

**GENERAL PRINCIPLES OF CONDUCT
OF THE ORGANIZATION, MANAGEMENT AND
CONTROL MODEL
PURSUANT TO ITALIAN LEGISLATIVE DECREE
231/2001
OF
Menarini Biotech srl**



MENARINI BIOTECH

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GENERAL PRINCIPLES OF CONDUCT OF THE ORGANIZATION, MANAGEMENT AND CONTROL MODEL

The authorities responsible for the departments, functions and services involved in the “ risk areas” are required, within the scope of their activity”, to respect the rules of conduct set forth below, pursuant to the principles provided by the Model and, specifically, by the Malesci Code of Ethics (hereinafter, also 'Code of Ethics').

It is strictly forbidden to:

- engage in conduct that would include the criminal acts set forth by the Decree 231/2001;
- committing any act does not in itself constitute a criminal offense included within those mentioned above, but may potentially become one;
- engage in or facilitate transactions that would give rise to an actual or potential conflict of interest with the Company, including activities that may interfere with the ability to make impartial decisions in the best interest of the Company and fully compliant with the Code of Ethics rules;
- engaging in or facilitating operations or activities that do not comply with the Code of Ethics;
- engaging in activities that are in contravention of the procedures and principles provided to prevent counterfeiting of distinctive marks of intellectual property or industrial products.

It is also required that:

- any activities and operations conducted on behalf of Malesci be characterized by maximum compliance with current law, as well as the principles of fairness, transparency, good faith and traceability of the documentation;
- maximum conformity between the acts performed and those required in accordance with the procedures is ensured, paying particular attention to the conduct of “sensitive” activities;
- those persons who exercise the role of oversight and supervision in relation to obligations associated with the performance of the aforementioned “sensitive” activities pay particular attention to the performance of those obligations and immediately inform the Supervisory Board of any irregularities and, in any case, all the information provided in paragraph 10.4 of the General Part of the Company’s Model.
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Below there are further principles of conduct to be observed to mitigate the risk of committing the relevant offenses pursuant to 231/01 Legislative Decree.

➤ **Crimes against the Public Administration (artt. 24 and 25 Decree 231/2001)**

It is strictly forbidden to:

- give, offer or promise money to government officials or persons responsible for government services, including healthcare workers (e.g., pharmacists, doctors, etc.);

- distribute, offer or promise gifts and presents whose value is not modest, in violation of the Code of Ethics and of company practice;
- agree, offer or promise other benefits, of any kind whatsoever, to government officials or persons responsible for government services, including healthcare workers;
- provide services on behalf of the Partners and/or consultants and/or suppliers that are not sufficiently justified within the context of the business relationship formed with them;
- pay fees to independent contractors that are not sufficiently justified in relation to the type of task to be conducted and the current local practices;
- present untrue or incomplete statements and/or documents and/or data and/or information to national, local or foreign governmental organizations, certainly not in order to obtain government grants, contributions or subsidized loans;
- to use amounts received from national or local governmental bodies as grants, contributions or loans, for purposes other than those for which they were originally intended.

Furthermore, to guarantee the principles in the preamble:

- in at-risk areas, the relationships with parties that may qualify as Government Officials or Parties Responsible for Government Services must be managed as a unit, by appointing one or more internal managers for each action or set of operations conducted;
- within the scope of the collaboration with the scientific sector, the fairness, suitability and accountability of the actions must be ensured, and these must be based upon the promotion of science and improvement of professional knowledge and carried out in cooperation with entities of proven reliability and national standing;
- association agreements with the Partners must be made in writing, emphasizing all the conditions of the agreement – specifically in relation to the economic conditions agreed for joint participation in the tender procedure;
- tasks assigned to independent contractors must also be provided in writing, indicating the agreed fee, and must be signed in accordance with the granted powers;
- no type of in-kind payment may be made;
- the statements made to national or local public bodies for the purposes of obtaining grants, contributions or loans must only contain true information and, in the event thereof, a special statement must be released.

➤ **Computer crimes and illegal data processing (art. 24 bis Decree 231/2001)**

All company resources and, specifically, those persons who hold positions relating to the use and management of information systems must base their actions upon the following principles of conduct:

- **Confidentiality:** ensures that certain information is preserved from improper access and used solely by authorized parties. Confidential information must be protected during both the

transmission and storage/maintenance phase so that such information is accessible solely to those persons who are authorized to review it;

- **Integrity:** ensures that any company information provided is actually that originally entered into the computer system and has only been validly modified. It should be ensured that the information is handled in a manner such that it cannot be tampered with or modified by unauthorized parties;
- **Availability:** ensures the availability of the company information in accordance with the requirements of process continuity and in compliance with the standards imposed by historical preservation.

Under the aforementioned rules, it is specifically prohibited to:

- alter electronic documents, public or private, that have evidentiary value;
- illegally access public or private computer or electronic information systems;
- illegally access one's own computer or electronic information system in order to alter and/or eliminate data and/or information;
- illegally keep or use codes, passwords or other means to access a computer or information system of competing public or private parties in order to acquire sensitive information;
- illegally keep or use codes, passwords or other means to access one's own computer or electronic information system in order to acquire confidential information;
- procure and/or produce and/or distribute equipment and/or software for the purpose of damaging a computer or electronic information system of public or private parties, the information, data or programs contained therein, or in order to interrupt, in whole or in part, or alter its operations;
- carry out fraudulent activities to intercept, impede or interrupt communications;
- modify and/or delete data, information or programs of public or private parties or of public utilities;
- damage information, data and computer or electronic information programs of third parties;
- destroy, damage or render unusable computer or electronic information systems of public utilities.

Accordingly, the above parties must:

- utilize the information, applications and equipment solely for official purposes;
- avoid introducing and/or keeping at the company (on paper, computers or by means of business tools), in any manner and for any reason, confidential documents and/or electronic media owned by third parties, except if obtained with the express authorization and for strictly work-related reasons;

- avoid transferring outside the Company and/or transmitting files, documents or any other confidential documents owned by the Company or other Group companies, if not for purposes strictly relating to the conduct of its own business;
 - avoid the use of software and/or hardware designed to intercept, falsify, alter or delete the content of electronic communications and/or documents;
 - utilize the internet connection for purposes and the time strictly necessary to carry out work activities;
 - comply with the procedures and standards expected, providing notice immediately to the competent units of any irregular uses and/or operations of the computer resources;
 - use on Company equipment solely of products officially acquired by that Company;
 - refrain from making copies of data and software that have not been specifically authorized;
 - refrain from using the available computer tools in a manner not in accordance with the required authorizations;
 - observe any other specific rule regarding access to the systems and the protection of the data resources and applications of the Company;
 - meticulously observe the company security policies for the protection and oversight of the computer systems.
- **Organized crime offenses; crimes of receiving stolen goods, money laundering, use of money, good or utilities of illegal origin; transnational crimes (artt. 24 *ter* and 25 *octies* Decree 231/2001; art. 10 Law 146/06)**

To guarantee the respect of the principles in the preamble:

- with respect to the commercial/professional reliability of the suppliers and of the partners, any information required must be requested, using the tools provided by external consultants;
- the tasks assigned to any services companies and/or individuals that oversee the economic/financial interests of the Company must also be prepared in writing, in the description of the contents and of the agreed economic conditions;
- it is necessary that the competent units ensure oversight of the regularity of the payments to all counterparties (including Group Companies); specifically, conformity between the party to whom the order is made and the party collecting the relative sum must be accurately reviewed;
- the oversight, whether formal or substantive (review the registered legal address of the counterpart company, review the credit institutions used, review of the use of trust companies), must be ensured with respect to company financial flows and payments through third parties and through Group companies;

- the minimum requirements established for selecting bidders for goods and/or services the Company intends to purchase must be strictly observed;
- criteria for the assessment of the tenders must be established;
- in the event of the negotiation of agreements/joint venture finalized upon the execution of investments, the utmost transparency must be ensured;
- full cooperation with Judicial Authorities is ensured, even by means of the refusal to influence any parties called to make statements or by requesting that such parties exercise the right not to respond.

➤ **Crimes against the industry and commerce and on matters of industrial property (art. 25 bis Decree 231/2001)**

To guarantee the respect of the principles in the preamble, Malesci:

- has rules regarding the use of materials protected by industrial property rights;
- ensure the oversight, also through the assistance of consultants, of the conformity with laws regarding marketing/publicity material presented overseas.

➤ **Corporate crimes (art. 25 ter Decree 231/2001)**

It necessary that all operations carried out as part of the “sensitive” activities receive suitable evidence.

In the performance of such operations, compliance with the principles of conduct set forth below must be ensured:

- ensuring compliance with the rules of conduct set forth in the Malesci Code of Ethics, with particular regard to the requirement to ensure that any operation and transaction be correctly recorded, authorized, verifiable, valid, consistent and appropriate;
- maintaining appropriate and transparent conduct, compliant with the current law and regulations, in the performance of all the activities related to the preparation of the balance sheet and other corporate communications, in order to provide members and third parties true and correct information regarding the income statements, balance sheets and financial reports of the company;
- maintaining appropriate and transparent conduct, compliant with current law and regulations, in the acquisition, preparation and presentation of the data and information necessary for arrival at a legal opinion relating to the balance sheets, income statements and financial reports of the Company;
- ensuring observance of the principles of integrity, fairness and transparency, so as to permit recipients to arrive at a well-grounded and informed opinion regarding the income statements,

balance sheets and financial reports of the Company and the conduct of its activities, as well as regarding the financial and related products;

- observing the requirements imposed by law for the protection of the integrity and efficacy of the share capital and to act in compliance with internal company procedures based upon those standards, so as not to jeopardize the rights of creditors and third parties in general in this regard;
- refraining from taking any action or initiative if a conflict of interest exists, or if there is, also on behalf of third parties, a conflict of interest with those of the Company;
- ensuring the ordinary operation of the Company and of the corporate bodies, guaranteeing and facilitating any form of internal oversight of the company management provided by law, as well as the free assembly of the meeting;
- refraining from engaging in sham or otherwise fraudulent transactions, as well as from disseminating false and/or incorrect and/or misleading news that might generate changes in the price of the financial instruments;
- handling with the utmost fairness and transparency the relationship with Government Authorities, including Oversight Authorities;
- making promptly, fairly and in good faith all the communications required by law and regulations to the Government Oversight Authority, not impeding the exercise of the oversight duties conducted thereby;
- behaving fairly and truthfully with press and information organizations;
- basing the activities and relationships with the other Group Companies on maximum fairness, integrity and transparency, so as to ensure compliance with the laws and regulations currently in force.

➤ **Crimes regarding infringement of copyright (art. 25 *novies* Decree 231/2001)**

All parties receiving the Model are strictly forbidden from:

- committing any act that, although not themselves the aforementioned criminal offenses, may become one in the abstract;
- copying, importing, distributing, selling, leasing, disseminating/transmitting to the public, holding for commercial purposes or, in any case, for profit, without authority, computer programs, protected databases or any works protected by copyright or associated rights, including literary, musical, multimedia, cinematic [or] artistic works;
- unauthorized dissemination through computer networks of any original work or part thereof;
- engaging in file-sharing through the exchange and/or sharing of any type of file by means of a peer to peer platform.

Furthermore, in order to perform the above actions, Malesci:

- has rules regarding the use of copyright-protected material;
 - provided for the formalization of research agreements and specific clauses for the management of copyrights;
 - provided for the prohibition on the installation and unauthorized use of file sharing systems.
- **Crime of inducing to withhold statements or to make false statements to judicial authorities (art. 25 *decies* Decree 231/2001)**

It is strictly forbidden to:

- coerce, in any manner and by any means, the will of parties summoned to make statements to appear before the Judicial Authority or to cause such parties to exercise their right to not appear;
 - cause, in any way, subjects summoned to make statements before the Judicial Authority, to make untrue statements;
 - give, offer or promise money, gifts, presents or other benefits to persons summoned to make statements before the Judicial Authority;
 - engage in any conduct that does not in itself specifically include the criminal offenses set forth above, but may become them in the abstract;
 - engage in or facilitate operations or activities that do not comply with the standards of the Code of Ethics.
 - Furthermore, in order to perform the above actions:
 - in relations with the Judicial Authority, it must be ensured that the defendants or suspects in a criminal proceeding, especially with respect to those procedures wherein Malesci may be directly or indirectly involved, are free to express their representations of facts when deciding to submit questions.
- **Crimes of employing third country citizens who are present illegally (art. 25 *duodecies* Decree 231/2001)**

All parties receiving the Model, particularly, must:

- always consider the protection of workers as prevailing to any economic consideration;
- in the event that recourse is made to temporary labor by means of special agencies, ensure that such parties use workers who are compliant with legislation relating to residency permits and expressly request commitment to the Model;

- ensure by means of specific contractual clauses that any third parties working in collaboration with the Company (suppliers, consultants, etc.) use workers who are in compliance with legislation relating to residency permits and expressly request commitment to the Model;
- comply with measures provided by the company procedures for the prevention of the use of illegal labor and the protection of workers;
- not use, in any manner, child labor or work in conjunction with parties using such labor;
- maintain a proper system for the proxies and powers of attorney related to the employment of labor;
- implement a system for monitoring the events related to residency permits (expirations, renewals, etc.).

➤ **Private Bribery (art. 25 ter Decree 231/2001)**

In relation to private individuals and relations with employees, it is prohibited:

- either directly or through an intermediary, to solicit or receive for oneself or for others, an undue advantage of any kind, or accept the promise of said advantage, in carrying out management or work roles of any type on behalf of the Company, in exchange for performing or omitting an action, in violation of the obligations of assigned office or those of general loyalty;
- either directly or through an intermediary, to promise, offer or provide an undue advantage of any kind to parties carrying out management or work roles of any type within the company or on behalf of an entity in the private sector, in exchange for the party carrying out or omitting an action in violation of their duty.

Furthermore, in order to ensure the principles indicated above are respected:

1. gifts, donations or courtesy expenses are to be adequately documented to allow for checks by the Supervisory Board;
2. any recruitment of personnel as well as the management thereof must comply with the company rules and must guarantee:
 - a) a resource planning process to be undertaken that takes into account the requirement;
 - b) the identification of the minimum needs required to cover the role and the relative level of remuneration in compliance with the provisions of the CCNL [Contratto Collettivo Nazionale di Lavoro (National Collective Labor Agreement)] (if applicable) and consistent with the compensation charts of reference;
 - c) the establishment of a personnel selection process that governs: (i) the research of multiple candidates based upon the complexity of the position to be held; (ii) the management of conflicts of interest between the selecting party and the selected party; (iii) the review, through various screening phases, of the conformity of the candidate with the established profile.

- d) the conduct of pre-employment checks whose purpose to the prevention of adverse situations that expose the Company to the risk of committing the crime;
 - e) authorization to reimbursement at appropriate levels;
 - f) the existence and the use of systems that ensure the traceability of the review of attendance and the fairness of the compensation paid.
3. the contracts among the Company and the representatives of the agencies, suppliers, consultants and clients must be made in writing with all their terms and conditions and in compliance with the following provisions:
- a) all third party contracts (with agencies, consultants, distributors, etc.) must contain a special clause governing the consequences of breach by such parties of the standards mentioned in the Model;
 - b) the agencies or their representatives, suppliers, distributors and, generally, third parties must be selected using transparent methods and according to previously-determined qualitative and quantitative criteria;
 - c) approval of the contract in accordance with appropriate authorizing levels.
 - d) in addition, management of the contracts must provide for the review of consistence of the order with the parameters of the contract itself regarding the completeness and accuracy of the invoice and its consistency with legal prerequisites, just as provided by the company procedures;
 - e) in relationships with companies, foundations, associations and other private entities, the types of relationships and the related management methods as well as the methods of collection, review and approval of the documents to be transmitted to their representatives;
 - f) the procedures for the oversight of the financial flows and the traceability of the payments must be observed.

GENERAL PRINCIPLES OF CONDUCT : HEALTH OFFENCES AND SAFETY AT WORK

As already stated in the General Part of the Model, the Company has adopted and implemented a specific policy for health and safety, focused on ethics.

In particular, the Company has always demonstrated a commitment to continual improvement of safety, in terms of preventing injuries, accidents and dangerous behaviours, as well as hygiene and occupational health, and the safety of plants, operations and maintenance.

To effectively implement its commitments at all levels, the Company aims to:

- consider the protection of employee health and safety a corporate objective to be achieved and continuously improved, in compliance with the technical and structural standards of the law in relation to plants, equipment, workplaces, and chemical, physical and biological agents, etc.;

- analyse and assess the risks of accidents in relation to legislative provisions, guarantee the safety of employees and the surrounding environment and adopt measures to limit any potential consequences;
- act in compliance with all national laws and local regulations in force, adopting necessary preventive measures for the activities and updating these in accordance with technical progress and experience;
- check that the design of plants, machines and equipment, as well as workplaces, is carried out in such a way so as to safeguard the health of employees;
- assign duties and responsibilities in the field of safety at work through the creation of a suitable organisational structure, such as emergencies, first aid, contract management, periodic safety meetings, consultations with workplace safety representatives;
- ensure all corporate structures participate, according to their duties and responsibilities, in the achievement of the defined safety objectives;
- ensure preventive, periodic and extraordinary health monitoring and information, development and employee training activities;
- guarantee availability of necessary protective and preventive equipment/devices and verify their use;
- prepare measures to ensure that third parties operating within the Company premises adopt the conduct, practices and procedures consistent with the principles of this Policy;
- conduct or verify the operation of plants and equipment in order to ensure their compatibility with the protection of employee safety;
- involve employees in the final definition of the objectives and in the implementation of the changes and improvements plan, providing them with all the tools and knowledge required to operate in accordance with safety provisions and procedures;
- ensure suitable supervision activities with reference to workers' observance of safe working procedures and instructions;
- periodically review the contents of the Risk Assessment Document (RAD) in order to verify its adequacy, effectiveness and applicability.

GENERAL PRINCIPLES OF CONDUCT: ENVIROMENTAL CRIMES

In carrying out its activity on behalf of Biotech, the recipients of the Model are required to comply with the behavior rules indicated below, which comply with the principles established by the Model and, in particular, by the Code of Ethics.

It is strictly forbidden to:

- to keep, promote, collaborate or give cause to the realization of behaviors that, taken individually or collectively, could integrate directly or indirectly criminal acts set forth by the Decree 231/2001;
- behaviors that, although they do not constitute such crimes as those considered above, can potentially become .

The recipients of the Model shall adhere to the following principles:

- always consider predominant the need to protect the environment as compared to any economic consideration;
- contribute, in accordance with their own competence, to the fulfillment of the duties included within the protection of the environment;
- always assess the effects of their conduct in relation to the risk of damage to the environment: any action that may have an impact upon the environment must aim at reducing to a minimum the real or potential damage that may be caused to the environment;
- pursuant to their training and experience, as well as the instructions and means provided or arranged by the employer, not engage in improper actions that might cause damage to the environment;
- refrain from undertaking on their own operations or actions that are not included within their own duties or, in any case, may cause damage to the environment;
- the measures provided by the company procedures to prevent the production and to reduce the harmfulness of waste must be respected;
- protection of the soil and subsoil, conservation of the territory as well as the protection of surface, marine and underground waters must be ensured;
- all the precautions necessary to hold air pollution to a minimum and to keep emissions below the limits established by law must be taken;
- the temporary storage and subsequent delivery of waste must be carried out under safe conditions and in compliance with current law;
- the procedures whose purpose is the prevention of environmental problems and limiting the damages in the event of their occurrence must be followed;
- attend specific training courses on environmental matters.

The Supervisory Body will have the right to carry out the checks deemed most appropriate on that on any activities carried out by the subjects above and assessed potentially at risk of commission of crimes.