Opella Brazil

Disclosure Report

Date Submitted: December 11th, 2024

Disclosure Materials

Certified B Corporations must complete a Disclosure Questionnaire to identify potentially sensitive issues related to the company (e.g. historical fines, sanctions, material litigation, or sensitive industry practices).

This component does not affect the company's score on the B Impact Assessment. If the company answers affirmatively to any items in the Disclosure Questionnaire that B Lab deems relevant for public stakeholders, then, as a condition of their certification, the company must:

1) Be transparent about details of the disclosure issues identified on the company's public B Impact Report
2) Describe how the company has addressed this issue
3) Demonstrate that management practices are in place to avoid similar issues from arising in the future, when necessary.

In all cases, the Standards Advisory council reserves the right to refuse certification if the company is ultimately deemed not to uphold the spirit and integrity of the community.

In addition to the voluntary indication of sensitive issues in the Disclosure Questionnaire, companies pursuing Certification also are subject to a background check by B Lab staff. Background checks include a review of public records, news sources, and search engines for company names, brands, executives/founders, and other relevant topics.

Sensitive issues identified through background checks may or may not be within the scope of questions in the Disclosure Questionnaire, but undergo the same review process and are subject to the same possible review by the Standards Advisory Council, including ineligibility for B Corp Certification, required remediation, or disclosure.

This document contains a copy of the company's completed Disclosure Questionnaire and related disclosure documentation provided by the company

Disclosure Questionnaire

Industries and Products

	Yes	No
Please indicate if the company is involved in production of or trade in any of the following. Select Yes for all options that apply.		
Animal Products or Services	☐	☑
Biodiversity Impacts	☐	☑
Chemicals	☑	☐
Disclosure Alcohol	☐	☑
Disclosure Firearms Weapons	☐	☑
Disclosure Mining	☐	☑
Disclosure Pornography	☐	☑
Disclosure Tobacco	☐	☑
Energy and Emissions Intensive Industries	☑	☐
Gambling	☐	☑
Genetically Modified Organisms	☐	☑
Illegal Products or Subject to Phase Out	☐	☑
Industries at Risk of Human Rights Violations	☐	☑
Monoculture Agriculture	☐	☑
Nuclear Power or Hazardous Materials	☐	☑
Payday, Short Term, or High Interest Lending	☐	☑
Water Intensive Industries	☑	☐
Tax Advisory Services	☐	☑

Outcomes & Penalties

	Yes	No
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies. Check all that apply.		
Anti-Competitive Behavior	☐	☑
Breaches of Confidential Information	☐	☑
Bribery, Fraud, or Corruption	☐	☑
Company has filed for bankruptcy	☐	☑
Consumer Protection	☑	☐
Financial Reporting, Taxes, Investments, or Loans	☐	☑
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)	☐	☑
Labor Issues	☐	☑
Large Scale Land Conversion, Acquisition, or Relocation	☐	☑
Litigation or Arbitration	☑	☐
On-Site Fatality	☐	☑
Penalties Assessed For Environmental Issues	☐	☑
Political Contributions or International Affairs	☐	☑
Recalls	☐	☑
Significant Layoffs	☐	☑
Violation of Indigenous Peoples Rights	☐	☑
Other	☐	☑

Practices

	Yes	No
Please indicate if the following statements are true regarding whether or not the company engages in the following practices. Check all that apply. If the statement is true, select "Yes." If false, select "No."		
Animal Testing	☑	☐
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)	☐	☑
Company prohibits freedom of association/collective bargaining	☐	☑
Company workers are prisoners	☐	☑
Conduct Business in Conflict Zones	☐	☑
Confirmation of Right to Work	☐	☑
Does not transparently report corporate financials to government	☐	☑
Employs Individuals on Zero-Hour Contracts	☐	☑
Facilities located in sensitive ecosystems	☐	☑
ID Cards Withheld or Penalties for Resignation	☐	☑
No formal Registration Under Domestic Regulations	☐	☑
No signed employment contracts for all workers	☐	☑
Overtime For Hourly Workers Is Compulsory	☐	☑
Payslips not provided to show wage calculation and deductions	☐	☑
Sale of Data	☐	☑
Tax Reduction Through Corporate Shells	☐	☑
Workers cannot leave site during non-working hours	☐	☑
Workers not Provided Clean Drinking Water or Toilets	☐	☑
Workers paid below minimum wage	☐	☑
Workers Under Bond	☐	☑
Other	☐	☑

Supply Chain Disclosures

	Yes	No
Please indicate if any of the following statements are true regarding your company's significant suppliers.		
Business in Conflict Zones	☐	☑
Child or Forced Labor	☐	☑
Negative Environmental Impact	☐	☑
Negative Social Impact	☐	☑
Other	☐	☑

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industry

Topic	Water Intensive Industry
Summary of Issue	Opella Brazil is part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella Brazil's operations include the entity's offices in São Paulo (SP, Brazil) and a manufacturing site in Suzano (SP, Brazil). Opella Brazil operates in the pharmaceutical industry which is recognised by B Lab as a water-intensive industry due to manufacturing and cleaning processes, although the company does not consider itself to be a water intensive industry and continues to minimise water use. Of the company's total water use, the most water intensive activities are related to the manufacturing site. The company uses municipality water, water wells and (in extraordinary situations) water trucks for manufacturing and cleaning, with water reduction efforts deployed at the site. Suzano is located in São Paulo State, Brazil which is not classified as a high water stressed area according to the World Resources Institute (WRI).
Size/Scope of Issue **(e.g. $ financial implication, # of individuals affected)**	In the previous fiscal year, 100% of Opella Brazil was derived from the production of medicines/drugs, food/dietary supplements, and cosmetics. The entity's manufacturing facility has a water intensity of 0.628 m3 per K/unit of product produced for its standard manufacturing processes.
Impact on Stakeholders	As a water intensive industry, the manufacturing of pharmaceutical products poses risks such as water stress or depletion of local water sources if water used is not appropriately managed. The company uses municipality water supply for pharmaceutical production and utilities. The main stakeholders affected are other water users in the regions of operation, such as local water authorities & regulators, residents, other industrial plants, farmers, and the local biodiversity.
Implemented	The company does not carry out an assessment of how it compares to other peers in the industry regarding water use and

Management Practices	management. All sites use global corporate standards to manage water and globally, Opella has the target of reducing water consumption by 20% in 2030, compared to 2019 levels as a benchmark. Opella's sustainability strategy is based on water stewardship principles: increasing water efficiency, assessing risks in each local watershed and defining a strategy aligned with local communities to properly manage the watershed the company relies on.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Topic	Chemical Intensive industries
Summary of Issue	Opella Brazil is part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella Brazil's operations include the entity's offices in São Paulo (SP, Brazil) and a manufacturing site in Suzano (SP, Brazil). Opella Brazil operates in the pharmaceutical industry which has been recognised by B Lab as a chemical intensive industry. The company is not involved in the production, operation, trade or sale of chemicals that meet the European Union's list of Substances of Very High Concern (SVHC). The company uses SVHC lab chemicals for quality control purposes on its sites. All product formulas are approved by local Health Authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. The level of the ingredients in the finished products remain adequate for the safe and intended use of customers.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	The use of SVHC substances for quality control purposes at the manufacturing sites is below 1 ton/year. Therefore, these facilities are exempted from restriction and authorization linked to REACH regulation.
Impact on Stakeholders	The primary potential impacts of chemical use in pharmaceutical products are potential negative effects on the environment and potential negative health impacts on workers exposed to chemical ingredients. Risks to workers exposed to chemical ingredients are mitigated through appropriate controls such as engineering controls and respiratory protection. In the last five years, Opella Brazil has not experienced any significant incidents and/or fines related to environmental or worker impacts of its chemical use.
Implemented Management Practices	All chemicals used are handled, stored, disposed of, and transported following corporate standards, local legal requirements, Standard Operating Procedures, and local Permits. Furthermore, wastewater is managed by complying

	with all local legal requirements, Standard Operating Procedures and Permits, assuring all wastewater parameters are within the defined local regulation limits. At the global level, the company has implemented a program to identify substances of potential future concern in our formula and plan their substitution or removal whenever possible from a technical or regulatory standpoint. This program includes a list of materials or substances to be banned, avoided, or restricted in Opella products. Moreover, Opella Brazil has documented HSE requirements to minimize the use of carcinogens, mutagens, reprotoxic and volatile organic compounds. All product formulas are approved by local Health Authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. Given the restricted regulation of the sector, the level of ingredients in the finished products remains adequate for the safe and intended use of consumers. At the local level, the company does not conduct an assessment and comparison with other companies regarding chemical use.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Animal Testing

Issue Date	Ongoing
Topic	Opella Brazil is a subsidiary of Opella and sells consumer healthcare products. Opella Brazil manufactures and sells but does not develop new drugs (eg. new drug molecules), therefore Opella Brazil is not required to perform animal testing.
Summary of Issue	Opella Brazil is part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella Brazil's operations include the entity's offices in São Paulo (SP, Brazil) and a manufacturing site in Suzano (SP, Brazil). As a company that manufactures pharmaceutical products, Opella is legally obligated to ensure the quality, safety, and efficacy of its medicines and other consumer healthcare products, for which animal testing is required in research and production. As a subsidiary of Opella, Opella Brazil can market over the counter (OTC) products because they have already been proven to be safe and effective. Opella does not engage in the regular practice of animal testing: It is only conducted when specifically required by regulatory authorities and no alternative methods can be applied. Animal studies would only be performed in rare situations to evaluate and assess major safety concerns, if literature/data was unavailable for the study endpoints needed, and when specifically required by Regulatory Authorities or to verify the rationale, safety, and efficacy of the combination of two or more ingredients and when no alternative methods can be applied. Animal studies would therefore generally only be conducted as a final resort if no alternatives are available or when required by Regulatory Authorities. In Opella Brazil, no animal testing was performed in the last five years since Opella Brazil does not research and develop new drugs molecules and it only manufactures and sells Over the Counter (OTC) products which have already been proven to be safe and effective.
Size/Scope of Issue ***(e.g. $ financial implication, # of***	Opella Brazil did not conduct animal testing in past 5 years. However, the company currently sells medicines that had to go

individuals affected)	through animal testing previously.
Indirect Impact on Stakeholders	Animal testing and experimentation is widely used to develop and test the safety of new drug molecules and/or food products. Many of these experiments can cause pain to the animals involved or reduce their quality of life in other ways. Opella Brazil does not develop new drug molecules and as stated above would only perform animal testing in rare situations when required by Regulatory Authorities. Animal testing and experimentation is widely used to develop and test the safety of new drug molecules. When the execution of this study is mandatory for Regulatory or safety reasons the company implement practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions.
Implemented Management Practices	Opella does not engage in the regular practice of animal testing. It only conducts when the regulatory and scientific merit is established and under strict ethical over-sight. Sanofi at a group level has a policy for the protection of animals that includes a 3R principle towards animal testing; seeking to exceed regulation and standards. The company tests products on animals only: - when a non-animal method is unsuited for the required use or not accepted by the authorities (replacement) - with the smallest number of animals necessary for quality science (reduction) - with the implementation of state-of-the-art practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions (refinement). Sanofi has Animal Ethics Committees with principles to ensure impartiality and independence of the ethical review. Opella rarely authorizes animal testing and only when the regulatory and scientific merit is established and under strict ethical over-sight. If animal testing is authorized, Sanofi monitors compliance by third parties (breeders, contract research organizations, not-for-profit collaborations). In addition to the legal obligations, Sanofi has set internal standards to align requirements across the world and to ensure high welfare considerations. All Sanofi sites maintain or seek independent accreditation of their animal care and use programs through recognized expert organizations such as AAALAC International. Sanofi applies the same principles to subcontractors and breeders; their animal welfare program is assessed by Sanofi professionals to ensure the consistency of

	the animal care. External partners are expected to comply with animal welfare laws and commit to the spirit of the Sanofi policy on the protection of animals. Sanofi professionals will evaluate animal care and use program of external partners on a regular basis and approve those that comply with Sanofi standards. Sanofi is also a signatory of the Marseille Declaration, a pharmaceutical industry declaration on animal housing and use (see link below). External stakeholders can raise concerns directly to the Chief Veterinary Officer through Sanofi.com.
Report	- Sanofi-policy-on-the-protection-of-animals-2018-EN.pdf - Marseille-Declaration-2022-signed.pdf (sanofi.com) - Responsible use of animals in research and production (sanofi.com)

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industry

Topic	Energy Intensive industries
Summary of Issue	Opella Brazil is part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella Brazil's operations include the entity's offices in São Paulo (SP, Brazil) and a manufacturing site in Suzano (SP, Brazil). Opella Brazil operates in the pharmaceutical industry which has been recognised by B Lab as an energy-intensive industry. Of the company's total energy use, the most energy intensive activities are related to the manufacturing site. The company tracks energy and emissions on a local level. Regarding Opella's consolidated operations, the company uses electricity and natural gas as the main sources of energy, with the offices in São Paulo (SP, Brazil) and manufacturing site in Suzano (SP, Brazil) using renewable electricity (100% in 2023; aligning with the objective to have 100% of sites worldwide using renewable electricity by 2025). Accordingly, the company relies on Power Purchase Agreements (PPAs), self-generated solar photovoltaic energy and renewable electricity certificates.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	In the previous fiscal year, 100% of Opella Brazil was derived from the production of medicines/drugs, food/dietary supplements, and cosmetics. The entity's manufacturing facility has an energy intensity of 0.23 kWh per product produced for its standard manufacturing processes.
Impact on Stakeholders	Energy-intensive activities, such as manufacturing activities, pose an environmental risk due to the related emissions derived from energy use. The extent of environmental impact is dependent on the energy sources utilised and the management practices in place to manage energy use.
Implemented Management Practices	Energy consumption and emission reductions are managed at site levels and coordinated at the global level to reach ambitious targets.

	The company uses the following best practices to minimise energy use and carbon emissions: • Energy efficiency • Renewable Electricity • Decarbonizing heat through electrification and new technologies While the company already decreased its Scope 1 & 2 emissions by 57% in 2023 compared to a 2019 baseline, the objective is to reach 65% emissions reduction & use 100% renewable electricity by 2025. Opella intends to establish a new science-based target (covering Scopes 1, 2 and 3). As part of this process, Opella is working to develop new baseline emissions data of our Scope 3 emissions.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Consumer Protection

Issue Date	2019-2023
Topic	Consumer protection (Undue advertising & lack of Consumer Safety Standards)
Summary of Issue	Opella Brazil is part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella Brazil's operations include the entity's offices in São Paulo (SP, Brazil) and a manufacturing site in Suzano (SP, Brazil). In the last five years, Opella Brazil experienced five (5) minor cases related to consumer advertising and technical complaints. No cases led to risk or harm to consumers. However, minor fines for two (2) closed cases were issued under the ANVISA damage prevention clause and three (3) cases are ongoing due to the company's appeal. - Case 1 (Dorflex® Icy Hot Arnica) A regulatory fine (Anvisa) related to advertisement issues on the product's website. The company was notified in 2016 & the case closed in 2021. - Case 2 (Dorflex®) A regulatory fine (Anvisa) related to potential issue in the product's secondary packaging. The company was notified in 2017 & the case closed in 2021. - Case 3 (Novalgina®) A regulatory notification (2019) followed by an infraction notice (Anvisa) in 2022 related to technical complaints involving Novalgina family products. Opella Brazil filed an appeal to Anvisa in September 2022. The case is ongoing. - Case 4 (Novalgina®) A regulatory fine related to product safety. A foreign body was detected inside the ampoule of Novalgina® injectable which imposed a mandatory product recall in 2021. In 2022 ANVISA issued the relevant infraction notice imposing a fine. Opella Brazil filed an appeal to ANVISA in January 2023. The case is ongoing.

	- Case 5 (Enterogermina®) A regulatory infraction related to advertisement issues on the product's website and social media account pages. The company was notified in 2021 and the infraction notice was issued in March 2023. Opella Brazil filed an appeal in April/2023. The case is ongoing. The company reaffirms that the entire process of development, manufacturing, and distribution of Opella's products undergoes regular inspection by the health authorities, as well as regulatory approval of all products. The company takes laws, regulations and consumer protection very seriously.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	The fines imposed in the two (2) closed cases are minor, together they represent less than 0,01% of the company's revenues.
Resolution	Two (2) cases are closed with fines issued under the ANVISA damage prevention clause. The other three (3) cases are still ongoing
Impact on Stakeholders	The five (5) cases resulted in no harm to consumers. The two cases related to Consumer Safety Standards (Case 3 & 4 Novalgina®) resulted in no consumer illness or injury. The cases related to advertisements issues did not result in damages to consumers.
Implemented Management Practices	For the closed cases, the company has paid minor fines and amended the advertising as required. For the ongoing cases, despite not being closed, the company has implemented a Corrective and Preventative Action (CAPA) plan.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Litigation & Arbitration cases

Issue Date	2019-2023
Topic	Labor litigation dispute
Summary of Issue	Opella Brazil is part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella Brazil's operations include the entity's offices in São Paulo (SP, Brazil) and a manufacturing site in Suzano (SP, Brazil). In the last five years, Opella Brazil experienced two (2) labor litigation cases regarding wage and hour disputes.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	Both cases represent less than 0.1% of the company's revenues.
Resolution	Case 1 was settled. Case 2 ruling was unfavourable
Impact on Stakeholders	The two cases relate to labor disputes. In labor dispute cases, the main stakeholders affected are the company's employees and direct collaborators (independent contractors & outsourced staff).
Implemented Management Practices	The company has established a workflow to evaluate labor practices for outsourced providers and avoid related situations. The company developed new programs for variable salaries in collaboration with internal departments