

Environmental and Social Review Summary (ESRS) Procaps - COLOMBIA

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

PROCAPS S.A. (the "Company", the "Client", or "Procaps") is a leading manufacturer of high-quality pharmaceutical products with activities ranging from their development to production and distribution in several Latin American countries. Established in 1977 in Barranquilla, Colombia, the Company expanded to other countries through acquisitions. It currently has production plants in Colombia, Brazil, and El Salvador, as well as distribution and sales operations in 13 countries throughout the region.¹ The Company's differentiating factor is innovation and the use of technology, positioning it as one of the leading export companies on the Colombian Caribbean Coast.

Procaps employs about 2,945 people in Colombia and operates under three corporate names: Procaps (the Company's headquarters in Barranquilla), Funtrition and Pharmayect in Bogota. This operation (the "Operation" or the "Project") will provide financing for the long cash cycles involved in launching new pharmaceutical products, including Research and Development (R&D), as well as regulatory capital expenditures related to compliance with COVID-19 protocols. The Operation will help the Company increase access to quality pharmaceutical products by expanding its production capacity both in Colombia and in other countries across the region through possible exports to its subsidiaries in Central America.

The scope of IDB Invest's environmental and social review included: i) an analysis of Company information and documents; ii) remote meetings with personnel in charge of management systems, human resources, and Procaps operations; iii) a virtual tour of its Barranquilla production plant; and iv) interviews with members of the communities surrounding the Barranquilla and Bogota plants. The Environmental and Social Due Diligence (ESDD) process did not include in-person visits to the Company's facilities due to travel restrictions implemented by the Colombian government as a result of the COVID-19 pandemic.

2. Environmental and Social Categorization and Rationale

The Project is a Category B project under the IDB Invest Environmental and Social Sustainability Policy because it may generate, among others, the following impacts and hazards: (i) increased generation of solid and hazardous waste; (ii) increased dumping; (iii) increased particle and gas emissions; and (iv) increased consumption of water, energy, gas, and chemical substances. The intensity of these impacts is expected to be low.

The Performance Standards (PS) triggered by the Project are: 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 and Safety.

¹ The scope of the operation with IDB Invest does not include production plants and commercial operations outside of Colombia.

3. Environmental and Social Context

3.1 General characteristics of the Project's site

The Company has three main operations in Colombia: (i) Procaps (headquartered in Barranquilla), which is dedicated to the production of Soft Gelatin Capsules (SGC) and Other Pharmaceutical Forms (OPF), (ii) Pharmayect, located in Bogota, which is dedicated to the manufacture of sterile pharmaceutical products (injectables, lyophilized powders, etc.), and (iii) Funtrition, also located in Bogota, which is dedicated to the manufacture of gelatin-based nutritional gummies. The headquarters are located in an industrial zone in the city of Barranquilla, while Funtrition and Pharmayect are in an industrial park located in Fontibón, Bogota.

The communities neighboring the Client's production plants are four Community Action Councils. Three of them are near the Barranquilla headquarters (San Salvador, Siape, and Las Flores neighborhoods); and one to the operations in Bogota (El Triángulo neighborhood). The Company has cultivated good relations with all of them through its Corporate Volunteer program and Fundación Procaps.

The Company has a Integrated Quality and Management System (IQMS) adapted to the context of each Operation, which takes into account their operational peculiarities and potential risks. The production plants (Barranquilla headquarters, Funtrition, and Pharmayect) have their respective Wastewater Treatment Plants (WWTP), each one in possession of a valid discharge permit. The Company's operations in Colombia make use of five natural gas boilers (one in Barranquilla and four in Bogota: two in Funtrition and two in Pharmayect), whose emissions undergo yearly monitoring and classification.

3.2 Contextual risks

As the Company operates in urban areas and major cities, it is exposed to potential citizen protests, which are sometimes suppressed by the police² through the use of force.

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

4.1 Assessment and Management of Environmental and Social Risks

4.1.a E&S Assessment and Management System

Procaps' IQMS is certified under Technical Standards ISO 14001:2015 and ISO 9000:2015, which include all of the Company's management systems underpinned by standard operating rules and procedures related to: Good Manufacturing Practices (GMP), Quality Management Systems (ISO 9001), Environmental Management Systems (ISO 14001), Business Anti-smuggling Coalition (BASC), Authorized Economic Operators (AEOs), Hazard Analysis and Critical Control Points (HACCP) Systems, Occupational Health and Safety Management Systems, and the certification by the Food and Drug Administration (FDA), which has allowed it to become the first Latin American laboratory to reach the United States market.

² Annual Report of the United Nations High Commissioner for Human Rights (OHCHR), 2019, Situation of human rights in Colombia, available at <https://www.hchr.org.co/index.php/informes-y-documentos/informes-anales/9136-informe-del-alto-comisionado-de-las-naciones-unidas-para-los-derechos-humanos-sobre-la-situacion-de-derechos-humanos-en-colombia-durante-el-ano2019>

Procaps also has an Occupational Health and Safety Management System (OHS-MS) whose main elements are described in a System Manual. The OHS-MS has been built around the requirements of the ISO 45001:2018 standard and the legislation in force regarding OHS-MS standards (Decree 1072 of 2015 and Resolution 0312 of 2019). Its implementation, maintenance, audit, and improvement processes involve an ongoing dialogue with partners, contractors, and customers.

4.1.b Policy

The Company has a Integrated Quality and Management Policy in force since 2010, which governs all aspects of its operations. It involves legal compliance, quality, occupational health and safety, risk management, and environmental issues. In addition, Procaps has a Corporate Social Management Policy and a Corporate Social Responsibility Policy, in force since 2019 and 2018, respectively.

4.1.c Identification of Risks and Impacts

The Company's production plants have developed matrices to identify and evaluate environmental aspects and impacts. The process to identify and evaluate environmental aspects and impacts contains a description of each of the Company's activities, establishing the environmental aspects likely to be encountered, as well as the positive and negative impacts as appropriate. Impact assessment is done using an Environmental Impact Assessment Matrix.

The significant negative impacts identified are mainly linked to the stages of cleaning and disinfection, manufacture and cooking of the gelatin container, and packaging, dispatch, maintenance, WWTP, boilers, sanitary filters, and area lighting. Environmental programs have been put in place to manage them, such as: Water and Energy Saving and Efficient Use Program; Fixed and Mobile Emissions Control Program; Noise Control Program; and Liquid, Solid, Hazardous Waste and Exploitable Waste Generation Control Programs.

4.1.d Management Programs

Each of the Plants has adapted its Environmental Management Plan (EMP). Thus, for example, Procaps Barranquilla has an annual EMP whose objectives focus on reducing water, energy, and gas consumption, and laboratory waste, as well as on maintaining the quality of the discharge and meeting legal requirements. Each program objective has its own related activities, leaders, deadlines, and indicators, as well as a consolidated budget for its execution in the corresponding year. In addition to the EMP, each plant has a Comprehensive Waste Management Plan (usable, unusable, liquid-sludge, and hazardous) and a Chemical Substance Control Plan.

The Company's operating procedures establish the relevant environmental aspects for each operational stage and set out the appropriate checks to be implemented. Environmental operational monitoring involves preventive and mitigation measures during plant startup and shutdown. They include the following main aspects: (i) non-domestic wastewater generation (dumping); (ii) hazardous waste generation; (iii) water use; (iv) energy use; (v) domestic wastewater generation; (vi) gas and vapor emissions; (vii) particle emissions; (viii) noise generation; (ix) non-hazardous waste generation; (x) chemical substance consumption; (xi) substance spillage; (xii) refrigerant gas leakage; and (xiii) non-domestic wastewater leakage to the street.

4.1.e Organizational Capacity and Competency

The Human Capital Vice-Presidency is in charge of the Occupational Health and Safety team. In each plant in Colombia, the operating team bears environmental responsibilities, which fall especially on the maintenance

and quality departments. For social issues, Procaps has formed a Social Management Committee, led by the Vice President of Corporate Affairs and Human Capital, the Communications Department Management, and Fundación Procaps.

Procaps manages competencies in terms of staff education, training, and experience. The Company has a training plan involving the entire organization, which includes, for each of the plants, topics related to comprehensive waste management, GMP in the food and supplements sector, and the Environmental Management and OHS plans.

4.1.f Emergency Preparedness and Response

The Company has an Emergency and Disaster Management Plan (EDMP), which involves: (i) a threat and vulnerability analysis; (ii) operational plans (including evacuation and mutual aid plans); (iii) resources to prevent, prepare for, and respond to emergencies; (iv) a program to assemble, train, and equip the brigade (includes organizing and implementing a timely first aid service); (v) a training program for all workers; (vi) a program to periodically inspect equipment related to prevention and emergency care, signaling, and alarms; (vii) procedures for planning, conducting, and evaluating emergency drills; (ix) medical emergency care procedures.

Procaps' organization for emergency care is based on three groups: (i) Emergency and Disaster Management Committee (EDMC), (ii) emergency brigades, and (iii) evacuation leaders. The EDMP establishes the brigade's duties and evacuation leaders before, during, and after emergencies based on the following scenarios: (i) firefighting, (ii) hazardous materials, (iii) evacuation, first aid, and (iv) search and rescue.

4.1.g Monitoring and Review

The Company has a documented procedure to manage internal IQMS audits, as well as a procedure to regularly monitor, measure, and collect OHS-MS compliance information. The procedures have indicators to track and assess compliance with the policy, OHS objectives, and the IQMS's programs. The environmental indicators relate to water, energy, and gas consumption; and to dumping, hazardous waste, emissions, and noise. The IQMS contains environmental operational checks intended for normal and abnormal conditions, which derive from preparing and subsequently updating the environmental risk analysis and environmental legal requirements.

The Company's operation is supervised by several regulatory entities, by international organizations³ associated to the export destinations of its products, and by certifying entities. Thus, in Colombia, the Company is supervised by and reports to (i) the National Institute of Food and Drug Administration (INVIMA); (ii) the Colombian Agricultural Institute (ICA); (iii) the Ministry of Health; (iv) the local environmental authorities (Barranquilla Verde and the District Environmental Secretary of Bogota); (v) the Colombian Institute of Technical Standards and Certification (ICONTEC); (vi) the Pension and Parafiscal Management Unit (UGPP); (vii) the Superintendency of Industry and Commerce; (viii) the Tax and Customs Directorate (DIAN); and (ix) the Superintendence of Corporations.

INVIMA performs periodic audits of Procaps facilities in order to verify compliance with the standards required to protect and promote public health. During these audits, INVIMA assesses the quality standards in

³ The Federal Commission for the Protection against Sanitary Risk (COFEPRIS) in Mexico, the National Health Surveillance Agency (ANVISA) in Brazil, the US Food and Drug Administration (FDA), Health Canada, Australian Therapeutics Goods Administration (TGA), Saudi Food and Drug Authority (SFDA) in Saudi Arabia, UK Medicines and Healthcare products Regulatory Agency (MHRA), the Peruvian Directorate General of Drug Supplies and Drugs (DIGEMID), and the Business Alliance for Secure Commerce (World BASC Organization).

compliance with GMP standards. The reports submitted by the Client to the environmental authorities mainly describe WWTP emissions and discharges. Procaps submits quarterly reports to the Drug Price Information System (SISMED) with the sales prices of drugs, stating their minimum, maximum, and average values, as well as the number of units sold per active ingredient.

4.1.h Stakeholder Engagement

Procaps conducts a communication, participation and consultation process with its employees and external stakeholders (suppliers, contractors, customers, community, authorities, among others). Its IQMS also includes a procedure called "Internal and External Communications related to the IQMS", whose purpose is to establish appropriate and effective communication channels for each stakeholder. The Company also features an External Requests and Requirements Matrix as well as a Communications Plan aimed at its internal collaborators, public opinion and the health sector in general. Communication channels include its website, e-mail and dedicated customer service hotlines in both Barranquilla and Bogota.

The Company engages in social projects through a joint effort between corporate volunteers and Fundación Procaps,⁴ promoting social competence as a shared commitment between the Organization and the Collaborators. Its Social Responsibility Policy therefore includes Procaps Volunteers (donations, training and recreation, educational impact, and social development) and Fundación Procaps as its key intervention channels. Moreover, the Company's Social Management Plan entails biannual meetings and ongoing communications with stakeholders and communities near the operation plants. The Procaps "Audience Relationship Plan" sets out a differentiated approach for each type of stakeholder and the communication activities to be conducted with each one.

As part of its response to the COVID-19 pandemic, between April and September 2020, the Company supported the Barranquilla BAQatón⁵ by donating resources to purchase tests and supplies for health professionals working in the contagion front line. Procaps also participated as a partner in the national initiative "Colombia Cuida Colombia" to mitigate the negative impact of COVID-19 on food security and health, and in the Campaign #JuntosPodemos, helping more than 4,300 families with food packages and a donation of 15,000 face masks to the Barranquilla City Hall to be used by health professionals conducting tests.

4.1.i External Communication and Grievance Mechanisms

The Company has various channels to receive petitions, grievances, complaints, or requests from stakeholders: e-mail, website, social media, and telephone. Procaps has well-developed communication channels and a Social Media Policy published on its website. It has used its Instagram and Twitter accounts for over 4 years.

The Company's IQMS contains the "External Stakeholder Management and Communications Procedure", which identifies different types of stakeholders and how to direct their communications depending on the issue to be addressed. This procedure defines the needs and expectations for information, action planning, accountability, and monitoring for each stakeholder. It also includes a communications log to record the issues brought forward by these groups, the responses given, and the information received by the Company. When visits or inspections are required, this procedure includes the forms used to document the event. Procaps also has a Corporate Communications and Reputation Policy.

⁴ <https://www.fundacionprocaps.com>

⁵ <https://www.camarabaq.org.co/baqaton/>

4.2 Labor and Working Conditions

4.2.a Working Conditions and Management of Worker Relationships

Procaps employs 2,945 people, 52% of whom are women. All positions in the Company have a Description of Assigned Responsibilities that specifies the roles, duties, indicators, additional job conditions, professional risks, job description, and competencies required.

All Company recruits sign an employment contract that defines their work system and conditions. The IQMS also includes a Contracting Procedure that defines the terms and conditions for direct, temporary, and foreign personnel recruitment. Procaps also offers its workers a benefits plan that goes well beyond what is required by law.

The Company has developed a Code of Ethics and Conduct, which is enforced through a Safe Principles and Standards (SPS) Ethics Line available on its website. It has also created an Ethics Committee and implemented procedures to investigate claims, penalties, violations, and reports. The Procaps Ethical Training Plan provides the public with the Company's mechanisms to prevent, monitor, and detect irregularities in the work environment.

The Company's Internal Labor Regulation (ILR) has been approved by the Ministry of Labor and made public in visible places within its facilities. It also has an Industrial Hygiene and Safety Regulation aimed at preventing occupational risks, and a Policy to Prevent the Consumption of Psychoactive Substances. Finally, the Company has a Joint Committee for Occupational Health and Safety that meets monthly, as well as a Workplace Coexistence Committee that meets quarterly or whenever immediate intervention is required, since it deals with possible workplace harassment situations.

4.2.b Protecting the Workforce

Procaps only hires adults. The Company has a recruitment department in charge of hiring processes, which also monitors compliance with the ILR. Operationally, Procaps has an OHS-MS that safeguards the health and safety of its workers and includes a procedure for hazard identification and risk assessment and monitoring. As part of its IQMS, Procaps also has an Onboarding, Re-Onboarding, and Job Training Process, as well as a Machine Safety Policy.

4.2.c Occupational Health and Safety

Procaps has an Occupational Health and Safety Policy and a general occupational hazard system, which identifies legal OHS requirements and establishes procedures to report and investigate occupational accidents and incidents.

Procaps has management plans and procedures in place to monitor the risks involved in the purchase, storage, and distribution of the chemicals used in their processes. They contain detailed guidelines and OHS requirements. The Company monitors the risks involved in the use of chemical products in order to prevent occupational incidents, accidents, and illnesses due to occupational exposure to these agents.

In response to the COVID-19 pandemic, Procaps has: (i) implemented biosecurity protocols that required the delivery of visors, alcohol, and face masks to all workers; (ii) established the need to sanitize the workstations

three times a day; (iii) implemented daily body temperature monitoring and antibody screenings for workers; (iv) adapted the working hours and schedules at the administrative level, deciding on three on-site and two remote working days per week; (v) exchanged computers for laptops to enable staff rotation and work in collaborative cloud environments; (vi) expanded transportation services to staff; (vii) set up more cafeterias in each of the plants to comply with social distancing protocols; (viii) relocated laboratory equipment to ensure social distancing; and (ix) provided psychological support to workers and their families to meet the personal challenges posed by COVID-19.

4.2.d Workers Engaged by Third Parties

Procaps has service providers that work within its plants and perform specific tasks, such as reusable waste management and canteen services. These suppliers are audited to make sure that their performance complies with all the valid regulations in force. The Internal Stakeholder Communication Procedure includes workers engaged by third parties and provides them with information relevant to their roles. These workers can also use the Ethics Line to report any workplace irregularities they may encounter.

4.2.e Supply Chain

Procaps suppliers are 52% micro and small businesses, 25% medium and 23% large. The Company cares about its interactions with suppliers, ensuring fair and inclusive sales processes for goods and services. To this end, Procaps has search, selection, and approval processes for suppliers, and purchasing procedures for raw materials, supplies, services, and products that address OHS management issues. The Company also supports the development of its suppliers.

4.3 Resource Efficiency and Pollution Prevention

4.3.a Resource Efficiency

Procaps' productive operations consume water, energy, and gas. To optimize their use, these consumptions are monitored against performance indicators. Furthermore, as part of its IQMS, Procaps features an "Environmental Management Program" and an "Efficient Management and Use of Resources Plan", which include measures for optimizing resource consumption at Procaps, Pharmayect, and Funtrition. One of these efforts is energy self-generation through the construction of a gas-fired thermal power station, which could supply up to 90% of the Barranquilla plant's demand.

4.3.b Pollution Prevention

Funtrition has a WWTP designed to treat a maximum daily flow of 4.0 m³ at a maximum load of 15,000 mg/l of wastewater. This system involves a preliminary treatment to retain fats and solids, followed by a physical-chemical treatment and an aerobic biological treatment, with a final polishing of the effluent by sand filtration. In 2019, Funtrition's discharge volume was 6.864 m³/year, the lowest of the three plants. The WWTP at the Procaps Headquarters in Barranquilla operates under an advanced oxidation process model, producing 24,961 m³ of treated industrial water in 2019. Finally, Pharmayect's treatment system consists of sedimentation, aeration, and neutralization processes, which produced a volume of 18,591 m³ in 2019.

Procaps' production equipment undergoes regular preventive maintenance to ensure optimum performance. WWTPs are managed and operated by expert technicians, who create permanent records on a monthly basis. The Company implements yearly physical-chemical characterization surveys to ensure that water discharges

into the sewage system meet all the corresponding safety requirements. The Company, as part of its IQMS, has a "Discharge Risk Management Plan" and an "Industrial Wastewater Treatment Procedure".

Gaseous and particulate emissions generated by the Operation through its natural gas boilers (five in total), are monitored through dust collectors (eight at the Barranquilla headquarters, six in Funtrition, and three in Pharmayect). Emissions are classified each year.

4.3.b.i Waste

Waste management at Procaps includes the entire production cycle, i.e. separation at the source, packaging, labeling, collection, registration, internal transport, storage, use, external transport, and final disposal. The Company handles its own waste and makes sure that it is disposed of in line with its "Comprehensive Waste Management Plan" (CWMP), which provides set objectives and targets with associated indicators and also identifies the waste generating areas within the Company.

The CWMP seeks to prevent and minimize waste generation, guaranteeing that it is suitably handled with the least possible risk and that it is disposed of in an environmentally safe manner by duly authorized operators. This is done through two operational procedures: (i) Handling and Final Disposal of Waste, and (ii) Storage and Final Disposal of Usable and Ordinary Waste. Each plant adjusts and frames the plans for its processes within the context of its own operations.

The CWMP also includes specific provisions for: (i) handling biochemical waste generated in the laboratories, (ii) laboratory safety, (iii) handling samples to be analyzed in the physicochemical laboratory, and (iv) destroying materials and products. Procaps ensures compliance with environmental legislation and GMP by providing an instruction manual for handling and transporting waste from different areas.

Procaps has a documented process by type of waste; the General Services area consolidates the generation data and the respective final disposal certificates issued by the authorized environmental managers. The Quality Area compiles this information and prepares the annual waste generation report, which includes monitoring indicators.

4.3.b.ii Hazardous Waste Management

The CWMP determines the types of waste generated by the Company's operations, defines their status, classifies them based on local regulations, determines the treatment method, and specifies the business name of the third party assigned for its final disposal.

In order to minimize the risks involved in hazardous waste generation, the Company participates in post-consumer plans and reverse logistics programs to guarantee the environmentally safe handling of hazardous waste. Procaps participates in the following plans and programs for the disposal of this type of waste: Punto Azul Program (expired medicines or drugs), Return Plan for Expired Veterinary Products, Collection Plan for Expired Products (pesticide products for veterinary use), EcoComputo Program (EEEW: Electrical and Electronic Equipment Waste), Lumnia Program (fluorescent lamps), LITO Program (EEEW and fluorescent lamps), Lead Recycling and Recovery Program (lead-acid batteries) and HP Planet Partners Program (printing toner).

The final disposal of hazardous waste is managed through suppliers duly authorized by the Environmental Authority and who comply with Decree 1076 of 2015 on the duties of the waste or hazardous waste carrier and those of the manager or receiver. Once the waste has been disposed of, these managers issue certificates

attesting to how the waste was treated. The Company also has a Chemical Control Plan that outlines the steps for handling waste in the event of decommissioning or dismantling of its activities.

4.4 Community Health, Safety and Security

4.4.a Community Health and Safety

In order to protect people and facilities, the Procaps Stakeholder Communication and Management Procedure specifies that the neighboring community needs to be informed on potential emergency response or evacuation measures. This is done through an Emergency Preparedness and Response Procedure, which recognizes mutual aid processes in the event of emergencies, including neighboring entities and organizations, relief groups and municipalities. In line with its OHS Manual, Procaps also ensures that external stakeholders are consulted about OHS issues through notices, meetings, or scheduled events.

4.4.b Security Personnel

Procaps has contracted security services with Interglobal Ltda., a company that specializes in providing protection, surveillance and private security services. Interglobal's personnel are in charge of gate control to Procaps' facilities and escorting the goods on their way to the port. They have been duly identified and authorized to perform their duties by the Superintendence of Surveillance and Private Security of the Colombian Ministry of Defense.

The service contract requires the security company to train all its personnel on an ongoing basis. Security personnel who carry weapons have the proper authorizations and training required by law. Procaps also employs its own security personnel, mainly devoted to protecting the families of senior executives; these personnel undergo psychological screening certifications.

4.5 Land Acquisition and Involuntary Resettlement

The Company operates within previously acquired or rented urban areas. The activities envisaged in this Operation do not involve any kind of involuntary physical or economic displacement.

4.6 Biodiversity Conservation and Natural Habitats

The Company operates within highly intervened urban areas. Consequently, the planned activities will not generate any kind of risk to biodiversity conservation or living natural resources management.

4.7 Indigenous Peoples

The Project will take place within the urban areas of the cities of Bogota and Barranquilla in Colombia, and will not affect indigenous communities or populations.

4.8 Cultural Heritage

The Project is not located in an area with an existing or potential presence of cultural heritage.

5. Local Access of Project Documentation

The documentation relating to the project can be accessed at the following links:
<https://www.procapslaboratorios.com> and <https://www.fundacionprocaps.com>