# B Lab

### 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 <u>here</u>.

#### 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 11 international sales and marketing subsidiaries across Europe, Central America, South America, and Asia. 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 includes branded prescription medicines, hospital products, molecular diagnostics, and over-the-counter / self-care products. Ferrer's main therapeutic areas are neurological disorders and pulmonary interstitial lung diseases, and it also has great expertise in the areas of pain, 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 to the industry are 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 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 <u>ICH Good Manufacturing Practice Q7A</u> and ISO 9001 standards. 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 standard.

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 critical 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.



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.

As such, Ferrer has an <u>Ethical Code</u> which sets up the main principles and values that govern its daily activity and that 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. In 2019, more than 200 hours of training were provided to new employees on the Code, and in 2020 an ethical climate survey was conducted across the whole organization. In 2021, the whole organization received the Ethical Code training.

The Ethical Code is supplemented by internal policies such as the Corporate Anti-bribery and anti-corruption Policy (ABAC Policy), the Corporate Promotional Compliance Policy and the Corporate Whistleblowing Management System Policy. Training on internal policies is periodically conducted.

Ferrer also adheres to the <u>The Code of Practice for the Pharmaceutical Industry</u> 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 the European Federation of Pharmaceutical Industries and Associations (EFPIA). Ferrer has an internal Corporate Promotional Compliance Policy in line with the Farmaindustria Code that sets forth the minimum standards on these topics, including promotional materials, samples, observational studies, congresses and consultancies. Such activities require a multi-step approval that follows a segregation of duties-based approach, and employees receive regular, mandatory training on this Policy and all related sales and marketing procedures.

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In accordance with the Farmaindustria Code and other relevant codes that Ferrer adheres at local level where Ferrer operates (affiliates), the company <u>publicly discloses its transfers of</u> <u>value</u> and payments made to healthcare professionals, healthcare organizations and patient associations, in addition to transfers of value related to R&D. Furthermore, these codes prohibit patients associations from promoting any particular prescription-only medicines and prohibit companies from requesting such activities from patients associations.

The company has a formal Ethics and Compliance Department and different governing bodies for the surveillance of the Corporate Compliance Management System.

Ferrer also has a <u>Code of Ethics for Third Parties</u> that establishes the main principles and values that govern its relationships with third parties. Contractual clauses are foreseen to adhere to the Code.

Ferrer has a Corporate Whistleblowing Management System and <u>whistleblowing channel</u> available for employees and third parties. During the whole process, Ferrer guarantees the rights of the involved parties (such as confidentiality, anonymity, proportionality, presumption of innocence) and of the process (such as security measures and data protection).

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. Currently, the company is not performing direct lobbying activities related to the pharma business. 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; the Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) in Mexico, and the Central American Federation of Pharmaceutical Laboratories (FEDEFARMA). Likewise, Ferrer complies with the requirements set out in the Code of Good Practice by the European Federation of Pharmaceutical Industries and Associations (IFPIA) 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.

Ferrer has a Corporate Anti-Bribery and Anti-corruption Policy and a Corporate Policy on

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Donations which sets up the main principles and approval process to carry out a donation, complying with Ferrer's Corporate Policy on Prevention of Conflicts of Interest which includes the obligation to report any personal relationship with Politically Exposed Persons and Public Officers. Ferrer does not contribute to any political parties or non-profit organizations linked to them. The company does not have any revolving door policy in place.

Among others, these are some of the controls Ferrer has in place:

- Due diligence of third parties with whom Ferrer establishes relationships, where Politically Exposed Persons (PEPs) are analyzed
- Communication by any employee of potential conflicts of interest including any personal relationship with PEPs and Public Officers
- Donations: approval of due diligence process of the organization and approval of the action on a segregation of duties-based approach
- Contractual clauses regarding compliance standards (Ethical Code, anti-corruption and anti-bribery and promotional compliance)
- Identification of representatives of the company before authorities and associations
- Training on a risk-based approach

Ferrer also has a risk management system where risks and controls are duly monitored through an IT tool and periodic reporting to the governing bodies is established.

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.

Ferrer's R&D strategy is focused on innovations related to unmet medical needs, including both incremental and disruptive innovations. Its general approach to R&D, current drug development pipeline, and annual investment in R&D activities (21 million EUR in 2020) are publicly disclosed in its <u>sustainability report</u> (p. 3; p. 50-52).

Regarding management of intellectual property, Ferrer typically only patents its products in its "main markets" (i.e. U.S., EU, Canada, Japan, China and some selected LatAm countries). In practice, this results in its products being free (non-protected) in most low- and middle- income countries. Currently, Ferrer does not sell "essential medicines" (as defined by the World Health Organization) outside of Spain, and the company plans to implement a voluntary licensing policy by the time the products currently under development reach the market.

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).

Ferrer is not currently involved in R&D for priority diseases, conditions, and pathogens identified in the Access To Medicine Index.

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 most of the countries where Ferrer operates, prices cannot be freely set, as they are highly regulated and need to be negotiated with local regulatory authorities, which have a set of rules to establish maximum selling prices. These regulations utilize some combination of value-based pricing, internal reference pricing, and/or external reference pricing.

In less regulated markets where Ferrer sells directly, the company also utilizes a combination of the before-mentioned pricing instruments, recommended by the World Health Organization, and conducts pricing studies in order to assess the payer's value assessment and willingness to pay.

Ferrer has a governance body to analyze and approve its pricing decisions. Price proposals are evaluated in terms of business case impact, Ferrer's sustainability, and particular details of each country's needs. Moreover, Ferrer takes into account different abilities to pay and makes an effort to reach the different segments of the population with those drugs that cover relevant diseases and where there is an unmet need (for example, when there is no generic alternative). The main mechanisms used to ensure access across all segments are:

- Getting public funding when possible, by listing the drugs in the Public Health System or via public tendering
- Integrating the different willingness-abilities to pay by adapting the pricing policy to the different population segments, with different price proposals for the different segments within a country following all applicable legal requirements.

In markets where Ferrer sells its products through partnerships, the company signs agreements with other pharmaceutical companies ("partners") that are then responsible for distribution and marketing of Ferrer products in a delimited territory. Based on anti-trust regulations, Ferrer



cannot control the pricing of its partners. Before the signature of any agreements, the business opportunity and the partner itself are analyzed to ensure that ethical and technical criteria are fulfilled. Partnership agreements include contractual clauses regarding the Ethical Code, the anti-corruption and anti-bribery policies, and the promotional compliance formal Code of Ethics, stipulating the minimum ethical expectations of the business partner.

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 assure 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 to 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 assure a correct understanding and commitment of 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 bottomline sales incentive. Training to these partners is also in place on a regular basis.