B Lab Statement on Opella - 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 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

Opella is the consumer healthcare business unit of Sanofi, a pharmaceutical company. Its portfolio spans across mainly five categories – Pain, Cough & Cold, Digestive Wellness, Multi-Vitamins and Allergy and includes brands like Allegra®, Enterogermina®, Buscopan®, Dulcolax®, Doliprane®, Essentiale®, Bisolvon®, and Mucosolvan®. Approximately 93% of Opella's annual revenue comes from non-prescription products (including pharmacy-exclusive medical devices). The company declared that 7% of its revenue stems from prescription products.

In 2023, Opella employed over 10,100 people and provided manufacturing, regulatory, medical (including medical information), quality, and pharmacovigilance oversight, as well as sales, and marketing activities for its products. The company has manufacturing sites in Brazil, Hungary, Poland, Mexico, Germany, North America, France, Vietnam, Australia, Japan, and Tunisia along with offices and corporate offices in Paris, Frankfurt, Hong Kong, Egypt, Turkey, Saudi Arabia, UAE, South Africa, Philippines, Thailand, Indonesia, Singapore, Malaysia, China, India, and Russia*, managing the business including externalized distribution activities in the UK, Spain, Portugal, Austria, Switzerland, Belgium, Luxembourg, Greece, Cyprus, Czech Republic, Hungary, Poland, Romania, Slovakia, Ukraine & Moldova. All manufacturing sites are licensed Good Manufacturing Practice (GMP) and Good Distribution Practices (GDP) Sites.

Opella 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), inhibits 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 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 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 are produced in accordance with all relevant local laws, regulations, and standards.

All Facilities of Opella (manufacturing sites, 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:

North America:

- US: Food and Drug Administration (FDA)
- Canada: Health Canada

LATAM

- Brazil: ANVISA (Brazilian Health Regulatory Agency)
- Colombia (INVIMA - Instituto Nacional de Vigilancia de Medicamentos y Alimentos),
- Ecuador (ARCSA - Agencia Nacional de Regulación Control y Vigilancia Sanitaria),
- Perú (DIGEMID - Dirección General de Medicamentos, Insumos y Drogas),
- Panamá (Farmacias y Drogas),
- Argentina (ANMAT - Dirección General de Medicamentos, Insumos y Drogas),

- México (COFEPRIS - Comisión Federal para la Protección contra Riesgos Sanitarios),
- Bolivia (AGEMED - Agencia Estatal de Medicamentos y Tecnologías en Salud),
- Costa Rica (Unidad de Registros Dirección de Regulación de Productos de Interés Sanitario Ministerio de Salud),
- República Dominicana (Dirección de Drogas y Farmacias, Dirección General de Medicamentos, Alimentos y Productos Sanitarios de DIGEMAPS),
- El Salvador (DNM - Dirección Nacional de Medicamentos),
- Guatemala (MSPAS - Ministerio de Salud Públicas y Asistencia Social),
- Honduras (ARSA - Agencia de Regulación Sanitaria),
- Nicaragua (MINSA - Ministerio de Salud Nicaragua),
- Paraguay (DINAVISA - Dirección Nacional de Vigilancia Sanitaria. Ministerio de Salud Pública y Bienestar Social Paraguay),
- Uruguay (Departamento de Medicamentos Ministerio de Salud Pública de Uruguay).
- Chile (ISP - Instituto de Salud Publica),
- Venezuela (Instituto Nacional de Higiene “Rafael Rangel”),
- Caribbean Islands:
    - Aruba (Ministry of Health Aruba),
    - St. Maarten (Inspectorade of Public Health Social Development and Labour, Ministry of Public Health),
    - Trinidad & Tobago (Chemist - Food and Chemistry Division Ministry of Health),
    - Curacao (Drug Registration Board (Ministry of Health of Curacao),
    - Jamaica (Standards & Regulations Division Ministry of Health Jamaica).

Europe Medicinal:

- EMA (European Medicine Agency)
- Italy: Italian Health Authorities (Ministry of Health – Italian Drug Agency)
- Germany: BfArM - Bundesinstitut für Arzneimittel und Medizinprodukte, Hessisches Landesamt für Gesundheit and Pflege, Bezirksregierung Köln
- France: Agence nationale de sécurité du médicament et des produits de santé (ANSM - National Agency for the Safety of Medicines and Health Products)
- Russian Federation – Ministry of Health of the Russian Federation, Ministry of Industry and Trade of Russia, Federal Service for Surveillance in Healthcare (Roszdravnadzor).
- Slovakia and Czech Republic: ŠÚKL – Štátny ústav pre kontrolu liečiv
- Poland URPL, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and GIF - Główny Inspektorat Farmaceutyczny
- Hungary: NNGYK - Nemzeti Népegészségügyi és Gyógyszerészeti Központ
- Ukraine: SMDC - State Service of Ukraine on Medicines and Drugs Control
- Romania: ANMDMR – Agenția Națională a Medicamentului și a Dispozitivelor Medicale din România
- Moldova: AMDM - Agenţia Medicamentului şi Dispozitivelor Medicale
- Austria: BASG - Bundesamt für Sicherheit im Gesundheitswesen (Federal Office for safety in Health Care) - "subcategory" AGES - Österreichische Argentur ür Gesundheit und Ernährungssicherheit GmbH
- Belgium: FAMHP – Federal Agency for Medicines and Health Products
- Switzerland: Swissmedic

- Spain: AEMPS - Agencia Española de Medicamentos y Productos Sanitarios
- Greece: EOF - Ethnikos Organismos Farmakwn (National Organisation of Drugs)
- Portugal: INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.
- United Kingdom: MHRA – Medicines & Healthcare products Regulatory Agency)

Europe Food Supplements:

- Slovakia: Úrad verejného zdravotníctva Slovenskej republiky
- Czech Republic: Ministry of Agriculture of the Czech Republic
- Poland: GIS - Główny Inspektorat Sanitarny
- Hungary: NNGYK - Nemzeti Népegészségügyi és Gyógyszerészeti Központ
- Romania: Ministry of Health / Institute for bioresources
- Moldova: Food Supplement Health Authority

Asia, Middle East, Africa:

- Japan - the Ministry of Health, Labor and Welfare (MHLW)
- Australia - Therapeutics Goods Administration (TGA)
- Vietnam - Drug Administration of Vietnam (DAV)
- China - the National Medical Products Administration (NMPA) and the Center for Food and Drug Inspection of NMPA (CFDI)
- South Korea - Ministry of Food and Drug Safety (MFDS)
- Hong Kong – Pharmacy & Poisons Board of Hong Kong (PPBHK)
- Thailand – Thailand Food and Drug Administration
- Philippines – Food and Drug Administration Philippines
- Indonesia – Indonesian Food and Drug Authority, Badan Pengawas Obat dan Makanan (BPOM)
- Singapore – Health Sciences Authority
- Turkey - Turkish Medicine and Medical Device Agency (TMMDA)
- Saudi Arabia – the Saudi Food and Drug Authority (SFDA)
- UAE – Ministry of Health Prevention (MOH)
- Tunisia – the Pharmacy and Drug Directorate (DPM) under the authority of the Ministry of Health
- South Africa – the South African Health Products Regulatory Authority (SAHPRA)

All company manufacturing sites are certified GMP 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 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 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. Opella 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 has policies and procedures designed to help ensure that officers, employees, agents, intermediaries, and other third parties comply with applicable laws and regulations.

- In North America, this includes but is not limited to the US Foreign Corrupt Practices Act.
- In Western European and Central Eastern European markets, this includes but is not limited to European Federation of Pharmaceutical Industries and Associations (EFPIA) and local Trade associations (inside and outside of the EU) and code transparency regulations
- In Brazil, this includes but is not limited to ANVISA (Brazil Health Regulatory Agency), ACESSA (Brazilian Association of the Industry of Products for Self-Care in Health), ABIAD (Brazilian Association of the Special Purpose Food Industry and Related Products), ABA (Brazilian Association of Advertisers), SINDUSFARMA (Pharmaceutical Industry Union), and CONAR (Brazilian Advertising Self-Regulation Council).
- In France : this includes but is not limited to the CSP (the French Public Health Code).
- In the Russian Federation this includes but is not limited to AIPM (Association of International Pharmaceutical Manufacturers – local branch of EFPIA) and ACHI (Association of Consumer Healthcare Industry)
- In AMEA markets, this includes but is not limited to the Asia Pacific Self Medication Industry Association (ASEA Region), the Singapore Association of Pharmaceutical Industries (SAPI), the Gabungan Perusahaan Farmasi Indonesia (Indonesian GP Farmasi - Pharmaceutical Company Association); the Pharmaceutical and Healthcare Association of the Philippines (PHAP), the Consumer Healthcare Industry Association of the Philippines (CHAP), the Philippines Association of Pharmacists in the Pharmaceutical Industry (PAPPI), the TSMIA (Thai Self Medication Industry Association), the Japan Self-Medication Industry (JSMI), the R&D-Based Pharmaceutical Association Committee, the Middle east and North Africa- Pakistan Self-medication

industry (MENAP-SMI), the Global Selfcare Federation (GSCF), and local pharma code transparency regulations.

Opella 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, 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 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, 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 complies with Sanofi Group policy on interactions with HCPs as well as regulations from the codes from the local pharma association such as:

North America & LATAM

- In North America and Hispanic Latin America, Opella directly handles the interactions with HCPs
- Brazil: Brazilian Association of the Industry of Self-Care Products in Health (ACESSA), Pharmaceutical Industry Union (SINDUSFARMA) and, Brazilian Association of the Special Purpose Food Industry and Related Products (ABIAD)

Europe:

- Germany: Opella complies with regulations from the codes from the local pharma association (FSA - Verein Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V.) where Sanofi GERMANY has a membership. In Germany, Opella Germany directly handles the interactions with HCPs based on the framework mentioned before

- France : NèreS (Trade association for OTC pharma industry “Nouvelle Ere de Santé Responsable - A new era of Responsible Care)
- Russian Federation - AIPM (Association of International Pharmaceutical Manufacturers – local branch of EFPIA) and ACHI (Association of Consumer Healthcare Industry). Moreover, in the Russian Federation, interactions with healthcare professionals are subject to specific legal requirements outlined in Federal Law No. 61-FZ "On the Circulation of Medicines" (dated April 12, 2010) and Federal Law No. 323-FZ "On the Fundamentals of Health Protection of Citizens in the Russian Federation" (dated November 21, 2011)
- Ukraine – Association of Pharmaceutical Research and Development - APRAD (local EFPIA)
- Romania– Asociația Română a Producătorilor Internaționali de Medicamente - ARPIM (local EFPIA)
- Hungary – Association of Innovative Pharmaceutical Manufacturers - AIPM (Innovatives) / Magyarországi Gyógyszergyártók Országos Szövetsége - MAGYOSZ (HU Manufacturers)
- Czech Republic – Association of Innovative Pharmaceutical Industry - AIFP (local EFPIA)
- Poland – Związek Pracodawców Innowacyjnych Firm Farmaceutycznych - INFARMA (local EFPIA)
- Slovakia – SARAP Slovenská asociácia spoločností v oblasti liekovej regulácie (Slovak Association of Regulatory Affairs Professionals)
- Brazil - Brazilian Association of the Industry of Self-Care Products in Health (ACESSA), Pharmaceutical Industry Union (SINDUSFARMA), and Brazilian Association of the Special Purpose Food Industry and Related Products (ABIAD)
- UK: PAGB (Proprietary Association Great Britain)
- Belgium: BACHI (Belgian Association of Consumer Healthcare Industry)
- Spain : ANEFP (Asociación para el Autocuidado de la Salud)
- Greece: SINDESMOS ETERION FARMAKON EVRIAS HRISEOS, abbreviated in Greek as Sindesmos EFEX in Greece (its corresponding English name is the ASSOCIATION OF GREEK SELF CARE INDUSTRY(EFEX))
- Portugal: Apifarma
- Switzerland: ASSGP (Association Suisse des Spécialités Pharmaceutiques Grand Public)
- Austria: (Interessensgemeinschaft österreichischer Heilmittelhersteller und Depositeure)

Asia, Middle East, Africa:

- Philippines - Pharmaceutical and Healthcare Association of the Phils (PHAP)
- Japan - Self-Medication Industry (JSMI)
- China - R&D-Based Pharmaceutical Association Committee in China
- Indonesia - Gabungan Perusahaan Farmasi Indonesia (Indonesian GP Farmasi - Pharmaceutical Company Association)
- South Korea - Korea Research based Pharmaceutical Industry Association (KPRIA)
- Vietnam - Vietnam American Chamber of Commerce Health Supplement Group

- Thailand - Thailand Self-medication Industry Association (TSMIA)
- Singapore - Singapore Association of Pharmaceutical Industries (SAPI)
- Malaysia - Consumer Health Association of Malaysia
- Egypt - co-created a guidance with the EDA where Sanofi AMEA has a membership.
- India - Uniform Code for Pharmaceutical Marketing Practices (UCPMP) and the Organisation of Pharmaceutical Producers of India (OPPI) Code for Pharmaceutical Practices.
- Turkey - code of Association of Research-Based Pharmaceutical Companies (AIFD)

In AMEA, the codes of ethics of the main industry associations to which the Sanofi Group is affiliated are:

- China: China Nonprescription Medicines Association (CNMA)
- Australia: Consumer Health Products Australia
- Japan: Japan Self-Medication Industry (JSMI)
- Middle East, North Africa and Pakistan Self-Medication Industry (MENAP-SMI)
- New Zealand Self-Medication Industry Association (NZSMI)
- Organisation of Pharmaceutical Products of India
- Pharmaceutical Association of Malaysia (PhAMA)
- Pharmaceutical Healthcare Association of the Philippines (PHAP)
- Selfcare Association of South Africa
- Taisho Pharmaceutical Co., Ltd
- Taiwan Pharmaceutical Marketing & Management Association (TPMMA)
- Thai Self-Medication Industry Association (TSMIA)

Each year, Sanofi Group publicly discloses the transfers of value made to healthcare professionals (among others) in line with the Ethics Code of the industry associations the company is members of and other applicable laws and regulations.

- In North America, this is in line with the US Sunshine Act and other applicable laws and regulations.
- In Western Europe and Central Eastern Europe, this is based upon the EFPIA and local pharma code transparency regulations.
- In Brazil, Opella complies with legal requirements established in the Health Code for the state of Minas Gerais, based on the state law nº 13.317 of 1999.
- In the ASEA zone, the Pharmaceutical Healthcare Association of the Philippines (PHAP), which is a member of the Global Self Care federation, mandates this disclosure in line with their rules. In Indonesia, the prevailing regulations mandate this, so they do declarations as required. In Egypt, declarations are based on Authority requests.

Whistleblowing

Opella 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 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 enlists a team from regulatory, medical, legal, and commercial sectors 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.*

Opella 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 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 local, 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 local laws, Sanofi Group discloses all expenditures related to federal 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 is engaged include broad, equitable access to over-the-counter (OTC) medicines and products; medicines reimbursement; 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, 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 is a member of several trade associations that represent and advocate on behalf of Opella, and other consumer healthcare companies, on consumer healthcare-related issues aimed at improving the environment for self-care. Trade associations for which Opella 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 may sit. The consumer healthcare industry trade associations that Opella participates in are:

North America:

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

LATAM

- Brazil: Brazilian Association of the Industry of Self-Care Products in Health (ACESSA)
- Brazil: Pharmaceutical Industry Union (SINDUSFARMA) and Brazilian Association of the Special Purpose Food Industry and Related Products (ABIAD).
- Colombia: Asociación Nacional de Empresarios de Colombia (ANDI),
- Argentina: Cámara Argentina de Medicamentos de Venta Libre (CAPEMVeL) and Cámara Argentina de Especialidades Medicinales (CAEME),

- Peru: Asociación Nacional de Laboratorios Farmacéuticos de Peru (ALAFARPE),
- Panamá: Federación Centroamericana y del Caribe de Laboratorios Farmacéuticos (FEDEFARMA),
- Ecuador: Corporación de la Industria Farmacéutica de Investigación (IFI),
- Mexico: AFAMELA (Asociación de Fabricantes de Libre acceso), ANAISA (Asociación Nacional de la industria de Suplementos Alimenticios) & CANIFARMA as ONE Sanofi (Cámara Nacional de la Industria Farmacéutica)

Europe:

- France: NERES (Trade association for OTC pharma industry “Nouvelle Ere de Santé Responsable - A new era of Responsible Care)
- Russia: Association of Consumer Healthcare Industry (ACHI), Association of International Pharmaceutical Manufacturers (AIPM); Association of European Businesses
- Germany: Bundesverband der Arzneimittelhersteller (BAH), Lebensmittelverband Deutschland e.V, and INTEGRITAS e.V. – „Verein für lautere Heilmittelwerbung”
- UK: PAGB (Proprietary Association Great Britain)
- Belgium: BACHI (Belgian Association of Consumer Healthcare Industry)
- Spain : ANEFP (Asociación para el Autocuidado de la Salud)
- Greece: SINDESMOS ETERION FARMAKON EVRIAS HRISEOS, abbreviated in Greek as Sindesmos EFEX. In Greece (its corresponding English name is the ASSOCIATION OF GREEK SELF CARE INDUSTRY(EFEX))
- Portugal: Apifarma (which is the Pharma Industry Trade association)
- Switzerland: ASSGP (Association Suisse des Spécialités Pharmaceutiques Grand Public)
- Austria: IGEPHA (Interessensgemeinschaft österreichischer Heilmittelhersteller und Depositeure)
- Slovakia: SARAP Slovenská asociácia spoločností v oblastiliekovej regulácie (Slovak Association of Regulatory Affairs Professionals)
- Czech Republic: SVOPL – Stružení výrobců volně prodejných léčivých přípravků
- Poland: PASMI - Polish Association of Self Medication Industry
- Hungary: Magyosz - Magyarországi Gyógyszergyártók Országos Szövetsége
- Ukraine: EBA – European Business Association
- Romania: RASCI - Romanian association of manufacturers of OTC medicines, food supplements and medical devices

Asia, Middle East, Africa:

- India: Organisation of Pharmaceutical Producers of India (OPPI) India: Advertising Standards Council of India (ASCI)
- India: Indo-French Chamber of Commerce (IFCCI)
- India: The Federation of Indian Chambers of Commerce & Industry (FICCI)

- Australia: Complimentary Medicines Australia (CMA)
- Asia Pacific: Asia Pacific Self Medication Industry Association (APSMI)
- Vietnam: Vietnam American Chamber of Commerce Health Supplement Group
- Philippines: Pharmaceutical and Healthcare Association of the Phils (PHAP)
- Philippines: Consumer Healthcare Industry Association of the Philippines (CHAP)
- Philippines: Philippine Association of Pharmacists in the Pharmaceutical Industry (PAPPI)
- Indonesia: Pengurus Pusat Gabungan Perusahaan Farmasi Indonesia (GP Farmasi)
- Singapore: Singapore Association of Pharmaceutical Industries (SAPI)
- South Korea: Korea Research-based Pharmaceutical Industry Association (KPRIA)
- Japan: The Federation of Pharmaceutical Manufacturers' Association of Japan (FPMAJ)
- Japan: Japan Federation of Self-Medication Industries (JFSMI)
- Japan: Japan Self-Medication Industry (JSMI)
- Japan: Japan Direct Selling Pharmaceutical Manufacturers Association (JDSPA)
- Japan: The Pharmaceutical Manufacturers' Association of Tokyo (PMAT)
- China: Chinese Nutrition Society（CNS）
- China: China Nutrition and Health Food Association (CNFA)
- China: China Nonprescription Medicines Association (CNMA)
- AMEA: GSCF: Global Self-Care Federation
- AMEA: MENAP-SMI: Middle East & North Africa – Pakistan Self-Medication Industry
- AMEA: ITDP: Institute for Transportation & Development Policy
- Turkey: Turkey Food Supplement and Nutrition Association (GTBD)
- Turkey: Turkey Pharmaceutical Manufacturers Association (IEIS)
- Turkey: Turkey Health Products Association (SURDER)
- Turkey: Turkey Association of Research-Based Pharmaceutical Companies (AIFD)
- Turkey: Turkey All Food International Trade Association (TUGIDER)
- Tunisia: SEPHIRE the union of innovative pharmaceutical companies in Tunisia
- Italy: Assolute
- Italy: Unione Italiana Food

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 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 companies).

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 currently work on the development of new molecules (e.g., active pharmaceutical ingredients or APIs), but rather on established APIs with well-documented scientific, clinical and safety data. Generally, new medicinal products with new active molecules, often referred to as new molecular entities (NMEs), typically require a prescription as they are subject to rigorous evaluation and approval processes to ensure their safety and efficacy. In 2023, approximately less than 5% of Opella's products were subject to patents. These patents are related to established APIs and not new medicinal products with new active molecules. Internal experts in intellectual property report directly to Opella's General Counsel, who maintains oversight of any intellectual property issues. The General Counsel is a member of Opella's executive leadership team.

As required by the local health authority, Opella 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 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 does not feature any of Opella 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. Opella's 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 2024 Sanofi Group achieved a score of 3.52 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 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 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 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 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's primary distribution channels are stationary pharmacies, e-commerce pharmacies, and wholesalers. Our product portfolio contains mostly products that do not require prescriptions. The company reported that 7% of its sales come from prescription-only products. Government regulations control prices of products that require a prescription:

- In Canada prescription pricing may be negotiated independently within each Canadian province.
- In Brazil the Government regulation agency (CMED) controls prices of products depending on whether they are controlled substances or not.
- In Western Europe and Central Eastern Europe, prices of products that require a prescription are controlled by government regulations, when reimbursed by the National Health System.
- In France prices of some products are controlled by government regulations, when reimbursed by the National Health System 64% of the Opella France's portfolio is price controlled.
- In Russia,prices for some medicines are controlled through Essential Drug List regulation. The limit of the selling price for medicines which are in the list is stated by the Government and also the wholesale and retail mark-up are defined. 22% of the Opella Russia portfolio is in the Essential Drug list (No-spa, Lasolvan, Zodak, Guttalax).
- In China: the National Medical Products Administration
- In Thailand: National Drug System Development Committee - under ministry of public health; announces reference drug price for public hospitals and National List of Essential Medicines (NLEM)

- In Vietnam: Circular 50 – Guiding to implement the state management of price of drug for human & Decree 54 & 155 – Drug Price Declaration Article 134,
- In Philippines: Updated Suggested Retail Price (SRP) for Emergency Essential Medicines and Medical Devices Executive Order 104 and 155.
- In Indonesia: Regulation of Ministry of Health No. 98 of 2015.
- In India, the Drug Price Control Order, 2013 (DPCO) has been issued by the Government of India under Section 3 of the Essential Commodities Act, 1955 to regulate the prices of drugs. DPCO restricts price and price revisions for the drugs covered under DPCO.
- In AMET (Africa Middle East & Turkey): 80% of the products are price controlled and the Health Authorities decide the price based on announced regulations for each country

Pharmaceutical or medicinal products that require a prescription are normally reimbursed by the government, thus subjecting them to the government's pricing policy. Opella does not intend to launch new products that require a prescription; however, it may engage overtime with health authorities to maintain the economic model of existing, reimbursed products.

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 sells to distributors, who will then sell to wholesale customers and to pharmacies (stationary and e-commerce). The structure of the consumer health market itself and Opella'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 follows Sanofi Group's internal Sales Incentives policy which includes an addendum specific to 'Sales Incentive Plans for Opella dedicated Sales functions.

Opella Incentive Plan has in its composition components:

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

Additionally, Opella promotes responsible sales practices in various ways including but not limited to, the following:

- **Incentive Structure.** Opella 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 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 utilizes a bonus committee to ensure appropriate ethical behavior and operational management is coached on ensuring ethical marketing and Opella's various internal control mechanisms are enforced. Additionally, Opella 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 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.

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