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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 and B Lab deems them to be material, the company must:

1) Be transparent about 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 systems are in place to avoid similar issues from arising in the future.

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

In addition to the voluntary indication of sensitive issues in the Disclosure Questionnaire, companies pursuing Certification also are subject to background checks 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.

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DISCLOSURE QUESTIONNAIRE

Company Name: Sanofi CHC NA
Date Submitted: July 11th, 2023

Industries & Products	Yes	No
Please indicate if the company is involved in production of or trade in any the following. Select Yes for all options that apply.		
Animal Products or Services		√
Biodiversity Impacts		√
Chemicals	√	More Details >>
Company Explanation Of Disclosure Item Flags		√
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	√	More Details >>
Tax Advisory Services		√

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		√

Outcomes & Penalties	True	False
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 Explanation Of Disclosure Item Flags		√
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	√	More Details >>
On-Site Fatality		√
Penalties Assessed For Environmental Issues		√
Political Contributions or International Affairs		√
Recalls	√	More Details >>
Significant Layoffs		√
Violation of Indigenous Peoples Rights		√
Other		√

Practices	True	False
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	√	More Details >>
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)		√
Company Explanation Of Disclosure Item Flags		√
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		√

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PROVIDED BY: Sanofi CHC NA UPDATED AS OF: July 11th, 2023

DISCLOSURE QUESTIONNAIRE CATEGORY	Environmentally Intensive Industries
TOPIC	Water Intensive Industries
SUMMARY OF ISSUE	Sanofi CHC NA does not consider itself to be a water intensive industry. Sanofi CHC NA operates in the pharmaceutical industry which has been recognized as a water intensive due to their manufacturing and cleaning processes.
SIZE/SCOPE OF ISSUE (e.g. $ financial implication, # of individuals affected)	In the previous fiscal year, 100% of CHCNA at Sanofi's revenue was earned from the sale of over the counter medicines/drugs, food/dietary supplements and cosmetics. NA CHC's water intensity was calculated in 2022 as 0.30 M3 per manufacturing unit.
IMPACT ON STAKEHOLDER(S)	As a water intensive industry, the manufacturing of pharmaceutical products poses risks such as water stress or depletion of local water sources if water use is not appropriately managed. The company has a plant in Chattanooga, Tennessee which sources its water from the public water supply, not considered a water stressed area.
IMPLEMENTED MGT PRACTICES	Although the company does not carry out an assessment of how it compares to others in the industry on a local level in relation to water use as there are no comparable consumer healthcare producers, benchmarks are performed on a global pharmaceutical producer level. Sanofi CHC NA does not have R&D, Bio-technology plants nor chemical plants to manufacture active pharmaceutical ingredients or excipients, nor manage biological products within its portfolio, activities generally recognized in the pharmaceutical industry as water-intensive. Globally Sanofi CHC has the target of reducing water consumption by 20% by 2030, with 2019 levels as a benchmark. All of Sanofi CHC's production sites will contribute to this global reduction, including the Chattanooga manufacturing facility, which is due to conduct a Gap Assessment in 2023 to establish a Water Efficiency Management Plan for NA CHC. 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.

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PROVIDED BY: Sanofi CHC NA UPDATED AS OF: July 11th, 2023

DISCLOSURE QUESTIONNAIRE CATEGORY	Other - Mandatory Animal Testing
ISSUE DATE	Ongoing
TOPIC	Sanofi CHC North America develops consumer healthcare products which do not require the use of animal testing during research. Animal testing is only performed in rare situations when required by Regulatory Authorities due to safety concerns.
SUMMARY OF ISSUE	As a company that creates and manufactures pharmaceutical products, the company 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 North America does not research and develop new drugs e.g., new drug molecules. Over the counter (OTC) products are on the market because they have already been proven to be safe and effective. Therefore, CHC would only perform animal studies in rare situations to evaluate and assess major safety concerns. Animal studies would therefore only be conducted as a final resort if no alternatives are available 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)	CHC North America at Sanofi has not conducted any animal testing in the past 5 years.
INDIRECT IMPACT ON STAKEHOLDER(S)	CHC NA 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. Many of these experiments can cause pain to the animals involved or reduce their quality of life in other ways.
IMPLEMENTED MGT PRACTICES	In the limited circumstance that Sanofi CHC NA is required to conduct animal testing due to regulatory requirements, Sanofi CHC NA 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 NA rarely authorizes animal use and only when the regulatory and scientific merit is established and under strict ethical over-sight. If animal testing is authorized, Sanofi CHC NA monitors compliance by third parties (breeders, contract research organizations, not-for-profit collaborations). External stakeholders can raise concerns in relation to animal testing directly to the Chief Veterinary Officer through Sanofi.com.
REPORT	Sanofi Animal Protection Factsheet: https://www.sanofi.com/assets/dotcom/content-app/documents/Animal-Protection.pdf Signed Marseille Declaration: https://www.sanofi.com/assets/dotcom/content-app/documents/Marseille-Declaration-2022-signed.pdf

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PROVIDED BY: Sanofi CHC NA UPDATED AS OF: July 11th, 2023

DISCLOSURE QUESTIONNAIRE CATEGORY	Litigation and Class Actions
ISSUE DATE	2019-2020
TOPIC	Complaints, Multi-district Litigation and Class Action lawsuits related to product content with potentially harmful long term effects.
SUMMARY OF ISSUE	The Company has various litigations across the US and Canada: 1. Sanofi CHC NA has various product liability litigations filed throughout the United States in multiple state and federal court districts (including multidistrict litigations). These various litigations allege claims of personal health injuries based on consumption or use of product ingredients, as well as economic loss claims, etc. 2. Litigation involving multiple plaintiffs across the USA and Canada, claiming personal injury and economic loss from a Sanofi CHC NA medication no longer on the market referred to as Zantac with ranitidine allegedly containing the chemical N-Nitrosodimethylamine (""""NDMA""""). Legacy Zantac with ranitidine was launched in the United States as a prescription medication by GSK in 1983 (GSK continued to market the Rx version until 2017). In 1995, GSK launched an OTC version of its Zantac with ranitidine 75mg formula. In 1997, generic ranitidine entered the market. In 1998, Pfizer acquired the OTC rights and in 2004 it launched a 150mg version of the product as well. In 2006, Boehringer Ingelheim acquired the U.S. OTC rights for Zantac, and in January 2017 Sanofi acquired those OTC rights. On September 13, 2019, FDA issued a statement alerting the public that some ranitidine medicines, including over-the-counter Zantac, contained a nitrosamine impurity called N-nitrosodimethylamine (NDMA) at low levels. NDMA is a known environmental contaminant found in drinking water, soil, and common foods, including meats, dairy products, and vegetables. People are routinely exposed to small amounts of NDMA every day. In October 2019, Sanofi issued a voluntary recall of all ranitidine Zantac OTC products in the U.S. and Canada. Since that time, the medical, scientific, and regulatory communities have extensively evaluated the safety of legacy Zantac's active ingredient ranitidine, and the data show there is no evidence of consumer harm from real-world use of legacy Zantac with ranitidine. Within days of FDA's September 2019 announcement, class actions and personal injury lawsuits were filed in U.S. courts, alleging that legacy Zantac with ranitidine caused various injuries.
SIZE/SCOPE OF ISSUE (e.g. $ financial implication, # of individuals affected)	1. These cases are ongoing, and it is not possible, at this stage, to assess reliably their potential financial impact on Sanofi CHC NA and/or stakeholders. 2. As of May 2023, there are approximately 90,000 Zantac cases filed in various U.S. state courts. Given that the litigation is ongoing, it is not possible, at this stage, to reliably assess the potential financial impact on Sanofi CHC. (CONTINUED ON NEXT PAGE)

IMPACT ON STAKEHOLDER(S)	1. The primary allegation in US product liability cases typically is that plaintiffs/consumers allegedly suffered injury or economic loss based on their consumption or use of product ingredients. 2. The medical, scientific, and regulatory communities have extensively evaluated the safety of legacy Zantac's active ingredient ranitidine, and the data show there is no evidence of consumer harm from real-world use of legacy Zantac with ranitidine. Over time, both FDA and the European Medicines Agency have evaluated the available data and have also found no evidence that ranitidine causes cancer. There is no potential impact on current consumers as the product has been off the market since 2019. The potential impact on consumers would relate to those consumers who purchased the legacy product and are now claiming economic, financial, or alleged long-term health impacts as purported in the litigation.
RESOLUTION	US litigations remain ongoing.
MANAGEMENT PRACTICES	1. These cases are ongoing and subject to dispute, and it is not possible, at this stage, to therefore assess their potential impact on Sanofi CHC NA management practices or internal controls. 2. Ranitidine, the active pharmaceutical ingredient at issue, is not presently sold on the market.

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PROVIDED BY: Sanofi CHC NA UPDATED AS OF: July 11th, 2023

DISCLOSURE QUESTIONNAIRE CATEGORY	Environmentally Intensive Industries
TOPIC	Chemical Intensive Industries
SUMMARY OF ISSUE	Sanofi CHC NA operates in the pharmaceutical industry which has been recognized as a chemical intensive. 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 does use SVHC lab chemicals for quality control purposes on its Chattanooga site. All product formulas are approved by US and Canadian 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 consumers.
SIZE/SCOPE OF ISSUE (e.g. $ financial implication, # of individuals affected)	The use of chemicals for quality control purposes in the Chattanooga site is approximately 1 ton/year. All finished products are safe for their intended use.
INDIRECT IMPACT ON STAKEHOLDER(S)	The primary potential impacts of chemical use in pharmaceutical products are potential negative effects to the environment and potential negative health impacts to workers exposed to chemical ingredients. Risks to workers exposed to chemical ingredients are mitigated through appropriate controls such as engineering controls and respiratory protection. Risks to the environment have been assessed as per the company “Pharmaceuticals in the Environment” program and are considered to be low. In the last five years, Sanofi CHC NA has not experienced any significant incidents and/or fines related to environmental or worker impacts of its chemical use.
IMPLEMENTED MGT PRACTICES	All of the chemicals used are handled, stored, disposed of, and transported following corporate standards, local legal standards, Standard Operating Procedures, and Permits including wastewater management. The company ensures that wastewater parameters are within the defined legal limits. Sanofi CHC NA has documented HSE requirements to minimize the use of Carcinogens, Mutagens, Reprotoxic, and volatile organic compounds. The company also proactively monitors the scientific literature and publications of health authorities worldwide to ensure state-of-the-art formulation and production. All of Sanofi's formulas are approved by Health Authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy.

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PROVIDED BY: Sanofi CHC NA UPDATED AS OF: July 11th, 2023

DISCLOSURE QUESTIONNAIRE CATEGORY	Recalls
ISSUE DATE	2018, 2019, 2020
TOPIC	Recalls due to potential presence of elemental impurities.
SUMMARY OF ISSUE	Sanofi CHC NA had one significant voluntary recall over the last 5 years, a Voluntary Class I recall of over-the-counter products containing ranitidine. Ranitidine, the active pharmaceutical ingredient at issue, is not presently sold on the market.
SIZE/SCOPE OF ISSUE (e.g. $ financial implication, # of individuals affected)	The recalled product represented 6.9% of total 2019 Sanofi CHC NA Net Sales in 2019.
IMPACT ON STAKEHOLDER(S)	NDMA is a known environmental contaminant found in drinking water, soil, and common foods, including meats, dairy products, and vegetables. People are routinely exposed to small amounts of NDMA every day. NDMA is classified as a probable human carcinogen. The medical, scientific, and regulatory communities have extensively evaluated the safety of Zantac's active ingredient ranitidine, and the data show there is no evidence of consumer harm from real-world use of Zantac. Over time, both FDA and the European Medicines Agency have evaluated the available data and have also found no evidence that ranitidine causes cancer.
IMPLEMENTED MGT PRACTICES	In October 2019, Sanofi issued a voluntary recall of all ranitidine Zantac OTC products in the U.S. and Canada. Ranitidine is not presently sold on the market.
UNRELATED RECALL INCIDENTS	Sanof CHC NA had 3 unrelated voluntary product recalls involving separate products over the last 5 years. Each was classified by Health Canada as a "Voluntary Type III Recall".