United Nations Development Programme
Country: Saudi Arabia
Project Document

Project Title:	Support SFDA Second strategic plan implementation
Project ID:	SAU10/82003

Expected CPD Outcome #3: Sustainable Development Mainstreamed across the Economy

Expected Output(s):	SFDA Capacity Development
Executing Entity:	Saudi Food and Drug Authority
Implementing Agencies:	SFDA

Project Summary

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. In its continuing efforts to achieve its vision, SFDA recently developed its second strategic plan from 2012 to 2016 which focuses mainly on building broad and deep capabilities, ensure thoroughness, transparency, and consistency in enforcement and communication, and complete the coverage of all relevant areas. UNDP's technical assistance in this project shall focus on the following outputs on the following outputs; 1- Capacity development of SFDA; 2- Ensure thoroughness, transparency, and consistency in enforcement and communication; 3- Complete the coverage of all relevant areas as per SFDA's mandate; 4- Develop systems and processes to improve pro-activity in addressing emerging risk

Programme Period:	2012 – 2016
Atlas Proposal ID:	SAU10/65588
Start date:	1st April 2012
End Date	31st December 2016
PAC Meeting Date	24th March 2012
Management Arrangements	NIM

Total resources required **US$ 17,759,492**

Total allocated resources:

- Government $ US$ 17,759,492
- Previous unbudgeted $

Agreed by (SFDA):
Dr. Mohammed AL Kanhal
Executive President

April, 4, 2012

Agreed by (UNDP):
Kishan Khoday
UNDP Resident Representative a.i

April 1, 2012

UNDP UNITED NATIONS DEVELOPMENT PROGRAMME

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I. BRIEF DESCRIPTION

Saudi Food & Drugs Authority (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 second strategic plan, based upon UNDP's comparative and competitive advantages in providing the required technical support.

In this context, the objective of this Project Document (PD) is to provide substantive support to SFDA, through enabling SFDA to implement Food, Drugs and medical Devices strategic goals and initiatives laid out in SFDA second 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.

This joint project will benefit SFDA –in specific- in terms of institutional capacity development to support SFDA in building broad and deep capabilities, help SFDA to ensure thoroughness, transparency, and consistency in enforcement and communication, complete the coverage of all relevant areas as per SFDA's mandate, and finally develop systems and processes to improve pro-activity in addressing emerging risk.

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.

II. SITUATION ANALYSIS

The 9th National Development Plan (NDP; 2010-14) has the overall theme of sustaining the development with a record $385 billion, 67% increase on 8th NDP, targeted at improving standards of living, regional development, economic diversification, knowledge-based economy and competitiveness, and human resources including youth and woman. The NDP is based on the tenets of long-term strategy towards 2024 with the overarching target of having the kingdom as, "a developed, thriving and prosperous economy, built on sustainable foundations."

As per the Ninth Development Plan, the plan envisages continued efforts to raise health standards for the entire population, through expanding health facilities to cope with population growth, and improve performance, quality of service and user satisfaction. The plan adopts a set of policies and programmes directed towards furthering the role of cooperative health insurance to cover more segments of society; achieving more decentralization in management and operation of health facilities; and supporting primary-healthcare facilities and their integration with secondary, specialist and referral care, and facilitating their availability to the entire population in all regions.

SFDA developed its first strategic plan for the period from 2007 to 2011 with a vision "to be 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 made some distinguished achievements by implementing its first strategic plan. For the food sector, for example, one main achievement is SFDA completed the inspection strategy on the borders of entry and also developed the border inspection processes according to ISO 17020. An example of the Drug sector achievements is its efforts to automate all drug and drug establishment processes using IT systems. Medical devices developed the national register which contains a list of all medical devices and establishments which is the first to be developed in Saudi Arabia.

In its continuing efforts to achieve its vision, SFDA recently developed its second strategic plan from 2012 to 2016 which focuses SFDA efforts on achieving high impact goals as set by its mandate. The second strategic plan focuses mainly on building broad and deep capabilities, ensure thoroughness, transparency, and consistency in enforcement and communication, complete the coverage of all relevant areas as per SFDA's mandate, and finally develop systems and processes to improve pro-activity in addressing emerging risk.

III. STRATEGY

The preliminary discussions between SFDA and UNDP focused on areas where UNDP could provide substantive support in building SFDA capacity in implementing its second strategic plan. This project document focuses on four major outcomes:

1. **Support SFDA in building broad and deep capabilities,** where UNDP competitive advantage in building institutional capacity could support SFDA in enriching its expertise by attracting, retaining and developing the appropriate human resources, enhance 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

2. **Support SFDA to ensure thoroughness, transparency, and consistency in enforcement and communication,** where UNDP competitive advantage in building institutional capacity could support SFDA in Improving industry and consumer awareness and intra-agency cooperation through interactive and coherent communication strategy, define internal control systems and institutionalize accountability, align with relevant stakeholders on an efficient enforcement model

3. **Support SFDA to Complete the coverage of all relevant areas as per SFDA's mandate,** where UNDP competitive advantage in building institutional capacity could support SFDA in fulfilling competencies and responsibilities outlined in mandate, also Optimize SFDA's role 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

4. **Develop systems and processes to improve pro-activity in addressing emerging risk**

   Where UNDP competitive advantage in building institutional capacity could support SFDA in establishing collaborative knowledge-sharing systems enabling early detection of potential hazards to food and feed control system, fortify preparedness to emerging threats by discerning early on market trends and emerging risks, and also Identify and swiftly act upon risks to patient safety

IV. RESULTS AND RESOURCES FRAMEWORK

Intended Outcome as stated in the Country Programme Results and Resource Framework: **3.Sustainable Development Mainstreamed across the Economy**				
Outcome indicators as stated in the Country Programme Results and Resources Framework, including baseline and targets: **Baseline:** Modest ability of previous strategies to achieve results in geographic balance of development. Target: Strategies serve as effective frameworks for balanced development				
Applicable Key Result Area (from 2012-16 Strategic Plan): Poverty Reduction and Achievement of MDGs. Democratic Governance				
Partnership Strategy: WHO – WFP – FAO – other agencies as needed				
Project title and ID (ATLAS Award ID): SAU10/82003 - Support SFDA second strategic plan implementation				
INTENDED OUTPUTS	**OUTPUT TARGETS FOR (YEARS)**	**INDICATIVE ACTIVITIES**	**RESPONSIBLE PARTIES**	**INPUTS**
Output 1: **Capacity of Institutional, individual and systems developed to serve processes and tools in all relevant sectors.** ***Baseline:*** None ***Indicators:*** No. of experts visits to support SFDA in building broad and deep capabilities ***Targets:*** *60% of capacities developed*	2012 – 2016 target: All visits and resulting reports and objectives finalized	▪ Enrich SFDA's expertise by attracting, retaining and developing the appropriate human resources ▪ Enhance SFDA key internal tools and processes to better support its mission ▪ Fully develop the required set of capabilities to take over key pesticides control processes ▪ Support ITP and shared services in building their capabilities	SFDA	▪ International Experts:17:$632,084 /NationalExperts/Travel/16:$ 494,903 ▪ Workshops: $100,000 ▪ Meetings/studytours: 100:$3,718,144 **$4,945,131**
Output 2: **Communication strategy and control frameworks prepared and executed** ***Baseline:*** None	2012 – 2016 target: Draft communication and control framework developed	▪ Improve industry and consumer awareness and intra-agency cooperation through interactive and coherent communication strategy ▪ Define internal control systems and institutionalize accountability	SFDA	▪ InternationalExperts $ 180,919 ▪ /National Experts/Travel/5:$

Indicators: No. of experts visits to support SFDA in ensuring thoroughness, transparency, and consistency in enforcement and communication ***Targets:*** 100% of strategy and frameworks prepared		▪ Align with relevant stakeholders on an efficient enforcement model		150,766 ▪ Meetings/ study tours:61:$ 1,839,348 ▪ Workshops: 10: $301,532 **2,472,566**
Output 3: **Standards, control systems and policies developed to cover food, drugs and medical devices** ***Baseline***: None ***Indicators***: No. of experts visits to support SFDA in Complete the coverage of all relevant areas as per SFDA's mandate ***Targets:*** 100% of relevant standards and control systems developed	2012 – 2016 target: Draft relevant documents	▪ Continue to fulfill competencies and responsibilities outlined in mandate ▪ Optimize SFDA's role regarding inspection of local market food businesses and water bottling plants ▪ Fully 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 ▪ Develop best practice policies for specific / emerging product categories	SFDA	▪ International Experts27/$814,137 National Experts/Travel/26:$ 783,984 ▪ Meetings/ study tours:183:$ 5,518,043 ▪ Workshops:10:$ $301,52 **7,417,697**

Output 4: **Systems and processes to improve pro-activity in addressing emerging risk developed** ***Baseline***: None ***Indicators***: No. of experts visits to support SFDA in Developing systems and processes to improve pro-activity in addressing emerging risk ***Targets:*** 50% of Systems and processes to improve pro-activity in addressing emerging risk developed	2012 – 2016 target: relevant systems in place	▪ Establish collaborative knowledge-sharing systems enabling early detection of potential hazards to food and feed control system ▪ Fortify preparedness to emerging threats by discerning early on market trends and emerging risks ▪ Identify and swiftly act upon risks to patient safety	SFDA	▪ International Experts5/$$149,852 National Experts/Travel/5: $149,852 ▪ Meetings/ study tours:35: $1,048,967 ▪ Workshops: 10: $299,705 **1,648,377**
Sub- Total				**$16,483,770**
Audit				**$17,500**
Miscellaneous (2.5%)				**$412,532**
Sub total				**$16,913,802**
GMS (5%)				**$845,690.09**
TOTAL				**$17,759,492**

Annual Work Plan
Year: 2012

EXPECTED OUTPUTS *And baseline, indicators including annual targets*	PLANNED ACTIVITIES *List activity results and associated actions*	TIMEFRAME				RESPONSIBLE PARTY	PLANNED BUDGET		
		Q1	Q2	Q3	Q4		Funding Source	Budget Description	Amount
Capacity of Institutional, individual and systems developed to serve processes and tools in all relevant sectors. ***Baseline:*** None ***Indicators:*** No. of experts visits to support SFDA in building broad and deep capabilities ***Targets:*** 12% of capacities developed	1. **Enrich SFDA's expertise by attracting, retaining and developing the appropriate human resources** - Attract and retain best talent -improve the expertise level of SFDA's employees - Conduct regular manpower planning studies as a basis for resource / budget allocation -Ramp up expertise for scientists in biologics and emerging novel drug categories -Ramp up expertise for inspectors in biologics and emerging novel drug categories		√	√	√	SFDA	SFDA	National 9: $164,025 & Int'l consultants 9: $164,025 Workshops:2: $36,450	**364,500**
	2. **Enhance SFDA key internal tools and processes to better support its**		√	√	√	SFDA	SFDA	National 5: $22,091& Int'l consultants/5: $22,091 & Committee's meetings/ study	**243,000**

	mission - Establish integrated IT system throughout SFDA - Achieve ISO accreditation for SFDA labs - Support other departments to advance animal feed expertise and enhance control - Integration of Feed Testing into Labs -Streamline, calibrate and prioritize drug registration process - Build up capacity / expertise of internal labs and contract private labs - Ensure consistency and quality processes through SOPs and QMS - Improve capabilities to monitor availability and security of drugs inside the KSA - Improve evaluation and standard setting processes - Build and upgrade IT services in the drug sector							tours:45: $198,818	

	- Launch Narcotics Drug System (NDS) and socialize narcotics regulations and guidelines - Introduce a quality management system for the MD								
	3. **Fully develop the required set of capabilities to take over key processes** - Acquire the capabilities and resources to conduct controls - Acquire the capabilities and resources to guide post-market inspections - Acquire the capabilities and resources to conduct audits				√	√	SFDA	SFDA	National 5: $14,727& Int'l consultants/5: $14,727 & Committee's meetings/ study tours:45: $132,545	**162,000**
	4. Support ITP and shared services in building their capabilities		√	√	√			SFDA	National 3:$20,000& Int'l consultants/3:$20,000	**40,500**
Output 2: **Communication strategy and control frameworks prepared and executed**	1. **Improve industry and consumer awareness and intra-agency cooperation through interactive and coherent communication strategy**		√	√	√		SFDA	SFDA	National 5:$17,357& Int'l consultants/5: :$17,357 & Committee's meetings/ study tours:25:$86,786	**121,500**

Baseline: None ***Indicators:*** No. of experts visits to support SFDA in ensuring thoroughness, transparency, and consistency in enforcement and communication ***Targets:*** 20% of strategy and frameworks prepared	- Strengthen alliance with governmental ministries and agencies by aligning on split of roles and responsibilities -Complete implementation of and full adherence to risk-based system across all departments								
	2. **Define internal control systems and institutionalize accountability** - Go live with all registration processes and licensing systems for local food manufacturers, warehouses, distribution centers, and relevant food products - Go live with all registration processes and licensing systems, and clearance systems for all foreign food manufrs., importers, and relevant products - Institutionalize quality management systems across food sector departments		√	√	√	SFDA		National 5:$28,929& Int'l consultants/5:$28,929 & Committee's meetings/ study tours:25:$14,4643	**202,500**

	3. **Align with relevant stakeholders on an efficient enforcement model** - Design and enforce an appropriate fee structure aiming at maximum cost recovery from registration and approval activities - Engage in close partnership with other agencies to ensure consistent enforcement of standards and policies			√	√	SFDA	SFDA	National 1:$6,231& Int'l consultants/1:$6,231 & Committee's meetings/ study tours:10:$62,308	**81,000**
Output 3: **Standards, control systems and policies developed to cover food, drugs and medical devices** ***Baseline***: None ***Indicators***: No. of experts visits to support SFDA in Complete the coverage of all relevant areas as per SFDA's mandate	1. **Continue to fulfill competencies and responsibilities outlined in mandate** - Develop and rollout GCC Rapid Alert System for Food and Feed and implement recall throughout KSA -Establish private food lab registry database and licensing capability - Establish export certification program -Build laboratory for analysis and testing of pesticides		√	√	√	SFDA	SFDA	National 10:$102,337& Int'l consultants/10:$102,337 & Committee's meetings/ study tours:20:$54,675	**109,350**

Targets: 20% of standards and control systems developed									
	2. **Optimize SFDA's role regarding inspection of local market food businesses and water bottling plants** - Fully transfer inspection of bottled drinking water and ice factories from MoMRA & MoC to SFDA		√	√	√	SFDA	SFDA	National 15:$86,569& Int'l consultants/10:$57,713 & Committee's meetings/ study tours:15:$86,569	**230,850**

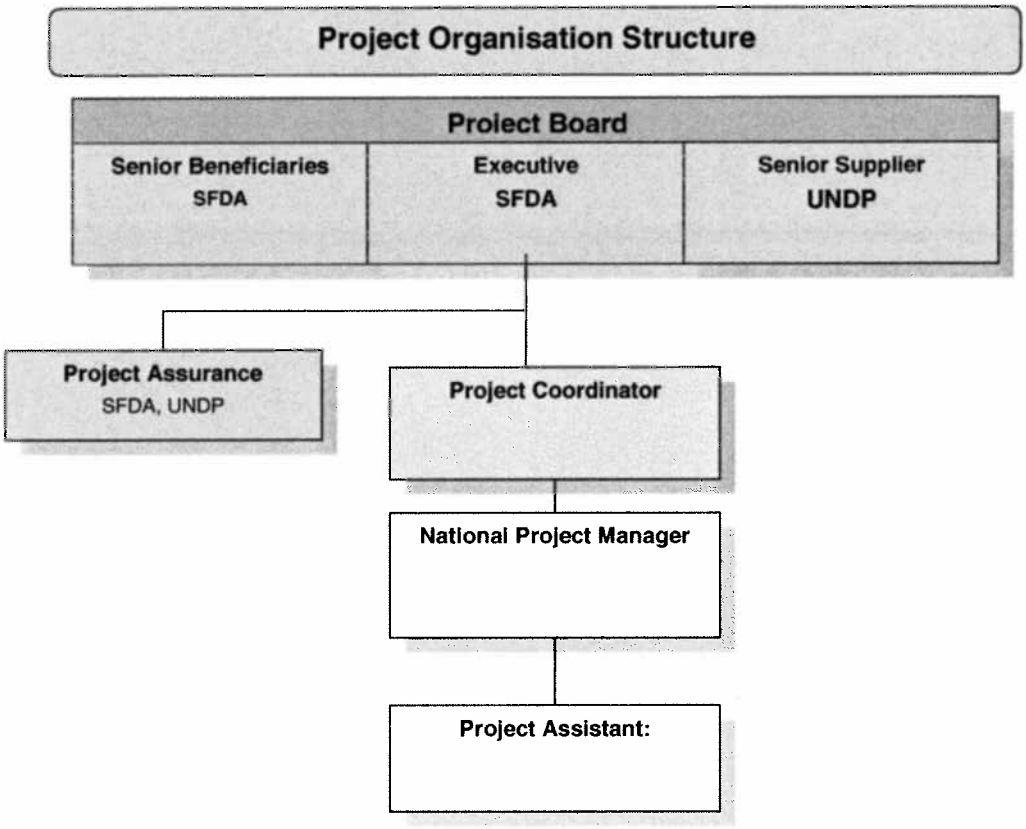
	3. **Implement effective processes to operationalize pesticide safety standards** - Develop, communicate and implement a streamlined process for registration / approval of materials and products		√	√	√	SFDA		Committee's meetings/13:$85,050	**85,050**
	4. **Reinforce safety of drugs, bio-products, health, herbal and veterinary products across the value chain** - Complete the veterinary products regulatory framework - Design and implement an adverse events reporting system for pesticides - Develop and complete the regulatory framework for pharmaceutical establishments - Approve and monitor clinical trials with clear and exhaustive guidelines and appropriate		√	√	√	SFDA	SFDA	National5:$37,969 & Int'l consultants/10:75,937 & Committee's meetings/ study tours:25:$189,844	**303,750**

	expertise and capabilities								
	5. Pursue the development of cosmetics standards and ensure the safety of cosmetics products - Finalize the structure of the cosmetics functions within SFDA - Pursue the listing and creation of standards for cosmetics products		√	√	√	SFDA	SFDA	National 5:$13,669& Int'l consultants/10:27,337 & Committee's meetings/ study tours:25:$68,344	**109,350**
	6. Tighten SFDA's control over manufacturing , import and export of medical devices - Fully transition medical devices inspections at POE - Devise policy to identify and control counterfeit devices - Establish local manufacturing oversight		√	√	√	SFDA	SFDA	National 5:$34,977& Int'l consultants/13:$90,941 & Committee's meetings/ study tours:15:$104,932	**230,850**
	7. Develop best practice policies for specific / emerging product categories - Draft, regulate & implement guidelines for specific products		√	√	√	SFDA	SFDA	Committee's meetings/ study tours:20:$7,290	**145,800**

	- Regulate & control the flow of special access medical devices - Implement & expand medical devices & establishments inspection program - Introduce oversight over radiation emitting devices								
Output 4: **Systems and processes to improve pro-activity in addressing emerging risk developed** ***Baseline:*** None ***Indicators:*** No. of experts visits to support SFDA in Developing systems and processes to improve pro-activity in addressing emerging risk ***Targets:*** 10% of Systems and processes to improve pro-activity in addressing emerging risk developed	1. **Establish collaborative knowledge-sharing systems enabling early detection of potential hazards to food and feed control system** - Establish clear channels for feedback from external stakeholders, particularly private sector and consumers - Develop crisis management strategy to ensure emergency response preparedness		√	√	√	SFDA	SFDA	National 5:$11,912& Int'l consultants /5:$11,912 Committee's meetings/ study tours:24:$57,176	**81,000**
	2. **Identify and swiftly act upon risks to patient safety** - Develop a clear process for crisis management and ensure required capabilities are available		√	√	√	SFDA	SFDA	National 5:$31,500& Int'l consultants /5:$31,500 Committee's meetings/ study tours: 20:$125,910	**189,000**

Sub- Total			**$ 2,700,000**
Audit			**$ 3,500**
Miscellaneous (2.5%)			**$ 67,588**
Sub total			**$ 2,771,088**
GMS (5%)			**$ 138,554**
TOTAL			**$ 2,909,642**

V. MANAGEMENT ARRANGEMENTS



Execution Arrangements

This 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 a 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.

National Project Manager

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 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.

Prior Obligations and Requisites

There are no prior Obligations and Requisites attached to this document

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

DATE	AMOUNT (USD)
2012	$2,908,960
2013	$3,199,856
2014	$3,519,842
2015	$3,871,826
2016	$4,259,008
Total	**$17,759,492**

1. The value of the payment, if made in a currency other than United States dollars, shall be determined by applying the United Nations operational rate of exchange in effect on the date of payment. Should there be a change in the United Nations operational rate of exchange prior to the full utilization by the UNDP of the payment, the value of the balance of funds still held at that time will be adjusted accordingly. If, in such a case, a loss in the value of the balance of funds is recorded, UNDP shall inform the Government (SFDA) with a view to determining whether any further financing could be provided by the Government (SFDA). Should such further financing not be available, the assistance to be provided to the project may be reduced, suspended or terminated by UNDP.

2. The above schedule of payments takes into account the requirement that the payments shall be made in advance of the implementation of planned activities. It may be amended to be consistent with the progress of project delivery.

3. UNDP shall receive and administer the payment in accordance with the regulations, rules and directives of UNDP.

4. All financial accounts and statements shall be expressed in United States dollars.

5. If unforeseen increases in expenditures or commitments are expected or realized (whether owing to inflationary factors, fluctuation in exchange rates or unforeseen contingencies), UNDP shall submit to the government on a timely basis a supplementary estimate showing the further financing that will be necessary. The Government (SFDA) shall use its best endeavours to obtain the additional funds required.

6. If the payments referred above are not received in accordance with the payment schedule, or if the additional financing required in accordance with paragraph above is not forthcoming from the Government or other sources, the assistance to be provided to the project under this Agreement may be reduced, suspended or terminated by UNDP.

7. Any interest income attributable to the contribution shall be credited to UNDP Account and shall be utilized in accordance with established UNDP procedures.

In accordance with the decisions and directives of UNDP's Executive Board:

The contribution shall be charged:

(a) [5%]cost recovery for the provision of general management support (GMS) by UNDP headquarters and country offices

8. Ownership of equipment, supplies and other properties financed from the contribution shall vest in UNDP. Matters relating to the transfer of ownership by UNDP shall be determined in accordance with the relevant policies and procedures of UNDP.

9. The contribution shall be subject exclusively to the internal and external auditing procedures provided for in the financial regulations, rules and directives of UNDP."

VI. MONITORING FRAMEWORK 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 submitted (annex 1), 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 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.

VII. QUALITY MANAGEMENT FOR PROJECT ACTIVITY RESULTS

Replicate the table for each activity result of the AWP to provide information on monitoring actions based on quality criteria. To be completed during the process "Defining a Project" if the information is available. This table shall be further refined during the process "Initiating a Project".

OUTPUT 1: Capacity of Institutional, individual and systems developed to serve processes and tools in all relevant sectors.		
Activity Result 1 (Atlas Activity ID)	Enrich SFDA's expertise by attracting, retaining and developing the appropriate human resources	Start Date: 1 March 20112 End Date: 31 Dec 2012
Purpose	*To Enrich SFDA's expertise by attracting, retaining and developing the appropriate human resources*	
Description	*Build SFDA capabilities to:* *- Attract and retain best talent* *-improve the expertise level of SFDA's employees* *- Conduct regular manpower planning studies as a basis for resource / budget allocation* *-Ramp up expertise for scientists in biologics and emerging novel drug categories* *-Ramp up expertise for inspectors in biologics and emerging novel drug categories*	
Quality Criteria *how/with what indicators the quality of the activity result will be measured?*	**Quality Method** *Means of verification. what method will be used to determine if quality criteria has been met?*	**Date of Assessment** *When will the assessment of quality be performed?*
Pre- and post- questionnaires or similar	Questionnaires	Annually
Expert feedback	Expert Report	Annually

OUTPUT 1: Capacity of Institutional, individual and systems developed to serve processes and tools in all relevant sectors.		
Activity Result 2 (Atlas Activity ID)	Enhance SFDA key internal tools and processes to better support its mission	Start Date: 1 March 20112 End Date: 31 Dec 2012
Purpose	*To Enhance SFDA key internal tools and processes to better support its mission*	
Description	*Build SFDA capabilities to:* *- Establish integrated IT system throughout SFDA* *- Achieve ISO accreditation for SFDA labs* *- Support other departments to advance animal feed expertise and enhance control* *- Integration of Feed Testing into Labs* *-Streamline, calibrate and prioritize drug registration process* *- Build up capacity / expertise of internal labs and contract private labs* *- Ensure consistency and quality processes through SOPs and QMS* *- Improve capabilities to monitor availability and security of drugs inside the KSA* *- Improve evaluation and standard setting processes* *- Build and upgrade IT services in the drug sector* *- Launch Narcotics Drug System (NDS) and socialize narcotics regulations and guidelines* *- Introduce a quality management system for the MD*	
Quality Criteria	**Quality Method**	**Date of Assessment**

how/with what indicators the quality of the activity result will be measured?	*Means of verification. what method will be used to determine if quality criteria has been met?*	*When will the assessment of quality be performed?*
Pre- and post- questionnaires or similar	Questionnaires	Annually
Expert feedback	Expert Report	Annually

OUTPUT 1: Capacity of Institutional, individual and systems developed to serve processes and tools in all relevant sectors.		
Activity Result 3 (Atlas Activity ID)	Fully develop the required set of capabilities to take over key control processes	Start Date: 1 July 20112 End Date: 31 Dec 2012
Purpose	*To Fully develop the required set of capabilities to take over key control processes*	
Description	*Build SFDA capabilities to:* *- Acquire the capabilities and resources to conduct controls* *- Acquire the capabilities and resources to guide post-market inspections* *- Acquire the capabilities and resources to conduct audits*	

Quality Criteria *how/with what indicators the quality of the activity result will be measured?*	**Quality Method** *Means of verification. what method will be used to determine if quality criteria has been met?*	**Date of Assessment** *When will the assessment of quality be performed?*
Pre- and post- questionnaires or similar	Questionnaires	Annually
Expert feedback	Expert Report	Annually

OUTPUT 1: Capacity of Institutional, individual and systems developed to serve processes and tools in all relevant sectors.		
Activity Result 6 (Atlas Activity ID)	Support ITP and shared services in building their capabilities	Start Date: 1 March 20112 End Date: 31 Dec 2012
Purpose	*To Support ITP and shared services in building their capabilities*	
Description	*Build SFDA capabilities to:* *-improve the expertise level of SFDA's employees in ITP and Shared Services* *- Conduct regular manpower planning studies as a basis for resource / budget allocation in ITP and Shared Services*	

Quality Criteria *how/with what indicators the quality of the activity result will be measured?*	**Quality Method** *Means of verification. what method will be used to determine if quality criteria has been met?*	**Date of Assessment** *When will the assessment of quality be performed?*
Pre- and post- questionnaires or similar	Questionnaires	Annually
Expert feedback	Expert Report	Annually

OUTPUT 2: Communication strategy and control frameworks prepared and executed		
Activity Result 1 (Atlas Activity ID)	Improve industry and consumer awareness and intra-agency cooperation through interactive and coherent communication strategy	Start Date: 1 March 20112 End Date: 31 Dec 2012
Purpose	*to Improve industry and consumer awareness and intra-agency cooperation through interactive and coherent communication strategy*	
Description	*Support SFDA to:* *- Strengthen alliance with governmental ministries and agencies by aligning on split of roles and responsibilities* *-Complete implementation of and full adherence to risk-based system across all departments*	

Quality Criteria *how/with what indicators the quality of the activity result will be measured?*	**Quality Method** *Means of verification. what method will be used to determine if quality criteria has been met?*	**Date of Assessment** *When will the assessment of quality be performed?*
Expert feedback	Expert Report	Annually

OUTPUT 2: Communication strategy and control frameworks prepared and executed		
Activity Result 2 (Atlas Activity ID)	Define internal control systems and institutionalize accountability	Start Date: 1 March 20112 End Date: 31 Dec 2012
Purpose	*To Define internal control systems and institutionalize accountability*	
Description	*Support SFDA to:* *- Go live with all registration processes and licensing systems for local food manufacturers, warehouses, distribution centres, and relevant food products* *- Go live with all registration processes and licensing systems, and clearance systems for all foreign food manufacturers., importers, and relevant products* *- Institutionalize quality management systems across food sector departments*	

Quality Criteria *how/with what indicators the quality of the activity result will be measured?*	**Quality Method** *Means of verification. what method will be used to determine if quality criteria has been met?*	**Date of Assessment** *When will the assessment of quality be performed?*
Expert feedback	Expert Report	Annually

OUTPUT 2: Communication strategy and control frameworks prepared and executed		
Activity Result 3 (Atlas Activity ID)	Align with relevant stakeholders on an efficient enforcement model	Start Date: 1 July 20112 End Date: 31 Dec 2012
Purpose	*To Align with relevant stakeholders on an efficient enforcement model*	
Description	*Support SFDA to:* *- Design and enforce an appropriate fee structure aiming at maximum cost recovery from registration and approval activities* *- Engage in close partnership with other agencies to ensure consistent enforcement of standards and policies*	

Quality Criteria *how/with what indicators the quality of the activity result will be measured?*	**Quality Method** *Means of verification. what method will be used to determine if quality criteria has been met?*	**Date of Assessment** *When will the assessment of quality be performed?*

Expert feedback	Expert Report	Annually

OUTPUT 3: Standards, control systems and policies developed to cover food, drugs and medical device		
Activity Result 1 (Atlas Activity ID)	Continue to fulfill competencies and responsibilities outlined in mandate	Start Date: 1 March 20112 End Date: 31 Dec 2012
Purpose	*To Continue to fulfill competencies and responsibilities outlined in mandate*	
Description	*Support SFDA to:* *- Develop and rollout GCC Rapid Alert System for Food and Feed and implement recall throughout KSA* *-Establish private food lab registry database and licensing capability* *- Establish export certification program* *-Build laboratory for analysis and testing of pesticides*	

Quality Criteria *how/with what indicators the quality of the activity result will be measured?*	**Quality Method** *Means of verification. what method will be used to determine if quality criteria has been met?*	**Date of Assessment** *When will the assessment of quality be performed?*
Expert feedback	Expert Report	Annually

OUTPUT 3: Standards, control systems and policies developed to cover food, drugs and medical device		
Activity Result 2 (Atlas Activity ID)	Optimize SFDA's role regarding inspection of local market food businesses and water bottling plants	Start Date: 1 March 20112 End Date: 31 Dec 2012
Purpose	*To Optimize SFDA's role regarding inspection of local market food businesses and water bottling plants*	
Description	*Support SFDA to:* *- Fully transfer inspection of bottled drinking water and ice factories from MoMRA & MoC to SFDA*	

Quality Criteria *how/with what indicators the quality of the activity result will be measured?*	**Quality Method** *Means of verification. what method will be used to determine if quality criteria has been met?*	**Date of Assessment** *When will the assessment of quality be performed?*
Expert feedback	Expert Report	Annually

OUTPUT 3: Standards, control systems and policies developed to cover food, drugs and medical device		
Activity Result 3 (Atlas Activity ID)	Implement effective processes to operationalize pesticide safety standards	Start Date: 1 March 20112 End Date: 31 Dec 2012
Purpose	*To Implement effective processes to operationalize pesticide safety standards*	
Description	*Support SFDA to:* *- Develop, communicate and implement a streamlined process for registration / approval of materials and products*	

Quality Criteria *how/with what indicators the quality of the activity result will be measured?*	**Quality Method** *Means of verification. what method will be used to determine if quality criteria has been met?*	**Date of Assessment** *When will the assessment of quality be performed?*
Expert feedback	Expert Report	Annually

OUTPUT 3: Standards, control systems and policies developed to cover food, drugs and medical device		
Activity Result 4 (Atlas Activity ID)	Reinforce safety of drugs, bio-products, health, herbal and veterinary products across the value chain	Start Date: 1 March 20112 End Date: 31 Dec 2012
Purpose	*To Reinforce safety of drugs, bio-products, health, herbal and veterinary products across the value chain*	
Description	*Support SFDA to:* *- Complete the veterinary products regulatory framework* *- Design and implement an adverse events reporting system for pesticides* *- Develop and complete the regulatory framework for pharmaceutical establishments* *- Approve and monitor clinical trials with clear and exhaustive guidelines and appropriate expertise and capabilities*	

Quality Criteria *how/with what indicators the quality of the activity result will be measured?*	**Quality Method** *Means of verification. what method will be used to determine if quality criteria has been met?*	**Date of Assessment** *When will the assessment of quality be performed?*
Expert feedback	Expert Report	Annually

OUTPUT 3: Standards, control systems and policies developed to cover food, drugs and medical device		
Activity Result 5 (Atlas Activity ID)	Pursue the development of cosmetics standards and ensure the safety of cosmetics products	Start Date: 1 March 20112 End Date: 31 Dec 2012
Purpose	*To Pursue the development of cosmetics standards and ensure the safety of cosmetics products*	
Description	*Support SFDA to:* *- Finalize the structure of the cosmetics functions within SFDA* *- Pursue the listing and creation of standards for cosmetics products*	

Quality Criteria *how/with what indicators the quality of the activity result will be measured?*	**Quality Method** *Means of verification. what method will be used to determine if quality criteria has been met?*	**Date of Assessment** *When will the assessment of quality be performed?*
Expert feedback	Expert Report	Annually

OUTPUT 3: Standards, control systems and policies developed to cover food, drugs and medical device		
Activity Result 6 (Atlas Activity ID)	Tighten SFDA's control over manufacturing , import and export of medical devices	Start Date: 1 March 20112 End Date: 31 Dec 2012
Purpose	*To Tighten SFDA's control over manufacturing , import and export of medical devices*	
Description	*Support SFDA to:* *- Fully transition medical devices inspections at POE* *- Devise policy to identify and control counterfeit devices* *- Establish local manufacturing oversight*	

Quality Criteria	**Quality Method**	**Date of Assessment**

how/with what indicators the quality of the activity result will be measured?	*Means of verification. what method will be used to determine if quality criteria has been met?*	*When will the assessment of quality be performed?*
Expert feedback	Expert Report	Annually

OUTPUT 3: Standards, control systems and policies developed to cover food, drugs and medical device		
Activity Result 7 (Atlas Activity ID)	Develop best practice policies for specific / emerging product categories	Start Date: 1 March 20112 End Date: 31 Dec 2012
Purpose	*To Develop best practice policies for specific / emerging product categories*	
Description	*Support SFDA to:* *- Draft, regulate & implement guidelines for specific products* *- Regulate & control the flow of special access medical devices* *- Implement & expand medical devices & establishments inspection program* *- Introduce oversight over radiation emitting devices*	

Quality Criteria *how/with what indicators the quality of the activity result will be measured?*	**Quality Method** *Means of verification. what method will be used to determine if quality criteria has been met?*	**Date of Assessment** *When will the assessment of quality be performed?*
Expert feedback	Expert Report	Annually

OUTPUT 4: Systems and processes to improve pro-activity in addressing emerging risk developed		
Activity Result 1 (Atlas Activity ID)	Establish collaborative knowledge-sharing systems enabling early detection of potential hazards to food and feed control system	Start Date: 1 March 20112 End Date: 31 Dec 2012
Purpose	*To Establish collaborative knowledge-sharing systems enabling early detection of potential hazards to food and feed control system*	
Description	*Support SFDA to:* *- Establish clear channels for feedback from external stakeholders, particularly private sector and consumers* *- Develop crisis management strategy to ensure emergency response preparedness*	

Quality Criteria *how/with what indicators the quality of the activity result will be measured?*	**Quality Method** *Means of verification. what method will be used to determine if quality criteria has been met?*	**Date of Assessment** *When will the assessment of quality be performed?*
Expert feedback	Expert Report	Annually

OUTPUT 4: Systems and processes to improve pro-activity in addressing emerging risk developed		
Activity Result 2 (Atlas Activity ID)	Identify and swiftly act upon risks to patient safety	Start Date: 1 March 20112 End Date: 31 Dec 2012
Purpose	*To Identify and swiftly act upon risks to patient safety*	
Description	*Support SFDA to:* *- Develop a clear process for crisis management and ensure required capabilities are available*	

Quality Criteria *how/with what indicators the quality of the activity result will be measured?*	**Quality Method** *Means of verification. what method will be used to determine if quality criteria has been met?*	**Date of Assessment** *When will the assessment of quality be performed?*
Expert feedback	Expert Report	Annually

((SFDA finance team should discuss this with legal department after finalizing document contents))

VIII. LEGAL CONTEXT

This project document shall be the instrument referred to as such in Article 1 of the SBAA between the Government of (country) and UNDP, signed on (date).

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

The executing agency 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 executing agency's security, and the full implementation of the security plan.

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

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

IX. ANNEXES

Annex 1: Risk Analysis Log

Annex 2:Terms of Reference: TOR for key project personnel should be developed and attached

Terms of Reference/Job Description for the respective long term advisors and short term experts/consultants will be set out upon commencement of the project.

Annex 1
Risk Log

Project Title: Saudi Food and Drug Authority Phase II	**ID: SAU10/82003**	**Date:**

#	Description	Date Identified	Type	Impact / Probability	Countermeasures / Management response	Owner	Submitted, updated by	Last Update	Status
1	Recruitment of Senior specialized experts		Staffing	High/Low	Advertise TOR's, Expedite issuance of Letter of Appointment	UNDP			
2	Lack of SFDA Reporting		Operational	Medium/Medium	Follow up with participating sectors, and link payment to status reporting	SFDA			
3	Change of SFDA national project manager/coordinator		Staffing	High/Low	Document and Share project documents with project team	SFDA			
4	Unavailability of subject matter experts in certain scientific areas		Staffing	Medium/Low	SFDA to post expert TOR ahead of time to avoid any delay	SFDA, UNDP			
5	Major changes to project scope		Scope	Medium/Low	Follow a change management process with signed change requests	SFDA, UNDP			

Annex 2
TERMS OF REFERENCES
SFDA Phase II
Post Title:

I. Background

II. Scope of work and Objective

III. Methodology

IV. Qualifications and Experience Required:

V. Duration:

VI. Duty Station:

VII. Payments:

VIII. Timing: