

United Nations Development Programme
Saudi Arabia



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Evaluation Report

**Terminal Evaluation for Project SAU10/82003 Saudi
Food and Drug Authority Phase II**

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Acronyms

APR	Annual Progress Report
AST	Arabia Standard Time
DAC	Development Assistance Committee
EU	European Union
GCC	Gulf Cooperation Council
GHC	Gulf Health Council
GMP	Good Manufacturing Practice
HTA	Health Technology Assessment
IFC	International Financial Corporation
ITP	Information Technology Planning
MoH	Ministry of Health
NTP	National Transformation Program
OECD	Organisation for Economic Cooperation and Development
PMS	Post Market Surveillance
QC	Quality Control
R&D	Research and Development
SDG	Sustainable Development Goal
SFDA	Saudi Food and Drug Authority
SOP	Standard Operational Procedures
UN	United Nations
UNDP	United Nations Development Program
USDA / FAS	United States Department of Agriculture / Foreign Agricultural Service
WHO	World Health Organisation

Executive Summary

Key Purpose of the Evaluation

The terminal evaluation assessed the *Project ‘Saudi Food and Drug Authority Phase II’*. It reviewed the performance of the Project against the objectives stated in the strategic and annual plans. The purpose of the evaluation was to provide systematic and timely evaluation of the Project. The focus of evaluation was on the assessment of achievements, quality and results of the Project. The evaluation looked for evidence of why and how these results are linked to the UNDP intervention. The project evaluation also assessed how the outputs of the Project have contributed to achieving high impact goals as set by the SFDA mandate.

The main objectives of the project are as follows:

1. Support SFDA in building broad and deep capabilities.
2. Support SFDA to ensure thoroughness, transparency, and consistency in enforcement and communication.
3. Support SFDA to 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

Main Analytical Points

The evaluation concentrated on the following specific evaluation criteria: relevance, effectiveness, efficiency, sustainability and impact. The evaluation answered specific questions regarding these criteria.

The Project needs to fit strategically into the complex and changing context of health system in Saudi Arabia. This is also important given the amount of government spending on this particular project. Relevance concerns the extent to which the Project and its intended outputs or outcomes are consistent with national and local policies and priorities and the needs of intended beneficiaries.

Effectiveness of the Project means whether the planned benefits have been delivered and received, and whether the intended beneficiaries participated in the intervention. Given the fact that the evaluation is a terminal evaluation of the Project, both the management processes and indications of the Project's contribution to national programmes were assessed. The evaluation examined the extent to which the objectives of the Project have been achieved as intended, and whether the effects of the Project have been facilitated or constrained by any factors.

Efficiency is the extent to which the cost of the Project has been justified by the benefits, whether or not expressed in monetary terms in comparison with similar project or known alternative approaches. Given the difficulty in quantifying the Project's contribution to higher-level objectives, the focus is on more operational elements of the Project.

Regarding sustainability the main question is whether SFDA will be able to continue its work. The evaluation assessed the necessary financial and human resources, adequate regulatory / legislative framework and the interest and commitment of governmental institutions / authorities.

The evaluation examined the extent to which the Project was both internally coherent and well aligned with other policies and programmes. Given the scale of the health challenges, both aspects are crucial. The former relates to the Project's structure and focus of its own actions and resources, while the latter refers to exploiting synergies and avoiding duplication with other initiatives at national and international levels.

The evaluation addressed the following cross-cutting issues: gender equality, good governance (in its reform agenda and decentralisation of the healthcare system) and social inclusion, in particular.

The Consultant followed a participatory and consultative approach ensuring close engagement with the project partners. The Consultant collected and analysed data on the Project as a whole. The Consultant reviewed all relevant sources of information, such as project documents, project reports, national strategic and legal documents, and any other materials that the Consultant considered useful for the assessment. Documents were provided by UNDP and SFDA as well as collected from public sources.

SFDA collaborated effectively and efficiently with the Consultant, and provided all necessary information and documentation, as well as access to the project premises and activities. Consultation and interviews were organized and scheduled for the Field Phase and allowed to elicit the views and perceptions of those with direct experience of the Project regarding its relevance and implementation and performance so far.

Main Conclusions

The Project has valid and appropriate objectives which are in line with the health policy and strategy in the Kingdom of Saudi Arabia (*Relevance*).

The Project significantly contributes to strengthening the capabilities of SFDA to target needs of the covered areas (i.e. food, drug and medical devices) (*Effectiveness*).

The Project benefits from the synergy between the project activities and the structure of SFDA, therefore, it supports SFDA implementing its mission (*Internal Coherence*).

The activities increased the Project's coherence with the national programmes (*External Coherence*).

SFDA seems to be capable to continue the activities in accordance with the Third Strategic Plan and by using the developed capacities of the institution (i.e. new organisational matrix structure) and the employees (i.e. outputs of the training programmes) (*Sustainability*).

SFDA continuously hires, employs and trains qualified female staff in increasing number (*Gender Equality*).

Strategies

To identify the future areas of collaboration between SFDA and UNDP needs were assessed by considering the needs defined by SFDA Sectors; objectives and initiatives of National Transformation Program 2020 that are relevant for SFDA; and SFDA Third Strategic Plan 2018-2022.

On the basis of the findings of the evaluation as well as considering the strategy and policy documents (i.e. United Nations Sustainable Development Goals, Saudi Vision 2030, National Transformation Program 2020, SFDA Third Strategic Plan) the following strategies are presented for consideration.

1. Assessment of the safety and effectiveness of new drugs and medical devices
2. Risk based evaluation and safe use of technologies
3. Continuation of building institutional and staff capacities
4. Regional and international collaborations and recognition
5. Internal communication and organisational culture
6. External communication and awareness

Recommendations

SFDA should:

- Maintain the focus on specific objectives and areas where the project provided added value.
- Maintain and strengthen links between the new project and the national policies (e.g. NTP2020, MoH Health Strategy) to maximize impact.
- Support the project management and coordination with UNDP.
- Maintain the monitoring of the progress of the new project according to the programmatic and action specific indicators set in the Logical Framework.

UNDP should:

- Design and propose a new project to further support SFDA implementing its Third Strategic Plan and building institutional and individual capabilities.
- Maintain the implementation of the activities of the new project in accordance with the plan of action.
- Maintain the monitoring of the progress of the new project according to the programmatic and action specific indicators set in the Logical Framework.

1. Background

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 Second Strategic Plan, based upon UNDP's comparative and competitive advantages in providing the required technical support.

The terminal evaluation assessed the *Project 'Saudi Food and Drug Authority Phase II'* in terms of relevance, appropriateness, effectiveness, efficiency, impact, and sustainability. It reviewed the performance of the Project against the objectives stated in the strategic and annual plans. The purpose of the evaluation was to provide systematic and timely evaluation of the Project. The focus of evaluation was on the assessment of achievements, quality and results of the Project. The evaluation looked for evidence of why and how these results are linked to the UNDP intervention. The project evaluation also assessed how the outputs of the Project have contributed to achieving high impact goals as set by the SFDA mandate.

On the basis of the project evaluation, the Consultant drafts a fully detailed and budgeted new phase Project Document. The Project Document introduces the overall and specific objectives of the new project along with its expected outputs/results, while it also includes proposed actions/activities and a Logical Framework. The Consultant prepares the Project Document based on both UNDP and SFDA inputs.

Please find the Terms of Reference for the terminal evaluation in *Annex 1*.

2. Evaluation Methodology

2.1. Scope of Evaluation

The evaluation concentrated on the following specific evaluation criteria: relevance, effectiveness, efficiency, sustainability and impact¹. The evaluation answered specific questions regarding these criteria. The evaluation questions were based on the questions given in the Terms of Reference for the terminal evaluation as well as considering sample questions proposed in the Consultant's Technical Offer. The evaluation questions were discussed with the representatives of SFDA during the interviews (*see below*).

Please find the Evaluation Questions in *Annex 2*.

2.1.1. Relevance

The Project needs to fit strategically into the complex and changing context of health system in Saudi Arabia. This is also important given the amount of government spending on this particular project. Relevance concerns the extent to which the Project and its intended outputs or outcomes are consistent with national and local policies and priorities and the needs of intended beneficiaries.

2.1.2. Effectiveness

Effectiveness of the Project means whether the planned benefits have been delivered and received, and whether the intended beneficiaries participated in the intervention. Given the fact that the evaluation is a terminal evaluation of the Project, both the management processes and indications of the Project's contribution to national programmes were assessed. Delivery of benefits and accomplishment of activities / results / outputs / outcomes were, of course, evaluated, too.

2.1.3. Efficiency

Efficiency is the extent to which the cost of the Project has been justified by the benefits, whether or not expressed in monetary terms in comparison with similar project or known alternative approaches. Given the difficulty in quantifying the Project's contribution to higher-level objectives, the focus is on more operational elements of the Project. Therefore, the

¹ Widely known as DAC criteria. The OECD Development Assistance Committee became part of the OECD by Ministerial Resolution on 23 July 1961. It is a unique international forum of many of the largest funders of aid, including 30 DAC Members. Asian Development Bank, African Development Bank, Inter-American Development Bank, International Monetary Fund, United Nations Development Programme and the World Bank participate as observers.

evaluation questions are related to the allocation of resources across objectives and expected results, practical implementation and resources.

2.1.4. Impact

The evaluation examined the extent to which the objectives of the Project have been achieved as intended, and whether the effects of the Project have been facilitated or constrained by any factors.

2.1.5. Sustainability

Sustainability of the Project requires consideration of different aspects (e.g. governance, access to health, funding) when addressing long-term impacts and outcome of the implementation of the Project. The main question is whether SFDA will be able to continue its work. The evaluation assessed the necessary financial and human resources, adequate regulatory / legislative framework and the interest and commitment of governmental institutions / authorities.

2.1.6. Coherence

The evaluation examined the extent to which the Project was both internally coherent and well aligned with other policies and programmes. Given the scale of the health challenges, both aspects are crucial. The former relates to the Project's structure and focus of its own actions and resources, while the latter refers to exploiting synergies and avoiding duplication with other initiatives at national and international levels.

2.1.7. Cross-cutting Issues

The evaluation addressed the following cross-cutting issues: gender equality, good governance (in its reform agenda and decentralisation of the healthcare system) and social inclusion, in particular. Principles of good governance include: stakeholder rights, integrity and ethical behaviour, disclosure and transparency, performance orientation, responsibility and accountability, and mutual respect².

² OECD, 2004

2.2. Evaluation Matrix

The Evaluation Matrix has been drafted for this evaluation and was used during the Field Phase and Synthesis Phase. The Evaluation Matrix follows the Terms of Reference and Logical Framework, and includes the evaluation questions and plans for collecting information to answer questions. The Evaluation Matrix was used to plan the Field Phase, collection and analysis of information, and writing report.

Please find the Evaluation Matrix in *Annex 3*.

The Consultant followed a participatory and consultative approach ensuring close engagement with the project partners. The Consultant collected and analysed data on the Project as a whole. This focused on what the Project was doing in terms of both its objectives and its implementation. This is comprised of two main methods: analysis of existing sources and consultation with key stakeholders.

2.3. Analysis of Existing Sources

The Consultant reviewed all relevant sources of information, such as project documents, project reports, national strategic and legal documents, and any other materials that the Consultant considered useful for the assessment. Documents were provided by UNDP and SFDA as well as collected from public sources.

As part of the assessment of the Project the Consultant reviewed policy and strategic papers on the health system in Saudi Arabia, studies, reports and other documentation on health problems and programmes. National health policy and programming documentation helped examine the Project's internal and external coherence. To examine project implementation and monitoring provisions, the Consultant collated and analysed relevant data provided by UNDP and SFDA. This covered such issues as the budget structure and management, allocation of funding according to objectives and activities.

Please find the list of documents consulted in *Annex 4*.

2.4. Field Visit Approach

The general purpose of the Field Visit was to check the findings of the First Phase of the evaluation conducted home-based against additional documents collected and meetings and interviews conducted with key stakeholders of the Project in Saudi Arabia, in addition to brief and discuss the process and outputs of the evaluation of the Project with UNDP.

During the Field Phase the following components of the Project were assessed: objectives; results; activities conducted to achieve the results; other key issues critical for the success of the project.

Data and information were collected from documents and other written sources, as well as key stakeholders were met and interviewed for further assessment and evaluation of the Project.

During the Field Phase the Consultant held a briefing meeting with UNDP and met the Saudi Food and Drug Authority. At the end of the Field Phase, the Consultant summarised his work, analysed the reliability and coverage of data collection, and presented preliminary findings in a meeting with UNDP.

2.5. Consultations with Saudi Food and Drug Authority

SFDA collaborated effectively and efficiently with the Consultant, and provided him with all necessary information and documentation, as well as access to the project premises and activities.

Consultation and interviews were organized and scheduled for the Field Phase and allowed to elicit the views and perceptions of those with direct experience of the Project regarding its relevance and implementation and performance so far. The Consultant conducted a series of semi-structured interviews with representatives of SFDA to learn more about all aspects of the design and implementation of the Project.

Please find the list of interviews conducted during the Field Phase in *Annex 5*. Please also find the minutes of meetings in *Annex 6*.

2.6. Limitations of the Evaluation

Limitations such as data availability and reliability, respondent bias and contribution bias had been considered when developing the evaluation methodology and planning the Field Phase. During the Field Phase, however, both interviews and collection of additional documents and information provided the Consultant with sufficient information about the Project and its progress to date. Therefore, accurate data on the implementation and administration of the Project was made available which allowed an extensive analysis of program effectiveness.

The evaluation findings are based on the views of key informants with interest in the Project. However, those were not biased in the responses regarding outcomes. The evaluation reduced the effect of respondent biases and validated interview results by ensuring that respondents understood the strict confidentiality of responses and including key informants who do not have any vested interest in the Project.

There were no difficulties encountered during the Field Phase. All stakeholders supported the Consultant by supplying all requested information, documents and were open for constructive discussions. In addition, the Consultant was provided with an office and free entrance to SFDA buildings.

3. Results of Evaluation

3.1. Findings Based on Answers to Evaluation Questions

SFDA regulates, oversees, and controls food, drug, medical devices, as well as sets mandatory standard specifications thereof, whether they are imported or locally manufactured. SFDA Laboratories ensures control over products and conducts test activities. Moreover, the SFDA is in charge of consumers awareness on all matters related to food, drug and medical devices and all other products and supplies.

The UNDP Project has been designed and organized around four specific objectives. Those focus on issues which are aligned with SFDA's mandate and strategic plans in the second phase. Indicators have been put in place to monitor progress.

The main objectives of the project are as follows:

1. Support SFDA in building broad and deep capabilities.
2. Support SFDA to ensure thoroughness, transparency, and consistency in enforcement and communication.
3. Support SFDA to 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

The expected outputs and planned activities are as follows:

Output 1. Capacity of institutional, individual and systems developed to serve processes and tools in all relevant sectors

Activity 1. Enrich SFDA's expertise by attracting, retaining and developing the appropriate human resources

Activity 2. Enhance SFDA key internal tools and processes to better support its mission

Activity 3. Fully develop the required set of capabilities to take over key processes

Activity 4. Support Information Technology Planning (ITP) and shared services in building their capabilities

Output 2. Communication strategy and control framework prepared and executed

Activity 1. Improve industry and consumer awareness and intra-agency cooperation through interactive and coherent communication strategy

Activity 2. Define internal control systems and institutionalize accountability

Activity 3. Align with relevant stakeholders on an efficient enforcement model

Output 3. Standards, control systems and policies developed to cover food, drug and medical devices

Activity 1. Continue to fulfil competencies and responsibilities outlined in mandate

Activity 2. Optimize SFDA's role regarding inspection of local market food businesses and water bottling plants

Activity 3. Implement effective processes to operationalize pesticide safety standards

Activity 4. Reinforce safety of drugs, bio-products, health, herbal and veterinary products across the value chain

Activity 5. Pursue the development of cosmetics standards and ensure the safety of cosmetics products

Activity 6. Develop best practice policies for specific / emerging product categories

Output 4. Systems and processes to improve pro-activity in addressing emerging risk developed

Activity 1. Establish collaborative knowledge-sharing systems enabling early detection of potential hazards to food and feed control system

Activity 2. Identify and swiftly act upon risks to patient safety

In addition, the expected outputs address challenges that Saudi Arabia faces as introduced in the strategy of Ministry of Health (MoH). The challenges for the health sector include the high costs of health services due to the accelerating development of medical technologies in hardware, equipment tools and advanced and expensive medical technologies, as well as the unremitting discoveries of new expensive drugs.

The UNDP project covered a comprehensive spectrum of components of SFDA Second Strategic Plan. The successful utilization of the technical support depends on the absorption capacities of the beneficiary and whether the implementation is supported by legislation and regulations considering long term impact on both SFDA and its clients and consumers.

Regarding the project management, to ensure coordination of the Project's activities and to increase coherence between the implementation of different components the UNDP needs to coordinate the activities in close cooperation with SFDA management under the common roof of the Project. UNDP is responsible for such coordination, while SFDA is also required to cooperate actively in organizing the Project activities as well as ensuring active participation in and contribution to the technical support provided. Mechanisms for pooling expertise in the Project and supporting SFDA during the implementation of its Second Strategic Plan have been seen and confirmed by achievements according to the Annual Progress Reports (APR) 2015-2017.

3.1.1. Relevance

The objectives of the Project are broadly valid and appropriate. They helped focus the resources on issues that generate the most added value for SFDA, while accommodating existing needs and fitting well with health policy in Saudi Arabia.

The activities succeeded in increasing the Project's coherence. They are in general consistent with the strategy of Ministry of Health. The Project's structure of relevant

objectives has served to ensure the relevance of individual activities. The activities have corresponded to needs and demonstrated clear and suitable objectives.

In order to protect and promote the right to health of the Saudi people and to establish and maintain an effective health products regulatory system responsive to the country's health needs and problems, SFDA performs the following functions:

- Observe the safety, security, and effectiveness of food and drug for humans and animal.
- Observe the safety of complementary biological and chemical substances, cosmetics and pesticides.
- Observe the safety of medical devices and its impact on public health.
- Ensure accuracy and safety of medical and diagnostic devices.
- Launch clear policies and procedures for food and drug, and plan to achieve and implement these policies.
- Conduct research and applied studies to identify health problems, their causes, determine its impact on public, with the consideration of methods for research / studies evaluation. The authority shall establish scientific bases for awareness and consulting services and executive programs in the fields of food and drug.
- Control and supervise licenses procedures for food, drug and medical devices factories.
- Disseminate and exchange information with local and international scientific and legal agencies, and setting up a database for food and drug.

The mission of SFDA is to ensure that only medicinal products are on the market, which are of good quality, effective and safe. The quality of medicinal products is controlled by inspections. Regarding drugs, a suitable pharmacovigilance system covers the aspects of effectiveness and safety. Independent and impartial analyses and quality control of medicinal products on the market are also conducted. These activities were addressed by the objectives of the Project.

While fulfilling its role, SFDA encourages cooperation with other public and private stakeholders from healthcare sector. For instance, in the standards committees to harmonise local and regional standards of medical devices SFDA require participation of different stakeholders. Also, the Standing Committee for medical devices and radioactive materials used in diagnostic and treatment, works with the Ministry of Interior to regulate and control medical devices and radioactive material.

3.1.2. Effectiveness

The planning and preparation of the Project was done in accordance with best practices. Then the project, through its impact on SFDA's operation according to its mandate and by strengthening its institutional, staff and systems capacities in all sectors, helped to ensure that only good quality and safe products are sold in the market and contributed towards the improvement of the supply chain management. The Project also supported SFDA in the

improvement of its business processes and systems in licensing, inspection and registration. Therefore, the Project improved the level of the quality of healthcare in Saudi Arabia.

The expected outputs of the Project will sufficiently be achieved through the activities. However, continuous professional development of staff, availability of needed equipment, maintenance of equipment, availability of funds for running the inspections and laboratories, etc., must also be considered for an effective long-term operation after the Project ends.

3.1.3. Efficiency

The terminal evaluation of the UNDP Project was not supposed to be a financial audit, instead the evaluation focused on whether the planned project objectives were achieved. To assess the utilization of funds made available for the Project, the Consultant reviewed the Annual Audit Reports of the Independent Auditor. In accordance with the Audit Reports, the statements of project expenses present fairly, in all material respects, the expense of 3,233,851 USD and 2,969,670 USD incurred by the UNDP Project for the periods from 1 January to 31 December 2016 and from 1 January to 31 December 2017, respectively. In the opinion of the auditor, the statements of project expenses were prepared in conformity with the approved project budgets and for the approved purposes of the Project, followed the relevant UNDP regulations and rules, policies and procedures, and were supported by properly approved vouchers and other supporting documents.

The Project added significant value and is cost-effective, as the activities are well designed and outcome-focused. The biggest driver of efficiency is how effective the action is in achieving its goals and therefore the value added by the Project. While it was not possible to measure effectiveness in quantitative terms, indications are positive, with evidence of many potential benefits from funded actions and generally good planning.

Monitoring and project control were ensured by regular reporting and feedback mechanisms, and, if deemed necessary, meetings between the relevant project partners and SFDA Sectors were organized. Administrative support for project and continuous control and communication between UNDP and SFDA was ensured by appointment of a Project Coordinator at SFDA.

3.1.4. Impact

The evaluation examined the extent to which the objectives of the Project have been achieved as intended, and whether the effects of the Project have been facilitated or constrained by any factors. The assessment proves the logical reasoning that links the needs, the objectives and a range of policy options to address the needs.

In each country, systems exist to control the quality of medicinal products and to inspect manufacturers, wholesalers, etc. Possible options are limited to the organisation of quality controls (private versus public service), payment schemes for receiving healthcare services (private out-of-pocket payment vs. state-regulated healthcare system), relocating the responsibilities from government e.g. to the manufacturers / wholesalers / importers.

The Project significantly contributes to the health status of the Saudi people. 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, is reduced. In this respect, all activities planned and achieved towards better quality control and inspections are useful for the health and safety of population.

The Project directly affected:

- 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 were 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 was strengthened in the project.

The Project indirectly affected the Saudi population, by ensuring access to better quality and controlled food and medicinal products.

Regarding the macroeconomic impact of the Project, spending on thorough control of medicinal products may result in increasing costs (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.

The social impacts of the Project may include the health gain and better outputs of health care services due to application of quality diagnostics and therapeutic technologies and products.

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

3.1.5. Sustainability

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

Governance: Who is responsible for the sustainability of the Project? Where is authority predominantly located (i.e. at local or national level)?

- The Project maintained strong ownership of SFDA in regulation regarding food, drug and medical devices products.
- The Project was 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: Has the Project improved access to quality and safe health care? Are vulnerable groups able to access to health services according to their health needs?

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

Funding: What are the sources of further funding and how is the fund/s allocated? Is the funding mechanism based on cost-effectiveness and cost-efficiency analyses? Are there incentives inbuilt in the healthcare financing system in Saudi Arabia?

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

Culture: Has the Project contributed to see health as a value? Do the functions of SFDA provide better health for the citizens of Saudi Arabia?

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

Health information: Who is the owner of the health (related) information and who is responsible for the collection and analysis of health (related) data? While connectivity and complexity of data bases as well as the need for information exchange are increasing, there are concerns over privacy and security that may lead to limitation of data connectivity and exchange.

- Development of IT systems and data management.
- Building individual IT capabilities.

Innovation: Has the Project contributed to promote 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 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.

3.1.6. Coherence

There is internal coherence in the Project as the structure provides a framework to fund and achieve activities in well-defined areas and fosters synergies between these activities.

The different sectors of SFDA should co-operate better than in the past, however. This will generate synergistic effects which could be further supported by the newly established Operations Sectors through its horizontal, cross-sectoral tasks and responsibilities (please refer to the new organisational structure introduced in *Figure 1* below).

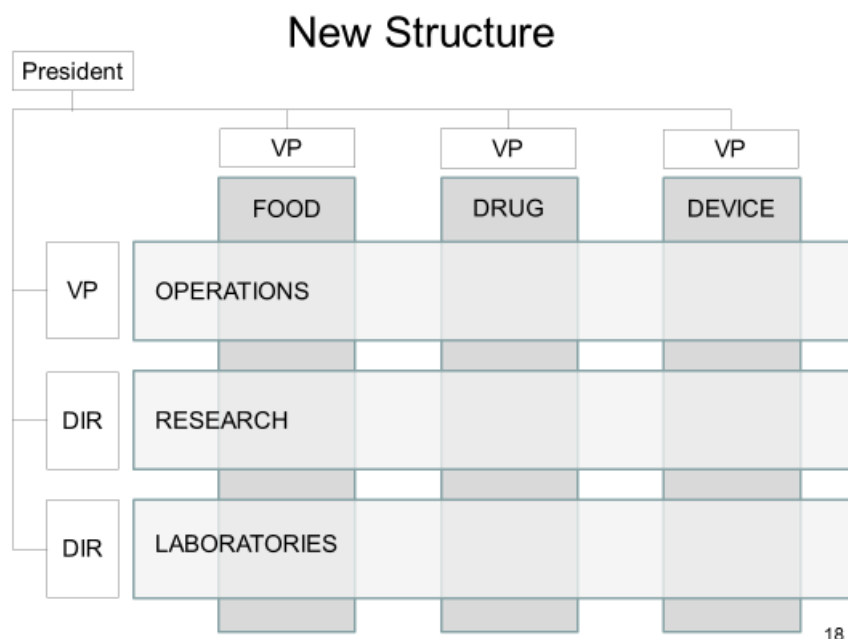


Figure 1 New organisational structure of SFDA

Synergistic effects can also be accomplished by using a common quality management system, purchasing laboratory consumables (reagents, chemicals, etc.) at institutional level instead of laboratory level due to increased buying power, a possibly reduced administrative overhead, easier and faster communication e.g. on scientific / analytical issues and support.

Saudi health policies need to be seen in regional and international contexts. In particular, the pharmaceutical sector is able to operate only in an international environment considering the global economic developments: quality control of raw / starting-materials, active pharmaceutical ingredients, finished products, mutual recognition of pharmaceutical good manufacturing practice (GMP) inspections, etc. The Project strengthens the links between international partners and ensures the benchmarking of SFDA operation, therefore provides external coherence.

3.1.7. Cross-cutting Issues

Healthcare sector being at the intersection of numerous problems, the Project targets the following cross-cutting issues, in particular: gender equality, good governance (in its reform agenda and decentralisation of the healthcare system), the rights of the vulnerable groups of population.

Both the Saudi Vision 2030, and on its basis the National Transformation Program (NTP) 2020 intend to open up the country to more employment opportunities for women and to empower women. SFDA has recently also employed qualified female staff for both technical, scientific and management positions which was not the case in the past years. Also, NTP 2020 includes several initiatives which aims at increasing the effectiveness of health system

through establishment of new centres for various domains of health care which can be seen as a reform agenda for decentralization of and strengthening the healthcare system. Once the healthcare system will be further built on the basis of principles of equity, accessibility and quality of health care services, vulnerable groups will have equal access to equal services. SFDA, through the outputs of the UNDP Project and by implementing its upcoming Third Strategic Plan prepared in accordance with the Saudi Vision 2030 and the National Transformation Program 2020, also contributes to the better performance of healthcare system, considering for instance the quality and safety of food, feed and medicinal products in accordance with the mission and mandate of SFDA.

Regarding good governance, the following apply. SFDA knows both its and its employees' rights and has a means of redress for violation of their rights. Decisions are based on the values held by SFDA. SFDA defined and agreed on a shared set of values, therefore decisions are based on a common understanding. The organization implements procedures to verify its operating and reporting systems. SFDA, within the Project in particular, established indicators to determine whether goals and objectives are being met. The leadership holds responsibility for running SFDA in accordance with its vision and mission, mandate and strategy plans. SFDA leadership and management respect a goal of building trust.

4. Overall Assessment

4.1. General Conclusions

The main general conclusions are the following:

- The Project has valid and appropriate objectives which are in line with the health policy and strategy in the Kingdom of Saudi Arabia (*Relevance*).
- The Project significantly contributes to strengthening the capabilities of SFDA to target needs of the covered areas (i.e. food, drug and medical devices) (*Effectiveness*).
- The Project benefits from the synergy between the project activities and the structure of SFDA, therefore, it supports SFDA implementing its mission (*Internal Coherence*).
- The activities increased the Project's coherence with the national programmes (*External Coherence*).
- SFDA seems to be capable to continue the activities in accordance with the Third Strategic Plan and by using the developed capacities of the institution (i.e. new organisational matrix structure) and the employees (i.e. outputs of the training programmes) (*Sustainability*).
- SFDA continuously hires, employs and trains qualified female staff in increasing number (*Gender Equality*).

4.2. Theory of Change

The overall objective of the UNDP Project is to support SFDA in implementing its Second Strategic Plan from 2012-2018, 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.

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

- To develop capacity of institutional, individual and systems to serve processes and tools in all relevant sectors.
- To prepare and execute communication strategy and control frameworks.
- To develop standards, control systems, and policies to cover food, drug and medical devices.
- To develop systems and processes to improve pro-activity in addressing emerging risks.

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.
4. Raising awareness and cooperation.
5. Evidence generation and dissemination.

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

Pathway to developed capacity of institutional, individual and systems to serve processes and tools in all relevant sectors (*Inputs 1 and 3*)

The Food Sector updated and took actions for Halal food products, which had no technical regulations or standards. Training courses were provided to SFDA inspectors. Technical requirements for meat processing based on HACCP were provided. Sampling requirements for microbiological analysis were updated. Customer complaints were investigated.

Regarding animal feed new technical standards were set, capability for monitoring animal feed hazards were strengthened, procedures for animal feed product categorization and evaluation were set, and training was delivered for inspectors.

The Drug Sector ramped up expertise for scientists in biologics and emerging novel drug categories. Members of the biologics team joined international committees. Various pharmaceutical guidelines were updated. New files for registration, variation and renewal were evaluated. Training was provided for employees. SFDA speakers participated in international conferences.

The Laboratories implemented ISO 17025 requirements and prepared for accreditation from international bodies. All tests were carried out according to approved standard operational procedures (SOPs). All instruments in work were calibrated and labelled with the recalibration date. The storage of reference standard materials and chemicals were improved according to the recommended storage conditions. Safety and biosafety measures were fulfilled in the laboratory premises. Continuous training was provided for the staff including in house and outside training. Receiving and handling process of samples sent for analysis were improved. Laboratories were prequalified by World Health Organisation (WHO) and supported for testing and analysis of feed samples.

Pathway to prepared and executed communication strategy and control frameworks (*Inputs 1 and 4*)

The Food Sector and Laboratories received support from food control laboratories and toxicology laboratory to ensure conformity or not of food product. Certificate was requested from food importers or BIPs to ensure conformity.

All E-systems for imported food were enforced. Food importers must register in the SFDA website and use the E-clearance. Registration of foreign establishments are still not compulsory except for meat and their products.

SFDA started to apply fees for issuing license for bottled drinking water manufacturers and for issuing export certificates for local food manufacturers. The electronic system is completed in 80%. All registration processes are still free of charge

Regarding animal feed, feed business awareness about technical standards for animal feed was raised. Workshops for feed business operators were held to explain feed law requirements.

Pathway to developed standards, control systems, and policies to cover food, drug and medical devices (*Inputs 2 and 3*)

The Food Sector completed and launched the electronic system on SFDA website for all local food exporters. Bottled drinking water manufacturers, ice manufacturers, and food manufacturers were inspected according to risks.

The Drug Sector initiated a strategic project to build adverse incidents reporting system for pesticides.

Pathway to developed systems and processes to improve pro-activity in addressing emerging risks (*Inputs 3 and 5*)

The Food Sector established the Risk Communication Unit. The Committee of Risk Management was redesigned. Risk assessment operating model was introduced. The International Risk Assessment Advisory Committee was established.

5. Strategies and Recommendations

5.1. Sustainable Development Goals

The seventeen goals of the United Nations (UN) call for action by all countries – poor, rich and middle-income – to promote prosperity while protecting the planet. They recognize that ending poverty must go hand-in-hand with strategies that build economic growth and address a range of social needs including education, health, social protection, and job opportunities, while tackling climate change and environmental protection.

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

Table 1 below introduces the SGD 3 targets that are particularly relevant for SFDA. Objectives of SFDA are presented according to its mandate and the Third Strategic Plan. Regarding the UNDP Project, the table also introduces how the Project is contributing towards the achievement of SDG. As 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.

Table 1 How is the UNDP Project contributing towards the achievement of Sustainable Development Goals?

SDG 3 Targets	SFDA mandate	UNDP project	SFDA Third Strategic Plan
<p>Achieve universal health coverage, including financial risk protection,</p> <p>access to quality essential health-care services and</p> <p>access to safe, effective, quality and affordable essential medicines and vaccines for all</p>	<p>Observe the safety of medical devices and its impact on public health.</p> <p>Ensure accuracy and safety of medical and diagnostic devices.</p> <p>Observe the safety, security, and effectiveness of food and drug for humans and animal.</p> <p>Launch clear policies and procedures for food and drug, and plan to achieve and implement these policies.</p>	<p>Output 3. Standards, control systems and policies developed to cover food, drug and medical devices</p> <p>Activity 1. Continue to fulfil competencies and responsibilities outlined in mandate</p> <p>Activity 4. Reinforce safety of drugs, bio-products, health, herbal and veterinary products across the value chain</p> <p>Activity 6. Develop best practice policies for specific / emerging product categories</p>	<p>Establish risk-based evaluation capability for the SFDA that achieves regional and international recognition while simultaneously balancing notified body participation is core to the strategic plan for medical devices. Emphasis will be placed on ensuring equal opportunity for products manufactured by both international and domestic companies.</p> <p>Establish a central medical device testing lab in Riyadh, conduct research activities and externalize to local testing labs.</p> <p>Accredit Riyadh reference and research drug testing lab, perform Post Market Surveillance (PMS) tests and explore externalizing local Quality Control (QC) labs</p> <p>Perform full assessment of new drugs and complex generics, adopting a new Committee model for registrations with expert input. Leverage the maturity effort for human drugs evaluation to build vet capabilities and adopt international best practices for cosmetics, herbal drugs & food supplements approvals.</p>
<p>By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination</p>	<p>Observe the safety of complementary biological and chemical substances, cosmetics and pesticides.</p>	<p>Output 3. Standards, control systems and policies developed to cover food, drug and medical devices</p>	

		<p>Activity 2. Optimize SFDA's role regarding inspection of local market food businesses and water bottling plants</p> <p>Activity 3. Implement effective processes to operationalize pesticide safety standards</p> <p>Activity 5. Pursue the development of cosmetics standards and ensure the safety of cosmetics products</p>	
<p>Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries,</p> <p>provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular,</p> <p>provide access to medicines for all</p>	<p>Conduct research and applied studies to identify health problems, their causes, determine its impact on public, with the consideration of methods for research / studies evaluation. The authority shall establish scientific bases for awareness and consulting services and executive programs in the fields of food and drug.</p> <p>Disseminate and exchange information with local and international scientific and legal agencies, and setting up a database for food and drug.</p> <p>Control and supervise licenses procedures for food, drug and medical devices factories.</p>	<p>Output 1. Capacity of institutional, individual and systems developed to serve processes and tools in all relevant sectors</p> <p>Activity 2. Enhance SFDA key internal tools and processes to better support its mission</p> <p>Activity 3. Fully develop the required set of capabilities to take over key processes</p> <p>Activity 4. Support ITP and shared services in building their capabilities</p>	<p>Improve access to registered products by exploring incentives for registrations and clarifying Marketing Authorization Holder responsibilities whilst supporting efforts to build public confidence and uptake of marketed generics. Encourage innovation by reviewing Phase 1 clinical trials and foster an environment for local R&D.</p>
<p>Substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries, especially in least developed countries and small island developing States</p>		<p>Output 1. Capacity of institutional, individual and systems developed to serve processes and tools in all relevant sectors</p> <p>Activity 1. Enrich SFDA's expertise by attracting, retaining and developing the appropriate human resources</p>	

<p>Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks</p>		<p>Output 4. Systems and processes to improve pro-activity in addressing emerging risk developed</p> <p>Activity 1. Establish collaborative knowledge-sharing systems enabling early detection of potential hazards to food and feed control system</p> <p>Activity 2. Identify and swiftly act upon risks to patient safety</p>	<p>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</p>
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5.2. Best Practices Implemented by SFDA

Best Practice Example 1: Technical Assistance Agreement Signed Between United States Department of Agriculture / Foreign Agricultural Service and Saudi Food and Drug Authority

The United States Department of Agriculture (USDA) Foreign Agricultural Service (FAS) leads USDA's efforts to help developing countries improve their agricultural systems and build their trade capacity. The agency also administers food assistance programs that benefit people in need around the world.

On the basis of the Technical Assistance Agreement signed between USDA / FAS and SFDA, FAS supported SFDA building staff capacities in inspection and laboratory services, food defense, surveillance and monitoring, pesticide registration and control.

Within the framework of the agreement SFDA employees participated in overseas trainings as well as attended international professional programmes and events. In addition, US experts visited Saudi Arabia and provided in-service trainings for SFDA staff.

While the agreement primarily served as a tool for building individual capacities of SFDA employees, it also contributed towards the establishment of international relations and raising awareness on SFDA activities in international technical/professional communities.

Therefore, the collaboration between SFDA and its US based counterpart ensured the achievement of SFDA mission in accordance with its strategic plans.

Best Practice Example 2: New Organisational Structure of Saudi Food and Drug Authority

The Saudi Food and Drug Authority according to its mandate covers the food, drug and medical devices sectors.

The goal of Food Sector is to ensure safety and security of food and feed, safety and security of pesticides and ease commercial traffic flow while maintaining safety of food and reinforcement of consumers and clients' confidence in food control authority.

The goal of Drug Sector is to ensure safety, security, quality and efficacy of drugs and issue licenses for drug marketing. The Sector ensures safety of medical plants, health and herbal products, conducts quality checks on drugs in the market and post-marketing of drugs, ensures safety of cosmetic products and provides drug information from trusted source to the public or healthcare providers who need such information.

The goal of Medical Devices Sector is to establish regulations and procedures for registration of medical devices and products and associated tools. The Sector ensures safety, quality and efficiency of medical devices and products, laboratory materials and supplies, medical glasses, contact lens and associated solutions and electronic products and avoids their

adverse impact on human health. The Sector also verifies safety and accuracy of medical and diagnostic devices calibration; builds comprehensive database for medical devices and products manufacturers and suppliers; builds necessary laboratories and physical testing locations for testing medical devices and products; monitors medical devices and products, laboratory materials, medical glasses, contact lens and associated solutions during marketing process to ensure they are stored properly according to SFDA conditions.

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.

SFDA Operations Sector consists of 8 executive departments and 25 departments. The executive departments are as follows: Executive Department of Registration and Licensing; Executive Department of Compliance and Enforcement; Executive Department of Inspection Support; in addition to the Riyadh and regional branches. The Operations Sector supports the Food, Drug and Medical Devices Sectors by providing expert services in licencing, inspection and registration, in particular.

SFDA Research Center is responsible for developing research related protocols. If lab testing is required the Research Center develops the lab protocol in collaboration with SFDA Laboratories for the research project, then SFDA Laboratories will do the lab testing and share the results with the Research Center. The Research Center provides primary research results to support decision making at SFDA. The Research Center is still building its capacities and seeking international partnerships.

The new matrix organisational structure (see *Figure 1* in Section 3.1.6. above) 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. While the vertical technical sectors can further focus on their mission and develop their capacities in accordance with their mandate in regulation and control of food, drug and medical devices, the horizontal supporting organisational units take over the less technical and more general, administrative and organisational functions from former, as well as those that are linked with research, international relations and awareness, in addition to lab testing. This organisational structure overall results in a more flexible and adequate share of tasks and responsibilities which enables SFDA to address issues and challenges by mobilizing and using the most relevant capacities, expert staff and resources.

5.3. Future Areas of Collaboration Between SFDA and UNDP

To identify the future areas of collaboration between SFDA and UNDP needs were assessed by considering the following:

- needs defined by SFDA Sectors;
- objectives and initiatives of National Transformation Program 2020 that are relevant for SFDA;
- SFDA Third Strategic Plan 2018-2022.

5.3.1. SFDA Needs

SFDA Sectors defined their needs for further development and improvement, therefore they request further technical support in the following areas (*Table 2*).

The Food Sector identified the following technical areas regarding the opportunity for receiving further technical support from UNDP: risk assessment and capacity building of laboratory and staff accordingly; strengthening capacities in regulation; pesticide control.

The Drug Sector is particularly interested in the following technical areas considering the opportunity for receiving further technical support from UNDP: improving capabilities to monitor availability and security of drugs; launching narcotic drug system and developing regulations and guidelines for narcotics; improving evaluation and standard setting processes; building and upgrading IT services in drug sector; identifying and acting upon risks to patient safety; developing crisis management strategy to ensure emergency response preparedness; listing and creating standards for cosmetics products.

The Medical Devices Sector requires further support to build its capabilities to provide full scale technical assessment. The Sector must be prepared to address technical questions and provide the required technical services in the most recent and fastly developing areas such as artificial intelligence in diagnostics and big data in research and planning, for instance.

The Operations Sector is particularly interested in receiving support in the following technical areas: blood products and blood bank; supply chain integrity for food, drug and medical devices; building capacities of staff in the Sector's key areas such as registration, licensing and inspection.

The Research Center is particularly interested in international collaboration with other Gulf Cooperation Council (GCC) countries in the region and participation in international researches.

The SFDA Laboratories are particularly interested in the following technical areas: building capacities of drug laboratories staff.

Table 2 Needs defined by SFDA Sectors

	Sectors					
	<i>Food</i>	<i>Drug</i>	<i>Medical Device</i>	<i>Operations</i>	<i>Research</i>	<i>Laboratories</i>
SFDA needs	Risk assessment and capacity building of laboratory and staff; Strengthening capacities in regulation;	Assessing new drugs (i.e. HTA); Risks for patient safety. Improving monitoring capabilities; Launching	Capacity and skills for big data and artificial intelligence	Supply chain integrity Expertise in blood banks Other trainings	Regional and international collaboration and coordination of researches Capacity and skills for big	Capacity building regarding drugs

	Pesticide control	narcotic drug system and developing regulations; Building and upgrading IT services; Crisis management strategy; Standards for cosmetics products			data in research	
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5.3.2. National Transformation Program 2020

The Saudi Vision 2030 encompasses strategic objectives, targets, outcome-oriented indicators, and commitments that are to be achieved by the public, private, and non-profit sectors. To build the institutional capacity and capabilities needed to achieve the ambitious goals of the Saudi Vision 2030, the National Transformation Program 2020 was launched across 24 government bodies operating in the economic and development sectors. The program uses innovative methods to identify challenges, seize opportunities, adopt effective planning tools, activate the role of the private sector, bring about implementation, and evaluate performances. It has also determined the interim targets to ensure the establishment of a solid foundation for government action and the continuity of innovative planning, implementation, and follow-up methods on the national level.

To transform healthcare the National Transformation Program 2020 includes the following strategic objectives:

1. To ease access to health services
2. To improve quality and efficiency of healthcare services
3. To promote prevention against health risks

The Program wants to restructure the health sector to make it a comprehensive and effective system. It will promote public health through the implementation of a 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. Furthermore, it will aim to continually improve health services by focusing on beneficiary experience and satisfaction in line with international standards and best practices.

Seventy initiatives have been elaborated to enhance the accessibility of healthcare services, to improve the quality and efficiency of the healthcare services as well as the safety of the healthcare facilities and to ensure adequate healthcare coverage with financial sustainability, and enable healthy living by promoting preventive healthcare to minimize the risks associated with health crises and diseases of communicable and non-communicable diseases.

Table 3 introduces the objectives and initiatives of the National Transformation Program 2020 that are relevant for SFDA.

Table 3 Objectives and initiatives of NTP2020 relevant for SFDA

	Sectors					
	Food	Drug	Medical Device	Operations	Research	Laboratories
NTP2020 Objectives	Objective 3 Promote prevention against health risks	Objective 2 Improve quality and efficiency of healthcare services Objective 3 Promote prevention against health risks	Objective 1 Access to health services Objective 2 Improve quality and efficiency of healthcare services	Objective 1 Access to health services Objective 3 Promote prevention against health risks	Objective 2 Improve quality and efficiency of healthcare services	Objective 2 Improve quality and efficiency of healthcare services Objective 3 Promote prevention against health risks
NTP2020 Initiatives	Initiative 25 Establish Halal Center Initiative 38 Establish the Standard Electronic System Initiative 56 Establishment and Activation of Nutrition Clinics Initiative 70 Pesticide Residue Inspection Center	Initiative 12 Technology Assessment Center Initiative 24 Establish an Electronic Tracking System Initiative 38 Establish the Standard Electronic System	Initiative 12 Technology Assessment Center Initiative 20 National Health Innovation Center Initiative 38 Establish the Standard Electronic System	Initiative 19 Development of Blood Transfusion Services Initiative 38 Establish the Standard Electronic System	Initiative 62 Health Research Center	Initiative 70 Pesticide Residue Inspection Center

In addition, the National Transformation Program 2020 includes some initiatives, which are addressing communication and patient safety, in particular. These areas are also important for SFDA, though they are not specifically linked to a sector but various functions and activities of SFDA need to be considered under these initiatives.

Regarding communication, *Initiative 67 Interactive Awareness Program* aims to establish specialized awareness campaigns based on the needs and level of awareness of the target

groups, as well as programs to introduce the role and regulations of the Saudi Food and Drug Authority.

Regarding patient safety, *Initiative 6 Ensure Compliance with Safety Standards in Health Facilities and Conduct Emergency Repairs* is concerned with the development of healthcare facilities to comply safety standards, as well as the training of workforce. *Initiative 13 Saudi Center for Patient Safety* aims to establish and launch the National Center for Patient Safety to promote a national culture of patient safety reporting and to raise awareness of safety issues. Finally, *Initiative 34 Quality and Safety Development in Health Sector* aims to implement the regulations and principles of quality management and patient safety based on globally proven mechanisms, in addition to spreading the culture of quality within healthcare institutions.

5.3.3. SFDA Third Strategic Plan 2018-2022

SFDA Third Strategic Plan (2018-2022) lays out the vision and strategic priorities for addressing the challenges that SFDA faces as the regulator of the food, drug and medical devices sectors. The plan helps SFDA to become a leading international regulator responsible for protecting the community and promoting access to safe products through sound regulations and effective controls. SFDA must respond to the rapid pace of innovation, the tighter integration of global supply chains, and the increasing demands of Saudi citizens for safe and healthy products.

Table 4 introduces the objectives of the Third Strategic Plan according to the sectors of SFDA.

Table 4 SFDA Third Strategic Plan 2018-2022

Objectives	Sectors					
	Food	Drug	Medical Devices	Operations	Research	Laboratories
<i>Objective 1</i> Strengthen enforcement and improve resource allocation by centralizing operational activities	x	x	x			
<i>Objective 2</i> Optimize SFDA lab operations by centralizing labs - acting as a reference lab for food and performing post-market surveillance testing for all three sectors, while externalizing routine QC testing	x	x	x			x
<i>Objective 3</i> Achieve financial sustainability by increasing revenue in line with international benchmarks while increasing efficiencies and delivering better services	x	x	x	x	x	x
<i>Objective 4</i> Take ownership of food safety across the value chain, by setting harmonized monitoring and control programs with our partners through effective collaboration	x					x
<i>Objective 5</i> Reduce food hazards by applying a robust risk- based model built on scientific evidence	x					
<i>Objective 6</i> Develop and apply clear regulatory requirements to ensure full compliance of domestic businesses and importers with the food and feed laws	x			x		
<i>Objective 7</i> Enhance the safety of imported food through applying effective control methodologies, systems and tools	x			x		
<i>Objective 8</i> Minimize impact of pesticides on consumers, users and the environment by introducing controls and traceability	x					
<i>Objective 9</i> Build trust and achieve recognition for SFDA's approval process for human and veterinary drugs by enhancing capabilities and simplifying evaluation pathways		x		x		
<i>Objective 10</i> Safeguard public and animal health by strengthening detection, surveillance and response to identified risks		x				x

<i>Objective 11</i> Increase access of human and veterinary drugs by collaborating with other government entities to adapt relevant policies and by supporting a vibrant pharmaceutical sector in the Kingdom		x				
<i>Objective 12</i> Reduce the regulatory burden for cosmetics, herbal drugs and food supplements by aligning their regulatory framework with international best practices		x				
<i>Objective 13</i> Become an internationally-recognized reference Regulatory Authority by building capabilities to perform independent evaluation within a flexible, risk- based, harmonized evaluation model			x	x		
<i>Objective 14</i> Enhance medical device safety and performance by improving adverse event reporting and by collaborating with international Regulators in order to take proactive action against identified issues			x			
<i>Objective 15</i> Protect patients and medical device operators by developing guidance and monitoring for safe use of medical devices in healthcare and non-healthcare facilities			x			x
<i>Objective 16</i> Increase organizational performance by fostering a collaborative and accountable culture, attracting and retaining talent, and clarifying responsibilities	x	x	x	x	x	x
<i>Objective 17</i> Design an IT strategy that is aligned with SFDA's business requirements and improves decision- making and operational effectiveness by deploying innovative systems	x	x	x	x	x	x
<i>Objective 18</i> Engage proactively with the public and other external stakeholders to promote safe and informed use of products and foster trust in SFDA	x	x	x	x	x	x
<i>Objective 19</i> Increase SFDA's role in the international community through effective collaboration, scientific contributions and mutual exchange of know-how	x	x	x	x	x	x

5.4. Strategic Areas for UNDP Support

Saudi Food and Drug Authority completed the implementation of its First Strategic Plan between 2007-2011 and its Second Strategic Plan between 2012-2016. The United Nations Development Programme provided technical assistance to SFDA and collaborated in achieving the strategic goals set in SFDA strategic plans. At the end of the UNDP Project the present terminal evaluation reviewed and assessed the achievement of the project objectives.

On the basis of the findings of the evaluation as well as considering the above-mentioned strategy and policy documents (i.e. United Nations Sustainable Development Goals, Saudi Vision 2030, National Transformation Program 2020, SFDA Third Strategic Plan) the following strategies are presented for consideration.

1. Assessment of the safety and effectiveness of new drugs and medical devices
2. Risk based evaluation and safe use of technologies
3. Continuation of building institutional and staff capacities
4. Regional and international collaborations and recognition
5. Internal communication and organisational culture
6. External communication and awareness

5.4.1. 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 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 shall establish risk-based evaluation capability for the assessment of medical devices.

Technical assistance should 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.

5.4.2. Risk Based Evaluation and Safe Use of Technologies

The Ministry of Health 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 National Transformation Program 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 shall 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 should 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 can be provided to the assessment of health technologies used at healthcare providers in order to ensure their quality and safe use. For instance, the healthcare quality assessment procedures developed and promoted in the Middle-East by the International Financial Corporation (IFC) could be considered as international best practice when planning technical assistance regarding healthcare quality and patient safety. IFC procedures help to understand the healthcare quality assurance and patient safety environment, including relevant regulations, supervising bodies, levels of compliance, key challenges, in addition to identify current levels of formal quality certification or accreditations relating to the health sector, including the private health sector.

5.4.3. 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, 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 along with SFDA Second Strategic Plan.

Further support should be provided to SFDA in building broad and deep capabilities in all relevant areas as per SFDA mandate. UNDP should 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.

5.4.4. 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 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 (pro)actively 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 programs such as unified drug procurement, central registration, and standardization of pricing, the Gulf Health Council 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 (please also consider this opportunity regarding the proposal on patient safety above).

SFDA should be supported in increasing its role in the international community. UNDP should 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, such as the one of the European Union, 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.

5.4.5. 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.

SFDA should be supported in developing and strengthening its organisational culture and internal communication. UNDP should 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.

5.4.6. External Communication and Awareness

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

SFDA should be supported in improving external communication and raising awareness on its role and functions. Technical assistance could 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.

5.5. Recommendations

SFDA should:

- Maintain the focus on specific objectives and areas where the project provided added value.
- Maintain and strengthen links between the new project and the national policies (e.g. NTP2020, MoH Health Strategy) to maximize impact.
- Support the project management and coordination with UNDP.
- Maintain the monitoring of the progress of the new project according to the programmatic and action specific indicators set in the Logical Framework.

UNDP should:

- Design and propose a new project to further support SFDA implementing its Third Strategic Plan and building institutional and individual capabilities.
- Maintain the implementation of the activities of the new project in accordance with the plan of action.
- Maintain the monitoring of the progress of the new project according to the programmatic and action specific indicators set in the Logical Framework.

Annexes to the Report

The report includes the following annexes:

- Annex 1. Terms of Reference for Terminal Evaluation
- Annex 2. Evaluation Questions
- Annex 3. Evaluation Matrix
- Annex 4. List of Documents Consulted
- Annex 5. List of Meetings and Persons Consulted
- Annex 6. Minutes of Meetings
- Annex 7. Field Phase Presentation

Annex 1. Terms of Reference for Terminal Evaluation

Terms of Reference for

Project SAU10/82003 - Saudi Food & Drug Authority Phase II

United Nations Development Programme, Saudi Arabia

Implementation Partner: Saudi Food & Drug Authority (SFDA)

A. MISSION OBJECTIVE

The terminal evaluation will assess the above indicated project in terms of relevance, appropriateness, effectiveness, efficiency, impact, and sustainability. It will review the performance of the project against the objectives stated in the strategic and annual plans.

The objective of the project evaluation is to assess how the outputs of the above-mentioned project have contributed to “achieving high impact goals as set by the SFDA mandate”. The assessment of this project was strategically placed at this particular time in order to promote needed adjustments, identify lessons learned and draw up a sustainability plan for the project prior to end 2017, date of project completion. The outputs of this project are to be evaluated for their contribution to the achievement of the objectives. Efficiency and effectiveness are of prime importance but also transparency and accountability. The review will illustrate intended and unintended results.

The evaluator will be tasked to provide recommendations aiming to improve various aspects of the project towards achievement and quality delivery of the project.

B. BACKGROUND

- **National Context**

Saudi Arabia has made considerable progress in improving the health status of its population in the last 30 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 education, health facilities, safe drinking water, environmental sanitation facilities and electric utilities throughout the Kingdom of Saudi Arabia. In addition to enhancing the overall standards of living, the Kingdom of Saudi Arabia provides wide networks of free or subsidized social services to their citizens. Moreover, the Kingdom has in the past 20 years has adopted a group of policies that supported the

development of the agriculture, and food processing and manufacturing sectors. This resulted in making the Kingdom a leading country in the region in regards of agriculture production, dairy produce, and food manufacturing. This has contributed to the excellent social indicators relating to survival, development and protection of human-beings.

In this context, 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 Kingdom.

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.

The Food and Drug Authority (SFDA) was established under the Council of Ministers resolution no (1) dated 07/01/1424 H, as an independent body corporate that directly reports to the Premier. The Authority 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 – Phase I (2005 - 2011)**

The UNDP SFDA Support Project SAU10/38929 - phase one was officially launched in 2005. The project mainly focused in 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. Phase I ended in December 2011. Achievements during Phase I include;

- Organizational structure and Job Descriptions developed
- The consultancy Committee assessed and reviewed SFDA policy
- IT strategy and work plan formulated
- Corporate Human Resources Developed
- The Institutional strategy was developed by Booz Allen Hamilton.

- Activated the role of SFDA in supporting the government in meeting its post accession commitments, as a result SFDA was tasked a focal point for PSP.
- **SFDA – Phase II (2012 - 2016)**

The second phase of the UNDP support started in 2012 to assist SFDA to effectively deal with the development of 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

The main objectives of this project are:

1. Support SFDA in building broad and deep capabilities,
2. Support SFDA to ensure thoroughness, transparency, and consistency in enforcement and communication,
3. Support SFDA to 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

C. SCOPE OF THE EVALUATION

The terminal evaluation project expected to address the following issues:

1. Assessment of results and achievements:

- Has sufficient progress been achieved vis-à-vis the outcome, "expanded national capacity for food, drug and medical devices including training as measured by the outcome indicator,
- What are the main factors (positive and negative) that affect the achievement of the outcome?
- Are the outcome indicators capable of measuring the achievement of the intended outcome?
- Have the outputs been achieved as measured by the output indicator?
- What are the main factors (positive and negative) that affected the achievement of the intended outputs?
- Are the output indicators capable of measuring the achievement of the intended output?
- What are the unintended results (positive and negative) and what are the contributing factors?
- Have the planned activities been successfully implemented? What are the factors affecting the successful or unsuccessful implementation of planned activities?

- What are the plans for monitoring and evaluation and are they done periodically as planned? Have the recommendations from monitoring and evaluations implemented? If not, what are the obstacles and what are the measures for improvements?
- Have the lessons learned from prior phases been effectively used?
- Are the results sustainable? Will the outputs & outcomes lead to benefit beyond the life of the existing programme?
- Is there an exit strategy?

2. Assessment of efficiency and adequacy:

- Review and assess the professional capacity and quality inputs and activities by the implementing Partner both at the central and branch level.
- Assess the efficiency and adequacy of the management structure.
- Assess the efficiency and adequacy of team structure and personnel distribution to effectively carry out the day-to-day activities in the field and in support of the activities.
- Have organizational arrangements been cost effective? How can they be improved?
- Has the Advisory Committee, an oversight advisory body, met as scheduled, and provided quality policy advice and recommendations to improve project implementation? What is the quality of their inputs to ensure that activities are on track and results are achieved in accordance with the project work plan?
- What kind and level of safety measures available in the field operation and to what degree are they followed? What is the level of awareness of the staff both in the field and at branches and at the central level on safety issues?

3. Assessment in the aspect of beneficiaries:

- Assess what partnerships established with local authorities, community leaders and members. What is the level and area of their participation and contributions?
- What level of understanding local authorities, community members including men, women, and children have on the issue and the UNDP project.

4. Gender aspect:

- Is gender issue adequately mainstreamed throughout the project? If not, what are the reasons, and what can be done?
- How does the project address gender aspect of the issue? If not, what are the reasons, what should be addressed, and how should they be done?
- How does the project contribute to the capacity building of women? If not, what are the reasons, and what can be done for capacity building of women?

5. Sustainability:

- Are there regular updates done effectively on national strategy, and are there mechanisms to inform or to train all staff on the updates?
- Is there national standard of operation built on international standard, and are there mechanisms to inform and train all related staff on the standard of operation?
- Are there refresh trainings systematically organized and periodically carried out to field staffs, staffs at the branches, central office on different subjects and units?
- Assess the national capacity of the SFDA in the area food, drugs, medical devices knowledge. What are the gaps, and measures for enhancement?
- Are all the necessary reports are produced in a good quality and submitted in a timely manner?
- Has the Institutional memory such as documents and data been stored in an organized and systematic fashion so that it is accessible and available when required?
- Has the organizational capacity built with clearly written out rules and regulations with clear understanding of them by the staff and having all the work processed according to them?

6. Assessment on organizational capacity:

- Are there statutes of national agencies clearly stating necessary information such as organizational structure, purpose, function, information on board etc? If so, assess the quality and identify the gaps if any.
- Are there any documents clearly stating guide-lines, manuals, which include information such as authorization capacity, work flow etc. If so, is staff regularly trained on them? Is the work done according to the written guidelines and manuals? What are the factors contributing to the current status? What and how should it be improved?
- What is the capacity of human resource department? Are the documents related to personnel systematically stored with sufficient level of confidentiality to the personal information? Are there policies regarding protection on personal information and are the staffs trained on them? What is the quality of the contracts prepared by the project? What is the quality of sign-in/out system? Is there systematic recording system for leaves, and what is the quality? What type of system are there to record the attendance of field staff?
- What is the capacity of logistic department? Are there guidelines and are staffs regularly trained on them? What kind of systems are there regarding assets and equipment? Are they properly recorded, maintained, used and stored?

7. Partnership Strategy / Visibility:

- Are there effective partnerships among parties involved in implementation of the project such as national entities, donors, civil society organizations and UNDP?

- Have the partnerships expanded during the second phase of the project? What were the factors affecting the change? How can the partnerships be further enhanced?
- What are the existing levels and strategies of ensuring visibility of donors? Are there rooms for enhancement?

8. Technical Assessment:

FOOD Sector:

- Fully transfer inspection of bottled drinking water and ice factories from MoMRA & MoC to SFDA
- Introduce a quality management system
- sharing systems enabling early detection of potential hazards to food and feed control system
- Achieve ISO accreditation for SFDA labs

DRUG Sector:

- Improve capabilities to monitor availability and security of drugs inside the KSA
- Launch Narcotics Drug System (NDS) and socialize narcotics regulations and guidelines
- 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

Medical Devices Sector:

- Fully transition medical devices inspections at POE
- Devise policy to identify and control counterfeit devices
- Introduce a quality management system for the MD

SPS Sector:

- Identify and swiftly act upon risks to patient safety
- Develop crisis management strategy to ensure emergency response preparedness
- Pursue the listing and creation of standards for cosmetics products

9. Recommendations:

- Recommendations need to be made on each topic and they must be objective, realistic, and practical so that they can be implemented in the phase III of the project.

- Recommend realistic time-frame for implementation of the recommendations.

D. DELIVERABLES

- Outline and presentation of the main findings should be prepared for the debriefing session at the end of the mission.
- The report should include executive summary, background, description of the evaluation methodology, results of the evaluation, and strategies and recommendations for continued UNDP assistance towards the achievement of the project
- The report should Identify how the project is contributing towards the achievement of SDGs
- Identify a best practice implemented by SFDA to be promoted, Identify future areas of collaboration between SFDA and UNDP
- The report should be submitted to the SFDA President and UNDP Resident Representative.
- The report should contain at least following annexes:
 - Terms of reference for the evaluation
 - Itinerary (actual)
 - List of meetings attended
 - List of persons interviewed
 - List of documents reviewed
 - Any other relevant material

The report should be submitted as one electronic copy and three signed hard copies.

- A comprehensive Project Document

E. EVALUATION CONSULTANTS

An international consultant will be contracted to perform the evaluation. The Consultant should have proven knowledge and relevant work experience in the field of Food and Drug, sound knowledge about results-based management (especially results-oriented monitoring and evaluation). Also, the Consultant should have an expertise in organizational management. The consultant will design the detailed evaluation scope and methodology, conduct necessary data collection activities including field trips, meetings and desk analysis. The consultant will take the overall responsibility for the quality of the evaluation report.

Knowledge of Arabic language is an asset.

Consultant will familiarize himself with the project through a review of relevant document prior to beginning travel to the region. These documents include at least:

- Project documents
- Project budgets
- Project work plans, progress reports
- Strategic plans
- SOPs (Standard Operating Procedures)
- Past reports on the project
 - UNDP guideline for evaluation
 - Evaluation reports
- National development plan

F. EVALUATION TIMEFRAME

20 working days in June – July 2018

- Preparation for evaluation, review of documents (1 days)
- Briefing (0.5 day)
- Field missions including desk reviews, field visits, interviews (11 days)
- Submission of outline on main findings and briefing session (0.5 day)
- Preparation of final report (3 days)

Total

12 days in Saudi Arabia

8 days in home country

G. QUALIFICATION

The Consultant/s must have an advanced degree in environmental / health science or equivalent. S/He should have at least 20 years of practical experience with demonstrated ability in project evaluation and formulation, especially for institutional capacity development. Knowledge of environmental, Food, Drug and Medical devices issues and efforts is essential.

Annex 2. Evaluation Questions

The evaluation concentrated on the following specific evaluation criteria of relevance, effectiveness, efficiency, sustainability and impact.

The evaluation answered specific questions regarding these criteria. The evaluation questions had been finalized before the Field Phase of the evaluation mission. The evaluation questions are based on the questions given in the Terms of Reference as well as considering the sample questions proposed in the Consultant's Technical Offer.

Relevance

Evaluation Question 1: To what extent are the objectives of the Project still valid and in line with the strategic goals and objectives of health policy in Saudi Arabia? (Validity of objectives)

EQ2: To what extent are the expected results of the Project sufficient to achieve the objectives of the Project? (Appropriateness of expected results)

EQ3: To what extent is the Project prioritised in the health policy and strategy documents in Saudi Arabia? (Relevance of Project)

Effectiveness

EQ4: How effective was the planning for the preparation of the Project? (Planning)

The evaluation examined the effectiveness of the planning in terms of the extent to which it has contributed to a strategic approach to defining the objectives of the Project; clarity regarding the availability of resources and budget allocation over time; and proven coherence between the objectives and results defined in the plan and the Project itself.

EQ5: In practice, to what extent is the Project contributing to the health policy priorities?

This question looked at effectiveness at a higher level, in terms of the Project's contribution so far to the objectives the national health policy and strategy.

Efficiency

EQ6: To what extent does the design of the Project lead to an efficient allocation of resources among objectives / expected results? (Allocation of resources among objectives / expected results)

EQ7: To what extent does the allocation of resources allow for an efficient implementation of the Project in terms of: funding mechanisms, simplification measures and operational costs?

While the main driver of the Project's ability to provide value for money is the effectiveness of its funded actions, it is also important to manage resources in a supportive but cost-minimising way.

EQ8: To what extent are the monitoring processes and resources sufficient and adequate to plan and promote the results of the Project? (Monitoring)

The evaluation assessed the monitoring processes and resources available and the extent to which they were sufficient and adequate (i.e. fit for purpose). Monitoring has two objectives: internal planning / assessment of results and promotion of results to stakeholders.

Impact

EQ9: What are the different options to meet the strategic goals and objectives of health policy in Saudi Arabia and whether the objectives of the Project achieve those?

EQ10: Who have been affected by the Project?

Sustainability

EQ11: Are the beneficiary institutions capable to continue the provision of benefits beyond the Project's end?

Coherence

EQ12: To what extent have the objectives of the Project led to more synergy, focus and coherence between the funded actions in delivering on the objectives? (Internal coherence)

The assessment of internal coherence of the Project involves looking at how well different funded actions are working together to deliver the Project's objectives. The Project was funded by the Government of Saudi Arabia and thus improving the co-operation between key stakeholders in the health area.

EQ13: To what extent are the objectives and expected results of the Project externally consistent / coherent with the national health policies and other programmes / actions?

The evaluation examined the conformity between the Project and other national health policies and programmes, and other public interventions, such as national health policies and other international actions.

Cross-cutting Issues

EQ14: To what extent are the cross-cutting issues addressed in the Project?

The Project is expected to promote good governance in the field of health through the following main dimensions: accountability, transparency, participation, non-discrimination and efficiency. The evaluation assessed whether the project partners ensure transparency and rationality in decision-making and in resource allocation.

Gender equality and social inclusion of the most marginalised should be a core principle of the Project. The evaluation assessed how the needs of marginalised communities and individuals can be met.

Annex 3. Evaluation Matrix

The Evaluation Matrix was drafted³ for the terminal evaluation for UNDP Project Saudi Food and Drug Authority Phase II and was used during the Field Phase and Synthesis Phase.

The Evaluation Matrix is a tool to plan the evaluation. It follows the Terms of Reference and Logical Framework, includes the evaluation questions and plans for collecting information to answer the questions. It guides the analysis since it brings all the sources together to address the questions. The Evaluation Matrix was used to plan the interviews during the Field Phase, collect and analyse information, and write the Final Report. The Evaluation Matrix includes: the questions to be answered; the criteria or indicators on which the answers are based; information sources and analysis methods.

In the Inception Phase the Evaluation Matrix was finalized according to the evaluation questions and identified any other questions relevant for the meetings and interviews. Three types of questions were prepared:

- Descriptive questions: questions about changes in outcome measures;
- Normative questions: questions about achievement of outputs;
- Cause-and-effect questions: questions about impacts.

Descriptive questions generally use non-experimental designs (e.g. simple cross-sectional, before-and-after, and case studies). Normative questions are similar to descriptive questions, and always assessed against a criterion: a goal, target, or result to be achieved. Cause-and-effect questions enable the evaluation to address “What would the situation be if the intervention had not taken place?” They may use experimental designs, and/or other analytical methods, including qualitative comparison.

Columns of the Evaluation Matrix include the questions, measures / indicators, targets / results, data source / data collection instrument and analysis approach (please see *Table 5* below). Therefore, the Evaluation Matrix addresses each of the key evaluation questions in accordance with the Terms of Reference; provides an overview of how the evaluation questions will be addressed; provides sources of information; links to the relevant parts of the methodology that will contribute to answering the questions; and describes how the findings from each of these will be concluded.

³ Based on: Linda G. Morra Imas and Ray C. Rist, *The Road to Results*. The World Bank, Washington, 2009

Table 5 Evaluation Matrix

Relevance					
Questions		Measure / Indicator	Main Sources of Information	Data Collection Methods	Data Analysis Methods
EQ 1	To what extent are the objectives of the Project still valid and in line with the strategic goals and objectives of health policy in Saudi Arabia? (Validity of objectives)	Please refer to Logical Framework	Strategy and Policy Papers, National Health Programme Documents, National Statistics; Project Documents and Reports	Collecting Documents; Interviews	Document Review; Descriptive / Normative / Impact Analysis
EQ 2	To what extent are the expected results of the Project sufficient to achieve the objectives of the Project? (Appropriateness of expected results)	Please refer to Logical Framework	Strategy and Policy Papers, National Health Programme Documents, National Statistics; Project Documents and Reports	Collecting Documents; Interviews	Document Review; Descriptive / Normative / Impact Analysis
EQ 3	To what extent is the Project prioritised in the health policy and strategy documents in Saudi Arabia? (Relevance of Action)	Please refer to Vision 2030 of Kingdom of Saudi Arabia and Saudi Vision for Health Care	Strategy and Policy Papers, National Health Programme Documents, National Statistics; Project Documents and Reports	Collecting Documents; Interviews	Document Review; Descriptive / Normative / Impact Analysis
Effectiveness					
Questions		Measure / Indicator	Main Sources of Information	Data Collection Methods	Data Analysis Methods
EQ 4	How effective was the planning for the preparation of the Project? (Planning)	Please refer to Vision 2030 of Kingdom of Saudi Arabia and Saudi Vision for Health Care and Logical Framework	Strategy and Policy Papers, National Health Programme Documents, National Statistics; Project Documents and Reports	Collecting Documents; Interviews	Document Review; Descriptive / Normative / Impact Analysis Cost-Benefit Analysis
EQ 5	In practice, to what extent is the Project contributing to the health policy priorities?	Please refer to Vision 2030 of Kingdom of Saudi Arabia and	Strategy and Policy Papers, National Health Programme	Collecting Documents; Interviews	Document Review;

		Saudi Vision for Health Care and Logical Framework	Documents, National Statistics; Project Documents and Reports		Descriptive / Normative / Impact Analysis
Efficiency					
Questions		Measure / Indicator	Main Sources of Information	Data Collection Methods	Data Analysis Methods
EQ 6	To what extent does the design of the Project lead to an efficient allocation of resources among objectives / expected results? (Allocation of resources among objectives / expected results)	Please refer to Logical Framework	Strategy and Policy Papers, National Health Programme Documents, National Statistics; Project Documents and Reports	Collecting Documents; Interviews	Document Review; Descriptive / Normative / Impact Analysis Cost-Benefit Analysis
EQ 7	To what extent does the allocation of resources allow for an efficient implementation of the Project in terms of: funding mechanisms, simplification measures and operational costs?	Please refer to Logical Framework	Project Documents and Reports	Collecting Documents; Interviews	Document Review; Descriptive / Normative / Impact Analysis Cost-Benefit Analysis
EQ 8	To what extent are the monitoring processes and resources sufficient and adequate to plan and promote the results of the Project? (Monitoring)	Please refer to Logical Framework	Project Documents and Reports	Collecting Documents; Interviews	Document Review; Descriptive / Normative / Impact Analysis Cost-Benefit Analysis
Impact					
Questions		Measure / Indicator	Main Sources of Information	Data Collection Methods	Data Analysis Methods
EQ 9	What are the different options to meet the strategic goals and objectives of health policy in Saudi Arabia and whether the	Please refer to Logical Framework	Strategy and Policy Papers, National Health Programme Documents, National Statistics; Project Documents and Reports	Collecting Documents; Interviews	Document Review; Descriptive / Normative / Impact Analysis

	objectives of the Project achieve those?				
EQ 10	Who have been affected by the Action?	Please refer to Logical Framework	Project Documents and Reports	Collecting Documents; Interviews	Document Review; Descriptive / Normative / Impact Analysis
Sustainability					
	Question	Measure / Indicator	Main Sources of Information	Data Collection Methods	Data Analysis Methods
EQ 11	Are the beneficiary institutions capable to continue the provision of benefits beyond the Project's end?	Please refer to Vision 2030 of Kingdom of Saudi Arabia and Saudi Vision for Health Care and Logical Framework	Strategy and Policy Papers, National Health Programme Documents, National Statistics; Project Documents and Reports	Collecting Documents; Interviews	Document Review; Descriptive / Normative / Impact Analysis Cost-Benefit Analysis
Coherence					
	Questions	Measure/Indicator	Main Sources of Information	Data Collection Methods	Data Analysis Methods
EQ 12	To what extent have the objectives of the Project led to more synergy, focus and coherence between the funded actions in delivering on the objectives? (Internal coherence)	Please refer to Logical Framework	Project Documents and Reports	Collecting Documents; Interviews	Document Review; Descriptive / Normative / Impact Analysis
EQ 13	To what extent are the objectives and expected results of the Project externally consistent/coherent with the national health policies and other programmes / actions?	Please refer to Vision 2030 of Kingdom of Saudi Arabia and Saudi Vision for Health Care and Logical Framework	Strategy and Policy Papers, National Health Programme Documents, National Statistics; Project Documents and Reports	Collecting Documents; Interviews	Document Review; Descriptive / Normative / Impact Analysis
Cross-cutting Issues					
	Question	Measure / Indicator	Main Sources of Information	Data Collection Methods	Data Analysis Methods

EQ 14	To what extent are the cross-cutting issues addressed in the Project?	Programme and Logical Framework	Strategy and Policy Papers, National Health Programme Documents, National Statistics; Project Documents and Reports	Collecting Documents; Interviews	Document Review; Descriptive / Normative / Impact Analysis
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Annex 4. List of Documents Consulted

Project Documents

Project Document for Project to Support Saudi Food and Drug Authority (2004)

Project Document for Project to Support Saudi Food and Drug Authority Second Strategic Plan Implementation (2012)

Project Document for Project Saudi Food and Drug Authority Phase II / Substantive Project and Budget Revision (2016)

Project Annual Progress Report 2015

Project Annual Progress Report 2016

Project Annual Progress Report 2017

USDA / FAS and SFDA Technical Assistance Agreement Progress Report 2017

Report of the Independent Auditor to UNDP (2017)

Report of the Independent Auditor to UNDP (2018)

Strategic and Policy Documents

Saudi Vision 2030

National Transformation Program 2020

Saudi Food and Drug Authority Third Strategic Plan 2018-2022

Other Documents

Ministry of Health Strategy⁴

Ministry of Health Initiatives⁵

Ministry of Health Saudi Patient Safety Taxonomy⁶

⁴ <https://www.moh.gov.sa/en/Ministry/About/Pages/Strategy.aspx>

⁵ <https://www.moh.gov.sa/en/Ministry/nehs/Pages/vision2030.aspx>

⁶ <https://www.moh.gov.sa/dept/en/Nutrition/News/Documents/Saudi-Patient-Safety-Taxonomy.pdf>

Annex 5. List of Meetings and Persons Consulted

AGENDA OF THE MISSION

Date	Activities	Participants	Comments
17/11/2018 Saturday	Arrival in Riyadh		
18/11/2018 Sunday	10:00 Meeting at United Nations Development Programme (UNDP) 12:00 Meeting with Saudi Food and Drug Authority (SFDA) Drug Sector	Consultant and UNDP staff Consultant, UNDP and SFDA staff	Please refer to minutes of meetings attached (1 and 2)
19/11/2018 Monday	10:00 Meeting with SFDA President	Consultant, UNDP and SFDA staff	Please refer to minutes of meeting attached (3)
20/11/2018 Tuesday	Reviewing national policy and strategy documents, and project documents Discussing evaluation methodology with SFDA Sectors	Consultant and UNDP staff	
21/11/2018 Wednesday	12:30 Meeting with SFDA Medical Devices Sector	Consultant and SFDA staff	Please refer to minutes of meeting attached (4)
22/11/2018 Thursday	10:00 Meeting with SFDA Department for Human Resources	Consultant and SFDA staff	Please refer to minutes of meeting attached (5)
23/11/2018 Friday			Weekend
24/11/2018 Saturday			Weekend
25/11/2018 Sunday	10:00 Meeting with SFDA Laboratory and Research Sector	Consultant and SFDA staff	Please refer to minutes of meeting attached (6)
26/11/2018 Monday	11:00 Meeting with SFDA Operation Sector 12:00 Meeting with SFDA Food Sector	Consultant and SFDA staff	Please refer to minutes of meeting attached (7 and 8)
27/11/2018 Tuesday	14:00 Debriefing with UNDP	Consultant and UNDP staff	Please refer to minutes of meeting attached (9)

28/11/2018 Wednesday	10:00 Meeting with SFDA Food Sector 11:00 Meeting with SFDA Program Management Department	Consultant and SFDA staff	Please refer to minutes of meeting attached (10 and 11)
29/11/2018 Thursday	Debriefing with SFDA (cancelled)	Consultant, UNDP and SFDA staff	Please refer to Field Phase presentation attached
30/11/2018 Friday	Departure from Riyadh		
11/12/2018 Tuesday	13:00 Skype call with Gulf Health Council (GHC)	Consultant and GHC staff	Please refer to minutes of meeting attached (12)

Annex 6. Minutes of Meetings

1. Meeting at the United Nations Development Programme

Date of the meeting:	18 November 2018
Time of the meeting:	10:00 AST
Place of the meeting:	United Nations Development Programme Diplomatic District, Riyadh, Kingdom of Saudi Arabia
Participants / Institutions:	Firas Gharaibeh, Deputy Resident Representative, UNDP Maysaam Tanim, Assistant Resident Representative, UNDP Asim Salah, Senior Programme Associate, UNDP Lajos Kovacs, Consultant

The Saudi Food and Drugs Authority (SFDA) completed the implementation of its First Strategic Plan for 2007-2011 and the Second Strategic Plan for 2012-2016. SFDA approached the United Nations Development Programme (UNDP) to seek technical assistance and to jointly collaborate in achieving its strategic goals in accordance with the plans. The project implemented during the Second Strategic Phase was extended until the end of 2018. The Saudi Government provided funds for the project, while UNDP provided the requested technical support.

The terminal evaluation will assess the relevance, appropriateness, effectiveness, efficiency, impact, and sustainability of the Project. It will review the performance of the Project against the objectives stated in the strategic and annual plans. The objective of the project evaluation is to assess how the outputs of the Project have contributed to “achieving high impact goals as set by the SFDA mandate”. The Consultant will also provide recommendations aiming to improve various aspects of the Project towards achievement and quality delivery of the project.

The evaluation will focus on the following aspects of the implementation of the Project, in particular: results and impact of the Project, capacities built by the Project, communication between project components within the organization of the beneficiary, best practices and benchmarks, lessons learnt and problem areas, administrative and technical aspects of project implementation, and plans for a new project considering the Third Strategic Plan of SFDA.

The Consultant will draft a new Project Document according to the findings and conclusions of the terminal evaluation. The proposal for the new project will be prepared in cooperation with UNDP in order to take into consideration the advantages in providing further technical support to SFDA.

2. Meeting with Saudi Food and Drug Authority, Drug Sector

Date of the meeting:	18 November 2018
Time of the meeting:	12:00 AST
Place of the meeting:	Saudi Food and Drug Authority Riyadh, Kingdom of Saudi Arabia
Participants / Institutions:	Adel Abdullah Alharf, Vice-President for Drug Sector, SFDA Khaled Waleed Alshahwan, Director of International Relations, SFDA Ali Mohammed Al-Humaidan, Executive Director of Pharmaceutical Products Evaluation Ali Al-Shahrani, Director of National Center for Pharmacovigilance Hassan Al-Whaibi, Executive Director for Regulatory Affairs: Asim Salah, Senior Programme Associate, UNDP Naif D. Al-Enazi, Project Coordinator, SFDA Maram J. Aljabr, Assistant Project Coordinator, SFDA Lajos Kovacs, Consultant

The Drug Sector is responsible for protecting the public health in Saudi Arabia by providing the following services, in particular:

- Licensing of the manufacture, import, export, distribution, promotion and advertising of medications;
- Assessing the safety, efficacy and quality of medications, and issuing marketing authorization;
- Inspecting and surveillance of manufacturers, importers, wholesalers and dispensers of medication products;
- Monitoring the quality and safety of marketed medications;
- Monitoring the adverse reactions of medications;
- Assuring the safety of cosmetic products;
- Building an affective relationship with the international authorities and scientific societies;
- Enhancing the society's pharmaceutical education;
- Setting up the rules, specifications and standards before issuing the drug's marketing authorization in the Kingdom;
- Monitoring and following up the marketed drug in order to observe the adverse reaction of it and to prevent of illegal marketing methods;

- Providing an independent information on medications to professionals and the public.

The Drug Sector played an active role in the UNDP Project. The Project helped the Drug Sector to improve the expertise of staff in biologics and emerging novel drug categories and to update guidelines for various drug categories. The Drug Sector also initiated a strategic project to build adverse incidents reporting system for pesticides.

Following this meeting the Consultant further discussed the participation of the Drug Sector in the project.

Considering the opportunity for receiving further technical support in a new UNDP project, the Drug Sector is particularly interested in the following technical areas:

- Improving capabilities to monitor availability and security of drugs;
- Launching narcotic drug system and developing regulations and guidelines for narcotics;
- Improving evaluation and standard setting processes;
- Building and upgrading IT services in drug sector;
- Identifying and acting upon risks to patient safety;
- Developing crisis management strategy to ensure emergency response preparedness;
- Listing and creating standards for cosmetics products.

3. Meeting with the President of Saudi Food and Drug Authority

Date of the meeting:	19 November 2018
Time of the meeting:	10:00 AST
Place of the meeting:	Saudi Food and Drug Authority Riyadh, Kingdom of Saudi Arabia
Participants / Institutions:	Hisham Bin Saad Al-Jadhey, President of SFDA Maysaam Tanim, Assistant Resident Representative, UNDP Asim Salah, Senior Programme Associate, UNDP Naif D. Al-Enazi, Project Coordinator, SFDA Maram J. Aljabr, Assistant Project Coordinator, SFDA Lajos Kovacs, Consultant

The President introduced to the Third Strategic Plan (2018-2022) that lays out the new vision and strategic priorities for SFDA to address the challenges that SFDA faces as the regulator of the food, drug and medical devices sectors. SFDA wants to become a leading international regulator responsible for protecting the community and promoting access to safe products through sound regulations and effective controls.

SFDA must respond to the rapid pace of innovation, the tighter integration of global supply chains, and the increasing demands of Saudi citizens for safe and healthy products. SFDA wants to meet these challenges by making informed decisions based on scientific evidence and by building effective partnerships with the private sector, other government entities and international partners. Regarding latter SFDA took a proactive role and visited as well as invited international partners aiming at building bilateral and multilateral cooperation.

SFDA benefits from the UNDP Project that has the following main objectives:

- Provide technical assistance and advisory services to SFDA
- Provide advisory services to the technical committees, oversee their work and support the implementation of their tasks
- Support SFDA develop specifications, standards and policies for food, drug and medical devices
- Build the capacities of SFDA and its staff in technical areas relevant for SFDA

SFDA has also made progress regarding gender equality by employing qualified female staff and being committed to continue hiring in all sectors and departments.

The evaluation will focus on the following aspects of the implementation of the project, in particular: results and impact of the project, capacities built by the project, communication between project component within the organization of the beneficiary, best practices and benchmarks, lessons learnt and problem areas, administrative and technical aspects of project implementation, and plans for a new project considering the Third Strategic Plan of SFDA.

4. Meeting with Saudi Food and Drug Authority, Medical Devices Sector

Date of the meeting:	21 November 2018
Time of the meeting:	12:30 AST
Place of the meeting:	Saudi Food and Drug Authority Riyadh, Kingdom of Saudi Arabia
Participants / Institutions:	Ali Aldalaan, Vice-President for Medical Devices Sector, SFDA Faisal Alshehry, Head of Specification Section, SFDA Fawaz Alshemas, Head of Scientific and Technical Assessment Section, SFDA Nasser Alaboudi, Director of Department for Protection and Radiation Safety, SFDA Mohamed Awad Ghrouy, Director of Department for Radiology Surveillance, SFDA Naif D. Al-Enazi, Project Coordinator, SFDA Maram J. Aljabr, Assistant Project Coordinator, SFDA

	Lajos Kovacs, Consultant
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In parallel with the growth of the Saudi health care sector the Saudi Arabian medical devices market is growing rapidly. Therefore, SFDA as a regulatory body has important role to ensure safety, quality and effectiveness of medical devices throughout their life cycle (pre-market, on-market and post-market).

The main objectives of the Medical Devices Sector are to protect and maintain public health within the Kingdom of Saudi Arabia by the implementation of provisions ensuring a high level of safety and health protection of patients, users and third parties with regard to the use of medical devices as it relates to their manufacture, supply and use during their lifecycle and to mandate measures, and allocate responsibilities, to ensure that medical devices placed on the market and/or put into service within the KSA comply with all relevant requirements and provisions of the Saudi Food and Drug Authority according to the Medical devices Interim Regulation and its implementing rules.

The Medical Devices Sector is also concerned with medical devices of personnel use or home use that are flooding the Saudi market without any basic regulatory requirements. The Sector is also in charge of regulating electronic and electromagnetic devices that are suspected to have adverse effect on human health.

Regarding the quality management of the Medical Devices Sector, the Quality Control Unit applies policy and standards on the related work processes to keep the consistency of procedures and provides assistance to the Sector's departments to implement quality assurance requirements toward improving their services.

In addition, the UNDP Project provided support in preparedness regarding the challenges of technological development and capacity building of the Sector staff by transferring knowledge in various onsite / in service trainings.

The Sector needs further support to build its capabilities to provide full scale technical assessment. The Sector must be prepared to address technical questions and provide the required technical services in the most recent and fastly developing areas such as artificial intelligence in diagnostics and big data in research and planning, for instance.

5. Meeting with Saudi Food and Drug Authority, Department for Human Resources

Date of the meeting:	22 November 2018
Time of the meeting:	10:00 AST
Place of the meeting:	Saudi Food and Drug Authority Riyadh, Kingdom of Saudi Arabia
Participants / Institutions:	..., Department for Human Resources, SFDA Naif D. Al-Enazi, Project Coordinator, SFDA

	Lajos Kovacs, Consultant
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Over the years 2016-2017, 170 staff of SFDA took part in some training. There were mainly 1-2-week trainings organized either in Saudi Arabia or abroad. Those who were trained abroad had to disseminate new information among SFDA employees following the training programme. The training programmes were developed according to the results of training needs assessment done beforehand. The UNDP Project contributed to building capacities of SFDA staff though, training is still needed in technical areas and management / leadership, in particular.

Technical Assistance Agreement was signed between the United States Department of Agriculture (USDA) Foreign Agricultural Service (FAS) and the Saudi Food and Drug Authority (SFDA) for training activities through April 2017. Please refer to the content and results of trainings provided within the framework of the agreement in the minutes of meeting with SFDA Food Sector below.

6. Meeting with Saudi Food and Drug Authority, Research Centre

Date of the meeting:	26 November 2018
Time of the meeting:	9:00 AST
Place of the meeting:	Saudi Food and Drug Authority Riyadh, Kingdom of Saudi Arabia
Participants / Institutions:	Maram Al-Hazmi, Project Manager, SFDA Sarah Al-Shammari, Project Specialist, SFDA Dalal Al-Khamees, Support Services Specialist, SFDA Maram J. Aljabr, Assistant Project Coordinator, SFDA Lajos Kovacs, Consultant

SFDA Research Center was established in late 2017 and is responsible for developing research related protocols. If lab testing is required the research center develops the lab protocol in collaboration with SFDA Laboratories for the research project, then SFDA Laboratories will do the lab testing and share the results with the Research Center. For instance, in the milk and dairy products study the research protocol was developed by the Research Center and the lab tests were conducted by SFDA Laboratory according to the lab protocol, while the Research Center developed the final report for SFDA Board.

The Research Center provides primary research results to support decision making at SFDA. For example, the Research Center has developed the National Pharmacoepidemiology Database to support the pharmacovigilance and pharmacoepidemiology departments

investigating drug adverse events in clinical settings. The National Pharmacoepidemiology Database has now more than 1 million hospital visit records.

The Research Center is still building its capacities and has not established an official relationship with the Gulf Health Council yet. However, the Center has already been in contact with some of the member states of Gulf Cooperation Council and assists them in developing and running their consumer behavior surveillance system on the basis of the achievement of a system in Saudi Arabia by SFDA Research Center last year.

The Research Center has achieved its strategic goals (e.g. building data base) planned for 2018. In 2019, the Center plans to build data analytics portal for the previously developed data base. In 2020, the main goal is to build a portal of data and analytical tools and to provide access to that for researchers and research institutions.

The Center has employed 2 senior researchers and 9 junior researchers with less than 2 years of experience. Within the framework of the UNDP Project the Research Center has established collaboration with experts (e.g. researchers, biostatisticians, health information technology experts) requesting support to build research capacity and develop staff skills.

The Research Center has accomplished the following activities so far:

- Conducted 7 national level surveys related to food and drug.
- Conducted 2 basic laboratory research studies.
- Developed the consumer behaviour surveillance system.
- Developed 3 training programs for its staff.
- Developed the National Pharmacoepidemiology Database.
- Developed the National Portal for Disclosure and Transparency.
- Developed the National Clinical Trial Registry and linked it with WHO, first in the Middle East.
- Organized the SFDA annual conference.
- Developed research infrastructure and policies.
- Provided scientific and technical support to SFDA departments.

Considering the opportunity for receiving further technical support in a new UNDP project, the Research Center is particularly interested in the following technical areas: international collaboration with other GCC countries in the region and participation in international researches.

7. Meeting with Saudi Food and Drug Authority, Operation Sector

Date of the meeting:	26 November 2018
Time of the meeting:	11:00 AST
Place of the meeting:	Saudi Food and Drug Authority Riyadh, Kingdom of Saudi Arabia

Participants / Institutions:	<p>Sami Saad Al-Sager, Vice-President for Operation Sector, SFDA</p> <p>Saad Al-Ghamadi, Deputy Assistant for Branches and Inspection, SFDA</p> <p>Abdullah Al-Khethairi, Executive Director of Compliance and Systems Enforcement, SFDA</p> <p>Bader Al-Ageel, Director of Licensing Department, SFDA</p> <p>Mohammed AL-Nasser, Executive Director of Riyadh Branch, SFDA</p> <p>Mohammed Daas, Executive Director of Inspection Support, SFDA</p> <p>Maram J. Aljabr, Assistant Project Coordinator, SFDA</p> <p>Lajos Kovacs, Consultant</p>
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SFDA Operations Sector consists of 8 executive departments and 25 departments. The executive departments are as follows.

The Executive Department of Registration and Licensing leads the development and update of operational manuals and procedures; manages the classification of new food, drug, pesticides and medical devices products as per standards; manages the registration and licensing of local and imported food, feed and pesticides, drugs and cosmetic products and medical devices; manages the creation of specialized internal and external technical committees in order to study and investigate complex applications.

The Executive Department of Compliance and Enforcement oversees and approves compliance framework and roadmap, enforcement guidelines and procedures, and follow up on proper implementation; oversees the coordination with SFDA Departments and external entities to decide on corrective actions for the identified infringements and violations; acts as an expert in the area of compliance and enforcement and provides expertise whenever needed for decision making purposes.

The Executive Department of Inspection Support approves inspection manuals / GMP inspection manuals and related updates to ensure best practices; oversees all digital inspection activities to ensure that all online selling points are abiding to SFDA standards; directs scheduling and prioritization of inspections based on set plans, priority areas defined by SFDA management, yearly vigilance plan, licensing and registration requests and ad-hoc requests; liaises with international GMP inspectors/auditors whenever support and expertise is needed for knowledge exchange and accurate findings and analysis.

The Riyadh and regional branches (Riyadh Branch, Mecca AlMukarramah Branch, Eastern Region Branch, Tabuk Branch, Jazan Branch) supervise the implementation of inspection plans on facilities and ensure compliance with the approved rules and regulations; oversee inspection activities and ensure those cover all the markets, ports and other facilities in Riyadh and the regions respectively, approve reports of non-conformity and ensure implementation of necessary corrective actions; oversee follow up visits on infringing parties and approve punitive actions.

Considering the opportunity for receiving further technical support in a new UNDP project, the Operations Sector is particularly interested in the following technical areas: blood products and blood bank; supply chain integrity for food, drugs and medical devices; building capacities of staff in the Sector's key areas such as registration, licensing and inspection.

8. Meeting with Saudi Food and Drug Authority, Laboratory Centre

Date of the meeting:	26 November 2018
Time of the meeting:	12:00 AST
Place of the meeting:	Saudi Food and Drug Authority Riyadh, Kingdom of Saudi Arabia
Participants / Institutions:	Mubark M. Alabudahash, Executive Manager, Drug Laboratory, SFDA Naif D. Al-Enazi, Project Coordinator, SFDA Lajos Kovacs, Consultant

The Pharmaceutical Laboratories assure their conformity with the requirements of the international quality and competence standards. They are responsible for the analysis of imported or locally manufactured drugs (human, veterinary), biological, healthy, herbal and cosmetic products in order to ensure their compliance with the standards of international pharmacopeia and World Health Organization as well as the authority's national standards.

The divisions of the Pharmaceutical Laboratories (i.e. Sample Receiving Section, Quality Assurance Section, Technical Maintenance Section, Analytical File Review Section, Experimental Animals' Center, Laboratory Informatics Section, Warehouse Section) have recently moved into their new facility which has been designed and equipped according to their tasks as well as to meet the international sector standards.

The human and veterinary products analysis department is responsible of checking the quality of human and veterinary medicines for registration. The herbal and food supplements analysis department is responsible of checking the quality of herbal and health products. The biological products analysis department monitors the quality of vaccines, serums and blood derivatives according to international requirements and pharmacopeia standards. The unknowns and complaint samples analysis department is responsible for the investigation of unknown products beside the traditional herbal mixtures to reveal the exact contents in addition to dealing with complaints from medicines.

Cosmetics' analysis laboratories are in Riyadh, Jeddah and Dammam. These laboratories analyse cosmetic products for clearance in different areas. Cosmetics' laboratory in Riyadh monitors the safety and quality of cosmetics marketed in Saudi Arabia. Cosmetics' laboratory in Jeddah is responsible for testing cosmetic products for clearance purpose through Jeddah Islamic Port or King Abdulaziz International airport. Cosmetics' Laboratory in Dammam is responsible for testing cosmetic products for clearance purpose through ports in the eastern region of Saudi Arabia.

The Pharmaceutical Laboratories have been equipped with qualified staff and modern instruments. In addition, they have been accredited and certified according to international accreditation and certification standards. The UNDP Project provided training and developing sources to the laboratories' staff in order to be able to perform all types of analysis that required by the sector. Two experts have provided in-service training for the Laboratories staff.

Considering the opportunity for receiving further technical support in a new UNDP project, the SFDA Laboratories are particularly interested in the following technical areas: building capacities of drug laboratories staff.

9. Debriefing at the United Nations Development Programme

Date of the meeting:	27 November 2018
Time of the meeting:	14:00 AST
Place of the meeting:	United Nations Development Programme Diplomatic District, Riyadh, Kingdom of Saudi Arabia
Participants / Institutions:	Firas Gharaibeh, Deputy Resident Representative, UNDP Maysaam Tanim, Assistant Resident Representative, UNDP Asim Salah, Senior Programme Associate, UNDP Lajos Kovacs, Consultant

Please refer to the Field Phase presentation on the main findings of the mission (*Annex 7*).

10. Meeting with Saudi Food and Drug Authority, Food Sector

Date of the meeting:	28 November 2018
Time of the meeting:	10:00 AST
Place of the meeting:	Saudi Food and Drug Authority Riyadh, Kingdom of Saudi Arabia
Participants / Institutions:	Saleh Aldosari, Vice-President for Food Sector, SFDA Faisal Al-Yami, Director of Compliance Department, SFDA Ayman Al-Ghanem, Senior risk assessment specialist, SFDA Khaled Al-Raoji, Head of the Department of Monitoring the Harmful Effects of Pesticides, SFDA Aloosh Al-Harbi, Senior Translator, SFDA Naif D. Al Enazi, Project Coordinator, SFDA

	Lajos Kovacs, Consultant
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SFDA Food Sector is responsible for ensuring the safety of food for the consumption of humans and animals, safety of pesticides. and setting up a clear food policy and the planning to achieve the objectives of this policy.

The Food Sector adopts the food policies in the Kingdom, reviews the existing control regulations and rules and sets up the plans that ensure the good quality and safety of food. It sets the health standards and requirements that should exist in the food industry and those who work in it, as well as sets up the health standards and requirements that should exist in the commercial sites that are related to the public health.

The Food Sector sets the regulations, procedures and requirements related to the control and inspection of animal sites, regulating the affairs of abattoirs and selling meat places in cooperation and coordination with the Ministry of Municipality Affairs. It also proposes regulations that control and regulate the importing and exporting of animal and plant products.

The food Sector also prepares and develops the training programs that would raise the efficiency of those who work in the food sector. It deals with the emergency issues in the field of food control.

The Food Sector took an active role in the UNDP Project. Regarding its expected outputs the Food Sector achieved the following activities, in particular: improved the expertise level of SFDA employees in food safety, pesticides and animal health, advanced animal feed expertise and enhanced control, improved industry and consumer awareness and intra-agency cooperation, defined internal control systems and institutionalized accountability, aligned with relevant stakeholders on an efficient enforcement model (e.g. license for bottled drinking water manufacturers), optimized SFDA's role regarding inspection of local market food businesses and water bottling plants, and implemented effective processes to operationalize pesticide safety standards.

Technical Assistance Agreement was signed between the United States Department of Agriculture (USDA) Foreign Agricultural Service (FAS) and the Saudi Food and Drug Authority (SFDA) for training activities through April 2017.

Under the Pesticide Program Activities, USDA / FAS completed Activities 1 and 2 on pesticide registration requirements. USDA / FAS, in collaboration with the University of Illinois at Urbana-Champaign, conducted pesticide inspection and registration trainings with members of SFDA. In July 2016, six pesticide inspectors from SFDA first travelled to Urbana-Champaign, Illinois for training on pesticide inspection methods. Afterwards, the SFDA inspectors travelled to Washington DC to receive training on U.S. government regulations for pesticide inspection. Following, four pesticide inspectors from SFDA received training in August 2016 on pesticide registration requirements.

Under the Food Safety Program Activities, USDA / FAS completed Activities 1-8 until the end of 2017.

USDA / FAS hosted five participants from SFDA and provided training on the equivalency process, in order to practice relevant operational procedures, techniques for inspection on exports and imports, and equivalency evaluation assessment (Activity 2).

Experts travelled to KSA for a follow-on activity to Activity 2, to ensure participants are applying what they learned in the initial training on equivalency (Activity 3).

USDA / FAS, together with the University of Maryland / Joint Institute for Food Safety and Applied Nutrition, conducted a series of laboratory trainings with sixteen participants from SFDA. In total, four laboratory activities were conducted between July and November 2016 on the detection of pathogens (e.g. Salmonella and Campylobacter, Staphylococcus aureus and vibrio, Listeria Monocytogenes and E. coli), the use of science-based risk assessments to identify compounds for testing as well as determining pesticides in food of plant and animal origins, and the detection of mycotoxins in food (Activity 4). One additional week of training was conducted in Saudi Arabia as a follow-on activity for the above mentioned four trainings. Technical experts travelled from U.S. to Saudi Arabia to conduct on-site trainings between June and September 2017.

Two experts from USDA / FAS travelled in April 2016 to Riyadh, Saudi Arabia to conduct meetings with SFDA to plan for the Food Defense Workshop and discuss other activities within the agreement, budget issues, and progress (Activity 5).

Between 16-18 October 2016, USDA / FAS conducted a Food Defense Workshop in Riyadh, Saudi Arabia with sixty Saudi participants in attendance from government, private sector, academia, and law enforcement. The workshop trainers were experts from USDA / FAS, USDA / Food Safety Inspection Service, U.S. Federal Bureau of Investigation, University of Minnesota Food Protection and Defense Institute, and private industry was represented by Periscope Consulting. This workshop aimed to enhance Saudi Arabia's ability to protect their food supply from intentional contamination. This workshop also presented Saudi Arabia with strategies on implementing a Food Defense Action plan to be adopted at each stakeholder level — government, law enforcement, academia, and private industry (Activity 6).

USDA / FAS in coordination with University of Minnesota's Food Protection and Defense Institute hosted eleven SFDA participants for the Food Defense Collaborative Exchange Program in Minneapolis, Minnesota in December 2016 as a follow-on activity from the Food Defense Workshop. Participants who attended the Food Defense Workshop were selected by SFDA to attend this program. Participants received additional technical assistance to equip them with advanced skills and competencies necessary to facilitate educational programs, vulnerability assessments, and food defense planning efforts in Saudi Arabia (Activity 7).

USDA / FAS hosted a Surveillance and Monitoring Exchange Program between 29 October and 5 November 2016 in Washington, DC. Ten SFDA participants learned about the development and implementation of various surveillance and monitoring programs in the U.S. Trainings were conducted by experts from the USDA Office of the Chief Scientist, USDA Federal Grain Inspection Service, USDA Agricultural Marketing Service, former EPA consultants, Maryland Department of Agriculture, Port of Baltimore, Maryland State of Office of Food Protection, Grocery Manufacturers Association, Virginia Department of Agriculture and Consumer Services, and the Joint Institute for Food Safety and Applied Nutrition (Activity 8).

Most recently, SFDA Food Sector has been reorganized. Its 150 staff are working in 3 departments, while other employees have been moved to the strengthened Operations Sector.

Regarding the opportunity for receiving further technical support in a new UNDP project, the following areas should be considered to be addressed by the project activities: risk assessment and capacity building of laboratory and staff accordingly; strengthening capacities in regulation; pesticide control.

11. Meeting with Saudi Food and Drug Authority, Programme Management Department

Date of the meeting:	28 November 2018
Time of the meeting:	11:00 AST
Place of the meeting:	Saudi Food and Drug Authority Riyadh, Kingdom of Saudi Arabia
Participants / Institutions:	... Programme Management Department, SFDA Naif D. Al-Enazi, Project Coordinator, SFDA Lajos Kovacs, Consultant

The meeting provided an opportunity for discussing the main findings of the terminal evaluation and checking the proposal for a new project against the ongoing and to-be-started projects of SFDA in accordance with its Third Strategic Plan 2018-2022.

The Third Strategic Plan 2018-2022 lays out SFDA vision and strategic priorities for SFDA as the regulator of food, drugs and medical devices sectors. SFDA wants to become a leading international regulator responsible for protecting the community and promoting access to safe products through sound regulations and effective controls. SFDA faces challenges due to the rapid pace of innovation, integration of global supply chains, and increasing demands of citizens for safe and healthy products. Therefore, SFDA needs to make informed decisions based on scientific evidence and by building effective partnerships with the private sector, other government entities and international partners.

The Third Strategic Plan, in accordance with these priorities, focuses on outcomes and measurable value to stakeholders, efficient and effective operations utilizing existing capabilities, relies on scientific evidence and risk assessment, and works with partners to effectively monitor and control different components of the value chain.

The 19 projects identified and planned for the technical areas and sectors of SFDA within the framework of the Third Strategic Plan are in line with and have been built on the strategic goals and initiatives of the Saudi Vision 2030 and the National Transformation Program 2020.

Considering the opportunity for a new UNDP project, the key areas to be addressed by its activities should be aligned with the above-mentioned strategic documents. The proposed priorities of a new UNDP project were reviewed and discussed in the meeting, and were found being in line with the current state of affairs at SFDA after the accomplishment of the

first two strategic phases (i.e. First Strategic Plan for 2007-2011 focusing on building regulatory framework and build-up essential capabilities required to assume regulatory responsibilities; Second Strategic Plan for 2012-2016 continuing building-up operational capabilities, addressing gaps in SFDA mandate, and developing organizational capabilities, policies and procedures) as well as the current needs of SFDA Sectors.

12. Skype call with Gulf Health Council

Date of the meeting:	11 December 2018
Time of the meeting:	13:00 AST
Place of the meeting:	Skype call
Participants / Institutions:	Sulaiman Aldakheel, General Manager, Gulf Health Council Hajed Hashan, Deputy General Manager, GHC Lajos Kovacs, Consultant

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 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 (pro)actively 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 programs such as unified drug procurement, central registration, and standardization of pricing, the Gulf Health Council 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.

Annex 7. Field Phase Presentation



Terminal Evaluation for Project SAU10/82003 Saudi Food and Drug Authority Phase II

Dr Lajos Kovács

Final Meeting, Field Phase

Riyadh, Saudi Arabia, 29 November 2018

UNDP SFDA Project

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.

To achieve its vision, SFDA developed its **2nd 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 focuses on the following outputs: *Capacity development of SFDA; Ensure thoroughness, transparency, and consistency in enforcement and communication; Complete the coverage of all relevant areas as per SFDA's mandate; Develop systems and processes to improve pro-activity in addressing emerging risk.*

The UNDP Project has been extended until the end of 2018 and UNDP also considers to further support SFDA during the implementation of its **3rd Strategic Plan** 2018-2022.

2

UNDP SFDA Project

Project title: Saudi Food and Drug Authority Phase II SAU10/82003

Programme period: 2015 – 2018

Start date: 1 April 2012

End date: 31 December 2018

Total budget: 24,095,324 USD

3

Terminal Evaluation

The **objective** of the project evaluation is *to assess how the outputs* of the above-mentioned project have *contributed to* “achieving high impact goals as set by the *SFDA mandate*”.

The **terminal evaluation** assessed the Project ‘Saudi Food and Drug Authority Phase II’ in terms of *relevance, effectiveness, efficiency, impact, and sustainability*.

It reviewed the *performance* of the Project against the objectives stated in the strategic and annual plans.

4

Workplan

Activity	Location	Working Days
<i>Inception phase/Desk phase</i>		
Preparation for evaluation	Home-based	Days 1-4
Initial document and data collection and definition of methods of analysis		
Review of documents		
<i>Field phase</i>		
Briefing	Saudi Arabia	Days 5-16
Field missions incl. desk reviews, interviews		
Data collection and analysis		
Discussion of new phase project with UNDP		
Debriefing		
<i>Synthesis phase</i>		
Final analysis of findings, overall assessment, conclusions and recommendations	Home-based	Days 17-20
Preparation of Final Report		
Drafting new phase project document		
Submission of Final Report and new phase project document		

Methodology of Evaluation

1. Review of the national context and SFDA (Background)
2. Scope of evaluation (Evaluation Questions)
3. Analysis of existing sources (Documents and Data)
4. Consultation with key stakeholders (Interviews)
5. Assessment of project performance

Background

Improvement of healthcare services provided to the Saudi citizens was a **strategic decision** by the Leadership.

The Ministry of Health has set the *strategy* in response to **major challenges**: the high costs of health services resulting from the development of *medical technologies* and expensive *new drugs*, the *increasing prevalence of chronic diseases*, the expensive *long term care services*.

MoH implemented **modern methodologies** in providing health care services: *patient-centered health* care system from primary health care to specialized services, preserving all *patients' rights*, *integrated* and *comprehensive health care* approach, studies on *privatization*, *management* and operation practices, *optimal use of resources*.

7

Documents and Data

National Legislative Framework

- Article 31 of the **Basic Law of Saudi Arabia**, "the State shall protect public health and provide healthcare to every citizen".
- **Ministry of Health Strategy** for 1431-1440 H, ratified by the Council of Ministers' resolution No. (320), dated 17/9/1430, corresponding to 7/9/2009.
- **Saudi Vision 2030**
- **National Transformation Program 2020**

Saudi Food and Drug Authority

- Organisational and technical documents
- **FDA Strategic Plan 2018-2022**

Project Documents

- Project Document/Contract and Budget
- Annual Progress Reports 2015-2017
- Financial Audit Reports 2016-2017

8

Meetings

UNDP	18 November 2018
SFDA Drug Sector	18 November 2018
SFDA President	19 November 2018
SFDA Medical Devices Sector	21 November 2018
SFDA Department for Human Resources	22 November 2018
SFDA Research Centre	26 November 2018
SFDA Operation Sector	26 November 2018
SFDA Laboratory Centre	26 November 2018
SFDA Food Sector	28 November 2018
SFDA Programme Management	28 November 2018

9

Evaluation Questions

RELEVANCE

Relevance concerns the extent to which a development initiative and its intended outputs or outcomes are consistent with national and local policies and priorities and the needs of intended beneficiaries.

EQ1: To what extent are the objectives of the Project still valid and in line with the strategic goals and objectives of health policy in Saudi Arabia?
(*Validity of objectives*)

EQ2: To what extent are the expected results of the Project sufficient to achieve the objectives of the Project? (*Appropriateness of expected results*)

EQ3: To what extent is the Project prioritised in the health policy and strategy documents in Saudi Arabia? (*Relevance of Project*)

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Evaluation Questions

EFFECTIVENESS

Effectiveness of the Project means whether the planned benefits have been delivered and received, and whether the intended beneficiaries participated in the intervention.

EQ4: How effective was the planning for the preparation of the Project? (*Planning*)

EQ5: In practice, to what extent is the Project contributing to the health policy priorities?

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Evaluation Questions

EFFICIENCY

Efficiency is the extent to which the cost of the project has been justified by the benefits, whether or not expressed in monetary terms in comparison with similar project or known alternative approaches.

EQ6: To what extent does the design of the Project lead to an efficient allocation of resources among objectives / expected results? (*Allocation of resources among objectives / expected results*)

EQ7: To what extent does the allocation of resources allow for an efficient implementation of the Project in terms of: funding mechanisms, simplification measures and operational costs?

EQ8: To what extent are the monitoring processes and resources sufficient and adequate to plan and promote the results of the Project? (*Monitoring*)₁₂

Evaluation Questions

IMPACT

The evaluation will examine the extent to which the objectives of the Project have been achieved as intended, and whether the effects of the Project have been facilitated or constrained by any factors.

EQ9: What are the different options to meet the strategic goals and objectives of health policy in Saudi Arabia and whether the objectives of the Project achieve those?

EQ10: Who have been affected by the Project?

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Evaluation Questions

SUSTAINABILITY

The Beneficiary's institution will be able to continue its work only if the necessary financial and human resources are available, an adequate regulatory/legislative framework will be in place, and the governmental institutions/authorities will stick to their commitments.

EQ11: Is the beneficiary institution capable to continue the provision of benefits beyond the Project's end?

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Evaluation Questions

COHERENCE

The evaluation will examine the extent to which the Project is both internally coherent and externally well aligned with other policies and programmes.

EQ12: To what extent have the objectives of the Project led to more synergy, focus and coherence between the funded actions in delivering on the objectives? (*Internal coherence*)

EQ13: To what extent are the objectives and expected results of the Project externally consistent/coherent with the national health policies and other programmes/actions?

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Evaluation Questions

CROSS-CUTTING ISSUES

Healthcare sector being at the intersection of numerous problems, the evaluation will assess the following cross-cutting issues: gender equality, good governance (in its reform agenda and decentralisation of the healthcare system).

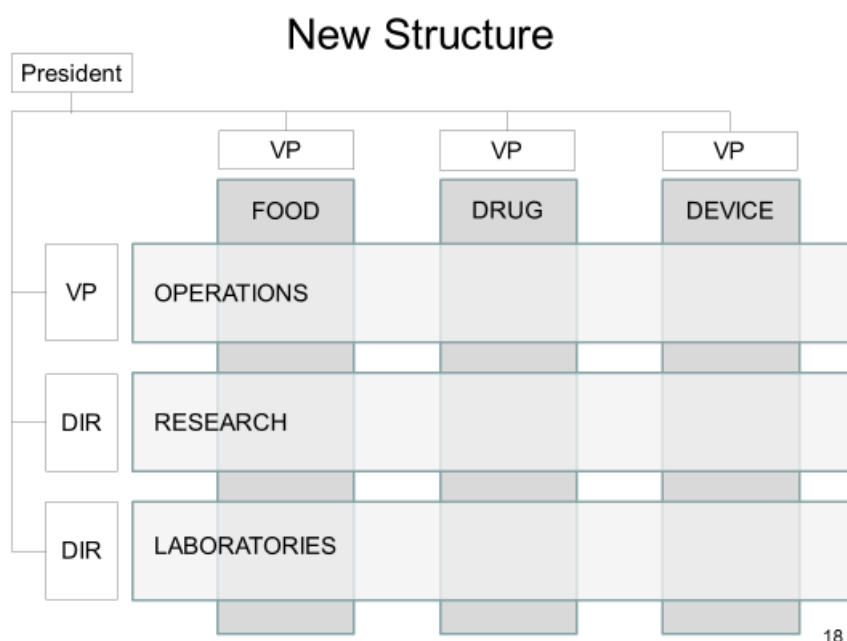
EQ14: To what extent are the cross-cutting issues addressed in the Project?

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Main Findings

- The Project has valid and appropriate objectives which are in line with the health policy and strategy in the Kingdom of Saudi Arabia (*Relevance*).
- The Project significantly contributes to strengthening the capabilities of SFDA to target needs of the covered areas (i.e. food, drug and medical devices) (*Effectiveness*).
- The Project benefits from the synergy between the project activities and the structure of SFDA, therefore, it supports SFDA implementing its mission (*Internal Coherence*).
- The activities increased the Project's coherence with the national programmes (*External Coherence*).
- SFDA seems to be capable to continue the activities in accordance with the 3rd Strategic Plan and by using the developed capacities of the institution (i.e. new organisational matrix structure) and the employees (i.e. outputs of the training programmes) (*Sustainability*).
- SFDA continuously hires, employs and trains qualified female staff in increasing number (*Gender Equality*).

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Recommendations

SFDA should:

- Maintain the focus on specific objectives and areas where the Project provided added value.
- Maintain and strengthen links between the New Project and the national policies (e.g. NTP2020, MoH Health Strategy) to maximise impact.
- Support the project management and coordination with UNDP.
- Maintain the monitoring of the progress of the New Project according to the programmatic and action specific indicators set in the Logical Framework.

UNDP should:

- Maintain the implementation of the activities of the New Project in accordance with the plan of action.

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For consideration

	Sectors					
	Food	Drug	Medical Device	Operations	Research	Laboratories
SFDA needs	<ul style="list-style-type: none"> • Capacity in risk assessment • Support in development,ent of regulations • Capacity in pesticide control 	<ul style="list-style-type: none"> • Assessment of new drugs • Drug safety 	<ul style="list-style-type: none"> • Capacity and skills for big data and arteficial intelligence • Safe use and medical device safety 	<ul style="list-style-type: none"> • Supply chain integrity • Expertise in blood banks • Trainings 	<ul style="list-style-type: none"> • Regional and international collaboration and coordination of researches • Capacity and skills for big data in research 	<ul style="list-style-type: none"> • Capacity building regarding drugs

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For consideration

	Sectors					
	Food	Drug	Medical Device	Operations	Research	Laboratories
NTP2020 Objectives	Objective 3 Promote prevention against health risks	Objective 2 Improve quality and efficiency of healthcare services Objective 3 Promote prevention against health risks	Objective 1 Access to health services Objective 2 Improve quality and efficiency of healthcare services	Objective 1 Access to health services Objective 3 Promote prevention against health risks	Objective 2 Improve quality and efficiency of healthcare services	Objective 2 Improve quality and efficiency of healthcare services Objective 3 Promote prevention against health risks
NTP2020 Initiatives	Initiative 25 Halal centre Initiative 38 IT Initiative 56 Nutrition Initiative 70 Pesticide	Initiative 12 HTA Initiative 24 e-tracking system Initiative 38 IT	Initiative 12 HTA Initiative 20 Innovation Centre Initiative: 38 IT	Initiative 19 Blood Bank Initiative 38 IT	Initiative 62 Research Centre	Initiative 70 Pesticide

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For consideration

	Sectors					
	Food	Drug	Medical Device	Operations	Research	Laboratories
SFDA 3rd Strategic Plan Objectives	Objective 1 Inspection Objective 2 Laboratory Objective 3 Financial sustainability Objective 4 Food safety Objective 5 Risk-based decision making Objective 6 Regulations Objective 7 Import Objective 8 Pesticide control Objective 16 People and organisation Objective 17 Technology Objective 18 Awareness Objective 19 International relations	Objective 1 Inspection Objective 2 Laboratory Objective 3 Financial sustainability Objective 9 Approval Objective 10 Safety Objective 11 Access Objective 12 Cosmetics Objective 16 People and organisation Objective 17 Technology Objective 18 Awareness Objective 19 International relations	Objective 1 Inspection Objective 2 Laboratory Objective 3 Financial sustainability Objective 13 Approval Objective 14 Surveillance Objective 15 Safe use Objective 16 People and organisation Objective 17 Technology Objective 18 Awareness Objective 19 International relations	Objective 3 Financial sustainability Objective 6 Regulations Objective 7 Import Objective 9 Approval Objective 13 Approval Objective 16 People and organisation Objective 17 Technology Objective 18 Awareness Objective 19 International relations	Objective 3 Financial sustainability Objective 16 People and organisation Objective 17 Technology Objective 18 Awareness Objective 19 International relations	Objective 3 Financial sustainability Objective 4 Food safety Objective 10 Safety Objective 15 Safe use Objective 16 People and organisation Objective 17 Technology Objective 18 Awareness Objective 19 International relations

Proposal for new project

Proposed key areas

1. Assessment of new drugs' safety and effectiveness
2. Risk based evaluation and safe use of technologies
3. Continuation of building institutional and staff capacities
4. Regional and international collaborations and recognition
5. Internal communication and organisational culture
6. External communication and awareness

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Thank you for your cooperation
and supporting the evaluation.

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