

ORGANISATION, MANAGEMENT AND CONTROL MODEL
PURSUANT TO ITALIAN LEGISLATIVE DECREE NO. 231/2001
OF
A. MENARINI FARMACEUTICA INTERNAZIONALE S.r.l.

GENERAL PRINCIPLES OF CONDUCT

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This is an English courtesy translation of the Italian language version of AMFI's Management and Control Model. The Italian language version will prevail in the event of any discrepancies with, or omissions in, the English translation.

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MAIN BEHAVIOURAL GUIDELINES

Heads of Departments, Functions and the services involved in areas at risk of a crime within the sphere of their activities, are obliged to comply with the rules of conduct set out below, in accordance with the principles stipulated in the Model, and especially in the AMFI Code of Ethics.

It is strictly forbidden to:

- engage in conduct such as to constitute the types of crimes envisaged by the Decree (see Annex to the Special Section "**Description of predicate offences**");
- putting in place any conduct, while not materially integrating any of the crimes applicable as above, could become applicable in abstract terms;
- put in place or facilitate transactions that could effectively or potentially create conflicts of interest with the Company, and also any activities that could interfere with their ability to impartially make decisions in the best interests of the Company and in full compliance with the rules of the Code of Ethics;
- putting in place or facilitating operations or activities that do not abide by the Code of Ethics;
- putting in place activities that are contrary to the procedures and principles of control required to prevent the crimes of counterfeiting distinctive signs of intellectual property works and industrial products.

It is also necessary:

- that all the activities and operations carried out on behalf of AMFI are distinguished by strictly complying with applicable legislation, and the principles of correctness, transparency, good faith and the traceability of documentation;
- that effective conduct strictly complies with the conduct stipulated in internal procedures, with special attention paid to the conducting of "sensitive" activities;
- that those who perform a function of control and supervision on formalities connected with carrying out the above sensitive activities must pay particular attention to implementing the formalities and immediately reporting any irregular situations to the Supervisory Board and, in any case, all information provided in paragraph 11.4 of the General Part of the Company's Model.

In addition to the aforementioned rules of conduct, the following are further principles of conduct to be observed in order to mitigate the risk of the predicate offences specified in each case.

- Crimes against the Public Administration (Art. 24 and 25 of Italian Legislative Decree no. 231/2001)

It is strictly forbidden to:

- donate, offer or promise money to a public official or persons in charge of public services, including healthcare professionals (e.g. pharmacists, doctors, etc.);
- distribute, offer or promise gifts and presents that are not of a modest value, in breach of the provisions of the Code of Ethics and corporate practices;
- agree on, offer or promise any advantages of any kind whatsoever, in favour of public officials or those in charge of public services, including healthcare professionals;
- provide services to Partners and/or consultants and/or suppliers that are not adequately justified

within the context of the associative relationship with the latter;

- pay fees to outsourcers that are not adequately justified in relation to the type of service that is provided and the applicable practices within the local environment;
- submit statements and/or documents and/or data and/or information that is untrue or incomplete to national, EU or foreign public bodies, and even more so when this is done to secure public funding, contributions or subsidised financing;
- to allocate amounts received from national or EU public bodies in the form of payments, contributions or funding, for purposes other than what they were originally intended.

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

- in risk areas, relations with parties qualifying as Public Officials or persons in charge of public services must be managed in a uniform manner, with the appointment of one or more people responsible internally for each action or series of operations carried out;
 - within the sphere of collaboration with the scientific world, the appropriateness, adequacy and documenting of initiatives must be ensured, with the latter based on spreading scientific knowledge and improving professional expertise, and must be conducted in collaboration with bodies of proven reliability and national standing;
 - association agreements with Partners must be defined in writing highlighting all the conditions of the agreement itself, in particular as regards the economic conditions agreed for joint participation in the tender procedure;
 - appointments conferred on outsourcers must also be put in writing, indicating the fee agreed and must be signed in accordance with the mandates conferred;
 - no type of payment may be made in kind;
 - statements made to national or EU public bodies, for the purposes of securing public funding, contributions or financing, must only contain information that is absolutely true, and once these have been obtained, appropriate accounting must be issued in this regard.
- **Computer crimes (Article 24-bis of Legislative Decree no. 231/2001)**

All company resources, and specially those that cover significant positions in the usage and administration of computer systems, must base their actions on the following codes of conduct:

- **Confidentiality:** guarantee that specific data is protected from undue access and is utilised exclusively by authorised people. Confidential information must be protected both during the transmission phase and in the storage/retention phase, so that the information is only accessible to whoever is authorised to be aware of it;
- **Integrity:** guarantee that all corporate data is actually the original data entered into the computer system and that only legitimate changes were made. It must be guaranteed that the information is processed in such a way that it cannot be tampered with or amended by unauthorised persons;
- **Availability:** guarantee that corporate data is available in relation to the requirements of continuity in processes and in compliance with the regulations that require its retention.

In particular, it is forbidden to:

- alter public or private IT documents with probatory value;
- abusively access the IT or ITC system of public or private parties;
- abusively access the IT or ITC system of public or private parties in order to alter and/or cancel data and/or information;
- abusively possess or utilise codes, passwords or other means of access to a computerised or telematic system of competitors, public or private parties, in order to acquire confidential information;
- abusively possess or utilise codes, passwords or other means of access to its own computerised or telematic system in order to acquire confidential information;
- conduct activities for the procurement and/or production and/or circulation of equipment and/or software in order to damage a computer or telematic system, of public or private parties, the information, data or programmes they contain, or to favour the total or partial interruption or the alteration of its functioning;
- illegally intercept, impede or interrupt communications;
- modify and/or cancel data, information or programmes of private or public parties or that are in any case of public utility;
- damage other parties' computer or telematic information, data or programmes;
- destroy, damage, render unserviceable IT or telematic systems of public utility.

The parties referred to above must therefore:

- use the information, applications and equipment exclusively for office purposes;
- avoid bringing into and/or storing in the Company (in paper, electronic format and by using corporate tools) on whatever basis and for whatever reason, documentation and/or computer material of a confidential nature and owned by third parties, unless these were acquired with the express permission strictly for work purposes;
- avoid transferring outside of the Company and/or transmitting files, documents, or any other confidential documentation owned by the Company itself or by another company in the Group, unless for purposes strictly pertinent to carrying out one's duties;
- avoid using software and/or hardware tools able to intercept, falsify, alter or eliminate the content of communications and/or computer documents;
- utilise the connection to the internet for the purposes and time strictly necessary to carry out one's work;
- respect the procedures and standards set, reporting any anomalous usages and/or functioning of computer resources to the competent functions without delay;
- only utilise products acquired officially by the Company on the Company's equipment;
- abstain from making copies of data and software that was not specifically authorised;
- refrain from utilising the compliance instruments available outside of the prescribed authorisations;
- comply with any other specific regulation referring to access to systems and the protection of the

Company's data and application assets;

- scrupulously comply with the provisions of the corporate security policies for the protection and control of computer systems.

➤ Bribery among private individuals (Article 25-ter of Legislative Decree No. 231/2001)

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

- solicit or receive, directly or through an intermediary, an undue advantage of any kind, or accept the promise of such an advantage, for oneself or for a third party, in the performance of management or work functions of any kind on behalf of the Company, in order to perform or omit an act in violation of the obligations inherent to one's role or of loyalty obligations in general;
- promise, offer or grant, directly or through an intermediary, an undue advantage of any kind to persons performing managerial or work functions of any kind within the company or on behalf of a private sector entity so that they perform or omit an act in breach of their duties.

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. the recruitment of personnel and its management must be done in compliance with the corporate procedures, ensuring:
 - a) a planning process for the resources to be appointed, taking into account effective needs;
 - b) identification of the minimum requirements to cover the role and the relative remuneration level, in accordance with the provisions under the National Collective Labour Agreements (CCNL) (where applicable) and the reference remuneration tables;
 - c) definition of a selection process for staff that governs that: (i) multiple candidates are sought in relation to the complexity of the role that needs to be covered; (ii) the management of conflicts of interest between the selectors and the selected applicant; (iii) during the screening phases, verification as to whether the candidates correspond with the defined profile.
 - d) pre-appointment checks conducted aimed at preventing prejudicial situations arising, which expose the Company to the risk of committing the contemplated crimes;
 - e) authorisation for the appointment from the appropriate levels;
 - f) systems that guarantee the traceability of attendance and correctness of the remunerations paid;
3. contracts between the Company and reference people from agencies, suppliers, consultants and customers must be defined in writing with all their conditions and terms and observe the indications of the points below:
 - a) contracts with all third parties (agencies, consultants, distributors, etc.) to contain a specific clause that governs the consequences of violating the rules in the Model;

- b) agencies or their reference people, suppliers, distributors and third parties in general must be selected according to transparent methods and based on predefined qualitative and quantitative criteria;
- c) approval of the contract based on adequate authorisation levels;
- d) furthermore, when managing contracts, checks must be done on the consistency of the order in relation to the parameters provided in the contract; on the completeness and accuracy of the invoice and its compliance with legislative prescriptions, and those set by corporate procedures;
- e) in the scope of relations with companies, foundations, associations and other private entities, the types of relations and the relevant ways in which these are managed must be identified, as well as the procedures for the collection, verification and approval of the documentation to be sent to the relative members;
- f) the procedures for controlling financial flows and the traceability of payments must be complied with;

➤ Organised crime, handling of stolen goods and money laundering and transnational crimes (Art. 24 *ter* and 25 *octies* of Legislative Decree no. 231/2001; Art. 10, Law 146/2006)

In order to ensure the general principles indicated above are respected:

- with regard to the commercial/professional reliability of suppliers and partners, all the necessary information must be requested, utilising in this regard the tools made available by external consultants;
- the appointments conferred to any service providers and/or natural persons that see to the Company's economic/financial interests, must also be put in writing, with the content and economic conditions agreed on specified;
- it is necessary for the competent functions to check on payments being made on a regular basis in respect of all counterparties (including companies in the same Group); in particular, a specific check must be done that the party on the order form corresponds with the party receiving the relevant payment;
- a formal and substantive check (check on the counterparty company's registered address, check on the credit institutions used, check on the use of any trust companies) and must be guaranteed with regard to corporate financial flows and payments to third parties and to companies within the Group;
- the minimum standards and requirements set for the purposes of selecting parties providing goods and/or services, which the Company intends acquiring, must be diligently complied with;
- the assessment criteria for bids must be set;
- maximum transparency must be ensured in the case of entering into agreements/joint ventures aimed at making investments;
- that full cooperation shall be guaranteed with the Judicial Authority, including the rejection of influencing any parties called to make statements or inciting the latter from availing themselves of the right not to respond.

- Crimes against industry and trade (Art. 25-*bis* and 25-*bis*1 of Italian Legislative Decree no. 231/2001)

In order to ensure that the general principles indicated above are respected, the Company:

- has rules in place on the use of material protected by intellectual property rights;
- ensures that promotional/advertising material presented outside the Company complies with regulations, with the support if necessary, of consultants.

- Corporate crimes (Article 25-*ter* of Legislative Decree No. 231/2001)

Based on the controlling principles outlined above, it is necessary that all operations carried out within the context of “sensitive” activities are properly documented.

When executing these operations, the following codes of conduct need to be respected:

- guarantee compliance with the conduct stipulated in the corporate Code of Ethics, with special reference to the requirement of ensuring that every operation and transaction is correctly recorded, authorised, verifiable, legitimate, consistent and appropriate;
- maintain correct and transparent conduct, in compliance with the applicable provisions of the law and regulations, in all the activities aimed at preparing the financial statements and the other corporate communications, in order to provide shareholders and third parties with true and correct information on the Company’s economic and financial situation and equity;
- maintain correct and transparent conduct, ensuring full compliance with the applicable provisions of the law and regulations, in the acquisition, processing and communication of the data and information necessary to enable a well-grounded judgement on the Company’s economic and financial situation and equity;
- guarantee compliance with the principles of integrity, correctness and transparency so as to allow recipients to form a substantiated and informed opinion of the Company’s economic and financial situation and equity, its outlook and on the related financial products;
- observe the prescription set by law to protect the integrity and effectiveness of share capital and to act in compliance with internal corporate procedures, which are based on these rules, in order not to generally prejudice the rights of creditors and third parties in this regard;
- abstain from carrying out operation or initiative when there is a conflict of interests, or when there is a conflict of interest between a third party and the Company;
- ensure proper functioning of the Company and corporate bodies, guaranteeing and supporting any form of internal control over company management envisaged under the law, as well as the free and regular exercising of the vote in Shareholders’ Meetings;
- abstain from putting in place simulated or otherwise fraudulent operations, and from disseminating false and/or incorrect and/or misleading information, which could cause changes to the price of financial instruments;
- manage relations with the Public Administration and Supervisory Authorities with the highest degree of transparency and correctness;
- promptly, correctly and in good faith carry out all the communications provided for in the law and regulations in relations with the Public Supervisory Authorities, by not impeding them from exercising their supervisory functions;
- maintain correct and truthful conduct in relations with the press and information bodies;

- conduct in respect of activities and relations with other Companies in the Group is based on the highest level of correctness and integrity, to ensure compliance with applicable legislation and regulations.

➤ Crimes relating to copyright infringement (Article 25-*novies* of Legislative Decree no. 231/2001)

All recipients of the Model are strictly forbidden from:

- putting in place any conduct, while not materially integrating any of the crimes applicable as above, could become applicable in abstract terms;
- duplicating, importing, distributing, selling, renting, disseminating/transmitting to the public, possessing for commercial purposes, or for gaining a profit there from of computer programmes, protected databases or any other work protected by copyright and related rights, including works with a literary, musical, multi-media, cinematographic, artistic content, without having the rights to do so;
- disseminating a copyright protected work or part thereof via telematic networks, without having the rights to do so;
- engaging in file sharing, with the exchange and/or sharing of any type of file via peer-to-peer platforms.

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

- the observance of rules on the use of material protected by copyright;
- the formalisation of research contracts and specific clauses to manage copyrights;
- the prohibition on installing and using file sharing systems without authorisation.

➤ Incitement not to make statements or to make false statements to the judicial authorities (Article 25-*decies* of Legislative Decree No. 231/2001)

It is strictly forbidden to:

- in any way and in any form, coerce the will of those called to make statements to the judicial authority or to induce those to avail themselves of the right not to respond;
- in any way, induce those called to make statements before the judicial authority to make false statements;
- donate, offer or promise money, gifts, gratuities or other benefits to people called on to make statements before the judicial authority;
- put in place any conduct, while not materially integrating the crime applicable as above, could become applicable in abstract terms;
- put in place or facilitate operations or activities that do not abide by the Code of Ethics.

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

- in relations with the judicial authority, especially where these refer to proceedings in which the Company could be directly or indirectly involved, it must ensure that the suspects or defendants can freely express their representation of the facts should they decide to submit to questioning.

- Employment of third-country citizens whose stay is illegal (Art. 25-*duodecies* of Legislative Decree no. 231/2001)

Recipients of the Model must adhere to the following principles:

- to always focus primarily on protecting workers in relation to any other economic consideration;
- in the case of temporary workers being used through appropriate recruitment agencies, to ensure that their appointees are in order regarding their residence permit, and specifically require the agencies to sign an undertaking to comply with the Model;
- to ensure, on the basis of specific contract clauses that the third parties with whom the Company collaborates (suppliers, consultants, etc.) make use of workers in order regarding their residence permit, and specifically require the former to sign an undertaking to comply with the Model;
- the measures provided for under corporate procedures aimed at preventing the employment of workers staying illegally and at protecting workers must be complied with;
- under no circumstances must child labour be utilised, and no collaboration must be established with those that exploit this;
- an adequate system of mandates and powers of attorney must be in place regarding the recruitment of workers;
- a monitoring system to be in place for the formalities related to residence permits (expiry, renewal, etc.).

- Smuggling (Art. 25-*sexiesdecies* Legislative Decree no. 231/2001)

In its relations with the Customs Authorities, recipients of the Model commit themselves to the scrupulous compliance of the Consolidated Law on Customs, Italian Presidential Decree 43/1973, the European Union Customs Code, EU Regulation No. 952/2013, and all other relevant national and international sources in force, adopting all control and supervisory measures suitable for the prevention of any possible conduct aimed at smuggling.

To this end, it is strictly forbidden:

- to remove goods from the customs control system set up for the assessment and collection of border duties, either by not declaring them to the customs authorities or by concealing them or falsifying transport and/or commercial documents;
- to inappropriately use foreign goods imported/exported duty free and with discounted border duties, by allocating them or using them in a manner that differs from the allocation or use that the relief or reduction was granted for;
- to bring foreign goods into the State as substitutes for national or nationalised goods shipped in cabotage or in circulation;
- to evade the payment of border duties through the artificial manipulation of goods or through the use of fraudulent means;

- omitting or delaying the submission of the customs declaration, or improperly handling customs formalities by providing untrue information about the quantity, quality or value of goods.

THE DUTIES AND TASKS OF THIRD-PARTY RECIPIENTS

As it also appears in the Company's Code of Ethics, Third parties coming into contact with the Company must cooperate to best of their ability and competencies in order to promote behaviour aimed at ensuring the health and safety of workers.

➤ The duties and tasks of Contractors

Contractors must:

- guarantee they have the professional technical qualifications in relation to the work to carry out on the basis of a project or works contract or service provision contract;
- incorporate the information provided by the Employer regarding the specific risks existing in the environment where they are destined to work, and on the prevention and emergency measures adopted by the Employer;
- cooperate with the Employer to implement the prevention and protection measures from risks at work affecting the activities referring to the works contract or service provision contract;
- coordinate the protection and prevention interventions for the risks that Workers are exposed to, together with the Employer.

➤ The duties and tasks of Suppliers

Suppliers must comply with the prohibition from manufacturing, selling, renting and allowing the use of work equipment, personal protection devices and installations not complying with applicable legislation and regulations on health and safety in the workplace.

In the case of items with financial leases subject to compliance certification procedures, these must be accompanied by the relevant documentation provided by the assignor.

➤ The duties and tasks of Designers

The Designers of premises, workstations and installation must comply with the general principles of prevention regarding health and safety in the workplace when making their project and technical decisions, choosing equipment, components and protection devices that adhere to legislative provisions and applicable regulations on the subject.

➤ The duties and tasks of Installers

For the part they are competent for, installers must abide by the regulations for health and safety in the workplace, as well as the instructions provided by respective manufacturers.

➤ Tasks of the Partner

The Partner is responsible, *inter alia*, for supporting AMFI in the management of the risks associated with the management of "Security" risks, i.e. the management of risks not strictly related to the work environment ("Safety risks"), but rather linked to factors external to the Company's organisation and business (health risk, dangers referable to natural causes, crime and terrorism, geopolitical risk, particular health protocols, complex macroclimate contexts, legal and regulatory transpositions similar but not identical to the provisions of Italian Legislative Decree 81/2008).

In particular, this support involves the performance of the following tasks:

- provide worldwide insurance for any emergency medical expenses;
- provide access to a special computer portal to be consulted for all country information, alerts, advice, geopolitically relevant news;
- provide specific assistance through teams of doctors, nurses, security and logistics experts capable of activating any type of emergency service anywhere in the world;
- ensure a connection to an Assistance Centre, complemented by an intelligence service to provide real-time alerts on pandemics, wars, riots, emergencies, natural events, and a tracking service for Menarini employees travelling.

REFERENCE PRINCIPLES OF ETHICS AND RULES OF CONDUCT FOR THE COMPANY REGARDING HSW

As already outlined in the General Part of the Model, since it was established, the Company has adopted and implemented a policy founded on ethics.

In particular, the Company pays constant attention to the continuous improvement of safety, understood as the prevention of injuries, accidents, and dangerous behaviour, as well as occupational hygiene and medicine, plant safety, operation and maintenance.

To effectively implement its commitment at all levels the Company's goal is that of striving to:

- consider the protection of the health and safety of workers 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 all the necessary preventive measures in its activities and updating them according to technical progress and experience;
- check that the design of the plant, machinery and equipment, as well as the workplaces, is carried out in such a way as to safeguard the health of workers;
- assign tasks and responsibilities regarding safety at work by creating a suitable organisational structure, such as emergencies, first aid, management of contracts, periodic safety meetings, consultation with workers' safety representatives;
- involve the entire company structure, according to its own attributions and competences, in the achievement of the assigned safety objectives;
- ensure the activity of preventive, periodical and extraordinary sanitary surveillance, as well as the information, education and training of the workers;
- guarantee availability of necessary protective and preventive equipment/devices and verify their use;
- provide measures to ensure that third parties operating within the company's premises adopt behaviours, practices and procedures that are 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 its own employees in the concrete definition of the objectives and in the implementation of the modification and improvement plan, providing them with all the tools and knowledge so that they operate in accordance with the safety provisions and procedures;
- ensure appropriate supervisory activity with reference to workers' compliance with safety procedures and work instructions;
- periodically review the contents of the Risk Assessment Document to verify its adequacy, effectiveness, and applicability.

GENERAL PRINCIPLES OF CONDUCT REGARD TO ENVIRONMENTAL PROTECTION

When conducting their activities on behalf of AMFI, Recipients of the Model are obliged to comply with the rules of conduct specified below, which are in accordance with the principles stipulated in the Model, and in particular, in the Code of Ethics.

More specifically, all the subjects to whom the Model is addressed are absolutely forbidden to:

- establishing, promoting or causing others to carry out conduct considered, both individually or collectively, to either directly or indirectly incorporate the cases of the crimes included among those under Article 25-*undecies* of the Decree;
- to behave in such a way that, although not constituting a crime among those considered above, could potentially become one.

The recipients of the Model shall adhere to the following principles, and must:

- always consider predominant the need to protect the environment as compared to any economic consideration;
- contribute, in accordance with their own competence, to the fulfilment of the duties included within the protection of the environment;
- always assess the effects of their conduct in relation to the risk of causing damage to the environment: every action that could have an environmental impact must focus on reducing the actual or potential damage that could be caused to the environment to a minimum;
- 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;
- observe all the measures provided by the company procedures to prevent the production and to reduce the harmfulness of waste;
- ensure the protection of the soil and subsoil, conservation of the territory as well as the protection of surface, marine and underground waters;
- take all the precautions necessary to keep air pollution to a minimum and to keep emissions below the limits established by law;
- carry out the temporary storage and subsequent delivery of waste under safe conditions and in compliance with current laws;
- procedures and the HSE IMS aimed at preventing environmental emergencies and limiting damage should they occur must be followed;
- attend specific training courses on environmental matters.

As regards any operation carried out by the above-mentioned individuals and assessed as potentially at risk of committing a crime, the Supervisory Board will be entitled to carry out the controls deemed most appropriate.

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- contribute, in accordance with their own competence, to the fulfilment of the duties included within the protection of the environment;
- always assess the effects of their conduct in relation to the risk of causing damage to the environment: every action that could have an environmental impact must focus on reducing the actual or potential damage that could be caused to the environment to a minimum;
- 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;
- observe all the measures provided by the company procedures to prevent the production and to reduce the harmfulness of waste;
- ensure the protection of the soil and subsoil, conservation of the territory as well as the protection of surface, marine and underground waters;
- take all the precautions necessary to keep air pollution to a minimum and to keep emissions below the limits established by law;
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