B Corp Requirements for Pharmaceutical Companies

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. For more information on the specific requirements, please refer to B Lab's position statement on Pharmaceutical Companies here.

The following questions will be used to evaluate whether your company must meet the industry specific requirements for pharmaceutical companies to be eligible for B Corp Certification, as well as provide an initial indication whether your company is likely to be meeting them. Please feel free to add your responses directly to this document.

Depending on your company's responses, B Lab may request additional information and/or require a decision by B Lab's independent Standards Advisory Council to determine your eligibility.

Summary of Company

ESTEVE is a global pharmaceutical company founded in 1929 and headquartered in Barcelona, Spain. The company operates through two main divisions: the pharmaceutical division, which focuses on the research, development, manufacturing, and commercialization of a diverse range of products, and the Contract Manufacturing Organization (CMO) division, which specializes in manufacturing active pharmaceutical ingredients (APIs) for other pharmaceutical companies.

The global headquarters in Spain serve as the central hub for strategic planning and international operations. The company has six pharmaceutical affiliates across Europe (in France, Germany, Italy, Portugal, and Spain) and, as of 2024, the United States. Additionally, ESTEVE operates a pharmaceutical manufacturing site in Germany, focusing on a specific segment of its product portfolio.

To support its global CMO operations and to ensure high-quality manufacturing services for pharmaceutical companies, ESTEVE manages five manufacturing plants for its CMO business: three in Spain, one in Mexico, and one in China.

ESTEVE has established distribution agreements and strategic partnerships to market its pharmaceutical products in 54 countries worldwide, including Andorra, Argentina, Armenia, Australia, Austria, Bahrain, Belgium, Brazil, Bosnia-Herzegovina, Bulgaria, Canada, Chile, Colombia, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Germany, Greece,

Hong Kong, Hungary, Iceland, Indonesia, Ireland, Israel, Italy, Japan, Latvia, Lithuania, Luxembourg, Malaysia, Malta, the Netherlands, New Zealand, Norway, Oman, Panama, Peru, Poland, Portugal, Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United Arab Emirates.

ESTEVE operates in these markets through a combination of licensing agreements, supply agreements, and distribution partnerships. Depending on the specific market and agreement structure, ESTEVE may hold Marketing Authorization Holder (MAH) status, or this responsibility may be assigned to its local partners.

ESTEVE is focused on addressing unmet medical needs. Its portfolio covers six therapeutic areas: (i) Central Nervous System (CNS): Treatments for managing movement and emotions, including antidepressants and anti-anxiety medications. (ii) Oncology & Pain: Solutions for cancer care and chronic pain. (iii) Ophthalmology: Medications for various eye conditions. (iv) Cardio-Metabolism: Products for heart and metabolic conditions, such as hypertension and diabetes. (v) Over-the-counter (OTC): Non-prescription products for minor ailments. (vi) Anti-Infectives & Others: Medicines for infections, including antibiotics and antivirals.

The CMO business model manufactures APIs for additional areas, including dermatology, Gastroenterology, Hematology, Immunology, and more.

In fiscal year 2023, pharmaceutical products accounted for 35% of total revenue, with 82% of this revenue coming from prescription medicines. The revenue breakdown by therapeutic area is as follows: (i) CNS: 19.1%, (ii) Oncology & Pain: 14.75%, (iii) Ophthalmology: 6.6%, (iv) Cardio-Metabolism: 24.7%, (v) OTC: 20.8%, (vi) Anti-Infectives & Others: 14.05%.

For the CMO business, APIs accounted for about 65% of revenue, with the largest share from Infectious Diseases and Vaccines (55.45%).

Since selling its generics business in 2019, ESTEVE no longer generates revenue from generic products.

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.*

ESTEVE 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, to verify it is meeting the above requirements regarding prohibited industry practices. The company's approach to managing these material topics to the industry are further detailed below.

Required Best Practices - All Companies

In order to be eligible, pharmaceutical companies must be able to demonstrate that they have the following practices in place and disclose them on their B Corp Profile:

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.*

ESTEVE operates in compliance with international quality assurance standards and stringent regulatory requirements. The company undergoes regular inspections and audits from regulatory authorities such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), Spanish Agency for Medicines and Health Products (AEMPS), Catalonian Department of Health, and Pharmaceuticals and Medical Devices Agency (PMDA).

ESTEVE adheres to GxP guidelines, quality standards for pharmaceutical development and manufacturing, as enforced by agencies such as the FDA and EMA, to ensure product safety and efficacy. ESTEVE complies with Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP), Good Distribution Practices (GDP), and Good Pharmacovigilance Practices (GVP). The commitment to quality and regulatory compliance is integrated throughout the pharmaceutical product lifecycle.

ESTEVE's control over the pharmaceutical product lifecycle differs between its two business units. In the CMO Business, ESTEVE manages drug development, manufacturing, and

distribution for client products, while the primary responsibilities for post-market activities typically rest with the client, unless otherwise specified. In contrast, the Pharmaceutical Business sees ESTEVE overseeing all phases of the lifecycle for its proprietary products. The lifecycle comprises four stages:

1. Drug Development: Includes research, clinical trials, and obtaining regulatory approvals before manufacturing. ESTEVE follows GCP and GLP standards. Since many development activities are outsourced to Contract Research Organisations (CROs), these third parties undergo regular audits to verify compliance with GCP and GLP.

2. Manufacturing: Focuses on producing pharmaceutical products while complying with quality, safety, and regulatory standards. ESTEVE's manufacturing operations including internal facilities and external CROs, comply with GMP standards for product consistency and quality. For externally manufactured products, ESTEVE selects and oversees CMOs. Prospective CMOs must provide certifications, quality policies, Standard Operating Procedures (SOPs), and Work Instructions (WIs), and undergo initial audits to formalize technical agreements. CMOs are reassessed every three to five years, with targeted audits for critical deviations and verification of the effectiveness of Operating Procedures (SOPs) training.

3. Distribution: Involves logistics and supply chain management to ensure product availability. ESTEVE adheres to GDP standards to ensure that pharmaceutical products are stored, transported, and handled properly, preserving their integrity and quality.

4. Post-Market Phase: Covers pharmacovigilance, ongoing drug safety monitoring, and regulatory compliance after product launch. After launching a product, ESTEVE employs a robust pharmacovigilance system to monitor drug safety and ensure compliance. A five-year pharmacovigilance plan is implemented in collaboration with affiliates and partners, enabling the reporting of adverse events to authorities based on their severity. ESTEVE's commitment to quality, safety, and compliance reinforces its reputation as a trusted partner in the pharmaceutical sector.

To mitigate the risk of counterfeit medicines, ESTEVE has established a procedure that includes: (i) Supplier Qualification & Audits: Authorised suppliers undergo regular audits and sign Quality Technical Agreements focused on counterfeit prevention. (ii) Client Legitimacy Verification: Clients must meet legal requirements before receiving products. (iii) Secure Manufacturing & Distribution: Medicines are produced through authorised supply chains in compliance with Marketing Authorisation. (iv) Employee Training: Staff are trained to identify and respond to counterfeit products. (iv) Code of Conduct: Employees follow a Code of Conduct for managing fraud or falsification cases. (v) Incident Management: Established protocols for reporting suspicious activity. Additionally, ESTEVE implements serialisation and aggregation in

line with EU regulations, including: (i) Anti-Tampering Devices: Security features to prevent unauthorised tampering. (ii) Data Matrix (Unique Identifier): A unique code for traceability. Pharmacists scan this code before dispensing; if counterfeit, an alert is triggered. These measures ensure patient safety and maintain the integrity of the pharmaceutical supply chain.

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.*

ESTEVE's Code of Conduct ESTEVE's Third Party Code applies to all employees and stakeholders. Both outline the company's principles, including: (i) Anti-Corruption and Bribery, ESTEVE has a General Procedure for the Prevention of Bribery and Corruption and Conflict of Interest, providing guidelines on risk management, accessible via the Compliance Department. (ii) Ethical Marketing: Transparency and accuracy in marketing are prioritized, adhering to all relevant laws and industry codes.

All employees sign an annual commitment to the Code of Conduct and the General procedure for the Prevention of Bribery and corruption, and undergo regular training in ethics and compliance.

ESTEVE's interactions with healthcare professionals, patients and organizations adhere to (i) complying with the Pharma Industry Code and local regulations, ensuring rigorous guidelines, (ii) disclosing collaborations and sponsorships on its corporate website and annual reports, and (iii) implementing a policy for ethical interactions with patient associations.

ESTEVE's Third-Party Code extends its ethical commitments to partners, setting clear expectations for suppliers, joint ventures, and other partners, including distributors, licensees, and co-marketers. This code is aligned with international standards such as the Pharmaceutical Supply Chain Initiative, the United Nations Global Compact, the UN Sustainable Development Goals (2030 Agenda) and the International Labour Organisation Fundamental Conventions.

Through these measures, ESTEVE ensures integrity, accountability, and responsible corporate conduct across its operations and relationships. To facilitate reporting of concerns, ESTEVE has established a confidential Ethics Channel. External stakeholders manage this channel to

ensure confidentiality and inclusivity. Reported violations are reviewed through the Ethics Channel to ensure accountability and prompt corrective action.

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.*

ESTEVE is committed to ethical standards and legal compliance. ESTEVE comply with the ethical codes of the Pharma Industry (Farmaindustria) in Spain, providing clear guidelines for responsible engagement with healthcare professionals and patient organisations.

ESTEVE do not engage in lobbying or policy advocacy. Its interactions with trade associations are conducted in accordance with legal and competition regulations. Details about its interactions and its annual donations to healthcare organisations are available on its Annual Report (page 66).

ESTEVE's Standard Operating Procedure On Grants and Donations, prohibits grants or donations to political entities. In alignment with its Code of Conduct, ESTEVE maintains open communication with public administrations, ensuring timely information disclosure.

ESTEVE has established a formal Policy governing interactions with Authorities, Politics and Decision Makers. This policy aims to ensure that all interactions are conducted in a transparent, ethical, and legally compliant manner, reflecting the company's values and its commitment to responsible business practices. It establishes internal guidelines for interacting with public institutions, regulators, and political stakeholders, reaffirming ESTEVE's commitment to upholding independence, integrity, and accountability in all external engagements. Key principles of the policy include: compliance with ESTEVE's Code of Conduct and ethics regulations, adherence to relevant laws and protocols, no gifts or advantages offered to public officials, transparent interactions conducted through official channels and documented appropriately, preference for written communication to maintain records, and prohibition of political contributions or payments to officials.

This policy has been formally integrated as an annex to ESTEVE's General Procedure for the Prevention of Bribery and Corruption Policy, making it binding across the organization. All employees are required to formally acknowledge the procedure and receive specific training to ensure proper understanding and implementation of its principles.

Required Best Practices - Companies Involved in R&D

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.*

ESTEVE's Research and Development (R&D) team collaborates within multidisciplinary groups across various stages, including drug design, molecular biology, pharmacology, clinical development, quality assurance, and regulatory affairs.

Currently, ESTEVE's R&D portfolio includes New Chemical Entities (NCEs) in neurology and analgesia, as well as advanced therapies for inherited metabolic disorders. The company focuses on late-stage development phases, ensuring that necessary non-clinical studies are conducted under the strictest regulations.

While ESTEVE does not have a specific Responsible R&D Policy, the company ensures that CROs adhere to all relevant ethical and regulatory standards. ESTEVE complies with EU, US, and local regulations through regular Quality Assurance audits and external inspections.

In 2023, the reported R&D expenses for the ESTEVE totalled €25,192 thousand, with €13,543 thousand allocated to the pharmaceutical business and €11,649 thousand to the CMO business.

ESTEVE's Code of Conduct and ESTEVE's Third Party Code express the foundation of respect for intellectual property and the obligation to comply with industrial copyright laws. The Global IP & Brands Team manages patent and trademark issues, implementing internal procedures to maintain IP rights and mitigate risks. When needed, ESTEVE engages external firms for specialised IP matters.

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).*

ESTEVE does not currently have any active research and development projects aimed at addressing the priority diseases, conditions, and pathogens identified in the Access to Medicine Index.

Required Best Practices - Companies Involved in Sales

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.*

ESTEVE aims to maintain transparent and fair pricing practices. Over the past five years, ESTEVE has worked to ensure that its prices remain accessible and affordable for consumers.

A significant portion of ESTEVE's portfolio, 75.5% (176 out of 233 products), consists of regulated products that are subject to pricing regulations set by health authorities, ensuring fairness and accessibility. For ESTEVE's non-regulated products, pricing is determined based on market conditions. In the case of pharmaceuticals, prices are set according to the PVL (labelling price) or data from health agencies. For over-the-counter (OTC) products, prices are based on the recommended retail price. Additionally, ESTEVE regularly reviews and adjusts pricing in line with each country's Consumer Price Index (CPI).

Compliance with pricing regulations is monitored by the commercial department, with support from the financial team, which reports directly to the Chief Commercial Officer.

In low- and middle-income countries (LMICs), ESTEVE adjusts its pricing to ensure that its products are affordable. In countries such as Argentina, Brazil, Colombia, South Africa, Turkey, and Peru, ESTEVE collaborates with local partners and adheres to local regulations to set prices that align with the local economic conditions. This approach aims to improve access to essential medicines and support healthcare systems.

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).*

ESTEVE's pharmaceutical sales teams must comply with all international and local regulations to ensure ethical selling practices and prevent any improper conduct, as outlined by the European Federation of Pharmaceutical Industries and Associations. ESTEVE offer financial incentives based on sales volumes in their assigned territories. The specific metrics for these incentives differ by team, role, and country. They are based on achieving sales targets within assigned territories and focus on meeting ethical work standards and legal compliance in the promotion of products. ESTEVE has implemented a Commercial Incentives Protocol for its pharmaceutical business that includes mechanisms to ensure ethical sales practices. This

protocol features a reporting channel for addressing non-compliance, procedures aimed at preventing bribery and corruption, and clear communication to staff regarding these measures.

The company has established regulations governing interactions with third parties and promotional activities, as well as a segregation of duties in the review of sales incentives. Additionally, ethics training is provided for sales staff, complemented by an internal code of conduct and a code of conduct for third-party, to ensure adherence to local pharmaceutical regulations.

Required Best Practices - Companies Listed on ATMI

8. *In addition to the above requirements, companies listed on the Access To Medicine Index must also achieve a score of 2.50 or higher in each of the Index's three specific topic areas. If listed, B Lab will review your company's scorecard in order to verify this requirement.*

ESTEVE, though not listed in the Access to Medicine Index, is committed to ensuring patient access to essential medicines. The company follows relevant regulations and employs pricing strategies to promote affordability, reflecting its commitment to ethical practices in the pharmaceutical industry.