



Government of Saudi Arabia

United Nations Development Programme

Project of Support to The Saudi Food and Drug Authority (SFDA)

Brief description

The newly established Saudi Food and Drug Authority (SFDA) has approached the United Nations Development Programme (UNDP) to seek technical assistance and to jointly collaborate in the area of establishing the structure of the authority, based upon UNDP's comparative and competitive advantages in providing the required technical support.

In this context, the objective of this PD is to provide substantive support to SFDA, through enabling the newly established organization to formulate its strategy and business plan; as well as develop the required institutional capacity to discharge its mandate and ultimately meet the national development plan's aspiration for a safe food and drugs management.

This joint project will benefit the SFDA -in specific- in terms of institutional capacity development, policy development, program coordination and monitoring, food and drugs quality and safety; as well as the Saudi society at large in terms of sustaining longevity and healthy life.

This nationally executed project aims at providing advisory services, specialized experts, and admin 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 and drug safety.

Section I - Part I. Situation Analysis

The problem to be addressed

Saudi Arabia has made considerable progress in improving the health status of its population over the last 30 years, which has been evident in the substantial increase in life expectancy at birth over the last three decades (1970-2000). Life expectancy has increased from 53.9 years to 70.9 years. The economic boom of the seventies and early eighties was used to establish necessary socio-economic development infrastructures, including the distribution and availability of basic services such as health facilities and safe drinking water throughout the Kingdom of Saudi Arabia. Moreover the Kingdom has in the past 20 years adopted a group of policies that supported the development of the agriculture, food processing, and manufacturing sectors. This has resulted in making the Kingdom a leading country in the region in regards of agriculture production, dairy products, and food manufacturing that has contributed to the excellent social indicators relating to survival, development, and protection of human-beings.

Nutrition and food security constitute an important target within the framework of the Millennium Development Goals approved in 2000 by the world leaders, including the Kingdom. The target set in this respect stipulates working diligently to halve the proportion of undernourished people and the proportion of underweight children under five years old. In the meantime, the present Five-Year Development Plan of the Kingdom (the 5th DP) aspires to upgrade nutritional standards and specifications.

The national institutional and legal framework and intended beneficiaries

On March 10, 2003, the Saudi Arabian Government decided to set up a Supreme Authority for Food and Medicine Control. The Authority, which will undertake all procedural, executive and control functions of current food and drug governmental organizations, will report directly to the Council of Ministers. It will be responsible for the following: the safety, security, validity and effectiveness of food and medicine provision for humans and animals; the safety of biological and chemical products, cosmetics and pesticides; safeguarding the impact of electronic products on public health, and scrutinizing standards of medical and diagnostic devices. The Authority will also set explicit plans for provision of food and drugs, conduct relevant studies, monitor the implementation of procedures relating to the issue of licenses for food, medicine and medical equipment to factories, exchange and publish information in cooperation with relevant local and international bodies, and build databases for food and drugs in the Kingdom¹.

The Saudi Food and Drug Authority (SFDA) will be run by a 15-member Board of Directors chaired by the Second Deputy Premier. The other members of the Board are: Minister of Municipal/Rural Affairs, Minister of Interior, Minister of Health, Minister of Commerce and industry, Minister of Agriculture, Minister of Water and electricity, Minister of Finance, Minister of Economy and Planning, President of the FDA (to be appointed), Executive President of the Saudi Arabia Standards Organization (SASO), Chairman of Chamber of Commerce and Industry council, and one appointed expert. The authority is on the organizational structure phase, identifying authorities of its board of directors, and spelling out detailed tasks of the organization.

Two stages have been laid out by the council of ministers for the SFDA to fully commence its duties: the first five-year period started on March 10 when the decree was issued and it involves mostly the organizational and staffing stage including establishing an administrative structure and organizational directory to enable the organization to achieve its goals. At the end of the first stage, the SFDA will have an executive organ that will be capable enough to perform all initial tasks and duties. It will be equipped with central laboratories at it's headquarter (not yet established). The first stage will also involve moving to the SFDA all food and drug related laboratories currently run by four government agencies namely:

¹ Ministry of Culture and Information website: <http://www.saudinf.com/main/y5490.htm>



SASO, the Ministry of Commerce, the Ministry of Agriculture and the Ministry of Health. Establishing close working relationship between the SFDA and local hospitals, universities and local and international private laboratories will be also accomplished at this stage. The second stage starts by March 2008 when the organization assumes its full executive role.

This joint project between SFDA and UNDP, *The Support to the SFDA*, will be the first stage of a long-run program supporting the vision of both KSA and SFDA of ensuring safe and high quality of food and drugs for the Saudi public. Hence it will benefit the SFDA in specific in terms of institutional capacity development, policy development, program coordination and monitoring, food and drugs quality and safety; and the Saudi society at large in terms of sustaining longevity and healthy life. Consequently, providing safe and secure quality of food and drugs would sustain high quality of life that would pave the way for further human development in terms of better life and longevity, improved productivity and per capita real income, and better education.

Linkages to the UNDP Country Programme

Within this spirit, the Saudi Food and Drug Authority (SFDA) has approached the United Nations Development Programme (UNDP) to seek technical assistance and to jointly collaborate in the area of establishing the structure of the authority, based upon UNDP's comparative and competitive advantages in providing the required technical support.

UNDP takes a holistic view to help build national ownership, national capacities and an enabling policy environment for effective decentralization, local governance and urban/rural development. The comparative strength of UNDP builds, especially, on Flexibility in its support with close attention to local needs.



Part II. Strategy

Global/national strategy

Preliminary discussions with the Acting Executive President of the Authority focusing on areas where UNDP could provide substantive support in building the capacity of SFDA in order to achieve its set goals and targets were held. Consequently the Acting Executive President of SFDA expressed interest in having consultants leading a field needs assessment study for the development of a comprehensive programme aimed at strengthening the establishment of the authority and laying down the foundation of its organizational structure.

How the project outputs will support achievement of the outcome and how UNDP will support policy development and strengthen national capacities and partnerships

This project document (PD) aims at providing substantive support to SFDA, through enabling the newly established organization to formulate its strategy and business plan; as well as develop the required institutional capacity to discharge its mandate and ultimately meet the national development plan's aspiration for a safe food and drugs management.

Upon the receipt of the Needs Assessment Report provided by the World Bank (WB), UNDP will provide a concept paper (CP) that streamlines the findings and recommendations of the report and prioritizes the areas that need to be addressed. Also, UNDP will develop a detailed work plan and costing for the institutional capacity development of the newly established authority. Furthermore, UNDP will apply sustainable and best international measures and practices in the field of food and drugs by building on the existing partnership with international organizations such as FAO and WHO to provide advisory services and specialized experts. Also, UNDP will assign specialized officers to provide admin support. In the process, these activities will help in developing the Authority's policy, advocacy, and executing capacity in the areas of food and drug safety.

Part III. Management Arrangements

The project will be nationally-executed through the SFDA. The Acting Executive President will be in charge of the management of this project and will be the coordination focal point with UNDP. All project personnel will be under the guidance and supervision of the Acting Executive President.

The amount estimated in the budget (US \$501,131) will be deposited with UNDP. Thereafter, payments for items identified in the project matrix (budget) will be made by UNDP after receiving disbursement instructions from the Acting Executive President. A financial report will be submitted to the Authority at the end of the project for the purpose of review and endorsement.

In the event that both parties decided to close this project and certain funds remained unutilized, UNDP will return the unutilized balance, after clearing all contractual commitments, to the Authority or transfer to a full fledged project depending on the preference of the Authority.

The budget is subject to review as needs arise and there is enough flexibility to transfer among project budget activities.



Part IV. Monitoring and Evaluation

The key corporate principles for monitoring, measurement and evaluation

The project has been designed to enable the project to be monitored in accordance with UNDP guidelines. This is reflected in the project Results and Resources Framework – see below – which incorporates outcomes and indicators for the project. However – as in any capacity building project – there are limitations on the extent to which measurable outcomes can be adopted. Lessons learned would be guided by the key principles of learning (as detailed in the new corporate Handbook on Monitoring and Evaluating for Results). Principles of relevance in the national context of the project are as follows:

- Help others actively **interpret** — rather than record — information so they can construct new knowledge for themselves;
- Use timely, effective and innovative **information management** strategies;
- **Derive performance standards** and learning from the various units/constituencies/communities of practice with which UNDP works to make UNDP assessments more participatory, contextually determined and independent;
- **Situate abstract tasks in authentic contexts** so that the relevance of the task is apparent and others can embed new knowledge;
- Extend to others the opportunity to work at problem solving by actively **sharing skills and expertise** with one another; i.e. “face-to-face” interaction without unnecessary dependence on information technology;
- Provide others with many **examples of a new concept** as well as an understanding of how essential features of the concept are reflected in a range of settings;

Section II - Project Results and Resources Framework

Intended Outcome: To provide substantive support to SFDA, through enabling the newly established organization to formulate its strategy and business plan; as well as develop the required institutional capacity to discharge its mandate and ultimately meet the national development plan's aspiration for a safe food and drugs management.			
Outcome indicator, baseline and target:			
Applicable MYFF Service Line: 2.6 Decentralization, local governance and urban/rural development (capacity development especially for local government planning and fiscal management)			
Partnership Strategy: Institutional Arrangement NEX			
Project title and ID: Support to Saudi Food and Drugs Authority (SFDA) / SAU10-38929			
Intended Outputs	Output Targets for (years)	Indicative Activities	Inputs
1. Institutional capacity developed		<p>Activity 1.1 A concept paper (CP) developed, which is based on the WB mission report, to capture the vision and mission of the newly created SFDA.</p> <p>Activity 1.2 Concept paper reviewed and approved by SFDA's board and its partners to support the needs assessment recommendations and chart the way for its implementation mechanisms and resources.</p> <p>Activity 1.3 A detailed work plan with costing component prepared for immediate implementation of the agreed upon recommendations of the needs assessment report through specified time frame.</p>	<p>National and International consultants for 10 man days to draft a CP and review it for SFDA approval around the 1st week of October 2004.</p> <p>National and International consultants for 20 man days to formulate a detailed work plan and budget around the 3rd week of October 2004.</p>



Part V. Legal Context

This project document shall be the instrument referred to as such in Article I of the Standard Basic Assistance Agreement between the Government of the Kingdom of Saudi Arabia and the United Nations Development Programme, signed by the parties on 04 January 1976. The host country- implementing agency shall, for the purposes of the Standard Basic Assistance Agreement, refer to the Government Cooperating Agency described in that Agreement.

The following types of revisions may be made to this project document with the signature of the UNDP Resident Representative (or Officer in Charge) only; provided he or she is assured that the other signatories of the project document have no objections to the proposed changes:

- (a) Revisions in, or addition of, any of the annexes of the project document;
- (b) Revisions which do not involve significant changes in the immediate objectives, outputs or activities of a project, but are caused by the rearrangement of inputs already agreed to or by cost increases due to inflation;
- (c) Mandatory annual revisions which rephrase the delivery of agreed project inputs, or reflect increased expert or other costs due to inflation, or take into account agency expenditure flexibility.

Annual Work Plan

United Nations Development Programme
 Saudi Arabia
 Year: 2004-2005
 Project Number: SAU10- 00038929
 Project Title: Support to the Saudi Food and Drug Authority (SFDA)

Expected Output	Key Activities	Timeframe				Resp. Partner	Planned Budget			Amount
		Q1	Q2	Q3	Q4		Fun d	Donor	Budget Description	
Institutional Capacity Development	Concept paper (CP) that prioritizes SAFD needs	x				UNDP	C/S	SA	2 National / International Consultants, 10 man days desk work, reviews & meetings	20,818
	CP reviewed & approved by SFDA	x				UNDP	C/S	SA	Presentation to SFDA	0
	Detailed work plan & costing	x				UNDP	C/S	SA	2 National / International Consultants, 20 man days desk work	35,198
Sub total									56,016	
Advisory Services	Consultancy Committees	x	x	x	x	UNDP/ WHO/ FAO	C/S	SA	67 Specialists in Medical Equipments &Prod	35,867
		100 Specialist in Drug Affairs	44,373							
		65 Specialists in Food	37,067							
		9 Specialists in Admin & Financial Affairs	3,733							
	Part Time Local Consultants	x	x	x	x	UNDP/ FAO	C/S	SA	1 Consultant in Food Affairs	8,000
	Specialized Experts	x	x	x	x	UNDP/ WHO/ FAO	C/S	SA	2 Experts in Medical Equipments &Products	59,920
		5 Experts in Drug Affairs	69,993							
1 Expert in Food		19,570								
Sub total									318,519	
Admin Support	Secretaries	x	x	x	x	NEX	C/S	SA	2 in Medical Equipments & Products	32,000
		2 in Drug Affairs	32,000							
		1 in Food	16,000							
Translators	x	x	x	x	NEX	C/S	SA	1 in Admin & Financial Affairs	32,000	
Sub total									112,000	
TOTAL									486,536	
UNDP CO									3%	14,596
Grand Total									501,131	

Section IV—other agreements

Since SFDA would like to tap the advisory services provided by certain specialized UN agencies (such as WHO and FAO), the required Letter of Agreement (LOA) will be signed to cover the inputs expected to be delivered by the other UN agency or agencies.

Annex I

Sectors	Member	Category	Cost per member	Travel cost	DSA/max 3 months	MeetingsYear	PeriodMonth	Cost/SAR	Cost US\$
Medical Equipments & Products									
A- Committees (6)	-	-				-	-	-	
1- Consulting Committees	20	A	1000	-	-	4	-	40,000	10,667
Committee A: Main	9	A	1000	-	-	2	-	18,000	4,800
Committee B: Partner	11	A	1000	-	-	2	-	22,000	5,867
2- Medical Equipments Categorizing	9	B	700	-	-	3	-	18,900	5,040
3- Medical Equipments & Products Registration	7	C	500	-	-	3	-	10,500	2,800
4- Protection from radiation	9	B	700	-	-	3	-	18,900	5,040
5- Electrical Equipments Categorizing	7	B	700	-	-	3	-	14,700	3,920
6- Medical Equipments Categorizing	15	B	700	-	-	3	-	31,500	8,400
Sub Total	67	-	-			19	-	134,500	35,867
B- Technical Experts	2	-	41,250	7,500	73,913	-	0.75	224,700	59,920
C- Admin Support/Secretaries	2	-	5000			-	12	120,000	32,000
Total	71	-	-			190	-	479,200	127,787
Drug Affairs									0
A- Committees (10)									0
1- Drugs Consulting	11	A	1000			3	-	33,000	8,800
2- Laboratory Reagents Consulting	11	B	700			2	-	15,400	4,107
3- Cosmetics	6	B	700			2	-	8,400	2,240
4- After Sell Pharmaceutical Services	12	B	700			2	-	16,800	4,480
5- Bioequivalence & Bioavailability & Clinical & Static Trial	8	C	500			2	-	8,000	2,133
6- Veterinary Drugs	8	C	500			2	-	8,000	2,133
7- Good Manufacturing	8	C	500			3	-	12,000	3,200
8- Primary Drugs Registration	12	A	1000			2	-	24,000	6,400
9- Preparatory Drugs Registration	12	A	1000			2	-	24,000	6,400

10- Herbs and Medications	12	B	700			2	-	16,800	4,480
Sub Total	100	-	-			22	-	166,400	44,373
B- Technical Experts		-							0
1- Bioequivalence& Bioavailability	1	-	41,250	7,500	18,478	-	0.75	56,916	15,178
2- Cosmetics	1	-	22,500	7,500	12,319	-	0.5	31,069	8,285
3- Clinical Informatics	1	-	41,250	7,500	73,913	-	0.75	112,350	29,960
4- Good Manufacturing Practices	1	-	22,500	7,500	12,319	-	0.5	31,069	8,285
5- Clinical Trial	1	-	22,500	7,500	12,319	-	0.5	31,069	8,285
Sub Total	5	-	-			-	-	262,472	69,993
C- Admin Support/Secretaries	2	-	5000			-	12	120,000	32,000
Total	107	-	-			-	-	548,872	146,366
Food									0
A-Committees (16)									0
1- Consulting (15)	60	C	500			120	-	132,000	35,200
2- Planning and Following Up (1)	5	B	700			2	-	7,000	1,867
Sub Total	65	-	-			122	-	139,000	37,067
B- Local Consultants/Part Time	1	-	5000			-	6	30,000	8,000
C- External Technical Experts	1	-	41,250	7,500	24,638	1	1	73,388	19,570
D- Admin Support	1	-	5,000			-	12	60,000	16,000
Total	68	-	-			123	-	302,388	80,637
General Admin of Financial & Administrative Affr.									0
A- Committees (2)									0
1- Continuous Evaluation	5	A	1000			2	-	10,000	2,667
2- Steering	4	C	500			2	-	4,000	1,067
Sub Total	9	-	-			4	-	14,000	3,733
B- Consultants/Part Time									0
1- HR Specialist	1	-	5,000			-	6	29,997	7,999
2- Accounting Systems Specialist	1	-	5,000			-	6	29,997	7,999
3- Auditing & Accounting Specialist	1	-	5,000			-	6	29,997	7,999
4- IT Specialist	2	-	5,000			-	6	59,994	15,998
Sub Total	5	-	-			-	-	149,985	39,996
C- Admin Support/ Translator	2	-	5000			-	12	120,000	32,000
Total	16	-	-			-	-	283,985	75,729
Grand Total	262	-	-			-	-	1,614,444	430,519

The Kingdom of Saudi Arabia (KSA)

Project of Support to the Saudi Food and Drug Authority (SFDA)

Project ID: SAU10- 00039829

Expected Outcome(s)/Indicator (s):

Decentralization, local governance and urban/rural development (capacity development especially for local government planning and fiscal management)

Expected Output(s)/Indicator(s): Creation of an enabling environment for SHD / local authorities and community representatives in rural and urban areas involved in planning and management of development activities, including the provision of public services. Capacity of and partnerships between local authorities and civil society organizations.

Implementing partner: The Saudi Food and Drug Authority (SFDA)

Other Partners: ---

Programme Period: One Year
Project Title: Support to the Saudi Food & Drug Authority (SFDA)
Project ID: SAU 10 -000 38929
Project Duration: One year (to be extended)
Management Arrangement: NEX

Budget US \$486,535
General Management Service Fee: US \$14,596
Total budget: US \$501,131
Allocated resources:
• Government US \$501,131
• Regular _____
• Other:
 ○ Donor _____
 ○ Donor _____
 ○ Donor _____
• In kind contributions _____
Unfunded budget: _____

Agreed by (Government): Mohammed Bin Ahmed Al-Kanhal /Acting Executive President of SFDA

Signature &Date: _____ 21/8/1425 H

Agreed by (UNDP): El-Mostafa Benlamlih /UN Resident Representative & UNDP Resident Coordinator

Signature &Date: _____ 6/10/2004

