



Environmental and Social Review Summary

MS Pharma - Scientific Mosul Iraq

This Environmental and Social Review Summary (ESRS) is prepared by MIGA staff and disclosed in advance of the MIGA Board consideration of the proposed issuance of a Contract of Guarantee. Its purpose is to enhance the transparency of MIGA's activities. This document should not be construed as presuming the outcome of the decision by the MIGA Board of Directors. Board dates are estimates only.

Any documentation which is attached to this ESRS has been prepared by the project sponsor, and authorization has been given for public release. MIGA has reviewed the attached documentation as provided by the applicant, and considers it of adequate quality to be released to the public, but does not endorse the content.

Country:	Iraq
Sector:	Pharmaceuticals
Project Enterprises:	Scientific Mosul for Factories Rehabilitation and Operation and Marketing Ltd
Environmental Category:	B
Date ESRS Disclosed:	May 12, 2014
Status:	Due Diligence

A. Project Description

GMS Ventures and Investments Holdings Ltd, organized and existing under the laws of Jordan ("GMS V&I Jordan" or the "Guarantee Holder"), has been awarded an 18-year contract by the Iraqi Ministry of Industry and Minerals for the rehabilitation and management of the State Company for Drugs and Medical Equipment – Nineveh ("NDI" or "Project") in Mosul, Iraq. The Project term includes 3 years rehabilitation from transfer date (09/01/2013) of facilities followed by 15 years operation. MS Pharma was setup in 2011 in Bahrain to consolidate the group pharmaceutical operations through El Kendi Pharmaceuticals (Algeria & Morocco), United Pharmaceuticals (Jordan), and their affiliates. MS Pharma is responsible for consolidating group policies, strategies and procedures to ensure systematic management approach and operation. Project Enterprise "Scientific Mosul for Factories Rehabilitation and Operation and Marketing Ltd" ("Scientific Mosul") was recently established as a subsidiary of GMS V&I Jordan to manage operations in Iraq. The Project funds will be used for raw material, packaging, salaries, buildings, labs, services, machinery and trainings for the production of branded generic drugs including tablets, capsules, ointments, syrups, sanitizers, ampoules, eye and oral drops, cancer medicines and sprays. In addition to the manufacturing operations, the project also includes the operation of an existing wastewater treatment unit, which will be rehabilitated as well as use of diesel generators for supplemental power supply that amount to about 10MW.

NDI produces pharmaceutical products through various manufacturing facilities:

- Nineveh Pharmaceutical facility that includes units that produce capsules, tablets, ointments, syrups, ampoules, eye and oral drops, sprays and sanitizers.
- Injections facility is the oldest facility, where its production started in 1982, and it used to produce 19 pharmaceutical products; however, operations are currently halted because the facility was destroyed in the 2003 Iraq invasion.
- Cancer medications facility is a new facility that started production in 2002.

NDI Pharmaceutical manufacturing is divided into two major stages: (i) the production of the drug manufacture) and (ii) secondary processing, the conversion of the active drugs into products suitable for administration. The principal manufacturing steps in the facility includes secondary processing such as granulation; drying; tablet pressing, printing, and coating; filling; and packaging. NDI production capacity is distributed over 6 main lines:

1. Solid dosage form, with capacity of about 400 million unit per annum, for plane, sugar and film coated tablets, powders and capsules including antibiotics (about 12 million unit per annum);
2. Liquids line for syrups, suspensions, and solutions with total capacity of about 24 million units per annum;
3. Sterile liquid line for eye drops with capacity of about 30 million per annum;
4. Inhalers and antiseptics with capacity of about 5 million per annum;
5. Ampoules with capacity of about 18 million per annum; and
6. Semi-solids line for ointments, creams, gels and suppositories with total capacity of about 24 million units per annum.

The facilities are in one compound with a total land area of 500,000 m² and built area of 34,891 m². It is located about 8 km to the Northwest of Mosul city and about 3.8 km west of the town of Tall Kayf.

Current utilization rate in NDI facilities is low and GMS V&I Jordan targets increasing utilization to about 90% after first year of rehabilitation. The rehabilitation plan includes civil works, installation of new air handling units, and HVAC system, fire-fighting system, and upgrade and enhancements of various machinery on several production lines. GMS V&I Jordan plans for Iraq operation to manufacture about 380 products within two years of which 20 new oncology products. The plant will be rehabilitated according to European Union Good Manufacturing Practice (GMP) as other operations of the group. Rehabilitation started first quarter 2014 and is expected to last for 3 years.

GMS V&I Jordan has requested MIGA to cover its investment in the Project for risks of expropriation, transfer restriction, war and civil disturbance and Breach of Contract for up to 18 years; details are in the Summary of Proposed Guarantee (SPG) disclosed on May 12, 2014.

B. Environmental and Social Categorization

This is a Category B project according to MIGA's Policy on Environmental and Social Sustainability dated October 2007. The Project is expected to have limited environmental and social (E&S) impacts that are generally site-specific and largely reversible. Those impacts can be avoided or mitigated by adhering to recognized Performance Standards, operating procedures, and guidelines as described in the following sections.

Key E&S issues related to the Project include the project enterprise's capacity to manage environmental, social, health and safety performance, worker health and safety, process hygiene and product quality, storage, handling of and use of hazardous chemicals, handling of hazardous wastes and emissions, wastewater, fire, life and safety, emergency response, and environmental and social management systems.

Information on how these E&S issues are, or will be, addressed by the Project to comply with MIGA's Performance Standards and WBG EHS Guidelines is contained in the following sections.

C. Applicable Standards

While all Performance Standards (PSs) are applicable to this proposed MIGA guarantee project, based on our current information the Project will have impacts which must be managed in a manner consistent with the following PSs:

- PS1: Social and Environmental Assessment and Management Systems;
- PS2: Labor and Working Conditions;
- PS3: Pollution Prevention and Abatement; and
- PS4: Community Health, Safety and Security.

E&S issues associated with the following PSs were not encountered during the assessment of the Projects:

- PS5: *Land Acquisition and Involuntary Resettlement* is not expected to be applicable as the Project involves no physical or economic displacement;
- PS6: *Biodiversity Conservation and Sustainable Natural Resources Management* is not triggered as there are no known impacts on conservation or biodiversity.
- PS7: *Indigenous Peoples* is not expected to be triggered as no known indigenous peoples are within the areas of the Project; and
- PS8: *Cultural Heritage* is not triggered as the Project is not located in areas of known historical or cultural significance.

The Projects will be required to comply with the WBG EHS General Guidelines and EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing.

D. Key Documents and Scope of MIGA Review

The documents reviewed by MIGA include:

- "Environmental and Socio-economical Assessment" by Al-Rawabi Environmental and Energy Consultancies dated July 2013;
- "MS Pharma Presentation" dated August 2012;
- "GMS Holdings Rehabilitation and Operation of NDI Project" dated Jan. 2013.
- Completed E&S due diligence questionnaire and attachments; and
- Definitive Application for a MIGA Guarantee;

MIGA's review of the Projects also included a site visit to the Guarantee Holder facilities in Jordan and correspondence comprising of environmental and social information submitted by the Project.

E. Key Issues and Mitigation

Key environmental and social (E&S) issues associated with the Project business activities are summarized in the following paragraphs:

PS1: Social and Environmental Assessment and Management Systems:

Social and Environmental Management System: NDI is certified for International Organization for Standardization for ISO 9001:2008 for Quality Management Systems. GMS V&I Jordan will build on existing management programs and systems in other facilities to be the basis of setting up an Environmental and Social Management System (ESMS), in accordance with the requirements of PS1. The management system will include detailed roles and responsibilities as well as reporting requirements to ensure that issues related to air pollution, vapors, noise level and waste management in the plant is well taken care of. GMS V&I Jordan also agreed to develop within an agreed timeframe Standard Operating Procedures (SOPs) that will cover all operational practices in accordance with international requirements including EU GMP requirements.

Management Programs: Currently in NDI there is no internal audits process. As part of NDI quality assurance system an audit process will be put in place within an agreed timeframe.

Organizational Capacity and Competency: NDI has a department for Quality Management with no specific role or responsibility for management of environment and/or social risks and/or impacts. GMS V&I Jordan will allocate responsibility for ESMS management and implementation. Managers and supervisors will also be part of the overall management commitment for ESMS implementation. A training program will be put in place within an agreed timeframe.

Emergency Preparedness and Response: NDI has a national set of procedures for firefighting and protection. The existing procedures outline roles and responsibilities of different personnel in the operations. NDI will update the existing procedures in a comprehensive emergency preparedness and response plan (ERP) and procedures manual. The ERP will also identify potential emergency situations and potential accidents that can have impacts on life and safety of workers and environment. NDI will include proper training plan for all employees on the ERP within an agreed timeframe.

PS2: Labor and Working Conditions

NDI employs a total of 1989 employees with female staff representing about 24%.

Human Resources Policies and Procedures: GMS V&I Jordan hired a consultant in 2013 to help in drafting corporate wide HR policies and procedures that will later be translated in local language. The Guarantee Holder will ensure that NDI national HR policy and procedures complies with national labor and employment law, including rights related to wages and benefits, hours of work, overtime, leave for illness, vacation, maternity and bonuses. MIGA review of the draft HR policy and procedures indicated compliance with requirements of equal opportunity, grievance mechanism and others. GMS V&I Jordan will be required to update within an agreed timeframe the HR policies and procedures to reflect the requirements of PS2.

Occupational Health and Safety (OHS): In Iraq, safety and risk assessments are conducted regularly by the Division of Health and Safety in the city of Nainawa. GMS V&I Jordan included

the recent findings in 2012 as part of the rehabilitation plan. GMS V&I Jordan promotes safe and healthy conditions in their operations which protect the health of workers and employees such as:

- Controlling the temperature and humidity of all plant areas according to limits set by the heat, ventilation and conditioning system (HVAC).
- Providing workers with special attire for each area.
- Providing personal protection equipment (PPE) as indicated in areas of operation.
- Distribution of emergency kits and fire extinguishers all over the plant floor.
- Periodic medical testing is performed for all employees according to type of work.

NDI has a basic safety and occupational health manual, that will be reviewed and updated to reflect the requirements of WBG EHS guidelines within an agreed timeframe.

PS 3: Pollution Prevention and Abatement

General Requirements

The main source of electricity is through four (2 MW each) main electrical combined cycle generators provided by the Ministry of Industry and Minerals. Electricity consumption for the year 2012 was about 5,500 kWh. NDI also has a 2,250 kVA diesel generator that utilized about 300 liters per hour and annual run time in 2012 was 160 hours to generate electricity and run two boilers (6 tons and 10 tons) for steam generation. Diesel fuel is stored in steel above ground storage tanks of different sizes which are not protected by secondary containment.

The main source of water to the facility is from the public network from the town Tall Kayf. Two storage tanks (above ground) are onsite, 2,000 m³ for domestic and industrial use and 1,500 m³ for firefighting purposes. Annual consumption in 2012 was about 650-850 m³/day of water. Water is used mainly for irrigation while production utilizes about 75 m³/day, 50 m³ for boilers, 40 m³ for cooling system, 75 m³/day for cleaning and about 300 m³/day for human use and consumption. Total effluent is about 200 m³/day. NDI has a wastewater treatment plant that is based on pH adjustment and biological treatment with a design capacity of 100 m³/day and actual operating capacity of about 50-70 m³/day.

GMS V&I Jordan confirmed that resource efficiency programs will be envisioned as part of the GMP program. To prevent or minimize pollution and to increase the resource efficiency the following will be done:

- The designer and the manufacturer of the equipment and utilities are asked to minimize power consumption, where possible.
- To decrease the exhaust emissions, the same existing boiler(s) will be tuned for optimum efficiency.
- Air filters will be installed on the air exhaust fans.

As part of the ESMS, GMS V&I Jordan will include monitoring plan for water effluent and air quality that is supported by third party assessment at least on annual basis.

NDI will have in place a self-monitoring program for workplace monitoring including ambient air quality as part of the ESMS reporting system.

NDI collects and segregates the waste that is currently disposed of by the government. Pharmaceutical waste is about 10 kg/day, paper waste is 24 tons per annum (tpa) while plastic

waste is 6 tpa and barrels and drums around 1440 kg per annum. As part of the ESMS, NDI will develop a waste management plan which will ensure proper identification and characterization of waste streams, means of storage and handling, signage and waste reduction opportunities (if possible).

NDI will upgrade existing storage facilities to reflect good international industry practice (GIIP) for chemical and hazardous material handling and storage as indicated in WBG EHS guidelines as well as GMP requirements.

Pesticide Use and Management: NDI uses pesticides for mosquitos, cockroaches, rats, flies, etc. Chemicals used are licensed by the national environmental authority and stored in specific locations within the plant area. GMS V&I Jordan will ensure that the ESMS will include procedures of storage and handling of pesticides in accordance with the requirements of PS3.

PS4: Community Health, Safety & Security

Community Health and Safety: NDI facilities for its employees include housing (90 units), kindergarten day care (average 70-80 children), elementary school service (about 120 students) and other services. The nearest community is about 4 km and is not directly adjacent to the plant due to the buffer wall area. Life, fire and safety or exposure to air emissions could pose a community risk. GMS V&I Jordan will establish preventive and control measures consistent with GIIP to ensure relationship with the community is properly maintained. As part of the ESMS, a community grievance system will be set in place.

Security Personnel: NDI uses unarmed 29 security personnel. In accordance with the requirements of PS4, training will be provided to security personnel to ensure compliance with PS4 requirements.

F. Environmental Permitting Process and Community Engagement

The NDI facility was established before the Iraqi environmental law, no specific environmental permits or impact assessment study was required by the national agency.

G. Availability of Documentation

[Environmental and Social Action Plan \(ESAP\)](#) is attached to this ESRS document.