Certified B Corporation

DISCLOSURE MATERIALS

Certified B Corporations must complete a Disclosure Questionnaire to identify potentially sensitive issues related to the company (e.g. historical fines, sanctions, material litigation, or sensitive industry practices).

This component does not affect the company's score on the B Impact Assessment. If the company answers affirmatively to any items in the Disclosure Questionnaire and B Lab deems them to be material, the company must:

1) Be transparent about the disclosure issues identified on the company's public B Impact Report
2) Describe how the company has addressed this issue.
3) Demonstrate that management systems are in place to avoid similar issues from arising in the future.

In all cases, the Standards Advisory council reserves the right to refuse certification if the company is ultimately deemed not to uphold the spirit of the community.

In addition to the voluntary indication of sensitive issues in the Disclosure Questionnaire, companies pursuing Certification also are subject to background checks by B Lab staff. Background checks include a review of public records, news sources, and search engines for company names, brands, executives/founders, and other relevant topics.

Sensitive issues identified through background checks may or may not be within the scope of questions in the Disclosure Questionnaire, but undergo the same review process and are subject to the same possible review by the Standards Advisory Council, including ineligibility for B Corp Certification, required remediation, or disclosure.

This document contains a copy of the company's completed Disclosure Questionnaire and related disclosure documentation provided by the company.

Certified B Corporation

DISCLOSURE QUESTIONNAIRE

Company Name: Chiesi Group
Date Submitted: May 2019

Disclosure Industries	Yes	No
Please indicate if the company is involved in production of or trade in any the following. Select Yes for all options that apply.		
Any product or activity deemed illegal under host country laws or regulations or international conventions and agreements		√
Gambling		√
Other: pharmaceutical industry	√ More Details >>	
Payday lending		√
Pornography		√
Wildlife or wildlife products regulated under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)		√

Disclosure Penalties	Yes	No
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies. Check all that apply.		
Diversity and equal opportunity		√
Employee safety or workplace conditions		√
Environmental issues		√
Financial reporting		√
Geographic operations or international affairs		√
Investments or Loans		√
Labor issues (internal and supply chain)		√
Marketing		√
Political contributions		√
Taxes		√
Bribery, Fraud or corruption		√

Supplier Disclosure	Yes	No	Don't Know
Please indicate if any of the following statements are true regarding your company's significant suppliers.			
Significant Suppliers employ workers under the age of 15 (or other minimum work age covered by the International Labour Organization Convention No. 138)			√
Significant Suppliers use any workers who are prisoners			√
Significant Suppliers have had an operational or on-the-job fatality			√
Significant Suppliers' sites have experienced accidental discharges to air, land or water of hazardous substances			√
Construction or operation of Significant Suppliers' facilities resulted in physical resettlement or economic displacement involving 5,000 or more people near their facility			√
Construction or operation of Significant Suppliers involved large scale land acquisition			√
Construction or operation of Significant Suppliers involved large scale land conversion and/or degradation			√
Construction or operation of Significant Suppliers involved the construction or refurbishment of dams			√
Significant Suppliers have had material fines or sanctions in the last five years regarding the issues indicated in DQ4.1			√
Significant Suppliers exploitatively operate in conflict zones			√

Disclosure Practices	True	False
Please indicate if the following statements are true regarding whether or not the company engages in the following practices. Check all that apply. If the statement is true, select "True." If false, select "False."		
Company is not formally registered in accordance with domestic regulations		√
Company has reduced or minimized taxes through the use of corporate shells or structural means	√ More Details >>	
Company does not transparently report corporate financials to government		√
Company facilities are located adjacent to or in sensitive ecosystems		√
Company does not provide clean drinking water to employees at all times		√
A portion of workers, contractors, subcontractors or day-workers are paid below minimum wage		√
Company does not have a signed contract of employment with each worker		√
Company employs workers under the age of 15 (or other minimum work age covered by the International Labour Organization Convention No. 138) and/or company does not keep personnel records that include evidence of the date of birth of each		√
Overtime work for hourly workers is compulsory		√
Company does not provide payslips or equivalent to all workers to show how wages are calculated and any deductions made		√
Company uses workers who are prisoners		√
Company prohibits workers from freely associating and bargaining collectively for the terms of one's employment		√
Company prohibits workers from freely leaving the site during non-working hours or at the end of their shift		√
Company keeps workers' original ID cards/Passports		√
Company exploitatively operates in conflict zones		√
Company employs individuals on zero-hour contracts		√
Company engages in practices involving animal testing	√ More Details >>	

Disclosure Outcomes	True	False
Please indicate if the following statements are true regarding if the company has experienced any of the following in the past 5 years. Check all that apply. If the statement is true, select "True." If false, select "False."		
Company has had an operational or on-the-job fatality		√
Company sites have experiences accidental discharges to air, land or water of hazardous substances		√
Construction or operation of company facilities resulted in physical resettlement or economic displacement involving 5,000 or more people near your facility		√
Material recalls due to quality control issues		√
Material litigation or arbitration against company		√
Company has filed for bankruptcy		√
Construction or operation of company involved large scale land acquisition		√
Construction or operation of company involved large scale land conversion and/or degradation		√
Construction or operation of company involved the construction or refurbishment of dams		√
Company has had material breaches of individual's confidential information		√

B Corp Certification - Disclosure Questionnaire Documentation

PROVIDED BY: Chiesi Group
UPDATED AS OF: May 22, 2019

DISCLOSURE QUESTIONNAIRE CATEGORY	Tax Reduction Through Structural Means
SUMMARY OF ISSUE	Chiesi USA has a coporate structure that provides certain tax benefits. The current corporate structure stems from a series of mergers and acquisitions over the past 10 years that resulted in Chiesi USA obtaining various product rights. These product rights were and continue to be held by intangible holding companies registered in Delaware. The company utilizes a single operating entity responsible for the operating activities (including product distribution) of the other entities. The operating entity's activities are performed under intercompany agreements, pursuant to which it pays royalties for use of the necessary rights. The royalty rates were determined by a transfer pricing study performed by Ernst & Young.
SIZE/SCOPE OF ISSUE (e.g. $ financial implication, # of individuals affected)	Chiesi USA's effective tax rate in 2017 was 36.5%
IMPLEMENTED MGT PRACTICES	"Intangible assets have not been transferred between entities, and remain with the entities where they were developed or acquired. No attempt has been made to move the intangibles from their original location in order to gain any tax benefits."
RELATED INCIDENTS Y/N	No

B Corp Certification - Disclosure Questionnaire Documentation

Chiesi Farmaceutici Spa

DISCLOSURE QUESTIONNAIRE CATEGORY: Animal Testing

SUMMARY OF ISSUE

Chiesi is required by law to conduct animal testing for certain types of pharmaceutical products per the requirements of international regulatory authorities such as FDA (The US Food and Drug Administration) and EMA (European Medicine Agency). Animal testing is only carried out when a non-animal alternative recognized by regulatory authorities is unavailable to assess the drug/product characteristics as required by legislation and regulatory authority requirements, through preclinical efficacy and safety, toxicology and development studies.

Chiesi group has its own R&D departments and entities, including its own laboratories. Chiesi Animal Care and In Vivo Testing Areas are in Italy. External partners, like Contract Research Organizations (CRO), when appropriate and applicable, perform animal testing, according to Chiesi standards. Chiesi guarantees that every scientific project carried out at its own laboratories or external contract research organizations is performed in compliance with National (D.Lgs 26/2014) and International Legislation (European Directive 2010/63/EU) on the protection of animals used for scientific purposes. On a regular basis, Chiesi Animal Care and In Vivo Testing Area is inspected and audited by local, national and international health authorities.

For local products specific to a particular Chiesi subsidiary, if animal testing is required by law it will usually be conducted by a third-party organization like a CRO. Only Chiesi USA had such local products requiring animal testing in the last 5 years.

SIZE/SCOPE OF ISSUE (e.g. $ financial implication, # of individuals affected)

The majority of Chiesi revenues come from products that have undergone some form of animal testing as mandated by legislation and regulatory authority requirements for approval and commercialisation. Given the extended timeline to develop and then commercialise a new medicine (10-15 years), the products which comprise this proportion of Chiesi’s current revenues may have undergone animal testing at some point in the last 50 years.

Because of the typical timeline for medicine development, animal testing does not usually occur within the same year that a product is ultimately sold. For example, in 2017 approximately 14% of Chiesi's sales came from products that underwent animal testing performed in the same year.

IMPACT OF STAKEHOLDERS*:*

Animal handling and care activities are managed fully in line with Good Laboratory Practice (GLP)-compliant procedures and working instructions. The related activities are undertaken by personnel who have received appropriate and relevant training, which is monitored and documented. A separate Quality Assurance Unit is responsible for monitoring the facility and all equipment. The Chiesi Animal Care and In Vivo Testing Area is a restricted and controlled-access area for authorized, qualified and trained personnel only. As outlined above, all the experimental activities performed within this area are authorized under national legislation.

The company utilizes this segregated and air-controlled area to guarantee animal health. All the facilities are built with suitable materials used in pharmaceutical areas, which are easy to clean. State-of-the-art equipment fulfilling US and European guidelines and legislation is used for animal housing. Environmental enrichment is guaranteed to all the species to boost mental and physical health and facilitate social interactions. There is separation of individual animals and their quarantine when needed. There are separate areas devoted to diagnosis, treatment and control of laboratory animal diseases. Animal health is checked daily by the animal care staff, seven days a week, and by an on-site veterinary professional on a regular basis. A specific veterinary care program is in place under the responsibility of the attending veterinarian who is certified in Laboratory Animal Science. The veterinarian provides guidance to investigators and all personnel involved in the care and use of animals. Recently the implementation of new laboratories that exploit advanced and less invasive methods of analysis, such as remote monitoring of vital parameters (via telemetry and plethysmography) and imaging technologies, is further enhancing the application of the 3Rs: the key principles and commitments to Replace, Reduce and Refine the use of animals.

Chiesi is member of EFPIA (European Federation of Pharmaceutical Industries and Associations) and adheres to EFPIA's public position on animal welfare in supporting the European Directive 2010/63/EU on the protection of animals used for scientific purposes, "Putting animal welfare principles and 3Rs into action". In line with the EU and EFPIA principles, Chiesi is further committed to ensuring the welfare of animals used in research and considers the use of animals to be ethically appropriate only when no alternative methods are available, or when the use is mandated by legal or regulatory requirements. More specifically, Chiesi has developed a plan based on the EFPIA comprehensive framework composed of a series of actions clustered in "Beyond Compliance" – "Leading by Example" – "Open Communication" with a set of initiatives for putting animal welfare principles and the 3Rs into action.

IMPLEMENTED MANAGEMENT PRACTICES

In 2014, Chiesi established an internal Animal Welfare Body (AWB) to strengthen the protection of animals used for scientific purposes. The AWB must produce technical, scientific, and ethical opinions on research projects that use animals for scientific purposes and on any modification of the projects in order to guarantee compliance with National and International Legislation on the protection of animals used for scientific purposes. The AWB also guarantees the appropriate training and competence of all personnel involved in the animal testing process, because the welfare of the animals used in procedures is highly dependent on the quality and professional competence of the personnel supervising procedures. The AWB also promotes best practice and technologies for animal housing and welfare and ensures that the methods chosen are able to provide the most satisfactory results, cause the minimum distress to animals, use the minimum number of animals, require the use of species with the lowest capacity to experience pain, suffering, distress or lasting harm that are optimal for extrapolation into the target species (human). Moreover, the AWB promotes, when possible, the use of alternative methods and strongly supports the implementation of the principles of Replacement, Reduction and Refinement with respect to animal testing.

OTHER MANAGEMENT COMMENTS

Chiesi agrees that animals are sentient creatures and they have an intrinsic value which must be respected, as must be the deeply respected ethical concerns of the general public as regards the use of animals in medicines development. However, the worldwide scientific community agrees that, despite being desirable to replace the use of animals in procedures by other methods, the use of animals continues to be necessary to protect human and animal health and the environment. For this reason, animal experimentation is performed only where a non-animal alternative is unavailable to assess the safety and the efficacy of new products, and to produce preclinical data needed to submit to regulatory authorities such as the FDA and EMA to obtain clearance for human studies and for the final approval of the product.

RELATED INCIDENTS (YES/NO)

Chiesi has not experienced any incidents or accidents with regards to its animal testing activities.

B Corp Certification - Disclosure Questionnaire Documentation

Chiesi Farmaceutici Spa

As a pharmaceutical company, Chiesi's business has several inherent social and environmental risks that are prevalent in the pharmaceutical industry. Below is a summary of the company's approach to managing these risks in the areas of affordability and pricing, ethics and compliance, political advocacy & lobbying, and traceability & product quality.

Affordability and Pricing

Chiesi Corporate product prices are currently governed by a Standard Operating Procedure, which defines roles and responsibilities for establishing the launch price for products as well as for subsequent variations.

National authorities in the European Union are free to set the prices of medicinal products and to designate the treatments they wish to reimburse under their social security systems. The Pharmaceutical Pricing and Reimbursement systems established by EU countries are very complex. Each Country uses different schemes and policies, adapted to its own economic and health needs. Chiesi operates, in each European Country, under the specific regulations for reimbursement and pricing of pharmaceutical products of the Country itself.

Prices of reimbursed products are often reviewed in Europe either on a regular basis, as consequence of International Reference Price System, or following new rules issued by local governments. In past 5 years, reviews and adjustments have always led to price reductions.

In the USA, where price is free, no significant increases have been applied to Chiesi Corporate products in the past 5 years. For example, the price of Curosurf in the USA has increased 2.5% on average year-over-year.

Ethics and Compliance

Chiesi abides by the rules and principles in the Code of Conducts defined by the national and international Associations of Pharmaceutical Industries in which Chiesi participates (e.g. the EFPIA - European Federation of Pharmaceutical Industries and Association, in Europe, and Farmindustria, in Italy).

To this end, the company has developed a Corporate Standard Operating Procedure (Corporate SOP) that governs all interactions with healthcare providers (HCPs) and healthcare organizations (HCOs), including promotional materials, donations, congresses, consultancies, medical samples and observational studies. All such activities require a multi-step approval that follows a segregation of duties-based approach. In addition, EU regulations require promotional information that is to be shared with HCPs be approved by the person in charge of the scientific

service within the company. The Corporate SOP prohibits remuneration for HCPs except in the case of scientific consultancy agreements, in which case a set of criteria for the qualification of the HCPs is specified and – based on such qualification – a set of tiers determining the relevant fees.

Donations towards patient associations are disclosed publicly where admissible, in accordance with applicable laws and regulations (see example here). Providing donations to patient associations requires the approval of the company's Legal department to ensure compliance.

Political Advocacy and Lobbying

With regard to political advocacy and lobbying activities, Chiesi does not make any corporate political contribution as stipulated in the company's Anti-bribery Policy. The company engages directly with EU Institutions on topics pertinent to the healthcare field, for which Chiesi is registered to the transparency register of the European Parliament and the European Commission.

Chiesi also participates in trade associations such as the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), European Federation of Pharmaceutical Industries and Associations (EFPIA), European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), and Farmindustria. The company's participation with these trade associations is strictly regulated by internal codes of conduct.

Traceability and Product Quality

Chiesi adopted a specific procedure in order to avoid counterfeiting, that utilizes an anti-tampering device and a randomised unique serial number for each package that is checked at the time of delivery. This procedure is already active in several countries (China, USA, and Korea) and has been extended to all EU countries in February 2019 and will be extended to Russia in 2020.

Medicine counterfeiting in Europe is regulated by the EU-FMD (European Falsified Medicine Directive), which applies to every participant in the healthcare supply chain in 32 European states: the 27 EU member states + 5 members in non-European economic areas: Norway, Iceland, Lichtenstein, Switzerland and UK. The pharmaceuticals products in scope are all prescription medicines (with a few exceptions as specified in the regulations), while product over the counter (OTC) are out of scope.