



## **B Lab Statement on Chiesi Group'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..."*

**Chiesi Group** 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](#).

### **Summary of Company**

Chiesi Group is an international pharmaceutical and healthcare group focused on research & development with 90 years of history, more than 7,500 employees worldwide, and a commercial presence in over 100 countries. The Group's main R&D center is based in Parma (Italy) and works alongside 6 other important research and development hubs in France, the USA, Canada, China, the UK, and Sweden to pursue its pre-clinical, clinical, and regulatory programs. The production sites are located in Parma, Blois (France), and Santana de Parnaíba (Brazil).

Chiesi Group has direct presence in over 30 countries: United Kingdom, Italy, Germany, France, Spain, Greece, USA, Canada, China, Brazil, Mexico, Pakistan, Turkey, Russia, Australia, New Zealand, Switzerland, The Netherlands, Poland, Belgium, Sweden, Denmark, Austria, Hungary, Czech Republic, Slovakia, Slovenia, Romania, Bulgaria, Colombia, Ireland, Japan plus the International Markets Development area (IMDD), which includes more than 70 countries where the Company is present via a network of partners.

To achieve its mission of improving people's quality of life by acting responsibly towards society and the environment, the Group researches, develops, and markets innovative therapeutic solutions in three focus areas:

- AIR (products and services which promote respiratory health)
- RARE (treatments and support services for patients with rare and ultra-rare diseases)
- CARE (products and services which support specialty care, including neonatology, and consumer self-care).



### **Chiesi Group's portfolio in 2024 included:**

- AIR therapy area accounting for 54% of revenues (main products: Foster, Trimbrow®, Clenil);
- CARE therapy area accounting for 24% of revenues (main products: Curosurf®, Kengreal, Envarsus, Cleviprex). The CARE therapy area includes Consumer Healthcare (CHC) products, which account for 3% of revenues, and over-the-counter products.
- OTC - medicines, including food supplements, which represent 2% of revenues. The portfolio comprises local Chiesi OTC products, which differ from country to country, and the NHCO portfolio (as of today, mainly available in France and Italy).
- RARE therapy area accounting for 22% of revenues (main products: Myalept, Ferriprox, Revcovi, Juxtapid, Elfabrio, Lamzede).

### **Chiesi Group'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.

**Chiesi Group** 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.

### **Chiesi Group'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.*



Chiesi's products are produced in accordance with applicable European and international laws, regulations and standards (e.g., [EMA EU Good Manufacturing Practices](#), [US FDA Code of Federal Regulations](#), [Brazilian/ ANVISA Good Manufacturing Practices](#)), in sites authorized by the relevant national and international regulatory bodies. Chiesi's plants (i.e., France, Italy, and Brazil) are regularly subjected to inspections and assessments by the competent health authorities to verify compliance with current legislation and internal regulations. The company also performs periodic self-inspections to maintain a high-control of the company's Quality Management System (QMS). The company has a QMS that defines and documents the organization's processes, procedures, and responsibilities for achieving quality policies, practices, and objectives, which applies to all stages of the drug life cycle, from clinical to commercial phases.

Chiesi requires all its suppliers and business partners to adhere to its standards and regularly audits the supply chain. The company also performs post-marketing surveillance studies, evaluating the side effects, safety, long-term risks and benefits, and efficacy of its drugs when used on a large scale. Chiesi implemented a pharmacovigilance system to continuously evaluate and update the benefit-risk ratio of its products. The company has adopted-whenever applicable, anticounterfeiting measures including serialization, aggregation, and security seals.

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.*

### **Anti-corruption and bribery**

[Chiesi's Group Code of Conduct](#) sets out the company's commitment to operate not only in accordance with the laws and regulations currently in force but also in an ethical manner. The purpose of the Code is to provide the business with a set of ethical principles with which it must comply in the following main fields: relations with stakeholders; health, safety, and environmental

matters; relations with Public Administration bodies; organizational matters, and corporate offences. The Group Code of Conduct was last reviewed and updated in July 2024.

Chiesi also has in place a [Group Anti-bribery Policy](#), which was last reviewed and updated in November 2023. The Policy provides comprehensive guidance to individuals working for Chiesi, in any capacity, on identifying and addressing bribery and corruption issues. This enables them to behave responsibly and adhere to anti-bribery regulations, ensuring Groupwide compliance.



Chiesi complies with the requirements outlined in [Italian Legislative Decree no. 231/2001](#) (“Decree 231”) across the entire Italian territory. This is facilitated through the implementation of an Organizational, Management, and Control Model (known as “Model 231”), which outlines Chiesi’s ethical commitments and responsibilities in preventing unlawful behaviour when conducting business. A Surveillance Body is in place to oversee the proper implementation of Model 231 and to regularly report its findings to the Board of Directors.

In March 2024, Chiesi Farmaceutici S.p.A. achieved [ISO 37001 Anti-bribery Management Systems certification](#). In order to ensure a harmonized approach to anti-bribery across the Group and as required by the ISO 37001 standard, Chiesi has committed to securing certification for all of its affiliates by 2027. There is a task force and a roadmap in place to support all affiliates in order to realize this ambition. Chiesi Italia S.p.A. was included in the certificate in February 2025.

When it comes to suppliers and partners, since 2020, Chiesi has adopted the [Code of Interdependence](#), which represents Chiesi's standard of conduct for suppliers, partners, and distributors. The document was developed in collaboration with strategic partners in 2019, and the last update is dated 2024, with publication on Chiesi’s website in 2025.

For suppliers’ assessment and evaluation, Chiesi utilizes [EcoVadis](#), an advanced third-party platform, to evaluate the sustainability practices of our strategic suppliers. One of the 4 areas assessed by Ecovadis is Ethics, which includes anti-corruption and bribery.

### **Lobbying and advocacy activities**

In their public affairs activities, employees and external partners are required to strictly comply with the rules of operation of the bodies and authorities with which they interact, refraining from any behavior that could be interpreted as undue interference in their operation. The relationship with counterparties must be based on principles of transparency, the data presented must be objective, and the requests made to counterparties must be based on legitimate interest, in full agreement with our corporate mission and aimed at developing policies of public common interest and to the benefit of society and the healthcare system.

The Group strives to provide its perspective to public policy debate through regular engagement with policymakers and other external stakeholders.

Chiesi also participates in most representative associations of the pharmaceutical industry at both a national and international level (e.g., Farindustria, [International Federation of Pharmaceutical Manufacturers and Associations - IFPMA](#), and [European Federation of Pharmaceutical Industries and Associations - EFPIA](#)).



### **Company interaction with HCPs and HCOs**

Chiesi has Group Guidelines on Interactions with Healthcare Professionals and Organizations, Patients and Patient Associations, which implements the provisions of the IFPMA and EFPIA Codes of Conduct by defining the main principles and rules to be followed while managing activities related to interactions with HCPs, HCOs and patients (including, but not limited to, promotional materials, congresses, scientific consultancies, market research, advisory boards and donations). According to the Group Guidelines, each activity must be assessed according to a specific approval flow implemented at the local level and defined according to a segregation of duties-based approach. Each Chiesi affiliate has implemented the Group Guidelines by integrating its principles with local legal and regulatory requirements (including the provisions of the Codes of Conduct adopted by national pharmaceutical industry associations).

Additionally, Chiesi has adopted a qualification and fair market value system to qualify HCPs and calculate the relevant fees for scientific consultancy services: Group SOP on Interactions with HCPs and HCOs provides a set of criteria (each Affiliate has to apply) for the qualification of the HCPs and – based on such qualification – a set of tiers determining the relevant fees. Each Affiliate is required to fill in the above-mentioned tiers according to the national “fair market value”, even with the support of IT tools (in Italy, by way of example, such fees are reported within the Operating Procedure on Promotional activities).

Chiesi makes annual disclosure of the transfer of values towards HCPs and HCOs, in terms of fees for consultancy services, participations in congresses and donations for HCOs, in accordance with EFPIA disclosure requirements and the [US Sunshine Act](#).

### **Ethical Marketing**

Chiesi recognizes multiple regulations ensuring the company adheres to ethical marketing principles. There are multiple governance committees and structures within the Chiesi organization to ensure adherence to these regulations and working norms. Standard Operating Procedures are in existence in relation to the following requirements:

- [EU Directive 2001/83](#) of 6 November 2001 on the Community Code relating to medical products for human use;
- IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) Code of Practice;
- EFPIA (European Federation of Pharmaceutical Industries and Associations) Code of Practice;
- US Food and Drug Administration (FDA) Office of Prescription Drug Promotion
- [Federal Food, Drug, and Cosmetic Act \(FDCA\)](#) and Title 21 of the Code of Federal Regulations Part 202 (21 CFR Part 202)



- US Office of Inspector General – Compliance Program Guidance for Pharmaceutical Manufacturers (68 Fed. Reg. 23731)
- Internal guidance consistent with the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Health Care Professionals
- Chiesi Group Code of Conduct, with specific reference to Ethical Marketing principles added in the last release in 2024
- Chiesi Group Code of Interdependence, with specific reference to Ethical Marketing principles added in the last update in 2024

Additionally, for those affiliates that are involved in direct marketing activities to consumers (Italy, France, Spain), local SOPs have been in place since the end of 2024.

### **Whistleblowing**

Chiesi Group's whistleblowing system, [SpeakUp&Be-Heard \(SU&BH\)](#), provides employees, business partners, and third parties with a secure and confidential platform to report concerns about unethical, illegal, or harmful conduct. This includes, without limitation, suspected breaches of the Group Code of Conduct or violations of laws and regulations related to human rights, diversity and inclusion, health and safety, the environment, bribery, data protection, antitrust, interactions with healthcare professionals and patients, and animal welfare. Reporters can choose to remain anonymous or identify themselves and can submit their report to either their local affiliate or to Chiesi's Corporate headquarters. Chiesi has a Group Guideline, "Use and Management of SpeakUp&BeHeard," which governs the whistleblowing management process and outlines procedures for submitting and managing reports, ensuring accessibility and transparency.

### **Enforcement of the Codes and Practices**

The policies above apply to all employees. The Code of Conduct, Code of Interdependence, and Anti-bribery Policy are included in our third-party agreements related to manufacturing, distribution, and supply of Chiesi products, as well as any agreement with or related to a healthcare professional or healthcare organization.

Chiesi's processes and procedures and its adherence to them are regularly subject to audits, conducted by Chiesi Group's Internal Audit function or by external auditors.

The ISO 37001 certification requires Chiesi to undergo a thorough audit every year to ensure ongoing compliance, and Chiesi has a comprehensive and regular training program relating to Anti-Bribery and other important topics.

- 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, and political contributions and donations.*

In 2022, Chiesi adopted its Global Public Affairs Guideline, subsequently reviewed in 2024. This Guideline establishes the principles and rules governing interactions with Institutions, which are binding upon all Public Affairs representatives and detailed as follows:

- Only appointed Public Affairs (PA) Representatives are entitled to conduct lobbying activities on behalf of Chiesi Group.
- The PA Representative should be clearly appointed by the legal representative of each company of the Group (or legal entities).
- The list of PA Representatives of each company of the Group shall be communicated by the legal representative to the Global Public Affairs Senior Director every year.
- Any subsequent modifications shall be notified within two weeks of when the change occurred.
- The Global Public Affairs Sr Director is responsible for the creation, maintenance, and archival of the list of PA representatives. He/she shall communicate the list to the Group Compliance Function in due time.
- The list will be disclosed on the internal website of the Group.
- PA Representatives oversee the respect of the policy by any third party instructed by Chiesi to represent Group interests vis-à-vis any type of legislative institution.
- PA Representatives shall report to the competent bodies (Public Affairs Committees or Affiliate leadership team) at least on a biannual basis.

PA Representatives must:

- identify themselves, indicating their names and position within Chiesi;
- ensure that their details are recorded in the Register of Lobbyists/transparency or equivalent national tools (where existing);
- ensure that Chiesi registrations on transparency/lobbyists registers are regularly updated (Registry contact persons are considered accountable);
- clearly declare business interests: a comprehensive agenda shall be communicated prior to organized meetings, as well as a follow-up communication briefly resuming the item(s) discussed;
- be transparent and honest when obtaining or trying to obtain information about the purpose of the request;
- respect the highest level of accuracy and veracity of all statements and information provided to the wider public and Government representatives on behalf of the company. Information should be based on the company's public position paper, the company's knowledge, or supported by evidence;
- use the information appropriately and ethically;





- be prepared to furnish verification of their adherence to the aforementioned prerequisites to the Global Public Affairs Sr Director;
- act only in the interest of the company and avoid any situation which, directly or indirectly, may represent a conflict of interests with respect to either the company or the Chiesi Group;
- avoid misleading, exaggerated, or extravagant claims about, or otherwise misrepresent the nature or extent of their access to Institutions;
- act in strict compliance with the Chiesi Group Anti-Bribery Policy and not engage in any conduct which is corrupt, dishonest, or illegal, or unlawfully cause or threaten any detriment.

Chiesi companies are allowed to use third parties for Public Affairs activities, provided only that:

- (i) the relationship is formalized in a written agreement clearly identifying the terms of the mandate;
- (ii) there is a clear contractual obligation on the third party to respect the terms of this policy and of Chiesi's Anti-Bribery Policy;
- (iii) the agreement is registered in an ad-hoc "public affairs third parties" register to be kept under the responsibility of the Public Affairs Representatives.

Chiesi respects the highest level of political neutrality and, in accordance with the provisions of the Anti-Bribery Policy, does not allow any direct or indirect contribution, in whatever form, to political parties, political or union organizations, or in favor of their relevant representatives, unless such contributions are allowed by Applicable Laws. In such cases, specific rules must be defined at the local level in order to establish in which specific cases political contributions are allowed and the relevant approval flow to assess such requests.

Chiesi is registered on the transparency register of the European Parliament, the European Commission, and the US Congress and is a member of trade associations such as the International Federation of Pharmaceutical manufacturers and Associations (IFPMA), European Federation of Pharmaceutical Industries (EFPIA – EU – Board member), the [European Confederation of Pharmaceutical Entrepreneurs](#) (EUCOPE - EU), the [Biotechnology Innovation Organization](#) (BIO – US – Board member), [Farmindustria](#) (Italy - Board member) and [Assobiotech](#) (Italy – Board member). Chiesi affiliates are also members of several EFPIA member associations. Company participation with these trade associations is strictly regulated by internal codes of conduct.

In the US, Chiesi has comprehensive policies in place to ensure compliance with applicable laws and regulations, including but not limited to anti-bribery laws, in each jurisdiction in which Chiesi operates. [Chiesi, as a company, does not make political contributions, but—outside of its general compliance policies—does not specifically regulate the ability of its individual employees to do so, where allowable under applicable law.]





In the last five years, Chiesi has engaged in government affairs activities in the US, including through the use of registered lobbyists, primarily in three areas: first, Chiesi engaged in advocating for an in-development product intended to treat opioid-dependent infants as a result of material opioid usage. The campaign was intended to educate U.S. lawmakers on the epidemiological and physiological differences between neonatal opioid withdrawal syndrome and Opioid addiction in fully grown adults; second, Chiesi is a member of the International Pharmaceutical Aerosol Consortium, which is an organization aimed at building consensus and contributing to effective regulations and standards for the orally inhaled and nasal product industries; and third, Chiesi has a designated government affairs role within its rare disease business unit which is responsible for monitoring and engaging in public policy issues relevant to rare disease product manufacturers and patient communities.

*4. For companies involved in research & development, public disclosure of their R&D and intellectual property strategies, and disclosure of annual resources invested in both internal and collaborative R&D activities.*

Chiesi strategically allocates a significant proportion of revenues in research and development (around 20% of annual revenues; 24.3 % of 2024 revenues) to the development of innovative drugs to address unmet medical needs with new therapeutic solutions. The Group's R&D staff comprises 1330 employees (out of a total of about 7500 employees).

Chiesi, based on the [JRC EU Industrial R&D Investment Scoreboard](#) published in December 2024, is confirmed as the first among Italian pharmaceutical companies, second among Italian manufacturing companies, and fifteenth among European pharmaceutical companies for investments in research as % of revenues. In 2024, R&D expenses amounted to 829 M€, of which 21.4% were dedicated to RARE diseases, 11.3% to the CARE therapeutic area (including neonatology), and 67.3% to the AIR therapeutic area (including respiratory diseases such as asthma and COPD).

R&D investment (829 M €) is publicly disclosed on the [Group's 2024 Sustainability Report](#) (p.18).

To access cutting-edge expertise and knowledge in the development of new drugs and the conduct of clinical studies, we set up ad hoc collaborations with world-renowned international universities and academic groups. Partnerships typically take place in the early phases of drug discovery, as well as during clinical studies.

The Group has a policy to implement Clinical Trial Transparency and Data Sharing. The Group developed a [portal](#) where Chiesi clinical trial data can be requested by external researchers



under specific and pre-defined requirements. The Group conducts clinical trials in accordance with the EFPIA requirements.

In accordance with local legislative and applicable requirements on clinical studies, the Group also discloses in public registries (e.g., EU Clinical Trials Register, Clinical Trials in the European Union - EMA, National Library of Medicine), the Clinical Protocol and Study-related Information and the Summary Results of all clinical studies sponsored by Chiesi Farmaceutici S.p.A. Clinical studies sponsored by Chiesi, their publicly disclosed, study-related and results-related information, are made available on the Chiesi Clinical Study Register portal in accordance with the policy.

Chiesi's intellectual property (IP) and patent strategy is a multifaceted approach designed to protect its innovations from product discovery to product on the market. It prioritizes securing strong, foundational patents while also using a mix of other patent types to provide comprehensive protection.

### **Patent Strategy**

The company's strategy is built around several key types of patents:

**Composition of Matter and Combination Patents:** These are considered the most fundamental and are filed early in the drug discovery phase, often one to two years before a new drug or combination product enters clinical trials. They are the strongest form of protection, as they protect the active substance itself.

**Formulation, Device, and Manufacturing Patents:** These patents provide additional layers of protection for a product. They cover specific aspects like how a drug is formulated, the device used to deliver it (e.g., an inhaler), or the manufacturing process. These are filed later in the development process and can provide a competitive advantage, though they may not prevent competitors from entering the market with alternative solutions once the main "composition of matter" patent expires.

**Use Patents:** These are obtained to protect new uses for existing molecules, providing additional coverage for treating patients with the same drug for a different condition.

**Improvement Patents:** Filed later in a product's life cycle, these patents protect significant innovations, such as a new propellant gas for an inhaler, even after initial patents may have expired.

### **Patent Management and Defense**



Chiesi has a robust system for managing its patent portfolio, from patent filing to potential litigation:

**Invention and Filing:** The company's inventors, who may include external collaborators, work with qualified in-house and sometimes external patent attorneys to write and file patent applications. This process is a reliable way to assess the patentability of a new innovation.

**Licensing and Acquisitions:** Chiesi's strategy extends beyond internal R&D. They license or acquire patents from external sources, like academic labs, through agreements that often include upfront fees, milestone payments, and royalties. This recognizes and rewards the value of external intellectual property.

**Litigation and Defense:** As a patent's life nears its end, it's common for generic drug companies to challenge its validity. Chiesi actively defends its patents through legal means, sometimes engaging qualified external litigation counsel. In certain cases, they may reach a settlement to allow a generic competitor to enter the market earlier in exchange for ending the lawsuit.

*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).*

Chiesi is engaged in R&D projects which address asthma and COPD, as well as some conditions associated with premature birth and rare diseases - thalassemia and sickle cell - included in the [Access to Medicine Index priority list of diseases](#).

Among the countries listed in the Access to Medicine Index, Chiesi currently has affiliates in Brazil, Mexico, and Pakistan, and as of 2023, the Group is also present in Colombia through a company acquisition.

The healthcare system in Brazil, Mexico, and Pakistan is quite fragmented. Generally, in these countries, it is composed of two large segments with different dynamics and abilities to meet the needs of patients:

- The Governmental healthcare market, which is basically free for all “eligible” citizens
- The Private healthcare market, which is fully out-of-pocket

People may very likely experience difficulties in having equal access to healthcare, and the challenges of the healthcare system are linked to the broader social challenges that these countries face.



The fragmentation of the healthcare system has an important impact on pharmaceutical products' price definition. While private markets, as 100% out-of-pocket, can involve free pricing (e.g., Pakistan) with commercial dynamics comparable to consumer markets, reimbursed markets are very different. Below are some highlights on Chiesi's access practices in the countries in scope, with additional information.

### **Pakistan**

In Pakistan, where Chiesi is the leading pharmaceutical company in the respiratory segment, the company's initiatives focus on reducing neonatal mortality and increasing access to respiratory medicines. Key efforts include:

- Partnership with the government: Providing medicines for neonatal care at either free or subsidized rates to reduce the financial burden on families.
- Tiered pricing: Offering discounts to government institutions and foundation hospitals that serve underserved communities.
- Direct discounts: Providing discounts on specific products to improve patient access.
- Capacity building: Empowering doctors and paramedical staff through training and capacity-building initiatives.

### **Brazil**

Chiesi's strategy in Brazil addresses the significant shortage and unequal distribution of pulmonologists, which disproportionately affects the 70% of the population served by the public health system. Initiatives focus on strengthening primary healthcare to improve the diagnosis and management of respiratory conditions.

"Conexão Pneumo" project: This program trains general practitioners in the public health system to perform spirometry tests and accurately diagnose respiratory conditions. For example, in one municipality, this initiative eliminated a waiting list of 1,000 patients in just 11 months.

Incorporating therapies into the public system: The company has worked to make its treatments, such as Trimbow®Technology, available through the Unified Health System (SUS).

Neonatology and rare diseases: Chiesi has partnered with medical education institutions to train over 200 healthcare professionals in neonatal care, targeting institutions with low Human Development Index (IDH) and high mortality rates. In rare diseases, they support patients with Sickle Cell Anemia and Thalassemia by providing access to diagnostic imaging (MRIs) and working to secure reimbursement from the government.

### **Mexico**



In Mexico, Chiesi focuses on a differentiated pricing strategy and multi-partner collaborations to improve affordability and access.

**Differentiated pricing:** The company offers its products to the public sector at an average price that is 63% lower than the private market, ensuring wider access.

**Neonatology focus:** Recognizing the lack of focus on neonatology in public policy, Chiesi has a five-year goal to train a large number of healthcare professionals and caregivers—including 800 neonatologists, 3,500 pediatricians, and 6,500 nurses—to improve outcomes for newborns.

**Patient education:** The company also works with healthcare institutions to improve early diagnosis and management of Asthma and COPD through targeted education and providing access to validated tools.

### **Colombia**

As a "Benefit and Collective Interest Company," Chiesi Colombia is dedicated to supporting patients with rare and ultra-rare diseases.

**Therapy access and regulatory support:** The company provides therapies through "Named Patient Supplies" and works to ensure their products are included in the national health plan. For example, they provided early treatment access for ADA-SCID patients in 2025.

**Comprehensive patient support programs:** Their Patient Support Program (PSP) offers a range of services, including nutritional and psychological guidance, transportation assistance, and specialized wound management for patients with Epidermolysis Bullosa (EB).

**Diagnosis and collaboration:** Through the "Diagnose Support Program" (DSP), Chiesi provides access to genetic tests, which led to a 46% increase in tests in 2024. They also collaborate with patient organizations and contribute to public policy, including the Colombian Consensus on HoFH management. The company even extends support to patients living in conflict zones.

In addition to these country-specific strategies, Chiesi has a health equity strategy, including efforts to support vulnerable populations in countries where the company is currently present, and a Global Health strategy focused on expanding access to essential neonatal drugs in Sub-Saharan Africa.

### **Chiesi Health Equity strategy**

Chiesi's Health Equity Strategy, a key part of the company's patient-related commitment, aims to address and eliminate avoidable and unfair differences in health among diverse groups. It



evolved from a 2022 initiative focused on "Access to Healthcare" to a broader "Health Equity" framework in 2023, aligning with the WHO's definition.

The strategy's three core pillars are:

- Determinants of Health: Considering social and environmental factors that impact health.
- Access to Healthcare: Ensuring people can get the care they need.
- Measurement & Stakeholder Engagement: Working with various groups and tracking progress to improve the strategy.

The company identifies health inequities by mapping them along the patient journey, a methodology used to pinpoint unmet patient needs. This approach has led to various projects in over 30 countries, primarily in the AIR and CARE therapeutic areas. Examples of these projects include:

- UK: [The FRONTIER Hull project](#) works with the NHS to improve early diagnosis of COPD, a condition where public awareness and screening programs were impacted by the COVID-19 pandemic.
- Spain: The company developed a robust methodology to analyze health inequities in respiratory conditions. This led to a multi-stakeholder group creating a document for policymakers and a questionnaire to help physicians improve patient adherence to inhaler therapies.

### **Chiesi Global Health strategy**

The strategy focuses on reducing infant mortality in low-resource settings, particularly in Sub-Saharan Africa (SSA). The strategy's primary goal is to address the severe inequities in neonatal care by improving access to essential medicines and strengthening local healthcare systems.

The strategy was developed after the successful MAISHA pilot project, which began in 2021. This project focused on improving access to caffeine citrate, a life-saving treatment for premature babies, in Ethiopia, Tanzania, and Uganda. The pilot's success led to the formal approval of a long-term global health strategy in 2024.

This new strategy is guided by core principles:

- Inclusive Business Model: A financially sustainable model that supports local investment in healthcare systems.
- Portfolio and Geographic Expansion: Plans to offer a wider range of neonatal products and expand into more low-income countries.
- Multi-Stakeholder Partnerships: Collaborating with various partners to maximize impact.
- Risk Mitigation: Ensuring the long-term viability and success of the program.



A dedicated team as part of the CARE Franchise, with the execution function included in the International Markets Development Division, was formed to implement this strategy, and they have already achieved key milestones. For instance, they used the WHO Collaborative Registration Procedure to quickly register their product in Ethiopia, demonstrating their commitment to efficient and impactful action. The company's overall vision is that "Every Newborn Counts, Everywhere."

### **Paolo Chiesi Foundation (Chiesi Group's corporate foundation)**

[The Chiesi Foundation](#) is committed to improving access to quality care and alleviating the suffering of patients affected by neonatal and chronic respiratory diseases in the Global South. The Foundation supports international scientific research and develops international cooperation programs to transfer medical knowledge at the local level and to empower families in the healthcare process, through the implementation of two different healthcare models, in partnership with various stakeholders:

— The NEST (Neonatal Essential Survival Technology) model aims at reducing neonatal mortality rates by improving the quality of neonatal care in countries with limited resources, paying specific attention to premature, sick, unwell, and small for their gestational age babies. This model is currently implemented in Benin, Burkina Faso, Burundi, Ivory Coast, and Togo.

— The GASP (Global Access to Spirometry Project) model focuses on developing specific clinical skills to diagnose and manage chronic respiratory diseases, such as asthma and chronic obstructive pulmonary disease (COPD), by introducing spirometry capacity and training activities. Furthermore, the program delivers patient education through medical training. This model is currently implemented in Guyana, Nepal, and Peru.

### **Drug Donations**

Medicine donations are part of our access strategy, and particularly since 2016, we have had in place a partnership with [IHP – International Health Partners](#). IHP works with the healthcare sector and medical NGOs to send high-quality medical aid, targeting people around the world who have little or no access to healthcare or essential medicines. In 2018, 4.4 million treatments were sent to 34 countries. Since 2016, Chiesi has contributed 130.000 inhalers (donated every two years) to IHP's Essential Health Packs, which are pre-packed kits containing essential medicines, and to its Disaster Response Program. The packs reached 20 different countries, including Kosovo, Zambia, Nepal, Nigeria, and Lebanon. Additionally, in 2024, over 80.500 units of drugs were donated by Chiesi Group to support different situations (emergencies, conflicts, climate change events, etc.).

### **Global Rare Diseases and Access**





Chiesi's strategy for helping with global rare diseases and access is focused on addressing the unique challenges faced by these patients, who are often underserved. The company's approach combines a direct presence in key countries with specific programs designed to overcome barriers to care and treatment.

Rare disease patients face significant hurdles, including:

- **Diagnostic Delays:** The average diagnosis takes five to eight years due to a lack of awareness among healthcare professionals.
- **Limited Treatments:** With only a small percentage of rare diseases having approved treatments, options are scarce and often very expensive.
- **Lack of Awareness & Other Barriers:** Many rare diseases lack patient support groups, and patients often face geographic barriers, dispersed populations, and social stigma.

To combat these challenges, Chiesi's Global Rare Diseases Business Unit has a direct presence in more than 30 countries and has implemented several initiatives to ensure patient access.

**Expanded Access Programs (EAPs) and Compassionate Use (CU):** These programs allow patients with serious or life-threatening conditions to gain access to Chiesi's investigational medical products outside of clinical trials when no other treatment is available.

**Online Portal:** In 2024, the company updated its EAP with a new online portal to simplify the submission process for healthcare providers. The portal includes clear eligibility criteria for each rare disease product, which helps to streamline access for patients.

**Commitment to Accessibility:** The company's dedication to these programs is demonstrated by the number of patients helped. The number of patients benefiting from Chiesi's rare disease EAP increased from 193 in 2024 to 218 in 2025, highlighting its commitment to patient-centric care and access.

6. *For companies involved in sales, public disclosure of their 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.*

Chiesi is committed to pricing its offering according to the value it brings to patients, caregivers, the healthcare system, and Society as a whole. The Group ensures that prices reflect the benefit/value in terms of clinical improvement and patients' [Health-Related Quality of Life](#)



[\(HRQoL\)](#), often submitting to Health Technology Assessment\*, according to National processes and requirements. As an internal procedure, we also commit to verifying that our pricing policies are sustainable both in financial terms for the Company, with a return that supports our R&D investments, and in terms of being sustainable for the payers / National Health Service. This second element is tested by systematic use of Economic analyses, e.g., Budget Impact modelling (as necessary/appropriate).

The health economic evidence thus generated is part of the pricing and reimbursement submission package for new products, adapted to each Country using this information in their reimbursement process. For some products, according to the requirements of national health authorities, Cost Effectiveness / Cost Utility analyses are also performed, and they too constitute a part of the Global Value Package.

Chiesi USA (AIR/CARE) has a charter in place that governs pricing decisions. The local team develops pricing recommendations based on a comprehensive analysis of competitive dynamics, policy and regulatory shifts, and brand objectives mid-year. These recommendations are submitted as base, optimistic, and pessimistic assumptions into the budget process and, specifically for the US, are concurrently reviewed with the internal pricing committee for all products.

The impact on compliance across the Global Rare Diseases Business Unit, state price reporting triggers, and gross-to-net impact - including statutory government pricing impact - is reviewed in the above-mentioned pricing committee. Once endorsed, the price changes are submitted to the global leadership team as part of the budget approval process. Upon approval, they are submitted via PRIME (the internal Global Pricing Management tool) for global review and communicated to external compendia stakeholders.

*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).*

Chiesi'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. Chiesi states that the percentage of bonuses linked to sales shall not exceed 70% of the total bonus, and a minimum of 30% must be linked to non-sales-related measures.

The non-sales objectives rely on aspects regarding scientific knowledge and competencies of the sales agents, the promotion of the most convenient ways of interacting with the HCPs (e.g., digital channels), as well as, more generally, the level of personalization that the agent is able to achieve in the interactions and information conveyed to the HCP.



The company adheres to the EFPIA Code, which sets out key principles for pharmaceutical companies when promoting prescription-only medicines. Key points to note include:

- Promotion must be in line with Article 3, Promotion, and its Substantiation. In summary, promotion must be accurate, balanced, fair, objective, and sufficiently complete to enable the HCP to form his/her own opinion of the therapeutic value of the Medicinal Product for their patient(s).
- In line with Article 5, Acceptability of Promotion, Chiesi must always maintain high ethical standards.

Finally, Chiesi's sales agents and teams are fully trained and validated on the Code of Conduct as part of their initial sales training to ensure full understanding and adherence to the code. Regular training updates are also provided.

Chiesi is committed to providing comprehensive scientific information that is understandable to all recipients and does not overstate the real benefits of our products. The company, therefore, carries out regular internal audits of the information provided to the scientific community and patients, to ensure that it conforms to best practices in scientific information (included also in Chiesi's Code of Conduct).

With specific reference to the USA, promotional efforts are restricted to appropriate clinical use as directed by the approved FDA product labeling. In addition, the US team has recently deployed field-based Health Economic Value Specialists for key products. These individuals are incentivized to partner directly with customers to determine appropriate clinical use of key products – balancing improved clinical outcomes with a minimized cost-burden on the healthcare system. Chiesi has appointed a Compliance Officer to ensure that the code is fully adhered to by all Affiliates. In addition to adhering to the EFPIA Code of Conduct, all sales agents and teams must adhere to the Chiesi Code of Conduct and Ethics, the Anti Bribery Policy, the Group Code of Conduct, and performance must be aligned to Chiesi's People Performance Management Guidelines.

8. *[IF APPLICABLE] 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*

Chiesi is not present in the Access to Medicine Index.

## **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 [certification process](#), or
2. Breach of the core values articulated in our [Declaration of Interdependence](#) within the B Corp Community.