Environmental and Social Review Summary (ESRS)
Megalabs – REGIONAL

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1 General Information of the Project and Scope of Environmental and Social Review

Megalabs Group ("Megalabs" or the "Company"), through its holding, Mega Pharma Holding Uruguay, S.A. ("MPHU"), has requested financial assistance from IDB Invest to increase its regional production capacity of pharmaceutical products, reduce the region's dependence on imported products, expand access to quality medical products, and promote investment in new production technologies (the "Project" or the "Operation").

The Company's investment products are mainly located in Argentina, Uruguay, Mexico, Bolivia, Peru, Colombia, Chile, Dominican Republic and Ecuador, and include: (i) expanding the plants (enlarging existing facilities); (ii) building an antibiotics plant inside an existing plant; (iii) developing efficiency programs in terms of good manufacturing practices (GMP) and good laboratory practices (GLP); (iv) building warehouses on existing lands; (v) refurbishing[1] a new research and development (R&D) Center to replace the existing one; (vi) purchasing machinery and laboratory equipment to increase production capacity in the existing manufacturing plants; and (vii) purchasing utility vehicles (together, the "Project works and activities").

Due to restrictions arising from the COVID-19 pandemic,[2] the Environmental and Social Due Diligence (ESDD) process was conducted primarily virtually and included a review of, among other things, the following information: (i) environmental management policies, plans, manuals and procedures; (ii) human resources (HR) policy; (iii) occupational health and safety (OHS) programs; (iv) waste management procedures (hazardous, non-hazardous and special handling waste); (v) procedures for monitoring and evaluating environmental conditions (e.g., air emissions, noise and effluents); and (vi) emergency response plans. This process was complemented by remote interviews with HR, Industrial and Environmental Risk Management (IERM), and operating personnel associated to the Project.

2 Environmental and Social Categorization and Rationale

The Project has been classified as a Category B operation according with BID Invest´s Environmental and Social Sustainability Policy since it will likely generate environmental and social (E&S) and OHS impacts and risks generally reversible and mitigable through measures available with current technologies. These include: (i) risks to the health and safety of workers; (ii) the generation of polluting emissions to the atmosphere; (iii) the generation of solid (both hazardous and non-hazardous) and liquid (mainly industrial

[1] This is an adaptation, since the Company has selected an existing, unoccupied and fully equipped warehouse in a business complex located in an urban industrial sector as the new headquarters of the R&D center.

[2] COVID-19 is the infectious disease caused by the coronavirus discovered in Wuhan, China in December 2019 (https://www.who.int/emergencies/diseases/novel-coronavirus-2019)

and domestic wastewater) waste; and (iv) use of resources, mainly potable water, and energy. Most of these impacts and risks are estimated to be of moderate importance.

The different locations where the Project will be developed are subject to natural threats such as extreme temperatures, hurricanes, hailstorms, frost, and snowfall, as well as social threats that include vandalism and demonstrations or protests. All these threats, however, present a moderate to low risk in terms of both possible damage to the physical infrastructure of the plants and for employees and suppliers.

The Project will trigger the following International Finance Corporation (IFC) Performance Standards (PS): PS1: Assessment and Management of Environmental and Social Risks and Impacts; PS2: Labor and Working Conditions; PS3: Resource Efficiency and Pollution Prevention; and PS4: Community Health, Safety, and Security.

3 Environmental and Social Context

Megalabs is a group of companies in the pharmaceutical sector that specialize in the production and distribution of a wide array of drugs. The Company has 17 production Plants and six R&D Centers in different Latin American countries, all of which are certified by each country's health authority. Moreover, its companies provide it with a network of distribution and storage centers specialized in pharmaceutical logistics that incorporate state-of-the-art technology for the storage and handling of raw materials and drugs, which allows them to supply every country in the region while maintaining high safety standards and in the required times.

The Megalabs campus—the Company's main operating center—is located in the Science Park[3] of the Municipality of Nicolich, District of Canelones, Republic of Uruguay. It consists of a production plant, a development center where R&D projects for the entire region are conducted, a quality control laboratory, and a corporate center that performs administrative, financial, and technological tasks that affect the Company's operations throughout Latin America.

The Megalabs production plant in the Science Park has an area of 22,000 m^2 and has highly sophisticated equipment to properly conduct production and quality control tasks. Its processes are aligned with national and international regulations in force, which allows the Company to access the most demanding markets. The building has a building management system called SCADA ("Supervisory Control And Data Acquisition"), which allows the automation of services such as running water, steam, compressed air, and air conditioning. Moreover, the plant's building design allows observing the natural flows of the manufacturing processes, from the entry of raw materials at the materials reception area to the departure of the finished product from the shipping area.

The Company implements closed systems in which there is no direct contact with the product, except for the area where raw materials enter the production systems. In addition, incorporating automated processes in their plants' production lines allows them to access validation levels to ensure the quality of the products they manufacture.

One of the Company's greatest competitive advantages is the implementation of a vertical model. This model is characterized by an exhaustive control that covers all production stages, from engineering and

[3] The Science Park is a tax-free-zone in the outskirts of Montevideo, capital of the Republic of Uruguay.

cell culture to the production of the active pharmaceutical ingredient (biotechnological) and the manufacture of the finished product. In this regard, the plant at the Science Park has the Certificate of Good Manufacturing Practices and Good Laboratory Practices issued by the Ministry of Public Health of the Republic of Uruguay.

Furthermore, as part of its environmental and social commitments, the Company submits regular reports and statements[4] to the National Directorate of the Environment (DINAMA, for its acronym in Spanish) of the Ministry of Housing, Land Management and Environment (MVOTMA, for its acronym in Spanish) on compliance with applicable environmental regulations in connection with its operations.

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 E&S Assessment and Management System

The Company is developing an Environmental Management System (EMS) based on Megalabs' Environmental Policy. In this regard, Megalabs will continue to develop and implement an EMS that is specific to its operations, to include: (i) the existing environmental policy and industrial risk management policy; (ii) internal procedures to identify, evaluate, and manage possible environmental, social, and OHS risks and impacts associated with each Project activity, both for its own employees and for workers engaged by third parties (contractors and subcontractors); (iii) internal procedures to ensure compliance with the Environmental Management Plan (EMP); (iv) the necessary organizational capacity and competency, including defining roles and assigning responsibilities for the implementation of the ESMS; (v) emergency preparedness and response protocols; (vi) stakeholder engagement plans; (vii) external communications and grievance mechanism; (viii) information dissemination, decision-making, and community education protocols; (ix) protocols for the evaluation and continuous improvement of the ESMS; and (x) frequent audits and inspections of environmental, social, and OHS requirements under the environmental regulations of each country in which it operates.

Once adopted, the EMS will be evaluated regularly[5] to strengthen or update its components to meet applicable environmental, social, and OHS requirements.

4.1.b Policy

The Company has an Environmental Policy where it states its commitment to fostering the responsible growth of the business, fulfilling the laws and standards of the countries where it operates, reducing the risks and impacts of its processes and products, and using energy and natural resources efficiently.

The Company also has an Industrial Risk Management Policy in place, that states that safety is paramount to its work, and that it commits to: providing a safe working environment, fulfilling all OHS legal requirements, immediately reporting any presumably unsafe act or condition, and conducting a thorough

[4] For example, in Uruguay there are, among others: Minimum Operation Environmental Reports; Sworn Statement of Solid Waste Generation.

[5] By applying the Environmental and Social Management System, Implementation Manual - General, IFC, version 2.1, November 2015. Environmental and Social Management System Tools – General, IFC, version 1.2, November, 2015.

investigation thereof, as well as of any events or accidents that may occur, until their root cause is found and they can be avoided in the future.

4.1.c Identification of Risks and Impacts

4.1.c.i Direct and Indirect Impacts and Risks

For each new expansion, construction, or renovation project, the Company checks compliance with local environmental impact regulations and identifies and evaluates the environmental and social risks and impacts for each Project phase: design, expansion or construction, operation and maintenance (O&M), and closure or dismantling. Based on this last consideration and regardless of the mechanism used to comply with the country's E&S and OHS regulations, the Company, in addition to identifying and assessing the direct, indirect, and synergistic environmental, social, and OHS risks and impacts of each new facility and each Project phase, will take into account the following: (i) cumulative impact; (ii) greenhouse gas emissions ("GHG"); and (iii) relevant risks associated with natural hazards and climate change.

Furthermore, given that the Project's implementation and operation are dynamic, Megalabs will prepare a compliance matrix on E&S and OHS impacts for each phase of the Project throughout its operations, in order to obtain, track, and monitor the necessary local permits or licenses.

4.1.c.ii Gender Risks

In Latin America, there is significant gender inequality, defined as differential and unequal access to labor, educational, economic, and political participation opportunities based on sex or gender. This inequality is strengthened by pervasive cultural norms regarding acceptable roles for men and women, and is exacerbated by weak legal protections or inadequate social response. Such inequality results in gender-based discrimination, unequal access to public services, educational differences, wage and labor inequality, and lagging political participation rates. The 2021 gender gap index for Uruguay was 0.7, which places it in 19th place out of 26 Latin American countries.[6]

Gender-based violence and harassment (GBVH) is also a significant problem in Latin America and the Caribbean, which has the highest rate in the world. Brazil, Mexico, Argentina, Honduras, Colombia and Peru account for 81% of cases in Latin America. Although Uruguay has laws[7] and institutions[8] that ensure the protection of women, the number of reported cases of femicide in the country (19) ranks in last place (the lowest) for Latin America.[9] Gender-based violence and harassment escalated during the beginning of the COVID-19 pandemic. In Uruguay, calls to the sexual violence hotline increased by approximately 20% compared to 2019 rates.[10]

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6 The closer the index is to 1, the less gender inequality. "Gender gap index in Latin America 2021", Statista.

7 Law 19,580, which sets forth rules against gender-based violence against women (January, 2018); Law 19,538, which amends Art. 311 and 312 of the Penal Code, related to acts of discrimination and femicide (October, 2017); Law 18,561 on sexual harassment (September, 2009); and Law 17,815 Sexual, commercial or non-commercial violence against children, adolescents or incapacitated persons.

8 National Women's Institute (Inmujeres); National System for Gender Equality; National Gender Council; National Human Rights Institute and Ombudsman's Office; among others.

9 "Number of femicides in Latin America by country 2019", Statista.

10 "COVID-19: rise of gender violence in Latin America," Statista.

Nevertheless, due to the type of activity and the industrial line of business, and the fact that the Project's plants in industrial parks or zones or in urban areas, gender risk is considered low and mitigable through the application of the principles contained in the Company's Code of Ethics and Conduct.

4.1.c.iii Climate Change Exposure

Overall, the Project Plants' infrastructure is moderately exposed to physical climate change risks and hazards, as follows: (i) according to a global climate model, a high exposure to droughts and a moderate exposure to changes in precipitation patterns; and (ii) a high exposure to droughts, with a moderately increasing trend under the RCP 8.5 climate change scenario.[11]

Climate change exposure risk, however, is expected to be addressed by the measures proposed in the Emergency Plan, which is reviewed annually.

4.1.d Management Programs

Each Plant and R&D Center of existing operations have suitable mitigation and management measures described in the operating processes and in waste management and OHS plans. Nevertheless, the Company will prepare a specific Environmental Management Plan (EMP) for both the construction and O&M phase of all new Project infrastructure expansion or construction, which will detail the operating measures and controls to eliminate, transfer or mitigate each of the identified risks and impacts. Operating controls will include: (i) preventive controls intended to eliminate or decrease the frequency, probability, and severity of negative risks or impacts, supported by preventive and predictive equipment and machinery maintenance programs, as well as by ongoing training programs for employees and drill programs; and (ii) technical and operational recommendations based on adherence to national environmental and OHS regulations in each country where it operates.

4.1.e Organizational Capacity and Competency

Megalabs has a dedicated organizational structure for E&S and OHS matters, which is headed by the Head of Industrial and Environmental Risk Management (IERM), who reports to the Corporate Operations Management. The Head of IERM is responsible for ensuring compliance with environmental and OHS operating processes, as well as for the disclosure of risks and hazards and the participation of all employees in emergency identification and evaluation processes.

Moreover, at least once a year, the Company conducts a session to introduce or update the annual environmental and industrial risk management training plan for employees and personnel of the brigades responsible for managing each operating facility, where it presents and analyzes E&S and OHS risks and impacts for each facility and the regulations to be followed.

[11] A Representative Concentration Pathway (RCP) is a greenhouse gas (not emissions) concentration pathway implemented by the IPCC. The pathways describe different climate futures, all of which are considered possible depending on the volume of greenhouse gases (GHG) emitted in the coming years. RCPs—originally RCP 2.6, RCP 4.5, RCP 6, and RCP 8.5—are labeled from a possible range of radioactive forcing values in the year 2100 (2.6, 4.5, 6, and 8.5 W/m^2, respectively).

4.1.f Emergency Preparedness and Response

Megalabs complies with the OHS regulations of each country where it operates, and it has Emergency Plans and Contingency Programs in the event of accidents at its Plants and R&D Centers. It also has an Emergency Identification, Treatment, and Follow-Up Registry that indicates risk sectors by type of infrastructure, threat identification (mainly anthropogenic or technological ones such as fires, explosions, fuel or chemical leaks or spills, intoxication, collapse of shelving, crashes or runover, etc.), the mitigation treatment and the follow-up to be provided to ensure there is no future recurrence.

Nevertheless, in order to better align with PS-2 and fulfill the safety principles of the civil protection regulations of the countries where the Project will be developed, Megalabs will implement a policy that will require each expansion and construction of new Project facilities to have an Emergency Response Plan (ERP). These specific and updated ERPs will set out preventive mitigation and relief actions to safeguard the physical integrity of employees, visitors, suppliers, and people or clients in each establishment; they will contain measures to address the most probable risk scenarios threatening the facilities and ongoing production; and will define community communication and coordination mechanisms to handle any emergency situations that may arise in the Company. They will also include a set of specific procedures to coordinate, warn, mobilize, and respond to the occurrence or imminent occurrence of sudden events such as (i) natural hazards (earthquakes, hurricanes, tropical storms, floods, subsidence, etc.); (ii) human conflicts (vandalism, demonstrations, or civil unrest); and (iii) technological hazards (fires, explosions, fuel leaks, hazardous product spills, and worker and supplier accidents).

The specific ERPs for each new Project facility will focus on the following aspects: (i) emergency response procedures; (ii) qualified emergency response teams; (iii) emergency contacts, communication systems, and protocols; (iv) procedures for interaction with local and regional authorities on health and emergency resolution; (v) permanent emergency response facilities and equipment (e.g. first aid stations, fire hoses, fire extinguishers, sprinkler systems); (vi) evacuation routes and meeting points; (vii) training exercises, and drills or simulations that include other stakeholders; (viii) an annual training program; (ix) a root cause analysis procedure for each major accident or fatality; and (x) a description of the corrective actions needed to minimize the risk of recurrence.

Each ERP will contain an annual training program and a root cause analysis procedure for serious accidents or fatalities, as well as a description of the corrective actions required to minimize the risk of recurrence. Annual training programs are designed to strengthen effective emergency response and will include courses on: (i) first aid (basic life support, bleeding, shock, wounds and burns, fractures, mobilization of the injured, etc.); (ii) firefighting and prevention (firefighter safety, hose bending, fire extinguisher handling, etc.); and (iii) search and rescue, among others issues.

4.1.g Monitoring and Review

Megalabs will prepare and adopt an E&S and OHS compliance matrix to include a list of permits, licenses, and certifications required to operate each Project Plant, R&D Center, or facility. This matrix will be updated to include: (i) key performance indicators (KPIs) to measure the effectiveness of management and control procedures; (ii) a record of the fulfillment of contractual and local legal obligations; (iii) the competent authority in charge of granting authorizations or issuing permits; (iv) the date of issuance or effective date of each permit or authorization; (v) the person responsible within the Company for monitoring or compliance with each permit, and (vi) future compliance and communication procedures.

The Company will also prepare[12] a consolidated annual report on the compliance status of the progress of EMS actions with regard to the established KPIs; as well as the compliance status with IDB Invest's Environmental and Social Sustainability Policy. Based on the results of the internal audit, Megalabs will define specific measures to reduce impacts and improve efficiency and will document and report on its progress and new procedures, as well as on other certifications, depending on the country in which the operating site is located.

4.1.h Stakeholder Engagement

Megalabs will develop and implement a Stakeholder Management Plan adapted to the new Project R&D Center, including the following; (i) updated identification of all stakeholders, including local authorities, neighbors, and nearby communities (within a 1 kilometer radius of each facility); (ii) differentiated measures that allow the effective participation of the most vulnerable or dispossessed groups (if present); (iii) a mechanism to guarantee that representatives of the affected community are able to express their views; (iv) details on how information is disclosed to stakeholders; (v) details on the stakeholder engagement process in these communities and how they access the grievance mechanism; and (vi) mechanisms to implement and disseminate the updated management plan to all staff as part of the annual training plan.

This plan will identify the task force responsible for its implementation (e.g. the Head of IERM and a team of outreach workers) and define the protocols for the following activities: (i) interviews with the authorities and stakeholder representatives; (ii) stakeholder briefings; and (iii) media and social media management.

4.1.i External Communication and Grievance Mechanisms

4.1.i.i External Communication

Megalabs acknowledges its responsibility in offering truthful, complete, updated, and accurate information. To this end, the Company will prepare a Corporate Communications Policy that will ensure that all outward communications, including those intended for stakeholders, are conducted in a careful, responsible, and efficient manner. This policy will determine the official external communication channels (reports, websites, press releases, social media, transparency mailboxes, contact centers, focus groups, social events, etc.) to reach the corresponding stakeholders.

4.1.i.ii Community Grievance Mechanism

Megalabs has a formal mechanism to receive complaints and suggestions from the community and the public at large through its web page.[13] Nevertheless, the Company will improve its existing system by developing and implementing a Community Grievance and Suggestions Methodological Guide, which will be used to attend to and follow up on complaints and suggestions submitted by people or organizations in the vicinity of the places where it operates. This guide will establish that it must: (i) appoint a local community relations officer, who will attend to and follow up on complaints and suggestions, as well as

[12] Either internally (internal audit) or through an external independent E&S expert (external audit).

[13] https://megalabs.global/contacto/

report semi-annual performance indicators; (ii) establish a methodology to determine how complaints are captured, classified, evaluated, investigated and resolved, what follow-up and closure will be given, and how the EMS will be adapted or improved in terms of communication and information disclosure; and (iii) determine the communication channels to capture complaints and suggestions from neighboring individuals and organizations.

Communication channels must guarantee anonymity and confidentiality, and can include: (i) written media (pre-set forms) to be deposited in mailboxes in the facilities; (ii) calling a dedicated telephone line; and (iii) through personal email or from the Company's web page.

4.1.j Ongoing Reporting to Affected Communities

Megalabs, through its web page,[14] informs about its global sustainability vision. Moreover, the Company, through its Stakeholder Management Plan, will provide reports on its E&S performance to the communities and to whoever request them.

4.2 Labor and Working Conditions

4.2.a Working Conditions and Management of Worker Relationships

4.2.a.i Human Resources Policies and Procedures

Megalabs has a Code of Ethics and Conduct that sets out the standards of conduct and interaction between Company employees, managers, and board members with customers and potential customers, colleagues, competitors, government administration bodies and other regulatory entities, public and private entities, the media and all other persons and/or institutions they come into contact with. The Code considers, among other aspects, the following: (i) anti-corruption and conduct guidelines; (ii) antitrust; (iii) international trade controls; (iv) professional rigor; (v) product (drug) safety and quality; (vi) conflict of interest; (vii) respect for diversity and non-discrimination; (viii) employee health and safety; (ix) confidentiality; (x) intellectual property rights; (xi) confidential information and intellectual property rights of third parties; (xii) protection of personal information and data; (xiii) Company accounting; (xiv) environmental protection; (xv) external business relationships; (xvi) fair and equitable business practices; (xvii) advertising and marketing; (xviii) legal compliance; and (xix) reporting of illegal or immoral behavior.

The Company also has an Internal Labor Manual (ILM) that contains rules and conditions with regard to: the nature of the work; employee admission, suspension, and termination; duration of the workday, breaks, and paid annual leave; punctuality, paid and unpaid leaves of absence; wages; consumables, tools, materials, and equipment; training and formation; measures for health, safety, and the working environment; occupational risks; rights and duties of the Company; rights and duties of employees; employee prohibitions; lack of punctuality, attendance, and leaves; sanctions; and, in general compliance with federal and state labor laws, including the standards and foundations defined by the International Labor Organization (ILO).

To complement the Code of Ethics and Conduct, Megalabs has an Industrial Risk Management Policy that manages industrial risks and protects workers.

[14] https://megalabs.global/vision-global/

4.2.a.ii Working Conditions and Terms of Employment

The provisions contained in the Code of Ethics and Conduct and the ILM regulate the form and conditions of personnel selection and hiring; working days and hours, and their breaks; paid annual leaves; paid and unpaid leaves of absence; flexible work schemes to promote collaboration and productivity; wages and benefits; employee and employer rights and obligations; conduct and disciplinary measures; asset security; risk prevention; and how to proceed with regard to workers with disabilities, among others.

To reinforce awareness of these working conditions, the Company requires each employee to commit to complying with the Code of Ethics and Conduct and undertake to report any actual, potential or apparent deviation from the Code.

As regards wages, the Company applies what is established for the commercial sector and what is defined by the Wages Council regulated by Law 10449, which recognizes overtime, night hours, holiday hours, annual leave pay, vacation pay, and bonuses. The settlement of salary items is carried out in compliance with national regulations.

Megalabs recruits, selects, and hires talent through transparent, objective, and confidential processes that guarantee respect for the principles of equality and non-discrimination. Moreover, in its Code of Ethics and Conduct and the ILM, the Company states that employee recruitment, hiring, remuneration, evaluation, or promotion is based on their competencies, academic background, professional experience, performance, behavior, attitude, and candidates' level of identification with the Company's values.

4.2.a.iii Workers' Organizations

Megalabs, by committing to comply with applicable local legislation in the countries where it operates, recognizes the rights of workers to form and be part of labor organizations, and respects and assumes all responsibilities derived from such legislation, including international conventions and treaties that countries have signed with the ILO.[15] In addition, its Code of Ethics and Conduct and Collective Bargaining Agreement recognize the right to freedom of association and collective bargaining. Formal agreements between the Company and the union regarding safety and health are regulated mainly under Law 5,032 (occupational accidents, prevention measures) and Decree 406/88 (occupational safety and hygiene in industry and commerce).

4.2.a.iv Non-discrimination and Equal Opportunity

The countries where the Company operates are signatories to several ILO international conventions and treaties relating to workers' rights, including Convention No. 100 concerning Equal Remuneration for Men and Women Workers for Work of Equal Value and Convention No. 111 concerning Discrimination in Respect of Employment and Occupation. The Company, in addition to complying with these provisions and with each country's labor legislation, establishes in its Code of Ethics and Conduct and the ILM respect for individual diversity and equity, proceeding with fairness, equality, and impartiality, and seeking a positive and inclusive social impact. In addition, the Code of Ethics and Conduct sets out a zero tolerance

[15] Convention No. 87 concerning Freedom of Association and Protection of the Right to Organize and Convention No. 98 concerning the Right to Organize and Collective Bargaining.

stance against discrimination, harassment, abuse, and workplace harassment, and reaffirms the Company's commitment to promoting an environment in which no applicant, employee, supplier, or contractor is excluded or discriminated against participating in an internal or external selection process based on race, color, age, gender, gender identity, sexual orientation, marital status, ancestry, ethic or national origin, religion, disability or medical condition (including COVID-19), or any other discriminatory condition.

4.2.a.v Grievance Mechanism

The means of reporting or complaining about any inappropriate conduct, ethically questionable performance, or failure to comply with applicable laws and regulations or Megalab's policies and Code of Ethics and Conduct is through email or in person. These practices are reinforced through the Company's Open Door Policy, which seeks to generate a culture of openness in order to foster an environment of trust and exchange, with open channels of communication so that different points of view can be expressed at Megalabs.

Nevertheless, the Company will update this method through a Grievance Procedure that: (i) documents internal complaints or grievances from its employees, contractors, and subcontractors, detailing how these complaints or grievances are recorded, investigated, evaluated, and the follow-up and closure or resolution process for such complaint; (ii) provides a culturally appropriate and easily accessible system at any time (e.g., a mailbox or external box with printed or digital forms to register the complaint, grievance, or inquiry); (iii) accepts anonymity and provides confidentiality and protection against retaliation for employees who use it; and (iv) does not prevent, but rather provides access to other applicable legal or administrative remedies, justified by the seriousness of the violation, according to local national labor laws or regulations.

4.2.b Protecting the Workforce

Megalabs, in fulfillment of all legal labor obligations of the countries where it operates, respects employee and employer rights and duties, promoting equality and equity in human, civil, political, economic, social and cultural rights between men and women.

The Code of Ethics and Conduct and the ILM require compliance with applicable local laws, standards, and regulations in each country where the Company operates, as well as with the provisions of: (i) the United Nations Universal Declaration on Human Rights and its protocols; (ii) the International Conventions approved by said international organization and by the ILO on social rights; and (iii) the principles of the United Nations Global Compact for Business Leadership, in order to guarantee transparency and responsibility in business, interaction with the community, and responsibility with the environment.

4.2.c Occupational Health and Safety

Megalabs, as required by labor and OHS legislation in the countries where it operates, has an Industrial Risk Management Policy that contains its commitment to protect the physical integrity of its employees, and to prevent injuries and damage to their health. The Company also has an OHS Hazard Identification and Risk Assessment Procedure, which establishes and maintains a hazard identification mechanism, as well as the need to permanently evaluate risks and determine the legal controls necessary for OHS.

Concerning drills, the Company has an Emergency Drill Instruction that systematizes emergency drills so that the findings allow the identification of the Company's conditions and the level of staff training required to ensure the safety of personnel, third parties, visitors, and the community at large. This level of training is reflected in the Company's Annual Industrial and Environmental Risk Management Training Plan.

In Uruguay, the state of national health emergency due to the COVID-19 pandemic was concluded effective April 5, 2022.[16] Nevertheless, observing the recommendations and surveillance and control strategies for COVID-19 of the Ministry of Public Health and the sanitary guidelines of the World Health Organization (WHO), the Company has promoted actions to prevent contagion among its workers, such as: airing the work space, use of face masks in closed places, social distancing, adoption of disinfection routines, and proper hand hygiene.

4.2.d Workers Engaged by Third Parties

As required by the Code of Ethics and Conduct and the ILM, all of the Company's internal rules, policies, and procedures apply, without exception, to all employees worldwide and to the Company's business partners, including its suppliers, distributors, agents, contractors, and any other workers engaged by third parties that work with or for the Company. The permanence of both own employees and workers engaged by third parties depends on their compliance with the provisions of the Code of Ethics and Conduct, as well as with applicable local and national labor laws and regulations in the countries where it operates. These measures are reinforced through contractual clauses that have been incorporated into employment and service contracts.

4.2.e Supply Chain

Through its Code of Ethics and Conduct, Megalabs promotes respect for human rights in its internal operations and throughout its value chain. In this sense, the Company ensures the fulfillment of applicable legal provisions and the labor conventions ratified by the countries where it operates, including those relating to child labor[17] and forced labor.[18]

Nevertheless, in order to address the supply chain, Megalabs will develop and implement a Sustainable Purchasing Policy to regulate the purchase of goods (materials, equipment, etc.) and the contracting of services, which will require suppliers to comply with labor regulations (specifically the prohibition of child and forced labor, nor shall any product or service that employs them be incorporated into their business activities), OHS, and environmental protection requirements applicable in each country where it operates. This methodology will contain a provision that blocks current or potential suppliers that fail to comply with the country's labor and environmental legislation or Megalabs' policies (and thus prevents the Company from doing business with them).

[16] Decree No. 106/022 of April 5, 2022, repealing Decree No. 93/020 of March 13, 2020.

[17] Conventions No. 138 on Minimum age and No 182 on the Worst Forms of Child Labor.

[18] ILO Conventions No. 29 on Forced Labor and 105 on the Abolition of Forced Labor.

4.3 Resource Efficiency and Pollution Prevention

4.3.a Resource Efficiency

4.3.a.i Greenhouse Gases

Given the size of the expansion and construction works and the fact that the construction sites and the construction and material storage yards will be located close to each other (within a radius of approximately 2 km), greenhouse gas (GHG) emissions for the Project expansion and construction phases are expected to be less than 25,000 tons of CO_2 equivalent annually (tCO_2eq/year).

Nevertheless, throughout the Project, Megalabs will prepare an Annual GHG Emissions Inventory for every operation in each of the countries where it operates, where it will quantify both direct emissions from fuel consumption (scope 1) and indirect emissions from electricity consumption (scope 2). The variation of the results with respect to the base year (2021) will be reported annually and the causes for such variation will be explained.

Regardless, the Company is seeking to reduce its emissions through its sustainability approach aimed at optimizing the use of electricity and reducing fuel consumption (natural gas or fuel oil) for process steam generation.

4.3.a.ii Water Consumption

During the expansion and construction phase, water consumption at the Project Plants will remain at the estimated historical averages, based on the volumes authorized in the groundwater concessions (industrial process water for steam and HVAC[19] services) and the potable water supply agreements (through the public municipal water supply system) granted by the competent authorities in the countries where it operates. For O&M, the increase in water consumption will depend on the Project's new works and activities and will comply with existing permits, contracts, and concessions or, failing that, will modify or update the latter for the new operating conditions.

The operating sites have water efficiency plans and some plants, specifically those located in Uruguay (Science Park), have reuse systems that minimize water use.

4.3.a.iii Energy

During the Project plants' expansion and construction phase, no significant increase in historical average energy consumption is expected. The latter is provided by the public grid under a service contract with the authorized distributor and, in the event of emergency due to power outages in the grid, by backup generators. In the O&M phase, energy consumption will increase based on the Project's new works and activities and these will be monitored and quantified in the Annual GHG Emissions Inventory.

[19] An HVAC (heating, ventilation and air conditioning) system is an air conditioning and ventilation system that renews and treats air to provide health (i.e. purity, conditioning to achieve air suitable for breathing), temperature, and humidity conditions that are comfortable for people.

As part of the Sustainability Approach, the Company seeks to reduce its electricity consumption without altering its plant production volumes, through: (i) optimizing electricity expenditure by analyzing production hours and days; and (ii) reducing energy consumption in outdoor lighting, through the progressive replacement of LED lighting fixtures.[20]

4.3.b Pollution Prevention

4.3.b.i Waste

Megalabs, in compliance with environmental legislation on solid waste management in the countries where it operates (Decree 182/2013[21], for Uruguay), has a Waste Management Plan and Instructions for the Classification, Treatment, and Valuation of General Plant Waste, which sets out the guidelines for the classification, treatment, and recovery of waste derived from the Company's activities, in order to reduce its environmental impact.

Non-hazardous waste (Category II according to Uruguayan regulations) is transported by a third party manager authorized by the country's competent authority and taken for final disposal at authorized sites.

In 2018, based on the sorting prior to management of non-hazardous waste, a 20% volume reduction was achieved by recycling (mainly empty blister packs, uncontaminated work clothes, clean glass such as uncontaminated light bulbs, and PVC bushings and sheets) and 4% by composting placebos. The Company also began to recycle 8% of the initial stockpile,[22] such as cases and leaflets, and sorted clean glass.

4.3.b.ii Hazardous Materials Management

The Waste Management Plan and the Instructions for the Classification, Treatment, and Valuation of Waste from the Company's General Plant provide for the classification of hazardous waste (Category I according to Uruguayan regulations). The Instructions state that the persons in charge of the primary disposal of hazardous waste must be trained to carry out a correct disposal flow, in order to minimize contact of the contaminant with people and the environment. In compliance with the applicable legislation in each country, the need for destruction is also determined by the type of waste, and in those cases where the waste contains a controlled substance (for example, psychotropic product waste), requests for destruction must be authorized by the competent health authority (in Uruguay, this would be the Ministry of Public Health). Finally, the final management and treatment[23] is performed by a third-party company authorized by the country's environmental authority.

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20 LED, Light Emitting Diode.

21 Decree 182/013 of June 20, 2013 "Regulations for the environmentally sound management of solid industrial and assimilated waste" aims to establish a framework for the environmentally sound management of solid industrial, agro-industrial, and service waste, addressing all aspects involved in its holistic management.

22 The initial stockpile is necessary because there is a large amount of waste whose management has not been determined or whose final disposal has yet to be legally determined.

23 Incineration is the most widely used treatment method for hazardous pharmaceutical waste and is approved by the environmental authorities in the countries where the Company operates.

The Company has conducted activities intended to: (i) identify, control, minimize, give value to, and comprehensively manage hazardous waste; and (ii) promote a culture of reduction, starting with the elimination of the use of this type of waste or its substitution with non-hazardous products.[24]

4.4 Community Health, Safety and Security

4.4.a Community Health and Safety

The new Project works, both expansion and construction of new buildings and their ancillary service facilities, will be designed and built by competent and renowned contractors experienced in the construction and operation of this type of works, using international best practices and in keeping with the applicable national and international guidelines, standards, and building codes. Nevertheless, Megalabs will include specific clauses in its integral service contracts for the expansion and construction of new Project infrastructure that will cover any type of loss and hold it liable for any damage caused to the property of the State, a private individual, or the community in general, that may occur in the area of influence of any Project.

Megalabs operates the Project's properties and plants using applicable environmental and OHS best practices. In the specific and updated ERP for each new Project plant, the Company will have a section dedicated to community protection where the Company will coordinate with external authorities,[25] through personnel specialized in emergency command (fire, rescue, and evacuation brigades), to address leaks, spills, fires, or explosions that exceed the Company's response limits. Similarly, the Company, as set out in its Communication Procedure and through the Plant and Operations Managers and the Heads of IERM, it will inform the communities about the ERPs, the potential risks in its plants, its response and combat devices, alarm and communication systems, evacuation routes, and the internal and external drill programs.

Megalabs has a multiple business insurance policy that covers any type of loss of property, movable and immovable, within its premises, including property of third parties under its custody and control. These policies also cover damages to neighboring properties, environmental, and social damages outside its premises.

4.4.a.i Infrastructure and Equipment Design and Safety

In its production Plants and R&D Centers, Megalabs has leak and spill detection and containment equipment, fire alarm and firefighting systems, and emergency communication mechanisms that comply with each country's national regulations.

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[24] An example is the initiative to reduce the purchase of EZ-Fit Merck filtration units for the microbiological analysis of water, where, beyond economic savings, additional benefits were achieved, such as the reduction in the volume of hazardous waste, the use of special bags for its handling ("biohazard" bags), and the temporary storage space required prior to its transfer to the authorized manager (SSAA deposit).

[25] Persons or entities with technical, legal and judicial personality in each country where it operates, such as: Civil Protection, Red Cross, Firefighters, etc.

Nevertheless, based on the Fire Safety and Security Regulations and Building Codes of the countries where the Project will be developed, the design of the Life and Fire Safety (L&FS) Systems of the new Project facilities shall adopt the international standards of the National Fire Protection Association (NFPA) and the Fire Safety and Prevention requirements of the IFC's General Environmental, Health, and Safety Guidelines.

In this regard, after construction but prior to occupancy and operation of the new Project facilities, the Company will engage qualified L&FS professionals to certify:[26] i) that all Project facilities and buildings, whether completed or under construction, were built in accordance with the approved L&FS designs; ii) that all equipment was installed according to the L&FS design; and iii) that all L&FS equipment was tested following international requirements.

4.4.b Security Personnel

Megalabs has a security and surveillance service, provided by a specialized security company (outsourced service) duly registered and regulated by the public security legislation of each country where it operates. Nevertheless, the Company will ensure that the corresponding service contracts include provisions allowing it to: (i) conduct reasonable investigations to ensure that security personnel do not have a criminal record and have not been implicated in cases of abuse; (ii) verify the details of any required training on the use of force; (iii) verify any restrictions and procedures used should personnel carry firearms; and (iv) identify the details of environmental training and social awareness, including human rights.

4.5 Land Acquisition and Involuntary Resettlement

Megalabs acquired the land and facilities (existing warehouses within a business complex located in an urban industrial sector) for the adequacy of the Project's new R&D Center under strict compliance with PS-5, through agreements negotiated to the satisfaction of both parties (buyer and seller) and in compliance with the commercial and mercantile laws of the country where the construction will be undertaken. Hence, due to this purchase, involuntary resettlement, both physical displacement (relocation or loss of housing) and economic displacement (loss of property or access to property resulting in loss of sources of income and other livelihoods), was avoided.

Other than the adequacy of the Project's new R&D Center, for plant expansion or the construction of warehouses on existing properties, no involuntary physical or economic displacement is anticipated.

4.6 Biodiversity Conservation and Natural Habitats

No significant impacts on vegetation or alterations to biodiversity are foreseen for the Project's works and activities, since they will be carried out on land that is already disturbed or in existing facilities.

4.6.a Supply Chain

Megalabs is aware of the need to control and influence the environmental and social impacts of its suppliers. It will therefore develop a Supplier Selection and Evaluation Procedure intended to set a

[26] In Uruguay, it would be the authorization of the National Fire Department – Decree No. 150/016.

standard for the applicable requirements regarding property, environment, quality, and employee safety (with emphasis on the "Safety Data Sheets") that its suppliers must meet when registering as a new supplier and in their annual performance evaluation.

For supplier registration and for suppliers to remain approved, Purchasing Management, with the support of Corporate Operations Management, must request specific requirements from each raw material supplier, ranging from analysis certifications and Drug Master Files [27] (DMF) of each raw material, to certifications of non-use of prohibited substances, certificates of origin, and declaration of allergens, as appropriate. Requirements for suppliers of packaging, product handling, and packing materials shall include: mechanical drawings, specifications, and technical data sheets on the material (composition and raw materials) and its resistance, microbiological studies, tests and supports, and safety certificates, as applicable.

Regarding the annual evaluation of suppliers, the Purchasing Management, with the support of the Corporate Operations Management, shall consider: (i) the supplier's performance in terms of the percentage of compliance in time, form, and under the agreed conditions; (ii) the evaluation of safety, quality, environment, and worker safety, where on the one hand, certifications are evaluated (as applicable) and on the other, reports of deviations with impact on the process, such as impact on the production program, customer complaints, nonconforming products, impact on audits or with the regulatory authority (for example, the FDA[28] in the United States of America and the EMA[29] in Europe), product retention or downtime, environmental or safety impacts; and (iii) complete and updated documentation, depending on the type of product or service.

4.7 Indigenous Peoples

For the Project's works and activities, since they will be carried out on the Company's own, already intervened lands or in existing facilities within industrial parks, no impact on indigenous peoples' lands or resources is foreseen.

4.8 Cultural Heritage

The Project will not generate any cultural heritage impacts.

5 Local Access of Project Documentation

Megalabs provides additional information about its global vision on its website: https://megalabs.global/vision-global/.

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[27] A Drug Master File (DMF) is a document prepared by a pharmaceutical manufacturer and submitted solely at its discretion to the appropriate regulatory authority in the intended drug market. The document provides the regulatory authority with confidential and detailed information on the facilities, processes, or items used in the manufacture, processing, packaging, and storage of one or more medicinal products for human use. The DMF contains complete and factual information on the chemistry, manufacturing, stability, purity, impurity profile, packaging, and GMP status of any human drug product.

[28] Food and Drug Administration – FDA of the United States of America.

[29] European Medicine Agency – EMA.