B Lab Statement on Sanofi Consumer Healthcare, North America - B Corp Requirements for Pharmaceutical Companies

B Lab's independent Standards Advisory Council has rendered the following decision and guidance regarding eligibility for B Corp Certification for companies in the pharmaceutical industry:

"B Lab and its independent Standards Advisory Council have determined that pharmaceutical companies are eligible for B Corp Certification if they have not engaged in specific prohibited practices in the last five years AND are meeting additional industry specific practice requirements outlined below."

Sanofi Consumer Healthcare, North America at Sanofi is required to disclose a summary of how it complies with these industry requirements as a part of its B Corp Certification. For more information on the specific requirements, please refer to B Lab's position statement on Pharmaceutical Companies here.

About Sanofi Consumer Healthcare, North America

Sanofi Consumer Healthcare, North America (CHC NA) is a regional business unit of Sanofi's global consumer healthcare organization, one of Sanofi Group's four business units, and is structured as an independent company and subsidiary. CHC NA's portfolio spans four categories – Pain and Sleep, Digestive Wellness, Allergy, and Personal Care – and includes brands like Allegra®, Icy Hot®, Gold Bond®, and Dulcolax®. Approximately 99.83% of CHC NA's annual revenue comes from over-the-counter products and 0.17% comes from two prescription-only products in Canada.

In 2023, CHC NA employs 935 people and provides manufacturing, research and development, sales, and marketing activities for all of its products in the North American market. The company's manufacturing sites and distribution sites are based in Chattanooga, Tennessee, and are licensed Good Manufacturing Practice Sites (GMPs).

Sanofi Consumer Healthcare, North America's Disclosure on Prohibited Practices

Pharmaceutical companies engaged in the following practices in the last five years, as demonstrated through company disclosures or through material, justified, and unresolved stakeholder concerns, are currently ineligible for B Corp Certification:

- *Companies engaged in any form of lobbying or policy advocacy that endanger consumer safety, promote an anti-competitive environment (e.g. by opposing increased*

transparency measures), inhibit affordable pricing, or limit equitable access to medicine. This includes membership, Board involvement, or funding of industry associations that engage in such lobbying activities.

- *Companies utilizing intellectual property strategies for branded products to influence an unjustified delay to the introduction of an authorized generic product to the market (e.g. "evergreening" patents).*
- *Companies engaged in price gouging as evidenced by significant and unjustified year-over-year price increases to their products.*

Sanofi CHC NA, as part of Consumer Healthcare has been reviewed in accordance with B Corp Certification's Disclosure Questionnaire and background check requirements, including disclosure of its involvement in lobbying and advocacy activities, intellectual property strategies, and price changes in order to verify it is meeting the above requirements regarding prohibited industry practices. The company's approach to managing these material topics in the industry is further detailed below.

Sanofi Consumer Healthcare, North America's Disclosure on Required Best Practices

1. *Adherence to credible national and/or international standards of safety, quality, and efficacy covering all relevant stages of the drug life cycle (i.e. drug development, supply chain, manufacturing, and distribution), which should include explicit systems to manage the risk of substandard medicines.*

All CHC NA products are produced in accordance with all relevant US and Canadian laws, regulations, and standards, such as the Food and Drug Administration (FDA, US) and Health Canada (Canada).

CHC NA's facilities (manufacturing sites, distribution centers, commercial activities, and/or development centers) are monitored by the relevant regulatory bodies and regularly inspected by the FDA and the Health Canada to confirm the quality, efficacy, and safety of its products and compliance with applicable regulations. All company manufacturing sites are certified GMP sites and operate quality management systems in line with the ICH Quality Guideline Q10 on Pharmaceutical Quality System.

To maintain the quality, efficacy, and safety of products, CHC NA collects, manages, submits, when relevant, and monitors pharmacovigilance cases, quality complaints & medical inquiries. Any trends are assessed, and appropriate actions are taken to adjust the benefit-risk profile of products where necessary.

2. *A Code of Ethics and/or other policies applicable to all company employees and critical third parties that establish minimum expectations with regard to anti-corruption and bribery, lobbying and advocacy activities, company interactions with healthcare*

professionals/organizations, and ethical marketing (where applicable). The company must also have clear processes to enforce the Code, including an accessible whistleblowing channel, and regular training of staff and third parties on the Code.

CHC NA follows all applicable laws and regulations, overarching industry and Sanofi Group policies and procedures in relation to ethics, anti-corruption, and bribery, lobbying and advocacy, interactions with healthcare organizations/professionals and ethical marketing.

Code of Conduct & Training

The company's Code of Conduct requires all employees, and any critical third parties working on behalf of Sanofi and their subsidiaries, to comply with applicable laws and regulations, including anti-bribery and anti-corruption laws, as well as the specific principles and rules of conduct. The Code of Conduct outlines the company's approach to ethics and risk culture to enable employees to make decisions fairly and ethically and ensure ethical business conduct.

Furthermore, CHC NA has policies and procedures designed to help ensure that officers, employees, agents, intermediaries, and other third parties comply with applicable laws and regulations. In the North American market, this includes but is not limited to the US Foreign Corrupt Practices Act.

CHC NA ensures that all relevant employees receive and complete mandatory Ethics & Business Integrity (EBI) training, as part of the onboarding process, annually, as part of refresher training, and on an ad hoc basis as part of disciplinary actions/measures for identified employees, in line with its zero tolerance towards bribery and abuse of power strategy amongst employees, business partners and stakeholders. In CHC NA, there are annual audits of EBI policies and procedures by an internal control group and internal audit group. EBI policies and procedures undergo annual external audits as well as by internal auditors.

Suppliers

CHC NA conducts risk-based anti-bribery due diligence on their business partners, including suppliers, customers, and third-party sales and marketing intermediaries, before engaging them and periodically during their partnering. Any potential issue raised through this monitoring is reviewed and assessed to evaluate the need for a risk mitigation plan, including termination if required.

Additionally, the Supplier Code of Conduct (embedded within the code of conduct policy and shared with all suppliers) is part of CHC NA's responsible procurement approach and a key element of its vigilance plan. Supplier code of conduct commits suppliers and critical third parties working on behalf of CHC NA, to strictly observe and comply with all the fundamental principles expressed in all its activities and sites worldwide. Suppliers are also expected to ensure their own suppliers comply with the code of conduct requirements, apply its fundamental principles in the areas of human rights, working conditions, environment, and fight against corruption.

Interactions with Healthcare Professionals

All interactions with HCPs/organizations follow high ethical standards, policies, and regulations. CHC NA complies with Sanofi Group policy on interactions with healthcare professionals (HCPs). In North America, Sanofi CHC NA directly handles the interactions with HCPs.

Each year, Sanofi Group publicly discloses the transfers of value made to healthcare professionals in the United States, in line with the US Sunshine Act and other applicable laws and regulations. This includes any activities within the scope of Sanofi CHC NA.

Whistleblowing

CHC NA has established clear procedures and frameworks for employees to raise concerns or beliefs that any law, regulation, policy, or code has or may be violated. Employees have a duty to raise any concern through the appropriate channel.

As part of a global pharmaceutical company, CHC NA adheres to applicable codes on promotional activities (CHPA). The company has released a factsheet on its promotional activities.

Promotional practices

US: For all promotional practices, Sanofi CHC US abides by all applicable regulations, including the CFR and FTC guidelines. Sanofi CHC US enlists a team from regulatory, medical, legal, and commercial to ensure promotional activities are substantiated and not misleading, in compliance with internal standard operating procedures and applicable laws and regulations, on which all relevant internal stakeholders are trained.

Canada: For all promotional practices, Sanofi CHC Canada adheres to Health Canada policy and guidance for advertising practices as well as the Canadian Code of Advertising Standards. Sanofi CHC Canada enlists a team from regulatory, medical, legal, and commercial to ensure promotional activities are substantiated and not misleading, in compliance with internal standard operating procedures and applicable laws and regulations, on which all relevant internal stakeholders are trained.

3. *Public disclosure detailing the company's approach to government affairs, inclusive of lobbying/advocacy and political activities. This should include disclosure of the material issues that the company lobbies/advocates for, their trade associations, and the controls they have in place in regards to political contributions, lobbying/advocacy on the company's behalf, revolving door policy, political contributions and donations.*

Sanofi CHC NA follows Sanofi Group's internal Global Lobbying policies which apply to all Sanofi Group employees and Consultant lobbyists hired around the world. The Sanofi Group conducts direct lobbying activities for all North American subsidiaries, including Consumer Healthcare. Only authorized Sanofi employees and hired consultant lobbyists, where permitted, may engage in direct discussions with policymakers on Sanofi's behalf concerning legislative activity.

Sanofi Group's lobbying activity is governed by internal policies that ensure compliance with relevant US and Canadian federal and state/provincial laws, regulations, and guidance. Sanofi employees are provided training and compliance with the company's lobbying practices is monitored by the Internal Control & Risk Management Group.

In compliance with the U.S. federal law, Sanofi Group discloses all expenditures related to federal lobbying on a quarterly basis. The Sanofi group publishes an annual, public disclosure that outlines the approach to lobbying, requirements for ethical and transparent activity for lobbyists and hired consultants, as well as lobbying expenditures and political contributions, where applicable. It can be found at:
https://www.sanofi.com/dam/jcr:145f056b-9758-405a-96cc-092262140545/Lobbying.pdf

The issues on which Sanofi CHC NA is engaged include broad, equitable access to OTC medicines and products; regulatory pathway reform and standards; product quality and safety; supply chain flexibility; and packaging design, including sustainability, recycled content, and waste minimization.

Only authorized Sanofi employees and hired consultant lobbyists may engage in discussions on Sanofi's behalf concerning legislation and rulemaking activity without prior, expressed, and written Sanofi approval.

Per Sanofi Lobbying Policy, all Sanofi authorized employees and consultant lobbyists must ensure that:

- they remain compliant with all applicable laws and regulations;
- lobbying must be done with the purpose of advancing Sanofi's interests;
- they remain honest and transparent concerning whom, and for what, they are lobbying; they shall provide no gifts;
- hospitality must be made in strict compliance with applicable anti-corruption laws and regulations, Sanofi policies, and regulations and other regulations and codes (e.g. internal policies of the lawmaker);
- and any contract with a consultant lobbyist must include a detailed quotation of services, anti-bribery provisions, audit rights of Sanofi, and the consultant lobbyist's commitment to comply with local regulations.

The Organization for Economic Co-operation and Development (OECD) Principles for Transparency and Integrity in Lobbying were also used as a reference in developing our responsible Lobbying policy.

CHC NA Employees, who are not Sanofi Authorized Employees, must not engage in discussions on Sanofi's behalf about legislation, rulemaking or policy development with Public Decision Makers without prior review and written approval from Sanofi relevant Public Affairs or Government Relations manager. Information shared must be objective, reliable, accurate and up-to-date supported by evidence and must not misrepresent facts.

Trade Associations

CHC NA is a member of several trade associations that represent and advocate on behalf of Sanofi CHC NA and other consumer healthcare companies, on consumer healthcare-related issues aimed at improving the environment for self-care. Trade associations for which Sanofi CHC North America is a member, lobby on the behalf of the aggregated industry regarding business practices affecting quality, safety and access to consumer healthcare products. They do not lobby specifically on the behalf of any individual company. Positions taken by the Trade Associations on the behalf of the industry as a whole are derived by consensus of the member companies which are then approved by the Trade Associations Board of Directors, on which an executive from Sanofi CHC sits. The CHC industry trade associations that CHC NA participate in are:

- Consumer Healthcare Product Association (CHPA)
- Personal Care Products Council (PCPC)
- Food, Health, & Consumer Products Association (FHCP)

4. *For companies involved in research & development, public disclosure of its R&D and intellectual property strategies and disclosure of annual resources invested in both internal and collaborative R&D activities.*

R&D activities for CHC NA are focused on two priorities: 1) to develop and deliver innovative new products which meet the expanding needs of its consumers and 2) to provide the technical support to maintain existing products on the market, including necessary regulatory & pharmacovigilance activities and technical updates/remediation work when needed.

R&D in consumer healthcare may also encompass supporting Rx(prescription)-to-OTC “switches”. After Rx use of a medicine for a number of years, certain classifications of drugs may sometimes justify a change in Regulatory classification and move to a non-prescription status. Such Rx-to-OTC switches generally require extensive R&D work and investments to demonstrate the suitability (safety and efficacy) of previously prescription-only products to non-prescription status to make them more easily accessible to the public.

Of the projects currently in development in Sanofi CHC’s pipeline:

- 70% of R&D projects are Sanofi CHC initiated and are developed at the Sanofi CHC development centers.
- 30% of R&D projects are Sanofi CHC initiated and are developed at Contract Development and Manufacturing Companies (CDMOs) managed by Sanofi CHC.
- 0% of R&D projects are sourced from the Sanofi group, excluding Sanofi CHC. External companies are mainly CDMO (contract development and manufacturing company)

In 2023, Sanofi CHC began publicly disclosing its spend on R&D. Please find details via this link.

The Company files patent applications based on the innovation and benefit to patients and consumers. Sanofi CHC, as a consumer healthcare business, does not work on the development of new molecules (e.g., active pharmaceutical ingredients). Generally, new

medicinal products may only be supplied on prescription. In 2022, approximately less than 5% of Sanofi CHC's products were subject to patents. Internal experts in intellectual property report directly to Sanofi CHC's Chief Legal Officer, who maintains oversight of any intellectual property issues. The Chief Legal Officer is a member of CHC's executive leadership team.

As required by the local health authority, Sanofi CHC NA provides all the necessary information to the patient on the product packaging and leaflet. In addition, Sanofi CHC NA organizes educational programs that encourage the responsible use of medicines. e.g., by empowering consumers to use the products according to their licensed indication, including helping to raise awareness on the risks of overdose, misuse, or prolonged treatment.

5. *For companies involved in research & development for priority diseases, conditions, and pathogens identified in the Access To Medicine Index, R&D processes for both internal and collaborative R&D activities must include a framework to develop equitable access plans for such projects. Access plans must be project-specific and include detailed commitments and strategies to improve access to such products in low- and middle- income countries (LMICs).*

The Access to Medicine Index does not feature any of Sanofi's Consumer Healthcare products or innovations, as they do not have any active R&D projects to address priority diseases, conditions, and pathogens identified in the Access to Medicine Index. Sanofi's Consumer Healthcare products treat low severity conditions, for which there is in general, a wide range of alternatives.

The Consumer Healthcare division at Sanofi is not expected to meet B Lab's requirement in relation to companies listed on the Access to Medicine Index (ATMI). For reference, in 2022 Sanofi Group achieved a score of 3.47 on the ATMI..

6. *For companies involved in sales, public disclosure of its approach to pricing which, at a minimum, utilizes pricing instruments that are generally accepted by public health agencies to set prices in all markets (such as internal reference pricing, external reference pricing, and value-based pricing). Additionally, for sales in LMICs, pricing strategies must prioritize the payer's ability to pay across different segments of a country's population and aim to improve access to those in need.*

CHC NA deploys Price Pack Architecture strategies that provide consumers with the appropriate selection of products that is based on the economics of what the consumer market will bear. CHC NA uses a variety of analytical techniques to develop their Price Pack Architecture such as, but not limited to, price slope optimization work, competitive benchmarks, conjoint studies, and market research. Furthermore, as CHC NA innovates into new product spaces, the company will look to adjacent market segments to benchmark appropriate pricing metrics. The company will also, at times, engage in first party consumer research to determine how to develop meaningful innovation that consumers value.

CHC NA does not intervene directly or control the pricing made by our retail partners in accordance with US anti-trust regulations. The final shelf price is ultimately at the sole discretion of the retailer.

As CHC NA primary distribution channels are pharmacies and retailers, and their products do not require prescriptions, they are not subject to the same pricing requirements as other pharmaceutical companies.

0.17% of CHC NA sales comes from two prescription-only products in Canada. Prices are controlled by government regulations and in general, in Canada, prescription pricing may be negotiated independently within each Canadian province. Sanofi CHC Canada, does not launch new prescription products, therefore also does not deal with new drug pricing.

7. *For companies involved in sales, companies have financial incentive structures for sales agents/teams designed to encourage responsible sales practices and minimize the risk of overselling (for example, by decoupling bonuses from sales volume).*

As a consumer healthcare company, CHC NA's sales team sells to wholesale customers. Therefore, the way the consumer healthcare market is structured, their sales practices are responsible and inherently there is no risk of overselling. CHC NA follows Sanofi Group's internal Sales Incentives policy which includes an addendum specific to 'Sales Incentive Plans for CHC dedicated Pharmacy/Retail/Trade functions.

Sanofi CHC NA's Incentive Plan has in its composition components, such as:

- Financial (e.g., Net Sales),
- Executional (e.g., Distribution,) and,
- External (e.g., Market Share,)

Additionally, CHC NA promotes responsible sales practices in various ways including but not limited to, the following.

- **Incentive Structure.** CHC NA has financial incentive structures for sales teams that are specific to the sale of consumer products.

Sanofi's Code of Conduct. All sales representatives must undergo and complete Compliance training related to the company's global policies and Code of Conduct to qualify for any sales incentive bonus.

● **Training:** CHC NA also has specific mandatory training for their retailer teams, as well as mandatory Sales Representatives' training process for Sanofi CHC NA sales representatives, and its third parties. All sales representatives must undergo and complete Compliance training with the company's global policies and code of ethics to be able to qualify for any of their sales incentive bonuses.

● **Oversight:** CHC NA utilizes a bonus committee to ensure appropriate ethical behavior and operational management is coached on ensuring ethical marketing and CHC NA's various internal control mechanisms are enforced. Additionally, Sanofi CHC NA has an enterprise-wide framework to identify and manage abusive incentive compensation business practices, and regular audit checks are conducted to ensure compliance. The CHC NA Sales team utilizes a Customer Relationship Management (CRM) tool for sales visits designed to catch any misconduct, and regular audit checks are conducted to ensure compliant behavior with customers.