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GUIDELINES FOR REVIEWING NATIONAL PUBLIC HEALTH LAW

Public health law is generally considered as a key instrument to formulate and realize a national public health policy. Public health law is not a 'static' concept but evolves over time, depending on new understandings and developments. Updating and/or revision of the public health legal framework based on such new understandings in a comprehensive and coherent manner, is therefore crucial to make it work.

The idea of developing guidelines for reviewing national public health legislation is to strengthen the quality of public health legislation at national level. For that reason, it is conditional to identify underlying objectives (the conceptual framework), followed by mapping the public health legal framework, analyzing defined legal tools and actions to realize the public health objective(s), and to assess the effects of regulatory interventions. The outcomes may give reason to review the existing legal framework, whether it correspond with the underlying public health policy, or whether there is a need for modify, revise or even withdraw legislation, aimed at improving the quality of the national public health legal framework, and ultimately public health.

Key words: reviewing public health legislation, guidelines, health care, law of public health.

Introduction: Purpose and rationale

Public health law (both legislation and subordinate legal norms) is generally considered as a key instrument to formulate and realize a national public health policy. Public health law is not a 'static' concept but evolves over time, depending on new understandings and developments (e.g., SDG agenda, newly adopted international binding documents, technological developments, etc.). Updating and/or revision of the public health legal framework based on such new understandings in a comprehensive and coherent manner, is crucial to make it work.

The World Health Organization (WHO), and particularly the Regional Office for Europe, plays a key role in that revision process, for instance by means of providing technical advice on public health legal reforms. Instead of providing foreign public health legislation to be translated and incorporated into national law (the 'copy and paste' method), WHO is more focusing on advising individual member states how to improve their unique legal framework based on local needs, priorities, and international experiences. As a tool, several guidelines were developed, supporting member states in the European Region to review and modernize their legal framework of the national public health system. The underlying idea of this activity is enabling member states to evaluate their national legal framework (self-assessment) on public health, in terms of comprehensiveness and coherency.

Reviewing the public health legal framework, starts with identifying underlying objectives (the conceptual framework), followed by describing the public health legal framework, analyzing defined legal tools and actions to realize the public health objective(s), and analyzing the effects (intended and unintended) of regulatory intervention. The outcomes may give reason to reconsider the existing legal framework, whether it corresponds with the underlying public health policy, or whether there is a need for modify, revise or even withdraw legislation, aimed at improving the quality, completeness and coherency of the national public health legal framework, and ultimately strengthening public health.

Hereafter, public health is defined broadly as: "the science and art of preventing disease, prolonging life and promoting health through the organized efforts of society".* Building on this definition, public health law (PHL) is defined 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 legal safeguarded interests of individuals for the purposes of protecting or promoting community health'.**

PHL and more specific public health legislation has therefore four key functions or roles:

1. Define the objectives of public health and influence its policy agenda.

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* S. Chichevalieva, Developing a Framework for Public Health Law in Europe, WHO Regional Office for Europe (2011) p. 18.

** Common European understanding for public health law, in definition, scope and the drafting process (Chichevalieva (note 4) 6.

2. Authorize and limit public health action with respect to the protection of individual rights and freedoms, as appropriate.
3. Serve as a tool for prevention and promotion, and.
4. Facilitate the planning and coordination of governmental and nongovernmental health activities.*

In general, public health legislation should reflect these functions. Assessment of national public health legislation starts therefore with a critical review of its underlying functions. Such a systematic review can be supported by practical guidelines streamlining the review process based on 'sound practice'. Though voluntary, following these guidelines enable decision-makers to make public health law-making more predictable, and presumably of better quality.

Guidelines for reviewing public health legislation

The underlying idea of these guidelines is providing a framework for discussion on strengthening public health law in Europe. The guidelines are intended to evaluate the national public health legal framework, whether it contributes to the public health framework, and reviewing its compliance with international law. Such as analyses enables to measure a country specific status and progress in achieving the public health objectives.

The first step includes a baseline measurement of the country's legal framework. Measuring the country's status and progress in public health law (by a rudimentary scoring system), enables to identify priorities and formulate recommendations for (legal) action, or filling gaps in the regulatory framework. Subsequent (external) evaluations are necessary to identify progress made and ensuring the sustainability of public health law.

The guidelines share a number of important features: voluntary country participation; a multi-sectoral approach by both the external teams and the host countries; transparency and openness of data and information sharing; and the public release of reports. Such an approach refers to the format used in the 'joint external evaluation tool' developed under the International Health Regulations (2005) monitoring and evaluation framework.**

In total 9 guidelines have been formulated on public health law, including:

Guideline 1. The need for a conceptual framework of public health law

5. PHL reflects the need for a clear conceptual framework on the three core elements of public health: disease prevention, health promotion, and health protection, while respecting underlying principles of solidarity, equity and participation, engaging stakeholders in policy

* S. Chichevalieva and F. Chichevaliev, Developing a Framework for Public Health Law in Europe, in: A. den Exter (ed.), European Health Law, Maklu Antwerp (2017), p. 26.

** WHO, IHR (2005) Monitoring and Evaluation Framework, Joint External Evaluation Tool, 2016. See also, Public Health policy and legislation instruments and tools: an updated review and proposal for further research (WHO 2012); Review of public health capacities and services in the European region; Self-assessment tool for the evaluation of essential public health operations in the WHO European region (WHO 2015).

development and implementation.* The Ottawa Charter for Health Promotion (1986) takes such a broad and proactive view on health. The Charter defines the prerequisites for health as "peace, shelter, education, food, income, a stable eco-system, sustainable resources, social justice, and equity. It emphasizes the need for governments to build "healthy public policy".** Public health law will confirm and articulate the Tallinn strategy reflecting the following principles;

6. 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 vulnerable groups;***
7. Invest in health systems and foster investment across sectors that influence health, using evidence on the links between socioeconomic developments and health;
8. Make health systems more responsive and responsibilities with regard to their own health;
9. Engage stakeholder in policy development and implementation;
10. Foster cross-country learning and cooperation on the design and implementation of health system reforms at national and subnational levels, and
11. Ensure the health systems are prepared and able to respond to crises, and that countries collaborate with each other and enforce the International Health Regulations.****

A number of technical questions addressing that strategy can be raised, such as: i. is there legislation (primary and secondary legislation) governing the objectives of public health and its policy agenda; ii. is there legislation that authorizes and limits public health action with respect to the protection of individual rights and freedoms, as appropriate; iii. is there legislation for public health prevention and promotion; iv. is there legislation facilitating the planning, funding and coordination of governmental and nongovernmental health activities, and v. has an assessment of relevant legislation, regulation and other governmental instruments been carried out (to determine the functioning of the existing legal framework)?

The outcomes of these questions (i.e. a level of realization with scores 1-3) reveals whether or not each separate piece of legislation fits within the overall PHL concept and contributes to (one of) the underlying functions of public health law as defined above. Moreover, the scores enable evaluators to identify gaps and challenges.

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* WHO Tallinn Charter: Health Systems for Health and Wealth (Ministerial Conference 25-27 June 2008 Tallinn, Estonia.

** WHO Ottawa Charter for Health Promotion, First International Conference on Health Promotion, Ottawa, 21 November 1986.

*** As covered by the UN Sustainable Development Goals (SDG), more specific Goal no. 3 'Ensure health lives and promote well-being for all at all ages', as well as intersectoral levels of justice and peace under Goal no. 16 'promoting peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels'.

**** Idem note 7.

Guideline 2. Mapping the public health legal framework according to EPHO

Understanding national PHL starts with clustering the regulatory framework along the lines of the 10 essential public health operations (EPHOs), covering a wide spectrum of public health services under the public health legal framework.* This reveals a range of measures available to support the delivery of EPHOs, as well as critical gaps or omissions in the legal instruments and tools when incorporating EPHOs. The first step in the classification of documents into the EPHO subdivisions consists of reading and identifying the documents concerned in the area of closest proximity.

Essential public health elements are:

1. Surveillance of population health and well-being.
2. Monitoring and response to health hazards and emergencies.
3. Health protection, including environmental, occupational and food safety.
4. Health promotion, including action to address social determinants and health inequity.
5. Disease prevention, including early detection of illness.
6. Assuring governance for health.
7. Assuring a competent public health workforce.
8. Assuring organizational structures and financing.
9. Information, communication, and social mobilization for health.
10. Advancing public health research to inform policy and practice.**

This list enables policy makers to evaluate the quality and comprehensiveness of national public health services and relevant legislation. As the number and complexity of tools developed at global and European levels has increased, mapping different instruments and tools for which EPHOs are available, means therefore an extensive exercise.

The public health self-assessment tool provides a series of criteria with which national public health officials can evaluate the delivery of the EPHOs in their particular setting. The expanded list constitutes a comprehensive package of public health services that all member states should aim to provide to their populations. This list enables policy makers to define and evaluate the quality and comprehensiveness of national public health services and relevant legislation. Similar as under Guideline 1, a scoring system (scales 1–3) enables to systematize the evaluation and which health system functions need to be strengthened in order to improve performance of the operation.*** Although aimed at evaluating public health operations, the outcomes will also trigger regulatory intervention. Therefore, relevant in the assessment of national public health legislation.

In the end, the extensive mapping exercise enables to identify major strengths and weaknesses (critical gaps and shortcomings) of the national public health regulatory framework. The next step is addressing possible omissions/shortcoming in the regulatory framework.

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* WHO Regional Office for Europe, Self-assessment tool for the evaluation of essential public health operations in the WHO European region, WHO 2015, p. 3.

** Idem. p. 3.

*** Ibidem.

Guideline 3. Addressing gaps in the legal framework with the EPHO approach

What are the appropriate instruments and tools, to respond to the relative gaps to support the delivery of the 10 EPHOs? This is a key question when formulating a legal strategy to enhance the integration of health promotion, health protection and disease prevention. For some areas (health protection) legally binding tools can reflect higher potential gains, for other areas (health promotion) the use of alternative means (influence mechanisms) can be more effective. Furthermore, the cost-effectiveness argument can an important reason for considering legal intervention, or not.* Achieving a balanced approach with different tools based on evidence based policy considerations is therefore crucial.**

Such a balanced approach will take into account of so-called "best buy" interventions, i.e. a set of evidence-based "best buy" interventions that are not only highly cost-effective but also feasible and appropriate to implement within the constraints of health systems. For instance, with respect to non-communicable diseases, WHO already formulated a set of such "best buy" interventions, such as:

1. tobacco control measures: taxes, smoke-free indoor workplaces and public places, health information and warnings, and banning tobacco advertising, promotion and sponsorship; the Framework Convention on Tobacco Control (FCTC);
2. control of harmful alcohol use, including tax increases restricted access to retail alcohol, and bans on alcohol advertising;
3. promoting health diets and physical activity, including reduced salt intake in food, replacement of trans fats, and raising public awareness of diet and physical activity through mass media,*** and
4. International Health Regulations (IHR 2005).

Guideline 4. Compliance with international [and European Union] law

PHL should be based on uniform provisions that apply equally to all health threats. Significant gains in international uniformity regarding public health standards have been achieved through existing international/regional law in areas, such as sanitary standards, disease classifications, health threats, etc. Legal requirement for controlling health risks depends on how the disease is classified. International classifications of diseases (ICD) of WHO serve as a unifier and should be used in diseases classification.

Secondly, compliance with international human rights law. A key issue concerns: Does the current law and the public health regulatory framework respect international human rights law as addressed in various international treaties (IHR, FCTC, ICESCR, Disabilities Convention, etc.)?

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* WHO Regional Office for Europe, Public Health policy and legislation instruments and tools: an updated review and proposal for further research (2012) p. 2.

** R. Martin, 'Public Health Law', (2009) 5 Perspectives in Public Health, p. 200.

*** From burden to "best buys": reducing the economic impact of NCDs in low- and middle-income countries. Geneva WHO 2011.

Thirdly, compliance with European Union health law. Under the current treaty, the 'Treaty on the Functioning of the European Union' (TFEU), the Union and member states have shared competences in the area of common safety concerns in public health matters, and will take health protection into account in all its policies. More explicit health commitment has been made by the public health provision, Article 168(1) TFEU 'A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities', followed by more specific Union competences in this area, as well as internal market implications for the health sector.*

Compliance to international law starts therefore with a critical assessment of the national public health legal framework, whether it responds adequately to the standards set by international and European Union law?

Guideline 5. Reviewing the impact and effectiveness of public health law; a fitness check

PHL does not always respond to modern developments; does not delineate the responsibilities entrusted to public health agencies; fails to equip public health officials with powers necessary to control diseases, lacks adequate privacy protection standards, due process and risk assessment, etc.** A key question to be addresses is therefore: how well is public health law working? Has it met its purpose and is it fit for purpose? The introduction of an impact-oriented reporting and evaluation system enable a more systematic review of the impact and effectiveness of pieces of PHL.

How well is PHL working addresses a relatively new phenomenon in legal theory and practice: reviewing the effectiveness of public health law.*** Improving the effectiveness of the regulatory framework means in particular focussing on critical gaps and shortcomings. The key issue therefore is: How to improve the effectiveness of the public health regulatory framework at national level?

Evidence on the effectiveness of different legal instruments is currently limited. Therefore, further evaluation is needed to inform the future effectiveness of different mechanisms, including analysis of (cost-)effectiveness and feasibility and implementation. Adding a cost component to the assessment of the impact of PHL allows the identification of a set measures with the greatest value for money.

Evaluation, more specific, ex post evaluation, is an essential step of the legal process. It can be the final stage when new policies or regulation have been introduced and it is intended to know the extent of which they

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* In more detail, see A. den Exter and T. Hervey (eds), EU Health Law. Treaty Text and Legislation, Maklu Press Antwerp 2014.

** WHO (note 16) 12.

*** E.g., the European Commission has been dealing with the better regulation agenda under the REFIT program: European Commission. Communication on Better regulation: Delivering better results for a stronger Union. Brussels. 14 September 2016 COM(2016)615 final; European Commission. DG Market Guide to Evaluating Legistion, Brussels March 2008. A.P. den Exter, Health care law-making in Central and Eastern Europe. Maklu Press Antwerp, 2002.

met the goals they served for. It can also be the initial point to understand a particular situation as a result of an existing Law, providing elements to discuss the shortcomings of its existence.* Reviewing the outcomes and results of the regulatory intervention should be therefore a core function of regulatory institutions and it is an essential element for high-quality regulation.

Ex post evaluation serves various purposes. Among them, *ex post* evaluation can make important contributions to redefine new interventions and improve the quality of future decisions by pointing out to unintended consequences that had not been properly assessed before; it can enhance transparency by opening new possibilities for stakeholders' participation to better understand how they have been affected by the regulation; and it can bring additional accountability to the regulatory process. It can also contribute to reduce the risk of regulatory failure.

Only a few OECD countries have embarked in a systematic approach to *ex post* evaluation.** Although *ex post* evaluation is just in its infancy there are several lessons to be drawn. First, it is essential to establish clear criteria for analysis, prioritise the laws or areas to be tackled and guarantee financial and technical resources to conduct the review process, as well as institutional aspects relevant for the well-functioning of the unit in charge of these tasks.

In addition, strong co-ordination mechanisms between regulatory institutions and branches of government, as well as high political support are essential for a successful review. Consultation with stakeholders needs to be properly structured to get the most out of that exercise and ensure that content of the regulation is reviewed with care and reflects perceptions of how regulation affected interested parties.***

Guideline 6. Improvement of accountability mechanisms

Accountability is rooted in the principles of good governance and the fundamental values of a democratic society, including transparency, access to information, the use of explicit standards for the delivery of public health services and their quality ensured through regular scrutiny, inspection and accreditation,**** as well as public participation, civil society engagement, corporate compliance, etc.

For instance, countries can be held accountable for to monitor access to public health services and maternal and child mortality audits, measuring core indicators (such as the morbidity from chronic diseases, mental health disorders, NCDs), etc. But also private sector action is important strengthening public health. Will corporations collaborate with local communities to ensure that their activities do not harm health or the environment? Improving accountability could include improving state responsibilities to regulate the private sector, such as requiring corporate policies on respecting the right to

* OECD, Evaluating Laws and Regulations. The case of the Chilean Chamber of Deputies, 2012, p. 10.

** Idem, p. 12.

*** Idem, p. 71–72.

**** Chichevalieva (note 3) 32–33.

health, assessing the health impact of their policies and practices, acting on these findings, monitoring results, and providing remedies.*

Relevant questions assessing existing accountability machanisms concern: i. what are the current accountability tools (processes, interventions, policies) measuring public health progress; ii. are the accountability instruments effective; iii. how are the outcomes be shared with other stakeholders; iv. are the identified bodies equipped to undertake the required public health activities; v. what is needed for improving the accountability mechanisms; and vi. what is the role and responsibility of non-state actors to public health?

Guideline 7. Establishment of good enforcement and adequate powers to deal with public health risks

Modern public health legislation needs adequate enforcement powers to protect public health. For instance, in combating threats to public health, health officials need clear authority, flexibility and sufficient guidance to exercise the relevant powers. These powers include the power of entry and inspection, as well as administrative discretion to deal with risks to public health. Consequently, effective and constitutionally sound public health law should include a rational and reliable way to assess risk.**

Adequate penalties are part of the enforcement system for breaches of public health legislation. An effective system of justice supported by the right sanctions policy is essential and integral parts of the enforcement system. Penalties can have several possible components, including punitive and restrictive elements and prohibition from certain places or activities, rehabilitation drug treatment, and courses and programmes to address criminal behaviour and improve skills. 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.***

Apart from the traditional "negative" enforcement mechanisms (punitive measures), so-called positive enforcement mechanisms are incentives or other means for encouraging compliance in a positive way. The choice of enforcement mechanism will vary based on the situation and the scope of mechanisms available. What this means is that certain mechanism are meaningful and useful in certain situations but inappropriate in others.

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* E. A. Friedman, 'An Independent Review and Accountability Mechanism for the Sustainable Development Goals: The Possibilities of a Framework Convention on Global Health' (2016) 1 Health and Human Rights Journal.

** WHO. Enforcement of Public Health Legislation, WHO Western Pacific Region 2006, 12.

*** Chichevalieva (note 3) 39.

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Guideline 8. Provide fair procedures

When the use of administrative discretions increases, there is a corresponding need for fair and accessible rights of appeal against the decisions of authorized officers. The nature and extent of human rights interventions 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.*

Reviewing the regulatory system providing procedural and substantive safeguards, relevant questions are: i. what kind of (alternative) dispute settlement procedures are available; ii. do these procedures comply with the 'fair trial' principle, under Article 6 ECHR; and iii. are the safeguards stipulated by law practical and effective, i.e. the individual must "have a clear, practical opportunity to challenge an act that is an interference with his rights".**

Guideline 9. Public Health Funding

Public health services have a history of chronic underfunding and unstable budgets. To cope with that, member states should guarantee adequate and stable public health budgets, set by law. What is more, the decision-making process on public health financing needs to be transparent and based on accurate public health financing data. Also, public health resource allocation should comply the current and future needs stipulated by the national public health program.

In addition, as the responsibility for public health is neither limited to one level of government nor to a single ministry, all levels must make a much stronger commitment to ensure the timely availability of sustained

* Idem 36–37.

** European Court of Human Rights, Guide to Article 6 of the Convention – Right to a fair trial (civil limb) (2013).

and adequate resources (financial, human and supportive) for the optimal delivery of public health services in all communities.

Assessing the level of spending needed for public health agencies, raises the following questions: i. what are major sources of public health funding; ii. what are the major players and their roles in the budget process; iii. what is the role of parliament setting funding parameters on public health and the flow of funding from the national, territorial and local levels; iv. what are sources of national budget information; v. has an assessment of relevant legislation, regulations, and other government instruments have been carried out (to determine if they facilitate adequate funding of public health needs); vi. does the assessment also identify adjustment needs for relevant legislation, regulation and other government instruments for public health funding; and vii. how does the country ensures coordination between national, regional and local public health funding frameworks?*

Final remark

Effective legislation is essential for improving public health. These guidelines aim at supporting public health officials and the legislative branch of the Ministry of Health of a member state to assess existing public health legislation in a more consistent manner, while taking advantage of good international practice. At the same time we recognise that reviewing public health legislation according these guidelines alone is not sufficient. Making public health legislation work successfully, i.e. improving health and reducing health inequalities, also requires member states to strengthen legal and administrative capacities/ resources to enact and implement public health law.

Екстер А., Горяінов О. М.

Правила перегляду національного законодавства про громадське здоров'я

Запропоновано правила перегляду національного законодавства про громадське здоров'я з метою його удосконалення на національному рівні. Зазначено, що перегляд законодавства про громадське здоров'я передбачає таку послідовність дій: визначення мети перегляду; встановлення особливостей національної законодавчої бази про громадське здоров'я; аналіз правових інструментів і заходів, необхідних для реалізації поставлених цілей; аналіз результатів регуляторного впливу. Окреслено функції права громадського здоров'я, до яких віднесено визначення завдань громадського здоров'я і його програмної політики; надання дозволу та встановлення обмежень; проведення заходів у сфері громадського здоров'я в контексті захисту прав і свобод громадян; слугування інструментом для промоції та попередження; сприяння плануванню і координації урядових і неурядових заходів у сфері охорони здоров'я.

Виокремлено дев'ять правил перегляду національного законодавства про громадське здоров'я: 1) окреслення понятійного апарату права

* J. Alper, et al, Financing Population Health Improvement: Workshop Summary, Institute of Medicine, Washington 2014; J. Kutzin et al, Implementing Health Financing Reforms. Lessons from countries in transition, European Observatory on Health System and Policies, WHO, 2010.

громадського здоров'я; 2) окреслення законодавства про громадське здоров'я відповідно до основних операцій системи громадського здоров'я; 3) заповнення прогалин правового регулювання громадського здоров'я згідно з основними операціями системи громадського здоров'я; 4) визначення відповідності міжнародному праву та праву ЄС; 5) оцінка впливу та ефективності права громадського здоров'я; 6) удосконалення механізмів відповідальності; 7) забезпечення повноважень щодо подолання ризиків громадського здоров'я; 8) забезпечення існування справедливих процедур; 9) фінансування громадського здоров'я. Кожне правило охарактеризоване.

Ключові слова: перегляд національного законодавства про громадське здоров'я, правила, охорона здоров'я, право громадського здоров'я.

Экстер А., Горяинов А. Н.

Правила пересмотра национального законодательства об общественном здоровье

Предложены правила пересмотра национального законодательства об общественном здоровье с целью его усовершенствования на национальном уровне. Отмечено, что пересмотр законодательства об общественном здоровье охватывает следующие действия: определение цели просмотра; установление особенностей национальной законодательной базы об общественном здоровье; анализ правовых инструментов и мер, необходимых для реализации поставленных целей; анализ результатов регуляторного влияния. Определены функции права общественного здоровья, к которым отнесены определение задач общественного здоровья и его программной политики; предоставление разрешения и установление ограничений; проведение мероприятий в сфере общественного здоровья в контексте защиты прав и свобод граждан; служение инструментом продвижения и предупреждения; содействие планированию и координации правительственных и неправительственных мероприятий в сфере здравоохранения.

Выделены девять правил пересмотра национального законодательства об общественном здоровье: 1) определение понятийного аппарата права общественного здоровья; 2) очерчение законодательства об общественном здоровье в соответствии с основными операциями системы общественного здоровья; 3) заполнение пробелов правового регулирования общественного здоровья согласно основным операциям системы общественного здоровья; 4) определение соответствия международному праву и праву ЕС; 5) оценка влияния и эффективности права общественного здоровья; 6) усовершенствование механизмов ответственности; 7) обеспечение полномочий по преодолению рисков общественного здоровья; 8) обеспечение существования справедливых процедур; 9) финансирование общественного здоровья. Каждое правило охарактеризовано.

Ключевые слова: просмотр национального законодательства об общественном здоровье, правила, здравоохранение, право общественного здоровья.

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