



Sanofi Consumer Healthcare Italy

Disclosure Report
Date Submitted: November 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 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 checked="" type="checkbox"/>	<input 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 Industry

Topic	Water Intensive Industry
Summary of Issue	<p>Sanofi CHC Italy operates in the pharmaceutical industry which is recognised as a water-intensive industry due to manufacturing and cleaning processes.</p> <p>The company's manufacturing facility is located at Origgio, in Lombardy region, Northern Italy. Although the region is not a water stress area, the company is working on a water use reduction plan.</p> <p>The company's plant (biotechnological) uses municipal water for production and underground water for the plant utilities and serves as a global hub for the production of key brands under Sanofi CHC's portfolio.</p>
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	<p>In the previous fiscal year, 100% of Sanofi CHC Italy was derived from the production of self-medication medicines/drugs, food/dietary supplements, and cosmetics</p> <p>Sanofi CHC Italy has a water intensity of 0.77 liter per unit of product produced for its standard manufacturing processes.</p>
Impact on Stakeholders	<p>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.</p> <p>The company uses municipal water supply for pharma production and underground water supply for the plant's utilities.</p> <p>The main stakeholders affected are other water users in the region, such as local water authorities & regulators, residents, other industrial plants, farmers, and the local biodiversity.</p>
Management Practices	<p>The company does not carry out an assessment of how it compares to other peers in the industry regarding water use and management.</p> <p>Globally, Sanofi CHC has the target of reducing water consumption by 20% by 2030, with 2019 levels as a benchmark.</p> <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 properly manage the watershed the company relies on.</p>



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industry

Topic	Chemical Intensive industries
Summary of Issue	<p>Sanofi CHC Italy operates in the pharmaceutical industry which it is 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). At Origgio manufacturing plant, the company does use SVHC lab chemicals for quality control purposes. All product formulas are approved by the Italian Health Authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy.</p> <p>The level of the ingredients in the finished products remain adequate for the safe and intended use of consumers.</p>
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	The use of chemicals for quality control purposes at the Origgio site is approximately 1 ton/year. Given the reported use is below 1 ton/year, the facility is exempted from restriction and authorization (processes linked to SVHCs) in the EU.
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 Italy has not experienced any significant incidents and/or fines related to environmental or worker impacts of its chemical use.</p>
Management Practices	<p>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.</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 Italy has documented HSE requirements to minimize the use of Carcinogens, Mutagens, Reprotoxic and volatile organic compounds.</p> <p>All product formulas are approved by Italian 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> <p>At the local level, the company does not conduct an assessment and comparison with other companies regarding chemical use.</p>



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Recalls

Issue Date	2018, 2019, 2022
Topic	Mandatory and voluntary recalls
Summary of Issue	<p>In the last five years, Sanofi CHC Italy experienced one (1) mandatory recall and six (6) voluntary recalls for several reasons as detailed below.</p> <ul style="list-style-type: none">- Recall 1 (Zerinol 300 mg + 2mg) Mandatory recall. Reduction of the shelf-life of the finished product from "60 months" to "36 months". In June 2022, the company initiated a Mandatory recall for batches that have reached the expiry date of 36 months. This product is no longer part of Sanofi Consumer Healthcare Italy's portfolio.- Recall 2 Voluntary recall. Impurity found in one of the medicine's excipients.- Recall 3, Recall 4 & Recall 5 Voluntary recalls. Presence of foreign bodies inside the products.- Recall 6 Voluntary recall. Possible contamination of the product with impurity.- Recall 7 Voluntary recall. Presence of a substance banned from cosmetic products following a new cosmetics regulation. This product is no longer part of Sanofi Consumer Healthcare Italy's portfolio. <p>Such recalls were all duly managed as per the global procedure in force, which is in line with international and local regulatory requirements. Each recall was properly managed by the Quality Department that focused on root cause analysis and corrective and preventive action, as appropriate.</p>
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	<p>Recall 1 represented around 6.5% of the company's overall production. Recall 2 represented around 0.1% of the company's overall production. Recall 3 represented around 0.04% of the company's overall production. Recall 4 represented around 0.1% of the company's overall production. Recall 5 represented around 0.1% of the company's overall production. Recall 6 represented around 1.7% of the company's overall production. Recall 7 represented around 0.1% of the company's overall production.</p>
Impact on Stakeholders	<p>None of the recalls resulted in consumer illness or injury.</p> <ul style="list-style-type: none">- Mandatory Recall 1 (Zerinol 300 mg + 2mg) No risks for consumers were identified. The recall was not related to product quality and no further stability out of specification (OOS) has been registered on this product since 2018.- Voluntary Recall 2 It may have caused temporary adverse health consequences.- Voluntary Recall 3 It may have posed a constraint for users but it is not likely to cause adverse health consequences.- Voluntary Recall 4 & Recall 5

	<p>It may have caused a mistreatment or a temporary health problem.</p> <ul style="list-style-type: none">- Voluntary Recall 6 <p>It may have caused health risks.</p> <ul style="list-style-type: none">- Voluntary Recall 7 <p>It may have posed a constraint for users but it is not likely to cause adverse health consequences.</p>
Management Practices	<p>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 preventive action, as appropriate. 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>



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Facilities located in sensitive ecosystems

Topic	The company has a manufacturing facility at Origgio, in Lombardy region, Northern Italy.
Summary of Issue	The company's biotechnological plant is located adjacent to the following sensitive ecosystems in Origgio. ZSC IT2050001 Pineta di Cesate (part of Natura 2000) ZSC IT2050002 Boschi delle Groane (part of Natura 200) ZSC IT2050006 Bosco di Vanzago (managed by WWF)
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	Sanofi CHC Italy has only one manufacturing facility at Origgio. Therefore, 100% of the company's area and production are located adjacent to sensitive ecosystems.
Impact on Stakeholders	Having facilities & operations near protected/sensitive ecosystems can potentially impact the quality of the ecosystem (flora, fauna and the natural dynamics of these natural systems) Potential impacts derived from the company 's operations are noise & light pollution, potential spills, air / soil / water pollution.
Management Practices	A biodiversity assessment was conducted by a 3rd party expert (Ramboll) in 2022 based on the methodology "BIODIVERSITY INDICATORS FOR SITE-BASED IMPACTS" developed by UNEP-WCMC, Conservation International and Fauna & Flora International. In sum, the Biodiversity Risk Mapping Report shows that Origgio has: - A Moderate (22%) exposure rating - A high (55%) Vulnerability risks - A High Biodiversity risks The company's standard operation has low risk of impacting the adjacent protected/sensitive ecosystems

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Other - Mandatory Animal Testing

Issue Date	Ongoing
Topic	Sanofi CHC Italy is a subsidiary of Sanofi CHC and sells consumer healthcare products. Sanofi CHC Italy manufactures and sells but does not develop new drugs (eg. new drug molecules), therefore Sanofi CHC Italy does not require the use of animal testing.
Summary of Issue	<p>As a company that manufactures pharmaceutical products, Sanofi CHC 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.</p> <p>As a subsidiary of Sanofi CHC, Sanofi CHC Italy can market over the counter (OTC) products because they have already been proven to be safe and effective. Sanofi CHC 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.</p>
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	Sanofi CHC Italy has not conducted any animal testing on the products in the Opella Healthcare Italy portfolio over the past 5 years. However, the company currently sells medicines that had to go through animal testing previously.
Impact on Stakeholders	<p>Sanofi CHC Italy does not develop new drug molecules and as stated above would only perform animal testing in rare situations when required by Regulatory Authorities due to safety concerns.</p> <p>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</p>
Management Practices	<p>Opella Healthcare Italy does not carry out animal testing at a local level. 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:</p> <ul style="list-style-type: none"> - 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). <p>Sanofi has animal ethics committees with principles to ensure impartiality and independence of the ethical review.</p> <p>Sanofi CHC 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).</p> <p>External partners are expected to comply with animal welfare laws and commit to the</p>

	<p>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.</p> <p>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. Further information can be found in the Sanofi Animal Protection Factsheet and Animal Protection Policy (links below).</p> <p>Sanofi is also a signatory of the pharmaceutical industry declaration on animal housing and use, Marseille Declaration (see link below)</p> <p>External stakeholders can raise concerns in relation to animal testing directly to the Chief Veterinary Officer through Sanofi.com.</p>
Reports	<p>Sanofi Animal Protection Factsheet</p> <p>Sanofi Policy on Animal Protection</p> <p>Signed Marseille Declaration</p>



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Litigation , Arbitration and Penalties

Issue Date	2020-2023
Topic	Penalties related to the late notification of shortage of medicinal product to the Health Authority.
Summary of Issue	<p>In the last five years, Sanofi CHC Italy had 19 penalties related to late notification of a shortage of medicinal products to the Health Authority.</p> <p>The shortage of medicinal products was communicated beyond the terms outlined in Art. 34, paragraph 6, of Legislative Decree no. 219/2006, as amended by Decree n. 35/2019 which resulted in penalties by the Italian Medicine Agency (AIFA).</p> <p>This issue is common across the pharmaceutical industry.</p>
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	The total penalties represent less than 1% of the company's revenues.
Impact on Stakeholders	This is a regulatory requirement. Therefore, the main stakeholders affected are the Health Regulatory Agency (AIFA) and final consumers.
Resolution	All penalties were paid by the company.
Implemented Management Practices	Sanofi CHC Italy is trying to improve internal ways of working to increase compliance with local regulatory requirements on shortages notifications.
Related Incidents	No related incidents