



Sanofi Consumer Healthcare Hispanic Latin America

Disclosure Report
Date Submitted: December 2023



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	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Biodiversity Impacts	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Chemicals	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Disclosure Alcohol	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Disclosure Firearms Weapons	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Disclosure Mining	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Disclosure Pornography	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Disclosure Tobacco	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Energy and Emissions Intensive Industries	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Fossil fuels Gambling	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Genetically Modified Organisms	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Illegal Products or Subject to Phase Out	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Industries at Risk of Human Rights Violations	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Monoculture Agriculture	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Nuclear Power or Hazardous Materials	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Payday, Short Term, or High Interest Lending	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Water Intensive Industries	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Tax Advisory Services	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Breaches of Confidential Information	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Bribery, Fraud, or Corruption	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Company has filed for bankruptcy	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Consumer Protection	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Financial Reporting, Taxes, Investments, or Loans	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Labor Issues	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Large Scale Land Conversion, Acquisition, or Relocation	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Litigation or Arbitration	<input type="checkbox"/>	<input checked="" type="checkbox"/>
On-Site Fatality	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Penalties Assessed For Environmental Issues	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Political Contributions or International Affairs	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Recalls	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Significant Layoffs	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Violation of Indigenous Peoples Rights	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Company prohibits freedom of association/collective bargaining	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Company workers are prisoners	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Conduct Business in Conflict Zones	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Confirmation of Right to Work	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does not transparently report corporate financials to government	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Employs Individuals on Zero-Hour Contracts	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Facilities located in sensitive ecosystems	<input checked="" type="checkbox"/>	<input type="checkbox"/>
ID Cards Withheld or Penalties for Resignation	<input type="checkbox"/>	<input checked="" type="checkbox"/>
No formal Registration Under Domestic Regulations	<input type="checkbox"/>	<input checked="" type="checkbox"/>
No signed employment contracts for all workers	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Overtime For Hourly Workers Is Compulsory	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Payslips not provided to show wage calculation and deductions	<input type="checkbox"/>	<input checked="" type="checkbox"/>

	Yes	No
Sale of Data	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Tax Reduction Through Corporate Shells	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Workers cannot leave site during non-working hours	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Workers not Provided Clean Drinking Water or Toilets	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Workers paid below minimum wage	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Workers Under Bond	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Supply Chain Disclosures

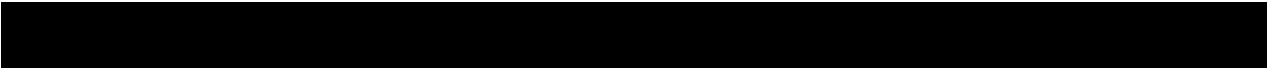
	Yes	No
Please indicate if any of the following statements are true regarding your company's significant suppliers.		
Business in Conflict Zones	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Child or Forced Labor	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Negative Environmental Impact	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Negative Social Impact	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>	<input checked="" type="checkbox"/>



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Company	Sanofi CHC Mexico
Topic	Water Intensive Industries
Summary of Issue	<p>Sanofi CHC Mexico operates in the pharmaceutical industry which has been recognised as a water-intensive industry due to manufacturing and cleaning processes.</p> <p>The company's manufacturing facility is located in a water stress area- Ocoyoacac municipality, in the state of Mexico (Lerma-Chapala Basin). Issues related to water use and management are water stress, water depletion, and water quality at the local water bodies.</p> <p>The company's main water source is deep wells located at the manufacturing facility which the company has permits to extract. Furthermore, the company also uses municipality water as a backup.</p> <p>The main risks identified by the company related to the facility's water management are:</p> <ul style="list-style-type: none">- Physical risk (water scarcity and water quality)- Regulatory risk (lack of regulations)- Reputational risk (biodiversity importance).
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	<p>In the previous fiscal year, 100% of Sanofi CHC Mexico's revenues was derived from the sale of over-the-counter medicines/drugs, food/dietary supplements, and cosmetics.</p> <p>In the last fiscal year, the company consumed 56,777 m3/year of water. Sanofi CHC Mexico has a water intensity of 0,51 liters of water per unit of product.</p>
Impact on Stakeholders	<p>The company has a plant in Ocoyoacac, a municipality in the State of Mexico. Considering the current situation of the Lerma-Chapala Basin, with the aforementioned risks identified, the company's operations contribute to the risk of water stress and depletion of the local basin if water management is not appropriate.</p> <p>The main stakeholders affected are other water users in the region, such as local water authorities & regulators, residents, other industrial plants & farmers, as well as the local biodiversity.</p>
Management Practices	<p>Sanofi CHC'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 manage properly the watershed the company relies on. Globally Sanofi CHC has the target of reducing water consumption by 20% by 2030, with 2019 levels as a benchmark. All Sanofi CHC's production sites will contribute to this global reduction, including the Ocoyoacac manufacturing facility.</p> <p>At Ocoyoaca site, the company has the following practices in place:</p> <ul style="list-style-type: none">- Initial filtration system (after water is withdrawn from the well)- Wastewater treatment plant for chemical water and biological water.- Treated wastewater is discharged into the river or stored in a tank for the fire protection system.- The wastewater effluent is analyzed weekly and monthly for internal control,



- Implementation of AWS Standard Indicators 1.3.2, 1.3.3 and 1.5.3 to gather additional data on site and watershed balance
- Installation of additional flow meters to better quantify site water withdrawals, reuse, consumption and improvement areas
- Development of a water efficiency roadmap
- Development of analysis/scenario of flood events to determine site exposure to flood risk

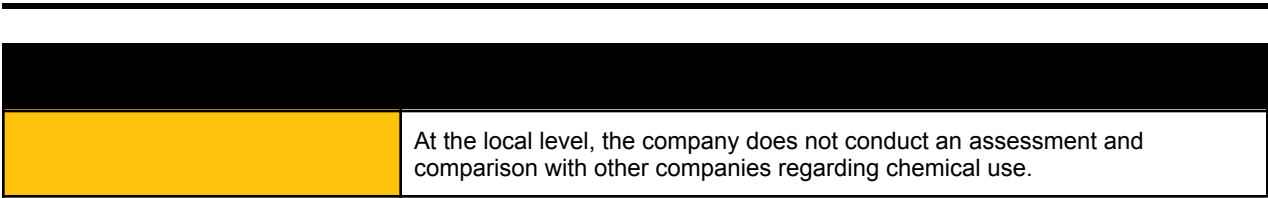
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Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Company	Sanofi CHC Mexico
Topic	Chemical Intensive Industries
Summary of Issue	<p>Sanofi CHC Mexico operates in the pharmaceutical industry which has been recognized as a chemical-intensive industry.</p> <p>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) under REACH. At Ocoyoacac's manufacturing plant, the company uses SVHC lab chemicals for quality control purposes. While REACH regulation is only applicable in the EU, resulting in Sanofi CHC Mexico not being required to comply with the REACH requirements, no formula produced in the Ocoyoacac site contains ingredients listed as SVHC according to the REACH criteria.</p>
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	<p>The use of chemicals for quality control purposes at the Ocoyoacac site is below 1 ton/year.</p> <p>Given the reported use is below 1 ton/year, the facility is exempted from restriction and authorization (processes linked to SVHCs) in Mexico.</p>
Impact on Stakeholders	<p>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.</p> <p>In the last five years, Sanofi CHC Mexico has not experienced any significant incidents and/or fines related to environmental or worker's health impacts for chemical use.</p>
Management Practices	<p>All of the 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.</p> <p>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 Sanofi CHC products. Moreover, Sanofi CHC Mexico has documented HSE requirements to minimize the use of Carcinogens, Mutagens, Reprotoxic and volatile organic compounds.</p> <p>All product formulas are approved by Mexican 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.</p>





Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Facilities located in sensitive ecosystems

Company	Sanofi CHC Mexico
Topic	The company has a manufacturing facility in Ocoyoacac, which is considered a sensitive ecosystem.
Summary of Issue	<p>As a subsidiary of Sanofi Consumer Healthcare, this company manufactures pharmaceutical products in a facility located near the following sensitive ecosystems in Ocoyoacac, a municipality in Mexico:</p> <ul style="list-style-type: none">- Ciénegas del Lerma / 5 km from site.- Parque Estatal Santuario del Agua Subcuenca Tributaria Río San Lorenzo / 8 km from site.- Parque Nacional Insurgente Miguel Hidalgo y Costilla "La Marquesa" / 15 km from site.
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	In terms of area, 100% of the company's facilities are located near sensitive ecosystems. Other than that, 82% of the company's manufacturing, in terms of value, also happens in this area.
Impact on Stakeholders	Having facilities/operations near protected/sensitive ecosystems can potentially impact the flora, fauna and quality of the ecosystem (e.g. noise & light pollution from the facilities, spills, air / soil / water pollution owing to company's operations). Also, there is a risk of negatively impacting the local communities.
Management Practices	<p>Sanofi Consumer Healthcare Mexico implements the following practices to address the risk associated with operations close to sensitive ecosystems:</p> <p>The company conducts a biodiversity assessment that considers the following criteria:</p> <ol style="list-style-type: none">(1) Proximity with natural/semi-natural areas,(2) Proximity with regulated/classified sensible areas,(3) Proximity with wetlands,(4) Potential interaction with an ecological corridor,(5) Potential presence of protected species / sensible habitats,(6) Anthropic pressure. <p>The last assessment was developed in 2022 and the company intends to update it every 3 years.</p> <p>Globally, Sanofi Consumer Healthcare has a global commitment to "protect biodiversity at our sites, particularly those located near sensitive natural areas. By 2025, our priority sites with the highest potential impacts on local biodiversity will implement specific biodiversity management plans. This approach will be extended to all our sites located near biodiversity-sensitive areas by 2030."</p> <p>The organization has a Biodiversity Management standard which describes the management of biodiversity by each site. As aligned with Sanofi's public commitments to Nature, the subsidiary's objective is to reduce the impacts on biodiversity of its direct operations – in particular at sites exposed to high risks</p>

	<p>for biodiversity. This standard sets out the following minimum requirements:</p> <ul style="list-style-type: none">- Design: biodiversity risks need to be considered for the design of new facilities/buildings or in case of revamping existing ones,- Operational: biodiversity risks need to be considered in its daily operations to reduce the local pressure of its activities on biodiversity and implement the best practices promoting biodiversity. <p>- The company reported there were no stakeholders' concerns raised in relation to this site.</p>
Report	Environmental Sustainability and Resilience commitments



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Animal Testing

Company	Sanofi CHC Mexico
Topic	Required animal testing by regulatory authorities
Summary of Issue	Sanofi Consumer Healthcare Mexico is legally required to perform animal testing on two products of its portfolio. Four batches are required to be tested per year. This is due to safety concerns and is required by the Health Authority. In very rare circumstances, the company may need to perform animal testing to ensure the efficacy of a specific product. However, this has not been done in the past 5 years. No product development occurs in Sanofi CHC Mexico.
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	Two products are required to be tested in animals, representing 4.7% of Sanofi CHC Mexico's portfolio. These products were divested in 2023 so are no longer part of CHC.
Impact on Stakeholders	<p>Sanofi CHC Mexico does not develop new drug molecules. The company used to perform animal testing in rare situations when it was required by Regulatory Authorities due to safety concerns. From mid-2023 no products from Sanofi CHC need to be tested on animals, as the products have been divested.</p> <p>Animal testing and experimentation are widely used to develop and test the safety of new drug molecules. Many of these experiments can cause pain to the animals involved or reduce their quality of life in other ways.</p>
Management Practices	<p>Sanofi CHC Mexico follows the principles laid out in the publicly available information on Sanofi's global position on animal testing "Responsible use of animals in research and production". This policy includes, but is not limited to, the following practices:</p> <ul style="list-style-type: none">- Any use of animals is overseen by ethics committees that monitor the care and use of animals, as well as the active implementation of the "3Rs" (replacement, reduction and refinement of animals in research and production), to which Sanofi has been committed for decades. Our approach is to use animals only in the absence of adequate alternative methods to achieve an identical result (Replace), to use the smallest number necessary for quality science (Reduce), and to use state-of-the-art practices to protect animal welfare and prevent animal pain and distress in living and procedural conditions (Refine),- Sanofi has signed the French Transparency Charter on the use of animals for scientific and regulatory purposes. This engagement has followed the signature of the Belgian agreement. Sanofi is globally committed to making information on the use of animals for scientific or regulatory purposes accessible to the general public. <p>All animal testing conducted in Sanofi CHC Mexico is outsourced. The outsourced services are certified by Health Authorities in Mexico to be in compliance with Mexican regulations. In addition to the legal obligations, external partners (contract research organizations, breeders and suppliers, and any other partners) are expected to comply with animal welfare laws and commit to the spirit of the Sanofi Policy on the Protection of Animals.</p>



	External stakeholders can raise concerns and questions directly to the Chief Veterinary Officer through this contact form .
Report	<p>1. Sanofi Animal Protection Factsheet: https://www.sanofi.com/assets/dotcom/content-app/documents/Animal-Protection.pdf</p> <p>2. Marseille Declaration: https://www.sanofi.com/assets/dotcom/content-app/documents/Marseille-Declaration-2022-signed.pdf</p>



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Recalls

Company	Sanofi CHC SOCOPAC
Issue Date	2020 & 2022
Topic	Mandatory and voluntary recalls
Summary of Issue	<p>Sanofi CHC SOCOPAC had two voluntary recalls and one mandatory recall over the last 5 years.</p> <ul style="list-style-type: none">- Selsun 2,5% shampoo <p>Sanofi CHC Peru has decided to prune the product, resulting in a mandatory recall per local regulation.</p> <ul style="list-style-type: none">- Buscapina Compositum N tablets. <p>As a precautionary measure, Sanofi CHC Panama conducted a voluntary recall in Panama due to a wrong leaflet in the product - Hyoscine butylbromide+Metamizol instead of Hyoscine butylbromide+Paracetamol.</p> <ul style="list-style-type: none">- Buscapina Fem 20mg/400mg tablets. <p>Out Of Specification (OOS) results for microbial testing was found for an already released batch on the market. As a precautionary measure, Sanofi CHC Colombia conducted a voluntary recall in Colombia.</p>
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	<p>Selsun 2,5% shampoo Sanofi CHC Peru. The recall included 42 batches of the product.</p> <p>Buscapina Compositum N tablets. The recall included 3 batches of the product.</p> <p>Buscapina Fem 20mg/400mg tablets. The recall included 1 batch of the product</p>
Impact on Stakeholders	<p>None of the recalls resulted in consumer illness or injury.</p> <ul style="list-style-type: none">- Selsun 2,5% shampoo <p>The assessment resulted in no risk to patient/subject/consumer.</p> <ul style="list-style-type: none">- Buscapina Compositum N tablets. <p>The Health Hazard Evaluation (HHE) concluded that the main theoretical safety risk would be the use in non-appropriate population due to missing information for paracetamol.</p> <ul style="list-style-type: none">- Buscapina Fem 20mg/400mg tablets. <p>The Health Hazard Evaluation (HHE) concluded that the cumulative weighted evidence is insufficient to confirm the risk(s) due to Out of Specification (OOS) of microbial contamination of affected batch of Buscapina fem tablet.</p>
Management Practices	<p>There are no similarities between the recall events. Recalls are managed by a global procedure which is in line with international and local regulatory requirements. Each recall is managed by the Quality department and includes root cause analysis and corrective and preventative action, as appropriate.</p> <p>The company has a global procedure called; "Escalation of Quality Events and Management of Quality Alerts" to address recall issues. It details the internal management of recalls and requires that all quality events and alerts are reported in a timely, structured, and concise way so that the risk assessment and associated mitigation plan is shared at the appropriate management level and subsequently managed with the adequate level of priority.</p>



Related Incidents (Yes/No)	No