

**CODE OF ETHICS**  
**PURSUANT TO LEGISLATIVE DECREE NO. 231/2001**  
**OF**  
**MALESCI**  
**ISTITUTO FARMACOBIOLOGICO S.p.A.**

## Table of contents

I.	Introduction	5
I.1	The Menarini Group's Global Code of Conduct and the Group's self-regulatory instruments incorporated in this Code of Ethics.	6
I.2	Recipients of the Code of Ethics	9
I.3	Structure of the Code of Ethics	10
II.	General Principles	11
II.1	Responsibility and Compliance with Legislation	11
II.2	Correctness, professionalism, efficiency	11
II.3	Spirit of service	12
II.4	Transparency	12
II.5	Impartiality	13
II.6	Integrity	13
II.7	Conflict of interest	13
II.8	Rejection of bribery in Italy and abroad	14
II.9	Anti-Money Laundering	15
II.10	Rejection of criminal organizations	15
II.11	Rejection of any form of terrorism	15
II.12	Workplace and worker safety	16
II.13	Protection of the environment	16
II.14	Correct use of computer systems	16
II.15	Protection of Industrial and Intellectual Property Rights	16
II.16	Confidentiality of Information	17
II.17	Data Protection and Relationship with the Authority for Personal Data Protection	17
III.	Ethical Principles in Relations with Employees and Collaborators	18
III.1	Value of Human Resources	18
III.2	Value of Training and Fairness in personnel selection	18
III.3	Protection of the Individual	19
III.4	Respect for Laws on Validity of Employee Residence Permits	19
III.5	Diligent and Efficient Use of Company Assets	19
III.6	Safeguarding of Corporate Image and Reputation	19
IV.	Ethical Principles in Relations with Patients	20
V.	Ethical principles in relations with shareholders, the market and competitors	20
V.1	Protection in relations with shareholders and the market	20
V.2	Corporate information and “price sensitive” information	21

V.3	Protection of Share Capital and Creditors	21
V.4	Accounting and fiscal control and transparency	22
V.5	Protection of transparency in financial and commercial transactions	23
V.6	Protection of relations with competitors	23
VI.	Ethical Principles in Relations with Public Institutions and Regulatory Authorities	24
VI.1	The Authorities and Public Institutions	24
VI.2	Political and trade union organisations and the promotion of non-profit activities	25
VII.	Ethical Principles in relations with customers, suppliers and consultants	25
VII.1	Customer Impartiality	25
VII.2	Correctness of Information and Communication with Customers	25
VII.3	Quality and Safety of Services Performed	26
VII.4	Correctness in Relations with Contracted Organizations	26
VII.5	Responsibilities with suppliers and consultants	26
VII.6	Criteria for Selection and Qualification of Suppliers and Consultants	26
VIII.	Rules of Conduct	27
VIII.1	Principles and rules of conduct for members of the Corporate Bodies	27
VIII.1.a)	Protection of Share Capital and Creditors	28
VIII.2	Principles and rules of conduct for Personnel	29
VIII.2.a)	Conflict of interest	31
VIII.2.b)	Relations with public authorities in the fight against corruption	31
VIII.2.c)	Relations with private individuals in the fight against corruption	33
VIII.2.d)	Relations with Suppliers and Consultants	34
VIII.2.e)	Relations with Customers	35
VIII.2.f)	Direct Scientific Information	35
VIII.2.g)	Congress Events, Visits to Company Laboratories, Professional development Courses and Investigator Meetings	38
VIII.2.h)	Relations of the Industry with the Scientific and Healthcare Communities and Patient Associations	46
VIII.2.i)	Participation in tenders	51
VIII.2.j)	Obligation to keep updated	51
VIII.2.k)	Confidentiality	51
VIII.2.l)	Diligence in using the Company's Assets	52
VIII.2.m)	Respect for Laws on Illegal Immigration	52
VIII.2.n)	Protection of Share Capital and Creditors	53
VIII.2.o)	Diligence for tax purposes	54

VIII.2.p)	Fighting money laundering, self-laundering and the handling of stolen goods	54
VIII.2.q)	Use of IT systems	55
VIII.2.r)	Protection of Industrial and Intellectual Property Rights	56
VIII.2.s)	Data Protection and Relations with the Personal Data Protection Authority	56
VIII.2.t)	Protection of health and safety in the workplace	56
VIII.2.u)	Protection of the environment	59
VIII.3	Rules of Conduct for Third-Party Recipients	59
IX.	Transparency in the Transferring of Value Among Pharmaceutical Industries, Healthcare Professionals and Healthcare Organizations	60
IX.1	Obligation of transparency	60
IX.2	Publication of Data on an Individual and Aggregate Basis	60
IX.3	Research and Development Expenses	61
X.	Internal control	62
XI.	Implementation and monitoring of observance of the Code of Ethics	62
XI.1	Dissemination and training on the Code of Ethics	62
XI.2	Duties of the Supervisory Board	63
XI.3	Infringements of the Code of Ethics and Relative Sanctions	63
XI.4	Reporting Possible Infringements of the Code of Ethics	64
XI.5	Policy of Non-Retaliation	65

## I. Introduction

MALESCI Istituto Farmacobiologico S.p.A. (hereinafter also “**MALESCI S.p.A.**”, the “**Company**” or simply “**MALESCI**”) is an Italian company which markets pharmaceuticals. Specifically, the Company markets drugs for the treatment of acid-related, cardiovascular and respiratory diseases.

Since 1978, the Company has been part of the MENARINI industrial group (“Menarini Group”), an international organisation operating mainly in the pharmaceutical and diagnostic sectors and which, due to its size, structure, and the particular importance of the sectors in which it operates, holds a position of social importance for the wider community.

Currently with over three billion Euro consolidated turnover and over seventeen thousand employees, the MENARINI Group and its products are present in more than 100 countries worldwide, with five of its researchers among the most renowned in the world. MENARINI research concentrates on currently unresolved pathologies in the fields of oncology, cardiovascular disease and pain/inflammation/asthma, with a particular focus on rare diseases. The wide range of interests and socio-economic contexts in which the Company is involved, together with Group's organisational approaches, requires the efforts of all involved to guarantee that the Company's business is carried out in compliance with the law and is characterised by fair competition, honesty, integrity, correctness and trust, in the primary safeguarding of patients' right to healthcare and with respect for the legitimate interests of clients, employees, commercial partners and wider society in areas where the Company operates.

The Code of Ethics adopted by MALESCI gathers, defines, and explains all the values, general principles and rules of conduct that must govern the company's activities, which the Company itself recognizes as having a positive ethical value and with which all those who operate within the Group's business context must comply, according to the canons of integrity, loyalty, and fairness. Indeed, the Company intends to base its conduct on integrity, a value that is not only of moral value, but is of fundamental importance in order to guarantee the continuity of the Company's action in compliance with the provisions of Legislative Decree 231/01.

Respect for company ethics is essential for the development of the company organization and of the relations between Personnel and those who collaborate with the Company in various ways, as well as between the Personnel and the general public. It contributes, therefore, to the effectiveness of the policies and control systems set up by the Company and influences and directs any behaviour that may escape the control systems.

The achievement of this goal, of course, requires absolute respect for the laws, regulations, and ethics in force in Italy and in the countries where the Company operates, in order to safeguard and protect the legitimate interests of all stakeholders: customers, the Sole Shareholder, citizens, employees, healthcare professionals, suppliers, business partners, etc.

The observance of this Code of Ethics is therefore of fundamental importance for the efficient operation, reliability and reputation of MALESCI towards the State, the public opinion, the medical profession and health operators in general. The observance of the Code of Ethics is instrumental in combating any illegal or improper conduct that could expose the Company to the risk of sanctions.

This Code of Ethics represents the revised and expanded version of the Code of Ethics already in force (and most recently updated in 2018). The same constitutes an integral part of the Model adopted by the Company.

This Code of Ethics has been drawn up in accordance with the principles indicated in the Confindustria Guidelines (in which Farmindustria - MENARINI IFR's reference association - participates), issued in March 2002, partially amended, and updated several times, most recently in March 2014.

It should also be noted that, in March 2009, Farmindustria issued the "Document for the identification of Guidelines for the construction of organization, management and control models pursuant to Legislative Decree no. 231/01 in the pharmaceutical sector", as well as the "Reference document for the certification of procedures relating to scientific information activities", also published by Farmindustria (the last of which was published by Farmindustria).

The Code of Ethics of FARMINDUSTRIA, an association of which MALESCI is also a member, is of fundamental importance in the context of the indications coming from the Trade Associations.

In particular, it codifies the ethical principles and the behavioural norms that must inform the relationships between the pharmaceutical industries, as well as between the latter and the scientific and health world.

By virtue of this, this Code of Ethics has been conceived in full compliance with the principles indicated in the Code of Ethics of FARMINDUSTRIA in the latest version approved on November 20, 2020.

#### **I.1 The Menarini Group's Global Code of Conduct and the Group's self-regulatory instruments incorporated in this Code of Ethics.**

This Code of Ethics incorporates all the instruments of corporate self-regulation aimed at protecting business ethics and combating any unlawful conduct which may find expression in the business operations of the Menarini Group.

These instruments, listed below and briefly described, are available for consultation also online at the following link: <https://sites.google.com/menarini.com/business-ethics-and-compliance/home>.

##### ***a) Menarini's Global Code of Conduct***

Like all the companies of the MENARINI Group, the actions and corporate organisation of MALESCI are also subject to the Group's Code of Conduct ("Menarini Global Code of Conduct"), a document which sets out the

values that inspire MENARINI's work worldwide.

The Group's Code of Conduct must guide the conduct of all the Directors, Managers, Employees and Third-Party Recipients in Italy and abroad; the document - which can be consulted in full - is divided into a series of provisions designed to protect the:

- integrity in the conduct of business;
- protection of Employees;
- protection of patients;
- integrity in managing information and protecting corporate assets;
- responsibility towards the public and the community.

In particular, many of the provisions of the Code of Conduct are designed to counter corruption in all its forms and meanings and fully meet the requirements of compliance with the most important international legislation on the subject (UK Bribery Act - FCPA).

It should be noted that the principles summarized above are fully implemented in some of the rules of conduct formalized in section VIII below.

#### ***b) Global Policies***

Like all the Companies of the Menarini Group, the actions and corporate organisation of MALESCI are also subject to compliance with the Global Policies.

Indeed, the Global Policies adopted by MENARINI IFR (hereinafter also the "Parent Company") incorporate the values, principles and rules of conduct that inspire MALESCI and the Group, as set out in the Menarini Global Code of Conduct and in this Code of Ethics, and define the guidelines to be followed in the pursuit and performance of business activities.

In view of the importance and relevance of the topics dealt with in relation to the areas and activities potentially at risk of committing offences pursuant to Legislative Decree 231/01, some of the Global Policies considered to be of particular interest are mentioned here, namely:

- *Global Anti Bribery Policy;*
- *Global Third Party Due Diligence Policy;*
- *Corporate Compliance Training Policy;*
- *Global Whistleblowing Policy;*

- *Conflict of interest Policy.*

In this regard, compliance with the Global Policies is mandatory for all employees of all MENARINI Group companies and for third parties with whom the Companies form contracts in Italy and abroad.

***c) Menarini Global Anticorruption Compliance Program (“GACP”)***

MENARINI IFR has also implemented a specific “Global Anticorruption Compliance Program” - (“GACP”) - common to all Group companies and again compliant with the most important national and international legislation on anticorruption (in addition to Italian Legislative Decree 231/2001, the UK Bribery Act and the FCPA).

The GACP establishes a series of internal rules regarding various activities which could be subject to corruption.

These internal rules outline the main elements which must characterise the Anticorruption Compliance Programmes of the Group companies, guaranteeing that they act with integrity, in line with the provisions of the GACP. These rules are expressly referred to in the values, principles, and rules of conduct of this Code of Ethics.

***d) Corporate Ethics & Integrity Policies***

Moreover, the Company acts in compliance with the Corporate Ethics & Integrity Policies, which set out the ethical standards and conduct requirements for the main activities carried out regarding ethical drugs. These Policies regard the following activities:

- Promotional Activities;
- Events;
- Hospitality;
- Samples;
- Gifts;
- Field Force Variable Salary;
- Disease Awareness Campaigns;
- Patient Support Programs;
- Fee for Service Arrangements;
- Market Research;
- Patient Access/Market Access;
- Patients Organizations;
- Grants & Donations;



- Responsible Communication.

The observance of such Policies is mandatory for all the Menarini Group Companies' employees and for the third parties with which the Companies form contracts in Italy and Abroad.

The values, principles and rules of conduct formalized in the **Menarini Global Code of Conduct**, in the **Global Policies**, in the **GACP** and in the **Corporate Ethics & Integrity Policies** are an integral part of this Code of Ethics and, overall, of the Model. Moreover, in view of the international scope of the Company's activities, these regulatory provisions must also be scrupulously observed by all Recipients.

Failure to comply with these provisions constitutes, therefore, a violation of the Model such as to expose the subjects held responsible for the non-compliant conduct to all the sanctions provided for in the Disciplinary System, in compliance with the principles provided for therein.

## **I.2 Recipients of the Code of Ethics**

Given that the main purpose of the Code of Ethics is to guide and direct the Company's activities in compliance with ethical principles, it is binding in respect of all Directors, Statutory Auditors, the Independent Auditor, and all employees, including executives and non-executives (hereinafter referred to as the "**Personnel**", "**Recipients**" or individually the "**Recipient**"), as well as being binding on those who, while not employees of the Company, operate directly or indirectly on its behalf, e.g. agents, collaborators in any capacity, consultants, suppliers, business partners, companies to which activities are outsourced, the Company Doctor (hereinafter referred to as "**Third-Party Recipients**").

Members of the Supervisory Board are also bound by the Code of Ethics within the context of performing their institutional roles.

All Recipients are obliged to observe and, insofar as they are competent, ensure the observance of the principles contained in the Code of Ethics, which is binding and applicable also to the activities carried out by the Company abroad.

The company's management is obliged to observe the content of the Code of Ethics when proposing and implementing projects, actions and investments aimed at increasing the long-term economic value of the business, including the well-being of its employees, customers, suppliers, and the Community.

It is the responsibility of everyone, but first and foremost the directors and managers, to promote the values, principles and rules of conduct contained in the Code, taking responsibility internally and externally and strengthening trust and cohesion in the Company.

Every employee of the Company must undertake to comply with the legislation and regulations applicable in all the countries where the Company operates. Employees must be aware of the laws and conduct required

to comply with these. Every employee is obliged to actively contribute to implementing the Code of Ethics. Under no circumstances can the claim of acting in the Company's interest justify adopting behaviour that is contrary to the conduct set out in this document or in the procedures governing the corporate activities.

The Code of Ethics should also inspire the activities conducted by the Company abroad, while duly respecting the differences that exist on a regulatory, social, and economic level.

Compliance with the rules of the Code shall be considered an integral part of the contractual obligations of the Company's employees pursuant to and for the purposes of the provisions of Articles 2104 et seq. of the Civil Code.

Violation of the rules of this Code, considered particularly serious, will also damage the relationship of trust established with the Company and may lead to disciplinary action and compensation for damages, without prejudice to the employees' compliance with the procedures set out in Article 7 of the Workers' Statute, in the collective labour agreements and any company regulations adopted.

### **I.3 Structure of the Code of Ethics**

The body of the Code of Ethics is divided as follows:

- a) the introductory part just summarized, within which the Recipients are also indicated;
- b) the general ethical principles, i.e. the values to which MALESCI gives prominence in its business activities and which must be respected by all Recipients;
- c) the principles and rules of conduct dictated with regard to each category of Recipient;
- d) the obligations of transparency of transfers of value between the Company, healthcare professionals and healthcare organizations;
- e) the methods of implementation and control of compliance with the Code of Ethics by the Supervisory Body.

The Code of Ethics is subject to ongoing amendments, supplements and implementations. The Board of Directors is the body responsible for making these amendments, which are introduced on the basis of specific Board resolutions, which are also adopted on the basis of potential suggestions and recommendations from the SB.

## **II. General Principles**

The reference ethical principles for all Recipients are defined below.

It is worth remembering that under no circumstances can the conviction of acting in the interest of MALESCI justify adopting behaviour that is contrary to the principles in this Code of Ethics, which should be ascribed primary and absolute value.

### **II.1 Responsibility and Compliance with Legislation**

MALESCI undertakes to comply with legislation, regulations and in general with the rules applicable in Italy and in all the countries it has links with.

It undertakes further to comply with the rules and principles of ethics and professional conduct set by sector associations and more specifically, those defined in the FARMINDUSTRIA Code of Conduct, carefully adopted with this Code of Ethics.

The Directors, Statutory Auditors, Independent Auditors and Personnel of MALESCI, as well as Third-Party Recipients, are obliged to comply with the laws applicable both in Italy and in other countries with which the Company has operational connections.

Under no circumstances may laws or professional standards be violated in order to pursue or achieve the interests of the Company. This applies both in relation to activities carried out within Italian territory, and in relation to any activities which may be associated with dealings with international operators.

### **II.2 Correctness, professionalism, efficiency**

MALESCI's Directors, Statutory Auditors, Independent Auditors and Personnel, in compliance with the regulations in force and the procedures established by the Company, must carry out their services with diligence, correctness and efficiency, making the most of their professionalism and assuming the responsibilities related to the duties incumbent upon them.

The pursuit of corporate profits is secondary to the principle of correctness. No Recipient shall accept or instigate on their own behalf or for others, or consequent to other pressure, any recommendations or indications that could prejudice the company or procure undue advantage for themselves, the Company or third parties; all Recipients must reject and shall not make undue promises and/or offers of money or other benefits, unless for commercial purposes, of modest value and not associated with demands of any kind. Should Recipients receive an offer or a request for benefits from a third party, except for commercial gifts

with a modest value, they must not accept the offer, nor abide by the request, and immediately report the matter to the SB, or send an appropriate report to the Company through the communication channels set up by the latter (indicated in section XI.4) for the appropriate initiatives.

Professionalism, dedication, loyalty, spirit of collaboration and mutual respect are required of each Recipient of this Code. The efficiency of the management that MALESCI pursues is achieved through the professional and organizational contribution that each of the human resources involved ensures in compliance with the principles of professionalism, transparency, fairness, and honesty.

The efficiency of the management is also pursued in the constant respect of the highest quality standards, pursued, if necessary, even to the detriment of the same management economy.

MALESCI under a different profile, also commits itself to:

- safeguarding and protecting the company's resources and assets, as well as managing its own assets and capital, adopting all the precautions necessary to ensure full compliance with current laws and regulations;
- ensuring an ongoing dialogue with the other companies of the Group while respecting their autonomy.

### **II.3 Spirit of service**

The Directors, Auditors, External Auditor, Personnel, as well as Third Party Recipients, must orient their conduct, within the limits of their respective competences and responsibilities, towards the pursuit of the main corporate objectives aimed at providing a service of high social value and usefulness to the community, which must be able to count on and benefit from the best quality standards.

### **II.4 Transparency**

The information disseminated both inside and outside the Company must be characterized by truthfulness, accuracy, and completeness. The constant observance of these rules of conduct enables the implementation of the principle of transparency.

Every operation and/or transaction, in the broadest sense of the term, must be legitimate, authorized, consistent, congruous, documented, recorded and verifiable over a period of ten years. More specifically, each operation and/or transaction must be adequately recorded and must allow for verification of the decision-making, authorization and implementation process. Each operation must also be accompanied by adequate documentary support in order to be able to proceed at any time with the execution of controls

that attest to the characteristics and motivations of the operation, as well as to identify the author of the authorization, execution, registration and verification of the operation.

## **II.5 Impartiality**

MALESCI condemns any form of discrimination based on sex, nationality, religion, personal and political opinions, age, health, economic conditions of its interlocutors, including third parties.

Any company or non-company resource who believes he/she has suffered discrimination has the possibility to communicate the circumstance to the competent bodies, which will proceed to verify the actual violation of the Code of Ethics, in accordance with the guarantees provided by the Model, on the subject of reporting.

## **II.6 Integrity**

MALESCI condemns and does not permit any act of violence or threat, even if only psychological, as such and when aimed at obtaining conduct contrary to the laws in force, including the ethical principles codified in this Code.

## **II.7 Conflict of interest**

MALESCI's Directors, Auditors, External Auditor, Personnel and Third-Party Recipients must avoid situations of real or potential conflict of interest, meaning those situations in which the pursuit of their own interest or that of a family member or relative is in conflict with the interests of the Company.

All Recipients of the Code of Ethics are required to report any situation of conflict of interest, even potential, to the competent bodies, in accordance with the provisions set out in the Model on reporting.

In any case, situations through which an Employee, Director or other Recipient may gain an undue advantage or profit on the basis of situations of opportunity of which he/she has become aware during the performance of his/her activity must be avoided.

The Company prohibits the appointment as its representatives of persons who are in conflict of interest or have family relationships or are closely linked in order to be able to unlawfully influence the decisions of any person belonging to the Public Administration or of politically exposed persons or their family members.

## **II.8 Rejection of bribery in Italy and abroad**

MALESCI pursues the objective of maximum integrity and correctness in its relations with public officials, persons in charge of public services and, more in general, with public institutions, in Italy and abroad.

In relations with public officials and, in any case, in relations with "politically exposed persons" or their family members and/or "persons closely connected" to them, as defined by Legislative Decree 231/2007, all Recipients must behave in a manner inspired by the utmost correctness and integrity, avoiding even just giving the impression of wanting to improperly influence decisions or request favourable treatment.

Illicit payments are prohibited in relations with Institutions or Public Officials, including their family members and persons closely connected to them. All Recipients must refrain from acknowledging or promising any form of benefit to public officials or persons in charge of a public service in order to remunerate the exercise of their public function and/or to use them for purposes unrelated to those of public importance or to remunerate the performance of acts contrary to their official duties.

All Recipients must categorically refrain from receiving or accepting the promise of any form of benefit as remuneration for any intermediation activities towards persons who may be qualified as public officials or persons in charge of a public service. All Recipients must refrain from exploiting or bragging about personal relationships with persons who may be classified as public officials or persons in charge of a public service in order to obtain any form of undue advantage.

The Company expressly prohibits corrupt practices, favouritism, collusive behaviours, direct and/or indirect solicitations, also through promises of personal advantages, towards any person who holds the position of public official or person in charge of a public service or who, in any way, can be traced back to the functions exercised by the Public Administration and/or bodies that are an expression of it, due to direct or indirect control by Public Bodies.

Acts of courtesy, such as gifts, are allowed only when they are of modest value and in any case such as not to compromise the integrity or reputation of either party and in any case such as not to be interpreted by an impartial observer as aimed at acquiring advantages in an improper manner.

These rules also apply to relations with those who, within other countries or international organisations, perform functions or activities corresponding to those of public officials or public service officers.

Relations with institutional interlocutors are maintained exclusively through the persons appointed for this purpose, also due to the role played.

The Company may use consultants, attorneys or third parties as its representatives in dealings with the Public Administration only if they are duly authorized in advance for that purpose and, in any case, limited to the performance of specific operations.

MALESCI prohibits all forms of corruption and believes that it is a fundamental and indispensable value that relationships with private individuals (suppliers, competitors, customers, consultants, business partners, etc.), between Directors and employees and between the Company's own employees are based on the utmost loyalty, integrity, fairness, and good faith.

## **II.9 Anti-Money Laundering**

MALESCI and all employees must not be implicated or involved in operations that may involve the laundering of criminal or illicit proceeds in the interest or to the advantage of the Company.

MALESCI pursues the objective of maximum transparency in commercial transactions and provides all appropriate tools to counter the phenomena of money laundering and receiving stolen goods.

Furthermore, the Company guarantees the respect of the principles of correctness, transparency and good faith in the relationships with all the contractual counterparts, even if they are part of the same Group.

## **II.10 Rejection of criminal organizations**

MALESCI repudiates any form of criminal organization (in particular mafia-type associations), whether national or transnational, and to this end undertakes not to establish any working, collaborative or commercial relationship with individuals or legal entities directly or indirectly involved in criminal organizations or, in any case, linked by ties of kinship and/or affinity with exponents of known criminal organizations, just as it does not finance or, in any case, facilitate any activity referable to such organizations. The Company adopts the measures necessary to prevent the danger of involvement - whether its own involvement or that of its

employees - in relations and activities entertained for any reason and in any way, even in the form of mere assistance and aid, with such organisations.

## **II.11 Rejection of any form of terrorism**

MALESCI repudiates any form of terrorism and undertakes to adopt - in the performance of its activities - all measures necessary to prevent the danger of the Company being involved in acts of terrorism.

To this end, the Company has set itself the objective of not establishing any relationship - neither of a working or a commercial nature - with persons involved in terrorism, whether natural or legal persons, and it also undertakes not to finance or facilitate any of their activities.

## **II.12 Workplace and worker safety**

MALESCI is fully committed to ensuring health and safety in the workplace. The Company undertakes to adopt the identification and prevention of risks related to the performance of its business activities, aiming at contrasting the risks at the source and guaranteeing their removal or, where this is not possible, their management.

To this end, MALESCI undertakes to adopt all the organizational, technical, and procedural measures to guarantee the protection of the safety and health of the workers. The Company will never seek advantages related to economic savings in terms of health and safety in the workplace.

## **II.13 Protection of the environment**

MALESCI recognizes that the protection of the environment is of fundamental importance, so that it will never look for advantages possibly related to the violation of environmental regulations or to economic savings in environmental policy.

## **II.14 Correct use of computer systems**

MALESCI has set itself the objective of correctly utilising computer and/or telecommunication services, in accordance with applicable legislation and in such a way that will guarantee the integrity and authenticity of the data processed, protecting the interests of the Company and of third parties, with specific reference to the Authorities and Public Institutions.

In this regard, the Company undertakes to adopt all the appropriate measures to ensure that access to telecommunication and computer data occurs in full compliance with applicable regulations and the privacy of the data subjects who may be involved, to guarantee the confidentiality of the information and to ensure that the processing thereof is carried out by persons specifically authorised to do so, thereby preventing undue interference.

## **II.15 Protection of Industrial and Intellectual Property Rights**

MALESCI operates in full compliance with applicable legislation on the protection of trademarks, patents, and other distinctive elements, including copyright legislation.

In particular, the Company does not permit the use of intellectual property that does not include the Italian Society of Authors and Publishers "S.I.A.E." stamp, or which bears an altered or counterfeit stamp.



Furthermore, the Company prohibits the reproduction of programmes and the contents of databases, as well as the appropriation and dissemination – in any form – of intellectual material with registered copyrights, even by revealing the relative content before it becomes public.

MALESCI does not allow for any reason or purpose, the use of products with counterfeit trademarks or other elements, nor the manufacturing, marketing or any other activity relating to products already patented by third parties and in respect of which it has no rights.

## **II.16 Confidentiality of Information**

Directors, Employees and collaborators of MALESCI must consider all information regarding company business, which they come into contact with during their relative tasks, as confidential and as exclusive knowledge of the company until publicly disclosed.

## **II.17 Data Protection and Relationship with the Authority for Personal Data Protection**

MALESCI protects the privacy of Directors, Statutory Auditors and Personnel, as well as Third-Party Recipients, in accordance with applicable regulations, in order to prevent the disclosure or dissemination of personal data without the consent of the data subject.

The acquisition, processing and storage of information and personal data of employees and other parties that the Company holds, is carried out in compliance with specific procedures aimed at guaranteeing that non-authorized persons and/or entities do not gain knowledge thereof. These procedures are systematically updated in compliance with applicable legislation.

The Company maintains its relations with the Guarantor for the Protection of Personal Data in respect of the utmost fairness, committing itself to obtain the necessary authorizations for the processing of sensitive data, as well as to comply with (any):

- prescriptions regarding the methods of data processing;
- prohibition of data processing;
- requests for information or the production of documents, any requests for access or verification, with respect to any proceedings pending with this authority.

### **III. Ethical Principles in Relations with Employees and Collaborators**

#### **III.1 Value of Human Resources**

Human resources represent the main factor underpinning corporate development. The management of human resources is based on respect for the individual and their professionalism within the general framework of current legislation.

MALESCI is aware that the high degree of professionalism of its employees and their dedication to the Company are essential and crucial aspects in the pursuit of the Company's objectives.

For this reason, the Company nurtures professional growth and development aimed at increasing the knowledge base and skills held, in accordance with applicable regulations on individual rights, with special regard to the moral and physical integrity of employees.

#### **III.2 Value of Training and Fairness in personnel selection**

MALESCI recognises the importance of training as a fundamental factor in increasing the skills of employees and the value of the business, guaranteeing the creation of opportunities for development and professional growth through coaching, training, and appropriate training tools.

The Company undertakes to ensure that in its own corporate organization the annual objectives set are such as not to induce unlawful behaviour and are instead focused on a possible result, specific, concrete, measurable and related to the time expected for its achievement.

Recognition of salary increases or other incentive tools and access to higher roles or positions are linked, in addition to the rules established by law or by the collective labour agreement, to the individual merits of employees, including, in particular, the ability to achieve company objectives with behaviour and organisational skills based on the Company's ethical principles, as set out in this Code.

MALESCI condemns any form of intercession and patronage. The selection of Personnel is done on the basis of matching up the profiles of candidates and their skills with the highest technical professionalism and utmost attention to respecting the ethical principles required by the Company.

Specifically, personnel are hired through regular employment contracts, following a strict selection process based on the curriculum vitae of each candidate. As regards employees, particular attention is paid to their competence, their human qualities, their moral integrity and their ability to comply with the principles codified in this Code. In relation to the Scientific Informants of Medicines (hereinafter I.S.F.) particular attention is paid to their technical and scientific preparation, their human qualities, their moral integrity and their ability to comply with the principles codified in this Code.

### **III.3 Protection of the Individual**

MALESCI recognises the need to protect personal liberty in all its forms and rejects any manifestation of violence, especially if aimed at limiting personal freedom. The Company undertakes to promote respect for this fundamental principle in its own activities and among its employees, collaborators, suppliers, and partners.

### **III.4 Respect for Laws on Validity of Employee Residence Permits**

MALESCI always considers the protection of employees above any economic advantage.

The company specifically undertakes to verify that third-country workers are in possession of a valid residence permit, both at the time of their employment and throughout their employment and, in the case of expiry of the permit, that they have renewed it.

In the case of temporary workers being used through recruitment agencies, it is nevertheless verified that the individuals appointed are in possession of a valid residence permit.

### **III.5 Diligent and Efficient Use of Company Assets**

Every employee of MALESCI is required to act with the diligence and efficiency necessary to safeguard and value company resources, guaranteeing they are used in the Company's best interests.

It is the responsibility of employees and collaborators not only to protect these assets but also to impede fraudulent or improper use, for their own advantage or that of third parties or Group companies.

### **III.6 Safeguarding of Corporate Image and Reputation**

The image and reputation of MALESCI represents an asset that employees and collaborators must safeguard through their behaviour in all situations, taking into consideration the evolution of the social context, of technology and of new tools available.

#### **IV. Ethical Principles in Relations with Patients**

The business activities that MALESCI is involved in, as well as its own corporate purpose mean that the Company assumes a specific responsibility towards patients, including on an ethical level.

To best implement and respect its ethical commitment towards patients, MALESCI commits and applies maximum effort in the research sector, also aimed at the development of medical, scientific, and therapeutic solutions which satisfy patients' needs as completely as possible.

In particular, MALESCI undertakes to:

- guarantee patients the marketing of highly specialised drugs which are the fruit of advanced scientific study;
- introduce drugs to the market which are exclusively aimed at protecting the physical integrity and health of patients;
- pay particular attention to safety aspects during drug evaluation;
- request that Personnel, within the scope of their skills, and experts carry out studies aimed at safeguarding the care requirements of patients, with respect for their freedom and dignity.

#### **V. Ethical principles in relations with shareholders, the market and competitors**

##### **V.1 Protection in relations with shareholders and the market**

MALESCI ensures a fair balance between the powers of management and the interests of shareholders and other stakeholders, as well as transparency and the knowledge of the market about management decisions and corporate events in general.

As part of the initiatives aimed at maximizing value for shareholders and guaranteeing the transparency of management operations, MALESCI defines, implements, and progressively adapts an articulated and homogeneous system of rules of conduct regarding both its internal organizational structure and relations with shareholders and third parties, in compliance with the most advanced standards of corporate governance in the national and international context. This is in the awareness that the ability of the company to establish efficient and effective operating rules is an essential tool for strengthening its reputation in terms of reliability and transparency and the trust of its stakeholders.

MALESCI believes it is necessary for shareholders to be able to participate in the decisions for which they are responsible and to make informed choices. The Company, therefore, undertakes to ensure the maximum

transparency and timeliness of the information communicated to the shareholders and to the Market in compliance with the regulations applicable to unlisted companies.

MALESCI also undertakes to take into due consideration the legitimate indications expressed by the shareholders in the appropriate venues.

## **V.2 Corporate information and “price sensitive” information**

MALESCI ensures the correct management of corporate information, with specific reference to "price sensitive" information. In this regard, all Company employees are required, within the scope of their assigned duties, to correctly manage any "price sensitive" information, undertaking to treat the same with the utmost confidentiality.

It is expressly forbidden for any Recipients to spread false information, or to carry out simulated transactions or other forms of artifice which are liable to provoke a significant alteration in the price of the Company's financial instruments, or those of the Group's other companies. All Recipients must also categorically refrain from seeking economic benefit for themselves or for third parties by exploiting privileged information of which they are aware for reasons relating to the office they perform in the interests of or on behalf of the Company, and from facilitating such exploitation.

## **V.3 Protection of Share Capital and Creditors**

One of the central aspects that ethically characterize MALESCI's conduct is the observance of principles of conduct aimed at guaranteeing the integrity of the share capital, the protection of creditors and third parties who establish relations with the Company, and, in general, the transparency and correctness of the Company's activities from an economic and financial point of view.

MALESCI, therefore, intends to guarantee the dissemination and observance of rules of conduct aimed at safeguarding the aforementioned values, also in order to prevent the commission of the corporate offences contemplated by Legislative Decree 231/01.

With specific reference to the drawing up of the financial statements, MALESCI considers the truthfulness, correctness and transparency of the accounts, financial statements, reports and other corporate communications required by law and addressed to shareholders or the public, an essential principle in the conducting of business and a guarantee of fair competition. This requires that the validity, accuracy, completeness of the basic information for the entries in the accounts be thoroughly investigated.

#### **V.4 Accounting and fiscal control and transparency**

All acts relating to the management of MALESCI must be correctly and truthfully represented in the accounts.

All operations performed are inspired by the following principles:

- maximum management fairness;
- completeness and transparency of information;
- legitimacy in terms of substance and form;
- clarity and truthfulness of accounting records in accordance with current regulations and internal procedures.

Accounting documentation must correspond to the above principles and must be easily traceable, as well as ordered according to logical criteria. In any case, the company payments to be made must be exclusively commensurate with the service and the methods indicated in the contract and cannot be made to a party other than the contractual counterpart.

Fiscal documentation must adhere to and be based on the accounting records; it must correspond to the above-mentioned principles and must be easily traceable, ordered and filed according to logical criteria for the entire duration provided for by the regulations in force.

The use of company funds for illegal or improper purposes is strictly prohibited. No one should be paid anything that is not based on properly authorized business transactions, or any illegal form of remuneration.

The Company requires that the inclusion of all items, such as receivables, inventories, investments, charges, in the financial statements be carried out in compliance with all applicable rules on the preparation and measurement of financial statements. The Company thus prevents the creation of false, incomplete or misleading entries and ensures that no secret or unrecorded funds are set up or deposited in personal accounts or invoices issued for non-existent transactions.

The documents certifying the accounting entries must allow for the rapid reconstruction of the accounting operation itself and the identification of any errors.

Internal company procedures regulate the performance of every operation and economic transaction, including reimbursement of expenses to employees and/or external collaborators in various capacities, and/or professionals, from which it must be possible to detect, in relation to the financial resources to be used or employed, the legitimacy, authorisation, consistency, congruity, correct registration and verifiability.

The Company may grant contributions or sponsorships to private individuals and public non-profit organisations, especially if aimed at social or cultural objectives, in compliance with accounting and tax

regulations, with procedures of absolute transparency, with specific reference to the criteria adopted and the congruity of the relative commitments.

Any form of offer or acceptance of money or other benefits aimed at altering the company's accounting and tax documents is indiscriminately prohibited.

It is against company policy and the law to carry out simulated transactions or transactions through third parties, or transactions without valid economic reasons, or transactions carried out for avoidance, abusive or evasive purposes.

The Company undertakes to supervise operations aimed at disposing of assets belonging to the Group in order to ensure that any conduct aimed at evading the payment of taxes is prevented when there is a tax liability.

#### **V.5 Protection of transparency in financial and commercial transactions**

MALESCI undertakes to ensure that all its financial relationships, including those with international operators, are conducted in full compliance with the laws and regulations in force. The Company undertakes to take all the necessary precautions to verify the reliability of such operators, as well as the legitimate origin of the capital and means used by them in their relations with the Company. Nevertheless, the Company bases its corporate management on the utmost transparency also in all commercial transactions.

#### **V.6 Protection of relations with competitors**

The free market imposes a situation of competition with the other operators present in the market that must be constantly inspired by the principles of fairness, loyal competition and transparency towards the operators present in the market. In accordance with national and EU Antitrust legislation, as well as the Guidelines and Directives issued by the Italian Antitrust Authority (“Garante della Concorrenza e del Mercato”), the Company does not put in place conduct or sign agreements which could adversely influence the competition regime between various operators in the relevant market or prejudice users or consumers in general, basing their conduct on fair trade, by preventing and condemning any form or kind of improper practices.

All employees involved in pricing, licensing, purchasing, sales, and participation in supply tenders, or dealing in some way with competitors, wholesalers, pharmacies, or associations, are directly involved in activities that are susceptible to initiating processes that could infringe Antitrust laws, if these are performed in a way that is not compliant with the provisions of the aforementioned legislation.

It goes against Company policy and legislation to put in place agreements, understanding, exchanges of information, discussions or communications with any competitor referring to prices, pricing policies, discounts, promotions, conditions of sale, markets, or production costs with the purpose of restricting or distorting free competition.

In order to prevent these phenomena at the outset, Personnel are obliged to respect the strictest confidentiality regarding the sensitive data referred to above.

The Company makes use of MENARINI IFR's dedicated Corporate Antitrust and Privacy Compliance Department, which focuses specifically on safeguarding market correctness and preventing any potential deviations from this. Similarly, any form of direct or indirect agreement is prohibited that is implemented or put in place with competitors in order to change or interfere with the course of public supply tenders, public procurement processes or other proceedings inherent to the procurement of goods or services by public administrations.

Furthermore, MALESCI undertakes not to unduly damage the image of competitor companies and their products.

## **VI. Ethical Principles in Relations with Public Institutions and Regulatory Authorities**

### **VI.1 The Authorities and Public Institutions**

MALESCI pursues the goal of the highest levels of integrity and correctness in relations with Public Institutions, the competent Authorities (Regulatory, Judicial, Administrative) and, more generally, with the Public Administration, in order to guarantee maximum clarity in the aforementioned relations.

With reference to the prohibition of any form of illicit remuneration for the benefit of representatives of the Public Administration, we expressly recall what has already been stated in the general ethical principles.

MALESCI also undertakes to adopt, in compliance with the laws in force, all appropriate measures to provide the cooperation requested by Public Institutions, the competent Authorities (Regulatory, Judicial, Administrative) and, more generally, by the Public Administration, as well as to provide them with all the information requested, in a complete, correct, adequate and timely manner.

The Company recognises the value of the judicial and administrative function: to this end, it prohibits any conduct aimed at or capable of interfering with the investigations or assessments carried out by the competent Authorities and, in particular, any conduct aimed at obstructing the search for the truth, also by inducing persons called upon by the Judicial Authority not to make statements or to make false statements.



The practice of negotiating and/or renegotiating drug prices based on untruthful data or indices is strictly prohibited. The use of untruthful data or results in order to obtain Marketing Authorisation for a drug is prohibited. Furthermore, it is also prohibited to send communications or authorisation requests based on falsified data or results to the competent Authorities.

## **VI.2 Political and trade union organisations and the promotion of non-profit activities**

MALESCI refrains from financing political parties, movements, committees and political and trade union organisations, or their representatives or candidates. It does not finance associations, nor does it sponsor events or congresses whose purpose is political propaganda.

MALESCI recognizes contributions and donations in favour of subjects with social, moral, scientific, and cultural purposes.

## **VII. Ethical Principles in relations with customers, suppliers and consultants**

### **VII.1 Customer Impartiality**

In the performance of its services, MALESCI guarantees fair treatment of customers (e.g. Pharmacists, healthcare professionals, wholesalers, healthcare bodies and institutions, Subcontracted Organizations). In line with the principles of impartiality and equal opportunities, the Company undertakes not to discriminate arbitrarily between clients, and to provide products and services of high quality which meet the reasonable expectations of clients and safeguard health and safety.

MALESCI works to offer services of the highest level in all its business areas, adapting to different local factors and legislation issued by Regulatory Bodies.

### **VII.2 Correctness of Information and Communication with Customers**

MALESCI undertakes to provide full and comprehensive information to customers regarding the characteristics, functions, costs, and risks of its services.

Specifically, communications, contracts, documents, and any other information issued must be:

- clear and simple, using clear language;
- complete and accurate, without omission of any element which is relevant to decision making;
- in full observance of data-protection provisions.

### **VII.3 Quality and Safety of Services Performed**

Quality is considered a fundamental, uncompromisable value for the success of the Company.

The Company's activities must therefore be aimed at guaranteeing service continuity and regularity, uniformity in the treatment of all users, improvement in the efficiency of services performed and the highest quality of raw materials used.

MALESCI has the goal of introducing at all levels of the organisation any innovation that is "useful and possible": technological, organisational, management and process based.

### **VII.4 Correctness in Relations with Contracted Organizations**

The activities that MALESCI is involved in, as well as its own corporate purpose mean that the Company assumes a specific responsibility towards public-sector clients, including on an ethical level.

To most effectively implement and respect its ethical commitment regarding public-sector clients, MALESCI undertakes and effectively guarantees to:

- employ the highest levels of correctness in participation in public tenders;
- avoid any conduct which may compromise the correct performance of tender procedures.

It is completely prohibited to pass on money, gifts, or other forms of benefits. Please see that already defined in the general ethical principles.

### **VII.5 Responsibilities with suppliers and consultants**

MALESCI sets up relationships with suppliers with the goal not only of a competitive service, but also of ensuring equal opportunities, correctness, impartiality, and fairness.

The Company sets up relationships with consultants with the goal of quality of service, absence of incompatibility, absence of conflicts of interest, and respect for the law, this Code of Ethics and that of Confindustria.

MALESCI undertakes to build relationships with suppliers and consultants that are cooperative and based on communication aimed at sharing knowledge and information.

### **VII.6 Criteria for Selection and Qualification of Suppliers and Consultants**

The criteria for selection of suppliers and consultants are also based on an evaluation of quality levels, their technical and professional suitability and their reliability and respect for ethics.

During the selection process, no undue pressure will be accepted aimed at favouring one supplier or consultant rather than another and such as to undermine the credibility and trust that the marketplaces in the Company regarding transparency and rigorous application of the Law and corporate procedures.

## **VIII. Rules of Conduct**

### **VIII.1 Principles and rules of conduct for members of the Corporate Bodies**

The Corporate Bodies of MALESCI S.p.A., aware of their responsibilities, as well as in compliance with all legal provisions, abstractly applicable to the company's activities, with the regulations in force and with the Articles of Association, are required to comply with the provisions of this Code of Ethics, informing their activities aimed at the growth of the Company and the pursuit of profit with the values of honesty, integrity, loyalty, fairness, respect for people and rules, as well as cooperation with the other top management of the Structure.

The Board of Directors shall conduct the Company's business in pursuit of the primary objectives of protecting the health of patients, treating their diseases as effectively and safely as possible — also by providing highly specialised services — respecting their dignity, as well as their freedom of self-determination and consent in undergoing any therapeutic prophylaxis, by offering state-of-the-art drugs of guaranteed reliability and top quality; these objectives, to which the pursuit of corporate profit must be subordinate, are implemented with the help of technically trained personnel who are constantly striving to respect ethical values, as set out in this Code.

In any case, it is the precise task of all the Corporate Bodies to promote the image and prestige of MALESCI, in full respect and having as reference points the above-mentioned objectives.

The members of the Corporate Bodies and, in particular, the Directors, in view of the sensitivity and centrality of their role, are required to:

- behave autonomously, independently and fairly towards public institutions in general, Regulatory and Control Authorities, private parties, economic associations, political parties, as well as any other national and international operator;
- behave with integrity, loyalty and a sense of responsibility towards the Company;
- ensure assiduous and informed participation in its meetings and activities;
- ensure the sharing of the company mission and the exercise of a critical spirit, in order to guarantee a significant personal contribution in the awareness of the role played;
- assess situations of conflict of interest - personal, as well as of family members and relatives - or of incompatibility of functions, assignments or positions outside and inside the Company, refraining from performing actions in situations of conflict of interest within the scope of one's activity;
- make confidential use of the information they become aware of for official reasons, avoiding taking

advantage of their position to obtain personal benefits, whether direct or indirect. All external communication activities must comply with the law and conduct practices and must be suitable for safeguarding sensitive and trade secret information;

- comply, within the limits of their responsibilities, with the rules of conduct dictated for MALESCI Personnel as set out in the following section.

It is expressly prohibited for Directors, directly or via intermediaries, to offer, promise or give money or other benefits to employees of the Company inducing them to breach the obligations of their role (e.g. falsification of company accounts).

Furthermore, it is prohibited, directly or via an intermediary, to solicit or receive money or other benefits for the performance or omission of an act in breach of their loyalty obligations.

#### ***VIII.1.a) Protection of Share Capital and Creditors***

The Corporate Bodies of MALESCI are required to:

- maintain a correct, transparent and collaborative conduct, in compliance with the law and internal company procedures, in all activities aimed at drawing up the financial statements and other corporate communications required by law and addressed to shareholders or the public, in order to provide true and correct information on the Company's economic, equity and financial situation;
- strictly observe the rules laid down by law to protect the integrity and effectiveness of the share capital (e.g.: mergers, demergers, acquisitions of companies, distribution of profits and reserves, etc.) and always act in compliance with internal company procedures, which are based on such rules, in order not to damage the guarantees of creditors and third parties in general;
- conduct any liquidation operations of the Company with regard to the overriding interest of the Company's creditors; it is therefore forbidden to divert the Company's assets from their destination to creditors, distributing them to shareholders before paying the creditors entitled to them, or setting aside the sums necessary to satisfy them.

Furthermore, MALESCI ensures the regular operation of its corporate bodies, guaranteeing and facilitating all forms of control over the management of the company as provided for by the law, as well as the free and correct formation of the will of the shareholders' meeting; the strict observance of the internal procedures prepared for this purpose by the Company and/or, in any case, the adoption of behaviour consistent with this principle is therefore required.

More specifically, with reference to the formation of the financial statements, MALESCI considers the truthfulness, correctness and transparency of the accounts, financial statements, reports and other corporate communications required by law and addressed to shareholders or the public, an essential principle in the

conduct of business and a guarantee of fair competition. This requires that the validity, accuracy, completeness of the basic information for the entries in the accounts be thoroughly investigated.

Consequently, no concealment of information or partial or misleading representation of economic, equity and financial data by management and persons subject to their direction and control is permitted.

Adequate supporting documentation of the activities carried out is, however, kept for each operation:

- the easy recording of accounts;
- the identification of the different levels of responsibility;
- the accurate reconstruction of the operation also to reduce the probability of interpretative errors.

Any negligence, omission, or falsification of which the corporate bodies become aware must be promptly reported to the SB.

## **VIII.2 Principles and rules of conduct for Personnel**

Personnel must adapt their conduct, both in internal and external relations, to applicable legislation, the FARMINDUSTRIA Code of Conduct, and the principles expressed in this Code of Ethics, as well as the rules of conduct indicated below, under the terms of the Model and applicable corporate procedures.

Specifically, Company Management is required to:

- conduct themselves based on integrity, loyalty and a sense of responsibility towards the Company;
- provide an example to their employees with their own behaviour;
- be aware of and scrupulously comply with legislative, regulatory and other provisions issued in the pharmaceutical and health sector;
- comply with the legislation referring to correct and transparent company management;
- ensure compliance with the Code of Ethics among employees;
- work in such a way that employees are always mindful of the principles in the Code of Ethics and aware that their compliance forms an integral part of rendering their services.

It is expressly prohibited that the Management, directly or via an intermediary, offers, promises, or gives money or any other benefit to those below them in the organisational hierarchy to induce them to carry out or omit an act in breach of the obligations of their role and in violation of the loyalty obligations of the Company.

Management may legitimately express positions contrary to those of the Corporate Bodies, provided that this is exclusively motivated by the need to improve the quality of the services provided. Information received

for Company-related purposes is deemed confidential, and any use of this unrelated to the fulfilment of corporate responsibilities is prohibited.

The Medical Scientific Department is also responsible for the following:

- the preparation of directives regarding employees, aimed at achieving its sector goals with ongoing attention to prioritising scientific aspects over promotional ones, and with particular reference to the correct disclosure of scientific and medical knowledge regarding the Company's drugs;
- ongoing adequate communication regarding applicable health laws and the directives, protocols and other provisions issued by FARMINDUSTRIA, EFPIA and IFPMA;
- ongoing verification regarding the training of medical personnel that work for the Company;
- ongoing verification of respect for the requirements of safeguarding patient-health;
- avoidance of any form of influence, interference or conditioning in the context of the planning and/or definition of content for the issue of CME (Continuing Medical Education) training in the health sector which may be sponsored by the Company;
- avoidance of any form of influence, interference or conditioning in the definition of content for technical scientific publications which may be used by the Company in the context of scientific/pharmaceutical information activities;
- verification that publication of medicinal products marketed by the Company respects legislative, regulatory and code-of-conduct provisions in this regard.

With specific reference to compliance and the effective implementation of Code of Ethics, the Personnel as a whole, are required to:

- abstain from conduct that is contrary to the roles stipulated in the Code of Ethics;
- avoid putting in place, initiating or participating in conduct that would constitute a crime as per the Decree;
- provide assistance to the Supervisory Board during audits and the monitoring it conducts, supplying the data and information requested;
- provide the reports to the SB as prescribed in this Code of Ethics;
- report any malfunctions or violations of the Code of Ethics to the SB, in compliance with the provisions under this Code.

Each Company employee is in any case responsible for acquiring knowledge of the laws and regulations that relate to his or her tasks, so as to recognise potential risks and, in such an event, to ask for support from the competent Company departments.

Personnel may at any time ask the Supervisory Board for clarification, either in writing or verbally, on the correct interpretation of the Code of Ethics or other protocols on the legitimacy of concrete behaviour or

conduct, and more generally on the compliance of certain behaviour with the Code of Ethics.

Personnel are in any case obliged to comply with the principles and rules of conduct set out below.

**VIII.2.a) Conflict of interest**

The Personnel shall avoid carrying out or facilitating operations in conflict of interest - actual or potential - with the Company, as well as any activity that may interfere with the ability to impartially take decisions in the interest of the Company, in compliance with the provisions of this Code.

The Personnel is obliged to inform the competent Bodies, in compliance with the provisions set out in the Model, of the presence of any interest, even if potential, of their own or of third parties, in the context of an operation in which they are involved. Such communications shall be precise and shall specify the nature, terms and origin of the advantage. Pending the decisions of the Company on this point, the persons concerned shall refrain from carrying out any operation.

**VIII.2.b) Relations with public authorities in the fight against corruption**

All relations with persons who can be qualified as public officials, politically exposed persons, their family members and in any case persons closely and notoriously connected to them, persons in charge of a public service, as well as any person belonging to the Public Administration shall be conducted in full compliance with the laws and regulations in force, as well as with this Code of Ethics, in order to ensure the absolute legitimacy of the Company's operations.

Relations with Public Institutions are reserved exclusively to the functions and responsibilities assigned to them by virtue of specific delegated or proxy powers.

MALESCI S.p.A. prohibits the Personnel from accepting, offering or promising, even indirectly, money, gifts, goods, services or favours (including in terms of employment opportunities or through activities - including commercial activities - directly or indirectly traceable to the employee) in relation to relations with public officials, public service officers, "politically exposed persons", their family members and in any case with persons closely and notoriously connected to them, aimed at influencing their decisions, with a view to more favourable treatment or undue benefits or for any other purpose.

Any conduct aimed in any way at promising or giving to a public official or a person in charge of a public service, to politically exposed persons, to their family members and, in any case, to persons closely and notoriously connected to them, money or other benefits in an attempt to induce them to perform an act of their office to obtain an advantage for themselves or for the Company is prohibited.

In particular, the following conduct is expressly prohibited:

- pay, offer, or promise, directly or indirectly, payments and material benefits of any entity to public officials or persons in charge of a public service, to politically exposed persons, to their family members and, in any case, to persons closely and notoriously connected to them, in order to compensate them for the exercise of their public functions and/or remunerate them for the omission of an act of their office or for acting contrary to their institutional duties;
- collect and then fulfil requests for money, favours, benefits from individuals or legal entities that intend to enter business relations with the Company, as well as from any person belonging to the Public Administration, from politically exposed persons, from their family members and, in any case, from persons closely and notoriously connected to them.

Any requests or offers of money, gifts (except for those of a modest value, intended as being customary, and interpreted as such by an impartial observer), any kind of favours, made or received by Personnel must be promptly brought to the attention of their immediate superior and the Supervisory Board.

Gifts and courtesies with respect to public officials or public officers are allowed only when of modest value and such that they do not in any way compromise the integrity and independence of the parties and cannot be interpreted as a tool to gain an unfair advantage.

In relations with the Public Administration and/or bodies directly or indirectly controlled by the Public Administration, employees or departments that by virtue of the duties they perform or the powers assigned to them, put in place requests, manage and/or administer grants, subsidies, loans, reimbursements from the State or other Public Bodies, are obliged to exercise their powers solely for the purposes for which they were conferred, to make use of other departments required in terms of company procedures, and to maintain accurate records of each transaction in order to ensure maximum transparency and clarity in the agreements and related movements of money.

In any case, during negotiations or in any other relationship with public administration, Personnel must abstain from directly or indirectly engaging in actions aimed at:

- offering employment and/or business opportunities to P.A. employees or their family members or kin, which would provide benefits for themselves or others;
- soliciting or obtaining confidential information that could compromise the integrity or reputation of both parties.

The Personnel is obliged to provide the necessary cooperation in the case of investigations, inspections or demands from Public Authorities.

Without prejudice to all the obligations in terms of applicable regulations, Personnel shall abstain during business negotiations, requests or trade relations with Institutions, public officials, with politically exposed



persons, their family members and persons closely linked and known to be linked with them, from undertaking any of the following actions:

- considering or proposing employment or business opportunities that could benefit employees of institutions or public officials on a personal level;
- offering or otherwise providing, accepting or encouraging gifts, favours or business practices or conduct that is not characterised by the fullest transparency, correctness and loyalty and that in any case does not comply with applicable regulations;
- soliciting or obtaining confidential information that could compromise the integrity or the reputation of the parties or that violates procedures open to public scrutiny that apply when entering into relations with the Public Administration.

**VIII.2.c) *Relations with private individuals in the fight against corruption***

It is prohibited for Personnel to solicit, accept promise of or receive, directly or via an intermediary, money or other undue benefits, of any type, from private individuals (e.g., Suppliers, customers, agencies, commercial partners, and consultants, but also Directors, or other Company employees, such as superiors, etc.) to perform or omit an action of their office, in violation of their professional obligations or those of general loyalty. This is an absolute rule, and it regards advantages of any nature whether they benefit the Company and/or the individual and/or third parties. It is also prohibited the mere agreement regardless of whether the act in breach of official duties is actually omitted or performed.

Similarly, it is prohibited for Personnel, directly or via an intermediary, to offer, promise or pass on money or any other undue benefit, whether economic or of any other nature, to private individuals (e.g. Suppliers, customers, agents, commercial partners and consultants, but also other Company employees such as those lower in the organisational hierarchy, etc.) to induce them to carry out or omit an action in breach of their role. This is an absolute rule, and it regards advantages of any nature whether they benefit the Company and/or the individual and/or third parties.

In particular, in relations between private individuals and in relations between employees, it is forbidden to:

- soliciting or receiving, directly or through an intermediary, an undue advantage of any kind, or accepting 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 office or of loyalty obligations in general;
- promising, offering or granting, 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 can perform or omit an act in breach of their duties.

It is acceptable to donate/accept gifts with a modest value, provided this complies with corporate procedures, and when it is not done with the intention of influencing the recipient.

#### **VIII.2.d)        *Relations with Suppliers and Consultants***

In their relations with suppliers and consultants, Personnel must behave with the highest level of correctness and transparency in compliance with applicable legislation and regulations, the Model and this Code of Ethics, as well as internal procedures, with specific reference to those regarding procurement and selection of suppliers.

In particular, with regard to tenders, procurement and supplies of goods or services in general, Personnel must:

- respect the internal procedures regarding the selection and management of relations with suppliers and consultants;
- not preclude any supplier that has the necessary prerequisites from the possibility of bidding to supply the Company, adopting objective evaluation criteria during the selection based on clearly stated and transparent procedures;
- secure suppliers' cooperation in constantly ensuring that the Company's customer needs are met in terms of quality, cost and delivery times;
- as far as possible and in accordance with applicable legislation, use products and services supplied by companies in the Group at competitive rates;
- comply and ensure compliance with the contractual conditions;
- maintain open dialogue with suppliers and consultants;
- report any problems arising with suppliers and consultants to their immediate superiors.

Recipients, and in general anyone procuring goods and/or services on behalf of the Company, including external consultants, must act in accordance with the principles of correctness, affordability, quality and legality, operating with the appropriate due diligence.

In order to guarantee compliance with these ethical principles, the criteria for selecting suppliers and consultants are objective and transparent. In accordance with applicable legislation and procedures adopted, this selection is based on objective evaluations regarding professional respect for ethics, economic and financial reliability, competitiveness, the quality of the services provided and/or services offered, and the economic conditions applied.

The supplier will also be selected on the basis of their capacity to guarantee observance of this Code of Ethics; the implementation of appropriate corporate quality systems; and the availability of suitable organisational means and structures.

Personnel must guarantee observance of corporate procedures regarding selection of consultants and suppliers, governance of relations with consultants through specific written contracts, purchase of supplies via purchase orders and the general traceability and documentation of such corporate processes.

#### **VIII.2.e)            *Relations with Customers***

The Personnel must base their relations with customers (e.g., pharmacists, health operators, wholesalers, health bodies and institutions) and suppliers on the utmost correctness and transparency in compliance with the laws and regulations in force, as well as with this Code of Ethics.

Specifically, in relations with customers, employees must:

- respect the internal procedures regarding the management of relations with customers;
- provide accurate and comprehensive information on products and services, to allow customers to make informed decisions;
- be truthful in advertising and other forms of communication.

#### **VIII.2.f)            *Direct Scientific Information***

##### **(a)            *General principles***

Personnel must observe applicable legislation and specifically the provisions contained in Italian Legislative Decree no. 219/2006, the FARMINDUSTRIA Code of Conduct and Guidelines relative to scientific information activities, and the applicable corporate procedures, with particular attention to scientific information and promotional initiatives regarding MALESCI products.

The Company is responsible for the promotional information and activities carried out regarding its products and those for which it holds sale rights, also where this is prepared and/or carried out by third parties (consultants, agents, agencies, etc.).

Personnel must verify that the contents of information is always documented and documentable and that there are no exaggerated statements, generalized, or hyperbolic assertions, or comparisons which cannot be proven or lack a clear objective basis.

It is prohibited for Personnel to use fax, email, automatic calling systems and other digital communication methods for the distribution of promotional material approved by AIFA [Italian Medicines Agency] except

- (i) where the documented consent of the doctor receiving the material has been obtained in advance, and
- (ii) in the event of an emergency which requires the restriction/exclusion of physical interpersonal contact.

**(b) Direct verbal communication with the doctor**

The Pharmaceutical Sales Reps (hereinafter PSRs) must present themselves to healthcare professionals indicating their role.

PSRs must not be healthcare professionals or health-sector workers and must not be involved in the use of the drug, even in an unpaid context, or be involved in any other ongoing activity that represents a situation of employment.

The Company undertakes to enable, as it effectively has enabled, the PSRs to provide healthcare professionals with information on the properties and characteristics of a drug to ensure the correct treatment application.

The Company undertakes to enable, as it effectively has enabled, the PSRs to collect information regarding its drugs in order to provide the fullest possible knowledge of the products marketed by the company.

The Company pays special attention to aspects regarding the safety of drugs, and undertakes to enable, as it effectively has enabled, the PSRs to always provide doctors with detailed information in the event of use of the drug not being recommended or being contraindicated.

During their activities, the pharmaceutical Reps must verify and act to ensure the availability of the Company's products in pharmacies and any other points of distribution.

**(c) Informational material**

MALESCI ensures the autonomy, independence and high standing of specialist publications used in the context of its scientific and pharmaceutical information activities.

To this end, Personnel are expressly prohibited from any form of conditioning, interpolation or manipulation that may, also only theoretically, compromise the scientific independence and objectivity of the content of specialist publications used as informational material.

The informational material regarding the drugs marketed by MALESCI, prepared and used by the Company in the context of scientific information activities with doctors, must make reference to the official documentation provided by AIFA upon the registration of the products, or that subsequently approved by the latter Authority in compliance with applicable legislation.

Where the information activity is carried out via IT, electronic or telephonic means, also via qualified third parties, the same legislative provisions defined by applicable law and the FARMINDUSTRIA Code of Conduct regarding scientific information must be fully observed.

Regardless of ministerial authorisation, no all-encompassing statements such as "drug of choice", "completely harmless" and "similar" are permitted, and it must not be categorically stated that a product is completely free of side effects or toxicity risks. Moreover, no potential side effects or toxicity risks associated with the medicines marketed must be omitted. Additionally, scientific citations must accurately reflect the

original meaning intended by the Author. Texts, tables and other illustrations taken from medical publications or scientific works must be reproduced accurately and in full, with precise indication of the source. Citations which, removed from their context, may be considered partial and/or contradictory in relation to the intention of their author must not be used.

Whenever MALESCI in any way secures or plans the use of informational material in publications, it is expressly prohibited for Personnel to present this material as editorially independent.

Material regarding medicines and their use, for promotional purposes or otherwise, sponsored by the company, must clearly indicate the fact that have been sponsored by the company.

**(d) *Promotional material***

Within the context of scientific information and the presentation of medicines to doctors or pharmacists, it is prohibited to give, offer or promise gifts, monetary benefits or other advantages.

Promotional material sponsored by MALESCI regarding drugs and/or their use must have a negligible value, must not be interchangeable and must be linked to the activity carried out by the doctor and pharmacist.

The name of the Company and/or the sponsored product must also appear clearly on this material.

It is prohibited to offer economic incentives aimed at compensating the time that healthcare professionals have taken away from their normal professional activities to attend conference events.

Promotional material aimed at doctors and pharmacists is acquired directly from the Company centrally, as defined by specific corporate procedures.

**(e) *Professional development and scientific collaboration***

It is permitted to provide free informational material regarding scientific consultation or work that is not specifically pertinent to the medicine, in the case of initiatives of high scientific value aimed at qualifying therapeutic performance. Distribution of such material may occur only in favour of public health structures, with the exception of material of a negligible perceived value, i.e. less than € 25.00 that may therefore be distributed directly to the doctor. Such material is nevertheless acquired directly from the Company centrally, as defined by specific corporate procedures.

Donations, loans for use and charitable initiatives referring to instruments strictly pertinent to the medical profession, may only be made in favour of universities, hospitals and nursing homes, in accordance with the Organisation's administrative procedures.

Outside the scope of clinical trials, it is not permitted to make donations or loans for use to the aforementioned structures of interchangeable devices – which may be used for purposes other than or alternative to the diagnostic or therapeutic use – such as smartphones, tablets or similar, for doctors' personal use outside of the structures or to be given to patients.

**(f) Advertising of medicinal products**

MALESCI demands respect for legislation and regulations regarding advertising of medicinal products.

It is categorically prohibited for Personnel to carry out any type of advertising or solicitation of advertising, aimed at the public, directly or indirectly, regarding pharmaceutical products subject to mandatory medical prescription.

Regarding the advertising of OTC drugs towards the public, Personnel must guarantee that the names of the medicinal product and the active ingredient are included, as well as the necessary indications for correct use and an invitation to read the package leaflet.

Furthermore, advertising of medicinal products to the public must be evident and transparent.

MALESCI upholds the rule of transparency for advertising in newspapers and magazines. Personnel must guarantee the separation of information and advertising, ensuring that the reader immediately recognises the promotional message, whatever its form, whether in text or tabular form.

**(g) Free samples**

Free samples of a medicinal product for human use may be issued only to doctors authorised to prescribe it and must be delivered exclusively via Pharmaceutical Reps following prior written request by the doctor carrying the date, stamp, and signature of the same.

The PSRs may deliver 2 samples to each doctor per visit for each dosage or pharmaceutical form of a medicinal product, exclusively within 18 months following the date of initial marketing authorisation of the product and up to a maximum of 8 total samples for each form or dosage. Furthermore, no more than four samples may be delivered per visit, up to a maximum of 10 samples per year, selected from the company's list of medicinal products which have been on the market for more than 18 months.

The other provisions of Art. 125 of Italian Legislative Decree no. 219/2006 are still applicable.

**VIII.2.g) Congress Events, Visits to Company Laboratories, Professional development Courses and Investigator Meetings**

**(a) General principles**

The Personnel must observe applicable legislation, as well as the provisions of the FARMINDUSTRIA Code of Conduct and applicable corporate procedures relating to scientific conferences, congresses and meetings on subjects pertaining to the use of drugs, professional development courses, visits to laboratories, and investigator meetings that represent an opportunity for the industry and healthcare professionals to meet and are attended by multiple participants.

When inviting a doctor to a conference or a congress, Personnel must acquire, in addition to agreement to take part in the congress, the doctor's express consent to the processing of their personal data (name, specialisation and observance of applicable legislation regarding the obligation to notify relative health structures of sponsored participation in the congress events) and eventual communication of this data to the FARMINDUSTRIA Monitoring Board for the sole purpose of monitoring conduct in relation to the specific conference, congress or laboratory visit in question. Consent to the publication of 'transfers of value' must also be requested.

This provision is applicable only to visits to the company's plants, non-CME congressional events, professional development courses and CME congressional events limited to cases of direct recruitment of doctors by the Company. MALESCI will have to produce such documentation to the Control Committee of FARMINDUSTRIA upon request of the latter, under penalty of the automatic formulation to the Jury of FARMINDUSTRIA of a specific proposal of sanction against the Company.

The participation of the Company in congress events must be connected to its role in the sectors of research, development and scientific information and must be inspired by ethical, scientific, and economic criteria.

Conferences and congresses abroad which are organised directly by the Company with predominately Italian doctors as participants are not allowed.

Reimbursement of air-travel tickets may only be made for economy class and reimbursement for accommodation may only be made for hotels with a maximum 4-star rating.

The Company may not invite the same healthcare professional to congresses, conferences, scientific meetings, and company-laboratory visits more than twice a year, except in the case of speakers or moderators or local CME initiatives organised in a hospital context that do not involve any form of hospitality other than coffee-breaks.

This limit of two event invitations per year is also inapplicable for training events regarding certain pathologies, in the case of substantiated and official statements by the World Health Organisation of potential health crises above a grade IV alert. In such cases, the exemption is applicable exclusively to initiatives which:

- are exclusively aimed at updating doctors regarding the pathology;
- are organised by public entities;
- take place at the locations of aforementioned public entities;
- have earned CME credits;
- do not provide for any form of hospitality;
- are the subject of prior notification to FARMINDUSTRIA.

When MALESCI organises an event directly, it must communicate the location of the event to the FARMINDUSTRIA Monitoring Board, furnishing this information in the context of a possible investigation along with scientific, logistical, and organisational reasoning for the choice of location.

Under no circumstances may scientific initiatives which also serve purposes of tourism be organised.

It is prohibited to organise or sponsor congress events that take place or involve hosting participants at the following structures: resorts, ships, castles outside of city centres, rural retreats, farm-tourism structures, golf clubs, thermal-bath centres or accommodation that offers well-being or spa treatments as a core service.

Personnel must implement these principles and guarantee their observance.

Doctors' invitations to conferences and congresses are subject to their specialisation being specifically linked to the topic of the conference event.

The primary objective of participation in or organisation of conferences and congresses at international, national and regional levels must be aimed at developing scientific collaboration with the medical community.

**(b) Congress venues**

Events organised directly or indirectly by the Company must be held in locations and places where the choice is based on logistical, scientific, and organisational reasons, with the exclusion of those aimed at catering. Events must be characterised by a relevant scientific programme. The territorial scope of origin of participants must be international, national interregional, regional, or local. It is prohibited for the Company to organise events in locations aimed exclusively at tourism during the following periods:

- from 1 June to 30 September regarding coastal areas;
- from 1 December to 31 March and from 1 July to 31 August regarding mountain areas.

Italian locations which are on the coast but are Regional or Provincial capitals and those which are home to important universities and hospitals, are exempt from this restriction. This is on the condition that the congress activities and hospitality for participants is concentrated within the urban centre of the capital, with the exclusion of structures positioned along portions of coastline equipped and suitable for bathing.

Personnel must implement these principles and guarantee their observance.



**(c) *Regional events and local scientific meetings***

Regional events and local scientific meetings are characterised by local participation with a provincial or single-region scope. The events must have acquired CME credits, and no hospitality may be offered in these cases, except for coffee breaks.

For events with more than six training hours, a “light lunch” may be offered in the interval between the morning and afternoon sessions within the structure in which the congress event is being held. These events must be held in venues such as hospitals, universities, scientific foundations, or conference halls which guarantee the scientific tone and standing of the event.

Personnel must implement these principles and guarantee their observance.

**(d) *Interregional events***

Interregional events must be characterised by a balanced participation of doctors from at least three different regions and must not provide for more than one overnight stay. These initiatives follow the same provisions defined by the FARMINDUSTRIA Code of Ethics for national events, described in detail in the following section. Personnel must implement these principles and guarantee their observance.

**(e) *National and international events***

MALESCI undertakes to ensure that at non-CME conferences, in Italy and abroad, organized by scientific societies or public and private bodies and institutions, and at conferences in Italy, organized directly by the Company, there is the presence at each event of at least 10% of doctors under 40 years of age. In any case, MALESCI guarantees the annual participation of 10% of physicians under 40 years of age.

The hospitality offered by MALESCI with reference to the congress events cannot present such characteristics as to prevail over the technical-scientific aims of the event.

Moreover, the hospitality offered cannot exceed the period of between 12 hours before the beginning of the Congress and 12 hours after its conclusion.

Any hospitality costs borne by the Company may concern general practitioners, hospital pharmacists, community pharmacists and, where applicable, nurses only in relation to CME events held in Italy.

Within the framework of congress events, in Italy and abroad, it is forbidden to organise or sponsor social, cultural or tourist initiatives and gala dinners. On the other hand, social dinners organised by the Congress for the collegiality of participants and included in the registration fee for the Congress itself are allowed.

Hospitality for accompanying persons at any level and in any form is also excluded.

Non-medical conference events organised at national level may not provide for fewer than six hours of effective work per day.

The above provision does not apply to events organised directly by national or international scientific

societies.

The hospitality offered by MALESCI at congress events is limited to travel, accommodation and payment of the registration fee for the congress.

During the conference days, the hospitality offered by the pharmaceutical companies may also include meals and beverages up to a maximum of 60 euros per Operator per meal, for events held in Italy.

For events held abroad, reference shall be made to the economic threshold established by the Code of Ethics of the country hosting the event, where identified. Otherwise, the limit remains fixed at 60 euros also for foreign events.

The principle of sobriety shall in any case be guaranteed and the meal shall preferably be offered in the same hotel where the guests are staying or in adjacent establishments.

Personnel must implement these principles and guarantee their observance.

***(f) Promotional material for use during congress events***

During conference events, gadgets may be distributed of a negligible value, pertinent to the doctor or pharmacist's profession, excluding items that graphically refer to the drug packaging. Gadgets may carry the name of the medicinal product and/or the active ingredient and/or the company name.

***(g) Sponsoring ongoing training in the health industry***

Training of health professionals takes place through programmes aimed at improving knowledge and skills, also on the basis of scientific and technological progress.

Provision of training is inspired by the principle of transparency and is exclusively aimed at improving the knowledge and skills of the professionals involved, also on the basis of scientific and technological progress. The content of training initiatives and educational goals must always be independent from commercial interests.

Without prejudice to scrupulous compliance with legislation and sector regulations (e.g. State and Regions Agreement of 02/02/17), MALESCI may sponsor training events in the health industry, providing that the sponsorship is always subject to a specific contract. It is absolutely prohibited for Personnel to condition, influence and/or involve themselves in the planning and/or definition of content for training events sponsored by the Company, as well as to identify and appoint, directly or indirectly, lecturers and moderators of such training events, in accordance with the regulations applicable to such types of events.

MALESCI has implemented a system of internal procedures aimed at verifying the economic appropriateness of sponsorship expenses incurred in support of CME events; the process of authorising sponsorship is also referred to the company's scientific manager.

Under no circumstances may the company name MALESCI or the names of medicinal products marketed by the Company be indicated in presentation of the training materials. The MALESCI logo may be indicated, according to the methods defined by the *National Manual of Accreditation for Provision of CME Events*, exclusively:

- A. before the start and after the end of the event;
- B. on the final page of take-away information, leaflets and the event programme.

During the event, indication of the active ingredient of drugs or the generic names of products of healthcare interest is permitted. No commercial name of a Company medicinal product may be used, even if unrelated to the topic in question.

MALESCI Personnel may not issue any payment, reimbursement, or support, directly, indirectly or via an intermediary, to doctors or moderators during the event. These provisions are exclusively the responsibility of the Provider.

Company representatives may be involved in the distribution of promotional material and take-away material for the event.

Access to the training room of a maximum of two Company representatives is allowed, avoiding their influence on training activities.

Invitations to CME events by Personnel of specialist doctors employed by public bodies or by private contracted structures must be sent to the competent public body/private contracted structure at least 60 days before the starting date of the CME conference event.

Personnel are forbidden from preparing invitations containing the names of these doctors unless the names are requested by the public body/private structure with which the doctor works and for which the body provides express authorisation.

The invitation must specify the hospitality costs incurred by MALESCI (e.g.: registration fee, travel, accommodation) and attach the scientific programme of the CME event.

If the public body/private structure under contract fails to reply within 30 days prior to the organisation of the CME conference, the Staff will be tacitly authorised to invite the identified healthcare professional, without prejudice to any more restrictive provisions adopted by the public body/private structure under contract to which the healthcare professional works (by way of example only: provisions requiring express authorisation from the public body/private structure under contract).

**(h) Ongoing education and training via the web**

The training and scientific medical updating initiatives carried out through electronic tools such as web meetings, e-meetings or FAD and similar events, may not include any form of hospitality and are not subject to any constraints in terms of duration.

In the context of these initiatives, it is absolutely forbidden to influence, influence and/or interfere, in any way whatsoever, in the planning and/or definition of the contents of the training events.

**(i) Professional development courses**

The rules defined for congresses, conferences and scientific meetings are also valid for medical scientific updating courses organised at any territorial level.

It is prohibited to organise or sponsor participation of healthcare professionals in professional development courses which do not have a medical scientific nature, such as language courses, IT courses, tax-related courses, and so forth.

However, it is permitted to sponsor professional development initiatives directly to healthcare professionals (i.e. the various figures in the medical profession: pharmacists, healthcare directors, technical and administrative personnel of public and private healthcare structures) with a scope strictly tied to healthcare management directly related to drugs, on the condition that such initiative take place in Italy, are organised by qualified parties, are held in hospitals or universities or other venues which guarantee a scientific tone and standing, and are concluded within a single day with at least 6 hours of activities. In these cases, companies will not be charged for hospitality except for a light lunch.

Sponsorship of initiatives lasting more than one day is also permitted only in the case of national-level events organised by companies qualified in the subject matter. In this case, pharmaceutical companies may also bear the costs of travel and hospitality for participants up to a maximum of one overnight stay.

**(j) Satellite symposiums**

If companies organise satellite symposia to coincide with congresses in Italy or abroad, they must comply with the current regulations and ethics provisions on Conferences and Congresses and, where applicable, the regulations on Continuing Medical Education. These initiatives must be held either within the main event or during the half-day preceding the beginning or following the end of the event. If the main event starts in the afternoon, the satellite symposium will be held in the morning of the same day or in the afternoon of the last day.

**(k) Visits to company laboratories**

MALESCI organises visits to company laboratories for doctors. The following rules of conduct must be respected in organising these visits:

- the visit must include adequate training-information space;
- the visit must not exceed the duration strictly necessary;
- hospitality offered is limited to the period of time defined by the FARMINDUSTRIA Code of Conduct (in particular, this is limited to the 12 hours before and 12 hours after the initiative);
- the visit may not be characterised by elements which undermine its primary technical purpose;
- reimbursement of travel expenses may only be made for air-travel tickets in economy class and accommodation in hotels with a maximum 4-star rating;
- hospitality is not permitted for companions of any position or type.

The organisation of laboratory visits of a tourism nature is not permitted under any circumstances.

**(l) Investigator meetings**

Investigator meetings - i.e., study meetings for investigators, concerning pre-clinical, clinical or observational studies - organised by the Company must have a number of participants proportionate to the number of Centres involved in the study, must be aimed at formulating a protocol to be filed with the Local Ethics Committee or proven by the existence of a specific protocol filed with the Local Ethics Committee itself, and must not have any promotional effects.

The duration of the initiative must comply with the work plan and must not feature any tourism-entertainment aspects or hospitality expenses for companions of any position.

The location must be selected according to the same criteria identified for conferences and congresses, and the same limits also apply regarding hospitality.

It is not permitted to organise or sponsor initiatives abroad regarding studies which primarily involve Italian Centres or for which most of the participants are Italian doctors. In the case that an intercontinental flight longer than 6 hours is required to reach the location of the Investigator Meeting, it is possible for participants to be flown business class. This provision is not applicable in the case of Investigator Meetings regarding observational studies.

**(m) Professional relations initiatives**

Professional relations initiatives with healthcare professionals (e.g., business lunches and dinners) may take place on the condition that the following are present:

- as a guide, no more than 6 healthcare professionals;
- company management personnel, also accompanied by an Area Manager or equivalent figure with the

express exclusion of those in territorial operations roles.

These initiatives must be characterised by sobriety and may not have a repetitive nature.

#### **VIII.2.h) *Relations of the Industry with the Scientific and Healthcare Communities and Patient Associations***

##### **(a) *Scientific consultations***

In the context of scientific collaboration between the Company and the scientific community, Personnel must respect applicable legislation, the provisions of the FARMINDUSTRIA Code of Conduct and applicable corporate procedures.

Collaboration may also be launched through scientific consultations, provided it is guaranteed that the initiative is appropriate, sufficient and documented.

The decision-making aspect of these initiatives is reserved to the company's executive management and has a collective nature in line with corporate procedures in this regard.

Specifically, Personnel must ensure that these forms of collaboration respect the following criteria:

- definition of a written contract between the doctor and MALESCI that specifies the nature of the service provided. The need for the service in question must be clearly identified;
- provision in the contract for the obligation upon the consultant to declare the relationship in existence with the pharmaceutical company on each occasion that they write or speak publicly regarding the subject of the collaboration;
- storage of documentation regarding services offered by consultants for a period of at least 3 years;
- quantification of the remuneration paid for the services offered according to criteria of cost-effectiveness and adherence to the market value of the services themselves. The appropriateness, adequacy and documentability of the initiative must also be guaranteed.

In all cases involving travel or any form of hospitality, the provisions of the previous paragraphs regarding conferences and congresses are applicable.

**(b) Bursaries**

Collaboration between MALESCI and the scientific community can also be initiated through bursaries.

In such cases, Personnel must ensure that bursaries:

- regard a project of significant scientific interest with specific, quantifiable objectives;
- are subject to the prior establishment of a specific Agreement with the structure where the beneficiary carries out their work, which defines all of the applicable conditions;
- are singular in nature and not recurring and are not repeated with the same Hospital or Operating Unit/Department within a three-year period (said time limit does not apply, therefore, in the case of different Operating Units/Departments even if they belong to the same Hospital).

Decisions regarding awarding of the bursary must be reserved to the company's executive management.

Furthermore, the Company must publicly disclose the list of bursaries issued for each Centre in the previous calendar year, together with the economic value of financing, on its website for at least three months, corresponding to the first trimester of each year.

**(c) Advisory boards**

Advisory Boards are composed of doctors and/or healthcare professionals that, in the capacity of consultants, provide opinions and support to the Company for the development of knowledge regarding its products and/or the pathologies associated with them, regarding clinical trials in progress and those planned and with reference to other research areas and other medical scientific topics, through peer-to-peer discussion.

Advisory Boards may also provide the Company with opinions regarding completed trials, on the use of products in the approved indications, on promotional material and the clinical routes of the approved indication.

Relations with professionals involved in Advisory Boards must be governed by a specific consulting contract.

Specifically, MALESCI Personnel must check that:

- a) before services begin, the nature of the services to be supplied must be defined in writing, as well as, without prejudice to the provisions of letter f), the basis of remuneration for the services;
- b) before the request for services and the definition of contracts with future consultants, a legitimate need for the services has been clearly identified;
- c) the criteria for selection of consultants are directly connected with the needs identified, and the subjects responsible for the selection of the consultants have the necessary skills to evaluate whether the specific healthcare professional meets these criteria;
- d) the number of healthcare professionals involved is not above the number reasonably necessary to meet the needs identified;
- e) services provided by the consultants are documented and appropriate use is made of the relative documentation;

- f) remuneration for the services is both reasonable and in line with the market value of the services provided.

It is expressly prohibited to utilise consulting contracts for the purposes of justifying otherwise undue remuneration to healthcare professionals.

In any case, involvement of a healthcare professional for the purposes of providing the relative service must never be aimed at inducing them to recommend, prescribe, purchase, supply, sell or administer a specific drug.

**(d) *Relations with scientific societies***

Collaboration with Scientific Societies and Medical Associations is inspired by the sharing of scientific knowledge and improvement of professional know how, and is carried out with organisations of proven reliability and national standing, with a clearly defined mission.

**(e) *Clinical trials and investigations related to drugs***

During the phase after the release of the Marketing Authorisation for the medicinal products, only clinical trials authorised under the terms of applicable regulations governing the subject are permitted.

It must be guaranteed that clinical trials, investigations of post-marketing monitoring and those carried out after release onto the market, are carried out exclusively for scientific purposes.

The performance of “Investigations Related to Drugs” – otherwise defined as “Non-Interventional Clinical Trials”, “Observational Studies” or “Epidemiological Studies” – is subject to observance of the provisions of the Circular of the Italian Ministry of Health no. 6 of 02 September 2002 “*Activities of Ethics Committees established under the terms of Ministerial Decree 18.03.98*” and the AIFA determination of 20/03/08 adopting the Guidelines for the classification and performance of observational studies on drugs and all other legislative and regulatory provisions, whether national, EU or international, as applicable.

The Company undertakes:

- to stipulate a written contract is defined with Bodies involved in the study which provides detailed specification of the characteristics of the Study and the nature of the services offered;
- to have the Study Protocol approved by the company Medical Department which will also provide for monitoring performance of the study through clinical monitors, in line with applicable data-protection legislation;
- to quantify the remuneration agreed for the Study is set on the basis of beneficial economic criteria and the market value of the work carried out;
- not to involve the PSRs in the Study regarding economic and financial aspects, and any



involvement on their part is subject, from a logistical point of view, to monitoring by the Medical Department and their appropriate prior training.

The study must not contain any elements of inducement or recommendations to purchase or prescribe a specific medicine.

In the case that, for the purposes of a trial or training initiative organised directly or indirectly by the Company, the use of instrumentation is necessary exclusively for the purposes of the trial or initiative, distribution to doctors of this instrumentation must be carried out via the Body or Bodies involved in the trial (ASL [Local Health Authority], University, Hospital or IRCCS [Treatment and Research Institute]) and relative use must be governed by a specific Agreement between the Company and these Bodies.

In any case, it is necessary to guarantee both the usage of the instrumentation on a temporary basis strictly for the purposes of the trial or training initiative and the return of the same at the end of the trial or initiative.

In the event that the trial or study consists of multiple phases, or if the Company must conduct multiple studies in quick succession at the same Body (where no more than 6 months elapse between the end of one study and the beginning of the next), the Body may send a formal request to the Company to retain the asset, specifying the duration of the next trial or study (or the duration of the next phase thereof) and the purpose for which the asset is used, provided that a declaration is made that the centre may not use the instrument for other purposes during the interval between one trial and the next. If the request is granted, MALESCI must formally respond to the Body in question. In any case, the maximum length of time for which use of the asset can be granted must not exceed the total duration of the trial or study. Moreover, the asset's suitability for use must be guaranteed for the entire duration for which it is granted for use.

At the end of the study, the return of the asset must be expressly documented and made available by the Company upon the request of the Monitoring Board in the context of investigation proceedings.

The withdrawal must be expressly documented and made available by the Company upon request of the Monitoring Board in the context of investigation proceedings. Again, in the context of these trials, it is not permitted to use IT tools (hardware or software) unless these tools are absolutely indispensable to the performance of the trial and there is functional incompatibility between these tools and those in use at the Bodies where the trial in question will take place, or there is risk of mixing of data functional to the performance of the trial – or obtained during the course of it – and that already present on the systems in use at the Bodies in question. This IT equipment shall, in any case, be available for use only for the purposes of the specific trial to which it is assigned.

**(f) Websites**

The Company's public website meets the requirements of the Law and applicable regulations, and guarantees indication of the source of information presented, the addressees of the information and the objective of the website. The Company guarantees that any promotional information regarding drugs for which public advertising is not permitted will be added to sections of the site reserved exclusively for doctors and pharmacists and accessible only to the same. Furthermore, the Company guarantees that any promotional messages regarding drugs advertised to the public will be featured on the site in compliance with applicable legislation.

**(g) Relations with patient's associations**

Direct or indirect financial support to patients' associations is provided in compliance with the following criteria:

- prior signing of an agreement aimed at regulating the amount of the funding and the purpose for which it is disbursed in accordance with corporate procedures;
- prior authorisation by the Association for the public use by the Company of the logo or material belonging to the Association;
- transparency and absence of promotional purposes;
- prohibition for the Company to include clauses aimed at making it the sole sponsor of a certain patients' association;
- compliance, as regards travel and hospitality, with the same procedures and limits provided for conventions and congresses;
- insertion on the Company's website, for a period of at least three months coinciding with the first quarter of each year, of the list of Patients' Associations supported in the previous year, together with the purposes underlying such support and the economic value of the funds granted to each Association.

For the sole purpose of supporting public health or research, contracts may be entered into between the Company and Patient Associations to provide specific services. It is also permitted to employ representatives of Patient Associations as experts or consultants for Services such as participation in advisory boards and speakers. To this end, a prior agreement or contract must be signed, specifying the nature of the Services provided and the criteria for payment for them. The need for such Services must be clearly identified and documented in the contract. The remuneration paid must be reasonable and must not exceed the normal market value of the Service provided. Lastly, each year pharmaceutical companies must publish the list of Patients' Associations for which service contracts have been concluded.

### **VIII.2.i) Participation in tenders**

When participating in a tender process, Personnel must:

- act in accordance with the principles of correctness, transparency and good faith;
- during the stage of reviewing the tender notice, assess whether the services required are appropriate and feasible;
- provide all data, information, and the details required during the selection of participants and officials to adjudicate the tender;
- should it refer to public tenders, interact with the appointed public officers in a clear and correct manner, avoiding any conduct that could compromise the free determination of the relevant officials.

Should the tender be awarded, in relations with the principal, Personnel must:

- ensure that negotiations and trade relations are conducted in a clear and correct manner;
- ensure the diligent performance of the contract-based obligations.

### **VIII.2.j) Obligation to keep updated**

In carrying out their activities in the interest of MALESCI, all employees are required to always maintain a high degree of professionalism.

In addition, all employees are required to keep up to date with the latest developments in their field of expertise.

### **VIII.2.k) Confidentiality**

Personnel must always exercise absolute confidentiality with respect to data, details, and information they have, even after having terminated their employment. More specifically, they must avoid disseminating this information or using it for their own speculative purposes, or those of third parties.

Furthermore, Personnel must exercise absolute confidentiality regarding information and data pertinent to strategic roles, functions and sensitive processes, especially where this refers to functions and processes that are exposed to any form of external solicitation.

Personnel must exercise absolute confidentiality in respect of information on the processes for the procurement of goods and services.

Any information, data or document which employees may become aware of during their work is the exclusive property of the Company; for example, but not limited to, any idea, formula, technique, invention, programme, business plan, marketing and sales plans and similar information that represents confidential

information and the exclusive property of Malesci S.p.A.

It is therefore prohibited to reveal similar information externally without specific authorisation, and to use it for one's own personal advantage. Without prejudice to the prohibition on disseminating information pertinent to the corporate organisation and production methods or to use this to cause prejudice, every employee must specifically:

- acquire and process only the data needed and appropriate for the purposes directly related to the role they carry out;
- acquire and process the data only within the context of specific procedures;
- store data in such a way that access is denied to unauthorised persons;
- disclose the data within the context of predetermined procedures and/or based on explicit authorisation from their superiors;
- ensure that there are no absolute or relevant constraints to the possible dissemination of information referring to third parties associated with the Company by any type of relationship, and if necessary, obtain their consent.

Information of a confidential nature may only be disclosed to the SB or the Judicial Authorities.

#### ***VIII.2.l) Diligence in using the Company's Assets***

Personnel must protect and safeguard the value and assets of the Company entrusted to them, and contribute to protecting the Company's assets in general, avoiding situations that could impact negatively on the integrity and safety of these assets.

In any case, Personnel must avoid using Company resources, goods, or materials for their personal advantage or for other improper purposes.

#### ***VIII.2.m) Respect for Laws on Illegal Immigration***

Personnel must observe the following principles:

- verification that workers from countries outside the EU are in possession of a valid residence permit, both at the moment of their employment and throughout their employment and, in the case of expiry of the permit, that they have renewed it;
- in the case of temporary workers being used through appropriate recruitment agencies, verification that appointed workers hold valid residence permits, and specific requirement upon the agencies to sign a declaration of compliance with the Model.

### **VIII.2.n)      *Protection of Share Capital and Creditors***

The Personnel are obliged to:

- maintain a correct, transparent and collaborative conduct, in compliance with the law and internal company procedures, in all activities aimed at drawing up the financial statements and other corporate communications required by law and addressed to shareholders or the public, in order to provide true and correct information on the Company's economic, equity and financial situation;
- strictly observe the rules laid down by law to protect the integrity and effectiveness of the share capital (e.g.: mergers, demergers, acquisitions of companies, distribution of profits and reserves, etc.) and always act in compliance with internal company procedures, which are based on such rules, in order not to damage the guarantees of creditors and third parties in general;
- conduct any liquidation operations of the Company with regard to the overriding interest of the Company's creditors; it is therefore forbidden to divert the Company's assets from their destination to creditors, distributing them to shareholders before paying the creditors entitled to them, or setting aside the sums necessary to satisfy them.

More specifically, with reference to the formation of the financial statements, MALESCI considers the truthfulness, correctness and transparency of the accounts, financial statements, reports and other corporate communications required by law and addressed to shareholders or the public, an essential principle in the conduct of business and a guarantee of fair competition. This requires that the validity, accuracy, completeness of the basic information for the entries in the accounts be thoroughly investigated.

Consequently, no concealment of information or partial or misleading representation of economic, equity and financial data by management and persons subject to their direction and control is permitted. Therefore, all internal and external collaborators involved in producing, processing, and accounting for such information are responsible for the transparency of the Company's accounts and financial statements. Every operation of economic, financial, or patrimonial relevance must be adequately recorded and for each recording there must be an adequate documentary support, in order to be able to proceed, at any time, to the performance of controls certifying the characteristics and motivations of the operation and allowing to identify who has authorised, performed, recorded, verified the operation itself.

Adequate supporting documentation of the activities carried out is, however, kept for each operation:

- the easy recording of accounts;
- the identification of the different levels of responsibility;
- the accurate reconstruction of the operation also to reduce the probability of interpretative errors.

The Company requires from its Personnel a great deal of dedication so that the management facts and the

operations carried out in the course of their activities are correctly and promptly represented in the accounts and correctly reflected in the tax declarations.

Each record must reflect exactly what is shown in the supporting documentation.

It is forbidden for managers and employees in charge of drafting corporate accounting documents to solicit, accept the promise of or receive from anyone, for themselves or for others, money or other undue benefits to perform or omit an act in violation of the obligations inherent to their office or their duties of loyalty.

Any oversight, omission or falsification that employees may become aware of must be promptly reported to the Supervisory Board.

#### **VIII.2.o)        *Diligence for tax purposes***

In the aim of guaranteeing the transparency, correctness, completeness and timeliness of tax fulfilments (concerning declaration obligations, calculation of taxes and payment of the same), the Personnel are required to carry out adequate controls in compliance with the provisions of corporate procedures, as well as to carry out training activities concerning said purposes.

The ongoing cooperation and collaboration of the Staff belonging to the different functions involved for the purposes of tax and accounting fulfilments (as well as in relation to the relevant payments) is expressly required in order to allow the Company to comply with all applicable accounting and tax regulations.

The Personnel are required to cooperate and cooperate with the officials of the financial administration when they expressly request clarifications in relation to all tax and accounting fulfilments kept by the Company; in this sense, Personnel must file the tax and accounting documentation in order to facilitate, where necessary, the financial administration in the subsequent reconstruction of their actions.

#### **VIII.2.p)        *Fighting money laundering, self-laundering and the handling of stolen goods***

Personnel are obliged to adopt the appropriate measures and precautions to ensure transparency and correctness in commercial transactions and to prevent the occurrence of money laundering (including in the form of self-laundering) and the handling of stolen goods.

Specifically, the Company makes it mandatory for Personnel to:

- stipulate in writing the duties assigned to any service providers and/or private individuals that see to the economic/financial interests of the Company, specifying the content and conditions of the terms agreed on, with reference to the supply of services;
- ensure, by all the competent Departments, the control of the regularity of the payments towards all the counterparts as well as to verify the coincidence between the subject to whom the order is

- addressed and the subject who collects the relevant amounts;
- check on the financial flows referring to accounts with companies in the Group (payments/intra-group transactions);
  - comply with the minimum standards and requirements set for the purposes of selecting parties providing goods and/or services, which the Company intends to acquire;
  - set the evaluation criteria for bids based on the suppliers and partners' commercial and professional reliability and to request and obtain all necessary information;
  - ensure maximum transparency in the case of entering into agreements/joint ventures aimed at making investments.

**VIII.2.q) Use of IT systems**

In the context of their professional activities, Personnel is obliged to use ITC and computer tools and services in full compliance with applicable legislation (in particular, regarding computer crimes, cyber security, privacy and copyright) and internal procedures.

The Company prohibits:

- unauthorised access to IT or ITC systems protected by security measures;
- distribution, damage, deletion or alteration of information, data or software belonging to others, to the State or to any other Public Body;
- production of false computer documents, whether private or public, effective for probative purposes;
- installation of equipment aimed at intercepting, preventing or interrupting communications relating to a computer or telecommunications system or to multiple interconnected systems;
- stealing, reproducing, or unauthorised distributing or handover of codes, passwords or other means of accessing a computer or telecommunications system protected by security measures.

The Personnel are prohibited from uploading borrowed or unauthorised software onto corporate systems; furthermore, it is prohibited to make unauthorised copies of licensed programmes for personal, corporate or third-party use.

Computers and computer tools made available by the Company may only be used for business purposes; consequently, the Company reserves the right to verify that computer content and the proper use of computer tools comply with company procedures.

It is also prohibited for personnel to send threatening and insulting email messages, and to use language that does not comply with the Company's linguistic style, or otherwise inappropriate language.

**VIII.2.r)            *Protection of Industrial and Intellectual Property Rights***

Personnel must respect the legitimate industrial property rights and intellectual rights of third parties and avoid unauthorised use of these rights, aware that breach of these rights may have serious negative consequences for the Company.

Specifically, in carrying out their activities, Personnel must avoid any conduct which may constitute a breach of industrial property rights, alteration or counterfeiting of distinctive marks of industrial products, or patents, designs or industrial models, whether national or international, as well as avoiding the importation, marketing or use or any other type of circulation of industrial products with counterfeited or altered distinctive marks or created in breach of industrial property rights.

All the Personnel must avoid unlawful and/or improper use, in their own interests, those of the company or those of third parties, of intellectual property (or parts of the same) protected under the terms of applicable legislation regarding violation of copyright.

**VIII.2.s)            *Data Protection and Relations with the Personal Data Protection Authority***

Every employee must:

- only access and process data required and directly related to their role;
- store such data so as to avoid third parties having access to it;
- communicate and disclose data in the context of predetermined procedures, following prior authorisation from the delegated official;
- ensure that no confidentiality restrictions exist regarding relations of any type with third parties;
- guarantee observance of any provisions issued by the Authority for Personal Data Protection or any prohibitions or restrictions adopted by the latter.

**VIII.2.t)            *Protection of health and safety in the workplace***

MALESCI considers the definition of a correct company policy for the health and safety of workers as a primary value, with the long-term objective of zero accidents at work.

The Company has adopted voluntary certifications. In particular, MALESCI complies with the standard BS OHSAS 18001:2007.

The Company, in step with its own development and technological progress, adopts the most suitable measures to eliminate the risks connected to the exercise of its business activities, guaranteeing healthy premises and choosing machinery, procedures and materials aimed at mitigating any risks that these may entail for the health and safety of the workers. In any case, the Company undertakes to carefully assess any residual risks in order to mitigate their possible consequences as far as possible.



The Employer, Occupational Health and Safety Manager, Company Doctor, Directors, Officers, and Workers must observe the provisions of Italian Legislative Decree 81/08.

Independently, in accordance with the provisions under the law, or on recommended by another party, the employer adopts all the measures needed to ensure and improve conditions in the work environment, especially with regard to hygiene and safety controls, as well as the procedures in place to constantly improve the corporate environment.

In observance of the provisions of Italian Legislative Decree 81/08 as amended, the Employer guarantees:

- observance of the technical and structural standards of the law related to plant, equipment and workplaces;
- performance of constant monitoring and periodic maintenance of its systems and equipment, wherever they are located and operational, to guarantee the highest levels of quality of its services;
- constant communication of information and training regarding the correct use of plant, equipment and machinery;
- risk assessment and definition of consequent health and safety measures;
- constant monitoring and adoption of suitable measures to protect against risk deriving from biological and chemical agents, manual handling of loads, and explosive atmospheres (this list is solely for illustrative purposes);
- organisation of activities, namely in case of emergencies, first aid, contract management, periodic safety meetings, consultations with workers' representatives for safety;
- health monitoring activities;
- worker information and training activities;
- supervision activities with reference to observance of procedures and operating instructions;
- periodic checks and audits regarding application and effectiveness of procedures adopted;
- acquisition of the documentation and certifications obligatory by law;
- constant improvement of requisites that have led to achievement of voluntary certification.

The Occupational Health and Safety Manager (hereinafter also referred to as OHSM) is appointed by the Employer.

In carrying out their duties and within the scope of relations with the Workers' Safety Officer, the OHSM must be considered as the employer's qualified consultant.

The Company Doctor must:

- work together with the Employer and the OHSM for risk assessment aimed at planning health-monitoring activities;
- plan and implement health monitoring for workers;
- institute, update and store a health file for every worker;

- periodically visit workplaces.

The workers, for their part, must observe the following rules:

- adopt safe conduct during work, i.e. working in observance of company regulations, procedures, operating Instructions, and general health and safety rules and provisions of the Code of Ethics;
- avoid conduct which is dangerous for the individual or for others;
- observe orders issued by superiors or by the Employer;
- observe tasks and operational activities assigned;
- take care of their own health and safety, and that of anyone at the workplace that their actions or omission thereof will have repercussions on, in accordance with training, instructions and according to the means provided by the Employer;
- together with the Employer, Managers and those Responsible, contribute to fulfilling the obligations set to protect health and safety in the workplace;
- abide by the directives and instructions given by the Employer, Managers and those Responsible for the purposes of collective and individual protection;
- correctly use work equipment, hazardous substances and preparations, means of transport, and safety devices;
- immediately report to the Employer, Manager or Superior of any inadequacy of tools and systems, as well as any potential danger that they become aware of, taking direct action in urgent situations, within the scope of their capability and possibilities, to eliminate or mitigate situations of serious and imminent danger;
- they must not remove or change safety devices, signs or controls without authorisation;
- make appropriate use of the personal protection devices made available to them;
- take care of the personal protection equipment made available to them, without making any modifications on their own initiative and reporting any defects or problems to the Employer or the Manager or Superior;
- they must not carry out operations or manoeuvres at their own discretion that do not fall within their remit, or that could compromise their safety or that of other workers;
- participate in the training and skills transfer programmes organised by the Employer;
- undergo the health checks required by applicable legislation or ordered by the Company Doctor;
- provide maximum cooperation in the activities of the Prevention and Protection Service;
- collaborate, adopting responsible behaviour which is in line with company rules, in the case of alarms or emergency situations;
- develop full awareness regarding implementation of the Organisational and Management Model adopted, working together with the figures responsible for health and safety objectives.

Contractors and service providers, suppliers, collaborators, etc. must also guarantee observance of the following rules:

- adopt safe conduct during their activities, i.e., working in observance of company procedures, instructions received, and general health and safety rules and provisions of the Code of Ethics;
- observe company signage;
- observe the contractual conditions governing the relationship between the parties;
- in the case of project or works contracts or service contracts, respect the health and safety provisions applicable in the scope of the cooperation and coordination activities between the parties and the corporate procedures aimed at their implementation.

#### ***VIII.2.u) Protection of the environment***

The Company is strongly committed to addressing and managing in a structured way, with medium-term policies and formalised programmes, the issues and problems related to environmental protection. In this field, the objectives are, on the one hand, the constant improvement of the company's behaviour and assets with a view to increasing compliance with current legislation and, on the other, the coordinated construction of a management system and an environmental report that highlights both the current excellent performance and the further progress that will be achieved over time.

The Employer and Personnel must comply with the requirements of the Consolidated Text 152/06.

#### **VIII.3 Rules of Conduct for Third-Party Recipients**

This Code of Ethics applies not only to Corporate Bodies and Personnel but also to Third-Party Recipients. These are understood to be subjects outside the Company who work, directly or indirectly, for the Company (e.g. agents, collaborators of any kind, consultants, suppliers, business partners), or the Auditor.

The Third-Party Recipients, like the other subjects, are obliged to comply with the provisions of the Code of Ethics and in particular with the ethical principles of reference and the rules of conduct laid down for the Personnel, in relation to their competence.

## **IX. Transparency in the Transferring of Value Among Pharmaceutical Industries, Healthcare Professionals and Healthcare Organizations**

### **IX.1 Obligation of transparency**

The Company must document and disclose every year, by means of a specific model and in full compliance with the provisions of the relevant corporate procedures, the transfers of value, both in money and in kind, made for promotional purposes or for the development and marketing of drugs for human use subject to medical prescription, made directly or indirectly to Health Operators and Health Organizations.

Both transfers carried out directly by the Company to the benefit of the recipient and those carried out indirectly on behalf of MALESCI through a third party must be documented and publicly disclosed.

The information must be published on the company website, and the Company is obliged to retain appropriate documentation for at least three years, showing that the Healthcare Professional provided their consent to the data being published.

The obligation of publication does not apply to transfers of value related to OTC medicines, promotional material as per subsection 2.13 of the FARMINDUSTRIA Code of Conduct, meals and beverages, or to drug samples.

Refer to the FARMINDUSTRIA Code of Conduct for details about the methods for publication of data connected to transfers of value and the relative time frames.

### **IX.2 Publication of Data on an Individual and Aggregate Basis**

On an individual basis, with respect to each recipient, the Company shall make public the amount relating to value transfers carried out during the previous year, referring to:

- a) expenses to participate in conferences and congresses, regarding registration fees, travelling and hospitality expenses (excluding meals and beverages);
- b) expenses for consulting and professional services not included under paragraph a), resulting from a specific contract between the Company and the individual Healthcare Professional, detailing the type of service provided.

In this regard, the Company shall do its utmost to secure the consent of Healthcare Professionals to publish the data.

Should the Professional not provide consent to the processing of personal data, the Company shall arrange for the data to be published on an aggregate basis, according to the methods defined by the FARMINDUSTRIA Code of Conduct.

The Company shall make public the amounts for value transfers made to each Healthcare Organization during

in the previous year with reference to:

- a) donations and contributions (including loans for use) whether in money or in kind;
- b) direct or indirect funding for conference events, made through healthcare structures or third parties, including the sponsoring of doctors at conferences and congresses, paying their registration fees or travelling and hospitality expenses;
- c) financial transactions related to consulting and professional services resulting from a written contract between pharmaceutical companies and institutions, organisations or associations that provide any kind of service not included in the previous categories a) and b).

If a transfer of value is carried out with reference to an individual Healthcare Professional, indirectly and through a healthcare structure or third party, this fact should be disclosed individually where possible, and only once.

### **IX.3 Research and Development Expenses**

Annual expenses paid by pharmaceutical companies for research and development activities must be publicly disclosed in aggregate form. These activities include those aimed at planning or performance of:

- a) non-clinical trials, as defined by Good Laboratory Practices;
- b) clinical trials, as defined by Directive 2001/20/EC;
- c) prospective observational studies, as per 4.4. of the FARMINDUSTRIA Code of Conduct, which involve the collection of data regarding patients by individual doctors or groups of doctors.

Expenses related to Investigator Meetings, Advisory Boards and hospitality must also be publicly disclosed on an aggregate basis where such expenses relate to the activities described in the aforementioned letters a), b) and c), along with a summary note indicating the methods used for the preparation of the data with reference to VAT information, currency or other fiscal considerations associated with the transfer of value in individual or aggregate form.

## **X. Internal control**

It is the Company's policy to disseminate at all levels not only a culture characterised by the existence and importance of controls, but also to transmit a mentality oriented towards the exercise of the same.

With its internal control system, MALESCI intends to pursue the general objectives of effectiveness and efficiency of its operations, of safeguarding the company's assets and resources, of compliance with laws, applicable regulations and internal procedures, and of reliability of accounting and financial data.

Each level of the organisation and each corporate function has, therefore, a specific responsibility to implement, maintain and monitor the proper functioning and effectiveness of the internal control system. MENARINI IFR's Corporate Internal Audit Department, in its monitoring of internal controls, will have full and unrestricted access to company data and documentation, and will report exclusively to the Board of Directors.

## **XI. Implementation and monitoring of observance of the Code of Ethics**

### **XI.1 Dissemination and training on the Code of Ethics**

MALESCI undertakes to ensure maximum and timely dissemination of this Code of Ethics both inside and outside the Company.

With particular reference to the Corporate Bodies and the Staff, it guarantees:

- the distribution of the Code of Ethics to all members of the Corporate Bodies and to all Personnel;
- displaying of the same in a place in the company's headquarters that is accessible to everyone, in order to allow verification of any notice of violation of the Code, as well as the assessment of facts and the application of appropriate sanctions in case of violation;
- help in interpreting and clarifying the provisions contained in the Code;
- the devising of systems for verifying effective compliance with the Code of Ethics.

The Supervisory Board pursuant to Legislative Decree 231/01 (hereinafter "**SB**"), which is responsible for monitoring the effective implementation of the Model, in collaboration with MENARINI IFR's Corporate Training Department, promotes and monitors training initiatives on the principles of the Code of Ethics, structured and differentiated according to the role and responsibilities assigned to the resources concerned. The training will be more intense and characterised by a higher degree of detail for persons qualified as "top management" by the decree, as well as for those operating in the so-called "risk" areas pursuant to the Model.

With particular reference to Third Party Recipients and any other interlocutor, the Company shall also take

care of:

- informing these subjects about the commitments and obligations imposed by the Code of Ethics, by delivering a copy of the Code;
- disseminating the Code of Ethics through the company's information systems;
- requiring them to comply with the Code of Ethics;
- having them sign clauses and/or declarations contained in and/or in any case attached to the relative contracts aimed, on the one hand, at formalising the commitment to comply with Legislative Decree 231/2001, the Model and the Code of Ethics and, on the other hand, at regulating the contractual sanctions that will be applied following the violation of this commitment. The Company shall ensure the definition and constant improvement of these clauses.

Any application doubts concerning this Code of Ethics will be promptly discussed with the SB.

## **XI.2 Duties of the Supervisory Board**

As already mentioned in the previous section, control over the implementation of and compliance with the Code of Ethics is entrusted to the Supervisory Board, which is responsible inter alia for:

- monitoring compliance with the Code of Ethics, with a view to reducing the risk of the offences provided for in the Decree being committed;
- formulating its own observations concerning both the problems of an ethical nature that may arise in the context of business decisions, and the alleged violations of the Code of Ethics of which it becomes aware;
- making available every possible instrument of knowledge and clarification concerning the correct interpretation and implementation of the provisions contained in the Code of Ethics;
- monitoring the updating of the Code of Ethics, formulating its own proposals for adaptation and updating;
- promoting and monitoring the implementation by the Company of communication and training activities on the Code of Ethics;
- reporting any violations of the Code of Ethics to the competent corporate bodies, verifying the effective application of any measures imposed.

## **XI.3 Infractions of the Code of Ethics and Relative Sanctions**

Compliance with the provisions in the Code of Ethics is deemed an essential part of the duties incumbent upon the Company's Corporate Bodies and Personnel; it also constitutes an essential part of the contractual

obligations undertaken by the so-called Third-Party Recipients.

Infringements of the Code of Ethics will result in sanctions being applied as stipulated in the Disciplinary System (which should be referred to) and/or with regard to Third-Party Recipients, according to the clauses in the relevant contracts.

With reference to Key Persons, different types of sanctions are provided for, ranging from a written warning, to a warning, to the reduction of emoluments up to the revocation of the office.

Different types of sanctions may be applied to Employees, ranging, in increasing order of seriousness, from verbal warning, written warning, fine and suspension within the limits provided for by collective bargaining and dismissal, in accordance with the applicable CCNL, as better detailed in the Disciplinary System to which reference should be made.

With specific regard to Third Party Recipients, specific contractual sanctions of graduated intensity are provided for on the basis of a specific clause included in the agreement or in the letter of appointment.

#### **XI.4 Reporting Possible Infringements of the Code of Ethics**

Should a person required to comply with this Code of Ethics become aware of a fact or circumstances that could represent the risk of an infringement, they are obliged to immediately report this to the Supervisory Board.

To this end, the Company has already set up appropriate dedicated communication channels; specifically, a special certified email address ([odvmalesci@legalmail.it](mailto:odvmalesci@legalmail.it)), together with an ordinary email address ([odvmalesci@malesci.it](mailto:odvmalesci@malesci.it)), to which any reports concerning non-compliance with the provisions of this Code may be sent. Reports may also be sent in writing, also in anonymous form, to the address: Malesci Istituto Farmacobiologico S.p.A. Supervisory Board, Via Lungo l'Ema, 7, 50012 Bagno a Ripoli (FI), Italy.

In this context, the Supervisory Board therefore plays a central role: as the ultimate recipient of the above-mentioned flows and reports, it ascertains their validity, through the tools and powers at its disposal during the in-depth analysis or investigation that follows the report.

Moreover, it is required to act in such a way as to ensure that the persons concerned are not subject to retaliation, discrimination or, in any event, penalisation. To this end, the Body ensures the confidentiality of the person making the report, operating in such a way as to guarantee full respect for the personal data of the person making the report.



## **XI.5 Policy of Non-Retaliation**

The Company strictly prohibits any retaliatory, discriminatory, or penalising behaviour towards anyone who, in good faith, reports a violation of this Code, a violation of the Organisational, Management and Control Model pursuant to Legislative Decree 231/2001 and/or an offence pursuant to the aforementioned Decree, or reports a potentially unlawful conduct through the Whistleblowing system implemented by the Company. The advancing of a report may under no circumstances constitute grounds for threats, harassment, discrimination, demotion, denial of benefits, suspension, or termination of employment.

Should it be discovered that retaliatory conduct has been adopted against a Code Recipient who has made a report, appropriate measures will be taken even if it turns out that the report was originally wrong.

In any case, the Disciplinary System provides for appropriate sanctions for those who make unfounded reports with malice or gross negligence.

Anyone who thinks he/she may be subject to retaliation, or is aware of retaliatory behaviour adopted against others, must immediately contact the Company's Supervisory Board at the appropriate certified email address ([odvmalesci@legalmail.it](mailto:odvmalesci@legalmail.it)) or by mail to the Supervisory Board at the following address: Malesci Istituto Farmacobiologico S.p.A. Supervisory Board, Via Lungo l'Enza, 7, 50012 Bagno a Ripoli (FI), Italy.