B Corp Certification - Disclosure Questionnaire Documentation
Chiesi Farmaceutici Spa

DISCLOSURE QUESTIONNAIRE CATEGORY: Animal Testing

SUMMARY OF ISSUE

Chiesi is required by law to conduct testing of all new drug candidates on live animals per the requirements of international regulatory authorities such as the FDA (The US Food and Drug Administration) and EMA (European Medicine Agency). In order to guarantee the highest level of safety and protection for patients and consumers, the national and international regulations governing the discovery, development, and manufacture of medicinal products mandate pharmaceutical companies to submit data on safety in animals, before they will approve the use of a compound for human clinical trials, throughout clinical development or license a new medicine for use in patients.

Chiesi Group has its own R&D departments and entities, including its own laboratories. Chiesi Animal Care and In Vivo Testing Areas are located in Italy. External partners, and third parties like Contract Research Organizations (CROs), when appropriate and applicable, may perform animal testing according to Chiesi standards. For local products specific to a particular Chiesi subsidiary, if animal testing is required by law it will usually be conducted by such 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 commercialization. Given the long timeline to develop (average now 15 years) and the very extended lifespan of the medicines in Chiesi's portfolio, animal testing on its current products may have occurred at some point during 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 brought to the market. For example, in 2021 only approximately 10% of Chiesi's sales came from products that underwent animal testing performed in the same year.

IMPACT OF STAKEHOLDERS*:*

The company utilizes a segregated and air-controlled area to guarantee animal and staff health. The animal facility is built with suitable materials used in pharmaceutical areas to permit effective cleaning and maintenance. State-of-the-art equipment fulfilling US and European guidelines and legislation are used for animal housing. Environmental enrichment is guaranteed to all the species used to boost their mental and physical health and facilitate social interactions.

Separate areas are devoted, as appropriate, to diagnosis, treatment and control of laboratory animal diseases. Animal health is checked daily by the animal care staff, seven days a week, 365 days per year, 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.

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 systematically to measure its effectiveness. A separate Quality Assurance Unit is responsible for monitoring the facility, and all the equipment and assessing that activities are performed according to the current standard operating procedures and working instructions. The Chiesi Animal Care and In Vivo Testing Area is a restricted and controlled-access area for authorized, qualified, and trained personnel only to assure an appropriate level of control and oversight. All the experimental activities performed within this area are authorized under national legislation.

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.

Recently, the investment in and implementation of new laboratories that use advanced and less invasive methods of analysis, such as remote monitoring of vital parameters (via telemetry and plethysmography) and imaging technologies, have reduced the number of animals needed for certain experiments and is further enhancing the application of the 3Rs in Chiesi: the key principles and commitments to Replace, Reduce and Refine the use of animals.

IMPLEMENTED MANAGEMENT PRACTICES

The following principles guide Chiesi's daily work and the definition of an improvement path to ensure an integrated and strategic approach to animal care, welfare, and treatment:

1. Chiesi Farmaceutici promotes a culture of care that includes the acceptance of an ethical approach to the use of animals as a primary value, with the commitment to go beyond the standard welfare regulations and guidelines governing animal testing toward a continuous improvement of all practices.

2. Chiesi Farmaceutici accepts animal testing only if there is no other appropriate, applicable alternative method and if the costs and benefits of procedures involving animals have been carefully considered and there is a clear expectation that the results can contribute to the protection and/or improvement of human or animal health.

3. The design of a study involving animals must ensure:

a. maximum application of the 3Rs principles – Replacement, Reduction, and Refinement,

b. positive opinion expressed by an independent ethics and scientific review panel,

c. adoption of all possible measures to preserve animal well-being, by using the most humane scientifically valid protocol, which must meet study and regulatory requirements and be in accordance with all applicable laws

d. use of the minimum required number of animals.

4. Animal health and welfare are promoted by ensuring that all animals have access to food, water, adequate housing, and the environment with the aim of satisfying their physiological, behavioral, and social needs, in addition to the full observation of local, national, and international guidelines and codes of conduct.

5. All personnel involved in the care and use of animals are appropriately and regularly trained by internal and external specialists.

6. Chiesi Farmaceutici guarantees the presence of experts in veterinary medicine, animal science, and animal welfare, qualified by training and experience, in order to guide programs promoting the highest standards of treatment and care of the animals.

7. Chiesi Farmaceutici has been recognized for the high quality of its program of care and use of animals through an independent, officially recognized organization, the AAALAC International - American Association for Accreditation of Laboratory Animal Care accreditation. AAALAC International is a private, non-profit organization that promotes the humane treatment of animals in science through voluntary accreditation and a performance-based, peer-reviewed assessment of animal care and use programs.

8. All of Chiesi's external collaborators including contract laboratories, research laboratories, partners, suppliers, and transporters must comply with Chiesi Farmaceutici animal protection principles.

9. Chiesi Farmaceutici ensures that its employees have full knowledge of the law on conscientious objection, concerning the rules on conscientious objection to animal testing (Law No. 413 of 12th October 1993).

In 2014 Chiesi established its own internal Animal Welfare Body (AWB) to strengthen the protection of animals used for scientific purposes. The AWB must review in advance all internal

research projects that foresee the use of animals for scientific purposes to confirm that they are supported by a relevant scientific justification/rationale and approves their execution after releasing motivated technical, scientific, and ethical opinions to guarantee the project compliance with National and International Legislations on the protection of animals used for scientific purposes. The AWB must guarantee that all the personnel involved in animal research are trained to standards that are approved by recognized professional bodies and that adhere to national guidelines since the welfare of the animals used in procedures is highly dependent on the quality and professional competence of the personnel supervising procedures. The AWB promotes the best practices and technologies for animal housing and welfare. The AWB ensures that the experimental method chosen is able to provide the most satisfactory results, causes the minimum distress to animals, uses the minimum number of animals, and requires the use of species with the lowest capacity to experience pain, suffering, distress, or lasting harm that are optimal for extrapolation into target species (human). Finally, the AWB promotes, when possible, the use of alternative methods and strongly supports the implementation of the principles of the 3Rs rules.

OTHER MANAGEMENT COMMENTS

Chiesi acknowledges the contribution that animals are giving to its medicines development and therefore the company believes that acting with due respect to the animals by establishing and ensuring high ethical and welfare standards is a fundamental and undeniable principle. These beliefs are morally and scientifically guiding our actions. However, the worldwide scientific community agrees that, despite being desirable to replace the use of animals in procedures with 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 regard to its animal testing activities.