**Terms of Reference**

**for Junior Non-Key Legal Expert** **to Support MoH on Approximation**

**with the EU in the Public Health Area[[1]](#footnote-1)**

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| --- | --- | --- | --- | --- |
|  | | **Level of Seniority** | **Number of days (total)** | **Special requests for endorsement** |
| Legal national non-key expert | | Junior | Up to 330 | Ministry of Health |
| **Component:** | Component 1, Sub-result 1.1 A regulatory PH framework is in place and aligned with EU requirements | | | |
| **Activities:** | Activity 1.1.1 Assistance in preparing/changing the regulatory framework, including required EU approximation, including identification and analysis of regulatory gaps, overlaps, and inconsistencies. | | | |
| **Logframe reference:** | To support the modernization and development of a sustainable Public Health System (PHS) that is able to ensure disease prevention and control standards in line with EU legislation, requirements and practices | | | |
| **Location:** | Kyiv, Ukraine | | | |
| **Intended start and end date:** | 01 January 2024 to 12 May 2025 | | | |
| **Total number of experts** | 3 (three) | | | |

1. **BACKGROUND & JUSTIFICATION**

**1.1. Introduction**

The project “Support to Ukraine for Developing a Modern Public Health System” forms part of the Ukrainian Reform Agenda, which is guided on the one hand by the Association Agreement (AA) signed with the European Commission and on the other hand by the National Health Reform Strategy 2015-2020[[2]](#footnote-2). Component 1 of the project concerns the consolidation and empowerment of the State Institution “Public Health Center of the Ministry of Health of Ukraine” (UPHC) under the Ministry of Health; Component 2 supports strengthening of the Blood Transfusion System in Ukraine, while Component 3 focuses on communication, visibility, and information surrounding the first two components.

The importance of public health for the relations between the EU and Ukraine is reflected in the Association Agreement in chapter 22. The candidate status of Ukraine was grated in June 2022 bringing the need for approximation to a higher level. Chapter 22 states that the Parties shall develop their cooperation in the public health field, to raise the level of public health safety and protection of human health as a precondition for sustainable development and economic growth. Such cooperation shall cover, in particular, the following areas:

(a) strengthen the public health system and its capacity in Ukraine, in particular through implementation of reforms, further development of primary health care, and training of staff;

(b) prevention and control of communicable diseases, such as HIV/AIDS and tuberculosis, increased preparedness regarding highly pathogenic disease outbreaks, and implementation of the International Health Regulations (IHR);

(c) prevention and control of non-communicable diseases, through exchange of information and good practices, promoting healthy lifestyles, addressing major health determinants and problems, such as mother and child health, mental health, and addiction to alcohol, drugs and tobacco, including implementation of the Framework Convention on Tobacco Control of 2003;

(d) quality and safety of substances of human origin, such as blood, tissues and cells;

(e) health information and knowledge, including also 'health in all policies'.

To that end, the Parties undertake joint activities for the gradual integration of Ukraine into the European networks in the public health field. Including gradually approximation of legislation and practice to the principles of the EU acquis.

Mainstreeting of health issues are also required related to most of the other chapters in the AA e.g., chapter 4 is related to sanitary and phytosanitary measures, chapter 6 deals with environment also as a health determinant, chapter 14 is related to information society including e-government, e-health and e-learning, chapter 20 deals with consumer protection including quality of medical devices and invitro-medical devices, chapter 23 is focused on education, training and youth also encompassing medical education and training, chapter 25 details the cooperation in the field of sport and physical activity including disease prevention, chapter 27 on cross-border and regional cooperation also related to access to health care, and chapter 28 on consumer and health protection.

The EU Report "Ukraine 2023" from 8th of November 2023[[3]](#footnote-3) contains conclusions on public health, such as:

* There has been some progress in the adoption of the Law of Ukraine "On the Public Health System" and its implementing legislation, but the legislation remains partially aligned with the EU acquis, for example, in relation to communicable and non-communicable diseases and cross-border health threats;
* In Ukraine, refugees have the right to the same healthcare services as Ukrainian citizens, but illegal migrants and asylum seekers are only covered by emergency care and have to pay the full cost after treatment. Some professional categories have additional rights funded by the Government, which splits public funds allocated to healthcare as a result of unequal access to healthcare. The main challenges people face when looking for healthcare are the cost of medicines and treatment, waiting times and transport;
* Despite launching an electronic healthcare system, including e-prescriptions, there is fragmentation and overlapping of data. There is no strategy for the healthcare information system in Ukraine, and the legislative framework needs to be finalised. The absence or limited quality of disaggregated health-related data is a key systemic problem that affects planning and policy development, as well as the implementation of health programmes;
* Ukrainian legislation is partially approximated to the EU tobacco control acquis. Ukraine has ratified the WHO Framework Convention on Tobacco Control and has made significant progress in its implementation. However, it has not yet ratified the Protocol to Eliminate Illicit Trade in Tobacco Products;
* Ukrainian legislation on communicable diseases and serious cross-border health threats is partially aligned with the EU acquis. It is necessary to develop implementing legislation to ensure effective prevention, preparedness (e.g., there is no universal epidemic preparedness plan) and emergency response plan;
* Ukrainian epidemiological surveillance systems are based on key EU principles, but need to be improved to ensure integration with the EU early warning and response system. The National Health Security Action Plan which will help eliminate threats of biological, chemical, environmental and unknown origin has not been adopted yet. The vaccination coverage rate remains far behind WHO global recommendations, also because of the war-related disruptions;
* The National Antimicrobial Resistance Action Plan for 2023-2025 is awaiting approval. Necessity to strengthen and ensure interoperability between the health and veterinary and food/security sectors on antimicrobial resistance and improve overall preparedness and emergency response planning;
* Monitoring rules for non-communicable diseases do not comply with global targets, and there is no special cancer screening programme for early detection of cancer, except for six free cancer examinations under the national health guarantee programme. There is no monitoring for early detection of cervical and mammary cancer;
* The national legislation of Ukraine on blood, tissues, cells and organs is partially aligned with the EU acquis. The donor blood tracking and reporting system has not been fully developed yet. Ukrainian legislation is not aligned with the EU acquis on cells for in vitro reproduction. There are no regulations on inspections of medical assisted reproduction centres;
* The Law on Medicinal Products, which will come into force after 30 months of martial law, introduced important changes to the previous legislation on human medicinal products. When it comes into force, it will be partially aligned with the EU acquis. There is still a lack of full compliance with international quality, safety and effectiveness standards for medicinal products in Ukraine. The Law is not aligned with the EU acquis on medicinal products for veterinary use and is partially aligned with the EU acquis on medical devices and medical devices for in vitro diagnostics;
* In terms of nutrition and physical activity, healthy lifestyles and disease prevention could play a more prominent role, while monitoring could be strengthened;
* The corruption in the provision of healthcare services and medical education, as well as patient self-payment in the public healthcare system, remain a cause for concern. Mechanisms for monitoring the provision of healthcare services and managing patient compliance need to be strengthened. The complaint monitoring mechanism could be an effective tool for preventing and investigating corruption, but is not widely known. After the e-stock system starts working, it will be an additional useful tool to increase transparency of the supply of medicines across the country;

Further to the support provided by the EU related to aligned with the EU acquis, EU is offering temporary protection to people fleeing the war. In addition, since the start of Russia’s war, the EU, Member States and the European Financial Institutions, within a Team Europe approach, have made available more than EUR 65,6 billionin financial, humanitarian, emergency and military support to Ukraine, enabling maintenance of essential public services including health care[[4]](#footnote-4).

WHO is estimating[[5]](#footnote-5) that due to the war Ukraine has experiencing 1.234 registered attacks on healthcare facilities (reported by WHO SSA tool) as of 6 October 2023, 14,6 million people are in need of health care, 5,1 million people are internally displaced and many regions are suffering from shortage of health care professionals and medical supply. Despite this MoH and the National Health Service of Ukraine (NHSU) continue to function and so does the public health surveillance system mainly coordinated through the Public Health Centre of the MoH and Regional Centres of Disease Control.

[The Health Cluster in Ukraine is](https://www.bing.com/ck/a?!&&p=131fd206e22b445cJmltdHM9MTY5ODc5NjgwMCZpZ3VpZD0yZjE3YTkyMy0zNjJiLTYwZTItMzEzNS1hNDY2MzdjMDYxZDYmaW5zaWQ9NTY4Mg&ptn=3&hsh=3&fclid=2f17a923-362b-60e2-3135-a46637c061d6&psq=The+Health+Cluster+in+Ukriane&u=a1aHR0cHM6Ly9oZWFsdGhjbHVzdGVyLndoby5pbnQvbmV3c3Jvb20vbmV3cy9pdGVtLzI2LTA0LTIwMjMtdGhlLWhlYWx0aC1jbHVzdGVyLWluLXVrcmFpbmUtMS15ZWFyLWFmdGVyLXRoZS13YXI&ntb=1) coordinating the efforts of different organisations involved in the humanitarian response at the national and sub-national levels, also within the health sector. During 2023 and 2024, Ukraine’s Humanitarian Needs Overview and Humanitarian Response Plan will be merged into one Humanitarian Needs & Response Plan.

The damage to the health sector due to the Russia war is estimated to USD 1,4 billion[[6]](#footnote-6) representing the cost of destroyed and damaged health infrastructure. The estimated losses of USD 6,4 billion includes the cost of removal of debris and demolition of the destroyed facilities, loss of income of private providers, losses from the financing of facilities that have not been fully operational, and the additional losses of the population’s health. The need of the health sector is estimated to be USD 15,1 billion to cover the accumulated infrastructure damage and losses to the health sector, as well as scale-up of critical health services for the population of Ukraine.

Ukraine is not yet a beneficiary of support provided by the Pandemic Fund, where the first round of application focused on surveillance, human resources and laboratory systems as part of improving prevention, preparedness, and response capacities.

As described above one of the main challenges of the MoH are its very limited human resources capacities. Therefore, MoH has requested the Project to provide a number of legal junior non-key experts to be accompanied by international senior experts to accelerate and support European integration processes in the healthcare sector in the following areas:

* + - 1. Public health, including the prevention and control of communicable and non-communicable diseases and cross-border health threats;
      2. Medical services, including cross-border medicine;
      3. Digitalisation of the healthcare system, including the legislative implementation of EU legal acts regulating the implementation of electronic registers and information bases.

**2. SCOPE OF WORK**

**2.1. Objective**

The overall objective of this project is to support the modernisation and development of a sustainable public health system able to ensure disease prevention and control standards in line with EU legislation, requirements and practices, with a view to the existing emergency and health security situation in the health sector in Ukraine.

The specific purpose of this assignment is to support the MoH and other relevant stakeholders in strengthening the public health system and its capacity in Ukraine, in particular through the adaptation of Ukrainian legislation to the EU acquis and support to the Ministry of Health in its approximation to EU healthcare legislation.

**2.2. Methodology**

At the beginning of their mission, the short-term expert will present the draft methodology to be applied for the implementation of this assignment and reporting modality to the MoH and the Team Leader that will provide comments based on which the methodology will be adjusted and approved.

**2.3. Context of the activities and issues at stake**

Under the leadership and supervision of the Team Leader, and with the guidance of international non-key experts, the legal junior non-key expert will support the following main issues:

1. EU legislation analysis and support the elaboration of a prioritised list (with deadlines) of legal provisions to be developed or amended to ensure full alignment with the EU requirements;
2. Support development of legal provisions required for the full alignment with the EU requirements following the priority list (analysing draft regulations for compliance with EU law, studies, information gathering, M&E, reporting, preparing tables of compliance, etc.);
3. Supporting the negotiation process with the European Union on Ukraine's accession to the European Union (organising meetings and dialogue with representatives of the European Commission's Directorates-General and agencies, exchanging letters, preparing reports and questionnaires);
4. Support coordination with international partners as Organisation for Economic Co-operation and Development (OECD), Parliamentary Assembly of the Council of Europe, (PACE), WHO and others.

**2.4. Deliverables**

1. Agreement on priorities and work plan, outlining which legal framework(s) and regulation(s) will be prioritised for completion during the Project period, and which legal frameworks and regulations will be initiated but not necessarily reach completion during the period of project implementation;
2. Training needs identified and priorities for trainings, seminars and workshops identified and agreed with MoH, and support is provided in organising trainings, seminars, workshops, study visits, and distributing of relevant training materials;
3. First drafts of regulatory acts
4. Final drafts of regulatory acts
5. Prioritised regulatory acts approved (or in decision making process) by relevant regulatory authority.
6. Communication sessions and meetings conducted, information analytical materials produced;
7. Assist in the organisation of study visits;
8. Report on the current level of collaboration between Ukraine and ECDC, DG-Santé and other relevant public health entities, the opportunities for the extensive communication and collaboration and modalities;
9. Meetings between officials from Ukraine and ECDC, DG-Santé and other relevant EU-public health entities conducted,

**3. BENEFICIARY, LOGISTICS AND TIMING**

**3.1. Beneficiary**

The overall beneficiary of the support described in this ToR is the population in Ukraine whereas the direct recipient is the Ministry of Health of Ukraine~~.~~

**3.2. Location**

Ministry of Health of Ukraine, Kyiv, Ukraine. (fulltime onsite)

**3.3. Commencement date and duration**

The assignment is expected to start by 01 January 2024 and to 12 May 2025 up to a maximum of 330 working days.

**4. ACTIVITY INPUTS**

**4.1. Experts’ Profiles**

Qualifications and skills

* Higher legal education;
* not less than 3 (three) years of professional experience in the legal field.
* experience in the development, support and participation in the process of approval of draft regulatory legal acts - not less than 1 (one) year (required).

Competencies

* Knowledge of the European integration procedures, especially in the healthcare sector;
* Experience in drafting regulations on the approximation of Ukrainian legislation to EU healthcare legislation will be an advantage;
* Excellent organizational skills, ability to work independently, strict adherence to completing assigned tasks in a timely manner;
* Outstanding analytical skills;
* Quality-oriented professional, constructive approach to obstacles and delays in planned performance;
* Excellent research and paper writing skills;
* Excellent communication skills, oral and written;
* Team player.

Language skills

* Fluency in English and Ukrainian (written and spoken).

The expert consents that GFA verifies the expert’s name against the database of publicly accessible sanctions lists. In case the expert’s name is found on any of the sanctions lists GFA may terminate the agreement with immediate effect.

**5. REPORTING REQUIREMENTS**

Weekly\* and monthly reports and a Final Summary Report upon mission completion, including all technical reports prepared.

*\*(Weekly reports can be very simple - oral report during one meeting per week with the project team or one page report what the expert was doing during the week and what are the plan for the coming week when team meetings are not possible ).*

1. Further in the text: legal junior non-key expert [↑](#footnote-ref-1)
2. A new National Health Strategy until 2030 is in the process of being drafted. [↑](#footnote-ref-2)
3. The Report "Ukraine 2023". Accompanying document to the Communication from The Commission to The European Parliament, The Council, The European Economic and Social Committee and The Committee of The Regions Commission. Communication on EU enlargement policy, 2023. Working Document, 08-11-2023. <https://neighbourhood-enlargement.ec.europa.eu/system/files/2023-11/SWD_2023_699%20Ukraine%20report.pdf> [↑](#footnote-ref-3)
4. EU Solidarity with Ukraine, StandWithUkraine, October 2023 [↑](#footnote-ref-4)
5. Emergency Situation Report, WHO Country Office in Ukraine, 6 October 2023 [↑](#footnote-ref-5)
6. Ukraine Rapid Damage and Needs Assessment, August 2022, World Bank, Government of Ukraine, European Commission. [↑](#footnote-ref-6)