Opella CEE (Central and Eastern Europe)

Disclosure Report

Date Submitted: September 13th, 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: Operations located in Conflict Zones

Topic	Company operates and has suppliers located in Conflict Zones
Summary of Issue	Opella CEE's legal entities are part of Opella, the consumer health care business unit of Sanofi, a pharmaceutical company. Opella CEE includes the assessment of the following entities: 1 - Opella Hungary-Poland (HQ, Manufacturing & R&D) 2 - Opella Czech-Slovakia-Ukraine-Romania (wholesale/retail) Opella CEE has ongoing operations in Ukraine, which is in an ongoing conflict due to the military aggression launched by the Russian Federation. Opella CEE is currently working in line with the Martial Law and continues to supply / make available essential medicinal products to the society in Ukraine. As part of its operations in Ukraine, the company also has direct suppliers related to marketing services and external workforce. Patients' health and well-being is a priority for Opella CEE and thus it continues operations in Ukraine supplying / making available essential medicinal products to the society. Opella CEE, in accordance with the national legislation and regulations imposed by the Martial Law, does not operate directly or indirectly in the territories within Ukraine that is currently occupied by the aggressor. The company also supplies / makes available essential medicinal products in countries outside of this military conflict.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	In the fiscal year end of 2023, 6% of Opella CEE's total revenue was generated through sales in Ukraine, while suppliers in Ukraine represent 2% of Opella CEE"s total expenses.
Impact on Stakeholders	Business activities located in conflict zones are considered high-risk as they are more likely to cause or contribute to the conflict and/or sociopolitical instability. Countries classified as conflict zones are more likely to have a weak rule-of-law or a corrupt judicial system, which could undermine the effectiveness of operational grievance

	mechanisms for these businesses and their suppliers. In addition, the safety of the company's workers and other potential human rights violations are at risk.
Implemented Management Practices	The company has taken measures to help its employees in Ukraine. Other team members working with Sanofi (including Oppela) from neighboring countries are supporting the colleagues and their families from Ukraine who have made the difficult decision to leave the country. Opella CEE based in Ukraine has moved supplies from high-risk areas to safer warehouse locations and has established new shipping centers in lower-risk zones; and embraced new partnerships to keep on top of logistics. The company is also committed to helping its patients and clinicians access sites safely, stay connected with each other through migration and disruption, and access their investigational medicines. Additionally, Opella CEE follows a set of Standards which provide a framework to enable it to work effectively with customers, patients and other stakeholders in accordance with the company's Code of Conduct and all relevant applicable laws, regulations, and industry guidelines. The Code has a section on the company's stand against bribery and corruption which ensures that the company's operations are not tied to the conflicts surrounding Ukraine and do not in any way exacerbate the conflicts. The company also has a Suppliers Code of Conduct in place. The company's suppliers and service providers undergo a risk based due diligence aiming at assessing any potentially exposure to corruption and/or any other illicit/ inappropriate practices.
Report	https://www.sanofi.com/en/media-room/our-response-to-the-situation-in-ukraine
Other Management Comments	Opella CEE is currently working in line with the martial law and continues to supply / make available essential medicinal products to the society in Ukraine. Opella also supplies / makes available essential medicinal products in countries outside of this military conflict.Patients' health and well-being is a priority for Opella and thus continues operations in Ukraine supplying / making available essential medicinal products to the society. Opella CEE, in accordance with the national legislation, does not operate directly or indirectly in the territories occupied by the aggressor.

	In daily operations Opella CEE in Ukraine follows all relevant Standards and Procedures applied for compliant cooperation with partners. The company also has a Suppliers Code of Conduct in place. The company's suppliers and service providers undergo a risk based due diligence aiming at assessing any potential exposure to corruption and/or any other illicit/ inappropriate practices.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industry

Topic	Water Intensive Industry
Summary of Issue	Opella CEE's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella CEE includes the assessment of the following entities: 1 - Opella Hungary-Poland (HQ, Manufacturing & R&D) 2 - Opella Czech-Slovakia-Ukraine-Romania (wholesale/retail) Opella CEE 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 in the manufacturing sites; Rzeszów facility in Poland, and Veresegyhaz facility in Hungary. - At Rzeszów's facility, the company uses municipal water for manufacturing and cleaning, with water reduction efforts deployed at the site, including the elimination of detergents from cleaning processes. The region is a medium-high water risk area. - At Veresegyhaz's facility, the company uses municipal water for manufacturing and cleaning, with water reduction efforts deployed at the site and consumption below 10,500 cubic meters per quarter. The region is a low water risk area.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	In the previous fiscal year, 100% of Opella CEE was derived from the production of self-medication medicines/drugs, food/dietary supplements, and cosmetics. Considering local contexts, each manufacturing site has its own water intensity as described below. - Rzeszów's manufacturing facility has a water intensity of 0.277 L per unit of product produced for its standard manufacturing processes. - Veresegyhaz's manufacturing facility has a water intensity of 0.288L per 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 Management Practices	The company does not carry out an assessment of how it compares to other peers in the industry regarding water use and 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 Industry

Topic	Chemical Intensive industries
Summary of Issue	Opella CEE's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella CEE includes the assessment of the following entities: 1 - Opella Hungary-Poland (HQ, Manufacturing & R&D) 2 - Opella Czech-Slovakia-Ukraine-Romania (wholesale/retail) Opella CEE 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 CEE 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 CEE 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: Other - Mandatory Animal Testing

Issue Date	Ongoing
Topic	Opella CEE is a subsidiary of Opella and sells consumer healthcare products. Opella CEE manufactures and sells but does not develop new drugs (eg. new drug molecules), therefore Opella CEE does not require the use of animal testing.
Summary of Issue	Opella CEE's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella CEE includes the assessment of the following entities: 1 - Opella Hungary-Poland (HQ, Manufacturing & R&D) 2 - Opella Czech-Slovakia-Ukraine-Romania (wholesale/retail) 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 CEE 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 CEE, no animal testing was performed in the last five years. Opella CEE does not research and develop new drugs molecules. Opella CEE manufactures and sells Over the Counter (OTC) products which have already been proven to be safe and effective.
Size/Scope of Issue *(e.g. $*	Opella CEE did not conduct animal testing in past 5 years.

financial implication, # of individuals affected)	However, the company currently sells medicines that had to go through animal testing previously.
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 CEE 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 oversight. 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 programs 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 Industries

Topic	Energy Intensive industries
Summary of Issue	Opella CEE's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella CEE includes the assessment of the following entities: 1 - Opella Hungary-Poland (HQ, Manufacturing & R&D) 2 - Opella Czech-Slovakia-Ukraine-Romania (wholesale/retail) Opella CEE 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 in the manufacturing sites; Rzeszów facility in Poland, and Veresegyhaz facility in Hungary. Regarding Opella's consolidated operations, the company uses electricity and natural gas as the main sources of energy, with the majority of sites using renewable electricity (87% in 2023 with the objective to have 100% of the sites by 2025). Accordingly, the company relies on Power Purchase Agreements (PPAs), self-generated solar photovoltaic energy and renewable electricity certificates. Furthermore, some sites uses a mix of biogas and natural gas for its operations.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	In the previous fiscal year, 100% of Opella CEE was derived from the prodution of self-medication medicines/drugs, food/dietary supplements, and comestics. Considering local contexts, each manufacturing site has its own energy intesity as described below. - Rzeszów's manufacturing facility has an energy intensity of 0.24 kWh per product produced for its standard manufacturing processes. - Veresegyhaz's manufacturing facility has an energy intensity of 0.13 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.