ANNEX C1: Twinning Fiche

Project title: Strengthening the capacity of Serbia's health sector for communicable disease surveillance

Beneficiary administration: Ministry of Health of the Republic of Serbia

Twinning Reference: SR 20 IPA HE 01 22

Publication notice reference: EuropeAid/175830/DD/ACT/RS

EU funded project

TWINNING TOOL

Abbreviations

AMR	Antimicrobial resistance
BC	Beneficiary Country
CA	Contract Authority
CD	Communicable Disease
CFCU	Department for Contracting and Financing of EU Funded Programmes, Ministry of Finance
CME	Continuous Medical Education
DL	Diagnostic Laboratory
ECDC	European Centre for Disease Control
EU	European Union
EQA	External Quality Assessment
EU	European Union
HIV	Human Immunodeficiency virus
IPA	Instrument for Pre-Accession Assistance
IPH	Institute of Public Health
IPHS	Institute of Public Health of Serbia
IS	Information System
IT	Information Technology
LIMS	Laboratory Information Management System
MoH	Ministry of Health
NPAA	National Plan for the Adoption of the Acquis
NRL	National Reference Laboratory
PH	Public Health
SR	Serbia
SARS-CoV	Severe acute respiratory syndrome Coronavirus
ToR	Terms of Reference
ToT	Training of Trainers
TW	Twinning
WHO	World Health Organization

1. Basic Information

1.1. Programme: Annual Action Programme for the Republic of Serbia, IPA 2020 – Indirect management with ex-ante control

For UK applicants: Please be aware that following the entry into force of the EU-UK Withdrawal Agreement[1] on 1 February 2020 and in particular Articles 127(6), 137 and 138, the references to natural or legal persons residing or established in a Member State of the European Union and to goods originating from an eligible country, as defined under Regulation (EU) No 236/2014[2] and Annex IV of the ACP-EU Partnership Agreement[3], are to be understood as including natural or legal persons residing or established in, and to goods originating from, the United Kingdom[4]. Those persons and goods are therefore eligible under this call.

1.2. Twinning Sector: Health and Consumer Protection (HE)

1.3. EU funded budget: EUR 1,000,000.

2. Objectives

2.1. Overall objective

To contribute to the strengthening of the institutional capacities and the legislative framework for fulfilling the requirements of EU membership in the area of public health, for effective participation in the EU communicable disease surveillance network and reduction of the risks of serious cross-border health threats.

2.2. Specific objective

To improve the system of communicable disease surveillance and outbreak investigations, by strengthening and harmonizing the laboratory diagnostics (including molecular methods) of the network of the institutes of public health (IPH) and national reference laboratories (NRL).

2.3. Condition

Through development of a regulatory framework for strengthened surveillance of communicable diseases system (standardized procedures for the detection, diagnosis, further characterization of pathogens and integrated e-system for surveillance), health sector will meet the objectives of relevant national policy documents.

- Public Health Strategy 2018-2026,
- Action plan for improvement of communicable diseases surveillance and response system in Serbia 2017-2020,

[1] Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community.
[2] Regulation (EU) No 236/2014 of the European Parliament and of the Council of 11 March 2014 laying down common rules and procedures for the implementation of the Union's instruments for financing external action.
[3] Annex IV to the ACP-EU Partnership Agreement, as revised by Decision 1/2014 of the ACP-EU Council of Ministers (OJ L196/40, 3.7.2014).
[4] Including the Overseas Countries and Territories having special relations with the United Kingdom, as laid down in Part Four and Annex II of the TFEU.

- Health Care Development Plan,
- 2016-2020 National Health Emergency Response Plan,
- National chemical, biological, radiological and nuclear (CBRN) defence plan,
- National Strategy for Prevention and Combating Terrorism with the Action Plan for Implementation for the period 2017-2021,
- National Strategy for Emergency Response and Rescue,
- Strategy for Integrated Border Management in the Republic of Serbia 2017-2020,
- National program for Health and Environment/Ostrava Declaration).

The intervention relies on the *EU cquis*: Decision 1082/2013 on serious cross-border threats to health EC Green paper on bio preparedness COM (2007) 399 Joint Framework on countering hybrid threats a European Union response JOIN (2016) 18, European Parliament resolution of 14 December 2010 on strengthening CBRN security in the European Union – an EU CBRN Action Plan (2010/2114 (INI)).

This Twinning project will directly contribute to further development of an effective, efficient and sustainable communicable diseases surveillance and response system in the Republic of Serbia, which shall be ready to diagnose, report, alert and respond to communicable disease health threats, in line with EU *acquis* on communicable diseases, ECDC standards and International Health Regulations.

The main expected outcomes of this intervention are strong, sustainable and adequate capacities of the health care system in Serbia to diagnose, monitor, alert and respond to communicable diseases, in order to make the health sector more aligned with those of the EU Member States as the negotiation process progresses (Chapter 28 - Consumer and health protection), as well as to effectively participate in the EU communicable diseases surveillance networks, including those under coordination by ECDC.

Prior to the COVID-19 outbreak, the Republic of Serbia developed, adopted and tested the Program for responding to health emergencies. In December 2018, the Ministry of Health (MoH) adopted the Program for Protection and Preservation in Crises and Emergencies – Health Sector Response, in partnership and working jointly with the WHO and the Institute of Public Health of Serbia. The Program is based on WHO recommendation for preparedness, response, and recovery in health emergencies, and has become an integral part of the overall country strategy for system-level preparedness, response and recovery. It has also served as the basis for all activities and measures that the Government of Serbia has taken in managing the emergency related to COVID-19 pandemic. Among others, the measures included a public communication strategy and a national coordination strategy from the highest level of administration. A public website (https://www.covid19.rs) was launched and updated twice a day, showing cumulative data since February 27, 2020. Another website provides detailed information about the national response (https://www.covid19.rs/homepage-english/). These websites provide chronological information on all activities since the begining of the COVID-19 pandemic.

3. Description

3.1. Background and justification:

The health system in the Republic of Serbia is organized and managed by three key institutions at national level: the Ministry of Health, the National Health Insurance Fund, and the Institute of Public Health of Serbia "Dr Milan Jovanović Batut". Apart from that, 355 facilities make up the country's network of public health care institutions, organized at the primary, secondary

and tertiary levels of health care, overseen by the Ministry of Health. The overview of the Serbian health system is presented in Annex 2.

In the Republic of Serbia, primary diagnostic testing services performed by 62 public microbiology laboratories distributed across a range of health care and public health institutions, upon request from general practitioners and hospital medical practitioners. Diagnostic microbiology laboratories are located at 25 general hospitals, 24 IPHsand 13 tertiary care centres and institutes. Diagnostic services are also offered by private laboratories, but there is no acurate data on the size of the private microbiology system. There are 25 functional National Reference Laboratories (NRL), officially nominated by the Ministry of Health in 2008.

The legal basis for this intervention is the Law on Protection of Population from Communicable Diseases, which is fully aligned with relevant *EU acquis*. A backbone microbiology surveillance system is in place, but it needs to be strengthened and harmonized. A national policy for health laboratory services defining the goals and objectives of the national laboratory system is partially in place.[5] Further improvements of the capacities of the system for the surveillance and control of communicable diseases in Serbia should meet European and international standards and guidelines, as well as the generally accepted practices of EU Member States in order to participate effectively in the future as a member of the European Network for the Control of Infectious Diseases of the Member States (Decision 1082/2013 / EC and Regulation (EC) No 851/2004; note: new EU legislative package on serious cross-border threats to health is currently in the pipeline for formal adoption procedure; this will replace the earlier legislative acts.

Specific disease programmes and other national activities, corresponding to EU actions and recommendations (concerning anti-microbial resistance, health care associated infections or generic preparedness) are not set in an appropriate organizational framework through existing strategic plans and adequate infrastructure and resources, ensuring an inter-sectorial approach. No official decree established a health coordination unit and defined its terms of reference. No diseases issues[6] are coordinated at National level. In addition to this, information exchange and liaison between the epidemiology service, reference laboratories, and sanitary and veterinary inspectorates is limited at National level. Communication and interdisciplinary collaboration between microbiologists, epidemiologists and public health policy experts is also insufficient.

Current diagnostic methods do not appear sufficient for provision of comparable data for some diseases. Capacity to confirm/identify and, if appropriate, further characterize pathogens according to EU standards is not or is partially in place. Diagnostic capacity towards EU laboratory confirmation criteria is insufficient.

Current specialist epidemiology training curricula, as described in the regulation, is lacking some key domains essential for epidemiological competencies by the European Union, such as risk assessment, analytical epidemiological methods of outbreak investigation, time series analysis, and surveillance system evaluation. National level surveillance is equipped with limited human resources and leadership to cover the needs of the country in relation to communicable diseases surveillance and applied research functions to support better prevention and control. Epidemiological surveillance methods used at regional levels are limited, and restricted at national level by dependence on supplied aggregated data. Limited

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1 The Twinning Light (TWL) "Improving microbiology diagnostic system quality in the function of surveillance of communicable diseases (CD) in the Republic of Serbia"

3 Diseases and special health issues under EU surveillance. Available at: https://ecdc.europa.eu/en/all-topics-z/surveillance-and-disease-data/diseases-and-special-health-issues-under-eu-surveillance

skills impede effective analysis, interpretation and dissemination of surveillance data which is useful information for data providers and stakeholders, including the Ministry of Health. There are financial shortcomings for producing data/information and clinical/primary diagnosis of communicable diseases under EU notification, and evidence supporting policy decision-making, as well as resource allocation. Although isolated information systems exist for microbiological laboratories and reporting of certain infectious diseases, there is effectively no integrated electronic national information system for surveillance on communicable diseases.

Outbreak[7] detection relies on local epidemiologists performing manual linkages between reported cases. Outbreaks are investigated with a descriptive approach and relying on intensive but basic microbiology testing, with weak attempts to identify causes and assess risks using epidemiological analytical methods.

Microbiology laboratories across the country do not have adequate technical facilities and technology. The National Reference Laboratories (NRLs) also have limitations in their technology. Because of the situation related to reference testing, capacity for surveillance and outbreak response support for some diseases remains substandard. There is a lack of equipment - for biosafety the percentage is 7%, for serology 8%, and for molecular diagnostics 5% of the existing equipment, mostly acquired between 2001 and 2010.

In this regard, through a two-year project, the level of knowledge, skills, capacities, competences and expertise of health professionals and associates will be raised, practical trainings will be conducted, reference and registration procedures improved, as well as confirmatory diagnostic procedures as the level of technological equipment shall be raised, so that the healthcare system as a whole could adequately conduct its daily activities, respond to challenges during outbreaks, emergencies and in case of suspicion of abuse of a biological and other agents. The intervention implies equal treatment of the entire population, that is, gender-based non-discrimination.

It is necessary to strengthen and maintain adequate capacities in Serbia's health care system to be prepared for prevention, detection and response to public health threats through harmonization and improvement of the existing system of control of communicable disease functioning, defined by the Law on Protection of Population against Communicable Diseases, so as to improve the coordination and quality of work of public health surveillance and response system/emergency preparedness and to define the basic standards of procedures for prevention, detection and response to biological hazards of general and cross-border interest. It is necessary to formulate clear, uniform and traceable procedures for data collection, reporting, assessment, and creating an integrated information system for all levels of the above mentioned system. It is also necessary to renew and upgrade equipment used in national diagnostic and reference laboratories for this purpose. Guidelines and trainings for doctors and healthcare professionals covering the diagnostics, management, epidemiology, the public health significance and investigation of priority communicable diseases, guidelines for outbreak investigations, guidelines for preparedness and response on public health and cross-border biological threats, etc should all be developed. Multi-sectoral, national and international coordination and communication should be strengthened.

The central coordinating and regulatory institution in the system for surveillance and response on communicable diseases in Serbia is the Ministry in charge of health with its *Republic expert committee for the protection of population from communicable diseases* ("Official Gazette of

[4] A disease outbreak is the occurrence of cases of disease in excess of what would normally be expected in a defined community, geographical area or season (WHO)

Republic of Serbia" No 15/2016), and IPH of Serbia, as the national focal point for epidemiological surveillance of communicable diseases and NFP for IHR, all of whom are responsible for further transposition, enforcement and monitoring of health-related EU regulations, including dissemination of quality and safety standards and raising the capacities of inspection services (NAD 2019-2025, Measure 2.3). The legal basis for this institutional framework is the Law on Protection of Population from Communicable Diseases[8], which is fully aligned with the relevant *EU acquis* as recommended in the Indicative Strategy Paper for Serbia 2014-2020 (Decision No 1082/2013/EU, 2000/96/EC, 2012/506/EC, 2000/57/EC, etc.) and Law on Public Health.

The intervention will contribute to the strengthening of human resources, capacities for surveillance and response on communicable diseases at local and national level, as well as for cross-border threats to public health, and will provide a better position of the health sector in the negotiation process related to the Chapter 28 - Consumer and health protection. The intervention relies on the following *EU acquis*: Decision 1082/2013 on serious cross-border threats to health, Regulation (EC) No 851/2004 on establishing ECDC; EC Green paper on bio preparedness COM (2007)399, Joint Framework on countering hybrid threats a European Union response JOIN (2016) 18, European Parliament resolution of 14 December 2010 on strengthening chemical, biological, radiological and nuclear security in the European Union – an EU CBRN Action Plan (2010/2114(INI)). Achieving the intervention goals will also prepare Serbia to participate effectively in EU communicable disease surveillance network of EU Member States (NPAA 2018-2021). Specifically, the intervention will scale up the capacities of different institutions in the area of (i) surveillance on communicable diseases and other specific health issues (staff, equipment, etc.); (ii) prevention and control of communicable diseases and other specific health issues; (iii) inspection control; (iv) financing; (v) early warning, risk reduction and management of national and global health risks (EC Progress Report 2018, Screening report Ch.28, 2030 Agenda for Sustainable Development).

3.2. Ongoing reforms:

The Ministry of Health of the Republic of Serbia is responsible for formulating and defining the strategic framework and policy in the field of health, health quality and health protection of the population, as well as implementing tasks and duties related to the health development. Regarding monitoring and reporting, the MoH is responsible for health and sanitary inspection monitoring within the domain of population protection from communicable and non-communicable diseases, safety of food and consumer goods in production and trade, and supply of population with hygienic drinking water.

The Institute of Public Health Serbia "Dr Milan Jovanovic Batut" with its network of 24 regional Institutes of Public Health is responsible for communicable disease surveillance, prevention and control in their respective jurisdictions in partnership with healthcare institutions and other relevant stakeholders. The relevant surveillance data is periodically collected, analysed and reported by the Institute of Public Health of Serbia to the Ministry of Health and other stakeholders at regional and national level, as well as to WHO, ECDC (European Centre for Disease Prevention and Control) and other international organizations.

On serious cross-border health threats, including communicable diseases, the surveillance and response capacity remains limited and needs to be modernized. In 2021, amendments to the *Law on protection of population from communicable diseases* were adopted to overcome

5 "Official Gazette of Republic of Serbia" No 15/2016

practical problems faced in applying legislation relevant to the COVID-19 pandemic. A centralized health information and communication system needs to be strengthened, improved and become complementary to the communicable disease surveillance system.

Regarding communicable diseases, attention needs to be given to effective and sustainable financing of disease-specific strategies, and to the raising of awareness, particularly on the importance of child vaccination. Additional work is needed on surveillance of anti-microbial resistance, quality control, and standardization of laboratory diagnostic methods, quality control and biosafety. The prescription of antibiotics needs to be strictly controlled to strengthen the fight against anti-microbial resistance. The overall objective of the *National Program for the Control of Bacteria Resistance to Antibiotics* is to improve the health and quality of life of the population of the Republic of Serbia by reducing the resistance of bacteria to antibiotics in medicine and veterinary medicine.

There were numerous interventions by the Government of Serbia during the COVID-19 pandemic. Among them, in order to provide all COVID patients with the best health care, the Republic of Serbia built and fully equipped three new hospitals. They are adequately distributed to cover large population catchment areas, in order to make health care available to the whole population. The Republic of Serbia invested more than EUR 85 million to build these hospitals and more than EUR 43 million to equip them.

Regarding the capacity of the health system in dealing with the COVID-19 crisis, the National Institute of Public Health 'Dr Milan Jovanovic Batut', in cooperation with the Ministry of Health and the relevant health institutions, continuously monitored the epidemiological development of the pandemic and informed the public, issuing guidelines and standard operating procedures to health institutions and to all country entrance points.

Even though the Republic of Serbia and the Ministry of Health constantly invest in human resources (workforce), infrastructure and equipment, there is still space for the health system to be significantly improved. Although the counter-epidemic measures during the COVID 19 epidemic implemented by the Government were well-devised, vulnerability of the existing system became evident. Serbia lacked resources in terms of personal protection equipment and medical equipment, medical expertise, and laboratory testing capacities as well as data processing and contact tracing. This led to a large number of medical personnel testing positive for the virus. Strong Government efforts directed at alleviating these shortages by numerous procurements of equipment and employment of new healthcare personnel during the crisis had favourable results.

3.3. Linked activities:

As part of the WHO Health Emergency Aid, the Balkan Hub was recently established in Belgrade with the aim of coordinating and providing technical support to Serbia and regional countries such as Albania, Bosnia and Herzegovina and North Macedonia in various aspects of health emergencies, including preparedness and application of international health rules, information exchange, emergency and high-risk communication activities in accordance with the WHO technical guidelines. The centre's head office is located in the Republic of Serbia due to the proven capacity to effectively and efficiently deal with major emergencies (e.g. floods in Serbia 2014).

A Twinning Light (TWL) project titled "Improving microbiology diagnostic system quality in the function of surveillance of communicable diseases in the Republic of Serbia" was completed in March 2018. The assessment of the capacity of microbiological laboratories in

the public and private health sectors, including the network of national reference laboratories, was the starting point for further planning of equipment procurement and definition of capacity building plans, standardization of diagnostic practices and improvement of the sensitivity of the epidemiological system to communicable diseases. Through the activities of the TWL project, as well as the ENCapLab assessment of laboratory capacities (ECDC questionnaire), deficiencies in the diagnostic capacities of the microbiological service in this area have been identified and will be the basis for this proposed intervention.

In October 2018, Serbia conducted a Joint External Evaluation (JEE) to objectively and comprehensively assess its capacities for full implementation of the International Health Regulations (IHR). Two processes (self-assessment and external evaluation) based on WHO methodology had enabled a consensus on the final ratings of Serbian capacities to prevent, detect early, adequately respond, and quickly recover from public health emergencies. JEE examined 19 technical areas, from general ones (legislation and financing) to very specific ones (laboratory capacity, surveillance of all kinds of public health threats, operating procedures for emergency response, zoonotic diseases, food safety, risk communication, Points of Entry – border crossings, immunization, chemical and radio nuclear incidence management, etc.).

Based on JEE findings and recommendations, which arose from this assessment, Serbian authorities, in cooperation with WHO developed the National Action Plan for Health Security (NAPHS). This document prioritizes the listed gaps, identifying intended outcomes, outputs, and particular activities to address those gaps and strengthen Serbian IHR capacities. Based on this comprehensive document, the key stakeholders (supported by partners) may now start strengthening the preparedness and readiness for all kinds of health emergencies.

In May 2020, the World Bank approved a loan to the Republic of Serbia in the amount of 100 million dollars (equivalent to EUR 92 million) for the implementation of the project titled: "Emergency Response of the Republic of Serbia to COVID-19" (HORSK). The project became effective on 10 December 2020, and the official completion date of the project was 31 May 2022. In December 2021, the Ministry of Finance sent a request to the World Bank to extend the project for 15 months. The goals of the WB Project are:

(a) response to the threat posed by COVID-19

(b) strengthening the national health system in order to raise the level of preparedness in Serbia.

Key activities carried out during 2021 include the procurement of 2,080 hospital beds delivered to 50 health care institutions, purchases of vehicles for the needs of the health care system, and the procurement of hygiene packages with personal protective equipment and hygiene products for vulnerable groups. These activities were carried out, and purchased items delivered to all public kitchens, all safe houses, as well as to drop-in centres for children in Belgrade.

This ongoing intervention addresses primarily the coordination of epidemiological surveillance system and microbiology laboratories in all entitled functions and the harmonization and quality improvement of diagnostic capacities, surveillance, outbreak investigation, alert and response, and NRL’s core function capacity in Serbia. Further establishment of multi sectoral approach and interoperability of emergency public health plans will be more feasible due to improved coordination, procedures, standards, system of reference laboratories and upgraded equipment in the area of communicable diseases, including surveillance, diagnosis, alert and response.

Serbia is participating in ECDC-IPA projects aiming to prepare national public health authorities for their participation in ECDC work, including in EU-level surveillance networks

on communicable diseases, ENLabCap, and in national focal points networks for public health functions as observers. The overall goal of such ECDC support is increase Serbia's capacity for EU-level data quality in terms of comparability, timeliness, and reliability of communicable diseases surveillance data.

As part of the ongoing ECDC-IPA6 project, Serbia is a beneficiary of the ECDC Action with Western Balkans on (i) preparatory measured for participation in ECDC, (ii) improvement of 'One-Health' responses to AMR, and (iii) enhancing surveillance of laboratory-confirmed severe acute respiratory infections (SARI).

3.4. List of applicable Union acquis/standards/norms:

The most relevant EU Decisions and Regulations related to communicable diseases are:

- Commission Implementing Decision 2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions[9].
- 2014/504/EU: Commission Implementing Decision of 25 July 2014 implementing Decision
- No 1082/2013/EU of the European Parliament and of the Council with regard to the template for providing the information on preparedness and response planning in relation to serious cross-border threats to health (notified under document C (2014) 5180[10].
- Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC[11].

  Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control[12]
- 2000/57/EC: Commission Decision of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council. - Official Journal, L 21/32; 26.01.2000
- 2017/253/EU: Commission Implementing Decision of 13 February 2017 laying down procedures for the notification of alerts as part of the early warning and response system established in relation to serious cross-border threats to health and for the information exchange, consultation and coordination of responses to such threats pursuant to Decision No 1082/2013/EU of the European Parliament and of the Council
- Commission Decision No 2009/363/EC of 31 April 2009 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the

6 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D0945

7 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014D0504&from=EN

8 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32013D1082 (note on new Regulation on serios cross border health threats here: https://www.consilium.europa.eu/en/press/press-releases/2022/06/23/provisional-agreement-on-new-eu-law-on-serious-cross-border-threats-to-health/)

12 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32004R0851

Community network under Decision No 2119/98/EC of the European Parliament and of the Council (OJ L 110, 1.5.2009, p. 58).

- 2014/504/EU: Commission Implementing Decision of 25 July 2014 implementing Decision No 1082/2013/EU of the European Parliament and of the Council with regard to the template for providing the information on preparedness and response planning in relation to serious cross-border threats to health (notified under document C(2014) 5180.
- Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC.

A list of corresponding and relevant legislation in the Republic of Serbia is presented in Annex 3.

3.5 Components and results per component

Component 1:

Further development of procedures and standards for coordinating national epidemiological surveillance and response system, in line with the EU regulatory framework. This will include the domains of diagnostics, management, epidemiology, public health significance and investigation of priority communicable diseases, guidelines for outbreak investigations, guidelines for preparedness and response to public health and cross-border biological threats, in line with ECDC strategies, policies and guidelines. It will also include the establishment of expert working groups, the definition of content, scope and form of procedures and structural and functional standards, their adoption and enforcement.

Result 1.1 – Established relevant expert working groups, involving all relevant institutions in the Republic of Serbia.

Result 1.2. - Relevant procedures and quality standards, aligned with EU regulations and benchmarks, including the relevant regulatory framework in the Republic of Serbia are implemented in the NRL.

Result 1.3. – Upgraded and updated relevant data and information sets and procedures for regular reporting on epidemiological surveillance and outbreak investigation.

Component 2:

The development of a computerized epidemiological surveillance system for communicable diseases, including all relevant information system (IS) components[13] for case registration, laboratory diagnostic and confirmation (reference laboratories), epidemiological case classification and data+ distribution, between all relevant entities, in accordance to EU case definitions. The IS should have functions for early warning and response and provide all required relevant data and indicators for data analytics and reporting systems. The sSystem should rely on existing or planned IS modules, as part of the National Integrated Health Information System (IHIS).

TW experts and stakeholders will define the objectives of surveillance (generic, disease specific) with a minimum set of data to be reported at national level, the data flow through the surveillance system (including the relevant time frame), and the functional mechanisms to exchange relevant information between different sectors/functional links with other relevant systems.

To improve the surveillance system on communicable diseases, a new information system (software) needs to be developed and implemented. The National surveillance information system, as a computerised network, will enable efficient and electronic reception of both clinical case-based communicable disease reports and laboratory confirmation of individual cases, and implement electronic dissemination, analysis, interpretation and reporting of clinical, laboratory and epidemiological information about cases of communicable diseases at both regional and national level (under defined appropriate data protection arrangements at,

[13] Procurement of laboratory equipment for microbiology diagnostics/confirmation, and hardware for integrated e-system for surveillance (based on existing needs analysis and technical specification, defined bidding procedures and quality criteria etc.) will be realized through a Supply contract, that should serve to complement the lacking and to upgrade the existing microbiological laboratory equipment and interlink all microbiological laboratory information systems in the country. Laboratory and IT equipment will be procured for all end-user beneficiary institutions with diagnostic microbiology laboratories (25 general hospitals, 24 IPH and 13 tertiary care hospitals and institutes).

different levels), and achieve the goal for real time threat detection. Laboratory diagnostic/confirmation system, as part of the National IHIS system, should at least encompass the following functionalities:

- Central module for laboratory diagnostic results storage, including structure data and finalized and signed results
- Central module for molecular/sequencing confirmation results storage

Module for results distribution between different and various ISs

Result 2.1. - Computerized epidemiological surveillance system (e-system) is developed, tested and deployed throughout the networks of IPH and NRL, and fully integrated with other IHIS components.

Result 2.2. - Human capacities to collect manage and process data and information on communicable diseases strengthened are in place in all IPH and NRL

Result 2.3. – Developed set of performance indicators to assess the functioning of the epidemiological surveillance e-system

Component 3:

Improving the knowledge and skills of health and other professionals and associates on epidemiological surveillance through field epidemiology pathsway and training programs (curricula, pilot trainings, accreditation as CME, etc.). In order to enable efficient analysis, interpretation and dissemination of surveillance data to professionals, data providers and stakeholders, decision makers (i.e. the Ministry of Health) and general public, the TW experts will exchange knowledge, best practices and know-how with the Operational working group and relevant professionals during the trainings of trainers. A pool of at least 20 master trainers will be created, encompassing epidemiologists and microbiologists in IPHs and NRLs, public servants and IT specialists in public health. Based on assessed training needs, key domains essential for epidemiological competencies in the EU and the practices in EU Member States, training curricula will be developed and accredited at national level as continuous medical education (CME). Capacity building activities will also be delivered to the representatives of the Ministry of Health of Serbia for further improvement of knowledge and skills of public servants for better system management, decision making and health policies development.

Result 3.1 – Training curricula and Trainers' Manual, based on required professional competencies and improved educational framework for health human resources, are developed and accredited as CME program(s)

Result 3.2 – Trainings deliveredto an initial group of 20 experts and future trainers (ToT).

3.6. Means/input from the EU Member State Partner Administration(s)*:

The project will be implemented between the final beneficiary country and EU Member State(s). The implementation of the project requires at least a Project Leader (PL) with responsibility for the overall coordination of project activities and one Resident Twinning Adviser (RTA) to manage implementation of project activities, Component Leaders (CLs) and pool of short-term experts (STEs) within the limits of the budget. It is essential that the team is equipped with sufficiently broad expertise to cover all areas included in the project description.

Proposals submitted by a Member State shall be concise and focused on the strategy and methodology and an indicative timetable underpinning this, the administrative model

suggested, the quality of the expertise to be mobilized and clearly show the administrative structure and capacity of the Member State entity/ies. Proposals shall be detailed enough to respond adequately to the Twinning Fiche, but are not expected to contain a fully elaborated project. They shall contain enough detail about the strategy and methodology, and indicate the sequencing key activities during the implementation of the project to ensure the achievement of overall and specific objectives and mandatory results/outputs. The Twinning Partners shall ensure that the EU funded Twinning project has a high and regular level of visibility.

The interested Member State(s) shall include in their proposals the CVs of the designated PL and the Resident Twinning Advisor, as well as the CVs of the potentially designated Component Leaders – CLs.

The Twinning project will be implemented in close co-operation among partners aiming to achieve mandatory results in a sustainable manner.

The set of proposed activities will be further developed with the Twinning partners when drafting the initial work plan and successive rolling work plan every three months, keeping in mind that the final list of activities will be decided in cooperation with the Twinning partner. The components are closely inter-linked and need to be sequenced accordingly.

The Member State side, through its Project Leader (PL) and RTA (Resident Twinning Adviser), will provide support to the responsible Serbian authorities in strengthening their capacities as well as in the implementation of this project. During project implementation, the RTA will be positioned in the premises of the Institute of Public Health of Serbia "Dr Milan Jovanovic Batut". The Twinning Partners will ensure for at least two visibility events to take place during the implementation of the project – the Kick-off Meeting and the Final Project Event.

3.6.1. Profile and tasks of the Project Leader (PL):

The MS Project Leader will manage the project team of selected member state(s) and co-ordinate the implementation of activities.

Tasks of the Member State Project Leader:

- Overall management and coordination of the project with MS and cooperation with the BC;
- Project reporting and supervision of the RTA;
- Ensuring backstopping and financial management of the project in the MS;
- Ensuring timely, effective and efficient implementation of the project and achievement of results, through proposed activities;
- Coordination of deployment and work of short-term experts;
- Coordination with RTAs, from the Member State side, the Project Steering Committee meetings, which will be held in Serbia every three months;
- Participation at Steering Committee meetings (every three months);
- Assuring compatibility with EU requirements;
- Overall responsibility and direction of the MS Twinning partner inputs and proposing corrective measures, if needed.

Profile of the Project Leader:

Requirements:

- High ranking official/senior civil servant currently working in an MS relevant system administration;
- Proven contractual relations to public administration or mandated body;
- University degree or equivalent professional experience of 8 years in the field of medicine;
- 3 years of professional working experience in the field of surveillance on communicable diseases
- Project management experience;
- Working knowledge of English language;
- Computer literacy.

Assets:

- Experience in implementation of EU Directives and standards for surveillance on communicable diseases and serious cross-border threats to health;
- Experience with EU funded project/Twinning rules and procedures;
- Experience in managing implementation of at least one similar project.

3.6.2. Profile and tasks of the Resident Twinning Adviser (RTA):

The RTA works on a daily basis with the Beneficiary Country (BC) staff to implement the project, and to provide support and coordinate project activities in the beneficiary country.

The RTA should have adequate experience and knowledge in the field of integrated surveillance on communicable diseases (CD) which will enable him/her to organize an interdisciplinary team for a successful implementation of the project. She/he should be an employee of a governmental competent authority for surveillance on CD in an EU Member State.

He/she will liaise with the BC Project Leader and will report to the MS Project Leader. The RTA will also be responsible for ensuring that experts' input and distribution of their working days will be used in the most efficient and effective way and in line with the agreed work plan to enable timely completion of project results. The duration of his/her secondment will follow the implementation of activities.

Tasks of the RTA:

- Responsible for monitoring of project implementation and proposing corrective management actions if required;
- Project management and coordination of the activities of the team members in line with the agreed work plan to enable timely completion of project results;
- Selection, mobilization and supervision of the short-term experts, together with the Project Leader;
- Facilitation of the contacts with relevant institutions in EU Member States in order to stimulate a proper exchange of information, data and experience;

- Organization of visibility events (kick-off and final event);
- Advice on related EU policies, regulation and best practice;
- Establish and maintain cooperation with all beneficiaries involved in the implementation of the project and other related projects (ensuring the avoidance of overlapping), in close coordination with the Project Leader;
- Responsible for the organization of the Project Steering Committee meetings and reporting on the project progress in cooperation with the Project Leader;
- Identifying and reporting to the Contracting authority, at an early stage, on all difficulties that may jeopardize the implementation of the project and the achievement of its results.

Profile of the RTA:

Requirements:

- University degree or equivalent professional experience of at least 8 years.
- At least 3 years of working experience in the field of surveillance on CD in the public administration of a Member State or Mandated body;
- Project management experience;
- Working knowledge of English language;
- Computer literacy.

Assets:

- Experience in implementation and/or managing of at least one similar project.
- Experience with EU funded project/Twinning rules and procedures;
- Experience in analysing and developing procedures in the field of surveillance on CD;
- Experience in context of public administration reform;
- Experience in conducting trainings.

3.6.3. Profile and tasks of Component Leaders:

The Twinning partner will decide on the profile, number and involvement of the short-term experts during the drafting of the project work plan.

Component Leaders should be identified by the Project Leader/RTA and have to be agreed with the beneficiary institutions in the course of designing and delivery of the expected project outputs. Main areas of expertise required by the team of short-term experts should cover the following fields of surveillance on CD (the list of fields is non exhaustive): law harmonization and enforcement; analysing needs and developing guidelines and operational procedures; training design and delivery.

Tasks of Component Leaders:

Component Leaders will provide specialized know-how for the individual tasks in this project. Therefore, the experts should have relevant professional experience in the area of surveillance on communicable diseases and minimum qualifications required, as well as specific skills needed for individual tasks. As a general approach, the Component Leaders will have

responsibility for the implementation of the Project and the achievement of the results, each for his/her individual mission tasks, as defined by individual ToR. They will also prepare the required reports and the output described.

Profile of Component Leaders:

Requirements:

- University degree in the relevant field depending on the area of expertise or equivalent of 8 years of professional experience in the relevant field;
- At least 3 years of specific working experience in the field of surveillance on CD or other relevant field depending of the area of expertise;
- Experience in providing assistance in the capacity building initiatives and trainings in the area of surveillance on CD, outbreak investigation, epidemiological data analysis etc.
- Working knowledge of English language;
- Computer literacy.

The concrete assignments will be subject to the preparation of the Twinning Contract and the recommendations of the Twinning partner(s).

3.6.4. Profile and tasks of other short-term experts (STEs):

The Twinning partner will decide on the profile, number and involvement of the short-term experts during the drafting of the project work plan. STEs should be identified by the Project Leader/RTA and have to be agreed with the beneficiary institutions in the course of designing and delivery of the expected project outputs.

Main areas of expertise required by the team of short-term experts should cover the following fields (the list of fields is non exhaustive): surveillance on communicable diseases law harmonization and enforcement analyzing needs and developing operational procedures and guidelines procurement and supply management training design and delivery. If needed, short-term expertise may also be requested to support with (regulatory/budgetary) impact assessments.

Tasks of the short-term experts:

STEs will provide specialized know-how for the individual tasks in this project. Therefore, the experts should have a relevant professional experience in administration and minimum qualifications required, as well as specific skills needed for individual tasks. As a general approach, the STEs will have responsibility for the implementation of the Project and the achievement of the results, each for his/her individual mission tasks, as defined by individual ToR. They will also prepare the required reports and the output described.

Detailed profiles and tasks of short - term experts, including the duration of their assignments, will be subject to the preparation of the TW Twinning Contract and the recommendations of the TW Twinning partner(s).

Profile of the short- term experts:

Requirements:

- University degree in relevant field depending of the area of expertise or equivalent of 8 years of professional experience;
- At least 3 years of specific working experience in the field of surveillance on communicable diseases or other relevant field depending of the area of expertise;
- Proven contractual relations to public administration or mandated body;
- Experience in conducting trainings.
- Working knowledge of English language;
- Computer literacy.

Assets:

- Published research papers in the relevant field of expertise;
- Professional experience in leading the teams of experts in the relevant field
- Professional experience in participating in international expert teams in similar activities

4. Budget

Implementation Modalities "Strengthening the capacity of the Serbia's health sector for communicable disese surveillance"	**Budget (€)**			**Timeline**	
	EU Contribution	National Contribution	Total	Launch of procedure	Contract Signature
Twinning	1.000.000	-	1.000.000	Q3 2022	Q1 2023

5. Implementation Arrangements

5.1. Implementing Agency responsible for tendering, contracting and accounting (AO/CFCU/PAO/European Union Delegation/Office):

The Implementing Agency of the project is the Central Finance and Contracting Unit (CFCU). The CFCU will be the Contracting Authority and it will be responsible for publishing tenders, concluding contracts and authorizing the Treasury to make contract related payments.

Ministry of Finance

Department for Contracting and Financing of EU Funded Programmes (CFCU) 3-5, Sremska St, 11000 Belgrade, Serbia

Mr Marko Jovanović, Assistant Minister/Head of Contracting Authority

Phone: +381 11 765 2547

E-mail: marko.jovanovic@mfin.gov.rs

Mr Darko Vasić, National Contact Point

Phone: +381 11 765 2577

E-mail: twinnning@mfin.gov.rs

5.2. Institutional framework

5.2.1. Counterparts in the Beneficiary administration:

5.2.1.1. Contact person:

Danijela Urošević, MD, MPH, Acting Assistant Minister/Senior Project Officer (SPO)

Nemanjina St, No. 22-26 11000 Belgrade, Serbia

5.2.1.2. PL counterpart

Institute of Public Health of Serbia "Dr Milan Jovanović Batut"

Dr Subotića St, No. 5

11000 Belgrade, Serbia

5.2.1.3. RTA counterpart

Danijela Simic, MD

Institute of Public Health of Serbia "Dr Milan Jovanović Batut"

Dr Subotića St, No. 5

11000 Belgrade, Serbia

6. Duration of the project

The implementation period of the Action is 24 + 3 months.

7. Management and reporting

7.1. Language

The official language of the project is the one used as contract language under the instrument (English). All formal communications regarding the project, including interim and final reports, shall be produced in the language of the contract.

7.2. Project Steering Committee

A project steering committee (PSC) shall oversee the implementation of the project. The main duties of the PSC include verification of the progress and achievements via-à-vis the mandatory results/outputs chain (from mandatory results/outputs per component to impact), ensuring good coordination among the actors, finalizing the interim reports and discuss the updated work plan. Other details concerning the establishment and functioning of the PSC are described in the Twinning Manual.

7.3. Reporting

All reports shall have a narrative section and a financial section. They shall include as a minimum the information detailed in section 5.5.2 (interim reports) and 5.5.3 (final report) of the Twinning Manual. Reports need to go beyond activities and inputs. Two types of reports are foreseen in the framework of Twining: interim quarterly reports and final report. An interim quarterly report shall be presented for discussion at each meeting of the PSC, with national project stakeholders and EUD representatives included. The narrative part shall primarily take stock of the progress and achievements via-à-vis the mandatory results and provide precise recommendations and corrective measures to be decided by in order to ensure the further progress.

8. Sustainability

In accordance with the provisions of the Law on Health Care[14] and the Law on Health Insurance[15], the implementation of epidemiological and sanitary-hygienic surveillance, special and emergency measures and programs for the prevention, control, elimination and eradication of communicable diseases, detection and response to outbreaks, hygienic-epidemiological systemic monitoring and assessment of risk factors from the environment that can have a harmful effect on human health, are financed directly by funds from the Budget of Republic of Serbia (further RS), from the division of the Ministry of Health. Funds for implementation of health care activities that are not defined by the Law on health care, emergency measures/programs of ratified international treaties and sanitary conventions recognized by the same Law, and for reimbursement of expenses for the use of infrastructure and resources are provided from the RS budget. Total funds allocated by the Ministry of Health on the annual level for the work of health care institutions and the implementation of public health activities (Institutes of Public Health and Institute of Virology, Vaccines and Sera "Torlak") are in the amount of RSD 995,020,000. In order to ensure sustainability of coordination, implementation of quality and safety regulation, full scope of services, application of new technologies and equipment, the Ministry in charge of health will contribute to the supply in the amount of EUR 0.45 million through the Budget of RS. The Ministry will use this newly developed system of codifying services to increase the level of savings and budget allocation for these services in the area of the surveillance and control of communicable diseases. The National Health Insurance Fund will finance the newly contracted services as required. IPH of Serbia should accredit applied epidemiology training curriculum as part of National continuing medical education program.

9. Crosscutting issues (equal opportunity, environment, climate etc…)

Cross-cutting issues will be addressed in the project so as to comply with the best EU standards and practice in that area and in a way which demonstrates how they will be dealt with within the project's framework, its activities and outputs. Support to anti-discrimination and gender equality policies are the core of the specific objectives in the HRSD/Health care sector and respective measures, while a sustainable development principle is integrated and promoted where applicable. Improving the system for high quality, access and effective public health services will have an impact on empowering the most vulnerable population to take active participation in society. Efficient and effective design and provision of quality public health services and health promotion will foster all citizens with equal access to healthcare. Progress

14 Articles 17, 70, 71 and 72 "Official Gazette of the Republic of Serbia", No. 25/2019

15 "Official Gazette of the Republic of Serbia", No. 25/2019

will be measured though official surveillance reports, incidence and mortality from communicable diseases.

The project will be implemented in a way that provides equal opportunities for participation for those within the MoH, IPHS, and other institutions. No discrimination will be made based on gender and activities such as training needs analysis, trainings will be organized in a way that makes them accessible for both men and women. The number of men and women participating in training events will be monitored during the project and this information will be used to identify any potential discrimination. Principle of gender equality will be implemented in all project activities and procedures. The project will result in procedures and measures that will implement this principle and by no means will not endanger it throughout the project implementation and upon its completion. For all activities, recycling of paper and the reduction of paper-based activities is recommended. As a general principle, sensitivity towards minorities and vulnerable groups, where meaningful, should be reflected in the improved provision of public services.

Last but not least, the intervention implies equal opportunities and treatment for the entire population, i.e. it is non-discriminatory in relation to gender, ability, belonging to minorities and/or vulnerable groups. When appropriate, professional associations will be included. During the preparation and implementation of the activities, special attention will be paid to location, resources, potential pollution, waste, land-based requirements and transports related to the intervention.

10. Conditionality and sequencing

10.1. Conditionality

Provision of support for financing the procurement of the equipment for the health sector through a Supply contract, that should serve to complement the lacking and to upgrade the existing microbiological laboratory and IT equipment and interlink all microbiological laboratory information systems in the country. Laboratory and IT equipment will be procured for all end-user beneficiary institutions with diagnostic microbiology laboratories (25 general hospitals, 24 IPH and 13 tertiary care hospitals and institutes). This is to be realized with the national co-financing of approximately EUR 0.45 million (indicative budget for all the equipment is EUR 3 million, with EU contribution of EUR 2.55 million).

10.2. Sequencing

Expert working groups will define procedures and standards, as well as guidelines for coordination of national surveillance and responses in the field of communicable diseases and guidelines for characteristics of software, which will support an integrated e-surveillance system at national level. The National surveillance system will be supported by procurement of upgraded equipment for microbiology diagnostics and confirmation, as well as procurement of the adequate software and interlinking of that software with microbiological laboratories and all relevant entities. These activities will lead to the establishment of integrated and harmonized electronic surveillance system, warning and response at the national level. There are no special requirements for sequencing between the results, but certain need for sequencing between the activities within the same result should be respected.

A needs analysis regarding the critical equipment and IT system was performed as the basis for development of a procurement plan, and precedes the supply of critical equipment for

microbiology diagnosis and confirmation and integrated e –surveillance system at national level.

11. Indicators for performance measurement

Result 1.1 – Established relevant expert working groups, involving all responsible institutions in the Republic of Serbia.

- Indicator 1.1.1. – Developed ToR and appointed members of the Health Policy Expert Group, encompassing representatives of the Ministry of Health, IPHS and the NRL (2022: No; 2023: Yes)
- Indicator 1.1.2. - Developed ToR and appointed members of the MoH Expert Group for Epidemiological Surveillance, encompassing epidemiologists, microbiologists and IT specialist from IPHS, IPH and NRL (2022: No; 2023: Yes)

Result 1.2. - Relevant procedures and quality standards, aligned with EU regulations and benchmarks, including the relevant regulatory framework in the Republic of Serbia are implemented in NRL.

- Indicator 1.2.1. – Percentage of NRL organizing national proficiency testing (2022: N/A; 2024: 50%; 2026: 80%)
- Indicator 1.2.2. – Percentage of diagnostic laboratories (DL) that are operational in line with developed procedures and quality standards (2022: N/A; 2024: 30%; 2026: 50%)

Result 1.3. – Upgraded and updated relevant data and information sets and procedures for regular reporting on epidemiological surveillance and outbreak investigation in line with EU *acquis* and reporting requirements/standards.

- Indicator 1.3.1. – Percentage of DL that have achieved the capacities to identify, confirm and, if appropriate, further characterize microbiological agents (2022: N/A; 2024: 25%; 2026: 60%)
- Indicator 1.3.2. – Number of NRL with proven diagnostic capacity to identify and confirm all 57 of mandated communicable diseases under EU epidemiological surveillance system and in accordance with the EU laboratory criteria (2022: N/A; 2024: 1; 2026: 2)

Result 2.1. - Computerized epidemiological surveillance system (e-system) is developed, tested and deployed throughout the networks of IPH and NRL, and fully integrated with other IHIS components.

- Indicator 2.1.1. – Project tasks and requests are consolidated and the comprehensive e-system project document developed (2022: N/A; 2023: Yes; 2024: Yes)
- Indicator 2.1.2. – Percentage of NRL where the epidemiological surveillance e-system is tested and deployed and users appropriately trained (2022: N/A; 2024: 10%; 2026: 60%)
- Indicator 2.1.3. – Percentage of DL where the epidemiological surveillance e-system is tested and deployed and users appropriately trained (2022: N/A; 2024: 10%; 2026: 40%)

Result 2.2. - Human capacities to collect manage and process data and information on communicable diseases strengthened are in place in all DL (including NRL)

- Indicator 2.2.1. – Percentage of DL (including NRL) with fully trained epidemiologists and microbiologists to use the epidemiological surveillance e-system and report in accordance with the regulatory framework (2022: N/A; 2024: 60%; 2026: 90%)
- Indicator 2.2.2. – Percentage of DL (including NRL) with fully trained IT specialists to support and maintain the epidemiological surveillance e-system (2022: N/A; 2024: 60%; 2026: 90%)

Result 2.3. – Developed set of performance indicators to assess the functioning of the epidemiological surveillance e-system

- Indicator 2.3.1. – Percentage of DL (including NRL) with capacities to collect data, monitor and report on the agreed set of epidemiological surveillance system performance indicators (2022: N/A; 2024: 30%; 2026: 100%)

Result 3.1 – Training curricula and Trainers' Manual, based on required professional competencies and improved educational framework for health human resources, are developed and accredited as CME program(s)

- Indicator 3.1.1. – Percentage of Training curricula and Trainers Manual developed and agreed (2022: N/A; 2023: at least 50%; 2024: 100%)
- Indicator 3.1.2. – Number of accreditetd CME courses based on training curricula (2022: N/A; 2023: 2: 2024: 3)

Result 3.2 – Delivered training to initial group of 20 experts and future trainers (ToT)

- Indicator 3.2.1. – Number of selected professionals that have completed the ToT (2022: N/A; 2023: 5; 2024: 20)

12. Facilities available

The Institute of Public Health of Serbia (IPHS) "Dr Milan Jovanovic Batut" (the beneficiary) will provide the MS Twinning partner with adequate office space for RTA and experts, meeting rooms and equipment necessary for relevant everyday activities and training foreseen within this twinning fiche. Within the central building of the IPHS, there will be dedicated office space with necessary office equipment for the purposes of project implementation. Meeting and conference rooms of the IPHS will be made available for project meetings and conferences through ongoing coordination with twinning partner's side.

MoH will dedicate all necessary human and institutional resources in order to guarantee an effective implementation of the respective project.

Component Leaders and short-term experts for the entire duration of their secondment (in particular a desk, a telephone line, PC with e-mail account and internet access, possibility to use fax & copy services) will have adequate conditions to perform their work while on mission to the BC, training and conference venues as well as presentation and interpretation equipment. The availability of the BC human resources (BC experts) during the implementation of the activities is required throughout the duration of the pproject.

ANNEXES TO PROJECT FICHE

1. The Simplified Logical Framework Matrix as Annex C1a (compulsory)
2. Overview diagram of the health system in the Republic of Serbia

3. Key legislation on communicable diseases and epidemiological surveillance in the Republic of Serbia
4. Provisional TW Project Budget (Annex A3)

Annex 1: Simplified Logical Framework Matrix

	Description	Indicators (with relevant baseline and target data)	Sources of verification	Risks	Assumptions (external to the project)
Overall Objective	To contribute to the strengthening of the institutional capacities and the legislative framework for fulfilling the requirements of EU membership in the area of public health	Progress made towards meeting the accession criteria under the chapter 28 in the area of epidemiological surveillance - Some progress achieved in the chapter 28 (2022) - Very good progress achieved in the chapter 28 (2024) - Very good progress achieved in the chapter 28 (2026)	- Progress Assessment / European Commission Annual Progress for Serbia, published on a yearly basis		Firm orientation in the country and speeding up of the EU accession Stable economic growth in the country
Specific (Project Objective)	To improve the system of communicable disease surveillance and outbreak investigations, by strengthening and harmonizing the laboratory diagnostics (including molecular methods) of the network of the institutes of public health (IPH) and national reference laboratories (NRL).	The epidemiological surveillance system in Serbia is functioning in accordance with the EU legislation and updated Serbian regulatory framework - N/A (2022) - Yes (2024) - Yes (2026)	- Annual Report of the Ministry of Health of the Republic of Serbia - European Commission Annual Progress for Serbia - ECDC feedback on quality of reported data to ECDC on EU notifiable diseases; ECDC-IPA6 project implementation report (Contribution Agreement 2019/409-781 and 2020/422-255)	Traditional approach in epidemiological surveillance and low institutional capacity for change	Supply contract to be realized in a timely manner

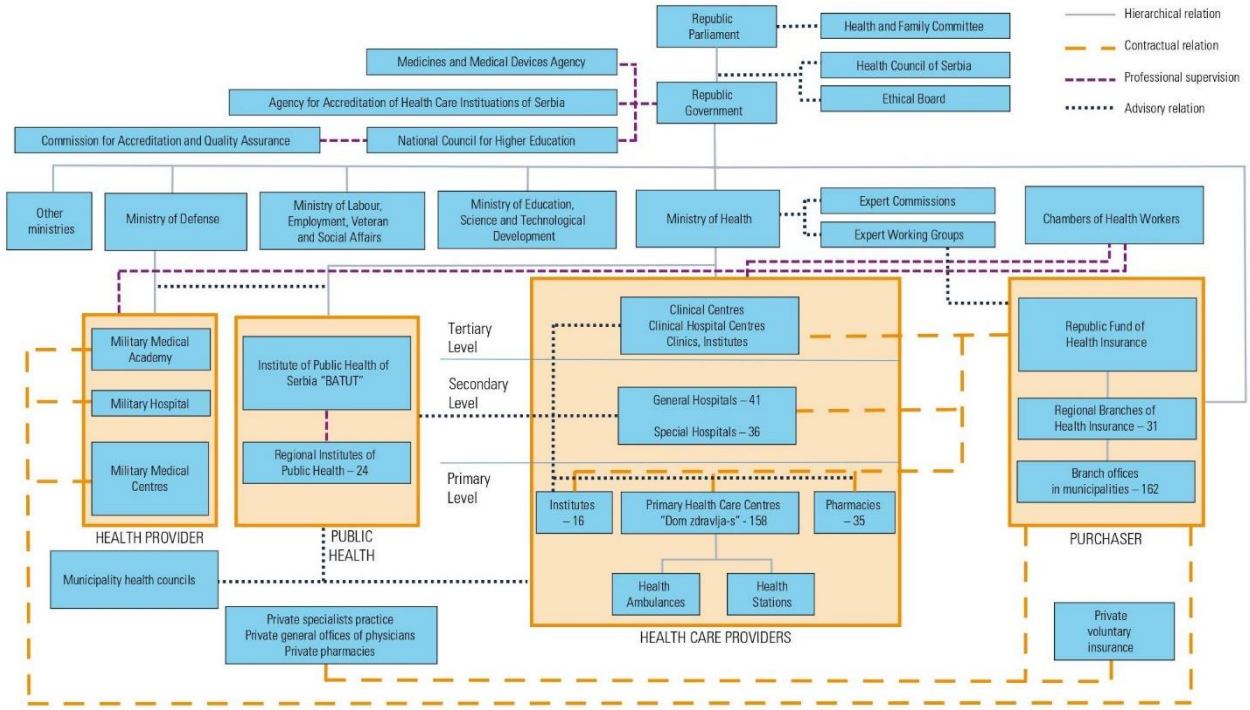
	Description	Indicators (with relevant baseline and target data)	Sources of verification	Risks	Assumptions (external to the project)
Mandatory results / outputs by components	**1.1 –** Established relevant expert working groups, involving all responsible institutions in the Republic of Serbia.	- **1.1.1.** – Developed ToR and appointed members of the Health Policy Expert Group, encompassing representatives of the Ministry of Health, IPHS and the NRL (2022: No; 2023: Yes) - **1.1.2.** - Developed ToR and appointed members of the MoH Expert Group for Epidemiological Surveillance, encompassing epidemiologists, microbiologists and IT specialist from IPHS, IPH and NRL (2022: No; 2023: Yes)	Decision of making this board will be signed by Minister of health of the Republic of Serbia (regular reports of Ministry of Health)		Coordination of policy making and technical organizations of Serbian health system
	1.2. - Relevant procedures and quality standards, aligned with EU regulations and benchmarks, including the relevant regulatory framework in the Republic of Serbia are implemented in NRL.	- **1.2.1.** – Percentage of NRL organizing national proficiency testing (2022: 0% 2024: 50%; 2026: 80%) - **1.2.2.** – Percentage of diagnostic laboratories (DL) that are operational in line with developed procedures and quality standards (2022: N/A; 2024: 30%; 2026: 50%)			
	1.3. – Upgraded and updated relevant data and information sets and procedures for regular reporting on epidemiological surveillance and outbreak investigation in line with EU criteria.	- **1.3.1.** – Percentage of DL that have achieved the capacities to identify, confirm and, if appropriate, further characterize microbiological agents (2022: N/A; 2024: 25%; 2026: 60%) - **1.3.2.** – Number of NRL with proven diagnostic capacity to identify and confirm all 57 of mandated communicable diseases under EU epidemiological surveillance system and in accordance with the EU laboratory criteria (2022: N/A; 2024: 1; 2026: 2)			

	Description	Indicators (with relevant baseline and target data)	Sources of verification	Risks	Assumptions (external to the project)
	2.1. - Computerized epidemiological surveillance system (e-system) is developed, tested and deployed throughout the networks of IPH and NRL, and fully integrated with other IHIS components.	- **2.1.1.** – Project tasks and requests are consolidated and the comprehensive e-system project document developed (2022: N/A; 2023: Yes; 2024: Yes) - **2.1.2.** – Percentage of NRL where the epidemiological surveillance e-system is tested and deployed and users appropriately trained (2022: N/A; 2024: 10%; 2026: 60%) - **2.1.3.** – Percentage of DL where the epidemiological surveillance e-system is tested and deployed and users appropriately trained (2022: N/A; 2024: 10%; 2026: 40%)			
	2.2. - Human capacities to collect manage and process data and information on communicable diseases strengthened are in place in all DL (including NRL)	- **2.2.1.** – Percentage of DL (including NRL) with fully trained epidemiologists and microbiologists to use the epidemiological surveillance e-system and report in accordance with the regulatory framework (2022: N/A; 2024: 60%; 2026: 90%) - **2.2.2.** – Percentage of DL (including NRL) with fully trained IT specialists to support and maintain the epidemiological surveillance e-system (2022: N/A; 2024: 60%; 2026: 90%)			
	2.3. – Developed set of performance indicators to assess the functioning of the epidemiological surveillance e-system	- **2.3.1.** – Percentage of DL (including NRL) with capacities to collect data, monitor and report on the agreed set of epidemiological surveillance system performance indicators (2022: N/A; 2024: 30%; 2026: 100%)			

	Description	Indicators (with relevant baseline and target data)	Sources of verification	Risks	Assumptions (external to the project)
	3.1 – Training curricula and Trainers' Manual, based on required professional competencies and improved educational framework for health human resources, are developed and accredited as CME program(s)	- **3.1.1.** – Percentage of Training curricula and Trainers Manual developed and agreed (2022: N/A; 2023: at least 50%; 2024: 100%) - **3.1.2.** – Number of accredited CME courses based on training curricula (2022: N/A; 2023: 2: 2024: 3)			
	3.2 – Delivered training to initial group of 20 experts and future trainers (ToT)	- **3.2.1.** – Number of selected professionals that have completed the ToT (2022: N/A; 2023: 5; 2024: 20)			

Annex 2. Overview of the health system in Serbia.

Adapted from *Bjegovic-Mikanovic V, Vasic M, Vukovic D, Jankovic J, Jovic-Vranes A, Santric-Milicevic M, Terzic-Supic Z, Hernández-Quevedo C. Serbia: Health system review. Health Systems in Transition, 2019; 21(3):i-211*



Annex 3. Relevant legislation on public health and communicable diseases in the Republic of Serbia.

Key legislation documents are:

- Law on protection of Population from Communicable Diseases (with by-lows);
- Decree on the Programme of Protection against Communicable Diseases;
- The Strategy for the Prevention and Control of HIV Infection and AIDS in the Republic of Serbia;
- Decree on the National Program for the resistance of bacteria resistance to antibiotics.

Specific set of rulebooks that are more closely defined by the Law on Protection of Population from Communicable Diseases include also:

- Rulebook on reporting of communicable diseases and special health issues (Official Gazette of RS, No. 44/17, 58/18)
- Rulebook on the manner of recording data on laboratory tests, deadlines and manner of notification of the results obtained (Official Gazette of RS, No. 73/17)
- Rulebook on immunization and the manner of protection of medicines (Official Gazette of RS, No. 88/17, 11/18, 14/18, 45/18, 48/18 - other regulation, 58/18, 104/18)
- Rulebook on the types and manner of implementation of epidemiological surveillance of communicable diseases and special health issues (Official Gazette of RS, No. 3/17)
- Rulebook on the method of monitoring zoonoses and zoonotic agents (Official Gazette of RS, No. 76/17)
- Rulebook on the program of mandatory and recommended immunization of the population against certain communicable diseases (Official Gazette of RS, No. 65/20)
- Rulebook on detailed conditions and manner of implementation of quarantine measures and conditions that must be fulfilled by facilities for this purpose (Official Gazette of RS, No. 90/16)
- Rulebook on conditions for disinfection, disinfection and pest control (Official Gazette of RS, No. 3/17)
- Rulebook on the healthfulness of pool water (Official Gazette of RS, No. 30/17, 97/17)
- Rulebook on the prevention, early detection and prevention of hospital infections (Official Gazette of RS, No.1/20)