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REVIEW OF THE PUBLIC HEALTH LAW IN THE CONTEXT OF WHO POLICIES AND DIRECTIONS

Introduction

The Law on Public Health in the Republic of Macedonia¹ (hereinafter LPH) is a recent law, adopted in 2010 and amended only once since then. This law specifies the fundamental functions and obligations of the public health, health care system, public health extraordinary circumstances, financing, supervision, as well as of the coordination and cooperation in the field of public health.

Taking into consideration its ambitiously defined goals, the Law is considered to be a valuable instrument in the process of establishing the new public health in the country and a response to the international obligations in the field, particularly to the International Health Regulations²

1 Law on Public Health (Official Gazette of the Republic of Macedonia, No 22/2010 and 136/2011)

2 World Health Organization, International Health Regulations (2005), Second edition <http://www.who.int/ihr/9789241596664/en/>

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and the Framework Convention on Tobacco Control³ of the World Health Organization.

The rapid development of strategies, policies and instruments in the field of public health by the World Health Organization (WHO) in the last couple of years, particularly the adoption of the Strategy for health and well-being Health 2020 in 2012⁴ and the European Action Plan for Strengthening Public Health Services and Capacity in 2012⁵ necessarily entails the analysis of the Macedonian Law on Public Health so as to establish if any amendment is needed given the latest development of policies and legislation in Europe in order to achieve the ambitiously defined objectives of the Law itself. In November 2013,⁶ WHO Expert Mission in cooperation with the Ministry of Health of the Republic of Macedonia initiated the dialogue on promotion of further public health development in the country, crucially dependent on the public health legislation and on LPH in particular.

In this context, the review aims to practically contribute to this dialogue among all interested parties through initiating a discussion about the importance of the legislation as an instrument for public health promotion by making reference to the 2010 Law on Public Health and the amendments that should be made in that regard.

The analysis of LPH presented in this review is made in the light of the latest WHO strategies, policies and documents related to public health: the Strategy for Health and Well-being Health 2020 (5), the European Action Plan for Strengthening Public Health Services and Capacity (6) and the Self-assessment Tool for Public Health Services and Activities⁷ while taking into consideration the findings of the WHO Expert Mission organized in November 2013 (2013) (7).

3 World Health Organization, Framework Convention on Tobacco Control, 2003 http://www.who.int/fctc/text_download/en/

4 Health 2020: a European policy framework supporting action across government and society for health and well-being, WHO Regional Office for Europe, 2012, http://www.euro.who.int/__data/assets/pdf_file/0006/199536/Health2020-Short.pdf

5 European Action Plan for Strengthening Public Health Capacities and Services, WHO Regional Office for Europe, 2012 http://www.euro.who.int/__data/assets/pdf_file/0005/171770/RC62wd12rev1-Eng.pdf

6 WHO Regional Office for Europe [Web site] <http://www.euro.who.int/en/countries/the-former-yugoslav-republic-of-macedonia/news/news/2014/03/initiation-of-a-national-policy-dialogue-on-public-health-in-the-former-yugoslav-republic-of-macedonia>

7 WHO Regional Office for Europe [Web site] <http://www.euro.who.int/en/health-topics/Health-systems/public-health-services/activities/assessment>

Analysis

1. *European strategies and policies and the Law on Public Health (2010)*

The WHO Strategy for Health and Well-being Health 2020 (5) clearly establishes the connection between the achievement of better health results and the substantial strengthening of public health services and capacity including the revision and the adjustment of public health legislation and its instruments.

The European Action Plan for Strengthening Public Health Services and Capacity (6) emphasizes the importance of the State's institutional capacity to generate a legislation that will ensure public health promotion as well as to develop both regulatory and enforcement mechanisms so as to protect the population, to strengthen disease surveillance and to monitor the implementation of the prescribed norms and standards.

Therefore, the adoption of the Law on Public Health as a separate law represents an appropriate response of the State and an indicator of the State's interest to legally protect the public health as a public good.

2. **Content analysis of the Law on Public Health (2010)**

The content of the Law on Public Health is analyzed considering the elements recommended to be included in any regulation in the field of public health (1:6): clear philosophical framework, definition of the regulation and the terminology used, international background, basic public health functions, clear distinction of the mandate/duties of the subjects, establishment of coordination mechanisms within the system, quality assurance, decision-making based on the best scientific evidence of any significant risk, implementation of the regulation, provisions regarding fair procedures, definition of public health services, establishing legal ground for partnerships in public health, financing and penal provisions.

LPH prescribes the implementation of the fundamental functions and obligations of public health, the public health system, the public health extraordinary circumstances and the financing of public health (Article 1). Amongst other definitions of basic notions in LPH, the Macedonian health legislation determines the term "public health" for the first time as a system of knowledge and skills for preventing diseases, prolonging life and promoting health through organized community efforts (Article 3, para.1, p. 1). Namely, it is for the first time that the Law underlines the importance of various risk factors to health such as environment, causes of diseases, lifestyle and socio-economic factors as well as the need for their surveillance through the public health system.

As for the international context, LPH explicitly sets the objective to ensure the implementation of the international health regulations. The Institute for Public Health is hence obliged to maintain international cooperation with its counterparts in the field of public health and to provide health-related data to international institutions as per law. Furthermore, LPH stipulates that every law on prevention against communicable diseases, food safety, health safety at work, environmental protection as well as on other health-related issues prescribed by law is applicable to public health. Thus, LPH implies the implementation of international laws relevant to the field in question (e.g. The Framework Convention on Tobacco Control (4)).

Moreover, the Law on Public Health determines the basis public health functions in line with the Ten Essential Public Health Operations of the World Health Organization (Table 10).

Furthermore, LPH contains provisions determining the mandate/duties of the subjects, the introduction of coordination mechanisms within the system, the quality assurance, the financing and the penal provisions. These provisions could be analyzed through the prism of their practical use and applicability. For example, LPH indicates several sources of income for the public health such as the Budget of the Republic of Macedonia, the budgets of the units of local self-government, private sources of income, donations and other sources prescribed by different law. In practice, the private sources of income provide for approximately 80% of the financial means (7). Regardless of the reasons for this state of affairs (the analysis of which is not in the focus of this review), it is of paramount importance to translate the general consensus on public health as a public good into an appropriate budget funding. As for their applicability, one good example is the concept of public health network that is not adequately defined with this law nor is normatively connected to the one prescribed by the Law on Health Care.

LPH does not contain provisions regarding the decision-making based on the best scientific evidence of any significant risk and leaves this issue up to the ethical approach of the decision-makers.

LPH contains provisions related to certain services (traditional and complementary medicine, tattooing, piercing, permanent make-up, acupuncture and beauty activities) and thus complicates the understanding and defining of public health services. Regardless of the reasons for incorporating these provisions into the law, they do not belong there due to their very nature and should be therefore regulated by different law.

LPH refers to partnerships in the field of public health (partnership with the population, inter-sectorial partnership) in a declarative manner but fails to define the means and mechanisms for creating and maintaining them.

Table 1: Comparative review of the fundamental public health functions as per the Law on Public Health (2010) and WHO European Action Plan for Strengthening Public Health Services and Capacity (2012)

	Fundamental public health functions, Law on Public Health (2010)	Fundamental public health functions, European Action Plan
1.	Monitoring and assessment of health and well-being among the population	Health and well-being surveillance among the population
2.	Identifying, anticipating, examining and mitigating health-related problems and dangers in the community	Emergency preparedness and response
3.	Health protection, assessment of needs and activities for health protection	Health protection including environmental protection, safety at work and food safety
4.	Disease prevention through preventive measures on primary and secondary level	Health promotion including activities in addressing social determinants and health inequalities
5.	Promotion of health and health education	Disease prevention and early detection
6.	Proposing adoption and implementation of laws and other provisions on health protection, particularly on safe food, air, water and land and safety at work	Good public health management
7.	Provision of competent multidisciplinary public health personnel	Provision of sufficient and competent public health personnel
8.	Supporting and conducting health-related research	Providing sustainable organizational structures and financing
9.	Development and planning of public health policies	Advocacy, communication and social mobilization for health
10.	Preparedness and management in public health extraordinary circumstances including prevention, reaction and mitigation of consequences	Promotion of research on public health for the purposes of the implemented policies
11.	Ensuring inter-sectorial partnership and community participation for the purposes of promoting health and reducing health inequalities	

The Analysis of the WHO Expert Mission (7), too, generally demonstrates that the law is plain i.e. it prescribes solutions that are not implemented or whose partial implementation does not deliver results within the system meaning that the Law itself does not cover certain aspects as indicated by the experts. Given the complexity and the number of recommendations provided by the WHO experts following their mission in Republic of Macedonia, it is

more than clear that the law needs thorough amendments for the purposes of implementing both the European Action Plan for Strengthening Public Health Services and Capacity and the 10 Essential Public Health Operations. This specifically refers to the philosophical framework within which the law would become an instrument for achieving objectives and implementing mechanisms for monitoring, assessment and reporting on these objectives. The aim of the proposed changes would be to improve the implementation of LPH so as to achieve the ambitious goals as defined by the law itself (in a declarative manner) which are not however appropriately developed.

The four-year long enforcement of LPH has demonstrated that the law itself is a poor instrument for achieving the ambitious goals it prescribes i.e. does not contribute to their completion. This is clearly the case given the current state of affairs regarding the health data and the necessity of intervention on the part of the Ministry of Health in the field of public health (Essential Public Health Operation 1) as well as the (non)functioning of the health evidence registers⁸ as per law.

It is therefore of great importance to consider the issues that are not determined by the Law on Public Health in regard to 1) Establishing a firm philosophical framework for public health or a strategy for public health, 2) Instrument for development assessment of public health and public health system, 3) Redefining the role and therefore the mission, values, principles, functions and the structure of the Institute so as to improve its role as a leader for modern public health, 4) Network of Public Health Centers, 5) Counseling body for public health and 6) System for monitoring, assessment and reporting in the field of public health.

- Strategy for Public Health. Article 3 of LPH prescribes adoption of a National annual program for public health which is not associated with any monitoring or assessment process or defined objectives. Moreover, it is not associated with any other documents related to strategic planning of the public health development in the medium and long term nor has anything similar been adopted. It is necessary to decide on strategic approach in the public health development. Hence, LPH should include the adoption of a National strategy for public health. A good example in that regard is the National strategy for anticorruption as a long-term legal document which indicates activities and performance indicators enabling the monitoring of the strategy implementation. A strategy of this kind would be considered a long or medium-term (depending on the decision-maker) objective of the

⁸ Law on Health Evidence (Official Gazette of the Republic of Macedonia, No. 20/2009 and 53/101)

State towards the promotion of public health system. Passing a strategy is closely connected with performance monitoring, assessment and reporting as well as with the adoption of operational documents concerning the strategy implementation, explained in the text below.

As a country with candidate status for EU accession, the Republic of Macedonia has remarkably efficient instruments at its disposal⁹, developed by the European Union, but has not implemented them so as to assess the previous state of affairs (prior to any measure proposition such as this strategy), the implementation of the operational documents of the strategy in question as well as the impact of the strategy all of which should be done in the final year of its implementation in order to determine the measures that need to be taken in the following period.

- *Instrument for development assessment of public health and public health system.* LPH does not prescribe the means by which the competent institutions will assess the progress made in the public health system during a certain period of time and whose findings should serve as a basis for an Action plan envisaged as a medium-term operational document. In addition, the Law does not specifically define the subject responsible for assessment. The criteria and the means for assessment as well as the instruments for improvement of the established weaknesses of the system are completely left out from the law or any other document referred to by the law that should be clearly delegating this responsibility. An extensive and significant activity, the assessment of the progress made in the public health system is to be done, in this case, in a non-systemized way by both non-unified criteria and vaguely and nonprofessionally defined indicators. As a result, the system lacks the big picture i.e. one unison attitude regarding the right destination that the public health system should take during a certain period of time. Hence, the WHO Expert Mission has reached the conclusion that it is necessary to introduce the WHO Assessment Instrument in order to fully examine the public health system in Republic of Macedonia and detect, based on the analysis of the factual situation, the key areas for action as well as the necessary activities and progress indicators. Translated into a Strategy for Public Health accompanied with an Action plan as a medium-term operational document, these findings would indicate the following steps to be taken, including the

9 European Commission, Impact Assessment Guidelines, 2009 http://impel.eu/wp-content/uploads/2010/01/European-Commission-Impact-Assessment-Guidelines-iaq_2009_en.pdf

legislative ones, for public health promotion. Furthermore, the State could continue passing annual operational plans as medium-term operational documents but solely if they are related to the long-term strategic development planning of both the public health system and public health in the country.

- *Redefinition of the role and therefore of the mission, values, principles, functions and the structure of the Institute so as to improve its role as a leader for modern public health.* The Law on Public Health stipulates the importance of the Institute for Public Health but fails to clearly specify its mission, values, principles, functions and structure, all of which should reflect the principles of the modern public health. It is therefore wise to take into consideration the relevant instructions (1) provided by the WHO experts. Their implementation would lead to structural changes of the Institute for Public Health aiming to:
 - Incite the Institute to take the leading role within the public health system by assuming responsibilities and competences related to public health and clearly defined by law;
 - Increase the coordination between public health institutions and other health care institutions (particularly in the primary health care) through multidisciplinary trainings, strengthened communication channels and structural relations;
 - Strengthen the trainings in public health;
 - Enable research, monitoring, evaluation and exchange of findings with the partners, including the international ones such as the Association of Schools of Public Health (ASPH) for further education, and the European Public Health Association (EUPHA) for maintenance of professional standards and research;
 - Provide greater focus on public health within the medicine-related training programs;
 - Reform the services, functions and activities in terms of their practical use so as to improve the cohesion and adjust them to the new challenges. A good example in this context is the communication for better health – it is crucially importance for better understanding of the citizens' needs (through behavior research). The correct use of the new technologies and social media would additionally contribute to the promotion of public health.
 - Revise the public health instruments and the monitoring of their effectiveness, as well as the efficiency assessment of various implemented instruments and the appropriateness for their

- extended use, maintenance or termination, and
- Develop standards, and monitoring and surveillance indicators for both the activities comprised within the Ten Essential Public Health Operations and the crucial public health services.
 - *Network of Public Health Centers.* The Law on Public Health introduces the Network of Public Health Centers only in a declarative manner. In the absence of actual provisions on the means for functioning of this network, organizational hierarchy and for functioning in terms of responsibility, reporting, transparency, monitoring and evaluation, this provision seems rather inessential and vague. It is only by amending LPH in terms of legally connecting this network to the public health network prescribed by the Law on Health Care¹⁰ that this problem could be solved.
 - *Counseling body for public health.* The instructions provided by the WHO experts following their mission in Republic of Macedonia also refer to the creation of a completely new body on national level that would be presided by the Minister of Health and competent to implement all urgent assessments, examine the existing regulation as well as to pass bylaws and other acts if needed. These instructions raise much more questions than they provide answers. Namely, the description of the duties to be attributed to this body corresponds almost fully to that of the responsibilities assumed by the Ministry of Health. By designating the Minister of Health as its chairperson, it becomes evident that the experts suggest creation of a parallel institution that would fulfill all above mentioned tasks. From a legislative point of view, these instructions are untenable. According to the Macedonian legislation, the Ministry of Health has the central role in the health system management as is it in every other country. It is highly possible that a mistake has been made in this part of the text. If that is the case, then it would be much more appropriate to understand the experts' instructions in a teleological way i.e. by taking into consideration the set goal: integration of the public health system and creation of a counseling body for public health. In this context, the strengthening of the Ministry's capacities by creating a sector for public health as well

¹⁰ Law on Health Care (Official Gazette of the Republic of Macedonia, No. 43/2012, 145/2012 and 87/2013)

as by creating or strengthening sectors for analytics, assessment and analysis would contribute to a more focused monitoring of the situation in the field, and to the integration of public health institutions. The modern tendencies in public health aim at taking measures and making changes based on the factual situation properly established by direct field research and data collection that is done by properly determined processes and parameters in order to obtain solid results that would either significantly improve the factual situation or solve an actual problem. The realization of research and the introduction of a system of this kind require substantial structural change and further capacity development of the entire health system. In addition, it is a fact that commissions for public health were introduced on both national and local level whose performance and results have not been analyzed. The creation of the National Committee for Health and Environment within the Macedonian Government under the leadership of the Prime Minister might be the best solution to the complex challenges in the field of public health in the country and should be therefore taken into consideration when making amendments to the Law on Public Health.

- *Monitoring, assessment and reporting progress in public health and public health system.* The Law on Public Health fails to provide provisions in regard to the introduction of mechanisms for continuous monitoring and evaluation of the public health, including its assessment, as a whole. Hence, there is big gap in one of the most important instruments of the public health system. This gap accentuates even more the general declarative nature of the prescribed provisions as they do not introduce mechanisms for continuous monitoring and evaluation and therefore hinder the access to relevant results related to both the progress made and the system's weaknesses. Furthermore, the Law does not specifically designate the subject responsible for public health monitoring and evaluation and consequently makes it impossible to determine the responsibility (as per this law). Given the context, it is of utmost importance to define by law the mechanisms ensuring direct access to information on the current state of affairs i.e. to give legal force to the selected

mechanisms so that they could be considered an official means for obtaining results for the entire system. If this role is assumed by the Ministry of Health, then the above mentioned regarding the sectors for public health, analytics, assessment and analysis is also relevant and applicable to this section.

Conclusion

Passing the Law on Public Health as a separate law represents an appropriate response of the State and an indicator of its interest to legally protect the public health. By doing so, the Macedonian health legislation defines the term “public health” for the first time as a system of knowledge and skills for preventing diseases, prolonging life and promoting health through organized community efforts. Furthermore, it is for the first time that the Law underlines the importance of various risk factors to health such as environment, causes of diseases, lifestyle and socio-economic factors as well as the need for their surveillance through the public health system.

As for the international context, LPH explicitly sets the objective to ensure the implementation of the international health regulations and implies the implementation of international laws relevant to the field in question. LPH determines the basic public health functions in line with the Ten Essential Public Health Operations of the World Health Organization. The implementation or applicability for the majority of the provisions of LPH is questionable. Regarding their implementation, LPH inadequately protects the public health as a public good, for which the evidence can be found in the factual funding of the public health. As for their applicability, one good example is the concept of public health network that is not adequately defined with this law nor is normatively connected to the one prescribed by the Law on Health Care.

The Law on Public Health does not contain provisions regarding the decision-making based on the best scientific evidence of any significant risk and leaves this issue up to the ethical approach of the decision-makers.

The Law on Public Health does contain provisions related to certain services (traditional and complementary medicine, tattooing, piercing, permanent make-up, acupuncture and beauty activities) and thus complicates the understanding and defining of public health services. Regardless of the reasons for incorporating these provisions into the law, they do not belong there due to their very nature and should be therefore regulated by different law.

LPH refers to partnerships in the field of public health (partnership with

the population, inter-sectorial partnership) in a declarative manner but fails to define the means and mechanisms for creating and maintaining them.

The four-year long enforcement of LPH has demonstrated that the law itself is a poor instrument for achieving the ambitious goals it prescribes i.e. does not contribute to their completion.

It is therefore of great importance to consider the issues that are not determined by the Law on Public Health in regard to 1) Establishing a firm philosophical framework for public health or a strategy for public health, 2) Instrument for development assessment of public health and public health system, 3) Redefining the role and therefore the mission, values, principles, functions and the structure of the Institute so as to improve its role as a leader for modern public health, 4) Network of Public Health Centers, 5) Counseling body for public health and 6) System for monitoring, assessment and reporting in the field of public health. The analysis of these issues presented in this review suggests the following amendments to LPH:

- Passing a Strategy for Public Health, as a legal obligation. Its development, implementation, monitoring and assessment would be based on the instruments of EU so as to assess the previous state of affairs (prior to any measure proposition such as this strategy), the implementation of the operational documents of the strategy in question as well as the impact of the strategy all of which should be done in the final year of its implementation in order to determine the measures that need to be taken in the following period.
- Introduction of Instrument for development assessment of public health and healthcare as a legal obligation. It should be done by following the example of the WHO Assessment Instrument in order to fully examine the public health system in Republic of Macedonia and detect, based on the analysis of the factual situation, the key areas for action as well as the necessary activities and progress indicators. Translated into a Strategy for Public Health accompanied with an Action plan as a medium-term operational document, these findings would indicate the following steps to be taken, including the legislative ones, for public health promotion. Furthermore, the State could continue passing annual operational plans as medium-term operational documents but solely if they are related to the long-term strategic development planning of both the public health system and public health in the country.
- Redefining the role and therefore the mission, values, principles, functions and the structure of the Institute so as to improve its role as a leader for modern public health.

- Establishing a legal connection between LPH and the Health Care Law through the public health network.
- Ensuring legal and factual integration of the public health system and creation of a counseling body for public health. In this context, the strengthening of the Ministry's capacities by creating a sector for public health as well as by creating or strengthening sectors for analytics, assessment and analysis would contribute to a more focused monitoring of the situation in the field, and to the integration of public health institutions. The creation of the National Committee for Health and Environment within the Macedonian Government under the leadership of the Prime Minister might be the best solution to the complex challenges in the field of public health in the country and should be therefore taken into consideration when making amendments to the Law on Public Health.
- Introduce progress monitoring, assessment and reporting in both public health and health public system; define by law the mechanisms ensuring direct access to information on the current state of affairs i.e. to give legal force to the selected mechanisms so that they could be considered an official means for obtaining results for the entire system. If this role is assumed by the Ministry of Health, then the above mentioned regarding the sectors for public health, analytics, assessment and analysis is also relevant and applicable to this section.

It is necessary for the Macedonian public health legislation to join the European tendencies aiming at changes based upon properly and directly determined factual situation through already established processes in the EU countries and specifically defined in the field of public health by the World Health Organization. It is only by determining the factual situation that appropriate measures could be taken towards improving the public health system and services.

Finally, it would be a significant legislative step to align the new provisions (of the Law on Public Health) with the remaining legislation related to health (not only with the Law on Health Care).

Filip CHICHEVALIEV

Резиме

REVIEW OF THE PUBLIC HEALTH LAW IN THE CONTEXT OF WHO POLICIES AND DIRECTIONS

Abstract

Legislation is a valuable mechanism in the promotion of public health as indicated by the increasing number of special public health laws being adopted in Europe. The Republic of Macedonia joined this trend in 2010 with the adoption of the Law on Public Health. The rapid development of strategies, policies and instruments in the field of public health on the part of the World Health Organization in the last couple of years, particularly the adoption of the Strategy for Health and Well-being Health 2020 (2012) and the European Action Plan for Strengthening Public Health Services and Capacity (2012) necessarily entails the analysis of the Law on Public Health so as to establish if any amendment is needed given the latest development of policies and legislation in Europe in order to achieve the ambitiously defined objectives of the Law itself.

This review aims to point out the necessary changes to be made so as to update the 2010 Law on Public Health in accordance with the European tendencies and transform it into a serious instrument for public health promotion in the Republic of Macedonia. Public health legislation is hereinafter 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 managing the health risks) as well as 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.¹²

Законодавството претставува значаен механизам во унапредувањето на јавното здравје, за што говори и сè поголемиот број на донесени специјални закони за јавно здравје во Европа. Република Македонија се вклучи во вакиот тренд со донесувањето на Законот за јавно здравје во 2010 година. Брзиот развој на стратегии, политики и инструменти во областа на јавно здравје на Светската здравствена организација во последните две години, а особено донесувањето на Стратегијата за здравје и благосостојба – Здравје до 2020 година (2012) и Европскиот акцискиот план за зајакнување на јавно-здравствените капацитети и услуги (2012), нужно наметнуваат анализа на Законот за јавно здравје во контекст на утврдување на потребите од негова измена во функција на следење на развојот на политиките и законодавството во Европа и реализација на амбициозно поставените цели на самиот закон.

Целта на овој осврт е да ги прикаже потребните промени за осовременување на Законот за јавно здравје од 2010 година, во согласност со европските текови, за тој да претставува сериозен инструмент во унапредувањето на јавното здравје во Република Македонија. Во овој труд под законодавство за јавно здравје се подразбираат правните овластувања и обврски на државата за обезбедување на услови во кои населението ќе биде здраво (како што се идентификување, превенирање и справување со ризиците по здравјето) и ограничувањето на овластувањата на државата за ограничување на автономијата, приватноста, слободата или други правни интереси на индивидуите со цел заштита и промоција на здравјето на заедницата.¹²

Endnotes

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