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**DEVELOPING EVIDENCE-BASED
PUBLIC HEALTH LEGISLATION:
CASE STUDY OF UKRAINE**

Current Ukrainian legislation in the field of public health is not evidence-based. Evidence-based legislation is seen as a trigger to improvement in public health. Using several internationally accepted public health frameworks in law-making process makes legislation evidence-based and helps revealing shortcomings of current legislation.

Ukraine lacks public health law as an entity: current public health legislation consists of multiple legal acts, with several articles in different laws duplicating each other. Apart from that Ukrainian legislation is not evidence-informed. Law-making is a prerogative of Verkhovna Rada (unicameral parliament of Ukraine). During the law drafting procedure, the committee of Verkhovna Rada may create special working groups consisting of researchers, NGOs and other stakeholders. Nevertheless, this requirement is not mandatory. Thus, Ukraine is a good model to illustrate the possibility of creating a single evidence-based national public health legislative act. Apart from that Ukraine and the European Union have signed an Association Agreement in 2014. Multiple articles of the Association Agreement focus on public health. Ukraine shall redesign its public health legislation in accordance with the Association Agreement's requirements. Redesigning Ukrainian legislation in accordance with the Agreement and using several public health frameworks to synthesize the new legislative act shall be seen as a trigger for positive change in Ukrainian public health. In order to ensure high transferability study focused exclusively on disease prevention. Current national and some European Union legislative acts were used as a basis, and several internationally accepted public health frameworks were used as a source of evidence. Nine national laws were used representing national legislation. Nine Directives, two Decisions, and three CJEU case-laws were used representing European Union legislation. Frameworks used were the SWOT analysis, the 2007 WHO framework for action, and the 2000 WHO framework for health performance assessment. Using SWOT analysis allowed to pick strengths and opportunities from national legislation. The result of the study was a chapter of a green paper (consultative document representing a draft of a law) that was synthesized using Ukrainian and EU legislation. This chapter was tested against the 2007 WHO framework that demonstrated that such

document covers all healthcare system's building blocks. Testing against the 2000 WHO frameworks revealed that some health goals cannot be satisfied even by such synthetic chapter, yet recommendations on improvement were provided. Virtually, all criteria shall be satisfied if frameworks are used as a routine method in legislative activities. In such a manner implementation of used methodology is recommended to national legislative power authorities as a standard of legislative activities, since it provides a trigger for changes within public health.

Key words: public health, health law, development of law, health systems and policy.

Public health is interdisciplinary focuses on disease prevention, health promotion, and health maintenance through different organized efforts [1]. Nevertheless, public health law reforms have not yet gained significant attention in public health [2,3]. Hence, public health law may be seen as an underused tool that may trigger reforms in public health, and deserves special attention [4].

Law reform is one of tools for improving public health. Improvements in legislation could bring benefits, such as keeping law up to date, compliance with international standards etc.

Ukraine has a primary obligation to promote and protect human rights, including enjoyment of the right to health. The Constitution of Ukraine guarantees protection of this right (Article 92, para. 1). This right should be realized by Ukraine individually or in cooperation with international parties [5].

European Union (EU) is one of international organizations whose body of law has a huge influence on the health of the individuals covered by it [6]. The body of laws of EU also extends to non-Union states via Association Agreements. An Association Agreement between the EU and Ukraine is in the process of ratification by all parties. It is part of the framework for cooperation between the EU and Ukraine. Multiple articles of the Association Agreement focus on the issues concerning public health [7]. Triggering changes in Ukrainian public health legislation does not only helps sustain welfare, but also allows Ukraine fulfilling the obligations posed in the Association Agreement in order to take full advantage of the Agreement.

Ukraine has a positive obligation to promote and protect its citizens' right to health. Positive obligations are ones that require active involvement of the state. Enjoyment of this right shall be progressively improved by all means including improvements in legal instruments [8-10]. Since the Association Agreement is binding in its nature, it requires a redesign of the national legislation in order to match the *acquis communautaire* (accumulated legislation) of the EU. The transition in the national legislation shall be used as an opportunity to introduce ground for shift from political will-driven to evidence-informed policy-making [11] in the field of public health and orientation towards the sustainable development of the society [12, 13]. It is essential for Ukraine to focus on the issue since current legislation is not evidence-informed [14].

As previously stated no known research has been done in this area while at the same time public health law may trigger reforms in the public health field. Ukraine

is a country that would serve well as an example for developing a contemporary evidence-based public health law.

Aim and research questions

The overall aim of this study is to illustrate the possibility of development of contemporary evidence-based public health law *via* synthesis of international and national legislation using several public health frameworks.

Specific research questions were to find out how are shortcomings of national legislation recognized, and what is a possible procedure to create an evidence-based legislation. Goals were to analyse current national legislation using public health framework approach, and to prepare a chapter of preliminary draft for the green paper for Ukraine on public health law. A green paper is consultative document of policy proposal for legislative bodies and consists of chapters. In accordance with the scope of the study one chapter was synthesized – the chapter on disease prevention.

Study design

Public health covers disease prevention, health promotion, and health maintenance [1]. EU's legal priorities are almost exclusively set on disease prevention. This should be taken into consideration since EU's legal materials were used as one of a bases for the current study. Covering disease prevention alone is also more feasible from point of view of transferability, since disease prevention, unlike health promotion and health maintenance, is almost exclusive prerogative of ministries of health and their executive bodies [15].

The chosen design was scoping review. The reason for this is the broad topic of the study that is taken as a stand-alone project and is not based on any previous studies conducted in the field [16]. Ukraine was used as a model.

The Constitution of Ukraine and the *acquis communautaire* of the EU are the cornerstone of the current study and represent the source of evidence that is relevant to the study. EU law in case of Association Agreement is supreme to national law. Apart from that, it is worth mentioning that EU law is stated to be evidence-based [11,17,18].

Summary of methodological considerations

The workflow of legal documentation assessment–development is a novel approach that is a result of combining three public health frameworks: SWOT analysis, the 2007 WHO framework for action and 2000 WHO framework for health systems performance. Principles may be described as follows. As an initial step a search for legal documents was performed. After that the legal documentation assessment followed using SWOT analysis. The second step was synthesis of the chapter of a green paper and it's analysis using the 2007 WHO framework for action. And the third step was final assessment of the new legal document using 2000 WHO framework for health systems performance.

Data sources

The data sources used in this thesis were EUR-Lex to access EU's *acquis*; CURIA database to access CJEU cases; and off-line legal database Liga: Zakon 9.4.1 (18.07.2016) developed by Informational-analytical centre Liga Ltd for national legislation. First data was accessed on the 20nd of January year 2017 and last entry was performed on the 19th of March year 2017.

Data mining – EU legislation

The list of binding legislation in the field of public health that is to be adopted by Ukraine has been taken from the Annex XLI to Chapter 22 of the Association Agreement and originally consisted of 17 documents. Nevertheless, two of Directives, apparently, lost their power. Another two were found incompatible with the Agreement. Council recommendations require no immediate legal actions, thus were not taken into account as well. One Decision has been added to the list. As a result final amount of EU legal acts taken into account was 11.

Since European Union legal system represents a pragmatic common law system it relies on both civil legal system legislation (treaties, regulations, directives, and decisions), and case laws and court rulings [19]. Case laws and court rulings are judicial decision derived from a particular law, and are cited as precedents and considered having same legal power, as a law. Each case has a legal basis. Legal basis is a core document regulating the issue. Based on above mentioned, all case laws and court rulings based on above mentioned EU legislative acts were taken into consideration. CURIA legal database used to search for case laws and court rulings. CURIA is a database consisting of cases brought to European Court of Justice. European Court of Justice is the highest court of the European Union interpreting European Union's law. Three cases were identified.

Data mining – National legislation

The Constitution of Ukraine is the fundamental law of Ukraine since year 1996. Until the adoption of the Constitution the fundamental law was the 1978 Constitution of the Ukrainian Soviet Socialistic Republic [20]. The former and the current Constitutions are taken into consideration since current national legislation is based on both of them. According to the 1996 Constitution health of the individual is recognized as a highest social value. The inalienable and inviolable right to health protection is fulfilled by state via ensuring sanitary and epidemiological welfare, which insures safe environment. The right to health is determined exclusively by the laws of Ukraine. The legislative power in Ukraine belongs to the Verkhovna Rada of Ukraine, which adopts laws and incorporates binding international treaties into national legislation [21].

Since the focus of the current study was on legislative power, only documents issued by Verkhovna Rada have been taken into consideration. All state institutions other than Verkhovna Rada are considered executive powers, thus legislation issued by those institutions was not taken into account. The basic regulatory document for legislative action in the field of national health care is a document called Fundamental principles of legislation of Ukraine on health care N 2801-XII issued by Verkhovna Rada on the 19th of November year 1992. Fundamental

principles focus on state policy in the field of health care, ensuring sanitary and epidemiological welfare, and prevention of spread of infectious diseases [22]. All legislation in the field of health care in Ukraine is based on those Fundamental principles. Based on the above mentioned, search criteria for mining relevant national legislation were set. The final list of nine legal acts has been created.

Data analysis

Methods for data analysis and synthesis were SWOT analysis for revision of current Ukrainian legislation, the 2007 WHO framework for action [23] and the 2000 WHO framework for health systems performance assessment for synthesized green papers chapter analysis [24].

SWOT analysis

The SWOT analysis is a simple and effective managerial tool initially developed for the industry and widely adopted in the policy-making that assists the process of strategic planning [25]. The SWOT analysis is a decision tool that helps achieving growth via internal analysis of strengths and weaknesses and external analysis of opportunities and threats [26]. SWOT analysis of each separate national regulatory document allowed to elaborate on whether to integrate those into the green paper of the public health law or abandon those. EU legislation was not analysed using SWOT analysis since it is assumed that it is valid and based on normative reasoning; apart from that EU regulations are supreme over the national law [27].

The SWOT analysis represents a framework that allows setting definitions of strengths, weaknesses, opportunities and threats depending on user's objectives.

After key data (relevant legislative documents) were collected, data was broken down into components (separate articles) and afterwards sorted into four large categories according to the relevance to the strengths, weaknesses, opportunities, and threats. Articles of high relevance to public health were identified as strengths. Articles of little relevance to public health were identified as weaknesses. Articles that could have lead to improvement after being merged with the *acquis* were identified as opportunities. Articles contradicting the Constitution or Fundamental principles of legislation on health are to be identified as threats. Only strengths and opportunities were preserved for further synthesis [28].

The 2007 WHO framework for action

Afterwards articles from EU and national legislation constituted sections of a chapter of a green paper that was run through the 2007 WHO framework for action. This framework is focusing on issues related to healthcare systems' improvement and takes into consideration factors that constitute systems' strengthening. Those factors that are analysed using the framework are six building blocks of health system: services, workforce, information, products, vaccines and technologies, financing, and leadership. Those blocks describe desirable capacities to be owned by the health system [23]. The 2007 WHO framework for action allowed assessing legislative coverage of the six health system's building blocks. In the current case 2007 WHO framework was used to ensure that sections of the chapter cover all factors addressing system's strengthening. Sections of the chapter were segmented

up to the saturation point. The saturation point was reached when each building block of the framework was covered by at least one section of the chapter.

The 2000 WHO framework for health systems performance assessment

The 2000 framework for health systems performance assessment is a decision-making tool that helps identifying factors that influence the performance of a health system via assessment of readiness to satisfy health system's goals. The 2000 WHO framework for health systems performance assessment was used to analyse each section of the newly developed chapter in order to observe whether the law was able to satisfy three main goals of the health care system: health, responsiveness, and fairness in financial contribution. Assessment of means (here: the new chapter) used to reach those goals helps policy-makers identifying factors that may severely influence the performance of the system and achieve better outcomes by adopting changes in the system's performance [24].

The newly synthesized chapter was tested against the matrix of health system's performance assessment. Matrix consisted of three main goals of healthcare. Each section of the chapter was tested against goals. First goal represents health. Second goal represents responsiveness. And third goal represents fairness in financial distribution. Second goal was fragmented into smaller sub-goals: respect for dignity, respect for individual autonomy, respect for confidentiality, prompt orientation to health needs, basic amenities, access to social support networks for individuals receiving care, and choice of institution and individual providing care. Each section of a chapter was tested against all sub-goals. Results from the matrix showed whether the goal or sub-goal is satisfied, not satisfied, or not applicable to the section.

Ethical considerations

The study is valuable in a way that it respects Ukraine's value system: national legislation system is to be used as a base for new proposal's synthesis, green paper adapted to existing state establishments. Selection bias is virtually reduced to zero since national and EU legislative databases were used; changes in the dependent variables, subject changes during the study, ambiguous temporal precedence were absent. This leads to conclusion that internal validity is high. External validity is high since current results may virtually be used within any civil law system. No individual risks or complications could have imply. There were no community level risks. Societal interests did not overweight interests of individuals [29].

Results

Selected legal documents from *acquis communautaire* overall represented 190 article of which 80 (42%) were identified as transferrable into the chapter of a green paper. Apart from that, three case laws and court rulings were used. Case laws and court rulings have been transferred into the chapter as separate articles of a law.

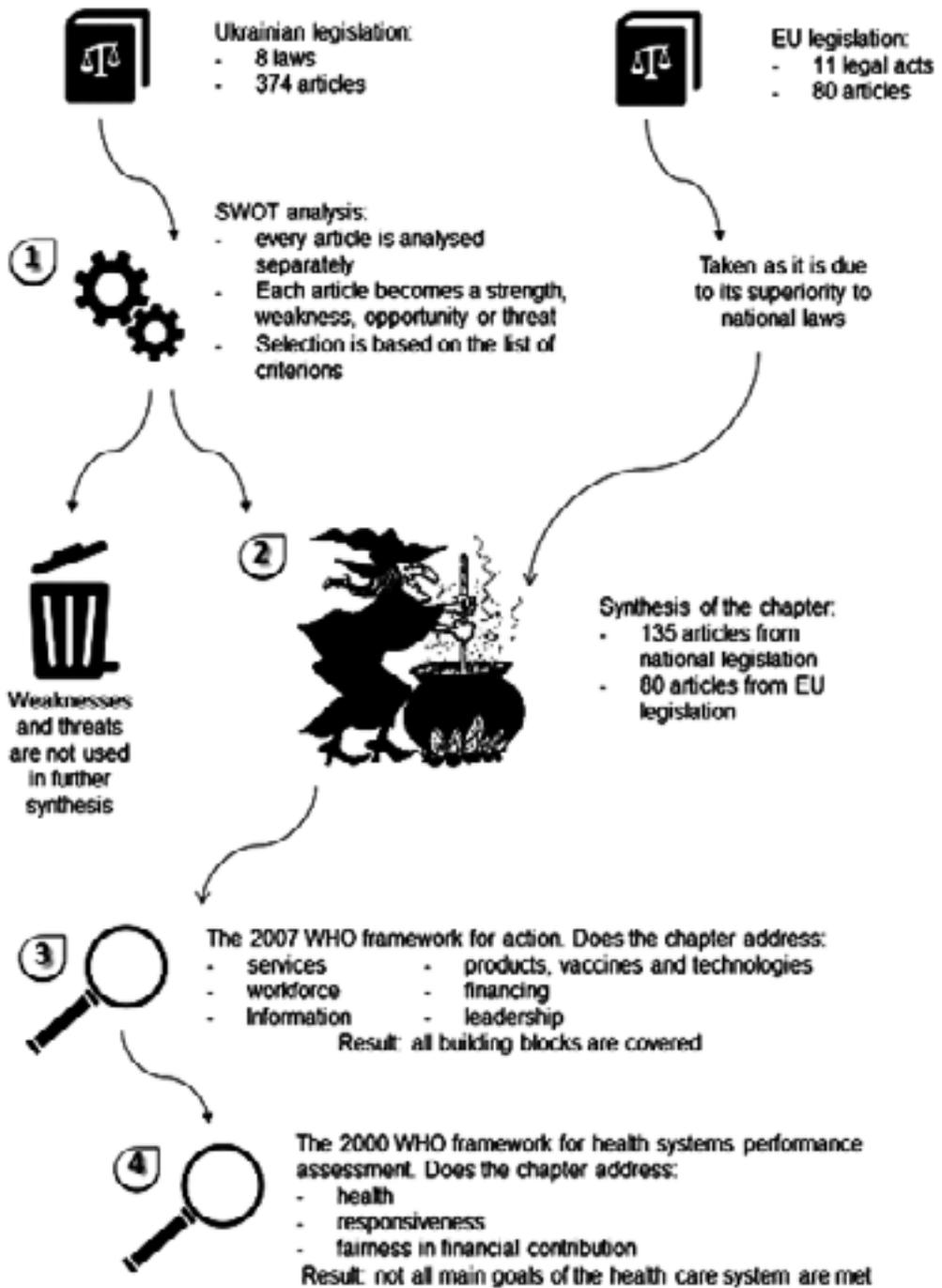


Fig. 1. Detailed workflow with results.

SWOT analysis

The final list of national legal acts was analysed using SWOT analysis principles (45). Selected national legal documents represented 374 articles of which 133 (36%) were identified as transferrable into the chapter of green paper.

The 2007 WHO framework for action

Using above mentioned selected articles a chapter on disease prevention of a green paper of the public health law has been synthesized. Separate articles from the *acquis communautaire* and national legislation have been used to synthesize the chapter. The 2007 WHO framework for action used in the synthesis revealed that sections of the chapter cover all factors addressing system's strengthening. Synthesized chapter satisfies health system basics, such as multiple stakeholder involvement, description of direct activities, safety aspects, quality assurance etc [23].

The 2000 WHO framework for health systems performance assessment

The 2000 WHO framework for health systems performance was designed in order to check whether health system addresses three main health system's goals: health, responsiveness (with multiple sub-goals), and financial contribution.

It was assumed that not all goals of the framework may be met by separate sections. Testing the chapter against the 2000 WHO framework for health systems performance assessment revealed that prompt orientation to health needs (e.g. surveys on satisfaction) is neglected throughout the document, and access to social network for individuals receiving care (e.g. social support during care) is neglected in section on Human organ and other anatomical material transplantation, section on Prevention of infectious diseases morbidity and spreading, and section on Population and territory sanitary protection. Respect for dignity and respect for individual autonomy are neglected in least two sections mentioned above. Such negligence may be justifiable since intentional transmission of an infection is considered to be criminal conduct and is penalized by law in accordance with Articles 121-123, 125, 130, 133 of Criminal Code of Ukraine.

The chapter

The chapter represents a draft legal document that is recommended as a pattern in policy-making for national stakeholders. The chapter on disease prevention consists of sections. Each section is dedicated to a specific field or issue. Section 1 defines terms. Section 2 sets the scope of application of the chapter of the law. Section 3 sets principles of state policy in relation to disease prevention. Section 4 sets state credentials and responsibilities. Section 5 elaborates on state and individual right and responsibilities. Section 6 covers prevention of infectious diseases morbidity and spreading. Section 7 covers immunization. Section 8 covers population and territory sanity protection. Section 9 covers human blood and blood components. Section 10 covers human organ and other anatomical material transplantation. Section 11 covers tobacco related issues. Section 12 covers medicinal products. Section 13 elaborates on clinical trials. Section 14 covers data collection, handling and sharing. Section 15 covers financing. And section 16 covers international cooperation and agreements.

Overall, it is seen that addressing shortcomings of current national legislation is feasible by using public health frameworks, such as SWOT analysis.

Creating a new legislative document using other public health frameworks, such as 2007 WHO framework for action and 2000 WHO framework for health systems performance assessment, is also feasible and provides possibility of addressing public health needs in an evidence-based way.

Discussion of findings

The use of three frameworks made it possible to successfully synthesize an evidence-based chapter of a green paper of a public health law for Ukraine that may provide a shift from politically driven initiatives to evidence-informed policy-making, in such a manner triggering positive changes in public health.

Adoption of international evidence-based law, such as European Union law, and introduction of evidence-informed law-making, such as the use of public health frameworks for synthesis, triggers positive changes, e.g. broader topic coverage, in the field of national public health.

It has been found that the public health is not mentioned in Article 3 of the document «Fundamental principles of legislation of Ukraine on health care No. 2801-XII issued by Verkhovna Rada on the 19th of November 1992».

Synthesis has revealed that some sections would not exist in the chapter if EU legislation would not be used, for example sections on human blood and blood components, clinical trials, and data collection, handling and sharing almost exclusively consist of articles adopted from EU legislation. In comparison with current national legislation the new chapter is comprehensive and evidence-based. The chapter reveals weaknesses of the current legislation and offers solutions in an evidence-based manner.

Public health frameworks used to synthesize public health legislation helps law-makers focusing their attention on the current state of art (e.g. strengths and weaknesses of the current legislation), and guide them through law making procedure (building blocks, health care goals) in an evidence-based manner.

Further development of chapters on health promotion and health maintenance shall apply. After the synthesis of two other chapters of a public health law using proposed public health frameworks is finished it is recommended for adoption as a model law for national policy-makers in Ukraine.

By applying the methodology that has been used in this project, such procedure may be performed virtually in any country with civil law system. In civil law-system main state functions are regulated via laws. Today 76 countries worldwide practice civil law, which makes results highly generalizable and transferrable [30]. Apart from that, the methodology for assessment and development of public health legislation also addresses WHO recommendations on development of framework for public health law in Europe [31].

The three-step legal documentation assessment – development framework, designed for the current project, is recommended as a tool for further development of lacking chapters as well as development of virtually any other national model law on public health.

Based on these results, further studies are needed on creating evidence-based legislation on two others main foci of public health – health promotion and health

maintenance. Disease prevention, health promotion, and health maintenance are three cornerstones of public health [1]. In such a manner, legal reforms shall address all three areas. It is worth mentioning that further studies on other law systems (common, shariah) should also be performed. Civil law is accepted only in 76 countries, while health is of high importance all around the globe. Yet, different legal systems should be addressed.

Conclusions and recommendations

Prompt orientation to health needs is neglected throughout the document, and access to social network for individuals receiving care is neglected in some sections of the green paper. Revision by national policy-makers shall address inclusion of regulations ensuring prompt orientation to health needs, and access to social services, having regards to current institutional capacities in Ukraine.

Revision of Fundamental principles of legislation of Ukraine on health care No. 2801-XII issued by Verkhovna Rada on the 19th of November 1992 is needed. Revision by Verkhovna Rada shall address inclusion of public health activities as ones that are regulated by the the Fundamental principles of legislation of Ukraine on health care.

Revision by national policy makers shall address excluding duplications in legislation. Implementation of a single legislative act is recommended to avoid collisions of decrees of Cabinet of Ministers of Ukraine that may have different legal basis (based on similar articles of different laws).

Merging national and international (EU) legislation in the field of public health ensures the accumulation of legislation within public health and helps covering wider spectrum of issues in a more sophisticated way. Synthesis of a public health law using public health framework helps creating evidence-based legislation. Both practices (merging and public health framework usage) are recommended to legislative power authorities for national legislative procedures.

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Мієтуліс А.

Розробка законодавства про громадське здоров'я, заснованого на доказах: приклад України

Висвітлено особливості законодавчого регулювання системи громадського здоров'я в Україні. З'ясовано, що в Україні немає нормативного акта, який би цілісно регламентував питання функціонування системи громадського здоров'я, а саме законодавство про громадське здоров'я складається з численних актів, норми яких часто дублюються. Встановлено, що законодавство України в сфері громадського здоров'я не базується на доказах.

Для дослідження обрано чинні національні законодавчі акти, законодавчі акти Європейського Союзу, а також відповідні міжнародні стандарти з питань громадського здоров'я. Завдяки використанню методу SWOT-аналізу, синтезу національного законодавства і законодавства ЄС запропоновано проект (green paper) розділу, присвяченого питанням громадського здоров'я. Обґрунтовано необхідність перегляду Закону України «Основи законодавства України про охорону здоров'я» з метою чіткого окреслення заходів у сфері громадського здоров'я, а також вилучення правових норм, які дублюються.

Ключові слова: громадське здоров'я, медичне право, розвиток законодавства, система охорони здоров'я і політика.

Миэтулис А.

Разработка законодательства об общественном здоровье, основанного на доказательствах: пример Украины

Освещены особенности законодательного регулирования системы общественного здоровья в Украине. Установлено, что в Украине нет нормативного акта, который бы целостно регламентировал вопросы функционирования системы общественного здоровья, а именно законодательство об общественном здоровье состоит из многочисленных актов, нормы которых часто дублируются. Установлено, что законодательство Украины в сфере общественного здоровья не базируется на доказательствах.

Исследовались действующие национальные законодательные акты, законодательные акты Европейского Союза, а также соответствующие международные стандарты по вопросам общественного здоровья. Благодаря использованию метода SWOT-анализа, синтеза национального законодательства и законодательства ЕС предложен проект (green paper) раздела, посвященного вопросам общественного здоровья. Обоснована необходимость пересмотра Закона Украины «Основы законодательства Украины о здравоохранении» с целью четкого определения мероприятий в сфере общественного здоровья, а также устранения дублирующихся правовых норм.

Ключевые слова: общественное здоровье, медицинское право, развитие законодательства, система здравоохранения и политика.

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