Sanofi CHC Western Europe

Disclosure Report

Date Submitted: March 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.

B Lab's Public Complaints Process

Any party may submit a complaint about a current B Corp through B Lab's Public Complaint Process. Grounds for complaint include:

1) Intentional misrepresentation of practices, policies, and/or claimed outcomes during the company's certification process
2) Breaches of the B Corp Community's core values as expressed in our Declaration of Interdependence

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	☐	☑
Fossil fuels 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: Other - Mandatory Animal Testing

Issue Date	Ongoing
Topic	Sanofi Consumer Healthcare (CHC) Western Europe is a cluster of subsidiaries of Sanofi CHC that sells consumer healthcare products. Sanofi CHC Western Europe does not perform research and development activities (eg. new drug molecules) that require the use of animal testing.
Summary of Issue	As a company that manufactures, and sells pharmaceutical products, Sanofi CHC is legally obligated to ensure the quality, safety, and efficacy of its medicines and other consumer healthcare products. As a subsidiary of Sanofi, Sanofi CHC Western Europe sells consumer healthcare products which have already been proven to be safe and effective and therefore do not require the generation of new animal safety data for their registration procedure. In summary, Sanofi CHC Western Europe would only perform animal studies in rare situations when required by Regulatory Authorities to evaluate and assess major safety concerns and if no alternative methods can be applied including if literature/data was unavailable for the study endpoints needed, and if performing human testing was unethical.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	Sanofi CHC Western Europe has not conducted any animal testing on its products portfolio over the past 5 years. However, the company sells healthcare products such as Over the Counter Products that rely on animal data generated previously to demonstrate the efficacy and safety of the treatment and/or to satisfy Regulatory Authorities requests.
Indirect Impact on Stakeholders	Sanofi CHC Western Europe 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. 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.
Management Practices	Sanofi CHC Western Europe does not carry out animal testing at the 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: - 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.

	Sanofi CHC rarely authorizes animal testing and only when the regulatory respective scientific merit is established and under strict ethical oversight. If animal testing is authorized, Sanofi CHC monitors compliance by third parties (breeders, contract research organizations, not-for-profit collaborations). 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. 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). Sanofi is also a signatory of the pharmaceutical industry declaration on animal housing and use, Marseille Declaration (see link below) External stakeholders can raise concerns in relation to animal testing directly to the Chief Veterinary Officer through Sanofi.com.
Report	Sanofi Animal Protection Factsheet Sanofi Policy on Animal Protection Signed Marseille Declaration

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Recalls

Issue Date	2022 & 2023
Topic	Mandatory and voluntary recalls
Summary of Issue	In the last five years, Sanofi CHC Western Europe experienced two (2) mandatory recalls and one (1) voluntary recall. - Recall 1 (Dexa-Rhinospray N Dexamethasone/ Tramazoline Nasal Spray) Mandatory recall in Belgium & Luxembourg. During routine stability tests, out -of -specifications results for 2 impurities were detected in 2 different batches. Voluntary recall in Belgium & Luxembourg. - Recall 2 (Selsun 1% Shampoo) Voluntary recall in Greece. Publication of an amendment of the EU regulation (1272 / 2008) which banned substances, which is part of several formulas of Selsun 1% (shampoo). Two fragrances used in the formulation of Selsun products were impacted. Because of this regulation, starting from 1 March 2022, all cosmetic products that include this substance must not be sold to the consumer anymore on the European market. - Recall 3 (Dexarhina spray) Mandatory recall in Greece. Out of Specifications results have been identified during long-term stability testing. The 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 including root cause analysis and corrective and preventive action.
Size/Scope of Issue *(e.g. $ financial implication, # of individuals affected)*	Recall 1 represented around 0.001% of the company's overall production. Recall 2 represented around 0.3% of the company's overall production. Recall 3 represented around 0.2% of the company's overall production.
Impact on Stakeholders	None of the recalls resulted in consumer illness or injury. - Recall 1 (Dexa-Rhinospray N Dexamethasone/ Tramazoline Nasal Spray) No consumers were affected. All other quality attributes tested for both these batches met specifications. Retain samples of the same batches met the specifications for the two impurities. - Recall 2 (Selsun 1% Shampoo) No consumers were affected. - Recall 3 (Dexarhina spray) No consumers were affected.
Management Practices	Recalls are managed according to global procedures 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 actions. The company has a set of global procedures to address quality alerts and recalls, defining the management and timely reporting and escalation of quality

	alerts and related mitigation plans. Summary of Corrective and preventative actions: - Recall 1 (Dexa-Rhinospray N Dexamethasone/ Tramazoline Nasal Spray - The product was transferred to a new CMO. - Recall 2 (Selsun 1% Shampoo) - The product was discontinued. - Recall 3 (Dexarhina spray - The product was transferred to a new CMO.