

United Nations Development Programme

Country: Moldova

Project Document

Project Title

Procurement Support Services to the Ministry of Health

UNPF Outcome:

Outcome 2.2 - People enjoy equitable access to quality public health and health care services and protection against financial risks

Implementing Parties:

UNDP, Ministry of Health

Brief Description

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

- (i) To procure medicines and health products for the National and Special Public Health Programmes starting in 2017.
- (ii) To strengthen the capacity of the Ministry of Health to ensure transparency, accountability and effectiveness of the public procurement of medicines, medical dispositives and other related products.
- (iii) To upgrade the storage conditions of Moldfarm in line with WHO and EU recommended good distribution practices (GDP)

Programme Period:

Key Result Area: Sustainable Development Pathway

Atlas Award ID: _____

Start Date: January 2017
End Date: December 2019

PAC Meeting Date: 2017

Management Arrangements: Support to NIM


Total resources required: (2017)

Total allocated resources:

Moldovan Government: 85 million MDL

UNDP Moldova: 100,000 USD

Agreed by UNDP:


Ms. Dafina Gercheva
UN RC, UNDP RR

Agreed by the Ministry of Health of Moldova

Ms. Ruxanda Glavan
Minister

Date:



I. DEVELOPMENT CHALLENGE

Moldova is a **lower-middle income** country with a total per capita health expenditure of US\$229 in 2014¹. According to the latest WHO estimates, public expenditures on health in the Republic of Moldova in 2014 constituted 10.4% of GDP, in line with both EU and global averages.

Health financing in Moldova is based on national **compulsory health insurance** since January 2004. Total public health spending covers all health care institutions. Interventions at central and local levels are funded through the national insurance scheme and currently comprise 90% of the public budget on health. The Ministry of Health administers about 10% of health spending, allocated for public health services, several national programs and administration at central level. External support to Moldova was growing over the past decade, in 2012 it accounted for about \$500 million per year.

The official national medicines policy document was updated in 2002 and the associated implementation plan was updated in 2007. The implementation of pharmaceutical policy is regularly monitored and assessed by the Medicines Agency and the Ministry of Health. There are three main ways in which pharmaceuticals can be procured or made available in Moldova; centralized tendering, hospital tendering and direct purchase by pharmacies. The 2011 WHO Public Health assessment mission (unpublished report) noted that the pharmaceutical market relies heavily on imported medicines (91.4% of total value) and, to a lesser extent, on local production (8.6% of total value).

In 2006, hospital procurement of medicines and health products was centralized and responsibilities were transferred to the Medicines Agency, which conducts annual tenders. This approach is also used for national programmes for the treatment of HIV/AIDS, TB, sexually transmitted diseases, noncommunicable diseases and the expanded programme on vaccines and immunization, as well special health programmes. It is common to have a limited number of bidders or no bidders at all. If there is only one bidder, the tender is repeated a second time, after which a winner is nominated. In a few instances when only one bidder was available in both rounds, the price in the second round was often higher as the bidder knew it was in a monopoly position and the Medicines Agency had to accept the second price offer².

Access to essential medicines/technologies, as part of the fulfilment of the right to health, is recognized in the constitution and national legislation; however, it remains a challenge. There are many reasons for the current lack of access, including prices. Prices of medical products are influenced by different factors such as wholesaler and pharmacy mark ups. Different measures can be taken to improve access to essential medicines. These are outlined in detail in the WHO Report on Availability and Affordability of Medicines and Assessment of Quality Systems for Prescription of Medicines in the Republic of Moldova published in 2012.

The country's public health system relies heavily on generic equivalents, not only for HIV medicines but in general. Moldova is bound by the WTO agreements and, since it has already been ratified, will also have to implement the additional requirements contained in the Deep and Comprehensive Free Trade Agreement (DCFTA) with the EU - as per the alignment schedule to be set by the Association Committee in Trade configuration, Art 438(4) of the AA. The remaining policy space for amendments that could facilitate access to affordable medicines is therefore limited. The validation agreement between the State Agency on Intellectual Property and the European Patent Office, if ratified, will further limit this policy space and will likely lead to an increasing number of patents in Moldova, including in the pharmaceutical sector which could limit the opportunities to procure generic equivalents.

¹ <http://data.worldbank.org/indicator/SH.XPD.PCAP> verified on 30 August 2016

² http://www.euro.who.int/__data/assets/pdf_file/0006/176388/E96712.pdf?ua=1

In 2014/2015³, the Moldovan public health system faced a severe crisis in ensuring adequate supply of medicines and pharmaceutical products to public medical institutions. As a result, a need emerged to identify safe and reliable supply mechanism, including the procurement of quality assured medicines and health products at affordable prices.

The United Nations has significant global experience in supporting governments with large-scale procurement. The Ministry of Health approached various UN agencies to explore the possibility to provide procurement support services to the Ministry.

UNDP is one of the largest procurers in the UN system. Apart from capacities on country office level to undertake both international and national procurement, the organization also has a specialized procurement support office and an office working exclusively on the implementation of large projects financed by the Global Fund to Fight AIDS, Tuberculosis and Malaria, which have significant procurement components. Building on the work of the UNDP-Global Fund partnership, an increasing number of governments and partners are requesting UNDP to help strengthen national capacities and systems specifically in the area of procurement and supply chain management of essential medicines and other health commodities.

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; as well as to upgrade Moldfarm public storage facilities in line with WHO and EU recommended GDP (good distribution practice) standards.

II. STRATEGY

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

- (i) To procure medicines and other health products for the National and Special Public Health Programmes starting in 2017;
- (ii) To help the Ministry of Health ensure transparency, accountability and effectiveness in the procurement of medicines and other health products.
- (iii) To improve the storage facilities of Moldfarm in line with WHO and EU recommended good distribution practices (GDP)

Starting in 2017 UNDP will procure medicines and other health products for treatment and diagnosis of diseases included in the "national and special programmes", in line with the detailed list provided by the MoH (Annex 2) to this project document. The list of health programmes and/or relevant medicines and health products may be revisited beyond this initial phase and subsequent years.

The list of medicines and health products is prepared by the Ministry of Health in line with their needs, specifications, quantities and delivery intervals – government and others – into the national public health system. This list is understood to be dynamic in nature and responsive to the demands on the national system and therefore subject to evolving needs. The needs for subsequent years are expected to be of similar nature, dynamic and responsive to the needs of MOH. UNDP however, reserves the right to decline any Procurement Services' request submitted pursuant to this Agreement.

In pursuit of the above objectives, the overall strategy of the project is the following:

³ <http://particip.gov.md/proiectview.php?l=ro&idd=3454>

- Assist the MOH in the cost-efficient, transparent and timely procurement of medicines and health products for selected number of National and Special health programmes;
- Build structural and human resource capacity for supply planning, forecasting monitoring and evaluation of procurement at the MOH;
- Support the MOH reform the national procurement and quality assurance system;
- Gradual transfer of procurement activities back to the MOH or designated agency;
- Support adaptation storage conditions of Moldfarm in line with WHO and EU recommended good distribution practices (GDP)

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 health products according to the cost sharing agreement with MOH (see Annex 1) and the Detailed List of Medicines developed and shared by the MOH (Annex 2);

As a result of UNDP assistance, the country will be supplied with critical medicines in an efficient and reasonable manner, contributing to increasing access to most vulnerable people to affordable and quality assured medicines and related health products. State institutions will be strengthened, by building their capacity and systems to ensure transparency, accountability, competition principles are respected.

III. RESULTS AND PARTNERSHIPS

Expected Results

The project will directly contribute to UNDAF Outcome 2 - People enjoy equitable access to quality public health and health care services and protection against financial risks

- National health care procurement system strengthened and the effectiveness of diagnosis and treatment of the patients of Moldova improved
- High quality health products requested by the MoH are procured and delivered on time and storage conditions of Moldfarm are renovated in line with WHO and EU recommended good distribution practices (GDP)

Partnerships and Stakeholder Engagement

Service delivery should be approached in a coherent and comprehensive fashion to avoid isolated and fragmented responses and small standalone projects. UNDP will ensure close coordination both within the UN, as well as outside. UNDP will complement capacities and resources from member states, the UN system as well as other multilaterals (e.g. World Bank and European Union) to assist Moldovan national counterparts in strengthening national institutions, systems and legal environments to enable responsive, inclusive and effective delivery of services, as well as identifying and overcoming the impediments which block the achievement of national, local, and globally agreed development goals. UNAIDS will be engaged in substantive coordination and will hold an advisory role for this specific project. Lead NGOs in the HIV sector will be involved through national coordination mechanisms.

The project will establish a strategic partnership with the Ministry of Health and related public agencies (Center for Centralized Health Procurement, Medicine and Medical Devices Agency, Moldfarm and others).

South-South and Triangular Cooperation (SSC/TrC)

The project will rely on the recent experience of neighbouring Ukraine and the successful cooperation that was established between the Ministry of Health of Ukraine and UNDP Ukraine. Considering that Ukraine and Moldova face a range of similar issues, the transfer of experience is envisaged from the outset of the project, including exchange at higher political levels, as well as at

the technical level. This approach will be further pursued, including, to the extent possible, triangular cooperation (with new EU MS, like neighboring Romania or Bulgaria).

Sustainability and Scaling Up

The project will directly address development of national capacities and strengthening of the national health care procurement system and thereby improve the effectiveness of diagnosis and treatment of the patients of Moldova. Being temporary in its nature, a smooth exit strategy will be developed in the first 6 months of the project, ensuring that by the end of the project, relevant systems are in place to conduct procurement of medicines in a transparent, efficient and accountable manner.

An important contribution to sustainability will also be to ensure the upgrade of national storage facilities in line with GDP standards, which will be for the first time in the country.

IV. GOVERNANCE AND MANAGEMENT ARRANGEMENTS

The project will be implemented as Support to NIM, the Minister of Health will be the National Coordinator of the project.

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;
- Facilitate the registration of medicines and health products that are not registered in Moldova or permit import of non-registered medicines in Moldova subject to available grounds and in line with the legislation and facilitates simplification of the procedure of assessment of compliance of medical devices;
- Facilitate all necessary national import permissions and approvals for importation of products to Moldova minimum 1 month prior to the expected arrival date of the procured products;
- Act or designate a recipient of medicines and other health 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 health products, quantities, quality requirements and budget agreed with the MOH in line with national and international regulations and to the entry point in the country or Moldfarm, as the designated delivery place for procurement done in Moldova;
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- Conduct competitive bidding processes at international levels in accordance with UNDP's procurement regulations and rules;

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 MOH with all the necessary documents for the clearance of all incoming shipments on a timely basis.

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 with the MOH, while the MOH will be a consignee and owner of the products. Distribution will be arranged through the State Enterprise MoldFarm 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 a communication strategy with media to report on procurement issues.

Support the review of regimen selection and treatment optimization opportunities and engage the normative guidance of UN partners, where applicable.

In light of special requirements and arrangements for medicines and health product procurement funded by the Government of Moldova, UNDP will also supply the following documents (original copies) for each of the goods under the Project:

1. Certificate of origin
2. Certificate of analysis of the pharmacopoeia standard or equivalent
3. Insurance certificate
4. Packing list
5. Invoice
6. Airway bill (for air shipments) or Bill of Lading (for sea shipments)

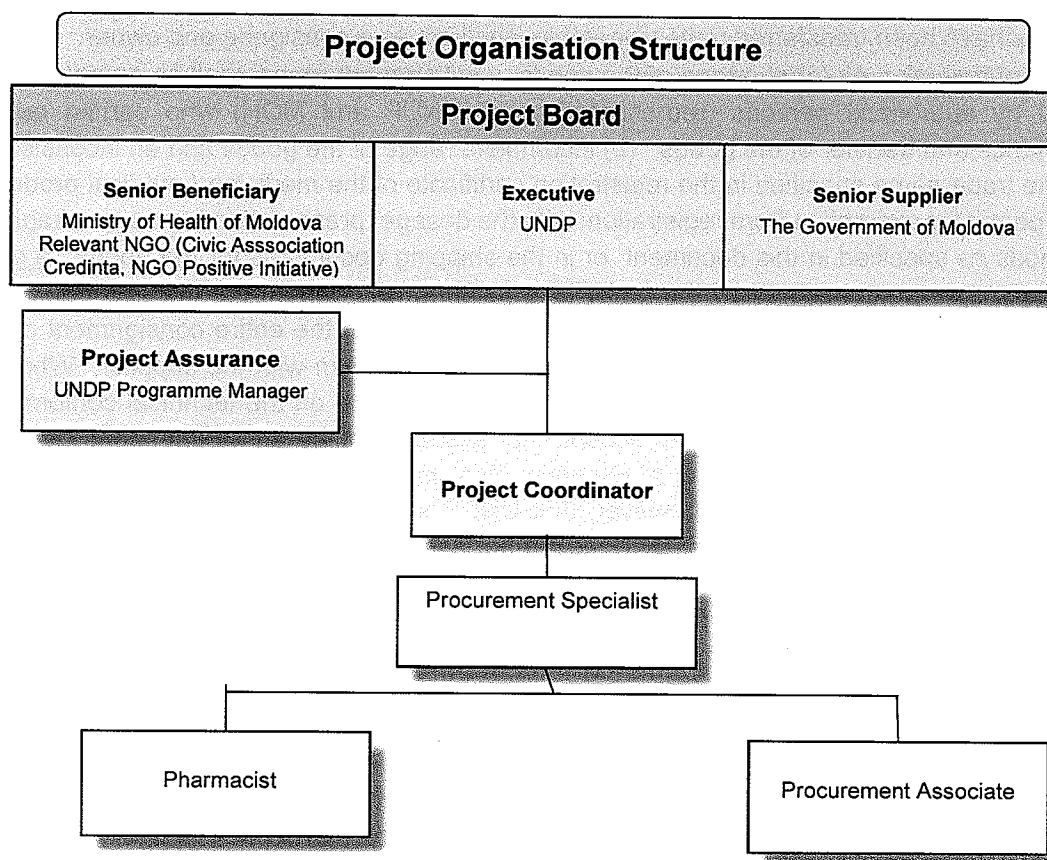
Key procurement steps

The below steps should be followed to complete the procurement and delivery process of the goods:

- MOH will request Procurement Services in accordance with this Agreement by submitting a complete list of requirements or Request for the Procurement Services to UNDP.
- Upon receipt of a Request for Procurement Services, UNDP will notify MOH of whether the Request for Procurement Services is accepted, is declined or is incomplete. UNDP reserves the right to decline any Request for Procurement Services delivered pursuant to this Agreement.
- In case of acceptance, UNDP will proceed with the relevant procurement process(es).
 - To expedite clearance, MOH and /or subordinated institutions will be the consignee of the goods. UNDP will not serve as consignee of the Supplies. Under this project, UNDP will arrange for shipment of the goods under CIP Chisinau Airport (2010), as agreed with MOH in each case.
- Purchase orders for medicines shall specify, based on technical specifications provided, that upon dispatch by the supplier such medicines shall have a minimum shelf life of 75% or two years whichever is the lowest unless otherwise agreed with MOH in writing.
- MOH shall facilitate registration of the medicines and medical products that are not registered in the Republic of Moldova and/or obtain waivers for the supply of unregistered items.
- MOH shall facilitate obtaining of all necessary import permissions and approvals for the goods to the Republic of Moldova. UNDP shall provide support if needed to service providers for customs clearing, in-country storage and distribution. The costs related to these activities shall

be considered a direct cost and shall be borne separately. MOH, after the medicines and health products have been transferred to its ownership, shall act as a consignee and owner.

- In case of detection of: (a) shortage of the goods; a subsequent report shall be prepared, to be signed by authorized persons (representatives of UNDP and MOH) who carried out the acceptance and transfer of the goods; (b) incomplete range of the goods and an inconsistency with the trade name specified in the registration certificate of the medicine / medical product or in the permit for exemption from registration; with the dosage, presentation form or packaging of the goods as specified in this document or in the shipping documents for the goods; a report shall be prepared and signed by the authorized persons who carried out the acceptance and transfer of the goods, which shall be grounds for the return of the entire consignment or part thereof to the supplier, or for passing a decision on further claim with the supplier. When the procurement is for medical related products, in case of dispute on the technical conformity or quality of the medicines, the Parties accept final assessment by an independent laboratory acceptable to the WHO Department of Essential Medicines and Pharmaceutical Policies. The Parties acknowledge and agree, however, that UNDP shall not reimburse MOH any amount related to above referenced goods. UNDP does not assume liability with regard to any claims arising out of or relating to or connected with the Project, including but not limited to those arising out of or relating to any defect in the quality or quantity of goods, the delivery of the goods, the use of the goods, the provision of services, or otherwise. UNDP will under no circumstances be liable for any incidental, indirect or consequential damages or for lost revenues or profits arising as a result of UNDP' procuring the supplies, or performance of its obligations or exercise of its rights under the Project. UNDP accepts no liability for any third party claims arising out of or related to the Project, including but not limited to those arising out of or relating to any defect in the quality or quantity of goods, the delivery of the supplies, the use of the supplies, the provision of services, if any, or otherwise. UNDP shall only reimburse recovered and/non committed amounts.
- The fulfillment of obligations under the Project shall be confirmed by the signing of the Act of Delivery (Transfer) of the Goods.



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 Moldova
- 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 Moldova and Specialized NGOs.

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 Moldova 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;
- 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.

V. MONITORING FRAMEWORK AND EVALUATION

In accordance with UNDP's programming policies and procedures, the project will be monitored through the following:

Within the annual cycle

- **Track Progress.** Following the frequency cited in the monitoring plan, progress data against the results indicators will be collected and analysed to assess the progress of the project in achieving the agreed outputs. National data sources should be used whenever possible. Slower than expected progress will be addressed by the project management. Beneficiary feedback will be part of regular data collection and performance assessment.
- **Monitor and Manage Risk.** Based on the initial risk analysis submitted (see annex 2), a risk log shall be actively maintained, including by reviewing the external environment that may affect the project implementation. Risk management actions will be identified and monitored using a risk log. This includes monitoring social and environmental management measures and plans that may have been required as per UNDP's Social and Environmental Standards (see annex 3). Audits will be conducted in accordance with UNDP's audit policy to manage financial risk.
- **Evaluate and Learn.** Evaluations shall be conducted in accordance with the evaluation plan. Knowledge, good practices and lessons should be captured and shared, as well as actively sourced from other projects and partners, and integrated back into the project. If a project evaluation is required (e.g., when mandated by partnership principles, or due to the complexity or innovative aspects of the project), it should be conducted in accordance with the project's evaluation plan.
- **Review and Make Course Corrections.** The project management will review the data and evidence collected (through all of the above) on a regular basis within the annual cycle, and make course corrections as needed. The frequency of review depends on the needs of the project, but an internal review of the available progress data against the results indicators is required at least quarterly. Any significant course corrections that require a decision by the Project Board should be raised at the next Project Board meeting.

Annually

- **Annual Project Quality Rating.** On an annual basis and at the end of the project, the quality of the project will be rated by the QA Assessor against the quality criteria identified in UNDP's Project Quality Assurance System. Any quality concerns flagged by the process must be addressed by project management.
- **Annual Project Review and Report.** The Project Board shall hold a project review at least once per year to assess the performance of the project and appraise the Annual Work Plan for the following year. An annual report will be presented to the Project Board for the review, consisting of progress data showing the results achieved against pre-defined annual targets at the output level, the annual project quality rating summary, an updated risk log with mitigation measures, and any evaluation or review reports prepared over the period. Any quality concerns or slower than expected progress should be discussed by the project and management actions agreed to address the issues identified. This review is driven by the Project Board and may involve other stakeholders as required.

Closure

In the project's final year, the Project Board shall hold an end-of project review to capture lessons learned and discuss opportunities for scaling up

VI. LEGAL CONTEXT

This document signed by the Ministry of Health of Moldova and UNDP together with the CPAP 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".

VII. ANNEXES

- 1. Cost Sharing Agreement between UNDP and Ministry of Health of the Republic of Moldova from January 2017**
- 2. List of Medication to be procured**
- 3. Risk Analysis.**
- 4. Results and Resource Framework**
- 5. Multi -Year Action Plan**
- 6. Project Quality Assurance Report**
- 7. Social and Environmental Screening Template** for projects \$500,000 or more [English][French][Spanish], including additional Social and Environmental Assessments or Management Plans as relevant.
- 8. Project Board Terms of Reference and TORs of key management positions**

Annex 3:

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	January 2017	Political	The senior officials of the Government and Ministry of Health could be changed, which may impact the entire project concept and approach P = 2 I = 5	Conduct necessary consultations with the Government	Project Manager	Project Manager	January 2017	No change
2	Ability to ensure medicines registration	January 2017	Operational	Ability of MoH and Medicines and Medical Devices Agency of Moldova to ensure the timely registration of medicines and other medical products or if needed can permit import of non-registered in Moldova medicines in line with the legislation and facilitates simplification of the procedure of assessment of compliance of medical devices. P = 3 I = 4	Conduct necessary consultations with MOH and Medicines and Medical Devices Agency	Project Manager	Project Manager	January 2017	No change
3	Availability of funds for advances	January 2017	Financial	The country is facing serious financial issues and availability of liquidity for advances to UNDP may be an issue. P = 2 I = 3	The project will develop a phased implementation plan, allowing quarterly /semi annual advances.	Project Manager	Project Manager	January 2017	No change

