public health officials employed by public authorities at different political and administrative levels. These responsibilities are those of ensuring that the relevant legislation, and regulations pursuant to that legislation (including mandatory guidelines to health care workers and others), are uniformly and universally complied with.

Their task may be more complex in those countries where the majority of physicians practising in local communities are private practitioners. They may well be diagnosing and treating the majority of TB patients, among people who consult them presenting symptoms.

Where this is the case, health ministries and other public agencies made responsible for communicable diseases control may need to review current arrangements and determine whether any changes are warranted.

The intent should be to create an effective partnership between private sector physicians and public health officials and to put in place systems and incentives that support the motivation of private practitioners (and private hospitals) to implement the guidelines for all their patients with infectious TB. An appropriate and mutually acceptable form of monitoring their performance needs to be in place.

IV. NORMATIVE PRINCIPLES AND VALUES THAT GOVERN PUBLIC ACTION

Normative principles that govern public action

To be sound, health legislation and regulation must be grounded in solid scientific and epidemiological evidence but it must also be based on the following normative principles:

Equality of treatment (before the law and public regulation): Prescriptions cannot be imposed arbitrarily on some people and not on others. If one is to request duties from one group and not from another, there must be strong and compelling reasons.

Relevance: Public action should be directly relevant to the policy objectives and the management of the problem to which the policy is addressed.

Proportionality: The duty which may be imposed must be commensurate with the benefit it brings. When considering a compulsory public health measure, it is necessary to weigh carefully the limitations which it would introduce in terms of human rights and liberties as compared with the advantages it is supposed to bring and the consequential damage of negligence or inaction.

Effectiveness: There must be a reasonable expectation that the provisions will result in effective action. It is not sufficient that a provision appears logical or has a scientific basis to be useful in reality.

Feasibility: It follows that all actions envisaged must be feasible, capable of being implemented in the real world given the actual cultural, social, political and material circumstances and constraints.

Social acceptability: The advocacy of morals is not a major role of the State, which usually only puts a halt to what clearly offends it. When dealing with communicable diseases, the authorities have to take into account what is socially acceptable in the community concerned.

Basic values in the foundations of public action

Health policy decisions are also considered with reference to basic values which motivate and constrain our actions. The following values, which are the cornerstones of healthcare systems, require careful consideration prior to effecting legislation concerning TB.

Respect for the person: Respect for the person is the most essential value in a society professing to adhere to the principles of human rights. It requires us to acknowledge and protect the dignity and autonomy of each individual. We must regard each individual's interests and aspirations as worthy of protection, except insofar as they violate the rights of others. The right to self-determination and privacy and the right to informed consent to medical treatment, flow from this principle.

Justice: Justice mandates that, in respecting persons, we must respect all persons equally. Equity in all our actions is required by the value of justice.

Beneficence: Beneficence is the value of doing good, of meeting the needs and interests of other persons. Our constant efforts to relieve suffering, to meet human needs, and to enhance the human condition are rooted in this value.

Non-maleficence: Similarly, we seek to advance the cause of mankind without causing harm along the way. The value of non-maleficence is also an aspect of our respect for persons. It permits limitations on an individual's liberty to pursue personal goals and choices, when others will be injured by those activities.

Responsibility: Because persons are autonomous agents worthy of respect, they also bear responsibility for their actions, in addition to enjoying fundamental human rights.

Thus, it is this set of rights, principles and values just outlined which provides the justification for the obligation placed on individuals to act in the interest of others in the control of communicable diseases.

V. LEGISLATIVE PRINCIPLES IN TUBERCULOSIS CONTROL

The following principles provide a basic framework of thought which should guide the formulation of legislation and regulation in support of tuberculosis prevention and control.

Legislation acknowledges and sustains a policy commitment to action.

Comprehensive legislation and regulation by the parliament or government makes the national commitment to action more public, resolute and solemn. It enables programmatic measures to prevent and control TB to be implemented effectively and efficiently.

Legislation has an important role in communicating government policy.

If the key elements of TB prevention and control programmes are set out clearly in a language that can be readily understood, legislation and regulations can then fulfil an important function in communicating government policy to the people. Indeed, long and complicated legislation is less likely to be understood and effectively enforced.

Comprehensive Communicable Diseases legislation facilitates inter-sectoral collaboration.

An important element of successful TB prevention and control is to secure cooperation between the various ministries and sectors of government. The Health Ministry has a vital and central role in TB prevention and control but it needs other sectors committed to supporting programme implementation.. Comprehensive communicable diseases legislation and TB regulations can help secure intersectoral collaborative support for TB prevention and control by placing appropriate obligations on other sectors' ministries and administrations. The consultation processes that precede new or amended legislation provide opportunities to seek, negotiate and secure such intersectoral collaboration.

Legislation should be regularly updated to reflect scientific knowledge and best practice.

Scientific knowledge and sound clinical and public health practice, all develop over time and are making continuous improvements. Legislation must take account of and be consistent with up-to-date scientific, clinical and public health knowledge of methods of TB prevention and control.

Legislation should remain appropriate to the circumstances of a particular country

Legislation is dependent on the resources of a country for its effective implementation. It should take into account its cultural and religious dimensions, social development, educational level, and financial resources. Moreover it should be tailored to the legal system and traditions of the country. Countries with scarce resources may need to implement priority systems to make the most effective us of those resources. Legislation may, therefore need to refer to the importance of having a priority system in place to give their due to major public health issues such as a comprehensive tuberculosis control strategy.

Legislation, bearing directly or indirectly on the TB control strategy, should be progressively reassessed.

Countries have legislation on health protection, and on communicable diseases as well as other legislation bearing on elements that would support TB programmes. Such existing legislation will need to be progressively assessed and evaluated. Both the continuing relevance and effectiveness of legislation itself and its implementation will need to be monitored and adapted as required to fit with programmes for TB prevention and control. Areas of legislation and regulation that may need to be assessed include those affecting: human resources for health, pharmaceuticals and pharmacological policy; social welfare, especially provision for the indigent and homeless; licensing and management of health and social care institutions; prisons and other correctional institutions; and other measures and provisions relating to health promotion and protection.

Legislation should be facilitative rather than coercive.

Voluntary measures respect the dignity and autonomy of the person and are resource efficient. Legislation should support and encourage the completion of therapy on a voluntary basis. This can best be achieved by appropriate, enabling and incentive measures. In particular it is necessary to make new provisions for health education, and the widest possible dissemination of information about TB and its treatment, including side effects of chemotherapy, counselling, and drawing up treatment plans jointly with the patient and their family. For instance, in communities and countries with a high incidence of TB, it is beneficial to make special efforts to disseminate simple, accurate information relating to TB/HIV co-infection; and, where feasible and affordable, to offer HIV testing and counselling in TB clinical settings and TB skin testing in HIV clinical settings.

In terms of enabling measures, the health services may need legislation that permits them to supply medicines and treatment free of charge and to have flexibility in the spending of budgets such as travel. This will give them easier access to patients in the home, workplace or elsewhere. They can also encourage patients to attend clinics or other treatment centres by providing meals and contributing to their travel costs, etc.

Where voluntary measures do not work, public health authorities need to be able to ensure compliance. Legislation should make provision for situations which range from voluntary to compulsory compliance. Compulsion must always be regarded as the action of last resort and respect the human rights of those affected .

Legislation should respect, protect and fulfil individual and social human rights and the rights of patients.

Health legislation is a tool to realize the right to health conceived in terms of health protection and access to health care. In this respect communicable diseases legislation should protect the health of the population by preventing the occurrence and spread of communicable diseases, ensure access to health care and to healthy living conditions to the population, and safeguard the individual and social rights of persons affected by measures to control communicable diseases.

Individual rights, of which patients' rights are part, aim at the protection of individual sphere and of individual liberty, they protect the dignity and integrity of the patient as a person. The question of patients' rights is central to the evolution of health legislation as the vulnerability

of the sick makes them easily subject to violation of their rights and more affected by shortcomings of social and health administrations. Rights and responsibilities of patients include: The right to autonomy and self-determination; to information, to informed consent; to confidentiality and privacy; to care and treatment; to non-discrimination. In addition to enjoying such rights, patients also bear responsibility to seek and get treatment, to abide with treatment, and the responsibility not to knowingly infect others.

Social rights, such as the right to health care, safeguard the participation of people in social goods, they require Governments to ensure an equitable distribution of social goods and a just participation of the individual in these goods. The right to health care aims at the quality and accessibility of health care, in financial as well as geographical terms. This approach is particularly relevant in the fight against TB which is no longer only a disease of the individual but above all a societal issue, particularly in the poorest countries.

Legislation should address international as well as national responses to the TB epidemic.

Although national legislation aims to achieve national self-sufficiency in TB management and containment, there should be legislative accommodation of regional or international collaboration. For example rather than expecting full national self-reliance there might be regional/international collaborative arrangements, particularly for smaller countries, that would give them the speed and reliability they need without having to build up national facilities from the ground.

A further international issue that national legislation might reflect is the one concerning movements of persons. It is acknowledged that tuberculosis in immigrants, refugees, displaced persons, cross-border populations, seasonal workers, visitors, students and those returning from countries that have a high incidence of TB is a major issue for TB control before, at, and after arrival. Current policies and strategies for the control of TB in these groups need to be evaluated on a priority basis to ensure they are effective. Strategies should be modified and/or developed as priority to effectively detect and prevent TB in these groups.

Legislation should support and recognize international solidarity in addressing the global TB epidemic. Accordingly legislation and voluntary agreements should allow industrialized countries to invest resources and expertise to provide support to TB control programmes in countries where the disease has a high prevalence.

VI. HUMAN RIGHTS IN LEGISLATION AND REGULATION FOR TUBERCULOSIS CONTROL

The synergy between health and human rights

The legislation should make explicit the synergy between health and human rights. The promotion of health requires the protection of human rights of vulnerable individuals and populations, because safeguarding human rights empowers individuals and enables them to take steps to improve their own health. This is especially important in respect of communicable diseases and in particular tuberculosis, for instance in encouraging self-reporting to health services and compliance with treatment.

The interaction between health and human rights is threefold: Firstly, vulnerability and the impact of ill health can be reduced by taking steps to respect, protect and fulfil human rights. Secondly, health policies and programmes can promote or violate human rights in the ways they are designed or implemented. Thirdly, violations or lack of attention to human rights can have serious health consequences.

There is a need to better take into account this mutually reinforcing linkage between the health and the human rights of populations; this offers a potential for new, creative ways to reduce the burden of tuberculosis in favour of disadvantaged groups by exploring how public health and human rights strategies can be synergized and embodied in policy, legislation and regulation for tuberculosis control.

The right to the highest attainable standard of health

The right to the highest attainable standard of health is a claim to a set of social arrangements - norms, institutions, laws, an enabling environment - that can best secure the enjoyment of this right. Other key human rights relevant to health include freedom from discrimination and the rights to participation, education, and information. Human rights are grounded in concrete governmental obligations and generate entitlements on individuals and groups with a particular emphasis on those considered most vulnerable.

The protection of human rights shall be one of the three main purposes of a Communicable Disease Control Act, together with the protection of the population from communicable diseases and the definition of public health responsibilities and requirements. The fulfilment of these three objectives forms part of the government's obligation to take steps to realize the right to the highest attainable standard of physical and mental health enshrined in both the Preamble of the WHO Constitution and in the International Covenant on Economic, Social and Cultural Rights that refer to measures necessary for the prevention, treatment and control of epidemic, endemic, occupational and other diseases.

The tension between public health and civil rights in communicable diseases legislation/TB regulations

Two distinct areas of human rights are protected under international law: civil and political rights on the one hand; and social, cultural, and economic rights on the other. Civil and political rights aim at the protection of the individual sphere and of individual liberty, they safeguard individuals from restraint, loss of freedom and discrimination whereas the goal of social rights is to safeguard a just participation of people in social goods. While individual rights are inherent to the individual as a human being, social rights, among which the right to health care are actually conditioned by the resources of a country.

In the field of tuberculosis control, the balance between individual civil rights and societal obligations is crucial when drawing up legislation which specify the circumstances in which it is permitted to apply involuntary measures. Communicable diseases legislation and TB regulations have intervened to mediate the tension between public health and individual civil rights. In this respect the role of communicable disease legislation consists in both defining and limiting Government authority to constrain, on behalf of public health, the civil rights of individuals.

It empowers the public health authorities:

- to test and screen;

- to require notification and reporting of cases;

- to mandate medical examinations, vaccinations, treatment;

- to isolate persons with infectious conditions;

- to trace and quarantine contacts.

For instance communicable diseases legislation and TB regulations:

- can limit the right to freedom of movement (in case of isolation or quarantine of an infectious person),

- can limit the right to autonomy and self-determination (in case of compulsory testing, screening, examination and treatment),

- can limit the right to privacy (in case of compulsory contact tracing or patient retrieval).

These are examples of restriction on rights that may be necessary for the public good and therefore can be considered legitimate under international human rights law.

Limiting human rights on grounds of public health

The law is a tool to both protect public health against tuberculosis and respect human dignity and rights, as stated in the objectives of the Communicable Diseases Control Act presented in Appendix 1. In fulfilling its duty to protect public health against a communicable disease hazardous to public health such as tuberculosis, the government may impose limitations on individual liberty. Where voluntary measures do not work, public health authorities need to be able to ensure compliance. Alone respect for human rights will not ensure public health; legislation should make provisions for situations which can range from voluntary to compulsory compliance. Compulsion must always be regarded as the action of last resort and respect the human rights of those affected. Before resorting to compulsion, therefore, Governments should ensure that public health measures comport with sound science, and comprise the least restrictive measures necessary to prevent and control TB.

Circumstances that limit human rights for Public Health purposes must be:

- Strictly provided by the law; (hence the importance of proper legislation)

- Neither arbitrary nor discriminatory;

- Based on objective considerations;

- Necessary to respond to a pressing public health need, (such as to prevent the transmission of TB and the development of the disease following infection).

- Proportional to this social aim;

- No more restrictive than necessary to achieve the intended purpose.

Even where such limitations on grounds of protecting public health are basically permitted, they should be of limited duration and subject to review. In this respect it is important that countries develop domestic legal standards of due process and equal protection.

Legislation should reach beyond the public health processes and beyond the civil rights concern, to also address the social welfare, social rights issues in the prevention and control of TB.

Human rights are broader than civil rights to be free from governmental restraint and discrimination. Individuals possess throughout their lives a set of positive entitlements to life, health, education and work. Under this positive human rights framework, governments have an obligation, within the constraints of their resources, to provide an environment conducive to the public's health and well-being. The specific responsibilities range from health promotion and disease prevention, to ensuring access to health care, basic housing and nutrition. Such economic, social and cultural rights manifest as powerful human rights concerns, particularly in vulnerable communities. Social rights should be better addressed in legislation and regulations for TB prevention and control.

To this aim, it is important that legislation embraces both non-discrimination but also affirmative efforts to correct inequities. A major public health and human rights issue in tuberculosis control is whether those who need, and want, treatment can actually get access to it. The legislation should adequately address the government's duty to put in place the prerequisites for successful treatment for all who need it. There is a need for a new balance in communicable diseases legislation and TB regulation to incorporate more positive, constructive, social and public health measures in order to better realize the right of access to health care. Legislation should reach beyond the medical processes and beyond the civil rights concerns to also address the social welfare and social rights issues in the prevention and control of tuberculosis.

In order to accomplish the overarching goal of facilitating access to successful tuberculosis treatment this document proposes the legislative strategy developed in the following section.

VII. LEGISLATION AS SUPPORT TO A COMPREHENSIVE TB CONTROL STRATEGY

Legislation and regulation do not stand alone, but need to be seen as essential supports to a comprehensive strategy of TB prevention and control. This section, which reflects WHO’s experience with DOTS, sets out the action required.

The global epidemic will only be contained and reversed if all countries make effective arrangements to provide standardised short-course chemotherapy (SCC) to, at least, all sputum smear positive TB patients. Effective treatment of cases with SCC cures the disease, prevents future transmission of TB bacilli and prevents the emergence of drug resistance, or, stated another way, **cure is the best prevention.**

Elements of an effective control strategy

The essential elements of the TB control strategy are valid in all situations both developing and developed. The elements of the expanded strategy may be appropriate in industrialized countries. An elaboration of the essentials of the strategy follows .

DOTS : the essential elements	Elements of an expanded DOTS strategy
Political commitment	Mobilisation of civil society
Case-finding with priority to detection of infectious patients by sputum smear microscopy of TB suspects presenting to general health services	Case-finding in high-risk groups, e.g. household and work contacts of an index case, occupational groups at risk. Rigorous contact tracing. Diagnostic methods other than smear microscopy and chest X-rays (e.g. routine culture for *M. tuberculosis*).
Standardised short-course treatment under direct observation for at least all smear-positive pulmonary TB cases (emphasis is on ensuring direct observation of and access to treatment rather than on patient motivation and contact tracing).	Preventive therapy (for all infected contacts of index cases). Use of professional outreach workers to ensure direct observation of treatment in the patient's home or chosen location. Possibility to tailor regimens when patients are found to fail standard SCC.
Secure drug supply	Second-line drugs for multi-drug resistant TB.
A surveillance and monitoring system allowing assessment of treatment results by using sputum smear microscopy.	Role of culture for *M. tuberculosis* in monitoring patient cure. Drug-resistance surveillance.

1. Political commitment

The commitment of governments to sustain TB control is one of the key components of the DOTS strategy; governments should make TB control a high political priority. The commitment should be manifest in national legislation and regulations relating to all aspects of a national TB control strategy, and in financial and technical support to national TB programmes.

1.1 Review of legislation and regulation

Providing for and protecting the health of the population requires a legal basis and strategy. Provisions that have been in force for very many years may need to be updated to reflect current public health approaches. Many of the older communicable disease laws pre-date modern methods of prevention and control. Legislation has also often been allowed to grow in a complex way, thus measures on TB control appear in various statutes but their relationship may not be clear nor effective.

There is a need to elaborate up-to-date laws on communicable diseases and regulations on TB. This will give greater impetus to sustained control efforts and make national legislation a more effective tool. The enactment of appropriate laws and regulations can support an effective national anti-TB strategy including the various components of modern TB programmes consistent with the public health strategy embodied in DOTS. Appropriate legislation and regulations help ensure that policies

and strategies aimed at controlling TB, are effective and sustainable. They must protect public health as well as safeguard the legal rights of individuals. At the same time they must give strong backing to programmes which produce results, through clear definition of duties and responsibilities at all levels: local, regional and national. It is essential that they also make provision for the human, technical and financial resources which are needed to do the job of preventing and curing TB.

An update of legislation and regulations would provide the opportunity to ensure that ethical, social and human rights aspects are fully integrated. An effort to consolidate legislative and regulatory measures should better support national TB policy and better inform health professionals and the public

Several Member States, with a long tradition of public health legislation, are already well along the way which will lead them to more useful and comprehensive set of legislation on communicable diseases. WHO is eager to support this trend in countries which still have to build the capacity, with less resources, to tackle often higher incidences of TB. There is a need to build the regulatory system to match the reality of TB today.

1.2 National TB control team

A national multidisciplinary TB control team should be established, responsible for all aspects of the national TB control strategy. Its expertise would cover all aspects of the management of TB and provide leadership and support to those working at regional and local levels. The responsibilities of the team (whether discharged directly or delegated to others) would include: policy development and the promulgation of strategic guidelines; programme planning; procurement and distribution of drugs and other supplies; monitoring and surveillance and preparation of periodic reports on progress with feed-back to all field workers; advocacy of the programme and securing adequate programme financing.

The team would prepare an authoritative programme manual for all workers. The manual would include an exposition of communicable diseases legislation and TB regulations and how they should be applied

1.3 National plan for TB control

A national TB control strategy, drawn up by the team, should specify clearly defined goals, targets and standards. These would constitute a national plan (a formalised national policy statement) to be periodically updated in the light of evaluation of results and changing circumstances. It should be adapted to the needs of the various areas of the country (in partnership with local communities), and integrated into the health system, in particular through the primary health care system. Each area of the country should be responsible for ensuring that its TB control programme achieves agreed upon national standards.

1.4 Allocation and use of resources

Financial provisions for the TB prevention and control strategy must include funds for drugs, network of laboratories, transportation, financial aid to patients, patient monitoring, regular training and supervision of health workers, etc.

In any situation in which MDR-TB is identified, a medical TB expert must be consulted . If necessary, an expert advisory panel should be convened to examine the case and may propose a

strategy to those responsible for TB control at national level, particularly when second-line drugs are to be used.

Explicit provision must be made to train health professionals, i.e. laboratory technicians and health staff in charge of diagnosis and treatment of TB cases. (WHO strongly advocates use of its standard training course on the management of TB). There must be sufficient laboratory facilities for proper case detection and monitoring of treatment results.

Support must be given for advocacy and social mobilisation as core activities (mobilisation of civil society support: associations of pneumologists, associations of patients, school education clubs).

1.5 International cooperation and solidarity

Activities of international cooperation in communicable diseases control should be regularly reviewed and changes made or negotiated where warranted. In particular this includes multi- and bilateral agreements which support or enable the comprehensive strategy of TB control to be implemented.

Although the aim of most countries will be to secure national self sufficiency in the human and technical resources necessary for its strategy, it may be that in some situations, at least for an interim period, there could be regional (inter-country) agreements for shared use of certain resources or facilities

2. Case finding

2.1 Diagnosis of infectious TB of symptomatic patients self-reporting to health services should be by sputum smear microscopy.

2.2 When necessary such patients should be referred to appropriate health facilities where sputum smear microscopy is available, for confirmation of diagnosis.

2.3 There should be universal adherence to a uniform definition of a notifiable case of TB.

2.4 All cases of TB, particularly pulmonary ones, should be reported to the appropriate local public health officials as soon as the patient is diagnosed. Regulations should specify persons required to report cases of TB, the time-frame for reporting and the consequences and sanctions to be invoked in cases of failure to report cases of TB. In this context, 'diagnosed' is defined as confirmation based on laboratory evidence (e.g. sputum smear and/or culture positive) or diagnosed by a physician.

2.5 Contact tracing should be initiated as soon as possible after the case is reported, assessing all contacts of smear-positive cases and offering preventive therapy when necessary.

2.6 All cases found to be positive by laboratories performing smear or culture for *M. tuberculosis* should be directly reported to public health authorities, thus enabling those authorities to cross-check these reported cases with reports by practitioners and ensure that all cases are notified.

2.7 While proper attention must be paid to issues of security and confidentiality, all cases must be reported to the appropriate public health authorities by physicians, other healthcare workers and laboratories.

2.8 Relevant demographic information must be generated to identify risk category, bacteriologic diagnosis and to monitor the TB control situation.

2.9 The clinical and control aspects of TB control strategy must be part of the core curriculum in the training of health professionals (e.g. physicians, nurses, paramedics), as well as being included in continuing medical/nursing education programmes.

2.10 Tuberculosis in immigrants, refugees, cross-border populations, visitors, students and those returning from countries that have a high incidence of TB is a major issue for TB control .Current strategies for the control of TB in these groups, specifically case-finding, need to be evaluated and modified or developed to ensure that they are effective.

3. Treatment

3.1 Standardised short-course chemotherapy must be provided to at least all confirmed sputum smear positive cases of TB, under proper case management conditions.

3.2 Proper case management conditions include direct observation of drug administration by an authorised health worker or a properly trained person in the community.

3.3 Patient compliance must be ensured by direct observation of recommended short-course chemotherapy with 4 or 5 drugs in the initial phase (2-3 months). In the continuation phase, to ensure that the patient undergoes a full course of treatment (4-6 months) to avoid relapse, there must be intermitted drug administration under observation or regular monitoring of treatment, at least on a monthly basis.

3.4 Adequately trained personnel must be available in all facilities and adequately supported to deliver TB control programmes.

3.5 Every case of active TB must have an assigned treatment observer, suitably trained and responsible for patient and following the treatment, especially monitoring compliance with treatment and checking for drug toxicity.

3.6 Patient and family education and counselling must be provided in all cases.

3.7 All hospitalised pulmonary cases must be managed according to agreed guidelines.

3.8 Any facility undertaking hospitalization must ensure effective control and administrative measures to prevent nosocomial transmission of TB.

3.9 In any situation in which MDR-TB is identified the person should be referred to a special institution/agency capable of dealing with MDR-TB .

3.10 Chemoprophylaxis (preventive treatment) should be offered to all contacts of active cases who are under five years of age and found without active TB.

3.11 Voluntary testing and counselling and chemoprophylaxis should be offered to groups of individuals at increased risk for the development of active TB, in particular those with other immuno-compromising medical conditions such as HIV.

3.12 Isoniazid prophylaxis must be continued for 6 to 12 months, with monthly monitoring for drug toxicity.

3.13 BCG is recommended as early in life as possible. An immunisation system must be in place to ensure prevention of the serious forms of TB in early childhood.

3.14 Issues of patients not adhering to prescribed treatment must be addressed. Possible responses include: identification and reporting of patients not adhering to prescribed treatment (unable or unwilling) and determining reasons for non-adherence; providing incentives and enablers to patients; instructions given to patients; application for isolation of patient for inpatient management (place, duration); authorised order; admission of the patient; right of appeal; court decisions; measures during isolation; suspension or early termination of isolation.

4. Secure drug supply

4.1 A system of regular supply of all essential anti-TB drugs must be established, ensuring good quality of the drugs.

4.2 A fixed dose combination of drugs must be available and supplied to patients

4.3 Drug procurement and the timely delivery of drugs must be properly planned.

4.4 There must be a sufficient buffer stock of TB drugs at every level.

4.5 TB drugs should be supplied free of charge to patients.

4.6 Records of drug management at local, regional and national levels must be maintained.

4.7 There must be systems established for ensuring the quality of TB drugs including procedures to control batch of TB drugs and to identify counterfeit drugs.

4.8 Envisage the regulation of the drug supply for TB through the public health system only.

4.9 TB drugs must be registered with the national drug regulatory authority.

5. Monitoring and accountability of programme supervision and evaluation of treatment

5.1 Measures should be taken to institute a comprehensive, national surveillance system for TB, as part of the regular health information system.

5.2 Recording and reporting system for programme supervision and evaluation of treatment outcome for each patient diagnosed should be established and maintained. It should include a laboratory registry, patient treatment card, and a TB register at district level.

5.3 Measures should be taken to ensure maintenance of confidentiality

5.4 There should be a laboratory to provide and coordinate services, such as the full range of required proficiency testing, quality control and standardisation .

5.5 Measures should be taken to ensure quality improvement in laboratory, public health and clinical settings through adequate supervision, work evaluation and outcome assessment.

5.6 Systematic reporting of treatment results with cohort analysis; aggregating data and analysis should be introduced universally at local, regional and national levels. The relevant feedback should also be systematically provided.

VIII. ESSENTIAL ELEMENTS IN A COMMUNICABLE DISEASES CONTROL ACT

A developed model of a Communicable Diseases Control Act is given in Appendix 1. Essential issues to be covered are presented in this section. These should be read in conjunction with the principles elaborated in the previous sections.

Scope of the Act

The Act should cover **all communicable diseases** which can be transmitted from man to man or from animals or environmental sources to man. A distinction should be made between **communicable diseases which are hazardous to public health (CDHPH)** and other infections.

A communicable disease is regarded as hazardous to public health for several reasons which may include: it is particularly infectious; it may occur frequently; it may produce a high mortality rate and may become so widespread that it becomes a significant hazard to public health. A specific regulation usually identifies all such diseases.

Purpose of the Act

- To protect the population from communicable diseases by preventing their occurrence or spread.
- To ensure that health authorities and other authorities implement the measures necessary to control communicable diseases and to coordinate their efforts.
- To safeguard the rights of individuals who are affected by measures taken to control communicable diseases pursuant to the Act.

Legal basis of the Act

The Act should provide the legal basis for the implementation of the various measures proven to be of value in combating communicable diseases, and for the continuous and systematic prevention and control of outbreaks.

These measures must be:

- necessary to prevent the transmission of a disease;
- justifiable from a medical point of view; and
- must not cause needless or unreasonable harm to those affected.
- the voluntary participation of affected citizens should always be sought.
- participation can be made compulsory if this is needed to prevent the spread of a CDHPH.

In extreme situations, measures may be made compulsory. Such compulsory measures are limited to:

- the medical examination of a suspected carrier;

- the isolation of a disease carrier;

- the treatment of the infected person where this will render the person non-infectious, involves no risk or major discomfort, and significantly reduces the period of isolation.

The Commission for Communicable Diseases Control (CCDC) (or other body assigned responsibility in legislation or regulation) decides if and when a compulsory measure should be employed regarding an individual. Provision should be made for such decisions to be appealed to the local district court.

Information to be given to infected persons

A medical practitioner shall, at the earliest opportunity, give to a person infected with a CDHPH information concerning the disease, in particular about:

- its infectivity and the modes of transmission,

- the relevant legislation and rights and responsibilities in this regard.

- disease-specific infection-control guidelines concerning what the infected person can do to prevent the disease from being transmitted to others.

Exceptions from the duty of secrecy

The Act shall provide for certain exceptions as regards healthcare workers'duty to protect their patients' privacy and to keep their information confidential, when it is necessary to prevent the dissemination of a CDHPH and consent has been sought and not been gained. If it is impossible to obtain sufficient cooperation from, or the consent of, an infected person, information may be given regarding the level of infectivity, notwithstanding the statutory duty of secrecy.

The Act shall enumerate the conditions that have to be fulfilled before a medical practitioner can make an exception with respect to the duty of secrecy. All conditions have to be fulfilled simultaneously:

- It must be a communicable disease that is hazardous to public health.
- It must be highly probable that there is a risk of transmission.
- It must be in the interest of communicable disease control.
- The medical practitioner shall, as far as possible, seek to obtain the cooperation or consent of the infected person so that the necessary information may be given.

Vaccination and immunisation

A national programme for vaccination and immunisation of the population shall be established by the Ministry of Health (or other body specified in the legislation or commissioned or instructed by the Ministry).

Local arrangements for providing this service to the entire population, e.g. through the local district health services, may be specified in the legislation, or the Ministry may be given authority to determine what arrangements should be made.

Compulsory medical examination

The Act should make provision for and state the conditions for compulsory medical examination.

If an infected person, or a person suspected of being infected, is opposed to being examined a decision may be made for a compulsory medical examination.Such a decision is made by the CCDC. The decision may be submitted to the local district court but this shall not delay its implementation.

Certain conditions have to be fulfilled before a decision to conduct a compulsory medical examination is reached:

- It must be ascertained whether there is an occurrence of a communicable disease that is hazardous to public health.
- It must be necessary to conduct an examination to prevent such a disease from spreading to others.
- The examination may be carried out only if there is no risk to the infected person.
- The medical practitioner shall, as far as possible, have sought the cooperation and consent of the infected person for the examination.

Compulsory medical isolation and treatment

The Act should foresee the possibility and state conditions for compulsory medical isolation and treatment

If an infected person refuses to be isolated, a decision may be made by the responsible body for communicable diseases control for compulsory isolation. The decision may be submitted to the local district court but this shall not delay its implementation.

Certain conditions have to be fulfilled before a decision on compulsory isolation and treatment is reached:

- It is a communicable disease that is hazardous to public health.
- Other measures which may prevent the occurrence or spread of the disease must have been tried.
- An overall evaluation has been made that this is clearly the most justifiable course of action in relation to the risk of the disease being transmitted and to the stress the compulsory measure is likely to entail.
- It is highly probable that other persons will otherwise be infected.
- The head physician of the department in which the person is isolated is authorised to annul the decision as soon as the conditions for hospitalisation are no longer present.

Right to assistance

The act should foresee a right to assistance. Any person who is in danger of being infected with a CDHPH is entitled to necessary assistance from the bodies designated in the legislation as responsible for communicable disease control in the form of vaccination, information and other necessary preventive assistance.

A person infected with a CDHPH is entitled to medical evaluation and diagnosis, treatment, care and other necessary assistance from the bodies designated in the legislation as responsible for communicable disease control. The legislation should specify that such assistance may not be denied on the grounds that there are no funds in adopted budgets to cover the costs.

Regulation

The Act should provide the Government, and specifically the Ministry of Health or central/national health administration with executive functions in communicable disease control, with the authority to supplement the Act with more detailed regulations on TB prevention and control.

IX. ESSENTIAL ELEMENTS IN TB CONTROL REGULATION

Regulations would be issued by the national health ministry (or another constitutionally appropriate body[1]) pursuant to the relevant sections of legislation[2] relating to the control of communicable diseases. A developed model set of regulations is given in Appendix 2. Essential issues are presented in this section. However, not all these elements are necessarily relevant in all countries as regulations are dependent on the resources and circumstances of the individual country for their effective implementation.

Purpose

Within the overall objective of the TB control strategy, which is to reduce mortality and morbidity and transmission of the disease until it no longer poses a threat to public health, the purpose of the regulations is to prevent the transmission of the TB infection and the development of the disease following infection.

Measures to control TB

The control of TB includes measures intended:

- to protect uninfected persons against TB infection
- to detect cases of infectious TB as early as possible after the onset of symptoms and to initiate treatment.
- to ensure that persons with active TB are given adequate treatment.

[1] According to the distribution of functions and responsibilities as specified in the Constitution or legislation or according to government practice.

[2] It is for Member States to determine whether to enact specific TB related legislation and regulations or TB specific regulations pursuant to comprehensive CD legislation. The guidance in this document is based on the latter preference.

- To notify and report cases of TB.
- To perform screening to detect TB infection and disease among close contacts of index cases.
- to prevent the development of disseminated disease in children by offering BCG vaccination.
- to prevent the development of the disease by offering prophylactic treatment to certain groups of infected persons.

Measures to control TB can include one or more of the following examinations:

- ordinary clinical examination and recording of relevant medical history by a medical practitioner,
- tuberculin testing,
- laboratory tests aiming to detect the presence of tubercle bacilli in expectoration, laryngeal smears, urine or in other test material and to determine the sensitivity of the detected tubercle bacilli to anti-tuberculous drugs,
- radiography and other imaging techniques of the lungs and other organs,

Measures to control TB also include, in high prevalence countries, systematically offering vaccination to all new born children as soon as possible after birth. Vaccination may be offered to unvaccinated persons who show a negative tuberculin reaction and in whom there are no contraindications.

The principle of responsibility

Health care workers who have duties under the provisions of the regulations are responsible for seeing that the relevant provisions are complied with.

Persons having a duty to undergo tuberculin testing

The categories of persons who should be required to be tested will depend on the differing circumstances of each country, particularly the epidemiology of TB and the resources available. The following are possible groups that in some circumstances would be included:

School pupils

Tuberculin testing of school pupils may be an option which the health authorities wish to consider. The arrangements for and conduct of the testing shall be the responsibility of the local medical officer in consultation with those responsible for the administration of schools.

Teachers and persons involved in the care of children

Teachers and other persons whose work regularly brings them into direct contact with children and young people when appointed to permanent or temporary full-time or part-time posts, or during training; all personnel have a duty to consult a medical practitioner in the event of persistent respiratory problems and to undergo any relevant examination prescribed by that practitioner. Employers must ensure that employees who are required to undergo testing for TB present themselves for examination.

Health care workers

Health care workers, especially those who will be working in settings where they will be likely to be exposed to infectious TB (e.g. in prison settings) have a duty, when appointed to permanent or temporary full-time or part-time posts, or prior to training, to undergo tuberculin testing.

This applies to appointment/training at institutions such as hospitals and other local health services institutions; odontological institutions and dental clinics where the treatment of patients takes place.

Employers have a duty to ensure that testing has been carried out before new personnel take up their duties. This duty also applies to educational establishments regarding students/pupils receiving training at the institution.

Exemption from the duty to undergo testing may be granted to a person who can document having shown a definite positive tuberculin reaction after an assumed TB infection or after vaccination against TB.

Military personnel and employees in other industries where special arrangements are required

The Communicable Diseases Control Act and TB regulations should specify military personnel and other groups of workers (according to industry, occupation, or place of work, e.g. ships at sea) for whom special requirements are laid down. In such cases, the regulations must specify the persons to which they apply and action to be taken, allocation of responsibility for taking action and for facilitating action and the designation of those with authority to grant any exemptions.

Foreign-born persons

Foreign-born persons intending to stay in the country (other than for a stated short period of time, e.g. not more than three months), who are not exempt from any residential permit requirement, have a duty to undergo medical examination for tuberculosis.

The examinations must be carried out as soon as possible and no later than three months after entry into the country. Refugees, asylum seekers and persons applying for a residential permit for the purpose of reuniting with their families must be examined within fourteen days after entry.

Exemption from the duty to undergo medical examination for tuberculosis may be granted to applicants from countries that have a low incidence of TB.

The health authorities have a duty to ensure that persons covered by the provisions in this section undergo medical examination for tuberculosis and must, in this connection, offer unvaccinated persons from countries that have a high incidence of TB, vaccination against TB, provided that they are tuberculin negative and there are no contraindications. This offer also applies to members of the foreign-born person's family resident in the country. Children of persons mentioned in the first paragraph shall be offered vaccination at birth. They also have a duty to ensure that later examinations for TB are carried out as necessary.

Implementation of measures, follow-up and cost issues
The duties of the local authorities (as specified in legislation)

Local authorities have a duty to ensure that their health services are able to carry out testing for TB in accordance with the regulations and to offer unvaccinated, tuberculin negative persons, vaccination against TB in connection with the testing, when this is indicated.

The local medical officer (designated responsible for TB control) is responsible for:

- ensuring that the testing for TB of groups of persons as specified in the regulations is carried out in accordance with the regulations.
- the testing of other risk groups for TB and to ensure the follow-up of cases of TB which are discovered through testing.
- delegating, when expedient, duties to other competent health workers.
- referring, if there is a suspicion of active pulmonary TB, the patient for confirmation of diagnosis and initiation of treatment.
- carrying out contact tracing in cases of TB that are confirmed infectious and in the case of new discoveries of tuberculin converters.

Regional authorities[3]

The regional authorities have a duty to ensure that the sufficient medical expertise is available to carry out testing for TB within the general health services system .

The regional medical officer

The regional medical officer shall supervise the implementation of measures to control TB. The Office of the regional medical officer is the appeal body for persons contesting decisions for instance relating to the restrictions in the performance of work and participation in teaching.

National TB monitoring and surveillance service

The national TB monitoring and surveillance service (or an equivalent agency designated by the Ministry of Health to take action) provides advice and guidance to institutions, medical practitioners and other personnel who carry out or take part in measures to control TB and to render specialist help to the local health services.

The primary function of the national TB monitoring and surveillance service also includes keeping a national TB register. When TB caused by multi-drug resistant tubercle bacilli is found, the National TB Monitoring and Surveillance Service/national TB register, has a duty to discuss the treatment programme with the specialist hospital department providing the treatment.

Follow-up

If it is discovered that a person has TB and needs treatment, treatment in or outside a hospital must be initiated by a competent health worker within the health care system. Continued treatment

[3] The authority responsible for planning and resource allocation, provision of specialist health services and supervision of the public health functions (including TB control) of local authorities. The regional medical officer is the authority's chief medical officer.

outside a hospital including observation of the intake of antituberculous drugs may be done under the direction of a competent health worker. If a patient with TB is found to have multi-drug resistant TB, treatment must be indicated and monitored by a specialist hospital department.

Payment and attribution of costs

Testing for TB pursuant to the regulations shall be free of charge to any person who has a duty to undergo such testing. This also covers other related costs e.g. travel expenses incurred to attend such testing. Treatment of persons with a confirmed diagnosis shall be free of all charges to the patient.

The local authorities have a duty to cover the cost of testing pursuant to the regulations which is carried out by the local health service and the regional authorities have a duty to cover the cost of testing carried out by specialist services.

Employers have a duty to cover the cost of testing for TB among those employees for whom special arrangements are laid down in the regulations, employees on ships etc.

The Armed Forces bears the cost of testing its personnel for TB.

Vaccination against TB of tuberculin negative persons is free of charge to the persons concerned. This also includes the travelling expenses incurred from attending vaccination. Local authorities, employers and the Armed Forces cover the costs of vaccination of their personnel.

Skills required of healthcare workers

Required skills**:** Tuberculin testing and vaccination against TB must be carried out by healthcare workers who are proficient in the techniques.

Training: The local authorities must ensure that an adequate number of qualified personnel are available to carry out testing for TB pursuant to these regulations.

Notification/reporting
Notification of new cases of TB

A medical practitioner who discovers a new case or assumed new case of TB, or relapse after treatment, must give notification the same day. These notifications must be sent to the local medical officer and to a designated unit of the health Ministry or central/national health administration that must then forward the report immediately to the National TB Monitoring and Surveillance Service/National TB Register.

Notification of initiation of treatment for TB

Health workers who initiate treatment on the suspicion or discovery of TB must give notification of the treatment that has been initiated to the local medical officer that is then sent forward to the National TB Monitoring and Surveillance Service.

The use of the anti-tuberculosis drugs such as rifampicin or equivalent must comply with the prescription rules established in the national drug formularies.

Notification of treatment outcome

The examining physician must report to the local medical officer and on to the National TB Monitoring and Surveillance Service the result of treatment, according to standard definitions. The local medical officer retains a copy of the report.

Report on contact tracing

The local medical officer must report on contact tracing. The report is given on a special form which is sent to the diagnostic centre or pulmonary out-patients department which enters the results of the contact tracing and sends the duly completed report back to the local medical officer and also to the National TB Monitoring and Surveillance Service.

Notification of laboratory findings

Microbiological laboratories (departments) must give notification the same day of any findings of tubercle bacilli and resistance results. Pathological-anatomical laboratories (departments) must give notification of any findings of lesions attributable to TB.

Registers

Registers of notifications received must be kept locally by the local medical officer and nationally by the National TB Monitoring and Surveillance Service/National TB register.

Notification forms

All notifications, as stated above, must be given on official forms drawn up for the purpose, pursuant to standard national guidelines relating to notification and reports of communicable diseases by medical practitioners and other healthcare workers. Information shall be issued by the health ministry pursuant to the national guidelines relating to notification and reports of communicable diseases by medical practitioners and other healthcare workers and local medical officers. The National TB Monitoring and Surveillance Service has a duty to print, store and distribute official forms in use. Medical practitioners who regularly carry out testing for TB have a duty to keep a stock of relevant forms.

Restrictions relating to the performance of work
Employees

If, during a pre-employment testing for TB a person is discovered to have infectious TB, this person, until rendered non infectious (2 to 3 weeks), must be delayed from taking up a post, performing work or participating in activities where there is a risk of other people being infected for as long as the medical practitioner deems the disease to be infectious. The same applies when the local medical officer discovers a person with infectious TB during screening of risk groups or when tracing contacts.

Pupils/students

If, a pupil/student at an educational institution, is discovered with infectious TB, this person must take leave of absence from participating in joint education where there is a risk of other people being infected for as long as the medical practitioner deems the disease to be infectious (2 to 3 weeks).

The same applies when the local medical officer discovers a pupil/student with infectious TB among pupils/students, during screening of risk groups or when tracing contacts.

Annulment of decisions and Appeals

In the above two cases, the persons shall take up employment, resume duty, go to school, when the person is free from infection and this person's condition is deemed to be stable. The previous measure must be annulled by the local medical officer or other designated competent person. Appeals against decisions are settled by the regional medical officer unless special provision has been made otherwise (e.g. for military personnel).

APPENDIX 1

MODEL LEGISLATIVE FAMEWORK

Chapter 1. Introductory provisions

§ 1-1 Scope of the Communicable Diseases Control Act :

The Act should cover all communicable diseases which can be transmitted from man to man or from animals or environmental sources to man. A distinction should be made between communicable diseases which are hazardous to public health (CDHPH) and other infections.

A communicable disease is regarded as hazardous to public health for several reasons which may include: it is particularly infectious; it may occur frequently; it may produce a high mortality rate and may become so widespread that it becomes a significant hazard to public health. A specific regulation usually identifies all such diseases.

- The provisions of the Act relating to services and measures shall apply to every person residing in the country.
- The Ministry of Health* (hereafter the Ministry) may issue regulations, which limit application of the Act in respect of persons who are not nationals, or who are not domiciled in the country. The Ministry may also issue regulations to the effect that the Act shall apply to persons who are residing abroad, but who have a connection with the country.
- The Ministry may issue regulations concerning application of the Act on national vessels and aircraft wherever they may be. The provisions of this Act shall apply subject to such limitations as are recognised in international law or which derive from any agreement made with a foreign State.

§ 1-2 Purpose of the Communicable Diseases Control Act:

- To protect the population from communicable diseases*[4] by preventing their occurrence and hindering them from spreading among the population, and by preventing such diseases from being brought into or carried out to other countries.
- To ensure that the responsible authorities and designated officials implement the measures necessary to control communicable diseases and co-ordinate their efforts to control such diseases.
- To safeguard the legal rights of the individuals affected by the measures to control communicable diseases pursuant to the Act.

§ 1-3 Legal basis of the Act

The Act should provide the legal basis for the implementation of the various measures proven to be of value in combating communicable diseases, and for the continuous and systematic prevention and control of outbreaks.

[4] All terms for which definitions are given in the following list are identified thus (*) the first time they occur in this text.

These measures must be:

- necessary to prevent the transmission of a disease;
- justifiable from a medical point of view; and
- must not cause needless or unreasonable harm to those affected.
- the voluntary participation of affected citizens should always be sought.
- participation can be made compulsory if this is needed to prevent the spread of a CDHPH.

In extreme situations, measures may be made compulsory. Such compulsory measures are limited to:

- the medical examination of a suspected carrier;
- the isolation of a disease carrier;
- the treatment of the infected person where this will render the person non-infectious, involves no risk or major discomfort, and significantly reduces the period of isolation.

The Commission for Communicable Diseases Control (CCDC) (or other body assigned responsibility in legislation or regulation) decides if and when a compulsory measure should be employed regarding an individual. Provision should be made for such decisions to be appealed to the local district court.

§ 1-4 Definitions (see list in appendix 3)

Chapter 2. Information to be given to infected persons. Exceptions to the statutory duty of secrecy. Duty to report and notify

§ 2-1 Information and guidelines

The examining or treating medical practitioner shall at the earliest opportunity give to a person infected with a communicable disease that is hazardous to public health (CDHPH) information concerning the disease, in particular about:

- its infectivity and the modes of transmission,
- the relevant legislation and rights and responsibilities in this regard.
- Disease-specific infection-control guidelines concerning what the infected person can do to prevent the disease from being transmitted to others.

If the infected person is a minor or an incapacitated person who cannot safeguard his/her own interests with regard to the risk of infection, both the infected person and, notwithstanding the medical practitioner's statutory duty of secrecy, those who are responsible for the care of the infected person, shall be entitled to information and guidelines.

If the infected person is between 12 and 16 years of age, both the infected person and, notwithstanding the medical practitioner's statutory duty of secrecy, those responsible for him/ her shall be entitled to information and guidelines.

Information must not be given to those who are responsible for such care if the infected person, or others who are aware of the infected person's situation, object to this being done, and the medical practitioner is of the opinion that the objections should be respected. The substance of the information and the guidelines shall be recorded in the patient's case records.

§ 2-2 Certain exceptions to the duty of secrecy.

When it is highly probable that there is or has been a risk of a CDHPH, being transmitted by an infected person, and when in the interest of communicable diseases control there is a need to provide information that is subject to the duty of secrecy, the medical practitioner shall as far as possible seek to obtain the cooperation or consent of the infected person so that the necessary information may be given.

If it is impossible to obtain sufficient cooperation from or the consent of the infected person, information may be given regarding status of infectivity and other essential information notwithstanding the statutory duty of secrecy. The medical practitioner may give such information to:

- Healthcare workers who are responsible for following up the patient or for ensuring that other healthcare workers, other patients or visitors are not infected, when it is highly probable that the healthcare workers, patients or visitors are in danger of being infected with a CDHP,
- Another medical practitioner in connection with tracing the source of infection,
- Any person who in all probability is in danger of being infected with a CDHPH,
- Any person who in all probability has been in danger of being infected with a CDHPH, when the information may prevent the disease from being transmitted to others, or is crucial to the initiation of medical treatment of the person who has been exposed to infection, or
- Any person, who in all probability has been in danger of being infected with a CDHPH because the infected person has behaved in a harmful manner.
- If the risk of transmission, is imminent and obvious, the information shall be given, unless the medical practitioner knows that another medical practitioner will provide the information or that those who are to have the information have already been apprised of it.

If the medical practitioner is in doubt as to whether the information should be given pursuant to the second paragraph, the medical practitioner may submit the question to the local medical officer* for comment. If the medical practitioner refuses to provide information, any person wishing to have the information pursuant to the second paragraph or the local medical officer may submit the matter to the regional medical officer*[5], who may decide that the information should be given.

When information is given on the basis of the provisions in the second paragraph, the medical practitioner shall inform the infected person, in writing, that such information has been provided. If the conditions in the first and second paragraphs are satisfied, a dentist, midwife or nurse may give the necessary information to the infected person's medical practitioner or to the local medical officer.

Healthcare workers who receive information pursuant to this section shall have the same duty of secrecy as the person who provides the information.

[5] See definitions and footnote 1. Where there is no regional authority/regional medical officer (as defined in this document) it is assumed that the function is carried out by a responsible officer of the health ministry or the central/national health administration (as defined in this document).

When this is necessary to implement measures to gain an overview and control of communicable diseases, the local medical officer, the regional medical officer or the Ministry (or central/national health administration*)[6] may demand information from public sources or private health services notwithstanding the statutory duty of secrecy.

§ 2-3 The duty of medical practitioners to report cases and the duty of nurses and midwives to give notification.

A medical practitioner who discovers that a person is infected has a duty to report the case, notwithstanding the statutory duty of secrecy. A nurse or a midwife who in the course of her activities discovers that a person is infected has a duty to give notification, notwithstanding the statutory duty of secrecy.

Any person who receives information which is subject to the duty of secrecy has the same duty of secrecy as the person who provides the information.

When a medical practitioner submits a report identifying a person, he/she shall inform the person concerned as to whom the reports will be given and what they will be used for.

The central/national health administration shall by regulations issue further provisions concerning: who shall report or give notification; the form and content of and time-limit for reports and notifications (e.g. special report forms and who may or shall receive reports and notifications); the recording, erasure and storage of the information reported.

Further regulations issued may only stipulate that information shall be given which can identify a person when the information is necessary to monitor the disease, prevent its occurrence or hinder it from spreading, or to implement measures pursuant to the Act.

Neither public nor private bodies may implement systems for the reporting of communicable diseases in humans without the consent of the Ministry (or central/national health administration).

Chapter 3. Examinations and vaccination

§ 3-1 Examination of the population

When this is crucial, in order to be able to judge which preventive measures or examinations, treatment or nursing measures are necessary to prevent the occurrence of a communicable disease or hinder it from spreading, the Ministry (or central/national health administration) may, by regulation, determine that the population, or particular groups of it shall have a duty to undergo x-ray examinations, tuberculin tests, blood tests, or other comparable tests that can be carried out without danger.

Such a duty may not include endoscopies, biopsies, spinal punctures or other similar examinations/interventions.

If the infected person is a minor or an adult who is legally incompetent to look after his/her own interests, the person responsible for the care of that infected person shall ensure that the latter fulfils the duties pursuant to the regulation.

[6] This text leaves open whether the Ministry will discharge executive functions in respect of CD control or whether these will be assigned to a central/national health administration or other designated body.

§ 3-2 Prior examination of applicants for jobs or admittance to an educational institution, examination of employees and persons enrolled in an educational institution

When infected persons may constitute a serious risk of transmission of a communicable disease in their work or their activity and when so required, to control communicable diseases, the Ministry (or central/national administration) may by regulation prescribe:

a) that applicants for jobs or for admittance to an educational institution shall undergo examination prior to their appointment or admittance

b) that employees or pupils and students shall undergo such examinations.

§ 3-3 Prior examination of patients

A health institution may require that a patient shall submit to a prior examination in respect of a communicable disease, before a diagnostic examination is carried out, and before the patient receives treatment or care .This requirement may not be established as a routine procedure and is submitted to the following conditions:

- It may only be required when such a disease will necessitate extraordinary preventive measures due to the risk of transmission to other patients or to the staff,
- and provided the measures can ensure significantly greater security against transmission of infection or entail significant relief and savings for the health service;
- and it must not cause a serious delay in the treatment of the patient, nor cause him/her to be exposed to risk or to unreasonable inconvenience.

Decisions regarding prior examination may be appealed to the regional medical officer.

§ 3-4 Examination of pregnant women

The Ministry may issue regulations regarding the duty of pregnant women to submit a blood sample or undergo necessary examinations that involve no risk, when the purpose of the examination is to determine whether there is reason to implement measures to prevent a CDHPH, from being transmitted to the child.

§ 3-5 The duty of the medical practitioner to examine infected persons

Medical practitioners shall be especially attentive to the possibility that patients may have a CDHPH. A medical practitioner who suspects that a patient has such a disease shall, with the consent of the patient, carry out or initiate such examinations as are necessary to ascertain if such a disease is present. In such case, the medical practitioner shall immediately and in consultation with the infected patient, make every effort to prevent the disease from being transmitted to others.

If there is any doubt, the medical practitioner shall contact the local medical officer who shall take over further clarification and follow-up, if the first medical practitioner proves not to have the necessary qualifications for the task.

A medical practitioner has a duty to examine an infected person, take a blood test or carry out other necessary examinations, when the CCDC has made a decision pursuant to §5-2 and the examination may be carried out at no risk.

§ 3-6 The duty of the medical practitioner to trace contacts

A medical practitioner who has certain knowledge or a suspicion of a CDHPH, and which is due to the transmission of infection from one person to another, shall trace contacts, if this is feasible and necessary in order to control the communicable disease. In such cases, the medical practitioner shall ask the infected person, from whom the infection may have been transmitted, when and in what way the transmission may have taken place and to whom he/she may have transmitted the infection.

Then the medical practitioner, possibly via the infected person, shall contact those from or to whom the infection may have been transmitted and examine them. This duty ceases to apply if it can be proven that the persons in question have already been examined or are receiving the necessary treatment or care.

If the medical practitioner is unable to trace and follow up potentially infected persons, he shall, notwithstanding the statutory duty of secrecy, notify the local medical officer of this if this is necessary in the interest of controlling a communicable disease. He/she shall then also provide information concerning persons with whom the infected person has been in contact. The same shall apply if the medical practitioner has reason to assume that an infected person is not following the individual infection control guidelines provided by the medical practitioner.

The medical practitioner shall always contact the local medical officer when there is a suspicion of a CDHPH which is caused by an environmental source of infection, for instance a disease caused by the transmission of infection through drinking water, foodstuffs or animals. The local medical officer shall undertake further clarification and follow-up if the first medical practitioner lacks the necessary qualifications for the task.

§ 3-7 Survey and methodological testing

Available blood, serum and other human biological material may not be analysed in respect of a communicable disease, for a non-diagnostic purpose, without the consent of the person from whom the sample derives. Laboratories and institutions may, however, carry out surveys using available sample material without the consent of those who have given the samples if the purpose of the survey is to:

- Monitor the development of an epidemic which is spreading among the population, or
- shed light on the occurrence of a communicable disease in the population or a part of it, or
- judge whether and, if so, how well the population is protected against a communicable disease against which it has been vaccinated,
- and if the result of the survey is of significance for efforts to control communicable diseases.

Laboratories and institutions may also carry out methodological testing using available sample material without the consent of those who have given the samples if the purpose of the testing

is to develop new methods or improve existing methods for the identification and description of a communicable disease.

The Ministry (or central/national health administration) may order a laboratory or an institution to carry out such surveys when this is deemed necessary for the control of a communicable disease.

It may also issue further provisions relating to the implementation of surveys and to the use of the results, including the duty of laboratories and institutions to report analysis findings, notwithstanding the statutory duty of secrecy.

§ 3-8 Vaccination and immunisation of the population

A national programme for vaccination against communicable diseases should be established and offered to the population.

When it is essential for the prevention of a serious outbreak of a CDHPH, the Ministry (or central/national health administration) may, by regulation, prescribe that the population or parts of it, shall have a duty to be vaccinated.

In this instance, the Ministry may decide, by regulation, that those persons who are not vaccinated shall:

- stay within specified areas,
- not be allowed to participate in organized assemblies with others, for instance in child care centres, schools, meetings or means of transport,
- take necessary precautions as further decided by the local medical officer.

When, in the event of a serious outbreak of a CDHPH, it is necessary immediately to vaccinate the population, or parts of it, in order to prevent significant impairment of public health, the Ministry (or central/national health administration) may order vaccination and measures as above mentioned.

The Ministry (or central/national health administration) may by regulation prescribe that healthcare workers, notwithstanding the statutory duty of secrecy, shall provide information necessary for the implementation of a control system based on vaccination registers, and lay down rules for such registers.

§ 3-9 Regulations relating to examinations and vaccinations

The Ministry (or central/national health administration) may issue regulations governing the detailed implementation of measures to control communicable diseases, including regulations regarding:

- which population groups shall be covered by the measures, and regarding exemptions,
- who may grant exemptions, and regarding supervision of implementation of the measures,
- the fact that certain examinations and vaccinations must only be carried out by specially approved healthcare workers, regarding who may grant approval, and regarding the training which those workers must undergo in order to obtain such approval,

- the duty of healthcare workers to carry out or assist in examinations and vaccinations,
- the fact that examinations or analyses shall be effected as decided by the Ministry (or central/national health administration), and that they must be carried out by a person approved by the Ministry (or central/national health administration),
- who will cover the costs of the measures.

Chapter 4. Other measures to control communicable diseases

§ 4-1 Prohibition against assembly, closure of establishments, curtailment of communication, isolation and removal of source of infection.

When it is necessary to prevent the occurrence of a CDHPH or to prevent it from spreading, the local council may decide to:

- prohibit meetings and gatherings or impose other limitations on social contacts wherever people are assembled,
- close establishments, or impose limitations on activities therein, where numbers of people assemble, such as child care facilities, schools, cinemas, swimming pools, sport stadiums, airports, shops, hotels or other companies and workplaces.
- stop or curtail communications.
- isolate persons in geographically limited areas or impose other limitations on their freedom of movement for a period not exceeding seven days at a time,
- order private or public establishments to clean, disinfect or destroy objects or premises. It may also order the destruction of household pets, the extermination of rats and other vermin, delousing or other measures to remove sources of contagion.

§ 4-2. Restrictions relating to the performance of work, and in teaching

A person infected with a CDHPH, who, through his or her work or participation in education, constitutes a serious risk that the infection will be transmitted to others, may be prohibited from performing this work or from participating in education for a period not exceeding three weeks if this is necessary for the control of communicable diseases. The prohibition may be extended for a period not exceeding three weeks by means of a new decision.

This decision is made by the local medical officer together with the hospital physician appointed by the regional authority.

The regional medical officer shall decide appeals against decisions. If the physicians who are to make decisions disagree, the regional medical officer shall take part in the decision. The Ministry (or central/national health administration) shall make a decision on the appeal when the regional medical officer has been involved on the first occasion. An appeal shall not have the effect of postponing implementation of decisions.

When, through their work or participation in education, infected persons may constitute a serious risk that the infection will be transmitted to others, the Ministry (or central/national administration) may by regulation prescribe that infected persons shall be prohibited from performing specific work or parts of said work or from participating in education.

§ 4-3 Quarantine provisions

The Head of State (or the department of government responsible for foreign trade or relations with foreign States) may lay down regulations to prevent communicable diseases from being brought into the country or spread to other countries (quarantine measures), in respect of persons, animals, means of transport, goods and objects which may conceivably transmit communicable diseases. Further requirements may concern examinations, removal of sources of contagion and documentation in connection with entry into and departure from the country and in connection with the import and export of goods.

§ 4-4 Transport of infectious material

The import, transport and other handling of infectious material that may transmit disease to people shall take place in a proper manner, so as to minimise the danger of infection. (Regulations should be drafted according to particular national or regional needs).

§ 4-5 Autopsy

The local medical officer may decide that an autopsy be carried out on a deceased person with a CDHPH if this is necessary to determine the nature of the disease or to demonstrate the presence of other conditions of which it is important to be aware in order to prevent the occurrence of such a disease or prevent it from spreading.

In the event of a serious outbreak of a CDHPH, the State shall bear the costs of the autopsies ordered.

§ 4-6 Funerals and transport of corpses

In the event of a serious outbreak of a CDHPH, the local authority may order that precautions shall be taken in connection with funerals, including decisions that deceased persons shall be cremated, or that other special measures shall be implemented in connection with funerals.

(Regulations should be drafted according to particular national or regional needs.)

§ 4-7 Hospital infections

The Ministry (or central/national health administration) may by regulation lay down provisions regarding measures to prevent hospital infections. Provisions may be laid down for healthcare workers and owners of establishments which are engaged in medical examinations, treatment or care, in order to prevent the occurrence of infections, or prevent patients, employees or others from becoming infected.

Special provisions may be laid down regarding protection against infection for patients who have impaired immunity, including provisions to the effect that such patients may be examined, treated or nursed only at institutions approved by the Ministry (or central/national health administration).

§ 4-8 Duty of the Media to provide information[7]

In the event of a serious outbreak of a CDHPH, the Ministry (or central/national health administration) may order any part of the domestic media to include announcements to the entire population or to limited population groups. Anyone who has communicated an announcement pursuant to this provision shall be entitled to compensation. An appeal against such order will not have the effect of postponing its implementation .

§ 4-9 The duty of healthcare workers to undergo training, follow professional guidelines and implement measures

Healthcare workers employed by the local authority shall have a duty to undergo necessary training so as to be able to participate in the special tasks required by efforts to control communicable diseases.

In the event of a serious outbreak of a CDHPH, healthcare workers shall have a duty to participate in and carry out necessary tasks related to the control of communicable diseases in accordance with the further decision of the local authority.

Healthcare workers shall have a duty to follow the order of the Ministry (or central /national health administration) to the effect that a CDHPH shall be prevented and that examinations, treatment, and nursing shall be performed according to specific professional guidelines, or that examinations or analyses shall be performed in the manner decided by the Ministry (or central/national health administration) or that they must only be performed by a person who has been approved by the Ministry (or central /national health administration).

A medical practitioner employed by (or under contract to) the local authority shall have a duty to take part in efforts to prevent the occurrence of a CDHPH and in the examination and treatment of a person who has been infected with such a disease, when this is necessary and pursuant to a decision by the local authority.

§ 4-10 The duty of other authorities to provide information and assistance

Officials in the police and relevant authorities for shipping, pilotage, customs ports, airports, food control, veterinary and other agencies as may be specified by regulation, shall have a duty to pay special attention to communicable diseases. They shall have a duty to assist with implementation of and compliance with the provisions contained in the Act (or in such other legislation and regulation as is relevant in the context).

These officials shall, notwithstanding the statutory duty of secrecy, notify the local medical officer when they have a strong suspicion of a CDHPH or when they discover a case of such a disease. The same applies when they learn of conditions which may lead to a clear danger of such a disease spreading and it is obviously necessary to seek help, or measures from the health services.

[7] In respect of CD it is a matter for countries whether to adopt legislation specifying the media's responsibility to disseminate information (e.g. on risks of infection). In certain countries, both government and the media may wish to work under a voluntary agreement. The essential issue is that there is an effective working relationship between public health agencies and the media that meets legitimate expectations of both parties.

In the event of a suspicion of a case of zoonosis that may be hazardous to human health or a communicable disease which may be transmitted to people through food, veterinary surgeons, the veterinary authority and food safety inspectors shall immediately notify the local medical officer or the regional medical officer; the police shall, upon request, assist with the implementation of relevant measures.

The Ministry (or central/national health administration) may, by regulation, prescribe further duties for other authorities, including deciding who shall cover the costs of assistance.

Chapter 5. The duties of infected persons - compulsory measures

§ 5-1 The duties of a person who is infected with a CDHPH

Any person who has reason to assume that he himself, or any person for whose care he is responsible, is infected with a CDHPH, shall as soon as possible notify a medical practitioner and consult the medical practitioner for the necessary examination .

A person infected with a CDHPH has a duty to give whatever information necessary as to from whom an infection may have been received. If the disease may have been transmitted through an environmental source of infection, such as drinking water, food or animals, the said person also has a duty to provide information concerning this. Moreover, the person has a duty to state to whom he or she may have transmitted the infection. Such information shall be given to the examining medical practitioner or to the local medical officer.

A person infected with a CDHPH has a duty to accept the individual infection control guidelines provided by the medical practitioner to prevent the disease from being transmitted to others and a duty to let him/herself be placed in isolation if necessary.

§ 5-2 Compulsory medical examination - hospitalisation for examination and short-term isolation

When it is necessary to prevent the occurrence of a CDHPH or prevent it from spreading, the medical practitioner or the local medical officer, as applicable, shall request an infected person to submit to a medical examination. If an infected person opposes such an examination, a decision may be made to hospitalise the said person for a medical examination and short-term isolation, if applicable.

Such compulsory medical examination or short-term isolation may only be implemented to ascertain whether there is an occurrence of a CDHPH and, if it is necessary to prevent such a disease from spreading to others, and provided the examination may take place at no risk. A decision may be made for compulsory isolation for a period not exceeding seven days.

When it is justifiable to carry out a medical examination without hospitalisation, out of consideration for the infected person or those who are to perform the examination, the examination may be carried out at an outpatient clinic or at another suitable place, with appropriate steps to maintain confidentiality.

Before a decision regarding compulsory medical examination or short-term isolation is made, the infected person shall be notified so that he or she has an opportunity to make a statement

concerning the issue. Notification may be omitted when it is not practically feasible or when it will entail a risk that an examination or isolation cannot be carried out.

Such decisions shall be made by the CCDC. However, regarding urgent decisions reference should be made to §5-8. Submitting the decision to the district court* shall not have the effect of postponing implementation.

§ 5-3 Compulsory isolation in hospital-compulsory treatment (conditions for)

When it is necessary to prevent the occurrence of a CDHPH or to prevent it from spreading, the medical practitioner, or the local medical officer, if applicable, shall ask an infected person to submit to isolation. If an infected person opposes isolation, and other measures to prevent the occurrence or spread of the diseases have been tried, or if it is highly probable that such measures will not be effective, a decision may be made to the effect that the person shall be placed in isolation in a hospital.

Such compulsory isolation may only be carried out if, after overall evaluation, this is clearly the most justifiable course of action in relation to the risk of the disease being transmitted and to the strain the compulsory measure is likely to entail, and it is highly probable that other persons will otherwise be infected. Decisions pursuant to this section may be made for a period not exceeding three weeks. The period of isolation may be extended by a new decision, for a period not exceeding six weeks at a time, for up to one year as from the first decision.

In connection with extension of the period of isolation, a decision may be adopted to implement compulsory drug therapy when this may significantly reduce the period of isolation. Compulsory drug therapy may only be implemented when it may render an infected person non-infectious and involves no risk or major discomfort. The Ministry (or central /national health administration) may, by regulation, lay down further provisions regarding such treatment.

Decisions regarding compulsory isolation in hospital and drug therapy shall be made by the CCDC. Bringing the decision before the district court shall not have the effect of postponing implementation. The compulsory isolation decision shall be annulled by the head physician of the department as soon as the conditions for hospitalisation are no longer present. The CCDC shall be alerted as soon as possible, and not later than three days before the infected person is discharged.

§ 5-4 Implementation of isolation in a hospital

Hospitalisation for compulsory examination and short-term isolation pursuant to section 5-2 or isolation pursuant to section 5-3 shall take place in a suitable hospital department or ward. The department or ward shall be specially adapted to accommodate infected persons so that they may receive the medicinal treatment and care that will make their period of isolation as short as possible.

During the period of isolation, care-related and security measures may be taken to ensure effective isolation. The measures shall be limited to what is absolutely necessary in relation to the risk of the spread of infection. As far as possible the patient shall be enabled to live as normally as possible and have contact with close relatives.

When special conditions so require, infected persons may be isolated in other institutions approved by the Ministry (or central/national health administration). The Ministry may by regulation prescribe further requirements as regards the physical and professional conditions at hospitals and other institutions used for isolation.

§ 5-5 Preparation for decision about compulsory measures by the Commission for Communicable Disease Control (CCDC)

A case concerning a decision pursuant to sections 5-2 or 5-3 commences with the preparation by the local medical officer of a written proposal for a compulsory measure pursuant to the relevant section. In the proposal, an account shall be given of the circumstances on which the local medical officer is basing the proposed measure.

The proposal shall be submitted to the regional medical officer, who shall immediately send it to the Commission for Communicable Disease Control (CCDC-see § 7-5 and § 7-6) . The Ministry (or central/national health administration) may itself bring a case before the commission.

§ 5-6 Appointment of a legal representative for the infected person

If the infected person has not already engaged a lawyer, the secretariat of the CCDC shall ensure that a lawyer is appointed for him or her.

The lawyer shall immediately be apprised of the proposal and the appended documents, and, if possible shall be given a time limit for written submission, presentation of documents and information as to which witnesses the lawyer wishes to call.

Without prejudice to the provisions of other national legislation, there shall be no limitations invoked on the infected person's right to see the case documents and on the infected person's right of access to their medical records when the CCDC has been requested to adopt a decision pursuant to the Act.

§ 5-7 Decision and grounds

The CCDC shall convene a panel of its members as soon as possible to discuss the case . The meeting of the commission may be attended by a representative of the person who has requested the decision and the infected person's lawyer. If any of the parties so desire, they shall be given an opportunity during the meeting to call witnesses and to present other material which it has not been possible to present during the preparation of the case.

The decision shall be made immediately after discussions in the CCDC have been concluded. The rules set out in the relevant national legislation (and any regulations) on the conduct of civil procedures concerning the substance and grounds of judgements shall apply correspondingly.

In notifying the decision of the CCDC, special attention shall be drawn to the right to have decisions reviewed .

§ 5-8 Urgent decisions

Urgent decisions pursuant to section 5-2 may be made by the local medical officer together with the hospital physician appointed by the regional authority pursuant to section 7-3, third paragraph. If they do not agree, section 4-2, third paragraph, shall apply correspondingly. An urgent decision pursuant to section 5-2 may only be made if the interests which the decision shall safeguard may be significantly prejudiced if the decision is not made or implemented immediately.

§ 5-9 Review of decisions

The decision of the CCDC may be brought before the district court, pursuant to the rules laid down in the relevant national legislation (and any regulations) concerning appeals by individuals

against decisions made by public authorities (and their agents) relating to their care and treatment. This also applies to urgent decisions pursuant to section 5-8.

Chapter 6. Right to assistance with communicable diseases control

§ 6-1 Right to assistance with communicable diseases control

Everyone is entitled to necessary assistance with communicable diseases control. Such assistance is to be regarded as part of the right to medical assistance, (as provided for in the relevant national legislation on the provisions of health services).

Any person who, after a professional evaluation, is reasonably assumed to be in danger of being infected with a CDHPH, is entitled to necessary assistance with communicable diseases control in the form of vaccination, information and other necessary preventive assistance. A person infected with a CDHPH is entitled to medical evaluation and diagnosis, treatment, care and other necessary assistance with communicable diseases control.

Such assistance may not be denied on the grounds that there are no funds in adopted budgets to cover the costs. Any person seeking assistance with communicable diseases control may appeal the decision to the regional medical officer, when he or she believes an error has been committed. Relatives also have the right to appeal.

The Ministry (or central/national health administration) may issue regulations to supplement this provision, and also with regard to protection against other communicable diseases.

§ 6-2 Free Services and measures

The Ministry may decide that services or measures pursuant to the Act shall be free of charge for any person who is in danger of being infected with communicable diseases, or who is already infected.

Chapter 7. Administrative agencies and their authority

§ 7-1 The responsibilities of the local authority

With regard to communicable diseases, the local authority shall ensure that the necessary preventive measures, opportunities to be examined, treatment and care are available to everyone domiciled or temporarily residing in its area.

The local authority shall also carry out the tasks related to control of communicable diseases that are prescribed by the Act or by provisions pursuant to the Act, including:

- obtain an overview of the nature and extent of communicable diseases occurring in its area;
- provide information on communicable diseases and offer advice and guidance with regard to preventive measures;
- ensure that individual preventive measures are effected;
- ensure that other measures pursuant to this Act (and, as appropriate, other legislation relating to the provisions of local authorities) are effected.

The local authority shall prepare and disseminate an official statement of the measures and services it will initiate to prevent communicable diseases or prevent them from spreading. (Such

a statement shall be updated whenever it becomes necessary/appropriate.) The local authority shall cooperate with all other public authorities/agencies whose spheres of responsibility are relevant to the measures.

The local authority shall exercise supervision and ensure that the rules of the Act are complied with and that decisions pursuant to it are implemented.

§ 7-2 The responsibilities of the local medical officer

The local medical officer shall carry out the tasks related to control of communicable diseases prescribed by the Act. A deputy should also be designated. In large urban areas, the contiguous local authorities may jointly appoint one medical officer to be responsible for matters of communicable disease control which affect the entire urban area.

The local medical officer shall:

- prepare a draft plan for the work of the health service related to control of communicable diseases, including contingency plans and measures, and organise and direct this work;
- keep him/herself regularly informed of the epidemiological status of communicable diseases in the local authority area;
- prepare proposals for preventive measures in the area;
- assist other officials of the local authority, healthcare workers and others who are responsible for tasks related to control of communicable diseases;
- provide the population with information and advice regarding control of communicable diseases
- execute all other tasks ensuing from the Act or from provisions (regulations) laid down pursuant to the Act, and help to ensure that effective measures are implemented to prevent the occurrence of communicable diseases and prevent them from spreading.

The Ministry (or central/national health administration) may lay down regulations prescribing that the local medical officer shall also have other tasks, and state the specific nature of each task.

§ 7-3 The responsibilities of the regional authority

With regard to communicable diseases, the regional authority, further to its statutory public health functions (see definitions in Appendix 3), shall ensure that all necessary specialised health services are available to the population of the regional area[8].

The regional authority shall prepare and disseminate an official statement of the measures and services it will initiate to prevent communicable diseases or prevent them from spreading. (Such a statement shall be updated whenever it becomes necessary/appropriate).

The authority shall appoint a hospital physician who can make decisions about restrictions on performance of work and urgent decisions, in cooperation with the local medical officer.

§ 7-4 The tasks of the regional medical officer

The regional medical officer shall pay special attention to CDHPH and shall keep the Ministry (or the central /national health administration) informed of the situation in the region. He/she

[8] Depending on the precise allocation of functions these would include examinations by specialists, laboratory tests, outpatient treatment and hospital treatment, proper isolation in a hospital.

shall decide on appeals against decisions by the local authority, unless provided for otherwise in the Act.

§ 7-5 The sphere of responsibility of the CCDC

Implementation of compulsory measures pursuant to sections 5-2 and 5-3 shall be decided by the CCDC. When a serious outbreak of a CDHPH occurs, several regional commissions may be appointed to act in the area of the outbreak.

The CCDC shall, either directly or through designated, competent agents, monitor the epidemiological status of the country as a whole and ensure that there are adequate supplies of vaccines and vaccination contingency plans. The CCDC shall ensure, either through its own professional resources or through designated, competent agents, that expert assistance can be provided when requested, for instance in connection with laboratory tests and other laboratory operations in the fields of microbiology, immunology, and entomology.

The Ministry (or central/national health administration) may decide that the CCDC shall also deal with other matters pursuant to the Act.

§ 7-6 The composition of the CCDC

The CCDC shall be composed of experts in communicable diseases control with qualifications specified for specialists under legislation/regulations governing specialisation in the medical profession. The Ministry (or central/national health administration) shall appoint CCDC members on a full or part time basis and shall decide the period of tenure. The Ministry may also appoint other (non-medical) specialists appropriate to the work of the CCDC.

In dealing with individual cases the CCDC shall appoint a panel consisting of a chairperson and two members, all of whom shall be drawn from the CCDC. The CCDC shall be supported by a competent secretariat provided by the Ministry (or central/national health administration). The members and secretariat of the CCDC shall have a duty of secrecy in accordance with the provisions of the national legislation relating to medical practitioners.

§ 7-7 The responsibilities of the Ministry (or central/national health administration)

The Ministry (or central/national health administration) shall have general responsibility for supervising local, regional and central government activities, and ensuring that they are in accordance with the Act and with regulations or individual decisions pursuant to the Act. By means of advice, guidance, information and decisions pursuant to the Act, it shall help to meet the needs of the population for services and measures in connection with communicable diseases.

When the activity for which any institution/authority is responsible, pursuant to this Act, is inadequate, unsuitable or unsatisfactory, the Ministry may intervene directly to instruct local, regional or government institutions to organise or carry out specific services or measures, cooperate, or follow specific professional guidelines to ensure the satisfactory and effective implementation of the Act..

§ 7-8 Regulation relating to organization, cooperation, sharing of costs and emergency preparedness for the control of communicable diseases

The Ministry may by regulation issue provisions concerning cooperation, and concerning which responsibility and which tasks local and regional authorities shall have pursuant to the Act (and any other legislation that bears on communicable diseases control).

The Ministry may issue regulations to the effect that any person wishing to engage in certain kinds of activity which may cause a risk of the spread of communicable diseases must apply for permission. The regulations may, among other things, establish quality standards and threshold limits for facilities, equipment and activities and qualification requirements for personnel associated with such activities.

For purposes of health-related, emergency preparedness the Ministry may require local and regional authorities and healthcare workers to implement necessary contingency measures to control communicable diseases. The Ministry may, by regulation, lay down further provisions concerning emergency preparedness and contingency plans in connection with a serious outbreak of a CDHPH.

Chapter 8. Penalties, damages, appeals, entry into force and transitional provisions

§ 8-1 Penalties

With the exception of breach of duties, pursuant to section §5-1, or duties covered by legislation relating to healthcare workers, contravention of the Act, or of regulations issued pursuant to the Act is punishable pursuant to the relevant provisions of the Civil and Penal Code (or comparable national legislation).

§ 8-2 Other offences covered by the Penal Code

Any person who wilfully or negligently spreads incorrect or misleading information which may, to a significant extent, counteract the implementation of measures which are necessary to prevent, stop or limit serious outbreaks of CDHPHs, shall be liable to fines or imprisonment. Such penalties shall be specified in the Penal Code. Accomplices shall be made liable to the same penalty.

Any person who, with just cause to believe that he/she is infected with a CDHPH, through negligence transmits the infection or exposes another person to the risk of infection shall be liable to imprisonment for a term, such penalty to be specified in the Penal Code. Accomplices shall be liable to the same penalty. If the aggrieved person is among those closest to the offender, a public prosecution shall only be instituted at the request of the aggrieved person, unless this is required in the public interest.

Any person who contravenes the regulations legally prescribed for the prevention or control of communicable diseases, or individual decisions made pursuant to the Act relating to the control of communicable diseases, knowing that he/she thereby causes a risk of the disease being introduced, or generally spreading among people or livestock, shall be liable to fines or

imprisonment, (such penalties shall be specified in the Penal Code); they shall be liable to a longer term of imprisonment, (such penalty to be specified in the Penal Code), if, as a result thereof, any person dies or receives serious injury to body or health (as defined in the Penal Code). Accomplices shall be liable to the same penalty.

However, no penalty shall be imposed for contravention of paragraph §5-1 of the Act.

§ 8-3 Damages for personal injury

The State has a duty to compensate an injury which, alone or in combination with other causes, may be a result of recommended or compulsory vaccinations implemented pursuant to the Act. This duty shall apply if the State cannot prove that one or more other causes are more probable.

The State may require that damages granted by it pursuant to the first paragraph shall be covered by a person who is liable pursuant to the ordinary rules regarding damages. Damages shall be assessed pursuant to the rules of the relevant legislation relating to damages. The Ministry (or central/national health administration) may appoint a board to deal with matters relating to damages pursuant to this Act, and may issue regulations concerning the activity of the board.

APPENDIX 2

MODEL REGULATORY FRAMEWORK

Regulation relating to the control of Tuberculosis

To be issued by the national health ministry (or another constitutionally appropriate body[9]) pursuant to the relevant sections of legislation[10] relating to the control of communicable diseases.This is a comprehensive set of measures; however, not all these elements are necessarily relevant in all countries as regulations are dependent on the resources and circumstances of the individual country for their effective implementation.

Chapter 1. Purpose, definitions, measures and responsibility

§ 1-1 Purpose

The purpose of the regulations is to prevent the transmission of TB infection and the development of the disease following infection.

§ 1-2 Definitions (see list in appendix 3)

§ 1-3 Measures to control TB

The control of TB includes measures intended:

- to protect uninfected persons against TB infection
- to detect cases of infectious TB as early as possible after the onset of symptoms and to initiate treatment.
- to ensure that persons with active TB are given adequate treatment
- to notify and report cases of TB
- to perform screening to detect TB infection and disease among close contacts of index cases
- to prevent the development of disseminated disease in children by offering BCG vaccination
- to prevent the development of the disease by offering prophylactic treatment to certain groups of infected persons.

Measures to control TB can include one or more of the following examinations:

- ordinary clinical examination and recording of relevant medical history by a medical practitioner,
- tuberculin testing

[9] According to the distribution of functions and responsibilities as specified in the Constitution or legislation or according to government practice.

[10] It is for Member States to determine whether to enact specific TB related legislation and regulations or TB specific regulations pursuant to comprehensive CD legislation. The guidance in this document is based on the latter preference.

- laboratory tests aiming to detect the presence of tubercle bacilli in expectoration, laryngeal smears, urine or in other test material and to determine the sensitivity of the detected tubercle bacilli to anti-tuberculous drugs
- radiography and other imaging techniques of the lungs and other organs.

Measures to control TB also include, in high prevalence countries, systematically offering vaccination to all new born children as soon as possible after birth. Vaccination may be offered to unvaccinated persons who show a negative tuberculin reaction and in whom there are no contraindications.

§ 1-4 The principle of responsibility

Healthcare workers who have duties under the provisions of the regulations are responsible for seeing that the relevant provisions are complied with, and for conducting internal control of their activities.

Chapter 2. Persons having a duty to undergo tuberculin testing

The categories of persons who should be required to undergo testing will depend on the differing circumstances of each country, particularly the epidemiology of TB and the resources available. The following are possible groups that in some circumstances would be included.

§ 2-1 School pupils

Tuberculin testing of school pupils may be an option which the health authorities wish to consider.
The arrangements for and conduct of testing shall be the responsibility of the local medical officer in consultation with those responsible for the administration of schools. The local medical officer shall have discretion (consistent with the intentions of the regulations) to bring forward or defer testing where this would be in the interests of the proper functioning of the schools and local public health services.

The local medical officer or any person so empowered by him/her may exempt a pupil from the duty to undergo tuberculin testing if it can be documented that the pupil has shown a definite positive tuberculin reaction after an assumed TB infection or after vaccination against TB.

The local medical officer or any person so empowered by him/her must ensure that the pupils and their parents or guardians are informed about testing for TB in schools and offer vaccination against TB to tuberculin negative pupils provided that there are no contraindications.

§ 2-2 Teachers and persons involved in the care of children

Prior examination

Teachers and other personnel have a duty when appointed to permanent or temporary full-time or part-time posts, or during training, to undergo tuberculin testing. Unvaccinated persons who show a positive tuberculin reaction also have a duty to have a chest x-ray, but such routine examinations must not take place more often than once a year.

Tuberculin testing must have taken place no more than three months, and an x-ray examination no more than one year, prior to taking up the post.

The provisions in this Section apply to all teachers and other persons whose work regularly brings them into direct contact with children and young people under the age of 15.

The school's or institution's administration has a duty to ensure that tuberculin testing and x-ray examinations, if any, have been carried out prior to taking up the post.

The local medical officer or any person so empowered by him/her may grant exemption from the duty to undergo tuberculin testing to a person who can document having shown a definite positive tuberculin reaction after an assumed TB infection or after vaccination against TB.

The local medical officer or any person so empowered by him/her is responsible for the implementation of prior examinations for TB and the officer shall, in this connection, offer unvaccinated personnel, covered by this provision, vaccination against TB, provided that they are tuberculin negative and that there are no contraindications.

Later examinations

Unvaccinated tuberculin positive personnel have a duty to have a chest x-ray once a year. Unvaccinated tuberculin negative personnel have a duty to undergo tuberculin testing every third year. All personnel have a duty to consult a medical practitioner in the event of persistent respiratory problems and to undergo any relevant examination prescribed by that practitioner.

The local medical officer or any person so empowered by him/her has a duty to ensure that later examinations of vaccinated personnel are carried out as necessary.

The local medical officer must ensure that employees, who are required to undergo regular testing for TB, present themselves for examination.

§ 2-3 Healthcare workers

a) Prior examination

Healthcare workers especially those who will be working in settings where they will be likely to be exposed to infectious TB (e.g. in prison settings) have a duty, when appointed to permanent or temporary full-time or part-time posts, or prior to training, to be tested for TB by tuberculin testing. Unvaccinated personnel who show a positive tuberculin reaction and who are going to work in child care clinics, maternity wards, children's wards, or who work with immunodeficient patients, must also have a chest x-ray, but such routine examinations must not take place more often than once a year.

Tuberculin testing must have taken place no more than three months, and an x-ray examination no more than one year, prior to taking up the post.

The provisions in this Section apply to appointment/training at institutions such as hospitals and other local health services institutions; odontological institutions and dental clinics where the treatment of patients takes place.

In cases of doubt, the local medical officer may decide whether an institution or part of such institution is to be governed by the provisions.

The health institution's administration has a duty to ensure that tuberculin testing and x-rays, if any, have been carried out before new personnel take up their duties. This duty also applies to

students/pupils receiving training at the institution. Unvaccinated tuberculin negative personnel must be offered work where they do not come into contact with patients or infectious material.

The local medical officer, or any person so empowered by him/her, may grant exemption, from the duty to undergo tuberculin testing, to a person who can document having shown a definite positive tuberculin reaction after an assumed TB infection or after vaccination against TB. The same applies if the person does not come into contact with patients or infectious material in the course of the work that is to be carried out.

The local medical officer, or any person so empowered by him/her, is responsible for the implementation of prior examinations for TB and shall in this connection offer unvaccinated personnel governed by this provision vaccination against TB, provided that they are tuberculin negative and there are no contraindications.

b) Later examinations

The local medical officer or any person so empowered by him/her has a duty to ensure that later examinations of vaccinated personnel are carried out as necessary.

§ 2-4 Employees in other occupations where special arrangements are required

The legislation on communicable diseases control may specify certain other groups of workers (according to industry, occupation, or place of work, e.g. ships at sea or offshore oil installations) for whom special requirements for tuberculin testing, x-ray examination, vaccination and treatment are laid down.

In such cases the regulations must specify the persons to whom they apply according to age, occupation, place of work, tuberculin status, previous history. They should also specify action to be taken, allocation of responsibility for taking action and for facilitating action and the designation of those with authority to grant any exemptions.

The regulations applying to these groups of workers should (except where their circumstances determine otherwise) be strictly comparable with those for other persons covered by these regulations.

§ 2-5 Military personnel

a) Non-commissioned personnel and cadets

Non-commissioned personnel and cadets attending colleges in the Armed Forces have, on entering the Forces, a duty to be tested for TB. The Armed Forces decide what testing for TB is to include at any given time.

Military physicians who carry out testing for TB can grant exemption from the duty to undergo tuberculin testing to non-commissioned personnel and cadets if they can document having shown a definite positive tuberculin reaction after an assumed TB infection or after vaccination against TB.

Tuberculin negative non-commissioned personnel and cadets who have not previously been vaccinated against TB shall be offered vaccination against TB provided there are no contraindications.

b) Officers and civilian employees

Officers and civilian personnel who apply for employment have a duty to be tested for TB by tuberculin testing. Unvaccinated personnel showing a positive tuberculin reaction also have a duty to have a chest x-ray unless this has been carried out within the past year.

Military physicians who carry out testing for TB or occupational health physicians employed in the Armed Forces may grant exemption from tuberculin testing under the usual conditions and make a decision about later examinations in individual cases.

Unvaccinated officers and civilian personnel who are tuberculin negative must be offered vaccination against TB provided there are no contraindications.

The military physician or occupational health physician may on further consideration grant exemption from testing for TB to civilian personnel who do not belong to a known risk group or are not going to perform work that is deemed to be especially risky.

§ 2-6 Foreign-born persons

Foreign-born persons intending to stay in the country (other than for a stated short period of time, e.g. not more than three months), who are not exempt from any residential permit requirement, have a duty to undergo medical examination for tuberculosis. If the foreign-born person is 15 years of age or more, he or she also has a duty to have a chest x-ray. The same applies if the foreign-born person is under 15 years of age and has shown a definite, positive tuberculin reaction which is not due to vaccination against TB.

The examinations must be carried out as soon as possible and no later than three months after entry into the country. Refugees, asylum seekers and persons applying for a residential permit for the purpose of reuniting with their families must be examined within 14 days after entry.

The local medical officer, or any person so empowered by him/her may grant exemption from the duty to undergo medical examination for tuberculosis to applicants from countries that have a low incidence of TB. The health ministry or designated central/national health administration should provide information about the countries or areas in the world that have a low incidence of TB.

The local medical officer, or any person so empowered by him/her, has a duty to ensure that persons covered by the provisions in this section undergo medical examination for tuberculosis as stated above. In this connection the officer must offer unvaccinated persons from countries, which have a high incidence of TB, vaccination against TB, provided that they are tuberculin negative and there are no contraindications. This offer also applies to members of the foreign-born person's family resident in the country. Children of persons mentioned in the first paragraph shall be offered vaccination at birth. The local medical officer or any person so empowered by him/her has a duty to ensure that later examinations for TB are carried out as necessary.

Chapter 3. Implementation of measures

§ 3-1 The duties of the local authorities (as specified in legislation)

Local authorities have a duty to ensure that their health services are able to carry out testing for TB in accordance with the regulations and to offer unvaccinated, tuberculin negative persons vaccination against TB in connection with the testing, when this is indicated.

When required, the local authorities must make the necessary arrangements for screening, e.g. mass miniature chest x-rays, and assist in carrying this out.

§ 3-2 The duties of the local medical officer

It is the responsibility of the local medical officer to ensure that the testing for TB of groups of persons is carried out in accordance with the regulations. The local medical officer is also responsible for the testing of other risk groups for TB and to ensure the follow up of cases of TB which are discovered through testing for TB in the Armed Forces and then referred to the civilian health service. When required, the local medical officer shall assist in carrying out selective screening in the district.

The local medical officer may, when expedient, delegate tuberculin testing, chest x-rays, vaccination against TB and observation of intake of anti-tuberculosis drugs to other healthcare workers or reach agreements with other healthcare workers on the execution of these tasks.

If there is a suspicion of active pulmonary TB, the patient must be referred to a pulmonary out-patients department or diagnostic centre.

The local medical officer must carry out contact tracing in cases of TB that may be infectious and in the case of new discoveries of tuberculin converters.

§ 3-3 The duties of regional authorities

The regional authorities have a duty to ensure that the sufficient medical expertise is available to carry out testing for TB at diagnostic centres, pulmonary out-patient departments, radiography departments, laboratories, etc.

§ 3-4 The duties of the regional medical officer

The regional medical officer shall supervise the implementation of measures to control TB. The office of the regional medical officer is the appeal body for persons contesting decisions for instance relating to the prohibition of their performance of work and participation in teaching.

§ 3-5 The duties of a National TB Monitoring and Surveillance Service

The health ministry (or central/national health administration) shall establish a National TB Monitoring and Surveillance Service (or designate some other body to take action) so that it is possible to provide advice and guidance to institutions, medical practitioners and other personnel who carry out or take part in measures to control TB, and to render services to the local health services in the form of selective screening and other measures to control TB.

The functions of the National TB Monitoring and Surveillance Service shall also include keeping a national TB register. When TB caused by multi-resistant tubercle bacilli is found, the National TB Monitoring and Surveillance Service/National TB register, has a duty to discuss the treatment programme with the specialist hospital department monitoring the treatment.

§ 3-6 Follow-up

If it is discovered that a person has TB and needs treatment, treatment in or outside a hospital must be initiated by a competent health worker within the health care system. Continued treatment outside a hospital including observation of the intake of anti-tuberculosis drugs may be done under the direction of a competent health worker.

If a patient with TB is found to have multi-drug resistant TB, treatment must be indicated and monitored by a specialist hospital department.

§ 3-7 Payment and attribution of costs

Testing for TB pursuant to the regulations shall be free of charge to any person who has a duty to undergo such testing. This also includes travelling expenses incurred to attend such testing.

Treatment of persons with a confirmed diagnosis shall be free of all charges to the patient and may include financial support e.g. for transport costs to the place of treatment.

The local authorities have a duty to cover the cost of testing pursuant to the regulations which is carried out by the various parts of the local health service. The local authorities also cover the costs of selective screening insofar as these are not covered by the screening service.

The regional authorities have a duty to cover the cost of testing carried out by specialist services, at diagnostic centres, pulmonary out-patients departments, radiography departments, laboratories, etc.

Employers have a duty to cover the cost of testing for TB among those employees covered by § 2-4 above, employees on ships etc.

The Armed Forces bears the cost of testing its personnel for TB.

Vaccination of tuberculin negative persons against TB is free of charge to the persons concerned. This also includes the travelling expenses incurred from attending vaccination. Local authorities, employers and the Armed Forces cover the costs of vaccination of their personnel.

Chapter 4. Skills required in healthcare workers

§ 4-1 Required skills

Tuberculin testing and vaccination against TB must be carried out by healthcare workers who are proficient in the techniques.

§ 4-2 Training

The local authorities must ensure that an adequate number of qualified personnel are available to carry out testing for TB pursuant to these regulations. When necessary, the local authorities must make sure that such personnel are given the required training in tuberculin testing and vaccination against TB. In each region the regional medical officer must appoint persons with specialist knowledge to give them training.

Chapter 5. Notification/reporting

§ 5-1 Notification of new cases of TB

A medical practitioner who discovers a new case, or assumed new case of TB, or relapse after treatment, must give notification the same day .

Notification must be given on the form for nominative notification of communicable diseases.

These notifications must be sent to the local medical officer and to a designated unit of the health ministry or central/national health administration that must then forward the report immediately to the National TB Monitoring and Surveillance Service/National TB Register.

§ 5-2 Notification of initiation of treatment for TB

The approved medical practitioner who initiate treatment on the suspicion or discovery of TB, see § 3-6, must give notification of the treatment that has been initiated.

Notification must be given on the form for additional information which the National TB Monitoring and Surveillance Service sends to the medical practitioner who has notified them of the new case of TB. The completed form for additional information must be sent to the local medical officer and to the National TB Monitoring and Surveillance Service.

The use of the anti-tuberculosis drug rifampicin or equivalent must comply with the rules regarding the prescribing of such drugs.

§ 5-3 Notification of treatment outcome

The examining physician must report to the local medical officer and on to the National TB Monitoring and Surveillance Service the result of treatment, according to standard definitions. The local medical officer retains a copy of the report.

§ 5-4 Report on contact tracing

The local medical officer must report on contact tracing. The report is given on a special form which is sent to the diagnostic centre or pulmonary out-patients department which enters the results of the contact tracing and sends the duly completed report to the local medical officer and the National TB Monitoring and Surveillance Service.

§ 5-5 Report on tuberculin status and vaccination status

School doctors must report tuberculin status and status for vaccination against TB for school pupils. The report must be submitted on a special form and sent to the local medical officer and to the National TB Monitoring and Surveillance Service.

§ 5-6 Notification of laboratory findings

Microbiological laboratories (departments) must give notification the same day of any findings of tubercle bacilli and resistance results. Pathological-anatomical laboratories (departments) must give notification of any findings of chronic specific inflammation where TB has been found or is highly likely.

§ 5-7 Registers

Registers of notifications received must be kept locally by the local medical officer and nationally by the National TB Monitoring and Surveillance Service/national TB register in accordance with any instructions issued by the health ministry (or central/national health administration).

§ 5-8 Notification forms

Notification of new cases of TB must be given on the form for nominative notification, issued by the health ministry (or central/national health administration) pursuant to the regulations for notification and reporting of communicable diseases by medical practitioners and other healthcare workers.

Notification of initiation of treatment and later control examination should be given on forms for additional information issued by the Health Ministry. Reporting on contact-tracing and tuberculin and vaccination status should be made on forms issued by the Ministry.

The national TB Monitoring and Surveillance Service has a duty to print, store and distribute official forms in use. Medical practitioners who regularly carry out testing for TB should be supplied with, and should keep a stock of, relevant forms.

Chapter 6. Restrictions relating to the performance of work

§ 6-1 Employees

If, during the testing of employees for TB as stated in § 2-2, 2-3, 2-4 and 2-5 a person is discovered to have infectious TB, this person must be prohibited from taking up a post, performing work or participating in activities, where there is a risk of other people being infected, for as long as the medical practitioner deems the disease to be infectious. The same applies when the local medical officer discovers a person with infectious TB among applicants for jobs or employees during screening of risk groups or when tracing contacts as stipulated in § 3-2.

§ 6-2 Pupils/students

If, during the TB control of pupils/students at an educational institution as stipulated in § 2-1, 2-3 and 2-5, a person is discovered with infectious TB, this person must be prohibited from participating in joint education, where there is a risk of other people being infected, for as long as the medical practitioner deems the disease to be infectious.

The same applies when the local medical officer discovers a pupil/student with infectious TB among pupils/students during screening of risk groups or when tracing contacts as stipulated in § 3-2.

§ 6-3 Decisions and annulment of decisions

Decisions regarding prohibition pursuant to § 6-1 for persons governed by § 2-2, 2-3 and 2-5 and decisions regarding prohibition pursuant to § 6-2 are made by the local medical officer.

Decisions regarding prohibition pursuant to § 6-1 for persons governed by § 2-4, first paragraph, are made by the competent person named in the regulations covering each occupation to which § 2-4 applies.

The question of prohibition, pursuant to § 6-1 and 6-2, shall be reconsidered when the person is free from infection and this person's condition is deemed to be stable. The decision must be annulled by the local medical officer or other designated competent person who makes the decision in accordance with the first and second paragraph.

§ 6-4 Appeals

Appeals against decisions, pursuant to § 6-1, for persons covered by § 2-2, 2-3, 5-6 and appeals against decisions, pursuant to § 6-2, are settled by the regional medical officer. Appeals against decisions pursuant to § 6-1, for persons covered by § 2-5, are settled by a special appeals body.

Chapter 7. Entry into force and repeal of current regulations

§ 7-1 Entry into force

The regulations enter into force on (date)

§ 7-2 Repeal of current regulations

The following current regulations are repealed with effect from (date).

APPENDIX 3

WORKING DEFINITIONS OF TERMS USED

BCG-Vaccinated person: a person who has been administered BCG vaccine (an attenuated strain of mycobacterium tuberculosis) and who usually is left with a definite scar on his/her skin as a result of the vaccination.

Case definitions:

-*A case of tuberculosis*: a patient in whom tuberculosis has been bacteriologically confirmed, or has been diagnosed by a clinician.

-*A definite tuberculosis case*: a patient with culture positive for the *Mycobacterium tuberculosis* complex (in countries where culture is not routinely available, a patient with two sputum smears positive for acid-fast bacilli -AFB- is also considered a "definite" case).

Case detection: the activity of identifying infectious cases, mainly among adults attending an out-patient health facility for any reason with cough for two or three weeks or more, through sputum smear examination.

Central/national health administration: the executive body responsible for action on national policy and the implementation of legislation where practice or the constitution determines that the health ministry does not have executive functions.

Cohort: a group of patients diagnosed and registered for treatment during a specific time period (usually one quarter of the year).

Commission for communicable diseases control: the responsible executive arm of the health ministry or the central/national health administration.

Communicable disease: a disease or carrier state which is caused by a micro-organism (specific infectious agent) or part of such micro-organism or by a parasite which can be transmitted among people. Diseases caused by toxins from micro-organisms shall also be regarded as communicable diseases.

Communicable disease that is hazardous to public health (CDHPH): is particularly infectious; may occur frequently; has high mortality or may result in serious or permanent injuries; may become so widespread that it becomes a significant hazard to public health.

Compulsory medical isolation: the temporary confinement of a person who has or who is suspected of having a communicable disease that is hazardous to public health (CDHPH).

Contact: a person exposed to a patient who has infectious TB.

Contact tracing: Interviewing, counselling, educating, examining, and investigating activities directed at persons who have been in close contact with patients who have infectious TB.

Directly observed treatment: a trained and supervised person observes the patient swallowing the tablets.

District court: the local court of first instance to which, as allowed by the legislation/regulations, an individual may appeal a decision about their treatment, e.g. compulsory medical isolation, or to which a decision may be submitted for confirmation.

Enabler: anything that helps the patient to more readily complete therapy (e.g. bus fare from home to place of treatment).

Exposure: the sharing of air with a person who has infectious TB.

Incentive: anything that motivates the patient to adhere to treatment.

Infected person: a person who has a specified communicable disease or who after examination by an expert is with reason assumed to be infected.

Infectious TB: TB disease which is communicable as determined by the bacteriologic examination of body secretions (sputa).

Local authority: the most local level of public administration with public health functions that include prevention and control of communicable diseases.

Local medical officer: an officer of the local authority with an appropriate medical qualification (specified under national legislation) in the management of communicable disease/TB.

Medical Isolation: an infection control practice to prevent the transmission of infectious diseases.

Ministry of Health/Health ministry: the department of government with the responsibility for formulating health policy and national health development strategy; drafting health legislation for consideration and approval by parliament; drafting and promulgating regulations provided for in, and pursuant to, legislation; and the discharge of specific functions which normally include regulations and/or supervision of services relating to disease prevention and control.

Multi-drug resistance (MDR-TB): which is usually the result of irregularity in taking drugs, is defined as resistance to at least INH and RMP, the two most potent drugs and the mainstay of anti-tuberculosis treatment.

Non-adherent: not taking medications as prescribed or not following physician's recommendations for the management of TB.

Non-infectious: not able of transmitting tubercle bacilli. A determination of non- infectiousness can be made when a patient shows significant clinical improvement (the resolution of cough and/or fever) and has negative sputum smears on two consecutive days, is culture negative or the TB site of disease is not the lung.

Pulmonary tuberculosis--sputum smear-positive (PTB+):

1) two or more initial sputum smear examinations positive for AFB, or

2) one sputum smear examination positive for AFB plus radiographic abnormalities consistent with active pulmonary tuberculosis as determined by a clinician, or

3) one sputum smear positive for AFB plus sputum culture positive for *M. tuberculosis.*

Quarantine: limitation on the freedom of movement of persons exposed to, or infected with an infectious disease, to prevent the exposure of other persons.

Regional authority[11]*:* the sub-national level of public administration with public health functions that include resource allocation and human resource planning and the technical supervision and monitoring of the public health functions of the local authorities within its geographic area.

Regional medical officer: the chief medical officer of the regional authority with overall technical responsibility for the proper execution of all public health functions including those exercised by local authorities.

Sputum smear examination: a laboratory technique, where Acid Fast Bacilli (AFB) are stained, then identified and counted through microscopy.

TB: disease caused by *Mycobacterium tuberculosis* complex.

Treatment outcome:

- *Treatment completed:* a patient who has completed treatment but who does not meet the criteria to be classified as a cure or as a failure.

- *Cure:* a patient who is sputum smear negative in the last month of treatment and on at least one previous occasion.

-*Treatment failure:* a patient who is sputum smear positive at five months or later during treatment.

*Tuberculin converter***:** a person who is assumed to have become tuberculin positive recently as a result of natural infection. This may be a previously tuberculin negative person, or a person who has previously been vaccinated against TB and who now has a definitely enhanced tuberculin reaction as a result of re-infection.

Tuberculin positive: a person who shows a definite positive reaction when tuberculin-tested by a recognised method. A definite positive tuberculin reaction in a person who has not been vaccinated usually indicates that this person is infected by tubercle bacilli.

Tuberculosis suspect: any person who presents with symptoms or signs suggestive of tuberculosis, in particular cough of long duration.

[11] In some Member States these functions may be exercised by the health ministry (q.v.) or by a designated central/national health administration (q.v.). In federal or confederal states the public health functions covered in these regulations may be allocated/devolved to a provincial government with autonomous powers specified in the Constitution.
Countries with highly pluralistic health systems may find it more suited to their culture to set up *ad hoc* bodies for the functions covered in these regulations whose functions and *modus operandi* are negotiated between the interested parties, but whose functioning is explicitly sanctioned by the government.

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(*) The documents marked with an asterisk can be consulted and downloaded from the web WHO TB page http://www.who.int/gtb/publications/TBBookRep.htm.