B Lab Statement on Chiesi - B Corp Requirements for Pharmaceutical Companies

B Lab's independent Standards Advisory Council has rendered the following decision and guidance regarding eligibility for B Corp Certification for companies in the pharmaceutical industry:

"B Lab and its independent Standards Advisory Council have determined that pharmaceutical companies are eligible for B Corp Certification if they have not engaged in specific prohibited practices in the last five years AND are meeting additional industry-specific practice requirements outlined below."

Chiesi 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 Chiesi

Chiesi Group is an international research-focused pharmaceuticals and healthcare group with over 85 years of experience, with more than 6,000 employees worldwide and a commercial presence in 100 countries. The Group researches, develops, and markets innovative therapeutic solutions in three focus areas: AIR (products and services that promote respiration, from newborn to adult populations), RARE (treatment for patients with rare and ultra-rare diseases), and CARE (products and services that support specialty care and consumer-facing self-care). Chiesi Group has direct Affiliates in 30 countries worldwide plus 68 countries where Chiesi is present with a network of partners.

The Group's Research and Development is based in Parma and integrates with six other major research centers in France, the United States, Canada, China, the United Kingdom, and Sweden, to promote its preclinical, clinical, and regulatory programs. Their production activity takes place in three plants located in Parma (Italy), Blois (France), and Santana de Parnaiba (Brazil).

Chiesi'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 endangers 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 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's Disclosure on Required Best Practices

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

1. *Adherence to credible national and/or international standards of safety, quality, and efficacy covering all relevant stages of the drug life cycle (i.e. drug development, supply chain, manufacturing, and distribution), which should include explicit systems to manage the risk of substandard medicines.*

Chiesi's products are produced in accordance with European and international laws, regulations and standards (e.g. EU Good Manufacturing Practices, US FDA, Sino FDA, Brazilian ANVISA), in sites authorized by the relevant national and international regulatory bodies. Chiesi's plants (i.e. France, Italy, and Brazil) are constantly subject to inspections and assessments to verify compliance with current legislation and internal regulations. The company also performs periodic self-inspections to maintain a high-quality control system. The company discloses that all its production and development sites in Italy have ISO 9001 certification, following the requirements of the Quality Management System (QMS), 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.*

Chiesi participates in associations of pharmaceutical industries at both national and international levels (e.g.: IFPMA (International Federation of Pharmaceuticals), EFPIA (European Federation of Pharmaceutical Industries and Associations), and national associations. The Board of Directors has appointed a Corporate Compliance Committee, charged with the supervision of all compliance-related topics.

Chiesi has also a Group Code of Conduct that expresses the Group's commitment to operating not only in accordance with the laws and regulations currently in place but also with certain principles and rules of conduct of ethical nature. The purpose of the Code is to provide a set of ethical principles each Affiliate shall comply within the following main fields: relations with stakeholders; environmental, health and safety matters; relations with Public Administration bodies; organizational matters and corporate offenses. The Code applies to all employers, partners, and third parties acting on behalf of Chiesi, including R&D services providers (CRO, CMO) as well as any commercial partner. Chiesi has been including the Code as part of the contracts with commercial partners, both retrospectively and whenever a new contract is signed. Lobbying and Advocacy are also addressed in the Code.

Chiesi's Code of Conduct was updated in mid-2021 and a Group roll-out plan was consequently launched, including all Chiesi employees and future new hires to ensure its Global delivery and formal acceptance. The Code is also available to all employees through Chiesi's internal website. For Chiesi Farmaceutici S.p.A. and Chiesi Italia S.p.A., the Code of Conduct is delivered through a digital system. A significant part of the Code's principles is also included in the general e-learning course on Law 231/2001. The training on Law 231/2001 is mandatory for all employees of Chiesi Farmaceutici S.p.A. and Chiesi Italia S.p.A. (with the only exception of workers in the manufacturing area) upon their hiring in Chiesi and is updated upon any revision of the Code or the 231 Model. In 2021 all employees were re-trained on the 231 Model as a consequence of its update. Constant monitoring of the training's completion is in place. At the affiliates level, the Code has been deployed and guidelines have been provided to ensure the delivery and acceptance of the Code for all employees. In the first semester of 2022 specific monitoring activities have been conducted by Corporate to ensure that the implementation,

deployment, and communication activities have been properly performed by all affiliates. Moreover, Corporate in 2022 has internally disseminated a specific Q&A document to further clarify the applicability of the Code in everyday work.

The company's Group Anti-Bribery Policy has the purpose to provide Chiesi employees (wherever located and wherever they operate) and whoever acts on behalf of Chiesi, in any capacity, with a set of general principles and rules on how to recognize and deal with bribery and corruption issues and how to comply with anti-bribery rules and regulations. Chiesi has also adopted specific internal Anti-bribery guidelines on contract management with the purpose to highlight, for each category of third-party agreements therein identified, the possible bribery and corruption risks that may arise, and the proposed contractual clauses aimed at preventing such risks. The contractual clauses have been adopted by each Affiliate of the Group.

Chiesi has its Code of Interdependence (Chiesi Suppliers Code of Conduct) that expresses the principles on which it intends to base its interactions with third parties and suppliers. All the contracts require third parties to confirm understanding of the Code of Interdependence and Anti-Bribery Policy.

Chiesi also has Group and national SOPs (standard operating procedures) on the management of Interactions with HCPs (health care professionals) and HCOs (health care organizations): The Group SOP on Interactions with HCPs and HCOs has implemented the provisions of IFPMA and EFPIA Codes of Conduct and defines the main principles and rules to be followed while managing activities related to interactions with HCPs and HCOs (in particular: promotional materials, congresses, scientific consultancies, market researchers, donations). According to the Group SOP on Interactions, each activity must be assessed according to a specific approval flow defined according to the segregation of duties-based approach. Each Chiesi Affiliate has implemented the Group SOP by adopting national OPs integrating Group SOP's principles with local laws and regulations requirements (including the provisions of the Code of Conduct adopted by National associations of pharmaceutical industries). Although Chiesi's international partners are independent distributors or licensees and therefore are themselves responsible for the interaction with HCPs, Chiesi requires contractual obligations to operate in full compliance with any local law, regulation, and deontological requirement.

Chiesi makes annual disclosures of the transfer of values towards HCPs and HCOs, in terms of fees for consultancy services, participation in congresses, and donations for HCOs, in accordance with local requirements (e.g. EFPIA disclosure requirements and US Sunshine Act).

In 2016 the company gained the highest score (three stars) on anti-bribery (Rating di legalità) from the AGCM (Italian Competition and Market Authority). The rating has been renewed in 2018 and 2020 with confirmation of the highest score.

The company has a confidential reporting system (whistleblowing system). In June 2017, Chiesi implemented a web-based reporting system (the "Confidential Reporting System – CRS"), hosted on an independent server, through which any employee has the possibility to communicate in an easy and safe way, either identifying him/herself or remaining anonymous, conducts considered as incorrect (or even illicit), which violate the Company's rules and may damage Chiesi (in particular, any conduct which may affect infringements of anti-bribery or criminal laws or which is related to possible violations of the Group Code of Conduct). The CRS applies to all Affiliates of the Group and the relevant use is regulated by a corporate policy. The CRS was last updated in 2022 (SpeakUp&BeHeard), in order to integrate the current system with the provisions of the new EU Directive on Whistleblowing no. 2019/1937. In the updated version of the system, reports are managed at Affiliate level by functions having the necessary independence and professional requirements to process the report (usually the Compliance function, so-called "Managers of the System"). For those Affiliates who do not have such a function, reports are managed by the Corporate Compliance Committee of Chiesi Farmaceutici S.p.A (made up of Chiesi Chief HR Officer, Group Compliance Officer, and Head of Internal Auditing). The Corporate Compliance Committee also manages reports affecting Chiesi Farmaceutici S.p.A. and those reports which are specifically sent by the whistleblower to Chiesi Corporate.

Chiesi has an internal SOP stating its ethical-marketing activities, the "Interactions With HCP and HCO" document. The document regulates Chiesi's activities on various topics, such as non-informational materials, symposia materials, congresses and events, websites and apps, etc). Those practices are also summarized in external documents, in particular Chiesi's Anti-Bribery Policy and Group Code of Conduct.

Although every affiliate is responsible for its own action in its respective markets, Chiesi's IMDD (International Markets Development Division) ensures that adherence to the Codes is a recurring discussion topic with partners and distributors, and Chiesi makes it clear that, as a member of the international code, it expects its partners to be fully compliant. IMDD represents the division managing the relationship with partners distributing Chiesi products in countries where the company is not directly present. Chiesi however checks materials to ensure that they are compliant with international standards and approve messages in line with international guidelines, such as:

- IFPMA and EFPIA Code of Practice
- US FDA Office of Prescription Drug Promotion
- US Office of Inspector General – Compliance Program Guidance for Pharmaceutical Manufacturers
- Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Health Care Professionals
- Chiesi Group Code of Conduct

- Chiesi Group Code of Interdependence
- Chiesi Group Anti-bribery Policy

The Code of Practice, Code of Interdependence, and Anti-bribery Policy are included in the company's 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 conducts regular audits of its processes and procedures. In addition, audits are regularly conducted by external auditors, as well as Chiesi Group Internal Auditing department.

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.*

Chiesi has internal guidelines for interacting with institutions as Public Affairs representatives, which are clearly appointed by the company itself, and acts in strict observance of Anti-Bribery Policy, Code of Conduct, and internal guidelines.

The Chiesi companies are allowed to use third parties for public affairs activities only on conditions 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 the Chiesi Anti-Bribery Policy; (iii) the agreement is registered, when requested, in ad-hoc "public affairs third parties" register to be kept under the responsibility of the Public Affairs Representatives.

Chiesi's Anti-Bribery Policy prohibits any direct and indirect donation as a company to political parties, politicians, or candidates for political office. In the last five years, Chiesi has engaged in government affairs activities in the US, including through the use of registered lobbyists, in primarily three areas.

First, Chiesi engaged in advocating for an in-development product intended to treat opioid-dependent infants as a result of maternal 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.

Third, Chiesi has a designated government affairs role within its rare disease business unit that is responsible for monitoring and engaging in public policy issues relevant to the rare disease product manufacturers and the patient communities.

Chiesi is a member of the following trade associations: the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the 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 Assobiotec (Italy – Board member). Chiesi affiliates are also members of several EFPIA member associations. Further information is available here.

Chiesi follows European policies related to the development of an innovative and competitive healthcare sector in Europe. Chiesi is also interested in policies promoting ESG compliance and embedding sustainability and climate action in companies' operations. The company also has a general interest in the EU Green Deal. More details on Chiesi's contribution are available here.

Chiesi follows the EU pharmaceutical strategy; the review of the EU & Pediatrics regulations; the review of the basic pharmaceutical legislation; and the review of the EU & UK F-gas regulation (517/2014), according to the position paper available here.

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.*

Chiesi allocates approximately 20% of its annual revenues to research and development for the development of innovative drugs to address unmet medical needs with new therapeutic solutions. In 2021, R&D expenses amounted to 478.8 M€, of which 70.7% were dedicated to the respiratory area; 8.4% to neonatology; 13.1% to rare diseases, and 7.8% to specialties. Chiesi's R&D team in 2021 was made of 994 employees.

Further details are publicly disclosed in Company's sustainability report.

Chiesi's clinical trial data can be requested by external researchers under specific and pre-defined requirements. Chiesi states its commitment to transparency and collaboration in the conduction of clinical trials, in accordance with EFPIA requirements, allowing the community to benefit from the process of knowledge sharing. In accordance with the local legislative and applicable requirements on clinical studies, Chiesi also discloses in public registries (e.g. EU Clinical Trials Register) the Clinical Protocol and Study-related Information, and the Summary Results of clinical studies sponsored by Chiesi Farmaceutici. Study-related and results-related information are made available on the Chiesi Clinical Study Register portal. Chiesi also

contributes to the EFGCP- EFPIA Roadmap Initiative to good lay summary practices, a multi-stakeholder initiative with over 60 participating organizations, with a focus on defining best practice guidelines for the implementation and dissemination of lay summaries aimed to allow non-scientific communities, including patients, to have a clear view of studies' details and results.

Regarding management of intellectual property, the composition of matter patents (new chemical/biological entities) or combination patents and use patents for repositioning existing drugs are written early in drug discovery, generally around one to two years before clinical development. This allows competitors to enter the market, upon expiry of the composition of matter patent, with alternative formulations/devices or manufacturing processes. Improvement patents, in the vast majority of formulation, device, or manufacturing patents, may be claimed later in a product's lifecycle to protect a significant innovation related to the specific combination of drug, device, and manufacturing. This situation still allows competitors to enter the market with similar products using alternative technical solutions.

Towards the end of the patent life, patents of major products are usually challenged by generic pharmaceutical companies aiming to get their revocations and to bring generic versions to the market well in advance of the patent expiry. Chiesi's defense of such challenges usually involves complex legal and IP scenarios. In fact, to stop litigation and allow access to the market of an alternative, generic version of Chiesi's product, Chiesi may enter into an agreement with one such company. This type of agreement only covers the period prior to patent expiry, thus allowing early access to generics and increased price competition. The defense of Chiesi's patent may involve qualified external litigation counselors from recognized patent law firms, with experience in the territory where a challenge is made, and with a broad knowledge of the local IP law.

The whole process is managed by the Corporate Intellectual Property and legal departments and overseen by the patent committee, which has, among others, the following members: President, Vice-President, CEO, Head of Legal, Head of R&D, Head of Intellectual Property and meets quarterly.

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 works in a co-creation model, which means that the company seeks inputs and insights from different stakeholders, including among others, patients, regulators, payers & Health

Technology Assessment bodies, and clinicians/HCPs, exploring access approaches/scenarios and gathering, understanding and incorporating relevant inputs and insights into clinical and commercial development plans.

Stakeholder insights/inputs are collected via different means/methods including primary and secondary research, engaging in early advice with Health Technology Assessment and Regulatory bodies (either together or separately), organizing advisory boards with participation from patients, payers and HCPs.

During R&D and commercial planning, Chiesi seeks to understand what potential alternative/novel access pathways exist, beyond the traditional ones. As an active member of the EFPIA working groups on market access, healthcare systems and HTA, Chiesi seeks to help shape approaches/strategies that support more equitable access to medicines especially in LMICs.

It is a common strategy to first try to get approval for new drugs in Europe, the United States, and China because these countries are seen as references by other countries and establish high regulatory standards. Once a new medication is approved in the aforementioned countries, Chiesi seeks additional approval where it has local affiliates and partners.

Chiesi is engaged in R&D projects that address asthma and COPD, as well as some respiratory conditions associated with premature birth, both included in the Access to Medicine Index priority list of diseases. Asthma and COPD are more prevalent in high-income countries, while neonatology products have demand in a much wider range of countries. The ability to use Chiesi's two main neonatal products in LMICs is oftentimes limited due to a variety of factors. In order to address these limitations Chiesi has engaged in a program with Bill and Melinda Gates Foundation to introduce these two drugs in Africa.

Among the countries listed in the Access to Medicine Index, Chiesi currently has affiliates in Brazil, Mexico, and Pakistan.

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[1], 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.*

[1] Defined as the 106 countries included in the geographic scope of the Access to Medicine Index.

In all countries except for the United States, at least one or more of the pricing instruments (IRP, ERP, value-based) is applied. For this reason, Chiesi is currently not meeting this requirement but as an existing B Corp, Chiesi has one recertification period (about three years) to meet the requirement and thus will need to update its practices by its next recertification period in order to maintain the certification. Chiesi commits to fulfill this gap, including a specific disclosure on this topic.

Chiesi develops its pricing strategies during clinical development based on the value of the product. Equitable components of value-based pricing are incorporated to consider the differences in the ability to pay in different markets, both across countries and within countries. In regions where Chiesi is present through its external partners, the pricing process is similar. Partners usually have a book of reference prices and the prices are regulated. Regulatory processes are also followed.

Regarding transparency on pricing methodology, Chiesi is committed to pricing its offering according to the value it brings to patients, caregivers, the healthcare system, and society as a whole. Chiesi makes sure that its prices reflect the benefit 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, the company also commits to verifying its pricing policies are sustainable both in financial terms for the Company, with a return that is feeding into its R&D investments, and in terms of being sustainable for the payers / National Health Service as well as patients in the market where they pay out-of-pocket. Examples of tools used to assess economically justifiable prices include cost-effectiveness and Budget Impact analyses. The health economic evidence thus generated is part of the pricing and reimbursement submission package for new products and adapted to each Country using this information in their reimbursement process.

Country tiering is also applied, allowing the definition of ranges that can be applied to geographical clusters in order to ensure affordability considerations are accounted for. The methodology starts from macroeconomic indicators, incorporating price analogs/benchmarks for those therapeutic areas where Chiesi is present and, where applicable, external reference price input.

The company states that it cannot intervene directly or control the pricing made by partners according to anti-trust regulations. In all the countries where this is allowed and in full compliance with local regulation, Chiesi is consulted by the partner during the price setting procedure, defines a sustainable supply price to the partner taking into consideration the internal global guidelines, and is informed by the partner once the price is formally approved. In countries where there are no pricing instruments in place, Chiesi discusses the pricing methodology for a local sustainable price with the partner and receives monthly sales reports in

units and value and average selling prices, and has the right to make internal auditing to check the consistency of the invoices.

In the vast majority of countries covered by IMDD partners, there are pricing instruments in place (i.e. reference countries, HTA, local pricing reference, Health Authority decision), especially for the reimbursed products. There are however countries where the pricing process for some class of products does not require specific instruments. In this case price methodology considers the manufacturing cost/supply price, the distribution and storage cost with cold chain (challenging issues in developing countries), the exchange rate and the inflation rate, landing cost, and the cost of entry into the market with the support of Pharmacoeconomics tools.

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. Also, objectives regarding environmental and social sustainability may be included, such as:

- Environment: Avoid CO2 through online meetings, paperless communication, and by use of public transfer instead of cars.
- Sustainability: Prefer sustainable partners for local meetings/congresses, e.g. vegetarian catering, local products, B-certified.
- Social responsibility: support local activities on world premature day.
- Customer experience: Structured Identification of unmet customer needs and development of project options in a cross-functional team to support better patient lives.
- Customer experience: Achieve a number of participants in Disease Management educational online meetings and achieve a certain level of customer satisfaction in customer evaluation.
- Customer experience: Responsible for the organization of the dedicated event on customer journeys in the healthcare system and how to improve with a number of expected physicians and above “good” satisfaction score in customer evaluation.

The company adheres to the EFPIA Code, which sets out key principles for pharmaceutical companies when promoting prescription-only medicines (guidelines available by using the attached link 160721-efpia-code.pdf). 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).