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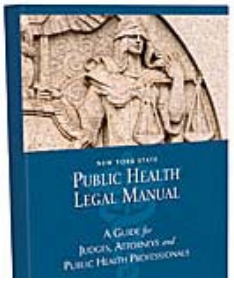
DEVELOPING A FRAMEWORK FOR PUBLIC HEALTH LAW IN EUROPE

By: Snezhanna Chichevalieva



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ABSTRACT

This document provides a framework for discussion about the development of public health law in Europe. The differences in legal and public health systems in Europe are reflected in public health legislation. A combined approach, involving the incorporation of public health issues into other legislation and the enactment of a specific public health law, is most likely to address the complexity of public health needs. The document advocates a common European understanding for the definition, scope and drafting process of public health law, and emphasizes the need for a clear philosophical framework. It specifically addresses risk-based approaches where it is commonly understood that a fundamental aim of public health regulation is to prevent, reduce and manage public health risks. The document concludes that public health law is intended to create an environment in which the promotion of health goes hand-in-hand with the protection of individual rights and the general principles of equality and justice.

Keywords

PUBLIC HEALTH - LEGISLATION AND JURISPRUDENCE - TRENDS
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About the author

Snezhanna Chichevalieva is a lawyer and a senior governmental officer. At the time of writing this report she was head of the international affairs and European integration department of the Ministry of Health of The former Yugoslav Republic of Macedonia. She was formerly the Assistant Minister and the Chief negotiator for public health of her country with the European Commission and was coordinating the process of transposing the European Union Acquis Communitaire into the national public health legislation. She is Chair of the Executive Committee of the South Eastern Europe Health Network, which undertook since its commencement in 2001 high profile regional and national strategic public health policy, legislation and services research, policy planning and implementation in a broad number of public health areas (public health services, human resources for health, mental health, tobacco control, food safety and nutrition, blood safety, etc.). Snezhana Chichevalieva has extensive experience in public health policy and legislation development.

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Foreword

The WHO European Region faces new challenges due to an epidemiological and demographic change, a growth in lifestyle-related chronic diseases, a great disparity in health threats and disease burdens within and between countries and, more starkly, their ability to tackle them. A central question for WHO and other actors in the public health field is therefore to what extent current public health instruments address these particular challenges in the 21st century.

In 2010 the Regional Office was asked by the European Regional Committee to strengthen public health capacity and services and review the effectiveness of available public health instruments for addressing key public health and health policy challenges in Europe. An important element in this is to strengthen regulatory frameworks for protecting and improving health..

The use of legally binding arrangements to protect population health is widespread. More recently there has been cost-effective action taken to reduce alcohol consumption through taxation and advertising bans; tobacco control measures related to advertising, taxation and smoke free environments; legislation to reduce salt content in food; and road safety measures.
However, besides a wide range of available instruments, there is significant variation between countries' deployment of specific instruments, as well as changes in national regulatory frameworks arising from a growth in pluralism and democratization. Additionally, evidence of effectiveness of the instruments in place is still currently limited. Therefore, an important aid to Member States' efforts to develop effective national and regional strategies and policies is to review the tools and instruments that currently exist.

Based on this analysis, the document sets out some guiding principles that could help the development of national public health laws. These principles describe a general approach to Public Health legislation that could be applicable to different legal systems with the potential for adaptation to the national context.
It is intended that during 2011, this work will be taken further with the development of a Public Health Framework for Action, in the context of the new European Health Policy: Health 2020.
The Public Health Action Framework will represent a unique opportunity for Member States to review their existing public health capacities and services and to define country specific policies to strengthen them. This process will form the basis for developing a much stronger public health function in Europe.
We at WHO hope this publication will make an important contribution to the discussion that would lead to a renewed focus on strengthening Public Health in Europe, within a broader and strategic context of the Public Health Framework for Action.

Zsuzsanna Jakab
WHO Regional Director for Europe

Executive summary

The purpose of this document is to provide a framework for discussion about the development of public health law in Europe. It addresses issues that are essential in any consideration of the process of drafting a public health law: firstly, the benefits of the public health law improvement process (why revise the law?); secondly, the framework for public health law (what should be the scope of the law?); and thirdly, the process of drafting public health law (how can the stakeholders be involved and different interests in the public health area integrated in the drafting of the law?).

Regulatory frameworks are complex and multifaceted. Where risks to the health of the population are considered to outweigh other considerations, including individual choice, legislation is the preferred policy instrument. In recent years the use of legally binding arrangements to protect population health has increased. In particular, aspects of environmental health, safety of food and drinking-water, occupational health and infectious disease control have been the subjects of public health legislation. *(49)*

The document reflects on some of the existing national public health laws in Europe as a source of experience. It clearly advocates a common European understanding for public health law, its definition, scope and the drafting process.

The law is merely one tool for improving public health. "Many of the problems observable in public health are remedied, not primarily through law reform, but rather through better governance, training, improved infrastructure, surveillance, epidemiological investigations, comprehensive counselling, continuing health education and innovative preventive strategies*".(8)*

Improving public health law could bring benefits such as: the updating of laws; compliance with national and international legal requirements; and improvements in the relationships between public health authorities and other relevant authorities, within country-specific vertical hierarchies of public health authorities, and between public health authorities and private and civil society initiatives in public health.

The document explores the trends in public health law today, specifically addressing risk-based approaches where it is commonly understood that a fundamental aim of regulation is to prevent, reduce and manage public health risks. The regulation of risk works both preventively and proactively and can be contrasted with traditional approaches to public health that tended to be purely reactive to the occurrence of a consequence. The document emphasizes the need to set up a clear philosophical framework for public health law, pointing to the Ottawa Charter as being useful to this end.

Public health law is understood as the legal powers and duties of the state to assure the conditions for the population to be healthy (such as identifying, preventing and ameliorating the risks to health) and the limitations on the power of the state to constrain the autonomy, privacy, liberty or other legally safeguarded interests of individuals for the purposes of protecting or promoting community health.

The main focus of the document is, however, on what should be considered within the framework of a public health law. An example of the contents of such a law is given, with short discussions of each item to indicate some of the reasons why the item should be scoped by the public health law and stir further discussion, using some examples from the wealth of existing legislation practices in European countries.

There is a wealth of documents on European level in public health systems that can be used as examples in further discussions on the framework for public health law in Europe.

While essential public health functions are seen as necessary parts of public health law, different organizations have slightly different ideas as to what constitutes them.

National public health law is influenced to a great extent by international law, especially that related to human rights, the international spread of diseases the tobacco epidemic and the public health standards for products. By ensuring that their public health legislation is up to date, soundly-based and properly implemented, states will come closer to realizing "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" in their populations*.(50)*

Clear demarcations of roles and responsibilities are of the utmost importance in a well-functioning public health act, which should at the same time provide for mechanisms and instruments for improving relationships, coordinating functions and resolving disputes.

Public health systems in Europe vary widely and are subject to national processes such as centralizing/decentralizing responsibilities for public health or organizational changes in public health agencies and their differing missions, organization and activities. Revisiting these systems at national level will contribute to improving existing services and ensuring accountability for them as well as quality assurance. Contemporary developments such are WHO process of developing a European framework for action to strengthen public health capacities and services in Europe that will accompany the European Health Policy, Health 2020, as well as EU Health Forum as a structure used by the Commission to encourage all stakeholder groups, regional and local organisations to get involved in the development and implementation of actions to protect and improve the health of European citizens *(51)*, are important contributers to further developing of European framework for public health.

The document advocates: (i) use of internationally agreed classifications of diseases (ii) the basing of public health decisions on the best scientific evidence of significant risk, (iii) the provision of enforcement and balanced and adequate powers to deal with public health risks, (iv) the provision of fair procedures in the protection of individual rights and (v) the constituting of statutory advisory bodies with appropriate monitoring and evaluation systems and reporting mechanisms.

It is commonly understood that proper funding of public health is essential and should be regulated so as to provide for the implementation of activities. Building an adequate sanctions policy, where appropriate, can also contribute to public health goals.

The document reflects on the diversity of national approaches to public health legislation. Whether the public health partnership is encompassed in a single public health act or a series of regulations is a question for national decision-making. What is essential is that legislation or regulations are functional.

The document presents the idea of public health legal services that offer a rich and powerful incentive for public and private agencies to increase free and subsidized legal services. At the same time, the legal services necessary from a public health perspective may not be those currently emphasized by providers. The vision of public health legal services in many ways favours prevention over crisis management and therefore calls upon the traditional providers of legal services to rethink their customary resource allocation models.

The definitions used in national public health laws in Europe differ significantly. They also differ among various organizations. The document looks at the terms and definitions used in international treaties, where appropriate. Creating a new common public health law glossary through revisiting existing glossaries might help to build a common understanding in the area of public health law.

The document concludes that public health law is intended to create an environment in which the promotion of public health goes hand-in-hand with the protection of individual rights and the general principles of equality and justice. Over the years, the importance of public health law has grown at both national and international level. As health and human rights are closely interlinked, it is important to integrate public health law and public health policy. It is to be expected that, especially in Europe, the impact of public health law on policy-making for public health will increase as a result of several developments, such as the internationalization of health care and health policy, the issue of consumer protection and the legalization of society. This requires a strategy to stimulate the fruitful relationship between public health policy and public health law.

Although there is broad consensus that public health law is essential to good public health, the objectives and content of the law pose a challenge. Public health law in many countries does not respond to modern developments; does not clearly delineate the responsibilities entrusted to public health agencies, boards and officials at different country-specific levels and the relationships between them; fails to equip public health officials with the powers necessary to control diseases; lacks adequate privacy protection standards, due process and risk assessment; and is still not based on up-to-date disease classification schemes that address contemporary health problems.

The lack of a consolidation of laws in some European countries presents a significant challenge to obtaining a complete picture of public health laws in the region. Creating directory of public health laws in Europe is usefull to sharing best legal practices in public health.

There are at least four possible roles for the law in advancing public health. The law can: (i) define the objectives of public health and influence its policy agenda, (ii) authorize and limit public health action with respect to protection of individual rights, as appropriate, (iii) serve as a tool for prevention, and (iv) facilitate the planning and coordination of governmental and nongovernmental health activities.

The differences in legal and public health systems in Europe are reflected in public health legislation. A combined approach, involving the incorporation of public health issues into other legislation as well as the enactment of a specific public health law, is most likely to address the complexity of public health needs. This decision will, however, depend on countries' circumstances.

This opens the door for a consultation process on what should be included in public health law as a single act, without prejudice to the existing dispersed public health legislation in some countries, or some single public health acts endorsed in others albeit with differing scope and purpose.

The following elements should be considered to be essential for inclusion in a single public health act:

- a clear philosophical framework;
- definition of public health law;

- definition of common terms in public health law;
- establishment of essential public health functions;
- due importance paid to the international public health law context;
- clear demarcation of the roles and responsibilities and establishing coordinative mechanisms in the system;
- improvement of existing services, inclusion of accountability and enhancement of quality assurance;
- use of internationally agreed disease classifications;
- public health decisions to be based on the best scientific evidence of significant risk;
- establishment of good enforcement and adequate powers to deal with public health risks;
- provision of fair procedures;
- establishment of statutory advisory bodies;
- setting-up of impact-oriented monitoring and evaluation systems and reporting mechanisms;
- establishment of a legal basis for partnerships in public health activities;
- provision of public health legal services;
- provision of funding;
- setting of adequate penalties, as appropriate.

The substance of the document and the proposed framework for a public health law are not intended to be exhaustive, but rather demonstrative of various elements in such a law that should provide baseline for its reform in Europe on the basis of the most recent collective international knowledge. In particular, it has taken into consideration those recommendations from the Georgetown University Law Center that are relevant to the development of public health law in Europ.*(8)*

Introduction

The beginning of the 21st century provided an early preview of the challenges to health that countries will be facing in the coming decades. The systems and entities that protect and promote public health, already challenged by problems such as obesity, toxic environments, large populations with inadequate access to health care and health disparities, must also confront emerging threats such as antimicrobial resistance and bioterrorism. The social, cultural and global contexts of nations' health are also undergoing rapid and dramatic change. Scientific and technological advances, such as genomics and informatics, extend the limits of knowledge and human potential more rapidly than their implications can be absorbed and acted upon. At the same time, people, products and germs migrate and nations' demographics are shifting in ways that challenge public and private resources.

Globalization is characterized by the rapid worldwide advance of money, resources, production and consumer needs *(1)*. This integration of socioeconomic conditions is highly complex and invariably results in the coordination of a wide network of countries in one single society. The comprehensive character of globalization has not only extended across oceans and geographical areas but also through various facets of society, where economic means define the social branches of education, health care and judiciary systems and vice versa.

Thus, many of the factors that determine physical well-being and health lie outside the framework of biotechnology, genetics and public health and within the context of social preconditions. When health is sacrificed for economic gain, the issue of medical care becomes one of human rights. Often the battle between the right to economic freedom and the right to physical well-being becomes one of the wealthy versus the poor on a global scale. The mortality rate of children in developing countries also reflects economic division. About 19% of deaths in the world are of children under the age of five years and almost 98% of these deaths occur in the developing world. A baby born in Sierra Leone is more than a hundred times more likely to die than a child from a developed European country *(2)*. Many of these deaths are preventable: "pneumonia, diarrhoea, malaria, measles and AIDS account for about half of under-5 deaths"*(3)*. This is not to say that abnormalities in physical health do not exist outside developing countries. While impoverished areas battle preventable ailments, developed countries with rising levels of affluence face "overeating, overdrinking, smoking pollution, illicit drugs and motor vehicle accidents" *(3)*.

The new public health will confront globalization in all its facets by "including all health activities in any one country … What happens in the rest of the world, including the effects of globalization, is of direct interest to each country, no matter how wealthy, industrialized, or isolated" *(3)*.

The future of health care must, therefore, be based in the context of globalization and in the interconnectedness between physical well-being and the structure of socioeconomic policies. While the lines dividing individual countries break down, the next generation of the medical workforce must be ready to encounter the international nature of health care on a daily basis. As shown above, in the globalized world of the 21st century, no individual or country can act in isolation. The commitment to quality health care must be demonstrated at all levels and resources, technology and information must be spread cross-culturally and internationally in order to work towards the ideal goal of health for all *(1)*.

Efforts to reduce inequalities in health face challenges in the increasing diversity of populations, while the widespread survival of people into old age underscores the need for effective policies to promote healthy ageing and to prevent disease and disability *(4)*.

The concept of health as a public good is widely accepted, as is the fundamental duty of government to promote and protect the health of the population.

A "public good" is a product or service which benefits everyone in the community. Public goods are characterized by: (1) value that has benefit to the community as a whole beyond any purchase price paid, (2) often requiring large initial investment costs that are generally too expensive for any individual or private corporation to afford and earn a reasonable return, (3) requiring a higher level of administration than any individual or company can arrange and (4) having value that accrues over time and is difficult to price properly. Public goods have "externalities," that is, value that accrues to people who benefit by other's consumption of them without paying for it themselves.

To address the social, economic and cultural environments at national, regional and local levels most effectively, the nation's efforts must involve more than just the traditional sectors − the governmental public health agencies and the health care delivery system. What is needed is the creation of an effective intersectoral public health system. Furthermore, the efforts of the public health system must be supported by political will, which comes from elected officials who commit resources and influence based on evidence and by "healthy" public policy, which comes from governmental agencies that consider the effects on health when developing policies for financing, agriculture, justice, education, commerce, labour, transport and foreign affairs, etc.

An effective public health system that can assure the nation's health requires the collaborative efforts of a complex network of people and organizations in the public and private sectors, as well as an alignment of the policy and practice of the government's public health agencies at different country-specific levels of the hierarchy. Governments have a specific responsibility to strive to create the conditions in which people can be as healthy as possible. For governments to play their role within public health systems, policy-makers must provide the political and financial support needed for strong and effective governmental public health agencies.

Although strengthening health-care systems is receiving increased attention, strengthening public health systems and institutions could save far more lives at lower cost. Public health institutes monitor, implement, and oversee programmes to prevent disease*.(52)*

The contemporary goals for public health in Europe are to improve health through more effective programmes and to understand better the causes of continuing disease and disability *(5)*.

Although health in Europe is better than ever before, there remain substantial challenges relating to premature disease (with variations geographically, between social groups and among minorities) and care for an ageing population. And while cardiovascular disease, cancer and injuries have not been conquered, new lifestyle diseases such as HIV/AIDS and obesity are spreading. In response to these challenges, there need to be improvements in public health systems for prevention, treatment and care, with an emphasis on effectiveness, efficiency and equity.

> Health law is intended to create an environment in which the promotion of health goes hand in hand with the protection of individual rights and the general principles of equality and justice. Over the years, the importance of health law has grown, both at national and international levels. As health and human rights are closely interlinked, it is important to integrate health law and

> health policy. It is to be expected that, especially in Europe, the impact of health law on health policy-making will increase as a result of several developments, e.g. the internationalization of health care and health policy, the issue of consumer protection and the legalization of society. This requires a strategy to stimulate the fruitful relationship between health policy and health law *(6)*.

Two of the most important tools that assist states in protecting their populations against threats to health are public health policy and public health law. Policy can exist without recourse to law, but where policy has been designed for a long-term purpose and where voluntary compliance has not proved successful, the heavier hand of the law may be needed if the policy is to be implemented. However, the law is not always an appropriate mechanism for achieving public health objectives *(7)*. Certainly, policy can exist without recourse to law and legislation may provide only legal mechanisms for implementation of policy. The law or legislation has to be based on policy objectives, principles and directions to ensure effective legal mechanism are in place. In conclusion, formulation of legislation has to be followed by policy development.

Public health law contemplates the responsibilities of individual people and organizations and the duties of the government to act for the health of society. Laws define the jurisdiction of public health officials and specify the manner in which they exercise their authority. Laws can also establish norms for healthy behaviour and create the social conditions in which people can be healthy. Legislatures, courts and administrative agencies serve as conduits for social debates on important public health issues within the legal language of rights, duties and justice.

The authors understand public health law as "the study of the legal powers and duties of the state to assure the conditions for people to be healthy (e.g., to identify, prevent and ameliorate risks to health in the population) and the limitations on the power of the state to constrain the autonomy, privacy, liberty or other legally protected interests of individuals for protection or promotion of community health" *(8)*.

Although there is broad consensus that legislation is essential to good public health, the objectives and content of the law remain a challenge. Public health law in many countries still does not respond to modern developments; does not clearly delineate the responsibilities entrusted to public health agencies, boards and officials at different country-specific levels and the relationships between them; fails to equip public health officials with the powers necessary to control diseases; lacks adequate privacy protection standards, due process and risk assessment; and is still not based on up-to-date disease classification schemes that address contemporary health problems.

Purpose of the document

This document aims to provide a framework for discussion about the development of public health law in Europe. It addresses issues that are essential in any consideration of the process of drafting a public health law: firstly, the benefits of the public health law improvement process (why revise the law?); secondly, the framework of public health law (what should be the scope of the law?); and thirdly, the process of drafting public health law (how can the stakeholders be involved and different interests in the public health area integrated in the process of drafting the law?).

The substance of the document and the proposed framework for a public health law are not intended to be exhaustive, but rather demonstrative of various elements of public health law that should provide a guideline for reform of public health law in Europe.

The document provides for an overview of the trends in public health law in Europe, as well as of some national regulatory frameworks for public health in Europe, as a source of experience. It also addresses the importance of the participatory democracy in the process of drafting public health law.

Acknowledging the complexity of public health law and the interdependence of various players in the system, the document explores the way to provide for the proper conduct of the legal powers and duties of the state to assure the conditions for people to be healthy (to identify, prevent and ameliorate risks to health in the population) and, at the same time, to set properly the limitations on the power of the state to constrain the autonomy, privacy, liberty or other legally protected interests of individuals for the purposes of protecting or promoting community health.

Consideration has been given to the need to identify a country's existing public health legislation by building or acquiring a national "snapshot" of all primary and secondary laws that might affect public health, before deciding on the framework of the national public health law. The legislative picture is more complex in nations with federal systems where both federal or national parliaments and state or other regional parliaments may be lawmakers.

The lack of consolidation of laws in some European countries presents a significant challenge to obtaining a complete picture of public health legislation.

Thus, providing for directory of public health legislation European level should be adding to the possibilities of exchange good practices .in legislating public health.

The benefits of a public health law improvement process

Public health law contemplates the responsibilities of individuals and the duties of government to act for the health of society. As such, public health law serves as a legal foundation and a framework for public health activity. Public health law should ensure that public health agencies are fully capable of responding to current and coming/emerging public health threats. Unfortunately, existing public health laws too often fail to take health determinants into account in carrying out their essential services and accomplishing their goals. Reform of the law seen as public health intervention can promote more effective decision-making and protect individual rights.

These public health interventions can be highly cost effective. They include actions to reduce alcohol consumption through taxation and advertising bans; legislation to reduce trans fats and salt content in food; tobacco control measures related to advertising, taxation and smoke free workplaces; and road safety through mandatory seat belt use, speed bumps and breath tests. While many of these actions would already be justified for other reasons, the cost effectiveness evidence is a further argument in favour of their implementation.*(1)*

Public health and public health legislation in particular, must be, increasingly, guarantees of the fundamental rights of individuals. Given the diversity of political, social and regulatory framework in Europe, it would be useful defining areas of common action and soft skills of health authorities, which would create a benchmark for individual fundamental rights protection "*against*" the actions of states, but also accelerate the epidemiological surveillance as well as common performances in public health.

It is important to be clear about the limitations of the legislative approach. The law is merely one tool in the improvement of public health. "Many of the problems observable in public health are remedied not primarily through reform of the law, but rather through better governance, training,

improved infrastructure, surveillance, epidemiological investigations, comprehensive counselling, health education and innovative prevention strategies. In making policy, public health authorities will have to consider prevailing social values and respect multiple constituencies, including scientists, politicians, community leaders and civil society." *(8)*

An example, among others, is Estonia, where public health law is being used as an instrument together with other improved communication and information technology, reforms in health system financing, economic growth, and other to enhance public health (Box 1). In addition, enhancing public health is based on evidence provided through research. For example, World Health Organization in collaboration with Estonian Government; Estonian Ministry of Social Affairs and Estonian Science Foundation carried out a study: Measuring burden of disease in Estonia to support public health policy in 2009, and as a result, have come to a conclusions that "cardiovascular disease and injuries, premature mortality, working age population, male and people from economically less developed regions should be the priority targets for public health interventions. Estonian main public health strategies now address burden of disease concerns highlighted by our study. *(74)*

Box 1. Public health law in Estonia

"An international observer of public health in Estonia would be struck immediately by the country's remarkable opportunities for the establishment of outstanding public health services. Some key factors underpin a propitious environment for public health. These include Estonia's small population (less than 1.4 million); a secure parliamentary democracy; recent membership of the European Union (EU), including a rapid achievement of all its membership requirements; impressive economic growth for many years prior to the current downturn; high investment in information and communication technology, including in the health sector; solidarity-based financing of the health system and a modern provider network of family medicine-centred primary health care, which deals with health prevention issues; and last but not least, the existence of official policy focused on public health goals and services."

Source: WHO *(9)*.

There are at least four possible roles for the law in advancing public health. Legislation can define the objectives of public health, authorize and limit public health action, serve as a tool for prevention and facilitate planning and coordination of overall public health activities.

Public health laws should establish the purposes, goals and core functions of public health, the personnel and infrastructure realistically needed to perform these functions and budgeting mechanisms that will provide reliable levels of support. When this is done, the law can influence the activities of government and can give legal frame to societal expectations of the scope and importance of public health. Especially in times of financial crisis, structuring public health law to embrace defined functions, funding mechanisms and the minimum infrastructure and personnel needs can provide a yardstick for health departments and policy-makers in the future.
Public health law must provide broad authority for the exercise of public health powers while at the same time limiting that authority where necessary for the protection of individual rights. In considering law reform, it is important to distinguish between duties and powers in public health. The legislature should impose duties on health departments to initiate a broad range of activities relating to surveillance, control of noncommunicable and communicable diseases, environmental protection, sanitation, the prevention of injuries and so on. It is important that health officials retain flexibility in the powers used to achieve public health purposes. The law must also place appropriate limits on those powers to protect human rights. This is best accomplished if:

- clear criteria are established for the exercise of compulsory powers (for example, requiring health authorities to use scientific evidence of a significant risk to public

health as the basis for exercising compulsory powers in order to prevent differences in exercising powers, possible infringements of individual rights or unlawful discrimination);

- procedural due process is provided for all individuals who face serious constraints on their liberty; and
- the privacy of individuals is protected.

Public health law is, and should be understood as, a tool for prevention. It should use a wide variety of legal means to prevent injury and disease by creating the conditions for people to be healthy.

Improving public health law could bring benefits such as: the updating of laws; compliance with national and international legal requirements; and improvements in the relationships between public health authorities and other relevant authorities, within country-specific vertical hierarchies of public health authorities, and between public health authorities and private initiatives in public health *(10)*.

Framework for a public health law: what should be considered

Trends in public health law

"Conceptualization of public health law is not easy. Lawmakers, judges, health officials, scholars and others have often viewed public health law at the intersection of other fields or disciplines including health law, health care law, forensic medicine, environmental law and bioethics. While public health law is conceptually linked to the fields of law and medicine or health care law, it is a distinct discipline which is susceptible to theoretical and practical differentiation from other disciplines at the nexus of the law and health." *(8)*

Most jurisdictions are in the process of reviewing their core public health acts. The identification of some key elements or principles, supported by examples of good practice, would seem useful to aid consistency in approach between the various jurisdictions.

Most public health laws in Europe today have been passed in response to specific disease threats such as tuberculosis, sexually transmitted diseases and HIV/AIDS.

Over the past decade, many countries have considered, strengthened, or created national public health institutes (NPHIs), often following a major event such as the outbreak of severe acute respiratory syndrome. *(52)*

The law has thus developed, layer upon layer, from one period to another. Certainly, older laws are not necessarily bad laws. A well-written statute may remain useful, efficacious and constitutional for many decades. Older laws are, however, often outmoded in ways that directly reduce their efficacy and conformity to modern legal standards. Older laws may not reflect contemporary scientific understanding of a disease, current medical treatments of choice or constitutional limits on the state's authority to restrict individual liberties. They may fail to allow public health agencies the discretion to modernize such enactments through administrative regulation. Some public health laws lag behind contemporary developments in constitutional law, discrimination law, health information privacy and other modern requirements.

Courts today have more exacting standards for equal protection under the laws, substantive due process and procedural due process. Public health powers that affect liberty (such as quarantine and directly observed therapy), privacy (such as reporting and partner notification) and autonomy (such as compulsory testing, immunization or treatment) may undergo more careful

scrutiny. At the same time, legal systems may require more rigorous procedural safeguards to be available before the exercise of compulsory powers.

Many health laws prohibit discrimination against persons based on their health status, such as an infectious disease. This may require health officials to adopt a standard of "significant risk" before resorting to compulsion. A significant risk may be defined as a direct threat to the health and safety of others that cannot be eliminated by modification of policies, practices or procedures. Thus, under this standard, adverse treatment, such as a decision to use compulsory powers, would only be permitted if the person posed a significant risk to the health or safety of others. A significant risk regarding communicable diseases would be determined through an individualized assessment of the mode of transmission, probability of transmission, severity of harm and the duration of infectiousness.

General or overlapping provisions concerning public health duties and responsibilities sometimes result in confusion about who has what public health powers and when those powers can be exercised. This confusion is understandable. Given the layer-upon-layer approach of public health law, even the most expert lawyers have difficulty in providing clear answers to public health officials about the authority to act. One major benefit of reform to public health law would be to provide greater clarity about legal powers and duties.

The utopia of a medical government—giving the political commands to doctors—has been a recurring dream in the history of public health. Sanitarians, hygienists, and eugenicists liked to envision themselves as rulers and reformers of society, …, which imagined daily life under "the despotism of some benevolent autocracy, such as a super-ministry of health". *(53)*

Instead of pursuing this utopia, improving the working relationships in public health complex stakeholders set up, should be established as an important goal. Public health practice involves complex relationships between governmental and nongovernmental entities and actors. These relationships are of several kinds: legislatures and public health authorities; national and regional; regional and municipal; urban and rural; public health authorities and the private sector; and among different public health authorities themselves (health and environment, traffic and health, etc.).

Integration organisations play important role in perceiving and guiding public health practice, as defined today. Thus, the EU has a legal duty to protect public health in all its policies and activities – including legislation governing Europe's internal market for goods and services.*(54)*

Risk-based approaches to public health law

A risk-based approach aims to consider the risks inherent in particular activities, products and behaviour (for example, of a factory, business or person) in order to ascertain whether a risk is of sufficient significance to merit society exercising some control over the activity. There are many definitions of risk, but it is usually considered to be a combination of the degree of probability of something going wrong coupled with a consideration of the gravity of the consequence in such an event. Controls or regulation might occur in an effort to prevent the occurrence of the undesirable consequence.

In public health, a fundamental aim of regulation is to prevent, reduce and manage public health risks. Risk regulation is both preventive and proactive and can be contrasted with traditional approaches to public health that tended to be purely reactive to the occurrence of a consequence. Risk regulation can also achieve other aims such as the reduction of inequalities and the enhancement of democratic values.

A risk-based approach includes that if the threat is of serious or irreversible damage, a lack of scientific certainty about the degree of risk is not a reason to do nothing. It may even be decided that even though a particular activity does present risks, regulation will not help to prevent the undesirable outcome, or might be only partially effective, or might be at too high an economic cost. Conversely, as is the case with tobacco control, activities might present risks that regulation will help.

If it is accepted that regulation must occur, there must be consideration of what kind of law or regulation will be most appropriate. Regulation might be by law or by alternative measures such as taxation, education or the provision of resources or by a mix of such approaches. Principles employed in the risk-based approach include:

- performance/outcomes versus prescriptive measures
- flexible versus inflexible responses
- self-regulatory controls versus more prescriptive responses
- development of bottom-up versus top-down controls
- participatory measures versus those that are imposed.

Enforcement of laws can also provide for flexible responses. The concept of responsive regulation is often included in modern laws to enable an appropriate response to a breach that seeks to ensure the achievement of compliance rather than the automatic imposition of a particular penalty. It might involve incentives and disincentives to act in certain ways. Regulation might also be performance-based, or even goal-based where a law sets a goal to be achieved but allows individuals or legal entities to decide on action to meet the goal rather than being told precisely what to do.

A clear philosophical framework

Public health law provides an opportunity to set a philosophical framework for public health.

The Ottawa Charter for Health Promotion, agreed in November 1986 at the First International Conference on Health Promotion, is useful example to this end *(11)*. It takes a broad and proactive view of health and defines the prerequisites for health as "peace, shelter, education, food, income, a stable eco-system, sustainable resources, social justice and equity. Improvement in health requires a secure foundation in these basic prerequisites".

The Charter recognizes that good health "demands coordinated action by all concerned: by governments, by health and other social economic factors, by nongovernmental and voluntary organizations, by local authorities, by industry and by the media". It emphasizes the need for governments to build "healthy public policy" and to "accept their responsibilities for health" through a wide range of strategies and initiatives, including the construction of healthy environments and the strengthening of community action.

A shared commitment to improve health as well as health care system operation was most recently captured in the 2008 WHO Tallinn Charter on Health Systems for Health and Wealth *(55)* which confirmed and articulated the following principles:

- Promote shared values of solidarity, equity and participation through health policies, resource allocation and other actions, ensuring due attention is paid to the needs of the poor and other vulnerable groups;
- Invest in health systems and foster investment across sectors that influence health, using evidence on the links between socioeconomic development and health;
- Make health systems more responsive to people's needs, preferences and expectations, while recognizing their rights and responsibilities with regard to their own health;

- Engage stakeholders in policy development and implementation;
- Foster cross-country learning and cooperation on the design and implementation of health system reforms at national and subnational levels; and
- Ensure that health systems are prepared and able to respond to crises, and that countries collaborate with each other and enforce the International Health Regulations.

Defining public health law

The essence of public health law is the definition of public health. The term "public health" has varying translations and meanings in the different European languages and cultures, but it generally indicates a population-level approach with a likelihood of society-wide benefits.

Public health has been defined by the World Health Organization (WHO) as "the art of applying science in the context of politics so as to reduce inequalities in health while ensuring the best health for the greatest number" *(12)*.

Another widely accepted definition of public health is that contained in the report *Securing good health for the whole population* (the Wanless report): "The science and art of preventing disease, prolonging life and promoting health through the organized efforts and informed choices of society, organizations, public and private communities and individuals" *(13)*.

WHO Europe, at the First meeting of the European Health Policy Forum for High-Level Government Officials in March 2011 in the paper "Strengthening Public Health Capacities and Services in Europe: Definitions vary depending on whether they are framed by the public health function and activities related to a public health workforce; whether they are normative or descriptive; or whether they incorporate wider social and economic factors influencing population health and health inequalities. From a pragmatic perspective a general definition is required, which may be used as a basis for describing in more detail the core activities of the public health function, but which is also sufficiently flexible to allow for debate on broader interpretations of what is involved in improving the health of the population in a given context and at a particular time.

After considerable internal and external consultation. the definition of public health originally put forward by Winslow in 1920 (56), and adapted by Acheson in 1988,(57) has been widely accepted, and is proposed for adoption: "Public health is the science and art of preventing disease, prolonging life and promoting health through the organized efforts of society"

Building on this definition of public health, public health law can be defined as: "The study of legal powers and duties of the state to assure the conditions for people to be healthy (e.g., to identify, prevent and ameliorate risks to health in the population) and the limitations on the power of the state to constrain the autonomy, privacy, liberty, or other legally protected interests of individuals for protection or promotion of community health" *(8)*.

From this definition five essential characteristics distinguish public health law from the fields of medicine and law:

- government: public health activities are primarily (but not exclusively) the responsibility of government rather than the private sector;
- populations: public health focuses on the health of populations rather than the clinical improvement of individual patients;
- relationship: public health contemplates the relationship between the state and the population, rather than the relationship between the physician and patient;

- services: public health deals with the provision of public health services to/for the community rather than personal medical services;
- coercion: public health possesses the power to coerce the individual for the protection of the community, as appropriate and within the framework of the international legal standards for protection of human rights (see: Siracusa Principles)

Public health pursues high levels of health, consistent with social justice.

Although these broad parameters help to distinguish public health law from other fields, it is useful to examine the concept of public health law further through the constitutional system of government.

Box 2: Tallinn Charter
"Within the political and institutional framework of each country, a health system is the ensemble of all public and private organizations, institutions and resources mandated to improve or restore health. Health systems encompass both personal and population services, as well as activities to influence the policies and actions of other sectors to address the social, environmental and economic determinants of health".
Source: Tallinn Charter, WHO Europe, 2008

For those who see public health as a particular area of government activity, public health legislation comprises the issues contained within the group of acts traditionally enforced by public health agencies. This includes the "core" public health acts and the laws relating to food, drugs, poisons, tobacco, radiation, etc. These central or "inner" laws are inevitably regarded as public health laws.

Box 3: A Portuguese success story: One nation begins to curb its salt intake *(58)* Law to reduce salt consumption in Portugal

Doctors from the Portuguese Society of Hypertension have spearheaded a unique mass-media campaign about the harmful consequences of consuming too much salt, which in turn has led to the Portuguese Parliament approving a law restricting the sodium content of processed foods.

On August 12, 2009, the Portuguese Parliament approved a law that was intended to: a) Establish standards to reduce the salt content in bread and set a maximum limit of salt content in bread, b) Encourage information on salt content on the labelling of pre-packaged foods for human consumption.
With this legislation the maximum allowed salt in bread is 1.4 g sodium chloride per 100 grams of bread or 0.55 grams of sodium per 100 g of bread (salt = sodium x 2.5).

WHO's International digest of health legislation online database gives a good example of what falls under or influences public health, and thus influences public health legislation *(14)*.

Regulatory frameworks are complex and multifaceted. Where risks to the health of the population are considered to outweigh other considerations, including individual choice, legislation is the preferred policy instrument. In recent years the use of legally binding arrangements to protect population health has increased. In particular, aspects of environmental health, safety of food and drinking-water, occupational health and infectious disease control have been the subjects of public health legislation.(59)

There is also an "outer" group of laws that have a significant effect on public health outcomes but which are not so readily seen as public health laws. For example, acts related to product safety and the liability for defective products address the public health issues of reduction of injuries. This group typically encompasses laws that address public health questions but which are administered by other agencies. Other examples include liquor licensing controls, environmental protection legislation and occupational and safety acts. National land law and town planning legislation can also influence the operation of public health law. Some also see legislation for the registration of health professionals as a public health matter. It needs to be appreciated, however, that there are many laws beyond the core group that play a role in shaping the state of public health in European countries today.

As already stated, law should be seen just as part of the puzzle of responding to public health challenges. There are also other action that serves the same purpose and goes beyond/or in addition to legislation. Positive example to this and is UKs "Responsibility Deal", where, notwithstanding government responsibility, a specific role is extended to multiply partners *(60)*, to improve public health and tackle health inequalities through their influence over food, alcohol, physical activity and health in the workplace, which gets to the core of the understanding that "Health is everybody's business" as well as that public health concerns should be dealt with in national frameworks, depending on multi faceted national systems, approaches and experiences. What is highly recommended is cross-fertilization at international level.

Box 4: Public Health Responsibility Deal

"What we eat, how much we drink and how active we are is heavily shaped by our environment. Creating the right environment can encourage and empower people to take responsibility for their health and make healthy choices".
Launched on 15 March, the Public Health Responsibility Deal has been established to tap into the potential for businesses and other organisations to improve public health and tackle health inequalities through their influence over food, alcohol, physical activity and health in the workplace.

Partners and their pledges
"Partners signing up to the Responsibility Deal have committed to take action to improve public health. This action is expressed as a series of pledges covering food, alcohol, physical activity and health at work. These pledges are not intended to replace Government action. The Government will continue to develop national policy, define priorities and communicate public health messages".

Source: (60)

Essential public health functions

The mission, duties, functions and powers of public health agencies and actors must be clearly stated in the law.

Essential public health functions have been described by Yach as:

> … a set of fundamental activities that address the determinants of health, protect a population's health and treat a disease. These public health functions represent public goods and in this respect governments would need to ensure the provision of these essential functions, but would not necessarily have to implement and finance them. They prevent and manage the major contributors to the burden of disease by using effective technical, legislative, administrative and

> behaviour-modifying interventions or deterrents and thereby provide an approach for intersectoral action for health … This approach stresses the importance of numerous different public health partners. Moreover, the need for flexible, competent state institutions to oversee these cost-effective initiatives suggests that the institutional capacity of states must be reinforced. *(15)*

Public health experts now believe that public health agencies should perform a set of ten defined essential public health functions that new developments on international arena of public health confirm of.

WHO has described the components of a functioning health system as including (among others) six essential building blocks: good health services; a well-performing health workforce; a well-functioning health information system; equitable access to medical products, vaccines and technologies; a good health financing system that raises sufficient funds for health and assures access; and leadership and governance *(16).* WHO will present the latest developments regarding 10 essential public health operations at the RC61 in 2011.*(61)* (Box 5).

It is worth noting that these essential public health functions vary according to organization. While most definitions have much in common, the Centres for Disease Control and Prevention, the Pan American Health Organization and WHO all have slightly different ideas of what constitute essential public health functions.

Box 5. Essential public health operations

"The background to developing essential public health operations (EPHOs) has been developed across the WHO European Region. The EPHOs, of which there are 10 at present, are a work in progress and are currently being used in a self assessment programme in the European Region. The 10 EPHOs are described in detail in Annex 1, and can be summarized as follows:

1. surveillance of diseases and assessment of the population's health
2. identification of priority health problems and health hazards in the community
3. preparedness and planning for public health emergencies
4. health protection operations (environmental. occupational, food safety and others);
5. disease prevention;
6. health promotion;
7. assuring a competent public health and personal health care workforce;
8. core governance, financing and quality assurance for Public Health
9. core communication for Public Health
10. health related research

Source:WHO(18)

policies on health, as reflected in Health in All Policies *(62)*, and ensuring effective governance arrangements and resources for core preventive activities."

Health in All Policies Approach derives from the need to address appropriately determinants of health and adds to the complexity of public health from legal perspective. This concept adds also to clarity of scoping the "outer group of laws" into public health legislation.

International context

The growth and development of international public health law in the last decade and a half is one of the most notable developments in global health policy. In this new era of global health governance, international law has an important (albeit limited) role to play in promoting and coordinating international cooperation and national action to protect and promote global health *(17)*.

National public health law is influenced to a great extent by international law, especially in relation to human rights, public health standards for products, the international spread of diseases and the tobacco epidemic.

By ensuring that their public health legislation is modern and soundly-based, states will come closer to realizing "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" in their populations *(18)*.

Human rights instruments

A wide variety of international instruments identify the right to health. It is contained in the Universal Declaration of Human Rights *(63)* and, more recently, has been recognized in the International Covenant on Economic, Social and Cultural Rights *(18)*. The Convention on the Elimination of All Forms of Discrimination against Women *(64),* adopted by the United Nations General Assembly on 18 December 1979, provides that states parties to that Convention shall take appropriate measures to eliminate discrimination against women in the field of health care. The Convention on the Rights of the Child *(65),* adopted by the United Nations General Assembly on 20 November 1989, provides that States Parties to that Convention recognize the right of the child to the enjoyment of the highest attainable standard of health.

In the European context, the Convention for the Protection of Human Rights and Fundamental Freedoms (*66)* and the European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment *(19)* have established frameworks for protecting human rights, the right to health included.

In addition, legislation of regional integration organisation, such as European Union (67) impacts national legislative process in public health, in a wide range of issues as Other Commission legislation in the public health domain, such are ageing, alcohol, antimicrobial resistance, communicable diseases, cross-border care, ehealth, healthy environments. illicit drugs, nutrition and physical activity, safety., pharmaceuticals, preparedness and response, rare diseases, tobacco, vaccination and other.

Public health standards for products

There are strong arguments for ensuring uniformity of public health standards for products (such as food or drug labelling), however they are achieved. WHO, the World Trade Organization, the Codex Alimentarius Commission, the Council of Europe and the EU are playing significant roles in this regards.

Significant gains in international uniformity regarding public health standards for products have been achieved through existing international/regional law in the respective areas. The overriding international/regional law resolves failures in complying with it at the national level.

The regulatory requirements are aimed at efficiency and business competitiveness. It is, however, essential that public health values are not compromised by those requirements and that regulators work closely with public health specialists in these processes.

The International *health regulations*

The International health regulations (2005) *(68)* is an international law which helps countries working together to save lives and livelihoods caused by the international spread of diseases and other health risks.

The regulations aim to prevent, protect against, control and respond to the international spread of disease while avoiding unnecessary interference with international traffic and trade. They are also designed to reduce the risk of the spread of disease at international airports, ports and land borders.

Born of an extraordinary global consensus, the International health regulations strengthen the collective defences against the multiple and varied public health risks that today's globalized world is facing and that have the potential to spread rapidly through expanding travel and trade.

The regulations establish a new set of rules to support the existing global outbreak alert and response system, to require countries to improve international surveillance and reporting mechanisms for public health events and to strengthen their national surveillance and response capacities. This makes the International health regulations a highly necessary and appropriate new public health instrument, central to ensuring international public health security.

The International health regulations were agreed by consensus among WHO Member States as a balance between their sovereign rights and a shared commitment to prevent the international spread of disease. Although they do not include an enforcement mechanism for states which fail to comply with the provisions of the regulations, the potential consequences of non-compliance are themselves a powerful tool for compliance. Perhaps the best incentives for compliance are peer pressure and public knowledge. The consequences of non-compliance may include a tarnished international image, an increase in the morbidity/mortality of affected populations, unilateral travel and trade restrictions, economic and social disruption and public outrage. Working together and with WHO to control a public health event and to communicate accurately how the problem is being addressed helps to protect countries against unjustified measures being adopted unilaterally by other states.

The responsibility for implementing the International health regulations rests upon all states that are bound by them and WHO. The state is responsible, through all of its sectors, ministries, levels, officials and personnel, for implementing the regulations at national level.

An adequate legal framework to support and enable all of the varied IHR (2005) State Party activities is needed in each State. In some States, giving effect to the IHR (2005) within domestic jurisdiction and national law requires that the relevant authorities adopt implementing legislation for some or all of the relevant rights and obligations for States Parties. However, even where new or revised legislation may not be explicitly required under the State Party's legal system for implementation of one or more provisions in the IHR (2005), revision of some legislation, regulations or other instruments may still be
considered by the country in order to facilitate performance of IHR activities in a more efficient, effective or otherwise beneficial manner. *(69)*

In addition, *The world health report 2007 − A safer future: global public health security in the 21st century* marks a turning point in the history of public health and signals what could be one of the biggest advances in health security in half a century *(20)*. The report explains how the revised international health regulations help countries to work together to identify risks and act to contain and control them. They are needed because no single country, regardless of capability or wealth, can protect itself from outbreaks and other hazards without the cooperation of others. The prospect of a safer future is within reach: this is both a collective aspiration and a mutual responsibility *(20)*.

The Framework Convention on Tobacco Control

The Parties to this Convention, determined to give priority to their right to protect public health, have recognized that the spread of the tobacco epidemic is a global problem with serious consequences for public health. This calls for the widest possible international cooperation and the participation of all countries in an effective, appropriate and comprehensive international response: the Framework Convention on Tobacco Control (2005) *(21)*.

In response to the Convention, national public health legislation (both the "inner" and "outer" groups of acts) has been changed across Europe to comply with it.

Protection of privacy

The flow of information is fundamental to public health and occurs in many different aspects of its practice: as part of patient management, as part of gathering and investigating population-based data on the incidence of disease, and in the course of inspecting and carrying out of routine public health functions.

The provision of information is dealt with by public health legislation in three different contexts:

- the obligation to report new cases of special disease, typically done by general practitioners and laboratories;
- provisions to require information relevant to the spread of disease, such as contact-tracing; typically it is an offence to refuse to comply with such a request;
- provisions related to access to named data for the purposes of epidemiological research.

However, communities both nationally and internationally are concerned about the collection and flow of information, and both governments and the courts have imposed checks on the gathering and use of information *(22)*. This goes right to the essence of the constitutional right to privacy in every constitution in Europe.

The right to privacy is a highly developed area of law in Europe. All the member states of the EU are also signatories of the European Convention on Human Rights. Article 8 of the Convention provides the right for the individual for respect for "private and family life, his home and his correspondence," subject to certain restrictions. The European Court of Human Rights has given this article a broad interpretation in its jurisprudence. In 1981 the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data was negotiated in the Council of Europe. This Convention obliges the signatories to enact legislation concerning the automatic processing of personal data, which many duly did.

EU Directive 95/46/EC on the protection of personal data sets up in principle that personal data should not be processed at all, except when certain conditions are met *(23)*. These conditions fall into three categories: transparency, legitimate purpose and proportionality.

1. *Transparency***.** The subject of the data has the right to be informed when his/her personal data are being processed. The controller must provide his/her name and address, the purpose of processing, the recipients of the data and all other information required to ensure the processing is fair (Art. 10 and 11).
2. *Legitimate purpose***.** Personal data can only be processed for specified explicit and legitimate purposes and may not be processed further in a way incompatible with those purposes (Art. 6 b).
3. *Proportionality*. Personal data may be processed only in so far as they are adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed. The data must be accurate and, where necessary, kept up to date. Every reasonable step must be taken to ensure that data that are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified. The data should not be kept in a form permitting identification of data subjects for longer than is necessary for the purposes for which the data were collected or for which they are further processed. Member States shall lay down appropriate safeguards for personal data stored for longer periods for historical, statistical or scientific use (Art. 6). When sensitive personal data (such as religious beliefs, political opinions, health, sexual orientation, race or membership of past organizations) are being processed, extra restrictions apply (Art. 8).

EU directives are addressed to the member states and are not, in principle, legally binding for citizens. The member states must transpose them into national law. Directive 95/46/EC on the Protection of Personal Data had to be transposed by the end of 1998. All EU member states have enacted their own data protection legislation.

Provisions for the protection of patients' privacy should be a feature of public health law. Epidemiology research should be undertaken with a single set of requirements, irrespective of which jurisdiction the information is emanating from. Access by individuals to their public health records should be considered as part of public health legislation.

Clear demarcation of roles and responsibilities and coordination mechanisms in the system

The constitution of the state is the starting point for any analyses concerning the distribution of governmental powers.

Although a constitution places no affirmative obligation on a government to act, to provide services or to protect individuals and populations, it does serve three primary functions: (i) it separates the powers, (ii) it limits the powers of government (in order to protect individual liberties), and (iii) it allocates power on different (country-specific) levels of authority.

A constitution separates powers between the legislature, the executive and the judiciary. This separation of powers provides for a system of checks and balances within the legal system in favour of protection of individual rights and freedoms.

The doctrine of separation of powers is essential to public health, since each branch of government possesses a unique constitutional authority to create, enforce or interpret health policy. The legislature creates health policy and allocates the necessary resources for it to be carried out. It is sometimes contended that legislatures may not respond adequately to the need

for public health legislation because of a lack of expertise in health sciences or because they can be influenced by popular benefits that may be inconsistent with public health objectives. They are, however, politically accountable for their actions.

While the executive administers health policy, its role in setting policy is also considerable. Executive agencies are legislatively charged not only with implementing legislation, but with establishing complex health regulations. They are created for the purpose of advancing public health: they can focus on public health problems for extended periods and they can bring significant expertise and resources to address these problems. Conversely, however, agencies focus too narrowly on single topics and do not cooperate and coordinate adequately with other agencies involved in the same (complex public health) issues. Therefore, the "health in all policies" approach remains to be further developed and implemented to guide the activities of different agencies towards a more integrated multisectoral approach to public health *(24)*.

The judiciary's task of interpreting the law in the case of legal disputes makes the role of courts in public health deceptively broad. Courts exert substantial control over public health policy by determining the boundaries of legislative and executive government power. They decide whether a public health statute is constitutional, whether an agency's action is authorized by legislation; whether agency officials have gathered sufficient evidence to support their actions and whether government officials and private parties have acted negligently. The judiciary has the independence and legal training to make considered decisions about constitutional claims regarding, for example, individual rights. Courts may, however, be less well equipped to review critically the substance of health policy choices and they may focus too much on individual rights at the expense of communal claims to public health protection.

We should here emphasise the role of European Court of Justice as another source of law binding for EU member states, but also to wider range of European countries which voluntarily adhere to its rulings, though not directed to them.

Box 6: The Court of Justice of the European Union

The Court of Justice of the European Union is the judicial institution of the European Union and of the European Atomic Energy Community (Euratom). Its primary task is to examine the legality of European Union measures and ensure the uniform interpretation and application of European Union law.

Through its case-law, the Court of Justice has identified an obligation on administrations and national courts to apply EU law in full within their sphere of competence and to protect the rights conferred on citizens by that law (direct application of EU law), and to disapply any conflicting national provision, whether prior or subsequent to the EU provision (primacy of European Union law over national law*).(70)*

A function of the constitution is to limit government power to protect individual liberties. Government action to promote the communal good often infringes individual freedoms. Public health regulation and individual rights may directly conflict. Resolving the tension between population-based regulations and individual rights is a challenge. Thus, while the constitution grants extensive powers to governments, it also addresses challenge through the guarantees of individual rights which a government cannot infringe without justification.

Public health law struggles to determine the point at which government authority to promote public health yields to claims of individual rights. Thus, public health initiatives (such as vaccination) have to conform in general to the principles of public health necessity, reasonable means, proportionality and the avoidance of harm (Box 7).

Box 7: The Siracusa Principles

The Siracusa Principles require that only as a last resort can human rights be interfered with to achieve a public health goal. Such interference can only be justified when all of the narrowly-defined circumstances set out in the Siracusa Principles are met:

- the restriction is provided for and carried out in accordance with the law;
- the restriction is in the interest of a legitimate objective of general interest;
- the restriction is strictly necessary in a democratic society to achieve the objective;
- there are no less intrusive and restrictive means available to reach the same objective;
- the restriction is not drafted or imposed arbitrarily, i.e. in an unreasonable or otherwise discriminatory manner.

Even then, such limitations should be of limited duration and subject to review.
Source: United Nations *(25).*

Clear demarcation of functions/powers looses importance to curtain level in the systems where public health is deeply rooted in the society and where there is public understanding of public health not just as everybody's business, but also everybody's responsibility. (See: Box 4: Public Health Responsibility Deal)

"The Constitution sets out clear commitments to patients, public and staff in the form of the rights to which we are entitled, the pledges which the NHS is committed to achieve, and the responsibilities which the public, patients and staff owe to each other to ensure the NHS operates fairly and effectively*".(71)*

Clarifying authority on different (country-specific) levels

Some of the main issues that are important in public health at national level are: how the agencies providing public health services are organized administratively and politically; their missions, duties and public health functions and powers to perform them; how they are funded; how all the relevant players coordinate their functions in public health; how public support and outreach is obtained, and how enforcement is organized and carried out.

Public health at the local level receives higher importance in countries with highly decentralized structures for public health. As in the case of national public health agencies, it is important to examine public health agencies operating on different country-specific levels according to their organization and structure, mission, duties, functions and powers, funding, coordination of functions, public support and outreach, accountability for meeting national standards, minimum standards, assurances, periodic reviews and enforcement.

In some countries, local authorities have by statute been assigned the primary responsibility for providing public health agencies. Alternatively, a rational approach might be for two or more contiguous local authorities to form a district health unit, if this was permissible under national legislation. This could be a cost-beneficial solution where funds are limited and populations small.

There is considerable variation in the ability of local authorities to carry out essential services. Some have a great deal of funding and expertise, while others have much less and are consequently less able to assure the conditions for the community's health.

Most of the money for public health services at local level comes from two sources. First, national funding is available for specific programmes. These might not, however, be designed according to the needs of the county. Local authorities should not lose the flexibility for needs-based assessments that are important in local governance. The second source is local revenues. The carrying out of public health functions at local level depends on sustainable local funding. Fiscal limitations negatively influence the level of public health services.

While local authorities seek continued autonomy and properly demand local flexibility, many public health experts believe that some minimum levels of service and quality are important. There are several ways in which municipalities may be held accountable, for example through minimum standards, assurances and periodic reviews. In addition, the national public authorities have several options for enforcing these standards and assurances, including withholding funds and taking over local functions and services. Some of the aspects of devolution in public health services can be seen in the example of Spain (Box 8).

Box 8: Devolving health services to Spain's autonomous regions: Summary points

"In 1981, Spain began a process of decentralization of the management of health services to its 17 autonomous regions; by 1995 seven autonomous regions (covering 62% of the population) had taken over health care provision. Although devolution may bring control of health services closer to the people who use them, it can lead to differing health policies between regions. Methods used to allocate resources for health services have not yet improved, so inequalities in resource allocation between regions continue Devolution can also lead to an increase in bureaucracy, with duplication of administration at central and regional levels. National health policies and the concept of a national health service must not be infringed and existing inequalities on the provision of services must continue to be addressed."
Source: Reverte-Cejudo D, Sánchez-Bayle, M *(26).*

Coordination of functions and resolving disputes

In addition to the agencies for public health, many other public agencies are active in fields influencing public health such as protection of the environment, protection from ionizing radiation, agriculture, youth, sport, mother and child, labour, employment, urban and rural planning, communication, justice, education and financing. This requires coordination mechanisms, preferably horizontally across government.

As regards the different country-specific levels of governance, vertical coordination mechanisms are also needed.
To add to the complexity of the issue of coordination, there is a need for horizontal coordination on the different country-specific levels of governance as well.
A clear demarcation of responsibilities is of the utmost importance to the successful performance of public health functions and tasks.

Structured, systematic relationships and coordination between agencies charged with public functions on different levels and in different subject areas (health or health-related) are valuable assets for rationalizing resources and adding value to public health activities.

Regular and meaningful exchanges of information between the stakeholders in public health are essential. Effective communication helps to plan in advance and avoid conflicts. It provides a

mechanism for responding to crises when they arise and it enhances trust among different groups in the public health infrastructure. However, legal reform in public health cannot by itself dramatically improve the complex interrelationships between public health authorities. Other techniques can be used to improve these relationships in different times and circumstances; such are case-by-case resolution, structured discussions, conflict resolution and others.

In many countries, national, regional and local inter- and intra-agency collaborations have been introduced in order to improve health outcomes. A study to evaluate the effects of interagency collaboration between local health and local government agencies on health outcomes has been performed in UK. *(72)* Although collaboration between local health and local government is commonly considered best practice, the review did not identify any reliable evidence that inter-agency collaboration, compared to standard services, leads to health improvement. A few studies identified component benefits but these were not reflected in overall outcome scores and could have resulted from the use of significant additional resources. Although agencies appear enthusiastic about collaboration, methodological flaws in the primary studies and incomplete implementation of initiatives have prevented the development of a strong evidence base.

This study objective was to look at the outcome of those cooperation on health of the population, which might need, as the authors rightfully put it, amongst other complete implementation of initiatives to development of a strong evidence base.

A final option is to try to formalize relationships. Rather than leaving their structure unspoken, this method would try to clarify them. This could be done by legislating for the forms and methods of coordination. Clearly establishing the rights and responsibilities of the public health stakeholders is the starting point to build the forms and methods of coordination in the public health infrastructure.

Public health has always been a matter for cooperative efforts between the public and private sectors. Increasingly governments are turning to the private sector (medical providers, hospitals, health insurers, not for profit organizations and so on) for assistance with public health goals. While governments must remain primarily responsible for public health, the private sector can play an important role in, for example, surveillance assistance and population-based screening.

As with the relationships between governmental public health agencies, the relationships between the public and private sectors can be formalized in law. Enhancing public-private partnerships in public health through providing a legal base for it is just one of the options. Opening public health funding to donations from the private sector may be another.

Nongovernmental not-for-profit organizations should also be seen as strong partners within the public health infrastructure. Some European countries provide a legal basis for delegating specific tasks to nongovernmental organizations through an open bidding process. This complements the activities of public health agencies and closes the gaps in capacity.

Public health system/changing the profile of public health authority

The main public health administrative agencies provide services at national level to assure the conditions for the health and safety of the population. They are assigned by statute broad responsibility for public programmes concerned with health-related affairs and needs. In Europe, the scope of health responsibilities varies among public health agencies, and thus also their organization, structure and tasks apart from the main functions of coordinating, overseeing and providing for public health services. There is an increasing need to give priority, visibility and funding to the public health agencies so that they can fulfil their tasks related to public health functions.

Centralizing/decentralizing public health responsibilities

Some countries have actively sought to centralize public health responsibilities in a single agency equipped with broad public health powers. While a super-agency may be in the best interests of the public health, such entities are politically difficult to create where public health functions are traditionally delegated to multifarious state and local agencies. Thus, the question of coordination among public agencies performing public health functions becomes of the utmost importance.

Box 9 illustrates how legislation in the Netherlands provides for decentralized public health responsibilities and enforcement of public health-related tasks by municipalities.

Box 9: Decentralized public health responsibilities in the Netherlands

"1. The municipal executive shall promote the establishment and continuity of and cohesion within a system of public health and the harmonization of that system with the curative health care system and the system for the provision of medical assistance in the event of accident or disaster.
2. Pursuant to subsection 1, the municipal executive shall at the least make provision for:
a. the acquisition of insight into the health status of the population based on epidemiological analysis;
b. the collection and analysis, every four years and in accordance with a uniform national standard, of data on the health status of the population, prior to the formulation of the Municipal Health Policy Document, referred to in Section 13, subsection 2;
c. monitoring of the health implications of governmental decisions;
d. support for the establishment, implementation and coordination of preventive programmes, including health promotion programmes;
e. the promotion of environmental medical care;
f. the promotion of technical hygienic care;
g. the promotion of psychosocial assistance in the event of disaster."
Source: Ministry of Health, Welfare and Sport *(27)*.

Organizational changes in public health agencies

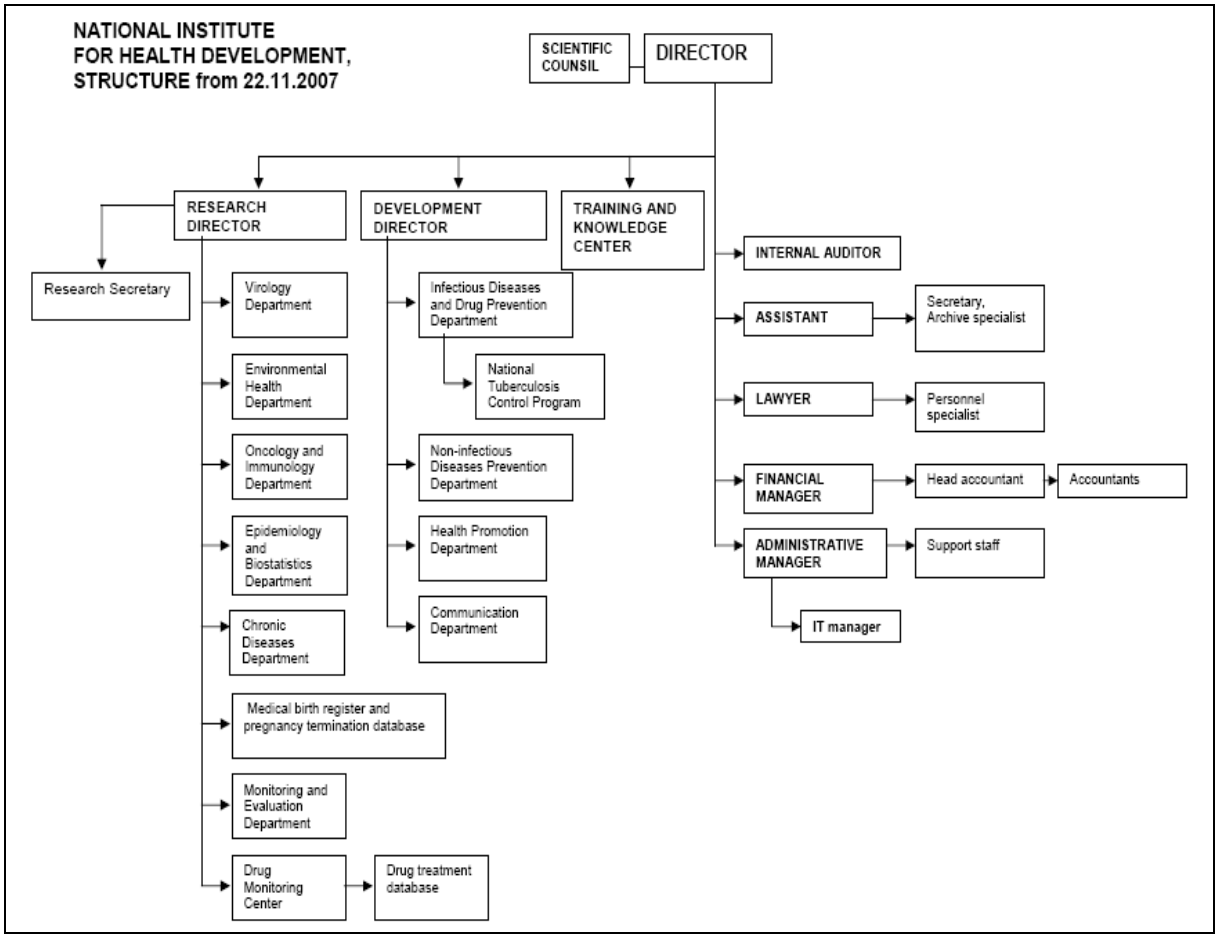
Improving the organizational, public and political position of the public health agencies depends on the political priority given to public health. Since these agencies are mandated by the law on public health to perform all or some public health functions, their duties and responsibilities should be clearly laid down. In some European countries these duties are referred to in the law as the tasks of public health agencies, namely:

- providing policy and strategy for public health;
- monitoring the health status of the population;
- planning, establishing priorities, drafting/proposing special public health programmes and action plans to improve public health and for screening, as well as drafting/proposing regulations in this area;
- implementing taxation, economic and other policies that stimulate healthy lifestyles;
- providing conditions for health education and empowerment of the population to take care of its own health;
- providing a system of quick response in emergency situations (such as epidemics, physical and chemical accidents and natural disasters);
- developing an integrated and uniform health information system;
- developing intersectoral cooperation in solving health problems;

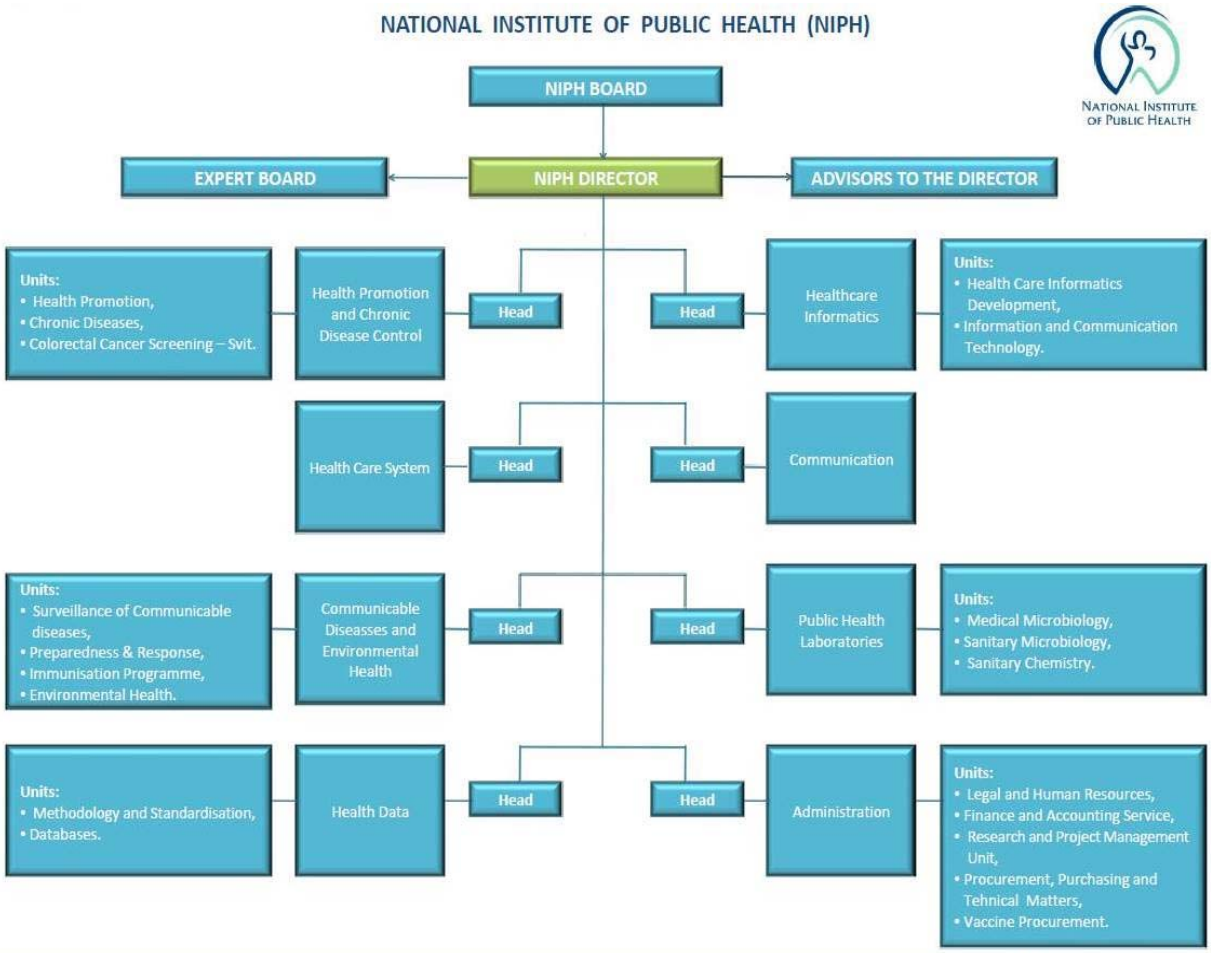
- evaluating the effectiveness, quality, accessibility and efficiency of health care services and programmes oriented towards the individual and the population;
- stipulating measures for protection of health care in laws and regulations;
- providing competence in public health human resources through training and continuing education;
- researching new approaches and innovative measures in solving the health problems of the population;
- creating the conditions for a rational and standardized network of public health agencies at regional/local level, etc.

Internal organizational change in public health agencies is important. It is decided by the tasks mandated and should be designed to establish a solid basis for the performance of such tasks. Thus, it differs significantly from country to country. Fig. 1 gives the example of the reorganized structure for public health in Estonia in 2007 *(9)*.

Fig. 1. Reorganization of the structure for public health in Estonia



Source: WHO *(9)*.



Public support and outreach programmes

Public support to public health activities is essential in making public health a political priority (especially for funding). Outreach activities among the community, the private sector, municipal officers and other stakeholders are important to the public agencies' future successes and can be a driving force behind them.

Public health agencies have to be active in constantly improving their visibility and importance. Various mechanisms need to be built into the agencies' regular work for outreach activities, depending on the stakeholder to be reached out to, that range from joint meetings as part of horizontal coordination activities among government agencies to effective dialogue, joint planning with local governments or specifically designed programmes for public relations. Different communication techniques should be designed according to whether the aim is outreach or gaining public support.

Improving existing services and accountability/quality assurance

WHO's definition of quality suggests that a health system should seek to make improvements in six areas or dimensions. These dimensions require that health care be:

- *effective*, adhering to an evidence base and resulting in improved health outcomes for individuals and communities, based on need;
- *efficient*, maximizing the use of resources and avoiding waste;

- *accessible*, available at the right time, geographically reasonable and provided in a setting where skills and resources are appropriate to medical need;
- *acceptable/patient-centred* and takes into account the preferences and aspirations of individual service users and the cultures of their communities;
- *equitable* and does not vary in quality because of personal characteristics such as gender, race, ethnicity, geographical location or socioeconomic status;
- *safe*, minimizing risks and harm to service users.

In its publication, *Quality of care: a process for making strategic choices in health systems*, WHO addresses the need for a capacity-building tool in health care quality *(28).*

WHO most recent developments (European Public Health Forum 2011) *(49)*_ clearly point out the following:

… Some health systems are increasingly aware of their deficiencies in respect of the synthesis, sharing and spreading of knowledge. They have therefore sought to place greater emphasis on ensuring that knowledge is spread and acted on. Knowledge management is a recognized skill. It is not a task to be undertaken lightly, but rather one that demands careful planning, and senior level engagement and championing.

A number of actions must be taken in respect of developing research and knowledge for policy and practice.

- Traditional approaches to evidence-based health should be replaced by a commitment to evidence-informed practice adopting knowledge exchange and co-production approaches.
- Evidence-informed public health demands the deployment of a mix of methods and disciplines in order to comprehend complex contexts and wicked problems.
- Knowledge sharing and management skills need to be supported and put in place.
- Public health practitioners should be encouraged to join a community of practice.
- Priority areas for research should be identified in close collaboration with academics and policy-makers.

Furthermore, WHO engages in consorted action on strengthening public health capacities and services in Europe: A framework for action" supports member states in developing Improving existing services and accountability, to provide for quality assurance , through:

- fostering public health leadership by creating specific positions of responsibility and accountability for public health matters;
- increasing coordination between public health structures and health care (especially primary care), through multidisciplinary training, enhanced communication channels and structural links;
- strengthening public health training through research, monitoring and evaluation and the dissemination of evidence with partners including the Association of Schools of Public Health (ASPH) for continuing education and the European Public Health Association (EUPHA) for maintaining professional standards and research.
- placing a greater focus on public health in medical training curricula;
- reviewing services, functions and operations from a practical perspective to improve coherence and better adapt to new challenges, such as communication for better health, which will be essential for better understanding the needs and perceptions of citizens (through behavioral research) and engaging in a positive and constructive exchange making the best use of new technologies and developments in social media;

- reviewing public health tools and instruments for the 21st century, including reviewing and monitoring their effectiveness assessing the efficiency of the different tools currently in place and the advisability of expanding, maintaining or discontinuing them; and last, but not the least:

• developing standards and indicators for delivering and monitoring EPHOs and core public health services.

Use internationally accepted classifications

Legal requirement for controlling health risks depends on how the disease is classified. International classifications of diseases of WHO serve as a unifier and should be used in diseases classification.

WHO classifications *(73)*
ICD-10 was endorsed by the Forty-third World Health Assembly in May 1990 and came into use in WHO Member States as from 1994. The ICD is the international standard diagnostic classification for all general epidemiological, many health management purposes and clinical use. These include the analysis of the general health situation of population groups and monitoring of the incidence and prevalence of diseases and other health problems in relation to other variables such as the characteristics and circumstances of the individuals affected, reimbursement, resource allocation, quality and guidelines.

The International Classification of Functioning, Disability and Health, known more commonly as ICF, is a classification of health and health-related domains. These domains are classified from body, individual and societal perspectives by means of two lists: a list of body functions and structure, and a list of domains of activity and participation. Since an individual's functioning and disability occurs in a context, the ICF also includes a list of environmental factors.

International Classification of Health Interventions (ICHI) The purpose of this classification is to provide Member States, health care service providers and organizers, and researchers with a common tool for reporting and analysing the distribution and evolution of health interventions for statistical purposes. It is structured with various degrees of specificity for use at the different levels of the health systems, and uses a common accepted terminology in order to permit comparison of data between countries and services.

Public health law should be based on uniform provisions that apply equally to all health threats. Public health interventions should be based on the degree of risk, the cost and efficacy of the response and the burden of human rights. These considerations cut across disease classifications. Implementation of a single set of standards and procedures through a single public health act would clarify legal regulations and could diminish future politically-motivated disputes about existing and newly-emerging diseases.

Basing public health decisions on the best scientific evidence of significant risk

There is a growing call for the use of evidence-based decision-making in public health policy. The nature of what constitutes appropriate evidence for policy-making is, however, contested. Some consider that only systematic reviews offer a suitable evidence base, but increasingly evidence-informed policy is being regarded as appropriate, taking into account colloquial and contextual evidence. Models of research utilization relevant for formulating policy have been

offered, but there remain many obstacles preventing research evidence of what works from being taken up in the policy process, which is essentially political. The different characteristics of the two worlds of researchers and policy-makers, including timeframes, interests and priorities, may be contributing to these gaps, preventing research outcomes from connecting with decision-makers *(29)*.

In combating threats to public health, health officials need clear authority, flexibility and sufficient guidance to exercise the relevant powers. Consequently, effective and constitutionally-sound public health law should include a rational and reliable way to assess risk and establish fair procedures.

Public health law should give public health authorities the power to make decisions based on the best available scientific evidence. Public health officials should examine scientific evidence and act on it within the framework of the law that supports such decision-making. If there is no scientific evidence, the law should provide for a flexible range of powers to address such instances in a way that would bring benefits.

Some working in the area of creating public health evidence are pioneering new approaches in an effort to strengthen the evidence base in public health and to provide practical guidance to policy-makers on which interventions might work in the long term and be most cost-effective.*(1)*

The construction of a basis of "best evidence" to support appropriate international political and legislative processes in public health could be useful as a means to overcome the barrier between researchers and decision-makers through the introduction of multidisciplinary elements.

An example of good practice in acknowledging effective practical application of the results of scientific research through the law is found in the Czech Republic in Article III of the Act 20/1966 Coll. from March 17, 1966 on the care of people's health (Box 10).

Box 10: Czech Republic: Act on care of people's health

"Article III: The main precondition for care of people's health is the permanent development of science and technology and effective practical application of results of scientific research. Science must permanently assure the sufficient quantity of needed knowledge and apply it to those sectors of national economy that influence people's health."

Source: Act 20/1966 Coll. *(30)*.

Final observations of the "Mobility and career of researchers: practices in Bulgaria and future challenges-E*CARE final conference, Plovdiv, Bulgaria, 15th of June 2011 *(78)* were to: clarify the state of the art, invest in higher education and research substantially and for long-term, enhance the promotion of scientific activities, invest in "brilliants, make closer the science and business, more internationalization: in a world of increasing circulation of knowledge and mobility of people, there is no place for excellence defined at national level.
Researchers at this conference also pointed out the importance of Council Directive 2005/71/EC of 12 October 2005 on a specific procedure for admitting third-country nationals for the purposes of scientific research, as legal document of EC which triggers several issues regarding enhancing scientific research that may be addressed by means of legislating, like retention of human resources for health, incentives for research development (proper taxation,

as one example), as well as supporting migration of human resources for research in public health, at the same time paying due attention to the challenge of brain drain from emerging or developing countries. To this extent, WHA63.16 - WHO Global Code of Practice on the International Recruitment of Health Personnel *(79)*, is particularly useful tool to be taken in consideration, together with other WHO documents on developing human resources for health *(80)*.

Box 11: Council Directive 2005/71/EC of 12 October 2005 on a specific procedure for admitting third-country nationals for the purposes of scientific research

(4) The number of researchers which the Community will need by 2010 to meet the target set by the Barcelona European Council in March 2002 of 3 % of GDP invested in research is estimated at 700 000. This target is to be met through a series of interlocking measures, such as making scientific careers more attractive to young people, promoting women's involvement in scientific research, extending the opportunities for training and mobility in research, improving career prospects for researchers in the Community and opening up the Community to third-country nationals who might be admitted for the purposes of research.
(5) This Directive is intended to contribute to achieving these goals by fostering the admission and mobility for research purposes of third-country nationals for stays of more than three months, in order to make the Community more attractive to researchers from around the world and to boost its position as an international centre for research.
(6) Implementation of this Directive should not encourage a brain drain from emerging or developing countries.

Back-up measures to support researchers' reintegration into their countries of origin as well as the movement of researchers should be taken in partnership with the countries of origin with a view to establishing a comprehensive migration policy.

As an example of legal complexity in research legislation, as an separate area of legislation relevant to construction of a basis of "best evidence" in public health, Bulgarian legislation on research scopes Patent Law, State Aids Law,Law for the Bulgarian Academy of Sciences, Law on Agrarian Academy, Labour Law, Law for foreigners, Law on taxes, Social Security Law and Innovation Act. *(78)*.

Enforcement, adequate powers to deal with public health risks

Modern public health legislation needs clear regulation-making power, given the moves towards national common requirements and standards in place of local controls. These powers include the power of entry and inspection, as well as administrative discretion to deal with risks to public health.

The implementation of national standards for the public health services depends on adequate enforcement tools. A government might withhold funds, or take over the implementation of public health functions at local level if these are not being properly delivered by the local authorities. What is essential is legislating adequate powers for national authorities to deal with public health risks.

An example from Hungary, the National Public Health and Medical Officer Service, shows in particular the complexity and wide scope of the tasks, including enforcement that such an authority has, although these would differ from country to country and depends on national legal and public health system. (Box 12).

Box 12: The Hungarian National Public Health and Medical Officer Service (ÁNTSZ)

"The Hungarian National Public Health and Medical Officer Service (ÁNTSZ) is a national institution financed by state budget and it is responsible for controlling, coordinating and supervising activities concerning public health (especially environmental, settlement, food hygiene and nutrition, child and youth health, radiobiology and radio hygiene and chemical safety), epidemiology, health promotion (health protection, health education and health maintenance), health service administration, and it also controls the health service. The head of the service is the Chief Medical Officer of Hungary who completes his task under the direct control of the Minister of Health.
The central organization of the three-tiered Service is the Office of the Chief Medical Officer (OCMO). The national institutions (see last page) fulfilling professional and methodological tasks are also controlled by the OCMO. Sub regional institutions are on the first level of the organizational structure, regional institutions are on the second level."

Source: Allami Népegészségyügyi és Tisztiorvosi Szogálat [Hungarian National Public Health and Medical Officer Service] *(31)*.

Fair procedures

If the use of administrative discretions increases, there is a corresponding need for fair and accessible rights of appeal against the decisions of authorized officers. Public health officials need ample and flexible powers to protect the common welfare. Likewise, the community needs to have confidence in the fairness of public health practice. The nature and extent of the process required depends on several factors including the nature of the interests affected, the risk of erroneous decision, the value of additional safeguards and the administrative burdens of additional procedures. Except in an emergency when a rapid response is critical, public health law should assure a fair and open process for resolving disputes about the exercise of powers and authority.

Statutory advisory bodies

A public health law should provide for a statutory advisory body to advise on matters relating to public health, including proposed regulations. Such a body should reflect a range of public health interests in the state, including national and local government and other stakeholders. An example is the Health Council in the Netherlands, which is an independent scientific advisory body with the task of providing the government and parliament with advice in the field of public health and health/health care research *(32)*.

Monitoring and evaluation system and reporting mechanisms

Systematic monitoring of the implementation of the act, as well as evaluation of its impact on health over time needs a well-prepared and functioning system. Regulatory impact assessment should be built into the act as a mandatory task for public health authorities and properly budgeted for to this end.

The preparation and harmonization of a single system of monitoring and reporting, both nationally and internationally, could be useful since it would allow access to the information needed in different countries simultaneously and in real time, which is vital as regards decision-making in public health.

Instruments for monitoring and evaluating the impact of multidisciplinary interventions in public health may also be useful, since they allow the rapid adaptation of standards and adequacy of responses by lawmakers and decision-makers.

The main challenge is developing monitoring and evaluation instruments, procedures and indicators to measure performance. Strong leadership is needed to accept the principle of accountability.

It might be necessary to include some assurances in contracts between national and local authorities which involve state funding of public health services. Again, the main challenge is to develop monitoring and evaluation procedures and indicators to measure performance against outcomes and/or impacts.

Monitoring and evaluation tools are necessary to assure the development and implementation of programmes based on population needs at all levels. For example, member states of the South-Eastern Europe Health Network are developing the project "Strengthening public health services", where they are working on the development of indicators for monitoring public health. This valuable exercise is being done under the umbrella of the WHO Regional Office for Europe *(33)*.

Funding

Funding presents a significant barrier to achieving the mission of a public health agency and the public health system. Relative to the enormous sums allocated to health care services, public health is very poorly funded.

Public health should be given priority in funding through ways such as the budget, revenue services, sales taxes, income taxes, tobacco settlement resources and public health programmes or plans.

It is a well known fact that legislation has financial implications. That is why many countries exercise regulatory impact assessment (RIA) to calculate financial and other implications of the legislation.

Impact assessment is a process aimed at structuring and supporting the development of policies. It identifies and assesses the problem at stake and the objectives pursued. It identifies the main options for achieving the objective and analyses their likely impacts in the **economic,** environmental and social fields. It outlines advantages and disadvantages of each option and examines possible synergies and trade-offs.

Efficient fiscal systems in the OECD have meant that increases in taxes on tobacco could reinforce other public health policies like rule-based restrictions on smoking in public places. Some countries have gone very far in this respect, with Ireland actually banning smoking in its famous pubs! Such courageous initiatives cannot succeed without institutional backing, whether legalistic or otherwise.*(75)*

Impact assessments are conducted internally by European Commission services when launching important legislative or non-legislative initiatives. As part of these assessments, all relevant stakeholders are consulted on a range of issues including problem definition, application of the subsidiary principle, options and impacts.

Before the European Commission proposes new initiatives it assesses the potential **economic**, social and environmental consequences that they may have. Impact assessment is a set of logical steps which helps the Commission to do this. It is a process that prepares evidence for political decision-makers on the advantages and disadvantages of possible policy options by assessing their potential impact. *(76)* As an example, proposal for a Directive on improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (amending Council Directive 92/85/EEC) was based on impact assessment. The list of impact assessments done by the EC can be found at EU impact assessment website.

As an example at country level in Europe, UK has introduced impact assessment (IA) in its system. In 2007 UK published a short structured template with regulatory proposals, new legislation and policy implementation. It concisely describes the issue and identifies costs and benefits that are likely to impact the public, private and/or third sector.

An IA must accompany any published new legislation (including European legislation). An IA is an important tool to ensure that the principles of good regulation are followed: proportionality, accountability, consistency, transparency, targeting. More on impact assessments done by the UK can be found at UK impact assessment website (77).

Adequate penalties

The modernization of public health legislation must include the setting of adequate penalties for breaches of public health legislation.

There can be no greater duty for any government than protecting the public − a responsibility shared across departmental and organizational boundaries. An effective system of justice supported by the right sanctions policy is essential and integral parts of making this happen.

As an example from many in Europe, the French Government has enacted a law making smoking illegal in public areas and in workplaces since January 2007. There are monetary penalties for smokers who do not respect the rules in public places (68 €) and for the employers if they allow employees to smoke in workplace (135 €). *(34)*

Penalties can have several possible components, including punitive and restrictive curfews and prohibition from certain places or activities, rehabilitation drug treatment, and courses and programmes to address criminal behaviour and improve skills. Offenders on community orders can be made to do many hours of unpaid work – frequently on a project determined by the community, meaning that the offender pays something back into the local community. This is not a soft option and evidence shows that these sentences can have a greater impact on re-offending rates. Community sentences can be more demanding because with the right conditions attached they can mean intensive and hard work and learning. Offenders can be confronted with their offending behaviour with the aim of getting them to change. This level of investment should be used where it will make a difference – for example, with less serious offenders where very short custodial sentences may not reduce re-offending as effectively.

Although this is a country-specific issue, evidence in the European region may be used to obtain the results needed in public health to reduce offending and re-offending.

Public health partnership: a single public health act or dispersed regulation

There are various approaches that could be taken legislatively at the national level.

In most European countries public health legislation is dispersed in various acts and regulations. Some apprehend that there can be another approach - to endorse a separate public health law setting out goals and funding arrangements, with at the very least an expression of the principles of collaboration and cooperation inherent in the concept of a national public health partnership.

There is no single example of the gathering together of public health legislation in one public health act, mainly due to the complexity and wide scope of the issues that influence public health and the stakeholders involved.

There are different ways of approaching public health legislation. In some countries there is no separate legislation and provisions related to public health are inserted into other relevant legislation. For example, issues concerning public health may be incorporated into general health. At the other end of the spectrum, some countries have tried to consolidate public health legislation, whereby all issues of relevance to public health are incorporated into a single law. Many countries have combined these approaches and thus have integrated components as well as a specific public health law.

There are advantages and disadvantages to each of these approaches. Consolidated legislation has the ease of enactment and adoption, without the need for multiple amendments to existing laws. The process of drafting, adopting and implementing consolidated legislation also provides a good opportunity to raise public awareness about public health, and to educate policy-makers and the public about human rights issues as well as other public health issues.

The principal advantage of inserting provisions relating to public health into non-specific relevant legislation are that, by virtue of being part of legislation, a much wider constituency is benefited.

Among the main disadvantages associated with dispersed legislation is the difficulty of ensuring coverage of all legislative aspects relevant to public health. For example, procedural processes aimed at protecting human rights in public health can be quite detailed and complex and may be inappropriate in legislation other than a specific public health law. Furthermore, this would require more legislative time because of the need for multiple amendments to existing legislation.

There is little evidence to show that one approach is better than the other. A combined approach, involving the incorporation of public health issues into other legislation as well as enacting a specific public health law, is most likely to address the complexity of public health needs. this decision would, however, depend on countries' circumstances.

When drafting consolidated public health legislation, other laws (from both "inner" and "outer" groups) will also need to be amended in order to ensure that the provisions of all relevant laws are in line with one another and not in contradiction.

In addition, the ideal resource for cross fertilisation both at national and international level is considered to be the creation and maintenance of a web-based users friendly version of the directory of and nation's laws in public health. Such applications of information technology result in enormous gains in accessibility to, knowledge and understanding of and compliance with, a nation's laws.

The changing context of public health law

Public health law has always been seen as public law. However, recent developments suggest that this may not necessarily remain the case. It may well be that future initiatives in public health will be driven more powerfully by private law remedies (or a desire to avoid them) than previously. There are many examples of how public health law is practised effectively in the realm of private law. A stronger tool for the implementation of public health legislation against smoking at the workplace than the public health act itself might be compensation claims against employers provoked by passive exposure to tobacco smoke. The same is true of the serving of alcohol to underage persons. These may be positive outcomes. There are also potential negative outcomes that need to be considered, such as the privatization of public health law where, in the absence of regulation, litigation would be seen to provide the main remedy. This would weaken the traditions of public health law. Litigation is costly and the impact on health would depend on the extent to which manufacturers, etc. could minimize the cost of a successful action through insurance. Public health experts might take on the role of expert witnesses in a process that would be lawyer-driven. The demands for information from regulators would increase through freedom of information requests or courts' discovery orders, and these would shape the manner of working. These possibilities are conjecture, but they are offered here as issues that need to be clearly seen and discussed further.

Litigation could prompt new directions in public health practice through challenging the validity of public health legislation or the process through which it has been developed. In particular, the tobacco industry is challenging legislation prohibiting the advertising of tobacco in many countries worldwide. A group of people have challenged the relevant act in Croatia on the basis of infringements of the right to equality.

This means that public health legislation must be broadly shown to be considered a reasonable and appropriate response to the public health problem being addressed and in proportion to the restrictions on commercial or other activity implied by the regulations. Obviously, legislative strategies need to be well thought out and collaboration needs to occur with research centres and through systematic data-gathering systems.

Notwithstanding these difficulties, public health regulators are accountable to the community. The bottom line seems to be that public health legislation must be, and must be seen to be, the well thought out and well justified answer to a public health problem.

Process of drafting public health law: participatory democracy in health

The Organization for Economic Co-operation and Development (OECD) emphasizes that participatory democracy does not take away governments' elected right and duty to make policy decisions; it gives new ways to exercise it and increased legitimacy to decisions made. The OECD handbook *Citizens as partners* reminds us that involving citizens in this way is a two-way relationship between government and citizens, in which citizens actively engage in decision- and policy-making *(35)*. It works on a principle of partnership.

Health care reform is not just about finding solutions to health care but about creating or recreating, a vigorous and resonant sense of what it means to be a citizen *(36)*. Half the battle of health care reform is increased ownership in a participative society. This is true for public health reform as well.

Physicians can uniquely give authoritative information about health and its disorders: what is wrong, what is likely to happen and what can be done about it. And when they act as consultants,

advisers and teachers (whether of patients or the public generally) they can be effective as peer participants in planning and decisions about health care at patient, community and national levels. It now behoves physicians and the medical profession to spend the time necessary and develop the skills needed to participate fully in this new participatory democracy, which has become such an important part of medicine and health care in society *(37)*.

In the area of public health, participatory democracy is unavoidable. Everybody is included: citizens, health professionals, governmental and nongovernmental organizations, the private sector and other stakeholders.

Thus, public health law should be a result of a process that uses the tools and techniques of participatory democracy, which itself should be linked to participatory accountability and participatory budgeting in public health. It should be seen primarily as a tool to improve relationships and the coordination of functions and to prevent disputes in public health (see section 4, sub-section on Improving relationships and the coordination of functions and resolving disputes).

Two examples of participatory democracy, out of many in Europe, in an electronic form are: (i) the United Kingdom Department of Health's invitation to "have your say" on the draft structural reform plan for the National Health Service *(38)*, and (ii) the assistance of volunteers, in cooperation with the Healthcare Reforms Steering Committee, in the production of a draft Green Book as part of the health care, including public health reform in The former Yugoslav Republic of Macedonia *(39)*.

National regulatory frameworks for public health in Europe

According to WHO's International digest of health legislation online database, the list of public health topics covered by legislation in the countries of the WHO Region for Europe is extensive *(14)*. As well as constitutional provisions relating to health and international treaties and other legal instruments, it includes general health codes or public health laws, human rights and other fundamental provisions covering wide areas that shape public health as already explained.

Most existing public health legislation in Europe relates to the control of communicable diseases *(14)*. Older approaches to public health led to laws that, to a large extent, relied on lists of diseases and recognized nuisances to health. Such laws operate against a modern risk-based approach to public health.

A primary role of public health legislation is to establish processes for the exercise of regulatory powers in the event that they are needed, with relevant checks and balances, especially clear accountability for the relevant authority for exercising such powers. In a world that is unable to predict all diseases, the exercise of such powers is becoming increasingly important. Modern public health legislation needs to enable a scaled response appropriate to possible health risks and to ensure the provision of essential public health services and functions. An example of this response is emergency power legislation *(14)*.

In some countries, specific public health issues and functions are covered by public health legislation even when they might not be the responsibility of the health authorities, whereas in others, some specific public health issues are the subject of separate legislation. It is argued that even where specific public health issues are not normally directly regulated by health legislation, there should be reserve powers under public health legislation that permits action by the health authorities should another agency be unable, or refuse, to act in response to a public health emergency. Some matters have to be included in a public health law if they are not regulated in

some other way. Environmental health risks are a good example, as they can be dealt with separately if there is an environmental health agency or ministry of environment, but otherwise might remain within the jurisdiction of the health authorities.

An analysis of legislation in various countries has shown that, rather than there being a core or minimum number of matters that different jurisdictions have found it necessary to include in their public health laws, there are significant differences between them, apparently because they were drafted to be appropriate to their particular legislative settings.

Table 1 Example of differences in the scope of public health law

	2007 PUBLIC HEALTH LAW IN GEORGIA	*THE ACT ON PROTECTION OF PUBLIC HEALTH IN THE CZECH REPUBLIC*
1.	general provisions (sections 1−4);	basic provisions (sections 1−2);
2.	duties and rights of citizens and professionals in the public health sector (section 5);	care for living and working conditions (sections 3−44);
3.	prevention of communicable diseases (sections 6−9);	prevention of occurrence and spread of contagious diseases (sections 45−75);
4.	detection of communicable diseases, isolation and quarantine (sections 10−15);	further obligations of persons in protection of public health (sections 76−77);
5.	guaranteeing biological safety (sections 16−21);	state administration in protection of public health (sections 78−95);
6.	providing a safe environment for public health (sections 22−23; under section 23, the tasks of the Department of Health include the establishment of quality standards for drinking-water in accordance with WHO recommendations);	competence of municipalities to take independent measures (section 96);
7.	Safety policy for chemical and technological procedures and products (Sections 24−26);	joint, transitional and final provisions (sections 97−109).
8.	policies for healthy lifestyles,. maternal health and child and adolescent health (sections 27−30);	
9.	competence of the government and local government bodies in the public health sector (sections 31−39):	
10.	financing activities to secure public health (sections 40−41);	
11.	compensation for damage and responsibility in the public health sector (sections 42−43);	
12.	final and transitional provisions (Sections 44−46).	

Estonia defines the purposes of its public health act as to protect human health, prevent disease and promote health, which are to be achieved through the performance of duties by the state, local governments, legal persons in public law, legal persons in private law and individuals, and through national and local measures *(40)*.

In the Netherlands, the act of 9 October 2008 regulating public health care matters (the public health act) brought together in a single act, to create a coherent statutory instrument, the Public Health (Preventive Measures) Act, the Infectious Diseases Act and the Quarantine Act, as well as provisions for the obligatory storage of digital data in the context of health care for young people *(26)*. It includes definitions, public health care activities, national and municipal health policy documents, municipal health services, infectious disease control, and finance and enforcement.

The Bulgarian Health Act is all-inclusive and regulates the social relations concerning the protection of the citizens' health (Article 1) *(41)*. Article 2 of this comprehensive law states:

The protection of the citizens' health as a condition of full physical, mental and social well-being is a national priority and it shall be guaranteed by the Government through the application of the following principles:

1. equality in the use of health services;
2. ensuring accessible and high-quality health care, giving priority to children, pregnant women and mothers of children aged up to one year;
3. priority of health promotion and integrated disease prevention;
4. prevention and reduction of the health risk to citizens as a result of adverse effects of environmental factors;
5. special health protection of children, pregnant women, mothers of children aged up to one year and people with physical and mental disabilities;
6. participation of the government in the financing of activities aimed at protecting the health of citizens.

In 2010, The former Yugoslav Republic of Macedonia endorsed a public health law regulating the essential functions and tasks of public health, the public health system, public health emergencies and the funding of public health activities *(42)*.

The establishment of adequate legal frameworks for public health is an important part of the health reform process for many countries. The WHO Regional Office for Europe provides guidance on the design and content of public health laws based on practical work with countries and its own public health and legal expertise. Public health laws have been developed with the support of WHO and endorsed by national parliaments in Albania, Kyrgyzstan and the Republic of Moldova *(43)*.

Public health legal services: a new vision

In recent years, the medical profession has begun to collaborate more and more with lawyers in order to accomplish important health objectives for patients *(44)*. This collaboration has stimulated a rethinking of the delivery models for legal services and of public health constructs, leading to the development of a concept called "public health legal services." The phrase encompasses those legal services provided by nongovernmental lawyers to people on low incomes, the outcomes of which, when evaluated in the aggregate using traditional public health measures, advance public health.

This conception of public health has emerged most prominently from innovative developments in the United States. It … departs from the commonplace understanding about public health law as concerned with the exercise of the state's public health power. Rather, it extends that understanding to include the exercise of individual rights by private lawyers that *also* advances the public's health. Just as it was once discovered that communities need access to health information, clean water, inoculation and regulation of hazardous activities and products as part of a comprehensive scheme for promoting and achieving health, so too the emerging vision suggests that community health promotion also requires affordable access to effective legal information and assistance.

The idea of public health legal services offers a rich and powerful incentive for public and private agencies to increase those free and subsidized legal services. At the same time, the legal services necessary from a public health perspective may not be the ones currently emphasized by providers. … The vision of public health legal services in many ways favours [prevention over crisis management] and therefore calls upon traditional legal services providers to rethink their customary resource allocation models, and may call for painful short-term choices between the new model and the always urgent demand for litigation and crisis-driven work. *(44)*

Definitions: glossary and reference terms

Public health legislation should limit definitions to terms used in the law. It is highly recommended that internationally developed and accepted terms should be used, such as those in international treaties, the International health regulations, the Framework Convention on Tobacco Control and other definitions established by WHO. Reference and comparability will be easier, as well as a common understanding among public health stakeholders in Europe. Box 11 gives an example from Estonia, although most of the public health acts scope terms and their definitions as well, but there are differences in them.

Box 13: Public Health Act of Estonia

"The Public Health Act of Estonia, passed 14 June 1995 (RT I 1995, 57, 978), entered into force 21 July 1995:
(1) The purpose of this Act is to protect human health, prevent disease and promote health, which is to be achieved through the performance of duties by the state, local governments, legal persons in public law, legal persons in private law and natural persons and through national and local measures.

In this Act, the following definitions are used:
1) "public health" means the science and art of disease prevention, extending life expectancy, promoting and improving mental and physical health through the organised efforts of society;
2) "health" means a state of physical, mental and social well-being of a person, not only the absence of disability or disease;
3) "health protection" means activities aimed at ensuring a physical and social environment which is safe for human health and at preventing health disorders and disease associated with the physical and social environment;
4) "health promotion" means the creation of behaviour and lifestyles which value and enhance health and the purposeful development of a physical and social environment which is conducive to health;
5) "disease prevention" means activities aimed at early detection of disease in persons and measures to prevent illness;
6) "health education" means the purposeful dissemination of information and formation of people's habits for the preservation and improvement of health;
7) "physical and social environment" means the aggregate of natural, artificial and social environmental factors with which people come into contact and which affects or may affect human health."

Source: Riigi Teataja [State Gazette] (40).

Many glossaries already exist, for example, WHO's health promotion glossary *(45),* glossary of globalization, trade and health terms *(46)* and glossary of humanitarian terms *(48)*. The EU has also developed a glossary in public health *(49)*.

Conclusions

Health law is intended to create an environment in which the promotion of health goes hand-in-hand with the protection of individual rights and the general principles of equality and justice. Over the years, the importance of health law has grown at both national and international levels. As health and human rights are closely interlinked, it is important to integrate health law and health policy. It is to be expected that in Europe, the impact of health law on health policy-making will increase as a result of several developments, such as the internationalization of

health care and health policy, the issue of consumer protection and the legalization of society. This requires a strategy to stimulate the fruitful relationship between health policy and health law.

A common understanding of the definition of public health law should be achieved throughout Europe as: "the study of the legal powers and duties of the state to assure the conditions for people to be healthy (e.g., to identify, prevent and ameliorate risks to health in the population) and the limitations on the power of the state to constrain the autonomy, privacy, liberty or other legally protected interests of individuals for protection or promotion of community health" *(8)*.

Although there is broad consensus that legislation is essential to good public health, the objectives and content of the law remain a challenge. Public health law in many countries remains ripe for reform. These laws often predate modern scientific and constitutional development; do not clearly delineate the basic authority and responsibility entrusted to public health agencies, boards and officials at national and local levels and the relationships between them; fail to equip public health officials with a range of flexible powers needed to control infectious diseases; lack adequate standards for privacy, due process and risk assessment; and are based on arbitrary disease classification schemes that no longer relate to modern disease threats or epidemiological methods of infection control and do not support a set of modern disease control measures that address contemporary health problems and incorporate due process safeguards.

The lack of a consolidation of public health legislation in some European countries presents a significant challenge to obtaining a complete picture of public health laws in the Region.

There are at least four possible roles for the law in advancing public health. The law can (i) define the objectives of public health and influence its policy agenda, (ii) authorize and limit public health action, (iii) serve as a tool for prevention, and (iv) facilitate the planning and coordination of governmental and nongovernmental health activities.

The following benefits could be achieved through a public health law improvement process: the updating of laws, compliance with contemporary international and other legal requirements, and improvements in the relationships between legislative and public health authorities, federal, state and county public health authorities, as appropriate, rural and urban public health authorities and public health authorities and private and civil society initiatives in public health.

The differences in legal and public health systems in Europe are reflected in public health legislation. A combined approach, involving the incorporation of public health issues into other legislation as well as the enactment of a specific public health law, is most likely to address the complexity of public health needs. This decision will, however, depend on countries' circumstances.

This opens the door for a discussion on what should be included in public health law as a single act, without prejudice to the existing dispersed public health legislation in some countries, or some single public health acts endorsed in others albeit with differing scope and purpose.

The following elements should be considered to be essential for inclusion in a single public health act:

- a clear philosophical framework;
- definition of public health law;
- definition of common terms in public health law;
- establishment of essential public health functions;

- due importance paid to the international public health law context;
- clear demarcation of the roles and responsibilities and establishing coordinative mechanisms in the system;
- improvement of existing services, inclusion of accountability and enhancement of quality assurance;
- use of internationally agreed disease classifications;
- public health decisions to be based on the best scientific evidence of significant risk;
- establishment of good enforcement and adequate powers to deal with public health risks;
- provision of fair procedures;
- establishment of statutory advisory bodies;
- setting-up of impact-oriented monitoring and evaluation systems and reporting mechanisms;
- establishment of a legal basis for partnerships in public health activities;
- provision of public health legal services;
- provision of funding;
- setting adequate penalties, as appropriate.

The substance of the document and the proposed framework for a public health law are not intended to be exhaustive, but rather demonstrative of various elements of such a law that should provide framework to further discussions focussed at reforming public health law in Europe.

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