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SOP 1, Template 2: Request for Categorical Exclusion (RCE)

**United States Agency for International Development (USAID)
for Ukraine and Belarus
Request for Categorical Exclusion (RCE)**

Program/Project/Activity Data:

Activity/Project Name:	Health Anti-Corruption: Safe, Affordable, and Effective Medicines for Ukrainians (SAFEMed) and “Health Systems Strengthening for a Sustainable HIV/AIDS Response in Ukraine” (HIV Reform in Action)	
Assistance Objective:	2 Governing Justly and Democratically	
Program Area:	2.2 Good Governance/2.2.4 Anti-Corruption Reform	
Country(ies) and/or Operating Unit:	USAID/Ukraine	
Originating Office:	Office of Health	Date: November 16, 2016
PAD Level RCE: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	DCN of Original RCE/IEE:	2014-URK-010
RCE/IEE Amendment: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	DCN of Amendment(s):	n/a
Supplemental RCE: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
If Yes, Purpose of Amendment:		
DCN(s) of Related EA/IEE/RCE/ER(s):	n/a	
Implementation Start/End:	AMD: 9/2019-FY 2022	LOP: 9/2014- FY 2022
Funding Amount:	AMD: \$20,000,000	LOP Amount: \$120,000,000
Contract/Award Number (if known):	n/a	
Recommended Determination: Categorical Exclusion		
Additional Elements:		
Government to Government: <input type="checkbox"/> Local Procurement: <input type="checkbox"/> Donor Co-Funded: <input type="checkbox"/>		

1. Project and Activity Description

1.1 Purpose and Scope of RCE

The Purpose of this Amendment is 1) to cover ongoing activities under a cost and time extension; 2) to add illustrative activities and mitigation measures under Objective 3 Anti-Corruption.

All conditions of the original RCE remain in effect. With this Amendment, all existing reporting requirements shall remain in place

The purpose of the Safe, Affordable, and Effective Medicines (SAFEMed) activity is to strengthen the pharmaceutical system in Ukraine to ensure transparency and cost-effectiveness for desired health outcomes. This contract will offer state of the art technical solutions to currently inefficient and corrupt pharmaceutical financing and procurement systems, and inefficient supply chain management practices.

The purpose of the HIV Reform in Action is to assist the Government of Ukraine (GoU) and civil society to strengthen Ukraine’s health care system and support health system financing reforms.

1.2 Project Overview

The SAFEMed program will work to address policy and legislative barriers that hinder establishment of efficient, cost-effective, free-of-corruption health procurement management and administration in Ukraine; assist the Government of Ukraine with price setting, including developing price-volume agreements to ensure the best prices for medicines and other health technology; support public sector and create innovative approaches that utilize technological advances to address supply chain management issues.

The HIV Reform in Action assists the Government of Ukraine (GoU) and civil society to strengthen Ukraine's health care system through: 1) enhancing national leadership and capacity for evidence-based and gender-sensitive HIV policy programming and implementation, 2) optimizing resource allocation for national and regional HIV/AIDS programs and supporting health financing reforms, and 3) strengthening human resources in the area of HIV/AIDS services to most-at-risk populations.

2. Project Description

Defined or illustrative activities under Component One—Health Financing systems and Pharmaceutical sector governance strengthened
1.1 provide technical assistance to address policy and legislative barriers that hinder establishment of efficient, cost-effective, free-of-corruption health financing, health procurement management and administration
1.2 support of development and adoption of evidence based pharmaceutical laws, policies, regulations, guidelines, and standard operating procedures (SOPs)
1.3 provide technical assistance to civil society organizations in their collaboration on demanding the best use of scarce health resources, improve trust in the healthcare system, ensure the proper use of quality-assured medicines, and promote good policy making
1.4 Build the capacity of the national and selected regional/ local GoU entities to design and establish a national purchasing agency
Defined or illustrative activities under Component Two—Health systems financing and Pharmaceutical sector optimized
2.1 support of development and adoption of evidence based pharmaceutical laws, policies, regulations, guidelines, and standard operating procedures (SOPs)
2.2 assist the Government of Ukraine with price setting, including developing price-volume agreements to ensure the best prices for medicines and other health technology
2.3 Support the Ministry of Health (MoH) and relevant Parliamentary Committees to define, develop, implement and update a basic benefits package of service, in consultation with civil society and patient organizations
2.4 Support MoH and selected oblast/ local authorities in the design and establishment of a performance-based payment system under 'money-follows-the-client' approach
2.5 Support the MoH in developing and implementing effective IT solutions to launch, manage and administer health system financing reforms
Defined or illustrative activities under Component Three— Availability and appropriate use of essential medicines increased
3.1 support of development and adoption of evidence based pharmaceutical laws, policies, regulations,

Defined or illustrative activities under Component Three— Availability and appropriate use of essential medicines increased
guidelines, and standard operating procedures (SOPs)
3.2 provide technical assistance in accurate quantification and forecasting to provide accurate, relevant, and timely data to inform decisions on pharmaceutical products and services
3.3 support public sector and create innovative approaches that utilize technological advances to address supply chain management issues

3. Justification for Categorical Exclusion Determination

The activities under the **Safe, Affordable, and Effective Medicines for Ukrainians (SAFEMed)** will not have an effect on the natural or physical environment and are among the classes of activities listed in 22 CFR 216.2(c)(2). Therefore, under §216.2(c)(1), neither an IEE nor an EA will be required for these activities. Instead, a categorical exclusion threshold determination is recommended for the following identified activities under 22 CFR 216.2(c)(2): 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3

- Activities 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3 under §216.2(c)(2)(i) Education, technical assistance, or training programs except to the extent such programs include activities directly affecting the environment (such as construction of facilities, etc.);

4. Limitations of the Categorical Exclusion Determination:

This categorical exclusion does not cover classes of actions normally having a significant effect on the environment under §216.2(d):

- i. Programs of river basin development;
- ii. Irrigation and water management;
- iii. Agricultural land leveling;
- iv. Drainage projects;
- v. Large scale agricultural mechanization;
- vi. Resettlement projects;
- vii. New land development;
- viii. Penetration road building and road improvement;
- ix. Powerplants;
- x. Industrial plants; and
- xi. Potable water and sewerage projects

In addition, this categorical exclusion does not cover activities that:

- Support project preparation, project feasibility studies, engineering design for activities listed in §216.2(d)(1);
- Affect endangered species ;
- Provide support to extractive industries (e.g. mining and quarrying);
- Promote timber harvesting;
- Lead to construction, reconstruction, rehabilitation, or renovation work;
- Support agro-processing or industrial enterprises;
- Provide support for regulatory permitting;
- Lead to privatization of industrial facilities or infrastructure with heavily polluted property;
- Assist the procurement (including payment in kind, donations, guarantees of credit) or use (including handling, transport, fuel for transport, storage, mixing, loading, application, clean-up of spray equipment, and disposal) of pesticides or activities involving procurement, transport, use, storage, or disposal of toxic materials--pesticides cover all insecticides,

fungicides, rodenticides, etc. covered under the Federal Insecticide, Fungicide, and Rodenticide Act; and/or

- Procure or use genetically modified organisms.

Any of these actions would require a Europe and Eurasia Bureau Environmental Officer (BEO) approved amendment to the categorical exclusion.

5. Mandatory Inclusion of Environmental Compliance Requirements in Solicitations, Awards, Budgets, and Work Plans

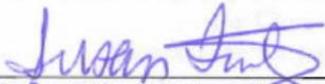
- Appropriate environmental compliance language, including limitations defined in Section 4, shall be incorporated into solicitations and awards for categorical exclusions.
- The implementing partner shall ensure annual work plans do not prescribe activities that are defined as limitations in Section 4.

6. Revisions

Under §216.3(a)(9), if new information becomes available that indicates that activities covered by the categorical exclusion might be considered major and their effect significant, or if additional activities are proposed that might be considered major and their effect significant, this categorical exclusion determination will be reviewed and, if necessary, revised by the Mission Environmental Officer (MEO) with concurrence by the BEO. It is the responsibility of the USAID Contract Officer's Representative (COR)/Agreement Officer's Representative (AOR) to keep the MEO and BEO informed of any new information or changes in the activity that might require revision of this determination.

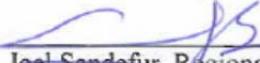
7. Recommended Determination for Categorical Exclusion:

Approval :



Susan Fritz, Mission Director
Date 11-21-16

Clearance:



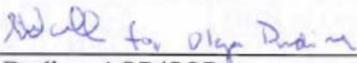
Joel Sandefur, Regional Legal Officer
Date 11/18/2016

Clearance:



Tatiana Kistanova, Mission Environmental Officer
Date 11/18/2016

Clearance:



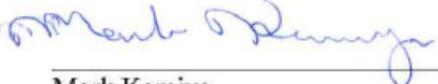
Olga Dudina, AOR/COR
Date 11/18/2016

Clearance:



Paola Pavlenko, AOR
Date 11/18/2016

Concurrence:



Mark Kamiya
E&E Bureau Environmental Officer
Date 11/22/2016

Distribution:

IEE File

MEO (to also provide a copy to AOR/COR)