PROJECT DOCUMENT

[Country: Saudi Arabia]

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Project Title: Support SFDA Third Strategic Plan Implementation

Project Number: **SAU10/115227**

Implementing Partner: Saudi Food and Drug Authority

Start Date: 1 April 2019 **End Date:** 31 December 2022 **PAC Meeting date:** 14 March 2019

Brief Description

Saudi Food and Drug Authority (SFDA) is the leading regional regulatory authority for food, drugs and medical devices with professional and excellent services that contributes to the protection and advancement of the health in Saudi Arabia.

Saudi Food and Drug Authority completed the implementation of its First Strategic Plan for 2007-2011 and its Second Strategic Plan for 2012-2016. The United Nations Development Programme provided technical assistance to SFDA and collaborated in achieving the strategic goals set in SFDA strategic plans 2018 -2022.

On the basis of the outputs of SFDA Strategic Plans and UNDP Projects, as well as considering the UN and Saudi strategy and policy documents, the new project has the following outputs:

1. Health Technology Assessment guidelines and improved capacities in assessment of the safety and effectiveness of new drugs and medical devices;
2. Improved quality assurance practices and developed patient safety policy documents and practice guidelines focusing on risk-based evaluation and safe use of technologies;
3. Capacities built in all relevant areas as per SFDA mandate;
4. Increased role of SFDA through regional and international collaborations and recognition;
5. Strengthened organisational culture and improved internal communication;
6. Improved external communication and raised awareness on SFDA roles and functions.

Contributing Outcome (UNDAF/CPD, RPD or GPD):	**Total resources required:**		**US$16,930,920**
Indicative Output(s):	**Total resources allocated:**		
		UNDP TRAC:	
		Donor:	
		Government:	US$16,930,920
		In-Kind:	
	Unfunded:		

Agreed by (signatures):

SFAD	UNDP
Prof. Hisham Bin Saad Al Jadhey **Chief Executive Officer**	**Mr. Firas Faleh Gharaibeh** **Resident Representative a.i.**
Date: 21/03/2019	Date: 21/03/2019

I. DEVELOPMENT CHALLENGE

Saudi Food and Drug Authority (SFDA) was established as an independent body corporate that directly reports to the Premier (Council of Ministers resolution No 1 dated 07/01/1424 H). SFDA's objective is to ensure safety of food and drug for man and animal, and safety of biological and chemical substance as well as electronic products. SFDA completed the implementation of its First Strategic Plan (2007-2011). Taking strategic planning as the planning approach to achieve its vision and mission, SFDA completed its forward-looking planning by developing its Second Strategic Plan (2012-2016). SFDA has approached the United Nations Development Programme (UNDP) to seek technical assistance and to jointly collaborate in achieving its strategic goals set out in SFDA Third Strategic Plan 2018-2022, based upon UNDP's comparative and competitive advantages in providing the required technical support.

The third annual strategic plan (2018- 2022) lays out the vision and strategic priorities for addressing the challenges that SFDA faces as the regulator of the food, drugs and medical devices sectors. SFDA vision is to become a leading international regulator responsible, for protecting the community and promoting access to safe produces through sound regulations and effective control.

As the Saudi economy continues to develop, SFDA must respond to the rapid pace of innovation, the tighter integration of global supply chains, and the increasing demands of the citizens for safe and healthy products. SFDA plans to meet these challenges by making informed decisions based on scientific evidence and by building effective partnerships with private sector, other government entities and international partner.

The Kingdom's "Vision 2030" comprises 96 strategic objectives, governed by a number of Key Performance Indicators (KPIs), that will be achieved through a number of initiatives codeveloped and executed by different governmental entities alongside private and non-profit organizations within the respective ecosystems. The Council of Economic and Development Affairs has set up an effective and integrated governance model with the aim of translating "Vision 2030" into multiple Vision Realization Programs VRPs working in parallel to achieve the strategic objectives & realize the vision. The National Transformation Program NTP (2018-2020) aims to develop governmental work and establish the needed infrastructure to achieve Vision 2030 ambition and requirement. SFDA has been identified as one of the main entities involved in the First Theme of Transform Healthcare. This Theme seeks to achieve a vibrant society by restructuring the health sector to become a comprehensive and effective system. It will promote public health through the implementation of new model of care that focuses on prevention and improving society's health awareness. It will also improve access to health services through optimal coverage, equitable geographical distribution, as well as comprehensive and expanded e-health services and digital solutions.

II. STRATEGY

Saudi Food and Drug Authority is the leading regional regulatory authority for food, drugs and medical devices with professional and excellent services that contributes to the protection and advancement of the health in Saudi Arabia. SFDA completed the implementation of its First Strategic Plan between 2007-2011 and its Second Strategic Plan between 2012-2016. The United Nations Development Programme (UNDP) provided technical assistance to SFDA and collaborated in achieving the strategic goals set in SFDA strategic plans.

Based upon UNDP's comparative and competitive advantages in providing the required technical support, SFDA requests to further collaborate in achieving its strategic goals set out in SFDA Third Strategic Plan (2018-2022).

In this context, the objective of this Project Document (PD) is to provide substantive support to SFDA, through enabling SFDA to implement food, drug and medical devices strategic goals and initiatives laid out in SFDA Third Strategic Plan; as well as develop the required institutional capacity to discharge its mandate and ultimately meet the national development plan's aspiration to achieve its vision. The overall objective of the Project is to support SFDA in implementing its Third Strategic Plan.

On the basis of the outputs of SFDA Strategic Plans and UNDP Projects, as well as considering the UN and Saudi strategy and policy documents (i.e. United Nations Sustainable Development Goals, Saudi Vision 2030, National Transformation Program 2020, SFDA Third Strategic Plan) the new project is attained through the following interventions (project objectives):

1. Develop Health Technology Assessment guidelines and improve capacities in assessment of the safety and effectiveness of new drugs and medical devices;
2. Improve quality assurance practices and develop patient safety policy documents and practice guidelines focusing on risk-based evaluation and safe use of technologies;
3. Build capacities in all relevant areas as per SFDA mandate;
4. Increase role of SFDA through regional and international collaborations and recognition;
5. Strengthen organisational culture and improve internal communication;
6. Improve external communication and raised awareness on SFDA roles and functions.

This nationally executed project aims at providing advisory services, specialized experts, and administrative support to SFDA. In the process, these activities will help in developing the authority's policy, advocacy, and executing capacity in the areas of food, drugs and medical devices.

Across all outcomes, the project modes of engagement include the following inputs:

1. Capacity building.
2. Support to planning and implementing processes.
3. Enhancing internal systems and processes, and communications.
4. Raising awareness and cooperation.
5. Evidence generation and dissemination.

The Theory of Change (ToC) is based on change pathways from project inputs to intermediate outcomes (project objectives).

Key Objectives:

Output 1. Assessment of the Safety and Effectiveness of New Drugs and Medical Devices

Health Technology Assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology (e.g. medicines, medical equipment) in a systematic, transparent, unbiased, robust manner. It is a systematic evaluation of properties, effects, and/or impacts of health technology. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.

The National Transformation Program (NTP) 2020 aims to establish a National Center for the assessment of healthcare technologies. SFDA Third Strategic Plan also sets drug and medical devices evaluation as strategic direction. SFDA shall perform full assessment of new drugs and complex generics. SFDA needs to establish risk-based evaluation capability for the assessment of medical devices.

Technical assistance will be provided to SFDA to develop national HTA guidelines to ensure timely, reliable, consistent HTA that is relevant to the needs of decision-makers and key stakeholders in the healthcare sector in Saudi Arabia. HTA assesses the effectiveness of health technologies in light of the funds used for their provision and whether resources are used efficiently. In this regard, SFDA

should extend the scope of its current assessment methods and consider the costs related to the use of health technologies in addition to the evaluation of their effectiveness and safety.

Output 2. Risk Based Evaluation and Safe Use of Technologies

The Ministry of Health (MoH) is committed to improve the quality and to ensure the safety of health services. Therefore, patient safety is considered as a top priority in Saudi Arabia. In this regard, MoH developed a framework for improving a common national understanding of terms and concepts relevant to patient safety.

The NTP 2020 also defined initiatives in relation to patient safety. There are initiatives to ensure compliance with safety standards in health facilities, and to implement the regulations and principles of quality management and patient safety based on globally proven mechanisms. In addition, the Saudi Center for Patient Safety will be established to promote a national culture of patient safety reporting and to raise awareness of safety issues.

SFDA Third Strategic Plan also sets surveillance and safe use of medical devices as strategic direction. SFDA needs to enhance collaboration with healthcare providers and establishments along with comprehensive data gathering initiatives will improve adverse event reporting and ultimately lead to safer usage of medical devices. Published guidelines and best practices will provide guidance to industry, setting expectations and improving communication.

Technical assistance will be provided to SFDA to enhance quality assurance practices and to develop healthcare quality and patient safety strategy and policy documents and practice guidelines. Assistance will be provided to the assessment of health technologies used at healthcare providers in order to ensure their quality and safe use.

Output 3. Continuation of Building Institutional and Staff Capacities

Based on its competitive advantage in building institutional capacity, UNDP has already supported SFDA in enriching its expertise by attracting, retaining and developing the appropriate human resources. In addition to, enhancing SFDA key internal tools and processes to better support its mission, develop the required set of capabilities to take over key processes, support Information Technology and Planning (ITP) and shared services sector in building their capabilities along with SFDA Second Strategic Plan.

Further support will be provided to SFDA in building broad and deep capabilities in all relevant areas as per SFDA mandate. UNDP will support SFDA to fulfil competencies and responsibilities outlined in mandate, and also further improve SFDA's performance regarding inspection of local market food businesses and water bottling plants, build out pesticide standards and related control infrastructure to cover the required scope as per SFDA's pesticide mandate, implement effective processes to operationalize pesticide safety standards, reinforce safety of drugs, bio-products, health, herbal and veterinary products across the value chain, pursue the development of cosmetics standards and ensure the safety of cosmetics products, tighten SFDA's control over manufacturing, import and export of medical devices, and develop best practice policies for specific / emerging product categories.

Output 4. Regional and International Collaborations and Recognition

In accordance with SFDA Third Strategic Plan collaboration, scientific contributions and mutual exchange of know-how are considered as strategic areas to make SFDA part of the international network of regulation of food, drug and medical devices. By having established the Research Center, in addition to other attempts to introduce SFDA to the international counterparts and other stakeholders in the sector, SFDA has already made a step towards collaboration, scientific contributions and exchange of know-how.

Regarding the region, the Gulf Health Council (GHC) aims to play a key role in dissemination of preventive and curative health awareness across the region. Its mission is to unite the efforts of Gulf Cooperation Council (GCC) Member States, among others the Kingdom of Saudi Arabia, to achieve unified Gulf Health Strategy to provide the highest levels of health for the citizens of Member States. In this context, SFDA can proactively take part in the activities of GHC to achieve its main objectives, such as those addressing the utilization of international experiences and strengthening collaboration with Arab, regional and international organizations working in the health field; the implementation of GCC Central Drug Registration Program for pharmaceutical companies to provide safe, effective and high-quality medicine through a unified procurement program for medicines and medical equipment and pricing of its products; and conducting joint health research among Member States. In addition to major programmes such as unified drug procurement, central registration, and standardization of pricing, GHC has several ongoing joint technical programs in GCC countries under the supervision of specialized technical advisory committees in such areas as health care quality and patient safety.

SFDA will be supported in increasing its role in the international community. UNDP will support SFDA to increase its role in the international community by bringing SFDA together with international counterparts and providing technical assistance in areas which are on the agenda of multilateral co-operations in the sectors relevant for SFDA. For instance, experiences in regulating internal markets and the mutual acceptance of registration of drugs and medical devices by national regulatory bodies would be relevant and useful for GHC as well as SFDA as a leading regulator in GCC Member States.

Output 5. Internal Communication and Organisational Culture

In accordance with SFDA Third Strategic Plan increasing organizational performance is considered as a strategic area to foster a collaborative and accountable culture, attract and retain talent, and clarify responsibilities.

SFDA has recently reorganized its structure and established new sector and centre. These are the Operations Sector and the Research Centre. SFDA Laboratories have been further developed to provide tests and other lab services for the Food, Drug and Medical Devices Sectors as they did in the past, too. The new structure allows SFDA to plan and conduct its functions in a more effective and efficient manner due to share and coordination of work of sectors, and allocation and use of resources according to the real need for those.

Therefore, SFDA will be required to enhance and strengthening its organisational culture and internal communication. UNDP will provide technical assistance to fine-tune the new matrix organisational structure and raise awareness on the intra-organisational job-share and cooperation between sectors in order to improve performance at SFDA level.

Output 6. External Communication and Awareness

In accordance with SFDA Third Strategic Plan external communication and awareness are considered as strategic direction.

SFDA will be supported in improving external communication and raising awareness on its role and functions. Technical assistance will be provided to SFDA to engage proactively with the public and other external stakeholders to promote safe and informed use of products and foster trust in SFDA. International best practices and benchmarks could be useful for defining the necessary and applicable methods and communication tools.

III. RESULTS AND PARTNERSHIPS

Expected Results

Output 1. Assessment of the Safety and Effectiveness of New Drugs and Medical Devices

Result 1.1. National HTA guidelines to ensure timely, reliable, consistent HTA that is relevant to the needs of decision-makers and key stakeholders in the healthcare sector in Saudi Arabia

Health technology is the application of scientific knowledge in health care and prevention. It can be a drug, medical technology, or health care service. Health Technology Assessment is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. The aim of HTA is to ensure the use of safe and effective technologies that are patient focused and seek to achieve best value. HTA assesses the effectiveness of health technologies in light of the funds used for their provision and whether resources are used efficiently. In this regard, SFDA should extend the scope of its current assessment methods and consider the costs related to the use of health technologies in addition to the evaluation of their effectiveness and safety.

Activity 1.1. Develop HTA guidelines for technologies relevant for SFDA, i.e. drug and medical devices

Result 1.2. Development of capacities on the regulation, evaluation and registration of new health technologies relevant for SFDA, i.e. drug and medical devices

Activity 1.2. Develop the capacity of SFDA Sectors on regulation, evaluation and registration of new drugs and medical devices

The main objective of the activity is to build the capacity of SFDA to regulate, evaluate and register novel drug and medical devices in Saudi Arabia. The activity will introduce international practice on regulation, evaluation and registration of new health technologies. Technical assistance will be provided to SFDA, specifically the Drug and Medical Devices Sector, and the Operation Sector through training courses and development of relevant reference materials.

Output 2. Risk Based Evaluation and Safe Use of Technologies

Result 2.1. Enhanced quality assurance practices

Activity 2.1. Develop capacity on the evaluation of comparability studies for blood and blood products

The main objective of the activity is to provide technical assistance to SFDA, specifically the Operation Sector, in the formulation of specific guidelines for the registration of blood and blood products, as well as the relevant tools and reference materials for dossier evaluation. The activity will deliver introductory courses on good tissue practice, existing policies, systems, and procedures for the registration of blood and blood products from benchmark countries such as the European Union (EU) and United States of America (USA), and internationally-recognized bodies such as the World Health Organisation (WHO) and country experience on the registration of these products. The activity will also develop blood and blood products evaluation and registration guidelines, process flow charts, internal procedures, and forms for evaluation.

Result 2.2. Assessment of health technologies used at healthcare providers in order to ensure their quality and safe use.

Beside medication errors on that patient safety initiatives focus in the clinical environment; medical devices also contribute significantly to patient injuries and deaths. Therefore, Saudi Food and Drug Authority should promote and support safe use of medical devices. Medical devices are subject to the general controls of SFDA according to its mandate. All manufacturers must register their

establishment, list any type of device they plan to market, and assure that their device is labelled in accordance with SFDA's regulations, before marketing clearance is given. Despite comprehensive control, safety concerns may arise with a device once it is on the market. To prevent injuries and death and to ensure safe use of medical devices, manufacturers and device users have to recognize and report problems that may contribute to poor patient outcomes. Lower risk devices require only documentation that proves they are as safe and effective as similar devices already on the market before receiving marketing clearance. However, once any device is marketed, it is subject to post-market surveillance controls.

Activity 2.2. Review international situation and best practices / benchmark for Saudi Arabia

The activity will compare international approaches to medical device regulation. It will describe how post market surveillance is organized differently in countries (e.g. highly-developed and emerging countries). The activity will analyse the strengths and weaknesses of pre-approval and post-approval surveillance systems for medical devices, along with presenting case studies according to different medical device categories. The review will highlight what the different medical device regulatory systems around the world can learn from each other.

Activity 2.3. Strengthen Supply Chain Management at SFDA Sectors

The activity will review the international pharmaceutical supply chain management systems, including systems and existing legal mandates that are currently in place or being considered (e.g. procurement and distribution systems by specific disease programs). The activity will also review inventory and order processing systems at the central and national levels. The activity will develop a national pharmaceutical supply chain management policy and implementation framework that addresses the supply chain management entirely (i.e. including burden of diseases, procurement, storage and distribution of drugs, and prescription processes with an appropriate monitoring framework, including performance indicators).

Activity 2.4. Training on Supply Chain Integrity of Health Products

The objective of the activity is to provide technical assistance to SFDA on the role of regulators on supply chain integrity of health products. The key tasks are to review the existing system, policies, procedures and processes on inspection related to Good Distribution Practices (GDP) and Good Storage Practices (GSP) of health products and to identify issues and gaps with the current systems, procedures and practices. In addition, an introductory course and classroom-type lectures/presentations, workshops will be delivered on existing policies, systems, procedures, and best practices on supply chain integrity of health products in benchmark countries.

Output 3. Continuation of Building Institutional and Staff Capacities

Result 3.1. Improved performance of SFDA regarding inspection of local market food business and water bottling plants

Activity 3.1. Improve SFDA's performance regarding inspection of local market food businesses and water bottling plants

The main objective of the activity is to develop clear regulatory requirements to ensure full compliance of local businesses and importers. Technical assistance will be provided in the implementation of Healthy Food Strategy.

Result 3.2. Established pesticide standards and related control infrastructure

Activity 3.2. Implement effective processes to operationalize pesticide safety standards as per SFDA's mandate

The main objectives of the activity are to ensure effective pesticide control and minimize the impact of pesticides on consumers, users and the environment. The tasks are to develop control mechanisms to minimize pesticide in agricultural and food products imported as well as in the local market.

Result 3.3. Reinforced safety of drugs, bio-products, health, herbal and veterinary products across the value chain

Activity 3.3. Review medicines post-marketing surveillance system and pharmacovigilance program

The objectives of the activity is to review and build capacity of SFDA Drug Sector by providing classroom-type lectures/presentations to all the participants and build their capacity in the identified areas such as: reporting forms and networks established, data collection, data management, evaluation, causality assessment, signal detection, risk communication, linkage with public health programs, risk-based approach for post-marketing surveillance.

The key tasks are to conduct a situational analysis of the current governance structure and tools used in the regulation of health commodities and equipment, human resources and facilities; review the existing policies on post-marketing surveillance and pharmacovigilance; assess the current internal process of SFDA, such as the coordination between offices both centrally and regionally and the current network of SFDA focusing on the coordination between SFDA and stakeholders and other government offices; identify issues, gaps, and bottlenecks with the current policies, systems, and procedures and come up with concrete recommendations for improvement with the current system; and identify alternative solution(s) based on a review of international regulatory models, their relevance to a predefined list of core principles and feasibility (i.e. cultural acceptability, institutional capacity, and political commitment).

Result 3.4. Developmed cosmetics standards and safety insurance of cosmetics products

Activity 3.4. Review database and cosmetics product registry

The activity will identify gaps in the current registration system and develop a strategic plan. Technical assistance will be provided to address current issues regarding the registry. The key tasks are to identify data entries that do not conform with the existing data entry rules; clean, correct and standardize entries in the registration and licensing database; and identify key requirements and specifications for cosmetics products registration system and outlining steps for improving the availability and use of strategic information for decision-making to ensure safety of cosmetics products.

Result 3.5. Established controls over manufacturing, import and export of medical devices

Activity 3.5. Develop the regulatory registration, evaluation, licensing / inspection of medical devices

The objective of the activity is to provide technical assistance to SFDA in the formulation of specific guidelines for the inspection, licensing, and registration of medical devices, as well as the relevant tools and reference materials for facility inspection and dossier evaluation. The activity includes the formulation of specific guidelines for registration of medical devices, provision of relevant reference materials as tools in marketing authorization dossier evaluation, and building capacity of SFDA through training courses in the inspection and licensing of establishments manufacturing and distributing medical devices, and in evaluation of applications for marketing authorization of these products, provision of relevant reference materials as tools in inspection, licensing, and marketing authorization dossier evaluation.

Result 3.6. Collection of best practice policies for specific / emerging product categories

Activity 3.6. Develop post marketing monitoring system and sampling methodology of health products

The objective of the activity is to provide technical assistance to SFDA in the development of guidelines on sampling methodology for all health products under SFDA's control. The key tasks are to review the existing system, policies, procedures, processes and practices in the conduct of collection of samples; identify issues and gaps with the current systems and procedures; deliver introductory courses in a classroom-type lectures/presentation, work-shops; and recommend on improvement of the current system by preparing guidelines, process flow charts, internal procedures, and forms for sampling.

Output 4. Regional and International Collaborations and Recognition

Result 4.1. SFDA role in the international community increased

Activity 4.1. Increase SFDA role in the international community by bringing SFDA together with international counterparts

The main objective of the activity is to increase SFDA role in the international community. The key tasks are to introduce SFDA to the international community and support bilateral / multilateral cooperation with international counterparts. Technical assistance will be provided in organizing international conference annually. The conference will provide SFDA with an opportunity for presenting the results of its regulatory function and establishing/developing partnership and cooperation with international counterparts in research. In addition, technical assistance will be provided in areas which are on the agenda of multilateral co-operations in the sectors relevant for SFDA. The activity will support SFDA by introducing experiences in regulating internal markets and the mutual acceptance of registration of drugs and medical devices by national regulatory bodies.

Result 4.2. Drug procurement processes and pricing policies developed

Regarding the region, the Gulf Health Council aims to unite the efforts of Gulf Cooperation Council Member States, among others the Kingdom of Saudi Arabia, to achieve unified Gulf Health Strategy. GHC is strengthening collaboration between regional organizations in the implementation of GCC Central Drug Registration Program to unify procurement and pricing for medicines.

Activity 4.2. Develop drug procurement processes

This activity would be particularly relevant and useful for strengthening the cooperation between SFDA and GHC. As SFDA as a leading regulator in GCC Member States has a key role regarding the plans and activities of GHC. The objectives of the activity are to review and recommend actions needed to put in place a national procurement system aligned with the system developed by GHC and introduced in the GCC Member States. The activity will strengthen SFDA in implementing the national drug procurement system and harmonize procedures at the central and national level. Further, the activity will define roles, functions and clear lines of responsibility for the complementary accountability mechanisms in place. The key tasks are to recommend on the establishment of medicine annual framework, international bidding, procurement system, and availability of quality medicines and medical supplies.

Activity 4.3. Develop drug pricing policies

The key tasks are to review the current pharmaceutical / drug pricing policies in Saudi Arabia and GCC Member States; update / determine the most relevant molecules / drugs in Saudi Arabia for price monitoring and regulation based on define criteria; recommend on new legislation; determine the formula for the price mark-ups of medicines in Saudi Arabia and GCC Member States.

Technical assistance will be provided to evaluate the current situation and recommend on the necessary development and changes in accordance with the regional policies of GHC. The activity will include an assessment of the following technical and administrative domains: pharmaceutical expenditure in Saudi Arabia and other GCC Member States; prices of medicines in Saudi Arabia and other GCC Member States; procurement processes in Saudi Arabia and other GCC Member States.

Output 5. Internal Communication and Organisational Culture

Result 5.1. Organisational culture and internal communication developed and strengthened

Changing an organization’s culture is one of the most difficult leadership challenges. That’s because an organization’s culture comprises an interlocking set of goals, roles, processes, values, communications practices, attitudes and assumptions. Changing a culture is a large-scale undertaking, and eventually all of the organizational tools for changing minds will need to be put in play.

Activity 5.1. Review organisational culture and recommend on developments

The main objective of the activity is to define a development strategy for strengthening SFDA organisational culture in order to make it a supporting factor to the effective performance of functions according to SFDA mandate. The strategy will include the review of SFDA vision and plans for the future, recommend steps of the implementation of management decisions, define roles and systems, and consider the measures to take to ensure the needed resources.

Result 5.2. Fine-tuned organisational structure and raised awareness on the intra-organisational job-share and cooperation between sectors

Activity 5.2. Fine-tune organisational structure and raise awareness on the intra-organisational job-share and cooperation between sectors

The main objective of the activity is to fine-tune organisational structure and raise awareness on the intra-organisational job-share and cooperation between sectors in order to improve performance at SFDA level. Technical assistance will be provided to SFDA in clarifying roles and responsibilities, fostering a collaborative and accountable culture, attracting and retaining skilled and trained workforce.

Output 6. External Communication and Awareness

Result 6.1. Improved external communication and raised awareness on SFDA roles and functions

Activity 6.1. Situational analysis of the Saudi regulatory and enabling environment

The main objective of the activity is to evaluate the environment and to recommend on actions and methodology towards the increase of awareness on SFDA roles and functions among the stakeholders in the professional community as well as the customers and consumers. The main tasks of the activity are to define the core principles and objectives of relevant health regulation and map the governance structure, mandates, frameworks, policies and activities of the national government, and determine whether they adhere to the core principles; assess the capacity of the concerned government offices to perform the basic regulatory functions of standards setting, informing, enforcing, performance monitoring, and legislative review; review international best practices and benchmarks applicable to the Saudi context; and design a research that will further improve the understanding of the regulatory environment and its recommendations enable SFDA to effectively address cultural acceptability and political support in its communication.

Result 6.2 Engaged proactively with the public and other external stakeholders to promote safe and informed use of products and foster trust in SFDA

International best practices and benchmarks can be useful for defining the necessary and applicable methods and communication tools.

Activity 6.2. Review clinical trial registration policies, systems, and procedures

The objectives of the activity are to conduct a review and revision of the existing policies, systems, and procedures for the registration of clinical trials, in particular, the registration requirements, internal evaluation process, and to identify issues and gaps, in addition to deliver introductory courses in good clinical practice from benchmark countries. The activity will recommend on preparation of guidelines, process flow charts, internal procedures and forms for evaluation.

Resources Required to Achieve the Expected Results

Across all outcomes, the project modes of engagement include the following inputs:

1. Capacity building.
2. Support to planning and implementing processes.
3. Enhancing internal systems and processes, and communications.
4. Raising awareness and cooperation.

5. Evidence generation and dissemination.

Partnerships

The Project will have the following partners/stakeholders: Ministry of Health; Ministry of Environment, Water and Agriculture; Ministry of Commerce and Investment; Gulf Health Council; sectoral agencies and associations (*Table 1*). Their interest in relation to the Project should be addressed by the Project considering the potential impact on the Project. The table below also presents the relative priority, which the Project will give to each stakeholder in meeting their interest.

Table 1. Stakeholder analysis

Stakeholders	**Interests**	**Potential project impact**	**Relative priorities of interest**
Ministry of Health	Regulation and supervision / control of SFDA Sectors	High	Medium
Ministry of Environment, Water and Agriculture	Regulating and cooperation with SFDA Food Sector	Medium	Low
Ministry of Commerce and Investment	Setting and carrying out commercial policies relevant for import of products under control of SFDA sectors	Medium	Low
Gulf Health Council	Regional cooperation and Central Drug Registration Program, incl. Drug pricing and procurement of drugs	Medium	Medium
Sectoral agencies and associations	Representing SFDA clients and customers	Low	Low

Risks and Assumptions

Overall key assumptions are a continued commitment to strengthen the health sector at national and local levels; policy dialogue between government and development partners to coordinate and further align development cooperation with national health strategy and policy; the Ministry of Health to maintain its strong stewardship role on the entire sector; and SFDA is able to build its capacities, in particular, designate, retain and recruit motivated and skilled staff to ensure the sustainability of interventions.

The following assumptions are also made for the Project to be successful, and that are believed to likely happen:

- Adequate human and financial resources will assure a smooth project implementation;
- Stability of the stakeholders and external working environment, which could be shaped by political and economic circumstances, throughout the whole project;
- Priority and importance of the Project is clearly stated and communicated to all parties involved;
- Stability and availability of qualified staff and experts, including staff with the necessary level of authority to make decisions, as and when required during the whole project lifecycle;

- The experts will work closely with the relevant sectors and departments in SFDA;
- All the necessary communication channels are established within the project and with other stakeholders;
- Appointed project experts fulfil their duties and are available for the required duration, in accordance with the project schedule;
- Continuous high-level support and promotion for the project;
- Requested information and documentation are available and provided;
- No changes in the legislative framework affecting negatively the healthcare system.

Apart from the failed assumptions, there may be a number of possible risks that may delay or prevent successful or timely achievement of the Project's objectives. A risk, in relation to the Project, can be defined as a possible event that could endanger the planned course or overall objective of the Project. The earlier the potential risks are identified, the quicker the proposed corrective action or mitigation plan can be implemented. The proposed mitigation plan for a risk usually depends on the likelihood of the risk and the measure of impact it will have on the project (*Table 2*).

Table 2 Risks and mitigation plan

Description of risk	**Probability**	**Impact**	**Mitigation plan**	**Responsible**
Lack of governance and capacity gaps to implement and monitor the strategy of Ministry of Health and the National Transformation Program in health	Low	Medium	Policy dialogue and capacity building	SFDA UNDP
Lack of cooperation on the part of SFDA or any of the stakeholders	Low	High	Implementation of an efficient project management structure and management processes	SFDA UNDP
Ineffective communication channels between UNDP/project team and SFDA, and within SFDA	Low	Medium	Pre-defined and approved communication channels	UNDP
Changes to the project requirements during the project	Low	Medium	Implementation of adequate project change management and controlling processes	UNDP
Retention of qualified staff and low commitment of the staff to the implementation of the project	Low	Medium	Taking measures to assure the availability as well as the requested quantity and quality of human resources The requirements are clearly defined during the Inception phase by UNDP	SFDA UNDP
Change or fluctuation in the composition of stakeholders	Low	Low	Continuous and overall stakeholder management during the project	SFDA UNDP
Changes in the organizational structure of the Ministry of Health	Low	Low	Providing timely and clear information on relevant changes in the organizational structure	SFDA
Misinterpretation of UNDP/project team tasks and deliverables	Medium	Medium	Careful description of activities and deliverables, refinement based on mutual understanding	SFDA UNDP

Description of risk	Probability	Impact	Mitigation plan	Responsible
Recruitment of specialized experts fails	Low	High	Advertise ToRs Expedite issuance of letter of appointment	UNDP
Lack of SFDA reporting and annual planning	Medium	Medium	Follow up with participating sectors, and link payment to status reporting	SFDA
Change of SFDA national project manager / coordinator	Low	High	Document and share project documentation with project team	SFDA
Unavailability of subject matter experts in certain scientific areas	Low	Medium	SFDA to post expert ToR ahead of time to avoid any delay	SFDA UNDP
Major changes to project scope	Low	Medium	Follow a change management process with signed change requests	SFDA UNDP
Language barrier	Low	Medium	Careful selection of experts Effective translation/interpreter service ensured by UNDP if needed	SFDA UNDP

In addition to the above-mentioned risks that were identified initially, there are a number of risks that may become apparent during the implementation of the Project. These can represent minor or major importance. It is assumed that the quality assurance systems of SFDA and UNDP will be sufficient to manage the small incidental risks that occur during the implementation of the Project. Regarding the management and mitigation of major risks that may arise during the course of Project implementation, that can only be achieved through the development of close collaboration between SFDA and UNDP and other stakeholders.

Stakeholder Engagement

The Project will significantly contribute to the health status of the Saudi people. The activities planned and to be achieved contribute towards better quality control and inspections, which are useful for the health and safety of population. The risk of food, feed and medicinal products on the market, which are falsified, of bad quality, with no active ingredients at all, etc., which might be fatal, especially for children or severe sick people, will be reduced.

The Project directly affects:

- The political and policy decision makers, as a number of laws, by-laws, and regulations need to be changed according to requirements due to the developed / improved processes / procedures of inspection, licensing and registration at SFDA.
- The employees of SFDA, whose capabilities will be developed through trainings received in the Project.
- The clients and customers of SFDA, whose manufacture, supply, wholesale and distribution are dependent on the regulatory function of SFDA, which will be strengthened in the project.

The Project will have social and environmental impacts. In addition, it will minimize, mitigate, and manage adverse impacts where avoidance is not possible, and ensure full and effective stakeholder engagement (please refer to UNDP's Social and Environmental Compliance Review and Stakeholder Response Mechanism).

The Project will affect the Saudi population, by ensuring access to better quality and controlled food and medicinal products. The social impacts of the Project will include the health gain and better

outputs of health care services due to application of quality diagnostics and therapeutic technologies and products.

Environmental impact is also expected from the strengthened / improved operation of SFDA. For instance, international standards require the implementation of management systems concerning environmental protection, like waste management.

The Project will have macroeconomic impact, too. SFDA's thorough control of medicinal products may increase the costs of operation (for instance, accredited laboratories may have higher running costs due to increase number of professionally qualified staff, high-tech equipment, regular maintenance, etc.), however, the consequently ensured quality and safe food and medicinal products, for instance, will reduce duration / severity of sicknesses, and create more safety for consumers.

South-South and Triangular Cooperation (SSC/TrC)

The new realities and current dynamics pose a number of unprecedented opportunities and challenges for achieving sustainable human development in the region. In this context, Overseas Development Assistance from Gulf Cooperation Countries and their South-South Cooperation is viewed as one of the potentially significant and effective drivers for change that offers a unique framework for identification and responding to the humanitarian and development challenges both regionally and globally. SFDA recognized as the regional leader in regards to food, drug and medical devices regulations, many countries among the Middle East are adopting the SFDA regulations and experiences about these products. SFDA also is leading many of recognized regional and international groups

The South-South Cooperation is a driver for development in Saudi Arabia. It includes dimensions directly or indirectly related to Saudi Arabia's national priorities. Therefore, it could help to further catalyse and speed up the process of development of Saudi Arabia in various domains, among others those related to the Sustainable Development Goals.

SDGs Achievement

Sustainable Development Goal (SDG) 3 is to ensure healthy lives and promote well-being for all at all ages. Among the targets there are actions aiming at increasing life expectancy and reducing mortality, and others that are to improve delivery of health care. While former require efforts to eradicate a wide range of diseases and address many different persistent and emerging health issues, latter ones focus on providing more efficient funding of health systems, increased access to health care, among some other key actions

SGD 3 targets are particularly relevant for SFDA. The Project's outputs were designed in accordance with the key areas where SFDA has responsibility for and can contribute to the safety and health of Saudi people through the regulation and control of food, drug and medical devices. The Project outputs and activities have impact on SFDA's functions and performance, which are linked with the targets of SDG3, consequently the Project contributes towards the achievement of SDGs.

Sustainability and Scaling Up

Sustainability of the Project requires consideration of the following aspects when addressing long-term impacts and outcome of project implementation:

***Governance*:**

- The Project maintains strong ownership of SFDA in regulation regarding food, drug and medical devices products.
- The Project is beneficiary-driven targeting capacity building.
- Strong leadership and governance are required. Leadership at the technical level is as critical as governance at the highest level.

***Access to health*:**

- There is a need for a legal framework for operationalization and implementation of regulatory function regarding food, drug and medical devices.

***Funding*:**

- Strengthened coordination of financial / funding sources is essential.
- Encouragement of efficient use of resources.

***Culture*:**

- Improved multi-sector collaboration.
- Impact of the project on SFDA, its clients and consumers.

***Health information*:**

- Development of IT systems and data management.

***Innovation*:**

- Sustainability requires institutional capacity building and additional staff with the needed skills and accompanying technology acquisition.

Improved performance in all relevant sectors and activities of SFDA (e.g. inspection) can generate higher income through new contracts, like analytical services, and from additional sources, like new clients. These revenues can supplement contributions from the government which may not be sufficient to cover the increased running costs. Developing the skills and competences of the staff, enlarging the scope of work of laboratories portfolio by introducing new modern analytical methods, creating more efficient organisation and management, and ensuring information exchange with International partners will also support sustainability of the improved performance of SFDA.

IV. PROJECT MANAGEMENT

Cost Efficiency and Effectiveness

The selected strategy of the intervention will deliver maximum results within the available funds. The Project is built upon the successful achievement of the previous strategic plans of SFDA, in addition to the broad scope of international experience and knowledge/awareness of best practices relevant for the Project in Saudi Arabia, which UNDP can bring into the intervention through mobilization of its team of experts. International best practices and lessons learnt in benchmark countries will be used to explore different options to achieve the maximum results. UNDP Country Office will ensure the utilization of resources and to cover all budgeted costs of project activities in accordance with the approved project budget.

Project Management

The Project will be administered jointly by SFDA as Beneficiary and UNDP Country Office in Riyadh. A Chief Technical Advisor / Team Leader (CTA) will be appointed to manage the project as well as oversee all technical project activities, monitor progress and report to UNDP via progress reports (quarterly and annually, too). The National Project Manager will be appointed by SFDA and has the authority to run the Project on a day-to-day basis on behalf of the Project Board within the constraints laid down by the Project Board. The CTA will submit the progress reports to the Project Board and act as a secretariat to the Board. The National Project Manager is responsible for the day-to-day management and decision making for the Project. The Project Board is the group responsible for making on consensus basis management decisions for the Project when guidance is required by the National Project Manager, including recommendation for approval of project revisions. In addition, internal coordination and monitoring bodies will be established including the necessary working groups and the committees, as needed.

The Project Board will meet at least one a year to review progress made, agree on the annual work plan and address issues raised by the CTA. A mid-term evaluation and a terminal evaluation will be conducted to assess achievements of the project, impact, efficiency and effectiveness. The results of both evaluations are to be present to the project Board.

The UNDP country office shall sponsor, at the request of SFDA, all project international individual contractors to be supplied in writing by the Project Manager to the UNDP, and also shall process all requests for visas and resident permit.

V. RESLUT FRAMWORK

Intended Outcome as stated in the Country Programme Results and Resource Framework: ***Public sector strengthened through improved efficiency, effectiveness, equity and accountability***

Outcome indicators as stated in the Country Programme Results and Resources Framework, including baseline and targets: ***Ease of Doing Business rank***

Applicable Output(s) from the UNDP Strategic Plan: ***Outcome 3: Countries have strengthened institutions to progressively deliver universal access to basic services***

Project title and Atlas Project Number: ***SAU10/115227 - Support SFDA Third Strategic Plan Implementation***

EXPECTED OUTPUTS	OUTPUT INDICATORS	DATA SOURCE	BASELINE		TARGETS (by frequency of data collection)						DATA COLLECTION METHODS & RISKS
			Value	Year	Year 1	Year 2	Year 3	Year 4	Year …	FINAL	
Output 1. **Assessment of the Safety and Effectiveness of New Drugs and Medical Devices**	1.1 National HTA guidelines	SFDA	0	2018		100%				100%	National policy documents
	1.2 Expert visits to support SFDA in building capacities	SFDA	60%	2018	70%	80%	90%	100%		100%	Project Reports
Output 2. **Risk Based Evaluation and Safe Use of Technologies**	2.1 Quality assurance practice documents	SFDA	0	2018	25%	50%	75%	100%		100%	National policy documents
	2.2 Report on assessment of health technologies used at healthcare providers in order to ensure their quality and safe use	SFDA	0	2018		100%				100%	National policy documents and reports
Output 3. **Continuation of Building Institutional and Staff Capacities**	3.1 Performance indicators / reports on inspection of local market food business and water bottling plants	SFDA		2018		100%				100%	Reports
	3.2 Pesticide standards and related control infrastructure	SFDA		2018						100%	National policy documents and reports
	3.3 Reports / documents on safety of drugs, bio-products, health, herbal and veterinary products across the value chain	SFDA		2018						100%	National policy documents and reports
	3.4 Reports / documents on cosmetics standards and safety of cosmetics products	SFDA		2018	25%	50%	75%	100%		100%	National policy documents and reports
	3.5 Reports / documents on control over manufacturing, import and export of medical devices	SFDA		2018						100%	National policy documents and reports
	3.6 Best practice policies for specific / emerging product categories	SFDA		2018						100%	National policy documents and reports

Output 4. **Regional and International Collaborations and Recognition**	4.1 Reports on international conferences and cooperation agreements on international research	SFDA	0	2018	25%	50%	75%	100%		100%	Project Reports
	4.2 Relevant documents on drug procurement and pricing policies	SFDA GHC		2018						100%	National policy documents and reports
Output 5. **Internal Communication and Organisational Culture**	5.1 Regulating documents / Standard operational procedures	SFDA		2018						100%	National policy documents and reports
	5.2 Internal organisational / communication guidelines	SFDA		2018	Yes	Yes	Yes	Yes		100%	SFDA strategy and policy documents
Output 6. **External Communication and Awareness**	6.1 Relevant documents (e.g. publications, media reports, memorandums / agreements, etc.)	SFDA		2018						100%	Media sources
	6.2 Relevant documents (e.g. research papers, publications, etc.)	SFDA		2018						100%	Scientific publications

V. MONITORING AND EVALUATION

In accordance with UNDP Programme and Operations Policies and Procedures (POPP) outlined in the UNDP User Guide, the Project will be monitored through the following:

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 captured in quality management table below;
- An issue log shall be activated in Atlas and updated by the Project Manager to facilitate tracking and resolution of potential problems or requests for change;
- Based on the initial risk analysis, a risk log shall be activated in Atlas and regularly updated by reviewing the external environment that may affect the project implementation.

Based on the above information recorded in Atlas, a Project Progress Report (PPR) shall be submitted by the Project Manager to the Project Board through Project Assurance using the standard report format available in the executive snapshot. Project lessons-learned log shall be activated and regularly updated to ensure ongoing learning and adaptation within the organization, and to facilitate the preparation of the lessons learned report at end of project.

- Monitoring schedule plan shall be activated in Atlas and updated to track key management actions/events.

within the annual cycle

- Annual review report – An annual review report shall be prepared by the Project Manager and shared with the Project Board. As minimum requirement, the annual review report shall consist of the Atlas standard format for the Quarterly Progress Reports (QPR) covering the whole year with updated information for each above element of 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 for the following year. In the last year this review will be the final assessment. This review is driven by the Project Board and may involve others as required. It shall focus on the extent to which progress is being made towards output, and that these remain aligned to appropriate outcomes.
- Project Quarterly Progress Report (QPR) – Progress reports will be submitted by the National Project Coordinator to Project Assurance and to the Outcome Board. Such progress reports should form a basis for decisions regarding further disbursement of UNDP resources.

In accordance with UNDP's programming policies and procedures, the project will be monitored through the following monitoring and evaluation plans (*Table 4-5*.).

Table 4. Monitoring Plan

Monitoring Activity	Purpose	Frequency	Expected Action	Partners (if joint)	Cost (if any)
Track results progress	Progress data against the results indicators in the RRF will be collected and analysed to assess the progress of the project in achieving the agreed outputs.	Quarterly, or in the frequency required for each indicator.	Slower than expected progress will be addressed by project management.		
Monitor and Manage Risk	Identify specific risks that may threaten achievement of intended results. Identify and monitor risk management actions using a risk log. This includes monitoring measures and plans that may have been required as per UNDP's Social and Environmental Standards. Audits will be conducted in accordance with UNDP's audit policy to manage financial risk.	Quarterly	Risks are identified by project management and actions are taken to manage risk. The risk log is actively maintained to keep track of identified risks and actions taken.		
Learn	Knowledge, good practices and lessons will be captured regularly, as well as actively sourced from other projects and partners and integrated back into the project.	At least annually	Relevant lessons are captured by the project team and used to inform management decisions.		
Annual Project Quality Assurance	The quality of the project will be assessed against UNDP's quality standards to identify project strengths and weaknesses and to inform management decision making to improve the project.	Annually	Areas of strength and weakness will be reviewed by project management and used to inform decisions to improve project performance.		
Review and Make Course Corrections	Internal review of data and evidence from all monitoring actions to inform decision making.	At least annually	Performance data, risks, lessons and quality will be discussed by the project board and used to make course corrections.		
Project Report	A progress report will be presented to the Project Board and key stakeholders, 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 long with mitigation measures,	Annually, and at the end of the project (final report)			

	and any evaluation or review reports prepared over the period.				
Project Review (Project Board)	The project's governance mechanism (i.e., project board) will hold regular project reviews to assess the performance of the project and review the Multi-Year Work Plan to ensure realistic budgeting over the life of the project. 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 and to socialize project results and lessons learned with relevant audiences.	Specify frequency (i.e., at least annually)	Any quality concerns or slower than expected progress should be discussed by the project board and management actions agreed to address the issues identified.		
Mid-term Evaluation	To ensure outputs and activities are aligned with strategy and carried on in a timely and relevant manner and to correct course of action if needed	May 2021	Independent mid-term evaluation		SFDA
Final Evaluation	For future planning and lessons learned	End 2022	Independent Final Evaluation		SFDA

VI. **MULTI-YEAR WORK PLAN,** *TABLE 6. MULTI-YEAR WORK PLAN2019 -2022*

EXPECTED OUTPUTS	PLANNED ACTIVITIES	Planned Budget by Year				RESPONSIBLE PARTY	PLANNED BUDGET		
		2019	2020	2021	2022		Funding Source	Budget Description	Amount
Output 1. **Assessment of the Safety and Effectiveness of New Drugs and Medical Devices**	1.1 Activity Develop HTA guidelines for technologies relevant for SFDA, i.e. drug and medical devices	250,000 USD	250,000 USD	250,000 USD	250,000 USD	SFDA		Experts Travel Workshops	1,000,000 USD
	1.2 Activity introduce international practice on regulation, evaluation and registration of new health technologies; - deliver training and develop training materials for Drug and Medical Devices Sectors, and the Operation Sector. 1.3 Activity - Perform skillset and capabilities gap analysis and determine development needs 1.4 Activity - Implement internal competency framework for MD evaluation and associated development opportunities in line with capability development framework, in collaboration with HR (e.g., induction/ yearlong training program for evaluators, tracking mechanism for type and technical area of training)	500,000 USD	500,000 USD	500,000 USD	500,000 USD	SFDA		Experts Travel Workshops Study tours	2,000,000 USD
	Sub-Total for Output 1								**3,000,000 USD**

EXPECTED OUTPUTS	PLANNED ACTIVITIES	Planned Budget by Year				RESPONSIBLE PARTY	PLANNED BUDGET		
		2019	2020	2021	2022		Funding Source	Budget Description	Amount
Output 2. **Risk Based Evaluation and Safe Use of Technologies**	2.1 Activity Develop capacity on the evaluation of comparability studies for blood and blood products - develop guidelines for the registration of blood and blood products and the relevant tools and reference materials for dossier evaluation; - deliver training courses on good tissue practice, existing policies, systems, and procedures for the registration of blood and blood products; - develop blood and blood products evaluation and registration guidelines, process flow charts, internal procedures, and forms for evaluation.	250,000 USD	250,000 USD	250,000 USD	250,000 USD	SFDA		Experts Travel Workshops Study tours	1,000,000 USD
	2.2 Activity Review international situation and best practices / benchmark for Saudi Arabia - compare international approaches to medical device regulation and describe how post market surveillance is organized in different countries; - analyse the strengths and weaknesses of pre-approval and post-approval surveillance systems for medical devices and present case studies according to different medical device categories.	250,000 USD	250,000 USD	250,000 USD	250,000 USD	SFDA		Experts Travel Workshops Study tours	1,000,000 USD

	2.3 Activity Strengthen Supply Chain Management at SFDA Sectors - review international pharmaceutical supply chain management systems, including systems and existing legal mandates that are currently in place or being considered (e.g. procurement and distribution systems by specific disease programs); - review inventory and order processing systems at the central and national levels; - develop a national pharmaceutical supply chain management policy and implementation framework that addresses the supply chain management entirely.	250,000 USD	250,000 USD	250,000 USD	250,000 USD	SFDA		Experts Travel Workshops Study tours	1,000,000 USD

	2.4 Activity Training on Supply Chain Integrity of Health Products - review the existing system, policies, procedures and processes on inspection related to Good Distribution Practices (GDP) and Good Storage Practices (GSP) of health products, and identify issues and gaps with the current systems, procedures and practices; - deliver training course and workshop on existing policies, systems, procedures, and best practices on supply chain integrity of health products in benchmark countries. 2.5 Activity Develop and publish best practices for safe use of medical devices for healthcare providers to describe the best practice of medical device management within facilities 2.6 Activity Identify with relevant local KSA experts, identify scientific committee chairs and complete SFDA's conflict of interest paperwork in order to support the different scientific committees as members (key pharmaceutical topics include sterile products	250,000 USD	250,000 USD	250,000 USD	250,000 USD	SFDA		Experts Travel Workshops Study tours	1,000,000 USD
	Sub-Total for Output 2								**4,000,000 USD**

EXPECTED OUTPUTS	PLANNED ACTIVITIES	Planned Budget by Year				RESPONSIBLE PARTY	PLANNED BUDGET		
		2019	2020	2021	2022		Funding Source	Budget Description	Amount
Output 3. **Continuation of Building Institutional and Staff Capacities**	3.1 Activity Improve SFDA's performance regarding inspection of local market food businesses and water bottling plants - develop regulatory requirements to ensure full compliance of local businesses and importers; - deliver training course on the implementation of Healthy Food Strategy.	200,000 USD	200,000 USD	200,000 USD	200,000 USD	SFDA		Experts Travel Workshops Study tours	800,000 USD
	3.2 Activity Implement effective processes to operationalize pesticide safety standards as per SFDA's mandate - develop control mechanisms to minimize pesticide in agricultural and food products imported as well as in the local market.	200,000 USD	200,000 USD	200,000 USD	200,000 USD	SFDA		Experts Travel Workshops Study tours	800,000 USD

	3.3 Activity Review medicines post-marketing surveillance system and pharmacovigilance program - deliver training on post-marketing surveillance and pharmacovigilance (incl. reporting forms and networks, data collection, data management, evaluation, causality assessment, signal detection, risk communication, linkage with public health programs, risk-based approach for post-marketing surveillance) for SFDA Drug Sector; - conduct a situational analysis of the current governance structure and tools used in the regulation of health commodities and equipment, human resources and facilities; - review the existing policies on post-marketing surveillance and pharmacovigilance; - assess the current internal process of SFDA, such as the coordination between offices both centrally and	250,000 USD	250,000 USD	250,000 USD	250,000 USD	SFDA		Experts Travel Workshops Study tours	1,000,000 USD

	regionally and the current network of SFDA focusing on the coordination between SFDA and stakeholders and other government offices; - identify issues, gaps, and bottlenecks with the current policies, systems, and procedures and come up with concrete recommendations for improvement with the current system; - identify alternative solution(s) based on a review of international regulatory models, their relevance to a predefined list of core principles and feasibility (i.e. cultural acceptability, institutional capacity, and political commitment).								

	3.4 Activity Review database and cosmetics product registry - identify gaps in the current registration system and develop a strategic plan; - identify data entries that do not conform with the existing data entry rules; - clean, correct and standardize entries in the registration and licensing database; - identify key requirements and specifications for cosmetics products registration system and outlining steps for improving the availability and use of strategic information for decision-making to ensure safety of cosmetics products.	200,000 USD	200,000 USD	200,000 USD	200,000 USD	SFDA		Experts Travel Workshops Study tours	800,000 USD

	3.5 Activity Develop the regulatory registration, evaluation, licensing / inspection of medical devices - formulate specific guidelines for registration of medical devices, provision of relevant reference materials as tools in marketing authorization dossier evaluation, - deliver training courses in the inspection and licensing of establishments manufacturing and distributing medical devices, and in evaluation of applications for marketing authorization of these products, provision of relevant reference materials as tools in inspection, licensing, and marketing authorization dossier evaluation.	250,000 USD	250,000 USD	250,000 USD	250,000 USD	SFDA		Experts Travel Workshops Study tours	1,000,000 USD

	3.6 Activity Develop post marketing monitoring system and sampling methodology of health products - review the existing system, policies, procedures, processes and practices in the conduct of collection of samples; - identify issues and gaps with the current systems and procedures; - deliver introductory courses in a classroom-type lectures/presentation, work-shops; - recommend on improvement of the current system by preparing guidelines, process flow charts, internal procedures, and forms for sampling.	200,000 USD	200,000 USD	200,000 USD	200,000 USD	SFDA		Experts Travel Workshops Study tours	800,000 USD
	Sub-Total for Output 3								**5,200,000 USD**

EXPECTED OUTPUTS	PLANNED ACTIVITIES	Planned Budget by Year				RESPONSIBLE PARTY	PLANNED BUDGET		
		2019	2020	2021	2022		Funding Source	Budget Description	Amount
Output 4. **Regional and International Collaborations and Recognition**	4.1 Activity Increase SFDA role in the international community by bringing SFDA together with international counterparts - introduce SFDA to the international community and support bilateral/multilateral cooperation with international counterparts; - organize international conference annually - organize meetings/workshops in areas which are on the agenda of multilateral co-operations in the sectors relevant for SFDA.	250,000 USD	250,000 USD	250,000 USD	250,000 USD	SFDA		Experts Travel Workshops Conference Study tours	1,000,000 USD

	4.2 Activity Develop drug procurement processes - review and recommend actions needed to put in place a national procurement system aligned with the system developed by GHC and introduced in the GCC Member States; - deliver training in implementing the drug procurement systems and harmonize procedures at the central and national level; - define roles, functions and clear lines of responsibility for the complementary accountability mechanisms in place; - recommend on the establishment of medicine annual framework, international bidding, procurement system, and availability of quality medicines and medical supplies.	100,000 USD	100,000 USD	100,000 USD	100,000 USD	SFDA		Experts Travel Workshops Study tours	400,000 USD

	4.3 Activity Develop drug pricing policies - review the current pharmaceutical / drug pricing policies in Saudi Arabia and GCC Member States; - update / determine the most relevant molecules / drugs in Saudi Arabia for price monitoring and regulation based on define criteria; - recommend on new legislation; - determine the formula for the price mark-ups of medicines in Saudi Arabia and GCC Member States; - evaluate the current situation and recommend on the necessary development and changes in accordance with the regional policies of GHC.	150,000 USD	150,000 USD	150,000 USD	150,000 USD	SFDA		Experts Travel Workshops Study tours	600,000 USD
	Sub-Total for Output 4								**2,000,000 USD**

EXPECTED OUTPUTS	PLANNED ACTIVITIES	Planned Budget by Year				RESPONSIBLE PARTY	PLANNED BUDGET		
		2019	2020	2021	2022		Funding Source	Budget Description	Amount
Output 5. **Internal Communication and Organisational Culture**	5.1 Activity Review organisational culture and recommend on developments - define development strategy for strengthening SFDA organisational culture in order to make it a supporting factor to the effective performance of functions according to SFDA mandate; - review of SFDA vision and plans for the future, - recommend steps of the implementation of management decisions, - define roles and systems considering the measures to take to ensure the needed resources.	50,000 USD	50,000 USD	50,000 USD	50,000 USD	SFDA		Experts Travel Workshops	200,000 USD

	5.2 Activity Fine-tune organisational structure and raise awareness on the intra-organisational job-share and cooperation between sectors - support SFDA in clarifying roles and responsibilities, fostering a collaborative and accountable culture, attracting and retaining skilled and trained workforce. 5.3 Activity Develop SFDA's change management framework: consultant to validate the change management framework and participate in pilot phase	50,000 USD	50,000 USD	50,000 USD	50,000 USD	SFDA		Experts Travel Workshops	200,000 USD
	Sub-Total for Output 5								**400,000 USD**

EXPECTED OUTPUTS	**PLANNED ACTIVITIES**	**Planned Budget by Year**				**RESPONSIBLE PARTY**	**PLANNED BUDGET**		
		2019	2020	2021	2022		Funding Source	Budget Description	Amount

Output 6. **External Communication and Awareness**	6.1 Activity Situational analysis of the Saudi regulatory and enabling environment - evaluate the environment and recommend on actions and methodology towards the increase of awareness on SFDA roles and functions among the stakeholders in the professional community as well as the customers and consumers; - define the core principles and objectives of relevant health regulation and map the governance structure, mandates, frameworks, policies and activities of the national government, and determine whether they adhere to the core principles; - assess the capacity of the concerned government offices to perform the basic regulatory functions of standards setting, informing, enforcing, performance monitoring, and legislative review; - review international best practices and benchmarks	100,000 USD	100,000 USD	100,000 USD	100,000 USD	SFDA		Experts Travel Workshops	400,000 USD

	applicable to the Saudi context; - design a research that will further improve the understanding of the regulatory environment and its recommendations enable SFDA to effectively address cultural acceptability and political support in its communication.								
	6.2 Activity Review clinical trial registration policies, systems, and procedures - conduct a review and revision of the existing policies, systems, and procedures for the registration of clinical trials, - identify issues and gaps, - deliver training courses in good clinical practice from benchmark countries; - recommend on preparation of guidelines, process flow charts, internal procedures and forms for evaluation.	50,000 USD	50,000 USD	50,000 USD	50,000 USD	SFDA		Experts Travel Workshops	200,000 USD
	Sub-Total for Output 6								**600,000 USD**

EXPECTED OUTPUTS	PLANNED ACTIVITIES	Planned Budget by Year				RESPONSIBLE PARTY	PLANNED BUDGET		
		2019	2020	2021	2022		Funding Source	Budget Description	Amount USD
Sub-total						SFDA/UNDP	GCS		15,200,000
Evaluations (mid-term/ terminal)									25,000
Miscellaneous and audit									93,617
Sub-total									15,318,617
General Management Support (3%)									459,558
Direct Project Costing (4%)									612,745
TOTAL									**16,390,920 USD**

VII. GOVERNANCE AND MANAGEMENT ARRANGEMENTS

Execution Arrangements

The Project will be nationally executed through SFDA. SFDA will assume implementation responsibilities with UNDP for recruitment of international and national advisors and other activities as noted in the annual work plan. All project activities will be done through standard project board mechanism to serve as a steering committee between SFDA and UNDP to ensure coherence of all activities under the project. UNDP will provide technical support to all activities through the UNDP Country Office in Riyadh and other related resources as appropriate.

Project Board

The Project Board is the group responsible for making on consensus basis management decisions for the Project when guidance is required by the National Project Manager, including recommendation for approval of project revisions. Project reviews by this group are made on annual basis, or as necessary when raised by the National Project Manager. The group is consulted by the National Project Manager for decisions. This group has two roles, one for executive representing the project ownership to chair the group, and senior supplier role to provide guidance regarding technical assistant to the project.

Project Assurance

Project assurance is the responsibility of each Project Board member, but the role can be delegated to a staff within each organization. The project assurance role supports the Project Board by carrying out objective and independent project oversight and monitoring functions. This role ensure appropriate project management milestones are managed and completed. The Assistant Deputy Resident Representative (ARR) UNDP Saudi Arabia will hold the Project Assurance role for the UNDP, and coordinator of SFDA would undertake this role for SFDA. The National Project Manager and Project Assurance roles will never be held by the same individual in SFDA.

Chief Technical Adviser/Team Leader

The CTA will be appointed under the project and has the responsibility to provide technical advice to the National Project Manager and SFDA on project implementation. The CTA will prepare the annual APRs and AWPs for the project and submit to the Board for clearance. The CTA is to monitor progress and update issues and risks logs and present to Board. The CTA is to provide technical high level advise to the SFDA.

National Project Manager

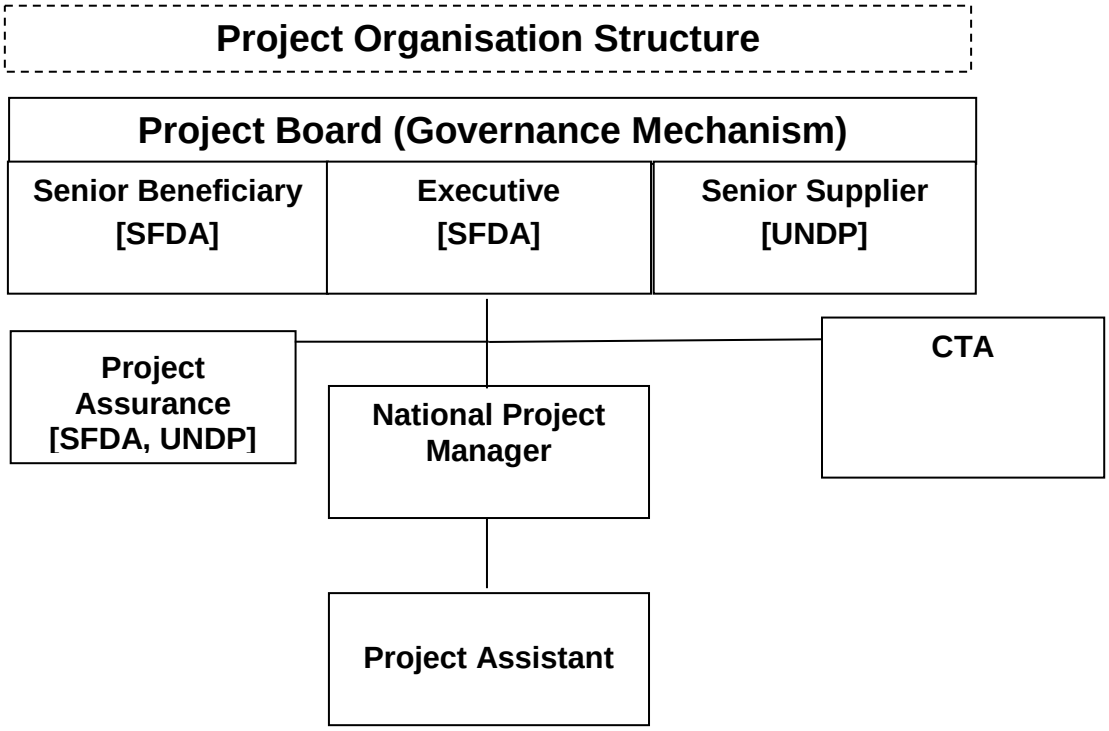
The National Project Manager (NPM) will be appointed by SFDA and has the authority to run the Project on a day-to-day basis on behalf of the Project Board within the constraints laid down by the Project Board. The National Project Manager is responsible for the day-to-day management and decision making for the Project.

The Project Manager's prime responsibility is to ensure that the Project produces the results specified in the Project Document, to the required standard of quality and within the specific constraints of time and cost. The National Project Manager is appointed by SFDA through letter to UNDP. SFDA will also provide counterpart staff, offices facilities and necessary office equipment (including computers) for project staff, and any other project support facilities as deemed necessary.

Project Assistant

The Project Assistant will be appointed by SFDA with the responsibility to carry on the day-to-day administrative and financial project support.

Figure 1 introduces the governance and management arrangements for the Project.



VIII. LEGAL CONTEXT AND RISK MANAGEMENT

Legal Context Standard Clauses

This project document shall be the instrument referred to as such in Article 1 of the Standard Basic Assistance Agreement between the Government of the Kingdom of Saudi Arabia and UNDP, signed on (4 January 1976). All references in the SBAA to "Executing Agency" shall be deemed to refer to "Implementing Partner."

This project will be implemented by the Saudi Food and Drug Authority ("Implementing Partner") in accordance with its financial regulations, rules, practices and procedures only to the extent that they do not contravene the principles of the Financial Regulations and Rules of UNDP. Where the financial governance of an Implementing Partner does not provide the required guidance to ensure best value for money, fairness, integrity, transparency, and effective international competition, the financial governance of UNDP shall apply**.**

Risk Management Standard Clauses

1. Consistent with the Article III of the SBAA, 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. To this end, 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.
2. 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 the Implementing Partner's obligations under this Project Document.
3. The Implementing Partner agrees to undertake all reasonable efforts to ensure that no 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/sc/committees/1267/aq_sanctions_list.shtml. This provision must be included in all sub-contracts or sub-agreements entered into under/further to this Project Document.
4. Consistent with UNDP's Programme and Operations Policies and Procedures, social and environmental sustainability will be enhanced through application of the UNDP Social and Environmental Standards (http://www.undp.org/ses) and related Accountability Mechanism (http://www.undp.org/secu-srm).
5. The Implementing Partner shall: (a) conduct project and programme-related activities in a manner consistent with the UNDP Social and Environmental Standards, (b) implement any management

or mitigation plan prepared for the project or programme to comply with such standards, and (c) engage in a constructive and timely manner to address any concerns and complaints raised through the Accountability Mechanism. UNDP will seek to ensure that communities and other project stakeholders are informed of and have access to the Accountability Mechanism.

6. All signatories to the Project Document shall cooperate in good faith with any exercise to evaluate any programme or project-related commitments or compliance with the UNDP Social and Environmental Standards. This includes providing access to project sites, relevant personnel, information, and documentation.

IX. ANNEXES

1. Terms of Reference for Project Board
2. Terms of Reference for Chief Technical Advisor / Team Leader
3. Social and Environmental Risk Screening
4. Standard Letter of Agreement for the Provision of Support Services
5. Schedule of Payments

ANNEX 1. TERMS OF REFERENCE FOR PROJECT BOARD

Background

Saudi Food and Drug Authority (SFDA) completed the implementation of its First Strategic Plan between 2007-2011 and Second Strategic Plan between 2012-2016. SFDA approached the United Nations Development Programme (UNDP) to seek technical assistance in achieving its strategic plans. Based upon UNDP's comparative and competitive advantages in providing the required technical support, SFDA requests to further collaborate in achieving its strategic goals set out in SFDA Third Strategic Plan (2018-2022).

In this context, UNDP is to provide substantive support to SFDA, through enabling SFDA to implement food, drug and medical devices strategic goals and initiatives laid out in SFDA Third Strategic Plan; as well as develop the required institutional capacity to discharge its mandate and ultimately meet the national development plan's aspiration to achieve its vision. The overall objective of the Project is to support SFDA in implementing its Third Strategic Plan.

This nationally executed project aims at providing advisory services, specialized experts, and administrative support to SFDA. In the process, these activities will help in developing the authority's policy, advocacy, and executing capacity in the areas of food, drugs and medical devices.

The above vision of the Project is attained through the following interventions (project objectives):

1. Develop Health Technology Assessment guidelines and improve capacities in assessment of the safety and effectiveness of new drugs and medical devices;
2. Improve quality assurance practices and develop patient safety policy documents and practice guidelines focusing on risk-based evaluation and safe use of technologies;
3. Build capacities in all relevant areas as per SFDA mandate;
4. Increase role of SFDA through regional and international collaborations and recognition;
5. Strengthen organisational culture and improve internal communication;
6. Improve external communication and raised awareness on SFDA roles and functions.

The project is coordinated by the United Nations Development Program in Riyadh, the Kingdom of Saudi Arabia.

Role and Main Functions

The Project Board is the group responsible for making on consensus basis management decisions for the Project when guidance is required by the National Project Manager, including recommendation for approval of project revisions. Project reviews by this group are made on annual basis, or as necessary when raised by the National Project Manager. The group is consulted by the National Project Manager for decisions. This group has two roles, one for executive representing the project ownership to chair the group, and senior supplier role to provide guidance regarding technical assistant to the project.

The Project Board will be responsible for the overall co-ordination, direction and oversight of the Project. The Project Board will guide SFDA and UNDP Technical Assistance Team in achieving the project activities and tasks, monitors progress of the project activities and ensures timely achievement of results as set out in the Project Document.

The role and main functions of the Project Board will be:

- To assess project progress and monitor all activities of the Project, as stipulated in the Project Document;
- To assess the performance of the Technical Assistance Team, consider the progress reports, and make recommendations as appropriate;
- To jointly discuss any critical points or bottlenecks for further project implementation and to propose and discuss remedy actions to be taken in order to tackle problems;
- To guide the development and monitor the implementation of individual schedules or work plans of the project, and jointly take decisions affecting timing, cost or project contents;
- To ensure close co-operation with relevant ministries and institutions, partner organisations, and other relevant actors, taking into account the complexity and ensuring transparency of the project;
- To facilitate access to the required institutions and information needed for the project implementation;
- To ensure that all reporting requirements of both the UNDP and the national authorities are met;
- To ensure compliance with the legal, regulatory and technical requirements in the Kingdom of Saudi Arabia.

The Chief Technical Advisor / Team Leader will organise Project Board meetings every six months, if not required and agreed otherwise. The Chief Technical Advisor / Team Leader will invite the Project Board members for the meetings. Minutes of meetings will be taken and distributed to all attendees.

The Chief Technical Advisor / Team Leader will submit the Progress Reports to the members of the Project Board at least one week prior to Project Board meetings. The Project Board will review the reports, advise, give guidance and ensure that appropriate measures are put in place to maximize the benefits of the project.

ANNEX 2. TERMS OF REFERENCE FOR CHIEF TECHNICAL ADVISOR / TEAM LEADER

Background

Saudi Food and Drug Authority (SFDA) completed the implementation of its First Strategic Plan between 2007-2011 and Second Strategic Plan between 2012-2016. SFDA approached the United Nations Development Programme (UNDP) to seek technical assistance in achieving its strategic plans. Based upon UNDP's comparative and competitive advantages in providing the required technical support, SFDA requests to further collaborate in achieving its strategic goals set out in SFDA Third Strategic Plan (2018-2022).

In this context, UNDP is to provide substantive support to SFDA, through enabling SFDA to implement food, drug and medical devices strategic goals and initiatives laid out in SFDA Third Strategic Plan; as well as develop the required institutional capacity to discharge its mandate and ultimately meet the national development plan's aspiration to achieve its vision. The overall objective of the Project is to support SFDA in implementing its Third Strategic Plan.

This nationally executed project aims at providing advisory services, specialized experts, and administrative support to SFDA. In the process, these activities will help in developing the authority's policy, advocacy, and executing capacity in the areas of food, drugs and medical devices.

The above vision of the Project is attained through the following interventions (project objectives):

1. Develop Health Technology Assessment guidelines and improve capacities in assessment of the safety and effectiveness of new drugs and medical devices;
2. Improve quality assurance practices and develop patient safety policy documents and practice guidelines focusing on risk-based evaluation and safe use of technologies;
3. Build capacities in all relevant areas as per SFDA mandate;
4. Increase role of SFDA through regional and international collaborations and recognition;
5. Strengthen organisational culture and improve internal communication;
6. Improve external communication and raised awareness on SFDA roles and functions.

The project is coordinated by the United Nations Development Program in Riyadh, the Kingdom of Saudi Arabia.

Main Tasks

The Chief Technical Advisor / Team Leader acts as the head of the Technical Assistance Team that ensures the achievement of the programme goals and responsible for the mobilisation, the supervision and the coordination of all experts foreseen under the contract. A Chief Technical Advisor / Team Leader will be appointed to manage the project as well as oversee all technical project activities, monitor progress. She/he reports to UNDP via progress reports (quarterly and annually) and is directly responsible for the tasks related to planning and coordination of the technical assistance requirements of the programme.

The Team Leader will be based at the Saudi Food and Drug Authority and will have the dual task of assisting the beneficiary in the implementation of the project, and coordinating the technical assistance inputs. Both tasks will entail the development of extensive working relationships with all SFDA Sectors and other stakeholders relevant to the project.

The main tasks assigned to the Team Leader are as follows:

- Develops and maintains a productive work environment for the project team;
- Ensures the quality of technical assistance inputs;
- Ensures the good performance of the project team, notably through the promotion of a productive working relationship with counterparts at national and local levels and the observance of a service approach to technical assistance;
- Monitors the performance of the project team;
- Reports immediately to UNDP any issue requiring its attention;
- Ensures the timely fulfilment of technical assistance activity planning and reporting requirements. In particular, the Team Leader supports SFDA in preparing/updating annual plans of activities and related financial requirements for project activities and expert mission costs.
- Provides relevant documentation and briefings to UNDP in advance of meetings or events in which it is to be represented;
- Performs other managerial tasks, especially in relation to the delivery of project activities foreseen in the Project Document;
- Organises Project Board meetings and invites the Project Board members for the meetings.

Individual Requirements

Qualifications

- A medical, economist or management degree with a Master's degree in public health or equivalent. Doctorate or PhD is an asset.

General Professional Experience

- A minimum of 10 years relevant professional experience with 5 years relevant international experience in at least three transition / emerging countries.
- Relevant experience in the Middle East is an asset.
- A minimum of 3 years experience as team leader in international development programs/projects.

Specific professional experience

- Strong experience in health systems development and health policies development, planning and implementation.
- Strong experience in health financing, specifically social health insurance
- Proven experience in public private partnerships in the health sector.

- Specific applied knowledge and practical experience of health management and system development techniques and strategic design.
- Experience with sector analysis and institutional capacity building.
- Experience in sector-wide approaches involving donor coordination and incorporating aid effectiveness.
- Experience in M&E schemes in the area of health policy is an asset.
- Experience of health governance of the regulatory system in a decentralisation context is an asset.
- Experience in the preparation of research proposals is an asset.
- Specific experience in other technical areas covered by the project is an asset.

Skills

- Ability to work in a changing, multi-cultural environment and establish harmonious and effective working relationships
- Excellent presentation skills
- Proficient user level computer skills of Office and other software
- An excellent verbal and written command of English is essential. Knowledge of Arabic language would be an added advantage.
- Proven experience in the management of international teams of experts of different technical backgrounds.
- Ability to interact in different cultural and multi-professional academic and institutional environments and to create good working relationships with peers and with political and professional hierarchies.

Position specification

UNDP offers a full-time position until December 2019 with a three-month probation period. The contract is renewable until December 2022 depending on performance and upon agreement with UNDP and SFDA. The position is based in Riyadh, the Kingdom of Saudi Arabia.

ANNEX [3]. SOCIAL AND ENVIRONMENTAL SCREENING TEMPLATE

The completed template, which constitutes the Social and Environmental Screening Report, must be included as an annex to the Project Document. Please refer to the Social and Environmental Screening Procedure and Toolkit for guidance on how to answer the 6 questions.

Project Information

Project Information	
1. Project Title	Saudi Food & Drug Authority phase ll
2. Project Number	SAU10/
3. Location (Global/Region/Country)	Saudi Arabia

Part A. Integrating Overarching Principles to Strengthen Social and Environmental Sustainability

QUESTION 1: How Does the Project Integrate the Overarching Principles in order to Strengthen Social and Environmental Sustainability?
Briefly describe in the space below how the Project mainstreams the human-rights based approach
It will enhance the safety of food and quality of drugs thus ensuring that both the standards and the principles of human rights are integrated into policymaking to guarantee basic rights are fulfilled in terms of food and drugs (the right to health)
Briefly describe in the space below how the Project is likely to improve gender equality and women's empowerment
This project's objectives does not differentiate between genders and serves the population at large
Briefly describe in the space below how the Project mainstreams environmental sustainability
This project will enhance and develop ways to environmental sustainability

Part B. Identifying and Managing Social and Environmental Risks

QUESTION 2: What are the Potential Social and Environmental Risks?	QUESTION 3: What is the level of significance of the potential social and environmental risks?			QUESTION 6: What social and environmental assessment and management measures have been conducted and/or are required to address potential risks (for Risks with Moderate and High Significance)?
Risk Description	***Impact and Probability (1-5)***	***Significance (Low, Moderate, High)***	***Comments***	***Description of assessment and management measures as reflected in the Project design. If ESIA or SESA is required note that the assessment should consider all potential impacts and risks.***
Risk 1: Could the Project potentially restrict availability, quality of and access to resources or basic services, in particular to marginalized individuals or groups	I = P =	**Low**	**Preservation of living organisms and that by finding out the causes and treatment system helps the environment**	

QUESTION 4: What is the overall Project risk categorization?		
Select one (see SESP for guidance)		**Comments**
Low Risk	■	
Moderate Risk	☐	
High Risk	☐	

QUESTION 5: Based on the identified risks and risk categorization, what requirements of the SES are relevant?		
Check all that apply		**Comments**
Principle 1: Human Rights	☐	
Principle 2: Gender Equality and Women's Empowerment	☐	
1. Biodiversity Conservation and Natural Resource Management	☐	
2. Climate Change Mitigation and Adaptation	☐	
3. Community Health, Safety and Working Conditions	■	
4. Cultural Heritage	☐	
5. Displacement and Resettlement	☐	
6. Indigenous Peoples	☐	
7. Pollution Prevention and Resource Efficiency	☐	

Final Sign Off

Signature	*Date*	*Description*
QA Assessor		UNDP staff member responsible for the Project, typically a UNDP Programme Officer. Final signature confirms they have "checked" to ensure that the SESP is adequately conducted.
QA Approver		UNDP senior manager, typically the UNDP Deputy Country Director (DCD), Country Director (CD), Deputy Resident Representative (DRR), or Resident Representative (RR). The QA Approver cannot also be the QA Assessor. Final signature confirms they have "cleared" the SESP prior to submittal to the PAC.
PAC Chair		UNDP chair of the PAC. In some cases PAC Chair may also be the QA Approver. Final signature confirms that the SESP was considered as part of the project appraisal and considered in recommendations of the PAC.

SESP Attachment 1. Social and Environmental Risk Screening Checklist

Checklist Potential Social and Environmental Risks		
Principles 1: Human Rights		**Answer (Yes/No)**
1.	Could the Project lead to adverse impacts on enjoyment of the human rights (civil, political, economic, social or cultural) of the affected population and particularly of marginalized groups?	NO
2.	Is there a likelihood that the Project would have inequitable or discriminatory adverse impacts on affected populations, particularly people living in poverty or marginalized or excluded individuals or groups?	NO
3.	Could the Project potentially restrict availability, quality of and access to resources or basic services, in particular to marginalized individuals or groups?	YES
4.	Is there a likelihood that the Project would exclude any potentially affected stakeholders, in particular marginalized groups, from fully participating in decisions that may affect them?	NO
5.	Is there a risk that duty-bearers do not have the capacity to meet their obligations in the Project?	NO
6.	Is there a risk that rights-holders do not have the capacity to claim their rights?	NO
7.	Have local communities or individuals, given the opportunity, raised human rights concerns regarding the Project during the stakeholder engagement process?	NO
8.	Is there a risk that the Project would exacerbate conflicts among and/or the risk of violence to project-affected communities and individuals?	NO
Principle 2: Gender Equality and Women's Empowerment		
1.	Is there a likelihood that the proposed Project would have adverse impacts on gender equality and/or the situation of women and girls?	NO
2.	Would the Project potentially reproduce discriminations against women based on gender, especially regarding participation in design and implementation or access to opportunities and benefits?	NO
3.	Have women's groups/leaders raised gender equality concerns regarding the Project during the stakeholder engagement process and has this been included in the overall Project proposal and in the risk assessment?	NO
4.	Would the Project potentially limit women's ability to use, develop and protect natural resources, taking into account different roles and positions of women and men in accessing environmental goods and services? *For example, activities that could lead to natural resources degradation or depletion in communities who depend on these resources for their livelihoods and well being*	NO
Principle 3: Environmental Sustainability: Screening questions regarding environmental risks are encompassed by the specific Standard-related questions below		
Standard 1: Biodiversity Conservation and Sustainable Natural Resource Management		
1.1	Would the Project potentially cause adverse impacts to habitats (e.g. modified, natural, and critical habitats) and/or ecosystems and ecosystem services? *For example, through habitat loss, conversion or degradation, fragmentation, hydrological changes*	NO
1.2	Are any Project activities proposed within or adjacent to critical habitats and/or environmentally sensitive areas, including legally protected areas (e.g. nature reserve, national park), areas proposed for protection, or recognized as such by authoritative sources and/or indigenous peoples or local communities?	NO
1.3	Does the Project involve changes to the use of lands and resources that may have adverse impacts on habitats, ecosystems, and/or livelihoods? (Note: if restrictions and/or limitations of access to lands would apply, refer to Standard 5)	NO
1.4	Would Project activities pose risks to endangered species?	NO
1.5	Would the Project pose a risk of introducing invasive alien species?	NO
1.6	Does the Project involve harvesting of natural forests, plantation development, or reforestation?	NO

1.7	Does the Project involve the production and/or harvesting of fish populations or other aquatic species?	NO
1.8	Does the Project involve significant extraction, diversion or containment of surface or ground water? *For example, construction of dams, reservoirs, river basin developments, groundwater extraction*	NO
1.9	Does the Project involve utilization of genetic resources? (e.g. collection and/or harvesting, commercial development)	NO
1.10	Would the Project generate potential adverse transboundary or global environmental concerns?	NO
1.11	Would the Project result in secondary or consequential development activities which could lead to adverse social and environmental effects, or would it generate cumulative impacts with other known existing or planned activities in the area? For example, a new road through forested lands will generate direct environmental and social impacts (e.g. felling of trees, earthworks, potential relocation of inhabitants). The new road may also facilitate encroachment on lands by illegal settlers or generate unplanned commercial development along the route, potentially in sensitive areas. These are indirect, secondary, or induced impacts that need to be considered. Also, if similar developments in the same forested area are planned, then cumulative impacts of multiple activities (even if not part of the same Project) need to be considered.	NO
Standard 2: Climate Change Mitigation and Adaptation		
2.1	Will the proposed Project result in significant greenhouse gas emissions or may exacerbate climate change?	NO
2.2	Would the potential outcomes of the Project be sensitive or vulnerable to potential impacts of climate change?	NO
2.3	Is the proposed Project likely to directly or indirectly increase social and environmental vulnerability to climate change now or in the future (also known as maladaptive practices)? For example, changes to land use planning may encourage further development of floodplains, potentially increasing the population's vulnerability to climate change, specifically flooding	NO
Standard 3: Community Health, Safety and Working Conditions		
3.1	Would elements of Project construction, operation, or decommissioning pose potential safety risks to local communities?	NO
3.2	Would the Project pose potential risks to community health and safety due to the transport, storage, and use and/or disposal of hazardous or dangerous materials (e.g. explosives, fuel and other chemicals during construction and operation)?	NO
3.3	Does the Project involve large-scale infrastructure development (e.g. dams, roads, buildings)?	NO
3.4	Would failure of structural elements of the Project pose risks to communities? (e.g. collapse of buildings or infrastructure)	NO
3.5	Would the proposed Project be susceptible to or lead to increased vulnerability to earthquakes, subsidence, landslides, erosion, flooding or extreme climatic conditions?	NO
3.6	Would the Project result in potential increased health risks (e.g. from water-borne or other vector-borne diseases or communicable infections such as HIV/AIDS)?	NO
3.7	Does the Project pose potential risks and vulnerabilities related to occupational health and safety due to physical, chemical, biological, and radiological hazards during Project construction, operation, or decommissioning?	NO
3.8	Does the Project involve support for employment or livelihoods that may fail to comply with national and international labor standards (i.e. principles and standards of ILO fundamental conventions)?	NO
3.9	Does the Project engage security personnel that may pose a potential risk to health and safety of communities and/or individuals (e.g. due to a lack of adequate training or accountability)?	NO
Standard 4: Cultural Heritage		
4.1	Will the proposed Project result in interventions that would potentially adversely impact sites, structures, or objects with historical, cultural, artistic, traditional or religious values or intangible forms of culture (e.g. knowledge, innovations, practices)? (Note: Projects intended to protect and conserve Cultural Heritage may also have inadvertent adverse impacts)	NO
4.2	Does the Project propose utilizing tangible and/or intangible forms of cultural heritage for commercial or other purposes?	NO

Standard 5: Displacement and Resettlement		
5.1	Would the Project potentially involve temporary or permanent and full or partial physical displacement?	NO
5.2	Would the Project possibly result in economic displacement (e.g. loss of assets or access to resources due to land acquisition or access restrictions – even in the absence of physical relocation)?	NO
5.3	Is there a risk that the Project would lead to forced evictions?	NO
5.4	Would the proposed Project possibly affect land tenure arrangements and/or community based property rights/customary rights to land, territories and/or resources?	NO
Standard 6: Indigenous Peoples		
6.1	Are indigenous peoples present in the Project area (including Project area of influence)?	NO
6.2	Is it likely that the Project or portions of the Project will be located on lands and territories claimed by indigenous peoples?	NO
6.3	Would the proposed Project potentially affect the human rights, lands, natural resources, territories, and traditional livelihoods of indigenous peoples (regardless of whether indigenous peoples possess the legal titles to such areas, whether the Project is located within or outside of the lands and territories inhabited by the affected peoples, or whether the indigenous peoples are recognized as indigenous peoples by the country in question)? If the answer to the screening question 6.3 is "yes" the potential risk impacts are considered potentially severe and/or critical and the Project would be categorized as either Moderate or High Risk.	NO
6.4	Has there been an absence of culturally appropriate consultations carried out with the objective of achieving FPIC on matters that may affect the rights and interests, lands, resources, territories and traditional livelihoods of the indigenous peoples concerned?	NO
6.5	Does the proposed Project involve the utilization and/or commercial development of natural resources on lands and territories claimed by indigenous peoples?	NO
6.6	Is there a potential for forced eviction or the whole or partial physical or economic displacement of indigenous peoples, including through access restrictions to lands, territories, and resources?	NO
6.7	Would the Project adversely affect the development priorities of indigenous peoples as defined by them?	NO
6.8	Would the Project potentially affect the physical and cultural survival of indigenous peoples?	NO
6.9	Would the Project potentially affect the Cultural Heritage of indigenous peoples, including through the commercialization or use of their traditional knowledge and practices?	NO
Standard 7: Pollution Prevention and Resource Efficiency		
7.1	Would the Project potentially result in the release of pollutants to the environment due to routine or non-routine circumstances with the potential for adverse local, regional, and/or transboundary impacts?	NO
7.2	Would the proposed Project potentially result in the generation of waste (both hazardous and non-hazardous)?	NO
7.3	Will the proposed Project potentially involve the manufacture, trade, release, and/or use of hazardous chemicals and/or materials? Does the Project propose use of chemicals or materials subject to international bans or phase-outs? *For example, DDT, PCBs and other chemicals listed in international conventions such as the Stockholm Conventions on Persistent Organic Pollutants or the Montreal Protocol*	NO
7.4	Will the proposed Project involve the application of pesticides that may have a negative effect on the environment or human health?	NO
7.5	Does the Project include activities that require significant consumption of raw materials, energy, and/or water?	NO

Annex [4].

AGREEMENT BETWEEN UNDP AND THE GOVERNMENT FOR THE PROVISION OF SUPPORT SERVICES

1) Reference is made to consultations between officials of the Government of the Kingdom of Saudi Arabia (hereinafter referred to as "the Government") and officials of UNDP with respect to the provision of support services by the UNDP country office for nationally managed programmes and projects. UNDP and the Government hereby agree that the UNDP country office may provide such support services at the request of the Government through its institution designated in the relevant programme support document or project document, as described below.
2) The UNDP country office may provide support services for assistance with reporting requirements and direct payment. In providing such support services, the UNDP country office shall ensure that the capacity of the Government-designated institution is strengthened to enable it to carry out such activities directly. The costs incurred by the UNDP country office in providing such support services shall be recovered from the administrative budget of the office.
3) The UNDP country office may provide, at the request of the designated institution, the following support services for the activities of the programme/project:
   a. Identification and/or recruitment of project and programme personnel;
   b. Identification and facilitation of training activities;
   c. Procurement of goods and services.
4) The procurement of goods and services and the recruitment of project and programme personnel by the UNDP country office shall be in accordance with the UNDP regulations, rules, policies, and procedures. Support services described in paragraph 3 above shall be detailed in an annex to the programme support document or project document, in the form provided in the Attachment hereto. If the requirements for support services by the country office change during the life of a programme or project, the annex to the programme support document or project document is revised with the mutual agreement of the UNDP resident representative and the designated institution.
5) The relevant provisions of the Agreement between the Government of the Kingdom of Saudi Arabia and the United Nations Development Programme signed in 4th January 1976 (the "SBAA"), including the provisions on liability and privileges and immunities, shall apply to the provision of such support services. The Government shall retain overall responsibility for the nationally managed programme or project through its designated institution. The responsibility of the UNDP country office for the provision of the support services described herein shall be limited to the provision of such support services detailed in the annex to the programme support document or project document.
6) Any claim or dispute arising under or in connection with the provision of support services by the UNDP country office in accordance with this letter shall be handled pursuant to the relevant provisions of the SBAA.

7) The manner and method of cost-recovery by the UNDP country office in providing the support services described in paragraph 3 above shall be specified in the annex to the programme support document or project document.
8) The UNDP country office shall submit progress reports on the support services provided and shall report on the costs reimbursed in providing such services, as may be required.
9) Any modification of the present arrangements shall be effected by mutual written agreement of the parties hereto.
10) If you are in agreement with the provisions set forth above, please sign and return to this office two signed copies of this letter. Upon your signature, this letter shall constitute an agreement between your Government and UNDP on the terms and conditions for the provision of support services by the UNDP country office for nationally managed programmes and projects.

On Behalf of the United Nations Development Programme (UNDP)

UNDP Resident Representative

Signature: ……..

Mr. Firas Gharaibeh

Date:

==========

On Behalf of the Kingdom of Saudi Arabia Government

Saudi Food and Drug Authority

Signature: ……..

HE Prof. Hisham S. AlJadhey

Date:

The schedule of Payments (USD) and UNDP bank account details:

DATE	AMOUNT (USD)
2019	**$3,232,730**
2020	**$5,554,258**
2021	**$3,232,730**
2022	**$4,911,202**
Total[1]	**$16,930,920**

SFDA

[1] if the value of payment is made in a currency other that the United States Dollar will be determined by applying the UN operational rate of exchange in effect of the date of payment: