



B Lab Statement on Ferrer's B Corp Certification

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..."

Ferrer 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 Ferrer

Ferrer is a vertically integrated pharmaceutical company headquartered in Spain. It has both R&D and manufacturing facilities in Spain and the United States, as well as 14 international sales and marketing subsidiaries across Europe, North America, Central America and South America. Ferrer's products are present in over 100 countries globally and are distributed through business partnerships in markets where the company does not have direct operations.

The company has a diverse portfolio of products that include branded prescription medicines, hospital products, molecular diagnostics, and over-the-counter / self-care products. Ferrer's main therapeutic areas are neurological disorders and pulmonary vascular and interstitial lung diseases, and it also has great expertise in the areas of pain management, dermatology, cardiometabolism, and rare diseases, which are those that affect 1 in 2,000 people or less.

Ferrer'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.

Ferrer 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.

Ferrer’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.*

Ferrer is compliant with the current most demanding international quality assurance standards, such as the European Medicine Agency (EMA), the U.S. Food and Drug Administration (FDA), and full implementation of the [ICH Good Manufacturing Practice Q7A](#) and ISO standards (such as e.g. Q7A on Good Manufacturing Practice and 9001 on Quality System, 13485 Medical Devices respectively). Ferrer is in possession of the corresponding national authority GMP and GDP certificates for its manufacturing sites and logistic warehouse respectively. The scope of Ferrer’s quality management system covers the entire life cycle of the drug, from drug development all the way through distribution and discontinuation, and also applies to outsourced manufacturing via contracted manufacturing organizations (CMOs). Its quality management system follows the [ICH Q9 Quality Risk Management](#) and [Q10 Pharmaceutical Quality System](#) standards.

Regarding Ferrer’s supply chain, the company has formal supply chain approval and monitoring systems for suppliers of raw materials, packaging materials, and critical services. Its processes include reviewing supplier documentation, conducting risk analyses, testing samples, and conducting audits for different product categories.

Across all stages of the drug lifecycle, Ferrer has various anti-counterfeiting initiatives that include verifying the authenticity and quality of the active ingredients and excipients, adhering to European Good Distribution Practice guidelines, and implementing unique identifiers and security seals for its products. Processes are in place that guarantee the identification of out-of-specification results or deviations from the approved standards, its root cause investigation and mitigation-related tasks.

Furthermore, Ferrer has an appropriate pharmacovigilance (PV) system in place to assume its responsibilities and liability for its products on the market and to ensure that the appropriate safety measures are taken when needed. The PV system is based on the applicable ICH

guidelines, Good Pharmacovigilance Practices (GVP) and global and local applicable regulations, to guarantee the correct analysis of safety information collected and received by Ferrer, for the maintenance of a positive benefit/risk balance on Ferrer products.

Finally, it is confirmed that the practices reported at the time of Certification are still in force.

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.*

Ferrer is fully committed to complying with applicable regulations and to act with honesty and integrity.

The commitment of the Corporate Board of Directors, the Corporate Board of Management, the Advisory Board on Ethics, Compliance and Audit and other committees, who are responsible of the surveillance of the Corporate Ethics and Compliance Management System (the "System"), is essential to ensure ethics and honesty in business. At Ferrer, members of the governing bodies and people who hold key positions are called to sign an Annual Statement on Ethics and Compliance.

Governing bodies are responsible for the Ethics and Compliance function, both at corporate and local levels, and are in charge of the design and deployment of the different programmes as well as guaranteeing a continuous improvement of the System. One of the commitments is to provide the right tools and support to facilitate the decision-making process of all Ferrer's people and the related compliance tasks. Ferrer's System considers the latest regulatory updates as well as the best practices of the sector and markets.

As such, Ferrer has an [Ethical Code](#) that sets up the main principles and values that govern its daily activity and is applicable to all employees, directors and management covering topics such as anti-corruption, donations, funding, sponsorship, and patronage. Regular training and engagement on the Code is conducted across the organization. The global launch of the course on Ethical Code was attended by +95% of Ferrer's people.

Ferrer is guided by the principle of zero tolerance for corruption, rejecting any related practice, as stated in their Corporate ABAC Policy. In 2023, Ferrer's Anti-Bribery and Anti-Corruption Management System was audited by an external audit team (Official Certification Entity AENOR) and certified under the requirements and best practices of ISO 37001, on Anti-Bribery Management Systems.

Attending to the sector where Ferrer operates, it is fundamental to ensure that their relations with Healthcare Professionals (HCP), Healthcare Organisations (HCO) and Patient Organisations (PO) and Consumers are based on a legitimate need, are efficient and comply with all legal provisions and sectoral codes to which Ferrer adheres, such as the [Code of](#)

[Practice for the Pharmaceutical Industry](#) of the Spanish Farmaindustria association, which establishes specific ethical guidelines for the promotion of prescription-only medicines, relationships with healthcare providers/organizations, and relationships with patients associations, all of it aligned with IFPMA, the code of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and local codes. Ferrer currently counts with the [Corporate Policy of Interaction with HCP, HCO, PO and Consumers](#), Donations Corporate Policy and the Corporate Policy on Validation of Informative and Promotional Content (former Corporate Promotional Compliance Policy, dated 2020). These policies are developed with corporate and local procedures and SOPs, which count with a multi-step approval process that follows segregation of duties-based approach, such as the Procedure of setting Fees to Healthcare Professionals (Fair Market Value). Additionally, the company [publicly discloses its transfers of value and payments](#) made to healthcare professionals, healthcare organizations and patient associations, in addition to transfers of value related to R&D, according to legal and sectoral requirements. Other regulations such as Data Protection, Anti-trust or Trade Control internal regulations are also to be highlighted and count with its deployment across the organization.

Compliance with legislation and internal regulatory framework is guaranteed through culture, internal processes and controls. All of it is monitored through Internal Risks Management System (supported by IT tool RSA Archer) and duly reported to the governance bodies. Ferrer counts with a Legal Risks Map, that is periodically reviewed and updated. Significant improvements have been done in the last years at Ferrer regarding risks management system. Thus, different risks maps have been developed internally to monitor and mitigate risks from a strategic, operational and legal perspective.

Ferrer strives to adopt a true culture of ethics and compliance not only internally, but throughout its value chain. Ferrer counts with a [Code of Ethics for Third Parties](#) that establishes the main principles and values that govern its relationships with third parties and a Corporate Sustainable Procurement Policy. From a preventive perspective, Ferrer counts with a [Corporate Policy on Business Partner Due Diligence](#), and IT tools to monitor ESG (including Compliance topics) of Third Parties. Compliance clauses are included in the different contracts, on a risk-based approach and audits to third parties are carried out.

Ferrer is aware of the importance of the Ethical Channel, available also for any third party and a speak-up culture to fight practices that may go against Ferrer's ethical values or the law. The Ethical Channel's form to report potential breaches is posted on the front page of [Ferrer's website](#) and the whistleblowing management system is supported by a software that guarantees the rights of the parties and the process. Ferrer's Corporate Policy on the [Whistleblowing Management System and Procedures](#) have been recently updated to align its contents with the Whistleblower Protection regulations a software has been selected to guarantee. Confidentiality, anonymity, equal treatment, and no retaliation principles are guaranteed during the whole process.

- 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.

Ferrer is guided by the principle of zero tolerance for corruption, rejecting any related practice. Ferrer's position on lobbying activities is conservative. Moreover, Ferrer is a member of the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE); in Spain, Ferrer is a member of FARMAINDUSTRIA, the National Trade Association of the Spanish-based pharmaceutical industry, the Association for Health Self-Care (ANEFP), the National Association of Manufacturers of Children's Dietetics (ANDI) and Autocontrol; APIFARMA and APORMED in Portugal; the FSA in Germany; BIA (Bioindustry Association) in the UK; the Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) in Mexico, and the Central American Federation of Pharmaceutical Laboratories (FEDEFARMA) and Cámara de innovación Farmacéutica (CIF) in Chile. Likewise, Ferrer complies with the requirements set out in the Code of Good Practice by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). Membership of Ferrer in these associations does not imply active participation in any aggressive lobbying activities.

From a perspective of strategy, the company believes that lobbying activities should not have the objective of putting consumers in danger, promoting anti-competitive initiatives, setting high drug prices or limit the equal access to treatments. So, their approach to lobbying is to participate and bring value to different discussions at national and international level about changes in legislation, access strategies, with the aim of reducing inequalities in healthcare and in access to treatment that exists in Europe for people living with PH and ALS and their caregivers.

Ferrer, as a EUCOPE member, has been participating in regular discussions on the new European Pharmaceutical Legislation proposal claiming for a global framework that facilitates companies to keep searching and developing new solutions for medical unmet needs. EUCOPE itself, and applicable to all members, has an internal code that ensures safe lobby activities.

Ferrer is also part of the EU ALS Expert Coalition, a diverse group including patients, HCPs, research, payers, and industry with the aim of issuing to European policymakers a set of recommendations regarding ALS patients' healthcare. The coalition itself has internal standards such as prohibiting discussions about products and focusing the discussion on the disease itself, the need for a better diagnosis, healthcare inequalities in European countries, among other topics.

Ferrer's strategy is based on a multistakeholder approach that helps the company acquire a deep understanding of the landscape & interdependencies among main stakeholders to manage the system's complexity. In this regard, Ferrer considers the patient community as a key stakeholder. They ensure that the voice of the patient is heard throughout the entire value chain. To ensure compliance in the interaction with patient organizations and patients, Ferrer has a Corporate SOP, which develops the principles and values set forth in Code of Ethics, Corporate Anti-corruption and Anti-bribery Policy as well as Corporate Policy on Interactions with HCPs, HCOs and POs Ferrer's relationships enable the company to react appropriately to

the evolving needs of the communities they serve guaranteeing an ethical and honest behavior in its daily activities, beyond compliance.

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.

In Ferrer's purpose of providing significant and differential value to people who suffer from severe pathologies, Ferrer has defined a clear global R&D strategy aimed at developing a pipeline of transformative therapeutic solutions capable of improving the lives of people who suffers from debilitating and/or high mortality diseases.

Ferrer has developed a Responsible R&D Policy based on the following strategic principles:

- Research and development in projects of high differential value;
- Research and Development in rare diseases and for which there are unmet clinical needs;
- Research and development in diseases with high mortality and/or disability;
- Ensure a sustainable and robust pipeline;
- Transparent and data-based decision-making;
- Selection of materials and suppliers based on sustainability criteria;
- Research and development committed to animal welfare;

The guidelines for the search for new products in Ferrer's pipeline include the search for new options in high mortality indications such as Amyotrophic Lateral Sclerosis, Progressive Supranuclear Palsy, and Interstitial Pulmonary Fibrosis for which there are no treatments or for which there are only symptomatic treatments. Ferrer also includes searches for solutions for highly debilitating diseases such as Rett syndrome, Friedrich's ataxia, pulmonary hypertension, and anti-trypsin deficiency. To guarantee transparency and transversality in the decision-making, Ferrer has implemented an internal committee to control the selection and entry of new projects into the pipeline (New Product Planning). The best opportunities are evaluated and selected according to strict criteria defined by the New Product Planning Committee that include the analysis of scientific soundness, clinical need, value positioning, technical and economic feasibility, and an exhaustive risk analysis. R&D investments are then monitored through the Development Committee to guarantee also transparency and multidisciplinary in R&D project decision-making and results evaluation as well as supervision of milestones, KPIs and targets.

Finally, several procedures have been implemented to ensure that all processes reduce environmental impact and are carried out guaranteeing the protection of Ferrer's people.

In 2023, the total amount invested in R&D activities was 55,000,000€.

Regarding intellectual property strategy, Ferrer has developed a "Position Statement regarding Patents" which captures the company's standard practice. This Patent Statement includes:

- Guidelines for applying a responsible patent policy that avoids the practice called

evergreening. These guidelines include that, after 20 years from the launch of a product in a given country, Ferrer will not exercise patent rights against the commercialization of a generic by a third party under the same terms on which it was initially launched.

- Commitment to not file patent applications or to enforce patents, in low-income countries to facilitate access to medicines in such countries.
- Implementation of a voluntary licensing policy in low-income countries, in favour of other manufacturers so that they can produce patented products.
- Commitment to making information related to our current and future patent portfolio more freely available to procurement agencies.

More information about Ferrer's R&D strategies is available on their [website](#).

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).

Through a public-private partnership between CNIC and Ferrer, the Fixed-Dose-Combination Polypill containing acetylsalicylic acid 100mg, atorvastatin (20mg or 40mg) and ramipril (2,5mg, 5mg and 10mg), was developed. This cv polypill has shown its efficacy in randomized clinical trials¹ in 2022. This evidence has led to its inclusion in the [World Health Organization \(WHO\) 2023 Essential Medicines List](#) (chapter 12.7) as a strategy for secondary CV prevention.

This list is internationally recognized for countries' health systems, helping them prioritize effective and affordable medicines. Including Ferrer's cardiovascular polypill in the WHO Essential Medicine list should facilitate two things: greater adoption of the drug by healthcare professionals and a greater number of people with cardiovascular disease benefiting from Ferrer's therapeutic solution.

In addition to this, Ferrer is a key partner of the World Heart Federation (WHF); it participates in the development of the Roadmaps which have become the cornerstone of WHF activities as resources for implementation to guide initiatives to support heart health globally, translating science into policy and influencing agencies, governments and policymakers alike, and as well in the [Emerging Leaders Programme](#), to form and develop a long-term cadre of experts who collaborate, research, and act to reduce premature mortality from cardiovascular disease globally.

In January 2024, the World Heart Federation (WHF) included Ferrer's cardiovascular polypill in its Roadmap For Secondary Prevention based on scientific evidence that the medicine is capable of improving outcomes and reducing cardiovascular death². This publication aims to facilitate the development of initiatives by health professionals, governments, and other political organizations so that they are able to reduce complications derived from cardiovascular

¹ Castellano JM, Pocock SJ, Bhatt DL, Quesada AJ, Owen R, Fernandez-Ortiz A, et al. Polypill Strategy in Secondary Cardiovascular Prevention. N Engl J Med. 2022 Aug 26. doi: 10.1056/NEJMoa2208275

² Laranjo L, Lanas F, Sun MC, Chen DA, Hynes L, Imran TF et al. World Heart Federation Roadmap for Secondary Prevention of Cardiovascular Disease: 2023 Update. Glob Heart. 2024 Jan 22;19(1):8. doi: 10.5334/gh.1278

disorders worldwide by 30% by the year 2030. The Fixed-Dose-Combination (FDC) Roadmap is about to be published and has the aim of identifying potential roadblocks on the pathway to effective prevention, detection and management of CVD, along with evidence-based solutions to overcome them.

Ferrer's Cardiovascular Polypill containing acetylsalicylic acid, atorvastatin and ramipril is now present in 7 countries of the European Union (Austria, Belgium, Germany, Greece, Ireland, Portugal, Spain) and 17 Non-European Union Countries (Armenia, Belarus, Bosnia, Chile, Costa Rica, Dominican Republic, El Salvador, Georgia, Guatemala, Honduras, Kazakhstan, Mexico, Moldova, Nicaragua, Panamá, Serbia and Ukraine). It still needs to be expanded to more countries to improve the prognosis of more patients with established CVD.

Ferrer claims to have a strong commitment to ensure that low- and middle-income countries (LMICs) can access the cardiovascular polypill. For this reason, their strategy has also included LMIC for registration. In fact, Ferrer registered the cardiovascular polypill in over 50 countries, including LMICs such as Angola, Benin, Cameroon, Congo, and Nigeria. As part of this process, some commercialization challenges led to withdrawing or canceling the registration in 27 countries, but Ferrer continues to explore ways to expand access in these regions. Additionally, Ferrer is an active member of the World Heart Federation and collaborates with them on the new FDC (Fixed Dose Combination) Roadmap which reflects a strategic approach focused on ensuring the polypill's availability, affordability, and adoption in LMICs. This partnership highlights a commitment to overcome barriers to access and indicates a proactive strategy to support sustainable availability in these markets.

The cardiovascular polypill developed by Ferrer is commercialized under the brand names of Trinomia®, Sincronium® (Central America), and Iltria® (Germany). According to Ferrer's Patent Statement, Ferrer has abandoned Trinomia's patent in 27 countries, of which 8 are lower-middle income economies, some of them with a high population (Egypt, India, Morocco, Pakistan, Philippines, Sri Lanka, Tunisia, Vietnam). In addition, the "Position Statement regarding Patents" commits Ferrer not to enforce patents, in the low-income countries listed on the document for countries where patents have not been abandoned.

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.

In 2022, Ferrer developed its Global Pricing Policy, which is a global guidance by which Ferrer implements prices. This Policy applies directly to all Ferrer people, globally, regardless of their hierarchical, functional, or geographical position.

The Global Pricing Policy describes Ferrer's principles for price setting, and it is based on 3 key pillars: (1) Value of the product, (2) Market affordability, and (3) Prices in other countries.

- Value of the product: Ferrer subscribes the World Health Organization (WHO) and follows the value-based approach, which sets prices according to the measurable benefits that patients and health systems find in comparison with other available treatments for the same condition.
- Market affordability: Ferrer employs a flexible pricing approach that considers the country's ability to pay and patient needs. Ferrer considers the possibility of each market and its segments to finance the product. It can happen that for some countries we have a different price for private and public markets.
- Prices in other countries: In many markets, national pricing authorities determine the price for pharmaceutical products by referencing its price from several different countries. As such, it is of utmost importance to guarantee a harmonization of the prices across markets, respecting the variability inherent to each market and its different levels of affordability.

Additionally, the Global Pricing Policy details Ferrer's position regarding price gouging (no price increases above the market annual inflation rate unless appropriately justified and approved by the Pricing Approval Committee) and price dumping.

In this context, 2 key pillars of the price-setting mechanism are the "Market Affordability" and the "Prices in other countries", which specifically attend to the market's ability to pay. To gather this information, Ferrer does pricing and payer research, and gathers information from market experts (affiliates, partners, and external consultants), ensuring that the price proposed is aligned with the country's expectations and people's ability to pay. In some cases, this can mean that there are different prices for the public and private sectors, if applicable.

In many of the markets in which Ferrer operates, prices are not determined freely, requiring negotiations with local authorities based on the incremental value of the product. Consequently, the ultimate maximum selling prices of any product undergo rigorous negotiations, consistently anchored on the 3 fundamental principles of Ferrer's Global Pricing Policy.

Even in free pricing markets, Ferrer adheres to the same pricing principles as in regulated markets. The approach to setting prices remains consistent, guided by Ferrer's key pricing principles irrespective of the market's pricing nature.

The final section of the Pricing Policy delineates the roles and responsibilities for implementation and governance, as well as how Ferrer ensures compliance with the Policy. Accordingly, Ferrer has established the Global Pricing Governance framework along with an approval workflow to streamline and track previous approvals.

The Global Pricing Governance guarantees that any pricing decision made by Ferrer is aligned with the company's values and strategy.

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).

Ferrer's direct sales teams have a combination of financial incentives related to both sales volume and qualitative objectives that ensure sales activities are aligned with the company's strategy. Quantitative objectives related to sales include indicators such as direct sales to pharmacies, transfers to pharmacies, and distribution surveillance to avoid shortages. The qualitative ones are designed to ensure sales teams adhere to the established work standards (for example, certify sales rep's level of scientific knowledge, promote an adequate use of promotional tools, or foster convenient ways to approach HCPs).

Additionally, sales staff perform annual reviews to evaluate adherence to the company's values. Regular mandatory training is conducted for all sales staff to ensure a correct understanding and commitment to the highest ethical and compliance standards. Finally, a selected group of sellers are also identified as Ethics & Compliance ambassadors in the sales team to continue fostering an ethical and compliance culture and to assure total alignment.

For sales through partners, Ferrer's International Partners Department has recently replaced its quantitative topline sales objective with qualitative objectives related to ensuring its business partners meet Ferrer's compliance criteria. It has retained a bottom-line sales incentive. Training for these partners is also put in place regularly.

Furthermore, the sales team leadership committees (both National Sales Managers, Business Unit Directors, and partner managers) have an incentive schema (Contribution Model) not directly related to the national sales but to general global milestones that ensure the whole organization is aligned and pursues Ferrer's global purpose. These global milestones are the same for all Ferrer leaders, irrespective of their area of responsibility.