B Lab Statement on Opella Central & Eastern Europe - 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."

Opella CENTRAL & EASTERN EUROPE 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 Opella Central & Eastern Europe

Opella Central & Eastern Europe legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. The cluster consists of seven legal entities (n=7) in the following countries: Poland (n=1), Hungary (n=2), Czech Republic (n=1), Slovakia (n=1), Ukraine (n=1), Romania (n=1).

Opella Central & Eastern Europe employs 1,153 people in total and provides regulatory, medical (including medical information), quality, pharmacovigilance oversight, and R&D in the scope as described in point 4 below, as well as manufacturing, sales, and marketing activities for its products in Central & Eastern European markets. The cluster has manufacturing sites in Hungary and Poland and manages the business including externalized distribution activities in the Czech Republic, Hungary, Poland, Romania, Slovakia, Ukraine & Moldova. All sites are licensed with Good Manufacturing Practice (GMP) and Good Distribution Practices (GDP) Sites.

Its portfolio spans mainly four categories – Digestive Wellness, Cough & Cold, Allergy and Pain, Stress & Fatigue, Vitamins and includes brands like Magne B6®, Essentiale®, No-Spa®, Ibalgin®, Algopyrin®, Mucosolvan®, Enterogermina®, Dulcolax®, Allegra®, Rhinospray ®. In the last fiscal year, 95% of the business' annual revenue came from Medicinal products and Medical devices while the remaining 5% of revenue from food supplement products.

Opella Central & Eastern Europe'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 endangers 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.*

Opella Central & Eastern Europe 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.

Opella Central & Eastern Europe'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 products of Opella Central & Eastern Europe are produced in accordance with all relevant European laws, regulations, and standards.

All facilities of Opella Central & Eastern Europe (manufacturing, distribution centers and commercial activities) are monitored by the relevant regulatory bodies and regularly inspected by the competent authorities, listed below, to confirm the quality, efficacy, and safety of its products and compliance with applicable regulations:

Medicinal products & medical devices

- SK: ŠÚKL – Štátny ústav pre kontrolu liečiv
- CZ: SUKL – Státní ústav pro kontrolu léčiv
- PL: URPL, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and GIF - Główny Inspektorat Farmaceutyczny
- HU: NNGYK - Nemzeti Népegészségügyi és Gyógyszerészeti Központ
- UA: SMDC - State Service of Ukraine on Medicines and Drugs Control
- RO: ANMDMR – Agenția Națională a Medicamentului și a Dispozitivelor Medicale din România

- Moldova: AMDM - Agenţia Medicamentului şi Dispozitivelor Medicale

Food supplement:

- SK: Úrad verejného zdravotníctva Slovenskej republiky
- CZ: Ministry of Agriculture of the Czech Republic
- PL: GIS - Główny Inspektorat Sanitarny
- HU: NNGYK - Nemzeti Népegészségügyi és Gyógyszerészeti Központ
- RO: Ministry of Health / Institute for bioresources
- Moldova: Food Supplement Health Authority

All company manufacturing sites are certified GMP (good manufacturing practices) sites and operate quality management systems in line with the ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use) Quality Guideline Q10 on the Pharmaceutical Quality System.

To maintain the quality, efficacy, and safety of products, Opella Central & Eastern Europe 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.*

Opella Central & Eastern Europe 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. Sanofi is generally subject to the strict requirements of the company's Code of Ethics.

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, Opella Central & Eastern Europe has policies and procedures designed to help ensure that officers, employees, agents, intermediaries, and other third parties comply with applicable laws and regulations. In Central & Eastern European markets, this includes but is not limited to the European Federation of Pharmaceutical Industries and Associations (EFPIA) and local Trade associations (inside and outside of the EU) and code transparency regulations.

Opella Central & Eastern Europe 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 Opella Central & Eastern Europe, 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

Opella Central & Eastern Europe 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 is embedded within the code of conduct policy and shared with all suppliers. It is part of the company'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 Opella Central & Eastern Europe, 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 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 (HCPs)

All interactions with Healthcare Professionals and organizations follow high ethical standards, policies, and regulations. Opella Central & Eastern Europe complies with Sanofi Group policy on interactions with HCPs as well as regulations from the codes from the local Trade associations such as:

- UA – Association of Pharmaceutical Research and Development - APRAD (local EFPIA)
- RO – Asociația Română a Producătorilor Internaționali de Medicamente - ARPIM (local EFPIA)
- HU – Association of Innovative Pharmaceutical Manufacturers - AIPM (Innovatives) / Magyarországi Gyógyszergyártók Országos Szövetsége - MAGYOSZ (HU Manufacturers)
- CZ – Association of Innovative Pharmaceutical Industry - AIFP (local EFPIA)

- PL – Związek Pracodawców Innowacyjnych Firm Farmaceutycznych - INFARMA (local EFPIA)
- SK – SARAP Slovenská asociácia spoločností v oblasti liekovej regulácie (Slovak Association of Regulatory Affairs Professionals)

Where relevant affiliates of Opella Central & Eastern Europe have a membership. In Central & Eastern Europe, Opella Central & Eastern Europe directly handles the interactions with HCPs based on the framework mentioned before.

Each year, Sanofi Group publicly discloses the transfers of value made to healthcare professionals (among others) based upon the EFPIA and local pharma code transparency regulations in Central & Eastern Europe. This includes respective activities within the scope of Opella Central & Eastern Europe.

Whistleblowing

Opella Central & Eastern Europe has established clear procedures and frameworks for employees to raise concerns or beliefs that any law, regulation, policy, or code of conduct has or may be violated. Employees have a duty to raise any concern through the appropriate channel e.g., via Manager, Sanofi Speak Up Line, Ethics & Business Integrity, and People and Culture function.

Promotional practices

As part of a global pharmaceutical company, Opella Central & Eastern Europe adheres to applicable laws and codes on promotional activities (e.g., Advertising laws as well as applicable Sanofi standard operating procedures regarding promotional & non-promotional materials.). The company has released a factsheet on its promotional activities.

Opella Central & Eastern Europe 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 regard to political contributions, lobbying/advocacy on the company's behalf, revolving door policy, political contributions and donations.*

Opella Central & Eastern Europe 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 Central & Eastern European 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 European,l 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 European law, Sanofi Group discloses all expenditures related to lobbying on a yearly 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 Lobbying (sanofi.com)

The issues on which Opella Central & Eastern Europe is engaged include broad, equitable access to over-the-counter (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.

Employees of Opella Central & Eastern Europe, 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's 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

Opella Central & Eastern Europe is a member of several trade associations that represent and advocate on behalf of Opella Central & Eastern Europe, and other consumer healthcare companies, on consumer healthcare-related issues aimed at improving the environment for self-care. Trade associations for which Opella Central & Eastern Europe is a member, lobby on behalf of the aggregated industry regarding business practices affecting quality, safety, and access to consumer healthcare products. They do not lobby specifically on behalf of any individual company. Positions taken by the Trade Associations on 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 Opella Central & Eastern Europe may sit. The consumer healthcare industry trade associations that Opella Central & Eastern Europe participates in are:

- SK: SARAP Slovenská asociácia spoločností v oblastiliekovej regulácie (Slovak Association of Regulatory Affairs Professionals)
- CZ: SVOPL – Stružení výrobců volně prodejných léčivých přípravků
- PL: PASMI - Polish Association of Self Medication Industry
- HU: Magyosz - Magyarországi Gyógyszergyártók Országos Szövetsége
- UA: EBA – European Business Association
- RO: RASCI - Romanian association of manufacturers of OTC medicines, food supplements and medical devices

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 Opella Central & Eastern Europe are focused on two priorities:

1) to develop and deliver innovative new products that meet the expanding needs of its consumers. Developing new products can mean launching new product formats that don't require us to develop new molecules. New formats can be e.g. smaller size packs, new forms like liquids or gels to make products accessible and/or convenient to consumers,

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 medicine for several 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 Opella's pipeline:

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

In 2023, Opella began publicly disclosing its spending on R&D. Please find details via this link.

The Company files patent applications based on the innovation and benefit to patients and consumers. Opella, as a consumer healthcare business, does not work on the development of new molecules (e.g., active pharmaceutical ingredients). Generally, new medicinal products with new active molecules may only be supplied on prescription. In 2023, approximately less than 5% of Opella's products were subject to patents. Internal experts in intellectual property report directly to Opella's General Counsel, who maintains oversight of any intellectual property issues. Opella General Counsel is a member of CHC's executive leadership team.

As required by the local health authority, Opella Central & Eastern Europe provides all the necessary information to the patient on how to use the product in a safe and appropriate manner via the leaflet and product packaging; moreover, Opella Central & Eastern Europe offers medical information services on all products.

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 (ATMI) 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, Sanofi Group in 2022 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.*

Opella Central & Eastern Europe 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. Opella Central & Eastern Europe 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 Opella Central & Eastern Europe 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.

Opella Central & Eastern Europe does not intervene directly or control the pricing made by the pharmacies /wholesalers in accordance with anti-trust regulations. The final shelf price is ultimately at the sole discretion of the pharmacies /wholesalers.

Opella Central & Eastern Europe's primary distribution channels are stationary pharmacies, e-commerce pharmacies, and wholesalers. <9% of Opella Central & Eastern Europe's sales come from prescription-only products. Prices of products that require a prescription are controlled by government regulations, when reimbursed by the National Health System. Opella Central & Eastern Europe does not launch new prescribed products that require reimbursement by the National Health System.

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, Opella Central & Eastern Europe's sales team sells to wholesale customers and to pharmacies (stationery and e-commerce) directly. The structure of the consumer health market itself and Opella Central & Eastern Europe's responsible sales practices ensure that there is no risk of overselling. Monthly internal controls of the stock reach in conjunction with the orientation towards external guidelines for a healthy stock range provide further protection. Opella Central & Eastern Europe follows Sanofi Group's internal Sales Incentives policy which includes an addendum specific to 'Sales Incentive Plans for Opella dedicated Sales functions.

Opella Central & Eastern Europe 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, Opella Central & Eastern Europe promotes responsible sales practices in various ways including but not limited to, the following.

- **Incentive Structure.** Opella Central & Eastern Europe 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:** Opella Central & Eastern Europe has a specific mandatory training process for their 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:** Opella Central & Eastern Europe utilizes a bonus committee to ensure appropriate ethical behavior, and operational management is coached on ensuring ethical marketing and Opella Central & Eastern Europe's various internal control mechanisms are enforced. Additionally, Opella Central & Eastern Europe has an enterprise-wide framework to identify and manage abusive incentive compensation business practices, and regular audit checks are conducted to ensure compliance. The Opella Central & Eastern Europe 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.