

United Nations Development Programme

Country: Ukraine

Project Document

Project Title

Procurement Support Services to the Ministry of Health of Ukraine

UNDAF Outcome(s):

Outcome 2.1: Improved access to and utilization of quality health, education and social services

Expected CP Outcome(s):

Outcome 2.1: Improved access to and utilization of quality health, education and social services

Implementing Parties:

UNDP, Ministry of Health of Ukraine

Responsible Parties:

UNDP, Ministry of Health of Ukraine

Brief Description

The overall objective of the Project is to strengthen the national health care procurement system and thereby improve the effectiveness of diagnosis and treatment of the patients of Ukraine. The specific objectives of the Project are:

- (i) To procure medicines and medical products for the National Public Health Programmes for 2015 and ongoing years as needed,
- (ii) To strengthen the capacity of the Ministry of Health of Ukraine to ensure transparency, accountability and effectiveness of the public procurement of medicines and other medical products.

Programme Period:

Key Result Area: Sustainable Development Pathway

Atlas Award ID: _____

Start Date: November 2015

End Date: December 2019

PAC Meeting Date: 2015

Management Arrangements: DIM

Total resources required: UAH 620,070,700.00 (2015)

Total allocated resources: UAH 620,070,700.00 (equivalent to USD 27,931,112.61, according to November Exchange Rate)

- o The Government of Ukraine: UAH 620,070,700.00

Agreed by UNDP:

Mr. Janthomas Hiemstra
UNDP RR a.i.

Agreed by the Ministry of Health of Ukraine

Mr. Alexander Kvitashvili
Minister

Date: 24 November 2015

I. SITUATION ANALYSIS

The Government of Ukraine procures medicines and other health commodities for 17 National Public Health Programmes. The allocated budget was about 2.2 billion UAH in 2014, and around 4 billion UAH in 2015.

According to the Coalition Agreement, the Ministry of Health of Ukraine should conduct procurement of medicines and medical devices through international organizations in 2015. The respective Law on Public Procurement and other legislative acts have been amended to provide a legal framework for a temporary (until 31 March 2019) public procurement procedure for medicines and other medical products by the UN and other international organizations. This type of procurement should be conducted on the basis of an agreement between such organizations and the Ministry of Health of Ukraine and in accordance with the internal policies and procedures of such organizations.

The adopted legislation aims at reducing corruption risks associated with public health sector procurements in the past. It is expected to reduce the delivery time and the costs, and to improve the quality of procured medicines, vaccines and medical products.

It is expected that amendments to the legislation will simplify, to a certain extent, the registration procedure, the labelling requirements and the procedure for importation of medicines into Ukraine, although some issues remain to be solved.

The procurement procedure related to the list of medicines and other medical products to be procured through UNDP and other international organizations, including the process of selecting international organizations, signing of respective agreements, registration of medicines, etc. are established by adoption of by-laws.

Since the UN has significant role and global experience in supporting governments with large-scale procurement, the Ministry of Health has approached UNDP and UNICEF to provide procurement support services, supported by WHO technical assistance in selection and use of essential medicines, quality standards etc.

UNDP has a specialized procurement office and a specialized office working on implementation of large projects financed by the Global Fund to Fight AIDS, Tuberculosis and Malaria – all have significant procurement components. Thus, these two UN Agencies have the skills and capacity to effectively and efficiently respond to the country's challenges in procurement and supply chain management.

The Government has also requested the UN to provide support to ongoing reform processes and to the establishment of a transparent, accountable, cost-efficient, equitable and sustainable national health procurement and quality assurance system in the next few years.

II. STRATEGY

The overall objective of the Project is to strengthen the national health care procurement system and thereby improve the effectiveness of diagnosis and treatment of the patients of Ukraine. The specific objectives of the Project are:

- (i) To procure medicines and medical products for the National Public Health Programmes for 2015 and ongoing years as needed,
- (ii) To strengthen the capacity of the Ministry of Health to ensure transparency, accountability and effectiveness of the public procurement of medicines and other medical products.

In 2015 UNDP will procure and support the MOH with distribution to the oblast level medicines and other medical products for treatment and diagnosis of tuberculosis, diagnosis of HIV, treatment for children with hemophilia A and B or Willebrand disease, treatment for children with chronic viral hepatitis B and C, treatment of viral hepatitis B and C, treatment for children with orphan diseases. The list of programmes/medicines could be extended further in 2015 and further years.

Although the capacity development is not a part of this immediate procurement support due to time and budget constraints, it is a clear intention of the UNDP to invest in sustainable results that can be achieved with an efficient and transparent national procurement service at the Ministry of Health. The capacity building efforts will be discussed at length in a separate document yet to be developed.

Thus, the overall strategy of the Project is the following:

- Assist the MOH in the cost-efficient, transparent and timely procurement of medicines and other medical devices of selected State Health Programmes;
- Build structural and human resource capacity for supply planning, forecasting, monitoring and evaluation for transparent and cost-efficient procurement at the MOH;
- Gradual transfer of procurement activities back to the MOH or designated agency;
- Support the MOH further reform of the national procurement and quality assurance system and capacity development processes;
- With the technical expertise of WHO to support the capacity building of the procurement and supply chain management system in the context of wider initiative aiming at strengthening of the Ukrainian healthcare system and creating a coherent pharmaceutical policy.

The scope of work in terms of the procurement support services to the MOH includes the following:

- Provision of procurement services for a range of medicines and medical products according to the Cost sharing agreement with MOH (see Annex 3);
- Support to MOH to receive and distribute medicines and medical products procured by UNDP.

III. RESULTS AND RESOURCES FRAMEWORK

Intended Outcome as stated in the Country Programme Results and Resource Framework: Outcome 2: Improved access to and utilization of quality health, education and social services				
Outcome indicators as stated in the Country Programme Results and Resources Framework, including baseline and targets: N/A				
Partnership Strategy: UNDP will forge close collaboration with the Parliament of Ukraine, Cabinet of Ministers, Ministry of Health of Ukraine, other UN agencies, civil society organizations and private sector in preparation, monitoring and implementation of the Project activities.				
Project title and ID (ATLAS Award ID): Procurement Support Services to the Ministry of Health of Ukraine				
INTENDED OUTPUTS	OUTPUT TARGETS FOR (YEARS)	INDICATIVE ACTIVITIES	RESPONSIBLE PARTIES	INPUTS
<p>Output 1: National health care procurement system strengthened and the effectiveness of diagnosis and treatment of the patients of Ukraine improved</p> <p>Baseline:</p> <p>a) 0 of agreed items and volumes procured</p> <p>b) 0 expenditure per programme</p> <p>c) 0 of resolved issues identified as constraints for the successful importation and registration of the agreed medicines and other medical products</p> <p>Indicators:</p> <p>a) % of agreed items and volumes procured</p> <p>b) % of expenditure per programme</p> <p>c) % of resolved issues</p>	<p>Targets (2015)</p> <p>a) at least 10% of agreed items and volumes procured</p> <p>b) at least 10% of expenditure per programme achieved</p> <p>c) at least 10% of resolved issues identified as constraints for the successful importation and registration of the agreed medicines and other medical products</p> <p>Targets (2016)</p> <p>a) at least 90% of agreed items and volumes procured</p> <p>b) at least 90% of expenditure per programme achieved</p> <p>c) at least 90% of resolved issues identified as constraints for the successful importation and registration of</p>	<p>Activity 1. Procurement of medicines and medical products for the National Public Health Programs as per the Annex 2 of the Cost-sharing agreement № 1 between UNDP and Ministry of Health of Ukraine</p> <p>Sub-activity 1.1. Procurement of TB treatment</p> <p>Sub-activity 1.2. Procurement of TB diagnostics</p> <p>Sub-activity 1.3. Procurement of HIV diagnostics</p> <p>Sub-activity 1.4. Procurement of hemophilia children</p> <p>Sub-activity 1.5. Procurement of hepatitis children</p> <p>Sub-activity 1.6. Procurement of hepatitis B and C adults</p> <p>Sub-activity 1.7. Procurement of orphan diseases</p>	<p>UNDP Ministry of Health of Ukraine (MOH)</p>	<p>Total budget for Output 1: USD 27,931,112.61,00</p> <p>1.For Activity 1: 2015: 72300 (materials and goods) – 26,601,059.63 USD 75100 (facilities and administration) – 1,330,052.98 USD</p>

<p>identified as constraints for the successful importation and registration of the agreed medicines and other medical products</p> <p>Gender Marker Rating and Motivation: 2</p>	<p>the agreed medicines and other medical products</p>			
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IV. ANNUAL WORK PLAN

Year: 2015

EXPECTED OUTPUTS <i>And baseline, indicators including annual targets</i>	PLANNED ACTIVITIES <i>List activity results and associated actions</i>	TIMEFRAME				RESPONSIBLE PARTY	PLANNED BUDGET	
		Q1	Q2	Q3	Q4		Funding Source	Amount
Output 1: National health care procurement system strengthened and the effectiveness of diagnosis and treatment of the patients of Ukraine improved	Activity 1. Procurement of medicines and medical products for the National Public Health Programs as per the Annex 2 of the Cost-sharing agreement № 1 between UNDP and Ministry of Health of Ukraine				x	UNDP Ministry of Health of Ukraine	MOH	72300 (materials and goods) 13,300,529.82 USD
	Sub-activity 1.1. Procurement of TB treatment							75100 (facilities and administration) 665,026.49 USD
	Sub-activity 1.2. Procurement of TB diagnostics							
	Sub-activity 1.3. Procurement of HIV diagnostics							
	Sub-activity. Procurement of hemophilia children							
	Sub-activity 1.5. Procurement of hepatitis children							
	Sub-activity 1.6. Procurement of hepatitis B and C adults							
TOTAL:								13,965,556.31 USD

V. MANAGEMENT ARRANGEMENTS

Roles and responsibilities of Ministry of Health and UNDP

The Ministry of Health will:

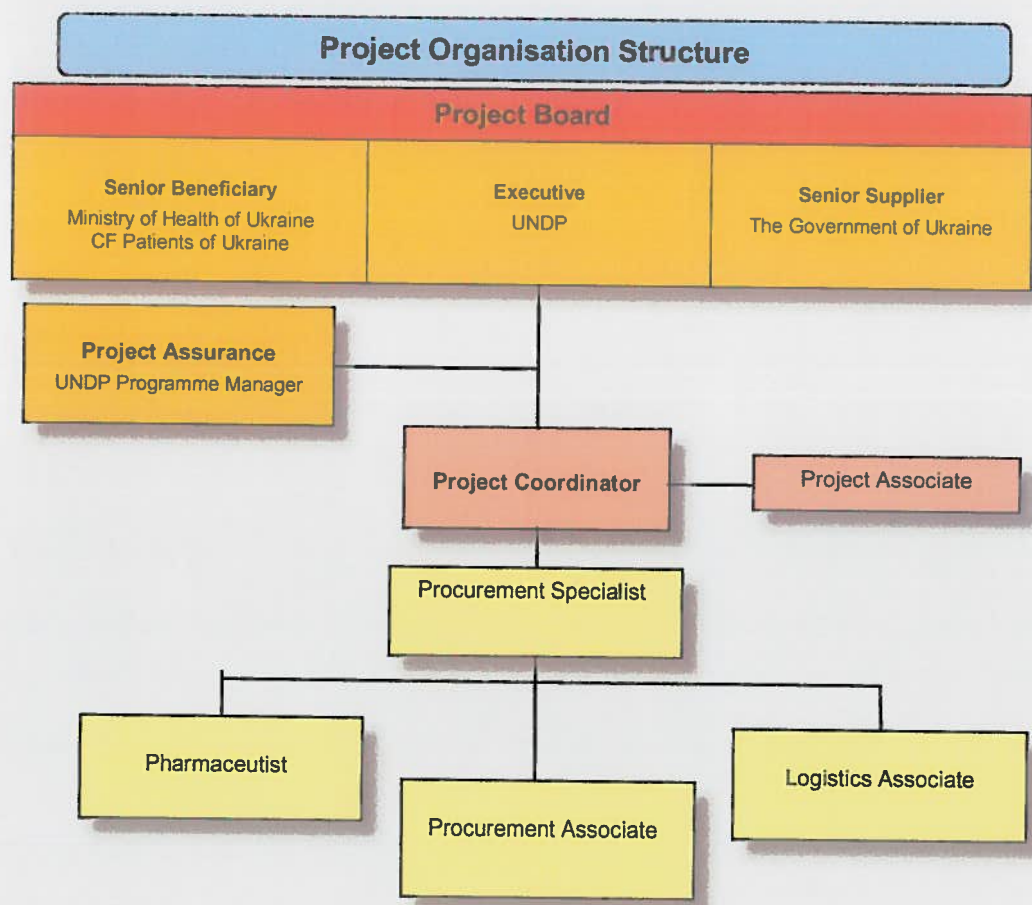
- Provide a list of products with specification and needs per year, in line with nomenclature and quality standards, quantities, budgets per programme, distribution details based on standard request for procurement of each agency;
- Appoint a focal point in the Ministry to coordinate day-to-day implementation activities and to respond to requests for clarifications within a period of 5 days after receipt of the request from UNDP;
- Disburse funds to UNDP in the amount of total budget allocation for the programmes to be procured by UNDP within 1 week after signature of the Cost-Sharing Agreement № 1 between UNDP and Ministry of Health of Ukraine;
- Agree (comment or reject) the prices and quantities provided by UNDP within 7 days;
- Facilitate the registration of medicines and medical products that are not registered in Ukraine or permit import of non-registered in Ukraine medicines subject to available grounds and in line with the legislation and facilitates simplification of the procedure of assessment of compliance of medical devices;
- Facilitate, according to the competence, getting all necessary national import permissions and approvals for importation of products to Ukraine minimum 1 month prior to the expected arrival date of procured products;
- Act or designate a recipient of medicines and other medical products and carry the overall responsibility for stock management and distribution. In this regard, conclude contracts with respective service providers for distribution;
- Ensure facilitation, in line with its mandate, customs clearance, tax and toll duties;
- Carry the overall responsibility for quality of medicines and other medical products from the moment of transfer of propriety right to the MOH;
- Provide guidance on reprogramming of any balance based on information provided by the UNDP within 2 weeks after receiving the information;
- Call for regular coordination and progress reporting meetings.

UNDP will:

- Procure and supply quality items according to the list of medicines and medical products, quantities and budget agreed with the MOH in line with international regulations and to the entry point in the country or the designated delivery place for procurement done in Ukraine;
- Conduct procurement procedures and inform the MOH on the prices and quantities of medicines and medical products to seek no-objection the MOH to proceed with purchasing;
- Provide regular updates to the MOH on progress of procurement, inform on eventual queries and/or action required by the MOH in relation to the procurement of specific products or product categories;
- Provide information on any expected savings as soon as available and assist the MOH with the reprogramming of such balance made during the procurement;
- Provide regular financial reports per programme to the MOH including financial statements and other relevant documents;
- Reimburse the MOH for the balance accrued during the procurement process and/or proceed with additional quantities as per amended agreement with the MOH;
- Provide support and cover the costs from the project budget, if needed, to service providers for customs clearing, in-country storage and distribution as agreed on with the MOH, while the MOH will be a consignee and owner of the products. Distribution will be arranged

through designated by MoH PE Ukrvaccina, PE Ukrmedpostch and PE Politekhmed, in accordance with the Resolution of the Cabinet of Ministers of Ukraine № 622 dated 22 July 2015, at the Initial stage of the project implementation; with a future potential switch to another qualified entity(ies) as agreed with MOH;

- Jointly with MOH implement communication strategy with media to report on procurement issues.



Due to the political, economic and social situation in the country, UNDP Ukraine has activated a mechanism referred to as Fast Track Procedures (FTP) aimed at improving UNDP's response to crisis, speeding up project implementation and addressing urgent needs. Therefore, in line with this mechanism, the implementation modality for the Project will be Direct Implementation Modality (DIM).

Project Board will be responsible for making, on a consensus basis, management recommendations for the Project when guidance is required by the Project Coordinator. Particularly, the Project Board will have the responsibility to review and endorse Project documents and revisions thereto, annual work plans, quarterly and annual project reports.

This Board contains three roles:

- Executive representing the project ownership to chair the group. For this project UNDP will assume the role of Project Board Executive.
- Senior Supplier role to provide guidance regarding the technical feasibility of the project. This role will be assumed by the Government of Ukraine.
- Senior Beneficiary role to ensure the realization of project benefits from the perspective of project beneficiaries (those who will ultimately benefit from the project). This role will be

performed by designated representatives of the Ministry of Health of Ukraine and NGO Patience of Ukraine.

Strategic communication issues related to project implementation should be an integral part of the Project Board meetings agenda.

Project Assurance: The Project Assurance role supports the Project Board by carrying out objective and independent project oversight and monitoring functions. This role ensures appropriate project management milestones are managed and completed. This role will be performed by a UNDP Ukraine Programme Officer.

The **Project Implementation Team** will be responsible for:

- Overall management of Project implementation;
- Coordination with stakeholders and project partners;
- Strategic, technical and methodological backstopping to Regional Implementation Teams;
- Monitoring of project implementation and quality assurance; and
- Knowledge management, reporting and visibility.

The core **Project Implementation Team** will consist of the following staff:

- Project Coordinator;
- Project Associate;
- Logistics Associate;
- Procurement Specialist;
- Procurement Associate;
- Pharmacist.

The **Project Coordinator** will be responsible for day-to-day management and his/her prime responsibility will be to ensure that the Project produces the results specified in the Project document, to the required standard of quality and within the specified constraints of time and cost. He/she will be eventually responsible for monitoring of activities and results to be delivered by project implementing partners.

Amendments to the Project documentation

The Project documentation (Prodoc, Cost-sharing Agreement between UNDP and Ministry of Health and annexes to the Agreement etc.) may be amended through an exchange of official letters between Ministry of Health and UNDP and Project Board approval. The letters exchanged to this effect shall become an integral part of the project documentation.

VI. MONITORING FRAMEWORK AND EVALUATION

In accordance with the UNDP programme operation policies and procedures (POPP), the project will be monitored through the following three main areas:

- a) Progress on procurement processes
- b) Budgetary follow-up per budget of the programme and implementing agency
- c) Bottlenecks and activities undertaken for importation and registration of medicines and medical products under UNDP Cost-Sharing Agreement

Within the annual cycle

- On a quarterly basis, a quality assessment shall record progress towards the completion of key results, based on quality criteria and methods.
- An Issue Log shall be activated in Atlas and updated by the Project Coordinator to facilitate tracking and resolution of potential problems or requests for change.
- A risk log shall be activated in Atlas and regularly updated by reviewing the external environment that may affect the project implementation.
- A Project Progress Reports (PPR) shall be submitted by the Project Coordinator to the Project Board through Project Assurance, using the standard report format available in the Executive Snapshot.
- A project Lesson-learned log shall be activated and regularly updated to ensure on-going learning and adaptation within the organization, and to facilitate the preparation of the Lessons-learned Report at the end of the project
- a Monitoring Schedule Plan shall be activated in Atlas and updated to track key management actions/events

Annually

- **Annual Review Report.** An Annual Review Report shall be prepared by the Project Coordinator and shared with the Project Board. As minimum requirement, the Annual Review Report shall consist of the Atlas standard format for the QPR covering the whole year with updated information for each above element of the QPR as well as a summary of results achieved against pre-defined annual targets at the output level.
- **Annual Project Review.** Based on the above report, an annual project review shall be conducted during the fourth quarter of the year or soon after, to assess the performance of the project and appraise the Annual Work Plan (AWP) for the following year. In the last year, this review will be a final assessment. This review is driven by the Project Board and may involve other stakeholders as required. It shall focus on the extent to which progress is being made towards outputs, and that these remain aligned to appropriate outcomes.

In addition, the Project will submit the interim report and the final report including a financial report to the Donor. The reports will clearly describe the achievement of the outcome set in the project document.

Audit Arrangement

The Project shall be the subject to the internal and external auditing procedures laid down in the Financial Regulations Rules and directives of UNDP.

VII. QUALITY MANAGEMENT FOR PROJECT ACTIVITY RESULTS

OUTPUT 1: National health care procurement system strengthened and the effectiveness of diagnosis and treatment of the patients of Ukraine improved		
Activity Result 1 (Atlas Activity ID)	Procurement of medicines and medical products for the National Public Health Programs as per the Annex 2 of the Cost-sharing agreement № 1 between UNDP and Ministry of Health of Ukraine	Start Date: November 2015 End Date: December 2019
Purpose	Procure medicines and medical products for the National Public Health Programs	
Description	Provide technical assistance in procurement of medicines and medical products for the National Public Health Programs in 2015 and next years	
Quality Criteria	Quality Method	Date of Assessment
Availability of the medicine and medical products in Ukraine Feedback from the main partners	Monthly progress reports; Financial statements issued upon completion of procurement activities; Opinions of counterparts.	Regularly, after completion of the specific activity

VIII. LEGAL CONTEXT

This document together with the CPAP signed by the MOH and UNDP which is incorporated by reference constitute together a Project Document as referred to in the SBAA and all CPAP provisions apply to this document.

Consistent with the Article III of the Standard Basic Assistance Agreement, the responsibility for the safety and security of the implementing partner and its personnel and property, and of UNDP's property in the implementing partner's custody, rests with the implementing partner.

The implementing partner shall:

- a) put in place an appropriate security plan and maintain the security plan, taking into account the security situation in the country where the project is being carried;
- b) assume all risks and liabilities related to the implementing partner's security, and the full implementation of the security plan.

UNDP reserves the right to verify whether such a plan is in place, and to suggest modifications to the plan when necessary. Failure to maintain and implement an appropriate security plan as required hereunder shall be deemed a breach of this agreement.

The implementing partner agrees to undertake all reasonable efforts to ensure that none of the UNDP funds received pursuant to the Project Document are used to provide support to individuals or entities associated with terrorism and that the recipients of any amounts provided by UNDP hereunder do not appear on the list maintained by the Security Council Committee established pursuant to resolution 1267 (1999). The list can be accessed via <http://www.un.org/Docs/sc/committees/1267/1267ListEng.htm>. This provision must be included in all sub-contracts or sub-agreements entered into under this Project Document".

IX. ANNEXES

Annex 1. Risk Log

RISK ANALYSIS

#	Description	Date Identified	Type	Impact & Probability	Countermeasures / Mngt response	Owner	Submitted, updated by	Last Update	Status
1	Political instability, possible changes in the Government	November 2015	Political	The senior officials of the Government and Ministry of Health could be changed, which may impact the entire project concept and approach P = 3 I = 5	Conduct consultations with the Government necessary response	Project Manager	Project Manager	November 2015	No change
2	Ability to ensure medicines registration	November 2015	Operational	Ability of MoH and State Administration of Ukraine on Medical Products to ensure the timely registration of medicines and other medical products or if needed can permit import of non-registered in Ukraine medicines subject to available grounds and in line with the legislation and facilitates simplification of the procedure of assessment of compliance of medical devices. P = 3 I = 4	Conduct consultations with MOH and State Administration of Ukraine on Medical Products necessary response	Project Manager	Project Manager	November 2015	No change
3	Devaluation	November 2015	Financial	Ukraine is experiencing fluctuation of foreign exchange rate and devaluation that will have direct impact on the Project cost. P = 3 I = 3	The Project will transfer the funds into USD dollars to mitigate potential currency losses	Project Manager	Project Manager	November 2015	No change

Annex 2: UNDP Approach to Procurement and Supply Management

UNDP – Overall Approach

The approach of UNDP is based on five pillars:

1. A pragmatic performance based approach to provide quality services as determined at the start of the programme.
2. Build capacity of national structures and human resources in parallel to the programme implementation
3. Strengthen national ownership by using the national structures and gradually transfer responsibilities.
4. Collaboration and coordination with national and international partners in health to increase efficiency
5. Linking health sector reform and capacity development with the broader reform and sustainable development agenda in countries.

UNDP Health and Development portfolio works in a close partnership with WHO at country, regional and global level. UNICEF is a strategic partner for UNDP in health procurement and other global health components. UNDP holds the Secretariat for the UN Informal Interagency Task Team on Sustainable Procurement in the Health Sector (SPHS); members are UNDP, UNFPA, UNEP, UNHCR, UNICEF, UNOPS, WHO and the multilateral global health financing organizations Gavi The Vaccine Alliance, the Global Fund and UNITAID.

UNDP – Procurement and Supply Chain Management Capacity Development

For the last 5 years UNDP has been taking a strategic approach to develop the capacity of national entities to manage Procurement and Supply Chain Management (PSM) and to build resilience and sustainability by strengthening national PSM systems.

This approach requires UNDP to work towards meeting the operational requirements and international standards set by WHO and other international reference agencies. UNDP has been and is doing this in many other countries.

In addition, UNDP has been actively engaged in coordinating among UN Agencies and other global health stakeholders the capacity building in sustainable procurement in the health sector including social and environmental aspects.

UNDP Implementation Arrangements

UNDP achieves this through the design of the implementation arrangements ensuring national systems are build up and used for key functions in sustainable PSM such as;

- Building national ownership and leadership of forecasting and quantification of health products and medicines;
- Support investments and implementation plans for improving central, regional country level procurement mechanisms
- Support in country logistics support systems for the downstream supply chain;
- Strengthen monitoring and evaluation of supply chain indicators and targets
- Quality assurance of health commodities throughout the supply chain;
- Work with the government and WHO to strengthen the legal framework on pharmaceuticals and other health commodities

- Collaboration with partners to integrate distribution networks at a national and sub national levels.
- Compliance with social and environmental standards in close collaboration with clients as well as the supplier and manufacturer network on global and country level.

The underlying principle is that investment in and optimization of sustainable national PSM systems, helps to build resilience and sustainability of the whole health system with positive synergies for other sectors in the country.

Annex 3. Agreement № 1 between UNDP and Ministry of Health of Ukraine signed on 27 October 2015

Annex 4. Terms of References for the Project staff