

## ANNEX I

of the Commission Implementing Decision on the Annual Action Programme 2013 in favour of Belarus

### 1. IDENTIFICATION

Title/Number	<b>International accreditation of testing laboratories for medical products and support to healthcare in Belarus (BELMED)</b> CRIS number: ENPI/2013/024-679		
Total cost	Total estimated cost: EUR 8.300.000 Total amount of EU budget contribution: EUR 8.000.000 This action is co-financed in joint co-financing by: - UNDP (including contributions of WHO, UNFPA, UNICEF) for an amount of EUR 300.000		
Aid method / Method of implementation	Project Approach Direct centralised management – procurement of services, supplies for Components 1 and 3 Joint management with UNDP for Component 2		
DAC-code	12191	Sector	Medical services

### 2. RATIONALE AND CONTEXT

#### 2.1. Summary of the action and its objectives

Healthcare has always been one of the key government priorities in Belarus. The interest of the Belarusian government to initiate co-operation in this sector is seen as an excellent opportunity to directly contribute to the welfare of the Belarusian population by sharing best EU experience. This project could also provide an entry point for further aid programmes in the healthcare sector. The proposed set of interventions was directly initiated by the Ministry of Health, thus it is based on explicit demand of the Beneficiary.

This intervention logic is based on emphasizing the central component of the project – support of quality infrastructure for pharmaceutical products, an area where both the EU and Belarus can take advantage of the successful implementation of past projects, thus ensuring the high probability of smooth implementation. This highly technical component is complemented by softer, directly population oriented and much more visible interventions aimed at supporting pilot projects to tackle major problems in the healthcare sector by promoting preventive activities against non-communicable diseases. A light and flexible technical assistance component will be further put at the disposal of the government to provide advice on a future possible reform agenda aimed at the overall modernisation of the healthcare system in

Belarus, in order to ensure its sustainability and best adaptation to the needs of the population.

## **2.2. Context**

### **2.2.1. Country context**

#### 2.2.1.1. Economic and social situation and poverty analysis

Belarus has a strong emphasis on human capital development, including support to public health. About 6% of the GDP is annually spent on health care financing. Having developed a strong hospital based healthcare system, Belarus nevertheless faces numerous challenges in the sector, which continues to function on a Soviet heritage pattern and has not undergone significant reform since independence of the country in 1990. Major problems are linked to high rates of non-communicable diseases, underdevelopment of primary and preventative care, and lacking quality control of healthcare services and products.

#### 2.2.1.2. National development policy

Modernisation of the healthcare system is one of the Belarus' development priorities reflected in main strategic documents – National strategy of sustainable socio-economic development until 2020, Programme of social-economic development of Belarus for 2011-2015 and National programme of demographic security for 2011-2015. These documents promote the objectives of improvement of public health as well as the quality increase of medical products and services.

### **2.2.2. Sector context: policies and challenges**

Belarus has its own national system of quality control for medical products, administered by the Ministry of Health and its branches. The coordination of these activities is ensured by the Department of pharmaceutical inspection of the Ministry of Health. The medical quality control system is represented by twelve laboratories, which ensure the full range of quality control activities. Nevertheless, the national system is disconnected from the international medical testing laboratories network and the test results are not recognised outside Belarus. As a result, Belarus finds itself currently excluded from the European information exchange network on quality of medical products thus having limited possibilities to react to possible irregularities on the medical market. In addition, Belarusian medical producers and institutions are forced to undergo costly overlapping inspections in the EU.

The health of the Belarusian population continues to be affected by inappropriate use of alcohol, tobacco, unhealthy diet and physical inactivity; factors which contribute to premature mortality from non-communicable diseases and injuries. According to the national official statistic review (2011) the life expectancy among men in 2010 was 64.6 years and for women it was 76.5 years which are well below the EU averages.

Currently, the public health response is weak and a systematic strengthening of the public health system is required to enable it to control risk factors adequately

including substantial capacity building in the areas of health promotion and education.

The proposed actions forming a single integrated project are in line with the priorities of the National Indicative Programme 2012-2013 for Belarus: promoting good governance standards and implementation of policy reforms (sub-priority 1.1) and sustainable modernisation of the country's economy including regulatory convergence and legislative approximation (priority area 2).

Several special national programmes focus on the specific problems listed above, that the project intends to tackle: National programme for prevention and overcoming of drunkenness and alcoholism for 2011-2015, National complex programme for prevention, diagnosis and treatment of oncologic diseases for 2010-2014, State programme "Cardiology" for 2011-2015, State programme for HIV-infection prevention for 2011-2015.

Effective combination of efforts of Belarus and the EU in this new cooperation area would contribute to the qualitative changes in health sector, bringing direct benefit to the people of Belarus.

### **2.3. Lessons learnt**

The project is meant to be a first step into a new area of co-operation between the EU and Belarus – healthcare. Belarus and the EU have a limited record of cooperation in the health sector but an extensive experience of work in the field of support to quality infrastructure. The experience of the projects Support to Quality Infrastructure in Food Safety (AAP 2009) and Support to Belarus in the field of Norms and Standards (AAP 2010) show that Belarusian counterparts are very willing to co-operate on technical proposals which can open doors to advocate necessary system changes and reforms in the concerned sector. The combination of technical supply with policy advice and capacity building proves to be the most efficient mode of intervention.

The "Evaluation of health sector in the Republic of Belarus" finalised in December 2012 confirmed the relevance of the raised problems and the existing needs of the Belarusian partners, especially relating to prevention of non-communicable diseases and support to quality infrastructure for medicines.

### **2.4. Complementary actions**

**Multilateral co-operation on health topics** (sector reform, HIV/AIDS and tuberculosis, approximation and implementation of EU practices) has been organised within the thematic platform on Economic integration and convergence with EU policies in the framework of the **Eastern Partnership**. This co-operation is aimed at possible partnership arrangements between partners' authorities and the Commission and EU Member States to strengthen institutional capacity and enhance preparedness to tackle the cross-border spread of diseases.

**EU thematic instruments** – Investing in People, Non State Actors and Local authorities, and the European Instrument for Democracy and Human Rights target health and social inclusion as important priority.

HIV prevention activities are managed by UNDP and funded by the **Global Fund to Fight AIDS, TB and Malaria** (GFATM). Financial resources currently designated by the GFATM for HIV programmes implemented by UNDP in Belarus amount to over USD 42 million. Global Fund's grants are implemented in close partnership with government and civil society.

A number of **local cross border cooperation** projects has also been realised in the healthcare sector.

## **2.5. Donor coordination**

Considering that healthcare is a specific and traditionally closed sector, international donor assistance has been until now almost exclusively channelled through specialised UN agencies: UNDP, WHO, UNAIDS, UNFPA, UNICEF. This pioneer project will draw considerably from the long experience of the UN family in the health sector. Necessary standing coordination mechanisms locally – regular meetings between the Delegation and the UNDP as representative of the UN agencies in Belarus, as well as globally, contribute to establishment of unified approaches and coordinated activities, in line with the principles of the Paris Declaration.

Coordination with the Beneficiary government, especially with the project partner – Ministry of Health – is ensured through the National Coordinating Unit, as well as through dedicated meetings closely monitored on the highest level by Ministry officials. An EU-BY technical dialogue in the health sector could be envisaged. Interaction with Member States is arranged through regular donor coordination sessions called by the EU Delegation.

## **3. DETAILED DESCRIPTION**

### **3.1. Objectives**

**Overall objective:** To contribute to the improvement of healthcare and wellbeing of the Belarusian people.

**Specific objective 1:** To strengthen quality support infrastructure for pharmaceutical products;

**Specific objective 2:** To contribute to efficient prevention of non-communicable diseases, including through implementation of pilot projects with active involvement of non-state actors on the local level;

**Specific objective 3:** To support the modernisation of the Belarusian healthcare system by providing competent policy advice.

### **3.2. Expected results and main activities**

#### **Expected results**

##### **Under specific objective 1:**

- Belarusian system of quality control of pharmaceutical products is strengthened

and upgraded, certified to international and European standards and integrated into the General European Official Medicines Control Laboratories network;

- A number of testing laboratory specialists have built their professional capacity, and visited the EU on study tours and internships.

#### **Under specific objective 2:**

- Evidence-based policies in the areas of alcohol, tobacco, unhealthy diet and physical inactivity formulated, implemented and evaluated;
- Health promotion approach integrated in primary health care (PHC) by introducing WHO recommended interventions and training of PHC staff on health promotion and prevention of non-communicable diseases;
- Information and education strategies on healthy live-styles promotion and non-communicable diseases prevention introduced with special emphasis on the local level with wide involvement of grass-roots civil society organisations;
- Participatory grant scheme to support local initiatives aimed at healthy life-styles promotion organised and implemented on the national level;
- Quality assured population-based screening for breast and cervical cancers are elaborated and introduced;
- Comprehensive system of child's injuries prevention developed and integrated into PHC.

#### **Under specific objective 3:**

- Healthcare sector modernisation agenda is discussed and presented to the government;
- A number of relevant officials took part in capacity-building and EU networking events.

#### **Indicative activities**

##### **Component 1 – International accreditation of Belarusian testing laboratories for medical products**

This component will contribute to the introduction of international standard of quality management ISO/IEC 17025 into Belarusian testing laboratories in the health sector. At the same time assistance will be delivered to ensure the integration of the Pharmaceutical Inspection of the Ministry of Health of Belarus into the Pharmaceutical Inspection Co-operation Scheme (PIC/S). The action will be completed by introducing the participating Belarusian testing laboratories into the network of official medicines control laboratories (OMCLs) of the European Directorate for the Quality of Medicines and Healthcare (EDQM).

The following indicative activities are expected to contribute to reaching project's results:

- Comprehensive audit of the existing testing laboratories, identification of capacity building and equipment needs;
- Capacity building programme for testing laboratories specialists (3 from each participating laboratory) including internships in one of the OMCLs Network institutions;
- Supply of necessary testing equipment, training of equipment operators;
- Audit and inspection to receive ISO/IEC 17025 standard qualification;
- Elaboration of action plan to join the PIC/S, including necessary training and capacity building for the employees of the Pharmaceutical inspection of the Ministry of Health;
- Preparation and implementation of EDQM audit and inspection to join the OMCLs Network;
- Introduction of the information exchange system on quality of medical products within the OMCLs Network.
- Launching cooperation with the European Medicines Agency and European medicines network.

### **Component 2 – Prevention of non-communicable diseases and promotion of healthy lifestyles:**

This component will deliver technical assistance to the Ministry of Health as well as implement several pilot projects. All indicative activities listed below are targeted to be implemented primarily on the local level with wide involvement of civil society organisations, local initiatives, and local authorities. Planned implementation of this component by UN agencies bring additional added-value taking into account the extensive experience and broad expertise of UNDP, UNICEF, UNFPA and WHO to working namely with the local level stakeholders. The coordination of different UN agencies will be ensured by UNDP office in Minsk, as lead UN agency in Belarus.

Indicative activities under this component include:

- Development of a national policy of health promotion and disease prevention for non-communicable diseases addressing effectively major risk factors (tobacco, alcohol, unhealthy diet, and physical inactivity) – WHO, UNDP, UNICEF; including a national information campaign on local (rayon) level supported by local health-care and social inclusion NGOs;
- Training of PHC staff on health promotion and disease prevention of non-communicable diseases - WHO, UNDP, UNICEF;
- Organisation of call for proposals for civil society organisations, local initiatives and local authorities aimed at promotion of healthy lifestyles – UNDP;
- Introduction of quality assured mass-screening and improvement of management of cervical and breast cancers, setting of quality assurance mechanisms, and capacity building of local health care specialists – WHO, UNDP, UNFPA;
- Improvement of quality of maternal and child health care and prevention of child morbidity – UNFPA, WHO, UNICEF;
- Development of a comprehensive system of child's injuries prevention– UNICEF, WHO, UNDP.

### **Component 3 – Support of the modernisation of the healthcare system:**

In the framework of this component relevant national stakeholders will receive technical assistance to identify the most important issues to be addressed in the modernisation of the healthcare system, including the financial sustainability of healthcare and introduction of best world practices (prioritisation of primary care, introduction of innovative financing mechanisms – health insurance).

The following activities could be envisaged:

- Supporting national and local health policy development in line with International Agency for Research on Cancer (IARC)/WHO standards (including sector policy assessment);
- Building capacity of relevant policy-makers;
- Drafting of a reform action plan.

### **3.3. Risks and assumptions**

#### ***Risks***

Considering the high interest of the Ministry of Health to implement the project and active involvement in the identification and initial formulation process, sound ownership is expected to be ensured. In this context the main risk refers to repercussions of possible collisions between the EU and Belarus on the political level. This risk will be mitigated by putting strong emphasis on the technical aspect of the project and its overall benefit for the population of Belarus.

The social consequences of modernisation of the healthcare system may affect the motivation of the Government to carry out the necessary changes. Mitigation measures should include a high-level of consultancy to the Government.

#### **Assumptions**

- Financial and economic stability;
- Government of Belarus' commitment to reform.

### **3.4. Cross-cutting issues**

Healthcare sector being at the intersection of numerous problems, the action will target the following cross-cutting issues: gender equality, good governance (in its reform agenda and decentralisation of the healthcare system), human rights, the rights of the child and vulnerable groups of population, and HIV/AIDs.

### **3.5. Stakeholders**

The Ministry of Health is the key institution in the organization of the Belarusian health system. Different departments within the Ministry of Health undertake planning in all aspects of human and physical resources, decide on the financing of services and administer the system.

The Regional Health Care Departments are significant agents in the organization of health care as they officially own all the state hospitals, as well as all polyclinics, outpatient clinics and feldsher - midwife points (FAPs) within their region. The Regional Health Care Departments are established and controlled by the Regional Executive Committee with the formal approval of the Ministry of Health. Although they are subordinated to the republican-level Ministry of Health, they do have limited

autonomy in the organization of services and, to a certain extent, their funding from the regional budgets. At district level, the Administration of the District Central Hospital works with the District Executive Committees (local government).

National and regional NGOs involved in social sphere and healthy lifestyles promotion are also important stakeholders.

Target groups include the relevant ministerial officials, employees of the national testing laboratories network, population at large.

Pharmaceutical producers will be also directly targeted by the project.

#### **4. IMPLEMENTATION ISSUES**

##### **4.1. Financing agreement**

In order to implement this action, it is foreseen to conclude a financing agreement with the partner country, referred to in Article 184(2)(b) of the Financial Regulation.

##### **4.2. Indicative operational implementation period**

The indicative operational implementation period of this action, during which the activities described in sections 3.2. and 4.3. will be carried out, is **60 months**, subject to modifications to be agreed by the responsible authorising officer in the relevant agreements.

##### **4.3. Implementation components and modules**

###### **4.3.1. Procurement (direct centralised management)**

<b>Subject</b>	<b>Type</b>	<b>Indicative number of contracts</b>	<b>Indicative trimester of launch of the procedure</b>
International accreditation of Belarusian testing laboratories for medical products (Component 1) and Support of the modernisation of the healthcare system (Component 3).	Services	1	III, 2014
Supply of necessary testing equipment, training of equipment operators (Component 1).	Supply	1	I, 2015
Evaluation and audit.	Services	2	III, 2016 I, 2018



#### **4.3.2. *Joint management with an international organisation***

A part of this action with the objective of contributing to efficient prevention of non-communicable diseases with active involvement of non-state actors on the local level will be implemented in **joint management with UNDP**.

This implementation is justified because the proposed action being the first EU national entry project in the health sector in Belarus, it appears reasonable to rely on the existing expertise of an experienced partner. Considering the specific mandate of UN agencies in the health field, extensive partnerships with healthcare civil society organisations and experience in activities at the local level in Belarus, component 2 will be implemented by UNDP.

Under the UN policy "Deliver as one" (DAO) UNDP will coordinate the contributions from other UN agencies according to the specific mandates of these agencies. UNDP will coordinate and manage the involvement of specialised UN agencies such as WHO, UNFPA, UNICEF, allowing for an integrated approach encompassing multiple intervention aspects into one single action. Moreover, UNDP proves to have an extensive network of non-state partners on the regional and local level, allowing for active and decisive implication of NGOs, local communities and local authorities.

**Co-financing** from UN agencies was confirmed on the level of **EUR 300.000**.

Joint management with this international organisation in accordance with Article 53d of Financial Regulation 1605/2002 is possible because the organisation is bound by a long-term framework agreement (FAFA). The project is furthermore elaborated jointly between the organisation and the Commission, and is a multi-donor action pooling funds of several donors which are not earmarked for specific expenditure.

The international organisation will award and implement all contracts implementing the action in accordance with the procedures and standard documents laid down and published by UNDP.

The change of method of implementation constitutes a substantial change except where the Commission "re-centralises" or reduces the level of budget-implementation tasks previously entrusted to the international organisation.

#### **4.4. *Scope of geographical eligibility for procurement in direct centralised and decentralised management***

Subject to the following, the geographical eligibility in terms of place of establishment for participating in procurement procedures and in terms of origin of supplies and materials purchased as established in the basic act shall apply.

The responsible authorising officer may extend the geographical eligibility in accordance with Article 21 (7) of the basic act on the basis of the unavailability of products and services in the markets of the countries concerned, for reasons of

extreme urgency, or if the eligibility rules would make the realisation of this action impossible or exceedingly difficult.

#### 4.5. Indicative budget

<b>Module</b>	<b>Amount in EUR thousands</b>	<b>Third party contribution (indicative, where known)</b>
4.3.1. – Procurement (direct centralised)	4.500	N.A.
4.3.2. – Joint management with UNDP	3.300	300
4.7. – Evaluation and audit	200	N.A.
4.8. – Communication and visibility	-	N.A.
Contingencies	N.A.	N.A.
<b>Totals</b>	<b>8.000</b>	<b>300</b>

#### 4.6. Performance monitoring

*Components 1 and 3:* The Delegation of the European Union to Belarus will carry out routine monitoring of the activities carried out by the Contractors. Objectively verifiable indicators (OVI), both qualitative and quantitative, will have to be part of the methodologies included in the technical proposals. Given the demand-driven character of the programme, the final OVIs must be designed properly and should be further revised at the start of the third year.

*Component 2:* The monitoring of the day to day implementation will be carried out by UNDP under its standard procedures, based on benchmarks to be agreed with the project beneficiaries and with the Delegation of the European Union to Belarus. It will include periodic assessment of progress and delivery of specified project results towards achievement of project objectives. Key indicators for performance monitoring will include such items as number of local initiatives implemented, community organisations formed, information events organised. Along with standard UNDP procedures, the Delegation of the European Union to Belarus will ensure proper implementation monitoring by conducting regular reviews of project progress and analysis of project performance.

#### 4.7. Evaluation and audit

The project will be evaluated/audited according to standard Commission procedures. Mid-term and/or final evaluation of the results achieved are envisaged. An appropriate allocation for each component is set aside for this purpose.

Results-oriented monitoring will complement regular evaluations when needed.

Evaluation/verification of the joint management components will be according to the Financial and Administrative Framework Agreement between the European Commission and the United Nations (FAFA).

#### **4.8. Communication and visibility**

Communication and visibility activities should follow the Communication and Visibility Manual for European Union External Actions. They should also be fully in line with the developments in the overall EU-Belarus relations. The project will aim, whenever possible and in line with EU's policy, for widespread dissemination of its achievements and results. On starting activities, communication and visibility plans will be prepared and submitted to the EU Delegation for approval as per the Communication and Visibility Manual for European Union External Actions.

Communication and visibility activities of the joint management components will be according to the Financial and Administrative Framework Agreement between the European Commission and the United Nations (FAFA).