

Environmental and Social Review Summary (ESRS)

Luminova - GUATEMALA

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1. General Information of the Project and Scope of IDB Invest's Environmental and Social Review

The transaction (the "Transaction") consists of a credit facility for Luminova Pharma Alliance Inc. ("Luminova" or "the Group") to finance working capital for growth and future expansion needs.

The environmental and social due diligence ("ESDD") of the Transaction consisted of evaluating the technical, environmental, health, safety, security, and social documentation submitted by Luminova; meetings with the Company's directors and Environmental, Health and Safety, Industrial Operations, and Human Resources Managers; and a field visit conducted in March 2022 by a consultant hired by IDB Invest to the production plants located in Villa Nueva ("Novoswiss") and Milpas Altas ("Helvetia") in the metropolitan region of Guatemala.

2. Environmental and Social Categorization and Rationale

The Project has been classified as a Category B operation according with IDB Invest's Environmental and Social Sustainability Policy since it will likely generate moderate and mitigable environmental and social impacts, which include: i) risks associated with labor conditions and employee occupational health and safety ("OHS"); ii) solid and liquid waste generation; iii) greenhouse gas emissions; and iv) potential impacts to communities as a result of a) the transit of trucks transporting raw materials, hazardous materials ("Hazmat"), or finished products and b) the subcontracting of armed security. These risks and impacts are deemed to be of medium intensity.

The Performance Standards (PS) triggered by the Transaction are: i) PS1: Assessment and Management of Environmental and Social Risks and Impacts; ii) PS2: Labor and Working Conditions; iii) PS3: Resource Efficiency and Pollution Prevention; and iv) PS4: Community Health, Safety, and Security.

3. Environmental and Social Context

3.1 General Characteristics of the Project's site

Luminova is a brand-name generic pharmaceutical laboratory that has been operating in Guatemala since 1976. The Group has two plants that produce drugs in solid, semi-solid, liquid, injectable, beta-lactam, penicillin, and cephalosporin forms. The Novoswiss plant is located in an industrial complex with no neighboring communities, while the Helvetia plant is adjacent to several communities.

3.2 Contextual Risks

Water extraction in Guatemala is currently unregulated. The population increase, as well as the lack of regulations (municipal development plans for water resource management, water use regulations, etc.) and their deficiencies and poor implementation are negatively affecting water resource availability and quality. Some visible impacts include overexploitation of the aquifers that supply the region and the pollution of almost all water bodies.

Lake Amatitlán is one of the most polluted water bodies in the country, as it receives domestic wastewater discharges from several municipalities, including Villa Nueva (where the Novoswiss plant is located), as well as from agriculture and several industries that are located in the surrounding areas. A physicochemical analysis conducted in 2016 by the Authority for the Sustainable Management of the Amatitlán Lake and Basin detected high total phosphorus and nitrogen concentrations, compounds that are indicators of the extent of the lake's hypertrophy.

Violence and insecurity are major problems in Guatemala. They are present in different intensities by state and social group.

4. Environmental Risks and Impacts and Proposed Mitigation and Compensation Measures

4.1 Assessment and Management of Environmental and Social Risks and Impacts

4.1.a Environmental and Social Management System

Luminova has implemented a sophisticated quality assurance system to meet superior production standards and product safety attributes. This includes a series of quality production procedures, processing facilities, highly qualified professional and operational personnel, equipment, state-of-the-art laboratories, and separate sealed areas to prevent contamination. Both the Group's self-assessment and the independent evaluation of its Environmental and Social Management System (ESMS), however, showed that it needs to improve its corporate policy, effluent management, pharmaceutical waste disposal, and stakeholder management, including by improving its external grievance mechanism.

4.1.b Policy

Although Luminova currently lacks a comprehensive policy that defines its environmental and social goals and principles, these commitments are included in its Code of Ethics and in various ESMS instructions, which ratify its commitment to abiding by applicable environmental and labor laws and regulations in Guatemala, and to preserving the human rights, health, and safety of its employees.

4.1.c Identification of Risks and Impacts

Luminova has a risk identification and characterization procedure for its OHS and product quality areas. Nevertheless, the Company will develop and implement E&S risk assessment procedures, which includes identifying the risks and impacts of its operations on communities.

4.1.c.i Gender Risks

Luminova has incorporated provisions to ensure the proper treatment of women working at its facilities in terms of: i) having separate locker rooms and showers by work area and gender; ii) ensuring appropriate working environments for pregnant women; iii) implementing zero tolerance policies towards gender-based violence; and iv) complying with local legislation and adhering to additional international practices on issues related to gender non-discrimination and equal opportunities for workers regardless of gender.

4.1.c.ii Climate Change Exposure

Guatemala is a country highly vulnerable to natural disasters, which have negative social impacts, especially on agriculture, housing, road and bridge infrastructure, and the economy and the environment. The country is ranked as one of the five most at risk countries in the world, in terms of the vulnerability of its gross domestic product (GDP) to natural disasters, given that 83.3% of GDP is generated in at-risk areas. The Company's emergency plans do not currently consider the risks of natural disasters such as hurricanes, volcanoes, and earthquakes.

4.1.d Management Programs

Luminova conducts a number of informal activities to manage its environmental and social risks and impacts. Its ESMS includes procedures to manage the following issues: OHS, human resources, and solid waste. Accordingly, the Company will develop procedures to manage its relationship with stakeholders and to address the following risks: i) efficient use of water resources; ii) emissions; iii) effluents; and iv) road safety.

4.1.e Organizational Capacity and Competency

Luminova has implemented corporate-level management functions for environmental, social, labor, and OHS issues, which include senior executives and a team of personnel who have assigned times and duties for these key functions. The Company provides ongoing training and induction in these key areas.

4.1.f Emergency Preparedness and Response

In all its facilities, Luminova has adopted emergency preparedness and response protocols that adequately address the risk of fire and chemical spills. These protocols include establishing brigades, conducting drills, and maintaining firefighting systems. It has also implemented training plans to ensure that all employees and security personnel are aware of procedures and contingency plans, including evacuation routes and meeting points.

Even so, Luminova will prepare and implement an Emergency Preparedness and Response Plan (EPRP) specific to each plant, identifying different emergency scenarios and defining response procedures for each case. Due to the plant's proximity to the communities, the Helvetia EPRP will involve the population in emergency response activities for emergencies whose consequences may

extend beyond the plant's boundaries, and the Company will coordinate with them to carry out emergency response drills.

4.1.g Monitoring and Review

Luminova has monitoring plans for certain critical areas and keeps statistics on occupational accidents and effluent characterization. The Company, however, lacks a formal procedure in its ESMS for evaluating and monitoring its E&S performance.

4.1.h Stakeholder Engagement

The Company has yet to implement a stakeholder communication, identification, and engagement mechanism. The Company will develop and implement a stakeholder engagement plan for its Helvetia facilities.

4.1.i External Communication and Grievance Mechanism

To date, Luminova lacks a formal mechanism to address questions, complaints, grievances, and suggestions from its stakeholders.

4.2 Labor and Working Conditions

4.2.a Working Conditions and Management of Worker Relationships

Luminova has 834 direct employees, 59% of whom are women.

4.2.a.i Human Resources Policies and Procedures

The Company, in compliance with Guatemalan labor laws, provides all of its employees with the benefits provided for in the corresponding legislation. The Corporate Organizational Development ("OD") Guideline documents Luminova's commitments to i) abide by local labor laws, ii) ensure discrimination-free recruitment and selection processes, and iii) provide a safe and accident-free work environment. The OD guideline will be updated to include explicit references to: i) the existence of the internal grievance mechanism; ii) zero tolerance of child labor and forced labor; and iii) recognition of the right to collective bargaining and freedom of association.

4.2.a.ii Working Conditions and Terms of Employment

The workday is 44 hours per week, Monday through Saturday. Luminova's employment contracts with its employees and its Internal Labor Regulations provide workers with information on their labor rights, including working hours, overtime, days off, breaks, grievance mechanisms, and disciplinary measures, among others.

4.2.a.iii Workers' Organizations

Luminova upholds employees' right to free association without fear of reprisal or retaliation. Approximately 48% of the workforce is affiliated with the Asociación Solidarista de Colaboradores de Unipharm, S.A. (ASOUNI). ASOUNI is a non-profit civil association to which workers contribute 5% of their salary, an amount that is matched by the Company. Through this association, affiliated workers have access to medicines subsidized by Luminova, concessionary loans, and groceries at below-market prices, via the communal pantry.

4.2.a.iv Non-discrimination and Equal Opportunity

In its Code of Ethics and in its Corporate OD Guidelines, Luminova declares its commitment to staff recruitment based on labor equality and with no discrimination by reason of gender, race, nationality, socioeconomic status, marital status, religion, political tendencies, disability, ethnic group, ideology, or sexual preference.

4.2.a.v Retrenchment

Luminova has no plans to undertake collective layoffs among its workforce.

4.2.a.vi Grievance Mechanism

Luminova employees can file complaints internally, anonymously, and confidentially through a dedicated hotline, by email, or drop boxes within the processing facilities. The mechanism is handled via a written procedure for receiving and processing internal complaints.

4.2.b Protecting the Workforce

The minimum age to work at Luminova is 18 years old. Child and forced labor are prohibited in direct and contractor operations. The ESDD process did not discover child labor or forced labor.

4.2.c Occupational Health and Safety

Luminova develops annual OHS work plans covering general activities to identify, prevent, and mitigate accidents, including internal audits, medical check-ups, and monitoring and training needs reports. The Company also has a medical clinic at its production plants, staffed with an occupational physician and an assistant nurse. It also has an annual health program for its different sites, where workers have access to laboratories, annual medical check-ups, awareness talks, as well as vitamins and dewormers.

The field visit confirmed that preventive and mitigating measures have been effectively implemented, including the availability of emergency showers, and the safe storage and handling of reagents and chemicals. Nevertheless, there was also evidence of some unsafe working conditions, such as improper power cable connections, stairs with steep slopes, and poorly located life and fire safety (L&FS) equipment. Some employees were also found not wearing Personal Protective Equipment.

Luminova keeps statistics and reports work accidents of its direct workers. During the last 12 months the Company recorded a total of 11 accidents plus 6 collisions, resulting in 143 days of disability, a Lost Time Injury Frequency Rate (LTIFR) of 6.79 and a Lost Time Injury Severity Rate (LTISR) of 88.25. Considering that the average LTIFR and LTISR reported by the U.S. Department of Labor for the pharmaceutical industry¹ (NAIC Code 3254) for the year 2020 are 3.50 and 28.0, respectively, the rates reported by the Company are higher than the industry average.

4.2.d Provisions for People with Disabilities

Luminova does not discriminate against employees based on their disability. Its production facilities have been adapted to accommodate these people. Nevertheless, some ramps with slopes that are not suitable for access by people with mobility disabilities were observed during the field visit.

4.2.e Workers Engaged by Third Parties

New Luminova employees are initially hired through an external contractor and, when a vacancy arises in specialized, performance-based operational positions, employees with more than 12 months of employment with the company are hired. To date, approximately 66 people have been hired under this modality.

4.3 Resource Efficiency and Pollution Prevention

4.3.a Resource Efficiency

The power supply source is through the public power grid. Energy consumption for the plants is about 1,000 megawatt-hours (MWh) per year. The Company has implemented some activities to improve resource efficiency, such as switching to LED lighting fixtures and motion sensors in the corridors of common areas.

4.3.a.i Greenhouse Gases

Luminova operates a series of gas and diesel boilers at both plants that generate greenhouse gas emissions (NO_x, SO_x and CO_x). At present, however, it neither monitors nor accounts for its emissions. Considering that the annual consumption of gas and diesel is approximately 140,000 gallons and 2,000 gallons, respectively, Luminova emits about 882 tons of CO₂ equivalent per year (Scope 1).

4.3.a.ii Water Consumption

To cover the basic needs of its employees, its production process, and cleaning the Helvetia plant, Luminova uses approximately 230 m³ of water per month from the public water supply. At Novoswiss, it consumes approximately 47.34 m³ of water per day, which comes from a well.

¹ <https://www.bls.gov/iif/oshsum.htm>

4.3.b Pollution Prevention

Luminova generates Volatile Organic Compound (VOC) and Particulate Matter (PM) emissions during the manufacture of its pharmaceutical products. Although the Company has implemented actions to prevent and minimize emissions, to date it does not perform any type of VOC and PM monitoring.

4.3.b.i Waste

Luminova's plants generate domestic and process wastewater. At Novoswiss, effluents are conveyed to a wastewater treatment plant (WWTP) where they receive physicochemical and biological treatment before final discharge to soakaways. At Helvetia, industrial wastewater is treated in a settling pond before being discharged into the soakaways, while ordinary wastewater is transferred to a septic tank. Luminova monitors effluent quality on a semi-annual basis, but the laboratory analyses do not include all of the parameters required under the World Bank's General Guidelines for the manufacture of pharmaceutical products.

The latest available data for Novoswiss, while reflecting compliance with local standards, also show concentrations above the maximum allowable concentrations under the World Bank's General Environmental, Health, and Safety Guidelines (the "General Guidelines") for biochemical oxygen demand (BOD), total phosphorus, total nitrogen, and total suspended solids (TSS).

The latest data available for Helvetia reflect BOD, total phosphorus, total nitrogen, TSS, and fecal coliform concentrations that exceed even the limits established by local laws. To improve this situation, Luminova is implementing a series of containment actions (enzyme rotation and shock dosing, and installation of on-line chlorine dosing), which will be supported by the installation of a WWTP consisting of an initial physicochemical process, followed by a biological polishing process and an anaerobic biodigester.

The resulting wastewater sludge from both plants is managed as hazardous waste and collected by Biorem, a company certified by the Guatemalan Ministry of the Environment.

Solid waste is managed according to best practices (reuse, recycling, treatment, disposal, and monitoring) to reduce environmental impacts. Solid waste collection is separated into household waste, paper and cardboard, plastic, metal, and glass. Potentially pathogenic waste from manufacturing is inactivated by sterilization prior to final disposal. The final disposal of pharmaceutical waste and biowaste from processing, laboratories, and rejects is carried out by an authorized waste disposal contractor.

4.3.b.ii Hazardous Materials Management

Luminova handles some hazardous materials (chemicals and liquefied gas) in its industrial operations. Storage and chain of custody are properly carried out to protect worker health and safety. According to the Company's OHS Plans, annual training on handling hazardous materials is conducted by the local fire department.

4.3.b.iii Pesticide Use and Management

The companies contracted by Luminova for rodent control use chemical formulations classified as Ia - extremely toxic and Ib - highly toxic by the World Health Organization (WHO).

4.4 Community Health, Safety and Security

Luminova subcontracts armed security personnel from an accredited security company qualified by the competent authority. This company, in coordination with Luminova's Head of Corporate Security, prepares a monthly risk analysis that is used to derive measures to protect the Company's assets and personnel. The annual training program for security guards is determined according to this evaluation.

The security company trains its personnel on the use of weapons as required by Guatemalan law. This training includes human rights issues. Land Acquisition and Involuntary Resettlement

The Project will not require land acquisition or produce involuntary resettlement, as it will be developed on Company-owned land.

4.5 Biodiversity Conservation and Sustainable Management of Living Natural Resources

The planned expansions will occupy highly modified sites where there are no species requiring special care.

4.6 Indigenous Peoples

The project will not affect any Indigenous peoples.

4.7 Cultural Heritage

There is no apparent evidence of archaeological remains or vestiges at the site of Luminova's plants. The Project does not include the construction of new infrastructure.

5. Local Access of Project Documentation

The documentation relating to the project can be accessed at the following link:
<http://www.luminovapg.com/#>