

**Code of Ethics**

**of**

**MALESCI**

**ISTITUTO FARMACOBIOLOGICO S.p.A.**

## Document inspection

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## I. Introduction

Istituto Farmacobiologico MALESCI S.p.A. (hereinafter also referred to as "MALESCI S.p.A.", "Firm", "Company", or, simply, "MALESCI") is an Italian company dedicated to the marketing of drugs. In particular, the Company markets drugs aimed at the treatment of acid-related diseases, antihypertensive drugs and diuretics for the prevention and treatment of the most common cardiovascular diseases.

Since 1978 MALESCI has been part of the Menarini Group (the "Group" or "Menarini Group"), an international industrial group operating mainly in the pharmaceutical and diagnostics sectors.

Today, with more than three billion of consolidated sales and approximately 16,000 employees, the MENARINI Group is present with its products in over 100 countries worldwide, and no less than five of its researchers are among the most cited researchers in the world.

The Menarini Group is the first Italian pharmaceutical company in the world, a guarantee of quality recognised at an international level. The results achieved are evidence of the effectiveness of a strategy focused on Research, Innovation and Internationalisation along with the ability to identify and meet the needs of physicians and patients alike.

One of the strengths of the Menarini Group lies in its cooperation with international partners: the objective is to create synergies that shall lead to advanced solutions, pharmaceuticals and services in the healthcare sector.

The attention to people's health and well-being, which has always been the cornerstone of the Menarini Group's mission, has also been the drive behind MALESCI's business.

In carrying out its business activities, because of the peculiarities of the market in which it operates, MALESCI S.p.A. is constantly focused on the expectations of the community and clients with the aim to guarantee the highest quality standard. Furthermore, it has always paid attention to the ethical aspects of the business and to the scientific training of its employees.

This Code of Ethics is an official document approved by the Board of Directors of the Company and shared by all the companies belonging to the Group which, in turn, shall see to the formal approval thereof. The ethical principles of this Code shall apply, regardless of location and without any distinction, to each company and business division of the Group.

The Code of Ethics contains all the standards and rules of conduct to which all the entities operating in the Group's corporate context are subject. The shareholders, directors, auditors, independent auditors, managers, employees and external collaborators (consultants, agents, service providers), both of the parent company and of the other companies, shall be required to comply with this Code in the performance of the duties and functions entrusted to them.

It is therefore appropriate to reiterate to all those who work within the Company or who are involved in attaining the Company's objectives, without distinction or exceptions, the importance of observing and enforcing these principles within the scope of their duties and responsibilities.

Being aware that a pharmaceutical company is evaluated, in addition to the quality of the drugs it markets, also on the basis of its ability to comply with the absolute ethical values and those set forth by laws and regulations, MALESCI S.p.A., through the adoption of its own Code of Ethics, has sought to:

- define and set out the values and principles underlying its business and relations with the Corporate Bodies, Personnel and in general all those who collaborate with the Company or deal with it, e.g. collaborators, patients, suppliers, institutions and third parties in general;
- formalise its commitment to act in accordance with integrity, honesty and fairness;
- inform its collaborators of the principles of conduct, values and responsibilities which they are required to strictly comply with in the performance of their activities.

In particular, the Company intends to base its conduct on integrity, a value that does not merely have a moral significance, but is of paramount importance to ensure the same continuity of action by the Company in accordance with the provisions laid down by Legislative Decree 231/01.

The achievement of this objective requires the absolute compliance with current Italian laws, international laws and the laws of the countries in which the Company operates, as well as the compliance of its actions with the principles of fair competition, fairness and good faith, respecting the legitimate interests of all stakeholders: clients, the sole shareholder, citizens, employees, healthcare professionals, suppliers, business partners, etc.

In particular, to this end MALESCI S.p.A.:

- implements transparently and respects the behaviour patterns inspired by autonomy, moral integrity and professionalism and develops the appropriate actions;
- complies with the current regulations at Community, national and regional level;
- respects the legitimate interests of patients, suppliers, personnel and external collaborators;
- complies with the principles enshrined in this Code of Ethics.

The compliance with the Company's ethics is key to the development of the organisation and the relations between Personnel and those who work with the Company in various capacities, as well as between the Personnel and the general public.

The compliance with corporate ethics also helps enforce the control policies and systems put in place by the Company and in any event it affects and guides any conduct that might escape the control systems.

Finally, the compliance with corporate ethics is ultimately a guarantee of conduct thereby permitting, in addition to the formal observance of the laws, also the fulfilment of the standards of fairness, equity and transparency vis-à-vis the Company's employees and stakeholders.

The observance of this Code of Ethics is therefore of fundamental importance to the proper functioning, reliability and reputation of the Company, as well as to avoid any involvement of the same in the possible perpetration of criminal activity conducted by Corporate Bodies, Managers or Employees.

Under no circumstances does the belief of acting for the benefit of the Company justify any form of behaviour that conflicts with these principles or with the procedures governing corporate activities.

The provisions contained in the Code of Ethics are designed to protect the standing and credibility of MALESCI S.p.A. vis-à-vis the State, the public opinion, the medical community and healthcare professionals in general.

The Company ensure the widest possible dissemination of this Code of Ethics and knowledge both inside and outside the Company.

### **I. 1 FARMINDUSTRIA's Code of Professional Conduct**

Of fundamental importance, within the scope of the guidelines by Trade Associations, is the Code of Professional Conduct of FARMINDUSTRIA, an association to which MALESCI S.p.A. also belongs to.

In particular, it enshrines the ethical principles and rules of conduct that shall guide the relations among pharmaceutical companies, as well as between the latter and the science and healthcare sector.

It is the main point of reference for the purposes of drawing up this Code of Ethics.

### **I. 2 MALESCI S.p.A.'s model and the purposes of the Code of Ethics**

The Code of Ethics adopted by MALESCI S.p.A. is an integral part of the Model adopted by the



Company, containing, *inter alia*, the general standards and rules of conduct to which the same attributes positive ethical value and to which all recipients of the Code are required to adhere to.

MALESCI S.p.A.'s Code of Ethics complies with the principles set out in CONFINDUSTRIA's Guidelines and in FARMINDUSTRIA's Code of Professional Conduct in the version approved on 19 May 2015.

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

Since the main purpose of the Code of Ethics is to guide and direct the Company's operations towards compliance with the ethical standards, it is binding upon the shareholders, all the Directors, Auditors, Independent Auditors, all its employees, including the top management and other personnel (hereinafter the "Personnel"), as well as all those who, despite not being employed by the Company, operate directly or indirectly for the same, e.g. agents, collaborators in any capacity, consultants, suppliers, business partners (hereinafter referred to as "Third-Party Recipients").

All Recipients are required to observe and, to the extent applicable, to enforce the principles enshrined in the Code of Ethics.

The Company's management is required to comply with the Code's contents in proposing and implementing projects, actions and investments aimed at increasing the long-term economic value of the business and the welfare of its employees, clients, suppliers and the Community.

It is everyone's duty, but first of all the directors and executives' duty, to promote the values and principles enshrined in the Code, by undertaking responsibility both inside and outside of the Company and strengthening trust, cohesion and team spirit, notwithstanding the operational autonomy of the individual companies.

Each Company employee shall commit to observing the laws and regulations in force in all countries where the Company operates. Employees shall be aware of the laws and conduct to put in place in order to comply therewith. Each employee is required to contribute to the implementation of the Code in a proactive manner.

Under no circumstances shall the claim to act in the interests of the Company justify the adoption of any conduct in conflict with the rules of conduct set forth herein.

The Code shall also inspire the activities carried out abroad by the Company while considering differences in regulatory, social and economic aspects.

Furthermore and above all, compliance with the provisions of the Code shall be deemed as an integral part of the contractual obligations to which the Company's employees are subject under and for the purposes of the provisions laid down by art. 2104 and following of the Civil Code.

Any breach of the rules of this Code, deemed to be especially serious, damages the relationship of trust established with the Company and may lead to disciplinary measures and compensation for damages, without prejudice to the employees' obligation to adhere to the procedures referred to in art. 7 of the Workers' Statute, of the collective bargaining agreements and of any corporate regulations adopted by the Company.

#### **I.4 Dissemination of and training on the Code of Ethics**

The Company is committed to ensuring a timely internal and external dissemination of the Code of Ethics.

With specific reference to the Corporate Bodies and the Personnel, it shall ensure:

- distribution of the Code of Ethics to all members of the Corporate Bodies and to the entire Personnel;
- posting thereof in a place of the company's office that is accessible to all, in order to allow the verification of any reports of breach of the Code, as well as the assessment of the facts and the application of appropriate sanctions in the event of a breach;
- support in the interpretation and clarification of the provisions enshrined in the Code;
- development of audit systems aimed at verifying actual compliance with the Code of Ethics.

The Supervisory Body pursuant to Legislative Decree 231/01 (hereinafter the Supervisory Body), which is responsible for checking the efficient compliance with the Model, in collaboration with the Organisational Development Department of the IFR Menarini Parent Company, promotes and monitors training initiatives relating to the principles of the Code of Ethics, which are structured and differentiated according to the position held and the responsibilities assigned to the resources concerned. The training shall be more intense and characterised by a higher degree of detail for those entities who qualify as so-called 'top managers' under the decree, as well as for those who work in areas so-called 'at risk' under the Model.

With specific reference to Third-Party Recipients and in any event to any other stakeholder, the Company shall also ensure to:

- inform the said entities of the commitments and obligations required by the Code of Ethics, by

delivery of a copy thereof to same;

- disclose the Code through the company's information systems;
- demand compliance with the Code of Ethics by the same;
- make them sign any clauses and/or declarations contained and/or attached to the related contracts aimed at formalising, on the one hand, the commitment towards compliance with Legislative Decree 231/2001, the Model and the Code of Ethics and, on the other hand, at governing the sanctions of a contractual nature that shall be applied following breach of said commitment. The Company shall take care of the definition and the constant improvement of such clauses.

Any doubts in terms of application associated with this Code shall be promptly discussed with the Supervisory Body.

#### **I. 5 Structure of the Code of Ethics**

The Code of Ethics consists essentially of four parts:

- the first part outlines the reference ethical standards, namely the values to which Malesci attributes importance as part of its business operations and which shall be observed by all Code Recipients;
- the second part sets forth the rules and principles of conduct laid down vis-à-vis the entities, including the so-called Third-party recipients, who are required to comply with this Code;
- the third part governs the methods with which the Supervisory Body guarantees the implementation and supervision over the compliance with the Code of Ethics;
- the fourth governs the transparency obligations of the transfers of value between the Company, healthcare operators and health organisations.

The Code of Ethics is subject to constant amendments, integrations and implementations. The Board of Directors is the competent body to make these changes introduced by specific resolutions adopted on the basis of any suggestions and guidelines coming from the Supervisory Body.

## **II. The reference ethical standards**

The reference ethical standards for all Recipients are defined hereunder. It is worth recalling that under no circumstances shall the belief of acting for the benefit of the Company justify conduct contrary to the principles of this Code, which shall be recognised as being core and overriding values.

### **II.1 Responsibilities and compliance with the laws**

MALESCI agrees to comply with the laws, regulations and in general with the regulations in force in Italy and in all the countries with which it has links.

It also undertakes to respect the ethical and professional rules and principles set forth by trade associations, particularly those set out in FARMINDUSTRIA's Code of Professional Conduct, duly incorporated in this Code.

MALESCI S.p.A.'s Directors, Statutory Auditors, Independent Auditors and Personnel are required to comply with the laws in force both in Italy and in other countries with which the Company has any operational links. In compliance with the regulations and procedures laid down by the Company, they shall fulfil their duties with diligence, efficiency and fairness, making the most of their professionalism and undertaking the responsibilities associated with the obligations incumbent upon them.

Under no circumstances is it permitted to pursue or serve the Company's interest in breach of the laws or professional principles. This applies as much with regard to the activities carried out within the Italian territory, as with reference to those that may be associated with the relations existing with international operators.

### **II.2 Fairness**

All the actions and transactions carried out and the conduct put in place by each of the Recipients of this Code in the fulfilment of their duties or engagement are guided by lawfulness in both form and substance, in accordance with the regulations in force and internal procedures, as well as fairness, loyalty and mutual respect.

The Recipients are required to diligently observe the laws, the Code and internal regulations. In no case may the pursuit of the Company's interest justify dishonest conduct in breach of the legislation

currently in force and this Code.

The pursuit of the company's profit is subject to the principle of fairness. Each Recipient shall refrain from accepting or engaging, for themselves or others, in any pressure, recommendations, reports that could harm the Company or undue advantages for themselves, for the Company or for third parties; each Recipient also rejects and does not make any promises and/or undue offers of money or other benefits, except when the latter are of a commercial and modest value and do not meet requests of any nature.

If the Recipient receives an offer or a request for benefits from a third party, except gifts for commercial purposes and of modest value, it does not accept such an offer, nor meets that request and immediately informs the Supervisory Body for the appropriate action.

In any event, MALESCI S.p.A.'s Directors, Statutory Auditors, Independent Auditors and Personnel shall act fairly in order to avoid conflicts of interest, that is, in general, all situations in which the pursuit of one's interests is contrary to the Company's interests.

In any event, it is necessary to avoid those situations through which an employee, director or other recipient can gain an undue advantage or profit on the basis of situations or opportunities which he/she became aware of during the fulfilment of their duties.

In particular, given the sensitive nature and central role of the position held, Directors and Managers are required:

- to adopt a conduct based on autonomy and independence with public institutions, private parties, business associations and political forces by providing the right information to define the company's legal structure and administrative activity;
- to behave with integrity, loyalty and a sense of responsibility towards the Company;
- to participate in the Company's activities in a constant and informed manner;
- to be aware of the role held;
- to ensure the attainment of the objective of treating patients while respecting their freedom and dignity.

### **II.3 Impartiality**

MALESCI disclaims and condemns all principles of discrimination based on sex, nationality, religion, personal and political opinions, age, health and economic conditions of its stakeholders, including its suppliers.

Anyone who deems to have suffered discrimination may report the incident to the Supervisory Body, which shall verify the actual breach of the Code of Ethics.

### **II.4 Honesty**

MALESCI S.p.A.'s Directors, Statutory Auditors, Independent Auditors and Personnel, as well as Third-Party Recipients shall be aware of the ethical and professional significance of their actions and shall not pursue personal or corporate benefits in breach of the applicable laws and the rules of this Code of Ethics.

When formulating the contractual agreements with clients, it is necessary to ensure that the terms are fully clear and comprehensible. It is also necessary to ensure conditions of equality among the parties.

### **II.5 Integrity**

MALESCI condemns and does not permit any act of violence or threat, including of a psychological nature, aimed at obtaining conduct that is contrary to the legislation in force, including the professional principles enshrined in this Code.

### **II.6 Transparency**

The information disseminated both inside and outside the Company shall be characterised by truthfulness, accuracy and completeness. The constant compliance with such rules of conduct enables the implementation of the principle of transparency.

In accordance with the principle of transparency, all operations and/or transactions, understood in the broadest sense of the term, shall be legitimate, authorised, consistent, reasonable, documented, recorded and verifiable within a ten-year period. In particular, each operation and/or transaction shall be duly recorded and shall allow verification of the decision-making, authorisation and implementation process.

All operations shall also be accompanied by adequate supporting documentation in order to proceed at any time with the performance of checks aimed at verifying the characteristics and reasons behind the

operation and such as to be able to identify the person responsible for the authorisation, implementation, registration, and verification of the operation.

Recipients, and in general, all the entities engaged in any purchase of goods and/or services, including external consultants, on behalf of the Company, shall act in accordance with the principles of fairness, cost-effectiveness, quality and legality to operate with due diligence.

In order to ensure compliance with these ethical standards, the criteria for suppliers' selection shall be objective and transparent and, above all, codified in a special procedure. This selection, in compliance with the laws currently in force and the procedures adopted, is essentially made on the basis of objective evaluations related to competitiveness, the quality of the services provided and/or the services offered and the economic conditions applied.

In any event, it remains understood that the supplier shall be selected also on the basis of its ability to ensure:

- compliance with this Code of Ethics;
- the implementation of adequate quality systems, if any;
- the availability of suitable organisational means and structures.
- compliance with labour regulations.

Specific procedures are in place to support the documentation of the overall selection and procurement process, in order to ensure the utmost transparency in the evaluation and selection of suppliers.

## **II.7 Responsibilities towards patients**

The business conducted by MALESCI and its corporate purpose ensure that the Company undertakes specific responsibilities, including of an ethical nature, towards patients.

In order to best implement and fulfil its ethical commitment towards patients, MALESCI S.p.A. undertakes and uses its best efforts in the research sector, also in order to develop medical-scientific and therapeutic solutions that might be as satisfactory as possible for patients.

Specifically, MALESCI S.p.A. undertakes to:

- guarantee to patients the marketing of highly specialised drugs that are the result of

advanced scientific studies;

- market drugs aimed solely at the protection of patients' physical integrity and health;
- pay the utmost attention to the safety-related aspects of the drugs;
- ask the Personnel, each to the extent applicable, and the opinion leaders to put in place studies aimed at meeting the requirements of patients' care with respect for their freedom and dignity.

## **II.8 Efficiency**

Each Recipient of this Code is required to exercise the utmost professionalism, dedication, loyalty, cooperation, and mutual respect. The efficiency of the management pursued by MALESCI is achieved through the professional and organisational contribution guaranteed by each of the human resources involved in compliance with the principles of professionalism, transparency, fairness and honesty.

The management efficiency is also pursued through the constant compliance with the highest quality standards, met, if necessary, also to the detriment of the same cost-effective management.

The Company, under a different point of view, also undertakes to:

- safeguard and preserve corporate resources and assets, as well as to manage its assets and capital base by taking all the necessary precautions to ensure full compliance with the laws and regulations in force;
- ensure an ongoing dialogue with the other Group companies respecting their autonomy.

## **II.9 Fair competition**

The free market implies competition with the other pharmaceutical companies; however, said competition shall be constantly guided by principles of fairness, fair competition and transparency towards market players.

In compliance with Antitrust national and Community legislation, as well as the Guidelines and directives of the Italian Antitrust Authority, the Company does not engage in conduct nor enters into agreements which may adversely affect the competition regime among the various operators in the reference market or such as to negatively impact users and consumers in general, thereby basing its conduct on fair trading, preventing and condemning malpractices of any kind or nature.

All employees involved in pricing or licensing activities or in the purchase, sale and participation in



tenders or who are dealing with competitors, wholesalers, pharmacies or associations, are directly involved in activities which, if carried out with any conduct not in line with the provisions of these regulations, are likely to trigger proceedings in violation of antitrust laws.

It is against Company policy and the law to put in place agreements, arrangements, exchanges of information, discussions or communications with any competitor concerning prices, pricing policies, discounts, promotions, sales conditions, markets, production costs that are aimed at restricting or distorting free competition.

In order to prevent phenomena of this kind, the personnel are required to observe the strictest confidentiality of such sensitive data.

The Company relies on the services of a specific Corporate Antitrust and Privacy Compliance Office established within the Parent Company, with which the Company has a special services contract in place.

Any form of agreement, whether direct or indirect, which is entered into or put in place with competitors in order to modify or disrupt public tenders, takeovers or other proceedings relating to the purchase of goods or services by public administrations is also prohibited.

MALESCI S.p.A. also undertakes not to unduly damage the image of competitors and their products.

## **II.10 Privacy protection**

MALESCI S.p.A. is committed to protecting the privacy of the Directors, Auditors and Personnel, as well as of Third-Party Recipients, in compliance with applicable regulations, in order to prevent the disclosure or dissemination of personal data without the consent of the data subject.

The acquisition and processing, as well as the storage of information and personal data relating to the employees and the other entities whose data is in possession of the Company shall take place in accordance with specific procedures aimed at preventing disclosure to any authorised persons and/or entities. Such procedures are compliant with current regulations.

## **II.11 Service mindedness**

The Directors, Statutory Auditors, Independent Auditors and Personnel, as well as Third-Party Recipients shall gear their conduct, within the scope of their duties and responsibilities, towards the pursuit of the main corporate purposes aimed at providing a useful service of high social value to the community, which shall benefit from the highest quality standards.

## **II.12 Value of human resources**

Human resources are the main factor underpinning the company's development. The management of human resources is based on respect for the personality and professionalism of each one of them within the general framework of the current legislation.

MALESCI S.p.A. is aware that the high professionalism of its collaborators and their dedication to the Company are essential and critical factors to the pursuit of the Company's purposes.

For this reason, the Company protects professional growth and development in order to enhance the wealth of skills possessed, in compliance with the current legislation on the rights of individuals, particularly with regard to employees' moral and physical integrity.

MALESCI condemns all forms of recommendation and patronage.

The Personnel's selection is made based on matching the candidates' profiles with the highest technical and professional skills and the utmost focus on the respect for the ethical principles set forth by the Company.

In particular, the Personnel are recruited following a strict selection based on the curriculum of each candidate. With regard to Managers, special attention is paid to the degree grade, the time taken to achieve it, the knowledge of foreign languages, any internship abroad, the human characteristics and traits of the individual candidate, and the person's ability to respect the principles enshrined in the Code. On the other hand, with regard to Pharmaceutical Sales Representatives (hereinafter, I.S.F.), special attention is paid to their scientific and technical preparation, their human qualities, their moral integrity and their ability to comply with the principles enshrined in this Code. In particular, MALESCI guarantees the creation of opportunities for professional development and growth through tutorship, training courses and the availability of adequate information tools.

The Personnel are hired on the basis of regular work contracts.

The Company undertakes to ensure that, within its own corporate organisation, the annual targets are set so as not to lead to illegal conduct and to ensure that they are instead focused on a possible, specific, concrete and measurable outcome which is related to the time set for its achievement.

Any salary increases or other incentives and access to senior positions or roles depend on the rules established by law or by the collective bargaining agreement, as well as to the individual merits of the employees, including especially the ability to achieve the company's goals with behaviour and organisational skills founded on the Company's reference ethical principles set forth in this Code.

### **II.13 Relations with public institutions and local entities**

MALESCI S.p.A. aims to the highest integrity and fairness in its relations with the public institutions and more in general with the Public Administration, in order to ensure the utmost transparency in institutional relations.

In their relations with Public Officials and in any event in their relations with 'politically exposed persons' or with their family members or with the 'individuals closely linked' to them, as defined in Legislative Decree 231/07, Directors and Managers shall behave with the utmost fairness and integrity, even refraining from giving the impression of wanting to improperly influence decisions or requesting special treatment.

Any illegal payments in relations with the Institutions or with Public Officials, including with their family members and the individuals closely linked to them, are prohibited. All Recipients shall refrain from making payments of any amount in order to gain improper benefits in representing the Company before the Public Administration.

The Company expressly prohibits practices of corruption, favouritism, collusion, direct and/or indirect solicitations, including through promises of personal benefits vis-à-vis any individual belonging to the Public Administration.

In particular, the following patterns of conduct are prohibited:

- giving or offering, directly or indirectly, money and material benefits of any kind to public officials, persons in charge of a public service, politically exposed persons, their family members and to the persons closely and openly associated with them, in order to influence or remunerate an act of their official duties and/or the failure to perform an act of their official duties;
- offering gifts or other gratuities which may constitute forms of payment to officials or

employees from the Public Administration, to politically exposed persons, their family members and to the persons closely and openly associated with them;

- accepting and then meeting requests for money, favours or compensation from natural persons or legal persons who wish to enter into business relations with the Company as well as from any individual belonging to the Public Administration, from politically exposed persons, their family members and the persons closely and openly associated with them.

Gratuities, such as gifts, are permitted only if they are of modest value and such as not to jeopardise the integrity or reputation of either party, or such that they cannot be interpreted by an impartial observer as being aimed at obtaining benefits in an improper manner.

The Company therefore prohibits, also in its relations with private entities, practices of corruption, favouritism, collusion, direct/indirect solicitations including through promises of personal benefits.

Notwithstanding the obligations imposed by the legislation in force, the Recipients shall refrain, during business negotiations, requests or business relations with the institutions, with the Public Officials, with politically exposed persons, with their family members and with the persons closely associated with them, from undertaking the following actions:

- examining or proposing employment and/or business opportunities that could benefit the employees of the Institutions or Public Officials in their personal capacity;
- offering or otherwise providing, encouraging or accepting gifts, favours or practices of business or conduct that are not based on the utmost transparency, fairness and loyalty and that in any case do not comply with current regulations;
- soliciting or obtaining confidential information that may compromise the integrity or reputation of both parties or that in any event are in breach of public procedures put in place when maintaining relations with the Public Administration.

Practices of negotiation and/or renegotiation of the price of drugs based on false data or indices are expressly prohibited. Price negotiation activities are based on the scientific evidence of the results that can be achieved through the marketing of drugs, they shall be carried out jointly and be conducted on the basis of the interdisciplinary nature of the various skills.

Relations with institutional partners are maintained solely through parties especially appointed for such purpose also on account of their capacity.

Nevertheless, MALESCI shall not be represented, within the scope of its relations with Public Institutions, with Public Officials, with politically exposed persons, with their family members, with the individuals closely linked to them, by the Directors or Managers in respect of which a conflict of interests may arise.

In this regard, the Company prohibits the appointment as its representatives of entities that have a conflict of interests or have family relationships or are closely linked thereto, such as to improperly influence the decisions of any individual belonging to the Public Administration or that may be politically exposed.

The Company may use consultants, agents or third parties as its representatives in dealings with the Public Administration only if they have been given prior authorisation to the fulfilment of each single transaction.

#### **II.14 Relations with the community and environmental protection**

MALESCI attaches the utmost importance to environmental protection, and consequently it shall never seek any advantages that may possibly be related to the violation of environmental legislation.

In particular, the Company identifies the industrial solutions with the lowest environmental impact.

#### **II.15 Relations with associations, trade union organisations and political parties**

MALESCI S.p.A. shall refrain from financing political parties, movements, committees and political and trade union organisations, or their representatives or candidates.

It does not even finance associations, nor does it sponsor events or conferences that have political propaganda as their object.

The Company may issue contributions and donations in favour of entities with social, moral, scientific and cultural purposes.

#### **II.16 Relations with international operators**

MALESCI undertakes to ensure that all its dealings, including of a business nature, with entities operating internationally, shall be conducted in full compliance with the laws and regulations currently

in force.

#### **II.17. Condemnation of all forms of terrorism**

MALESCI condemns all forms of terrorism and undertakes to adopt – while performing its business - all necessary measures aimed at preventing the risk that the Company may be involved in terrorism, in order to contribute to the establishment of peace among peoples and democracy.

To this end, the Company's objective is not to establish any relationship - neither of a professional or commercial nature - with entities involved in terrorism, whether natural or legal persons, and also undertakes not to finance or facilitate any of their activity.

#### **II.18 Individual protection**

MALESCI recognises the need to protect individual freedom in all its forms and condemns all manifestations of violence, especially if aimed at limiting personal freedom. The Company undertakes to promote the sharing of the same principles within the scope of its business and among its employees, collaborators, suppliers and partners.

#### **II. 19 Workplace health and safety protection**

MALESCI is fully committed to pursuing the objective of ensuring workplace health and safety protection.

To this end, the Company shall take the most appropriate measures to avoid the risks associated with the performance of its business activities and, where this is not possible, to ensure the proper assessment of the risks, with the aim to address them directly at the beginning and ensure the elimination thereof or, where that is not possible, to ensure that they are properly managed.

MALESCI is required to identify and adopt all the appropriate measures required to protect workers' safety and health, including prevention of occupational hazards, information and training, as well as the preparation of the necessary organisation and means.

#### **II.20 Condemnation of organised crime**

MALESCI condemns all forms of organised crime (mafia-type criminal associations in particular) of a national or transnational nature and to this end it undertakes not to establish any relationship of a professional, collaboration or business nature with entities, be they natural or legal persons, directly or

indirectly involved in criminal organisations or, in any event, bound by kinship ties and/or close links with the representatives of known criminal organisations, and shall not finance or otherwise facilitate any activity linked to such organisations.

The Company shall take appropriate measures to prevent the risk of its involvement or that of its employees in relations and activities howsoever entertained and for whatever reason, including in the form of mere assistance and support, with those organisations.

#### **II.21 Protection of industrial and intellectual property rights**

MALESCI operates in full compliance with the legislation concerning the protection of trademarks, patents and other distinctive signs and with copyright law.

In particular, the Company does not allow the use of intellectual property that is free of the S.I.A.E. mark or that is in any event equipped with an altered or counterfeit mark.

The Company also prohibits the reproduction of programmes and the content of databases, as well as the acquisition and dissemination - in any form - of protected intellectual property, including through the disclosure of the relevant content before it is made public.

The Company does not permit the use, for any reason and for any purpose, of products with counterfeit trademarks and signs and the manufacture or marketing or, in any case, any activity related to products already patented by third parties and over which it has no rights.

#### **II.22 Collaboration with the Authorities in case of investigations**

In recognising the value of full cooperation with the judicial and administrative authorities, whether at the national or international level, MALESCI aims to operate with the utmost integrity and fairness with regard to relations with the competent authorities.

To this end, the Company prohibits any conduct intended or suitable to interfere with the investigations or inquires conducted by the competent Authorities and, in particular, any conduct intended to hamper the search for truth, including through the incitement of parties summoned by the Court not to make statements or to make false statements.

The Company undertakes to take all the necessary measures to provide the cooperation requested by the Authorities in accordance with applicable regulations.

#### **II.23 Correct use of IT systems**

The Company pursues the objective of ensuring the correct use of IT and/or telecommunication services, in compliance with the legislation currently in force and in order to guarantee the integrity and authenticity of the data processed, with a view to protecting the Company's interests and those of third parties, with particular reference to public Authorities and Institutions.

To this end, MALESCI shall take all appropriate measures to ensure that access to electronic and computerised data shall take place in full compliance with the regulations currently in force and the privacy of the parties involved, if any, and to guarantee the confidentiality of the information and ensure that it is processed by entities specifically authorised to do so, thereby preventing any undue interference.

More specifically, the Company prohibits the following conduct:

- the unlawful access into computer or telecommunications systems protected by security measures;
- the destruction, damage, cancellation or alteration of information, data or computerised programmes belonging to third parties, the State or other public Entity;
- the exhibition of false electronic documents, whether private or public, having evidentiary effect;
- the installation of equipment designed to intercept, prevent or interrupt communications relating to a computerised or telecommunications system or among multiple systems;
- the unlawful removal, reproduction, distribution or delivery of codes, keywords or other means suitable to gain access to a computerised or telecommunications system protected by security measures.

## **II. 24 Relations with private entities and condemnation of corruption**

MALESCI, in condemning all forms of corruption, considers it of fundamental and essential importance to ensure that all relations with private entities (suppliers, competitors, clients, consultants, business partners etc.) be based on the utmost loyalty, integrity, fairness and good faith.

### **II.25 Protection of the share capital and creditors**

One of the key aspects that define the Company's ethical conduct is the compliance with the principles of conduct intended to ensure the integrity of the share capital, the protection of creditors and third parties entertaining relations with the Company, and, in general, the Company's transparency and fairness from an economic and financial point of view. Therefore, MALESCI S.p.A. intends to ensure the dissemination and observance of rules of conduct designed to safeguard the afore-mentioned values, in order to prevent the commission of the corporate crimes covered by Legislative Decree 231/01.



## **II.26 Accounting audit and transparency**

The Recipients are committed to ensuring that all actions relating to the management of the Company are represented in a true and fair manner from MALESCI S.p.A.'s accounting point of view.

All the transactions carried out are based on the following principles:

- utmost fairness from a management point of view;
- completeness and transparency of the information;
- lawfulness in form and substance;
- clarity and truthfulness of its accounting records according to relevant regulations and internal procedures.

The accounting documentation shall conform to the principles mentioned above and shall be easily traced and filed according to logical criteria.

In any case, the corporate payments to be disbursed shall be solely proportional to the service and according to the terms of the contract and may not be issued to an entity other than the contracting party.

The use of corporate funds for improper or illegal purposes is strictly prohibited. Under no circumstances shall anyone receive payments that are not based on properly authorised business transactions or be offered illegal forms of remuneration.

The Company requires that the entry in the financial statements of all assets, such as receivables, inventories, investments and expenses stems from the unconditional respect of all the applicable standards on financial statements preparation and evaluation. The Company therefore prevents the creation of false, incomplete or misleading records and ensures that no secret funds or unregistered funds are set up or deposited in personal accounts and that no invoices are issued against non-existent transactions.

The documents certifying the accounting records shall allow the swift reconstruction of the accounting transaction and the identification of any error.

The internal company procedures govern the execution of all business operations and transactions, including the reimbursement of expenses to employees and/or external collaborators in any capacity, and/or professionals, which shall be able to identify, in relation to the financial resources to be used or

used, the legality, authorisation, consistency, congruity, correct registration and verifiability thereof.

The Company may grant contributions or sponsorships, to private and public non-profit organisations, especially those aimed at social and cultural objectives, in compliance with accounting, budget and tax regulations, with procedures of the utmost transparency, with specific reference to the criteria adopted and the consistency of the related commitments.

## **II.27 Anti-money laundering**

MALESCI and all employees shall not be involved in operations that could give rise to the laundering of criminal or illegal proceeds in the interest of or to the benefit of the Company.

The Company pursues the utmost transparency in business transactions and adopts all possible means to combat the phenomena of money laundering and receipt of stolen goods.

Moreover, the Company ensures compliance with the principles of fairness, transparency and good faith in dealing with all contractual counterparts, even if they are part of the same Group.

## **II.28 Internal control**

It is the Company's policy to disseminate, at all levels of the organisation, not only a culture characterised by the existence and importance of a system of controls, but also to convey a mental approach geared towards the application thereof.

Through its system of internal control, MALESCI intends to pursue the general objectives of effectiveness and efficiency of its operations, protection of corporate assets and resources, compliance with laws, regulations and internal procedures, as well as reliability of accounting and financial data.

Each level of the organisation and each corporate function is, therefore, specifically responsible for implementing, maintaining and monitoring the proper functioning and effectiveness of the internal control system. As regards its internal control monitoring activities, Menarini IFR's Corporate Internal Auditing & Compliance Department shall have full and free access to the Company's data and documentation and shall report solely to the Board of Directors.

### III. Rules of conduct

#### III.1 Rules of conduct for Corporate Body members

MALESCI S.p.A.'s Corporate Bodies, aware of their responsibilities, in addition to compliance with the law, the regulations in force and the Articles of Association, are required to comply with the provisions of this Code of Ethics, thereby basing their activities in the pursuit of the company's profit and growth on values of honesty, integrity, fairness, transparency, respect for people and the rules, and cooperation with the Company's top management.

The entire Board of Directors is in charge of the responsible conduct of the Company in the pursuit of the goals of patients' care, the respect for their dignity and the offer of highly qualified drugs, all objectives to which the pursuit of corporate profit shall be subject.

The Corporate Body members are required:

- to engage in conduct based on autonomy, independence, and fairness with public institutions, private entities (including the company's creditors), business associations, political parties, as well as with any other national and international operator;
- to behave with integrity, loyalty and a sense of responsibility towards the Company;
- to ensure constant and informed participation in the meetings and activities of the Corporate Bodies;
- to ensure the sharing of the mission and a critical approach, so as to ensure a significant personal contribution based on the awareness of the position held;
- to assess situations of conflict of interests or incompatibility of functions, duties or positions outside and inside the Company, refraining from being involved in situations of conflict of interests within the scope of its activities;
- to process any information which they gain access to in the performance of their duties in a confidential manner, thereby refraining from taking advantage of their position to obtain personal benefits, whether direct or indirect. All communications sent outside the Company

shall comply with the laws and rules of conduct and shall be aimed at safeguarding sensitive information as well as inside information;

- to comply, to the extent applicable and within the scope of their responsibilities, with the rules of conduct set forth for Personnel in the following paragraph.

The Corporate Bodies are specifically tasked with promoting the Company's image and standing. This task shall be carried out by taking as the main reference point the respect and protection of patient care requirements, the provision of highly specialised services, and the marketing of scientifically advanced drugs, objectives which are implemented thanks to technically trained personnel who constantly focus on the compliance with ethical values, as laid down in this Code.

### **III.2 Rules of conduct for Personnel**

Personnel shall base their conduct, in both internal and external relations, on the regulations currently in force, on FARMINDUSTRIA's Code of Professional Conduct, as well as on the principles enshrined in this Code of Ethics, in addition to the rules of conduct set out below, in compliance with the Model and the company procedures in force.

More specifically, the Company's Top Management is required:

- to behave with integrity, loyalty and a sense of responsibility towards the Company;
- to represent an example for its employees through their conduct;
- to comply with the laws implemented in the pharmaceutical and health care sector;
- to comply with the laws relating to the correct and transparent management of the Company;
- to guide employees towards the observance of the Code;
- to ensure that employees are always mindful of the principles of the Code of Ethics and that their compliance is an integral part of their work.

The Management is entitled to express diverging views from those of Corporate Bodies, provided that this is purely conducive to the need to improve the quality of services offered. Information received in the performance of their duties is considered to be of a confidential nature and any use thereof not resulting from the institutional fulfilment of the duties is prohibited.

Furthermore, the Medical-Scientific Management is also required to take care of the following:

- the preparation of guidelines addressed to subordinates aimed at achieving sector-specific objectives, giving priority to the scientific aspect over the marketing one, with particular reference to the proper disclosure of medical and scientific knowledge about the Company's

drugs;

- adequate and constant information on current health laws and on the regulations and protocols disclosed by FARMINDUSTRIA;
- the constant check on the preparation of the medical staff working at the Company;
- the constant check on whether patients' treatment needs are being met.

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

- refrain from engaging in conduct contrary to the rules set forth by the Code of Ethics;
- not to engage in, give rise to or contribute to such conduct as to constitute any of the offences referred to in the Decree;
- cooperate with the Supervisory Body during the verification and supervision activities performed by same, thereby providing any information, data and updates it may request;
- submit the reports provided for by this Code to the Supervisory Body;
- report to the Supervisory Body any departures from or breaches of the Model and/or the Code of Ethics, in compliance with the provisions laid down in this Code and the Model.

In any event, it is recalled that:

- all actions and transactions, and in general the conduct put in place by the Company's employees in the performance of their professional duties shall be based on the utmost transparency, fairness and lawfulness;
- all the company's activities shall be carried out with the utmost care and professional rigour;
- each employee shall provide skills and expertise adequate to the duties assigned and shall act to protect the reputation and good name of the Company;
- relations among employees, at all levels, shall be based on the principles of probity, collaboration, loyalty and mutual respect.

In any event, all Company employees are responsible for acquiring knowledge of the laws and regulations relevant to their duties in order to recognise any potential risks and in such case request the support of the Supervisory Board.

The Personnel may at any time request clarification from the Supervisory Board, both in writing and verbally, as to the proper interpretation of the Code of Ethics or the protocols related to the Model, the lawfulness of concrete behaviour or conduct, or more in general the compliance of certain patterns of conduct with the Model or the Code of Ethics.

In any event, the Personnel are required to abide by the principles and rules of conduct set out

hereunder.

### ***III.2.a) Conflict of interests***

The Personnel shall refrain from engaging in or facilitating transactions involving conflicts of interest - whether actual or potential - with the Company, as well as any activity that may interfere with the ability to take impartial decisions in the best interests of the Company and in compliance with the provisions of this Code.

The Personnel are required to inform their superior of any interest on their own account or on that of third parties that they may have in an operation in which they are involved. Any such communication shall be precise and shall specify the nature, terms, and the origin of the advantage. Pending the company's decisions on the matter, they shall refrain from taking any action.

### ***III.2.b) Relations with the Public Authorities***

All relations with entities that qualify as Public Officials, politically exposed persons, their family members and in any event people closely and openly linked to them, or Persons in charge of a Public Service shall be conducted in full compliance with the laws and regulations in force, as well as with the Model and Code of Ethics, in order to ensure the absolute lawfulness of the Company's operations.

Relations with Public Institutions are reserved exclusively to the functions and responsibilities duly appointed by virtue of specific powers or attorney.

MALESCI S.p.A. prohibits the Personnel to accept, offer or promise, even indirectly, money, gifts, goods, services, benefits or favours (even in terms of employment opportunities) in their relations with Public Officials, Persons in charge of a Public Service, with politically exposed persons, with their family members and with persons closely and openly associated with them, aimed at influencing their decisions, in view of more favourable treatment or undue services or for any other purpose.

It is prohibited to engage in any conduct that is in any way aimed at promising or giving to Public Officials, Persons in charge of a Public Service, politically exposed persons, their family members and persons closely and openly associated with them, money or other compensation in order to induce them to perform an act of their official duties in order to gain an advantage for oneself or for the Company.

Any requests or offers of money, gifts (except those of modest value, intended as those of a customary nature in such circumstances as may be interpreted by an impartial observer), favours of any kind, given or received by the Personnel, shall be promptly brought to the attention of their superior and the Supervisory Board.

Gifts and gratuities to Public Officials, Persons in charge of a Public Service or, in any event, public employees are permitted only when, due to their modest value, they do not howsoever compromise the integrity and independence of the parties and may not be interpreted as a means of obtaining undue advantages.

In its relations with the Public Administration, the employees or the functions which, by virtue of their duties or powers, put forward requests, management and/or administration of grants, subsidies, loans, reimbursements from the State or other Public Entity are required to exercise their powers solely for the purposes for which they were conferred, to make use of the other functions required by company processes, to keep accurate records of each transaction to ensure the utmost transparency and clarity of the agreements and the related money transactions.

In any case, during negotiations or any other dealings with the Public Administration, the Personnel shall refrain from engaging, directly or indirectly, in actions aimed at:

- proposing employment and/or business opportunities which may lead to benefits, for themselves or others, to employees of the Public Administration or their relatives or in-laws;
- soliciting or obtaining confidential information that could compromise the integrity or reputation of one or both parties.

In the event of investigations, inquiries or requests from the Public Authority, the Personnel are required to ensure due cooperation.

### ***III.2.c) Relations with clients and suppliers***

The Personnel shall base their relations with clients (e.g. pharmacists, healthcare workers, wholesalers, healthcare entities and institutions) and suppliers on the utmost fairness and transparency, in compliance with the laws and regulations in force, with the Model and the Code of Ethics, as well as with internal procedures and, in particular, with those relating to client relations and those relating to procurement and supplier selection.

More specifically, as regards tenders, procurement and the supply of goods or services in general, employees shall:

- follow internal procedures for the selection and management of suppliers' relations;
- not prevent any supplier company meeting the necessary requirements from having the possibility of bidding for the supply of the company's services by adopting objective evaluation criteria in the selection according to established and transparent methods;
- obtain the suppliers' cooperation in constantly meeting the requirements of the company's clients in terms of quality, cost and delivery times;

- use to the largest extent possible, in compliance with the applicable laws, products and services provided by Group companies under competitive conditions;
- observe and enforce the contractual conditions;
- maintain an honest dialogue with suppliers;
- report to their superior any issues involving suppliers.

Conversely, with regard to client relations, employees are required to:

- follow internal procedures for the selection and management of clients' relations;
- provide full and accurate information about products and services so that clients can make informed decisions;
- provide truthful information in advertising communications or of another nature.

### **III.2.d) Direct scientific information**

#### **(a) GENERAL PRINCIPLES**

The Personnel are required to comply with the regulations currently in force, and in particular with the provisions laid down in Legislative Decree 219/2006, in FARMINDUSTRIA's Code of Professional Conduct and in the company procedures currently in force, with specific reference to scientific information and the promotional initiatives concerning MALESCI's products.

The Company is responsible for the information and promotional actions conducted on their products even if arranged and/or performed by third parties (consultants, agents, agencies, etc.).

The information contents shall always be documented and documentable. Exaggerated statements, universal and exaggerated claims and indemonstrable comparisons without any objective basis are inadmissible.

The use of fax, email, automated calling systems and other electronic communication means to divulge promotional material regularly approved by AIFA is prohibited, unless the Company holds a prior written and documented consent of the physician to whom the material is addressed.

#### **(b) VERBAL INFORMATION IMPARTED TO PHYSICIANS**

When presenting information on medicinal products to healthcare professionals, pharmaceutical sales representatives shall always qualify themselves and state the capacity in which they are acting. Pharmaceutical sales representatives shall not be engaged in healthcare or para-healthcare activities, or activities in any way connected to the use of drugs, even if gratuitous, or in any form of continuous activity resulting in actual employment.



The Company is responsible for allowing (and it actually does it) pharmaceutical sales representatives to provide information on the properties and characteristics of drugs to healthcare professionals so that drugs can be used for correct therapeutic purposes.

The Company shall also be responsible for allowing (and it actually does it) pharmaceutical sales representatives to collect feedback on their drugs in order to ensure the fullest information on the products being marketed.

The Company pays special attention to matters relating to drug safety and strives to enable, and actually enables, pharmaceutical sales representatives to always inform physicians in detail in those cases where the use of the drug is not recommended or contraindicated.

When performing their tasks, pharmaceutical sales representatives shall verify and ensure the availability of the Company's products in pharmacies or in any other points of sale.

*(c) INFORMATIONAL MATERIAL*

The information material concerning drugs marketed by MALESCI prepared and used by the Company as part of scientific information to physicians shall make reference to the official documentation provided by AIFA upon product registration or in that subsequently approved by the same Agency in accordance with the laws in force.

Where the scientific information activity is carried out using IT devices, mails or by phone, including through qualified third parties, the same regulatory provisions identified by the applicable law and Farindustria's Code of Professional Conduct on scientific information shall be fully respected.

Irrespective of ministerial authorisations, no general statements are admissible such as "the preferred drug", "absolutely safe", "fully tolerated" or similar and no categorical assertions shall be made stating that a product has no side effects or toxicity risk.

Scientific citations shall accurately portray the meaning intended by the author(s).

The texts, tables and other illustrations taken from medical reviews or scientific works shall be reproduced faithfully and in full, and with an exact indication of the source. No citations are admissible that appear partial and/ or contradictory with respect to the author's intentions when separated from the context in which they originally appeared.

*(d) PROMOTIONAL MATERIAL*

In the framework of information activities and the presentation of medicinal products to physicians or pharmacists, no prizes, pecuniary advantages or rewards in kind shall be granted, offered or promised. Therefore, promotional material concerning drugs and/or their use, sponsored by MALESCI, shall have a negligible value, shall not be exchangeable and in any case shall be connected to the activities

performed by physicians and pharmacists. This material shall also clearly indicate the Company name or the sponsored product.

The offer of any kind of financial incentives designed to compensate healthcare professionals for time spent on extraordinary professional activities in order to participate in congresses is prohibited under all circumstances.

It shall also be guaranteed that all promotional material for physicians and pharmacists shall be acquired directly by the Company through a centralised function, as provided for by specific company procedures.

*(e) PROFESSIONAL UPDATING AND SCIENTIFIC COOPERATION*

Free information material for scientific or professional consultation not specifically connected to medicinal products may be distributed provided that it is associated with initiatives of a highly scientific value, aimed at qualifying therapeutic services. The distribution of said material may be carried out solely to public healthcare facilities unless said material has a perceivably negligible value, namely a value of less than 25 euro, in which case it may be distributed directly to the physician. The Company shall procure such material directly through a centralised function, as provided for by specific company procedures.

As concerns donations, gratuitous loans for use and gratuities involving devices directly related to the medical profession, such offers may only be made in favour of university institutes, hospitals and clinics and in compliance with the administrative procedures of the Entity concerned.

*(f) ADVERTISING IN NEWSPAPERS AND MAGAZINES*

As regards newspaper and magazine advertising, MALESCI shall comply with the rule of transparency and thereby ensure the separation between information and advertising, thus guaranteeing the reader to be immediately able to recognise a promotional message, whatever its editorial or columnar layout.

*(g) FREE SAMPLES*

Free drug samples for human consumption can only be supplied in response to a written request from physicians qualified to prescribe that particular medicine and shall be delivered solely to pharmaceutical sales representatives. Written requests shall be signed, stamped and dated by physicians.

As regards the quantity/time limits, the Company shall adhere to the provisions laid down by Farindustria's Code of Professional Conduct.

### *III.2.e) Scientific conferences, conventions and meetings*

#### *(a) GENERAL PRINCIPLES*

The Personnel are required to comply with the regulations currently in force, as well as the provisions laid down by FARMINDUSTRIA's Code of Professional Conduct and the applicable company procedures, as regards conventions, congresses and scientific meetings held to discuss topics related in a variety of ways to the use of medicinal products, which allow the industry to meet healthcare professionals and involve different kinds of participants.

A Personnel member that intends to invite physicians to congresses or conferences shall, together with the physicians' acceptance, also acquire express consent to use their personal details (including name, the indication of any specialisations acquired as well as proof of their compliance with the general and regional laws on the obligation to inform their reference healthcare facilities of their sponsored participation in such conferences) and disclose such details to the Supervisory Committee for the sole purpose of enabling to check compliance with the Code of Professional Conduct during a specific convention, congress or laboratory visit. It is also necessary to request consent to the disclosure of "transfers of value".

MALESCI shall be required to submit said documentation to FARMINDUSTRIA's Supervisory Committee upon the latter's request, on pain of the case being automatically referred to FARMINDUSTRIA's Jury for the application of a possible sanction against the Company.

The Company's participation in conferences shall be related to the role performed in research, development and scientific information sectors and shall be based on ethical, scientific and cost-effective criteria.

No meetings or congresses may be directly organised by the Company outside Italy if it is to be mainly attended by Italian physicians.

Air travel costs shall be reimbursed only for economy-class and accommodation costs shall be reimbursed solely with reference to maximum four-star hotels.

In any event, the Company may not invite the same healthcare professional to congresses, conferences, scientific meetings and company laboratory visits more than twice a year. However, this restriction does not apply to speakers or moderators or CME local initiatives organised in hospitals that

do not entail any form of hospitality with the exception of coffee breaks.

Similarly, the limit of two annual invitations shall not apply to training events concerned with specific pathologies, in case of a public pronouncement by the World Health Organisation of potential healthcare crises higher than the IV alert level. In this case, derogation from the limit can only refer to initiatives:

- exclusively designed to update physicians on the pathology;
- organised by public organisations;
- held on the premises of the foregoing public organisations;
- that have acquired CME credits;
- that do not make provision for any kind of hospitality;
- for which prior information was sent to Farindustria.

It is forbidden to organise or sponsor congresses that are held or which provide the hospitality of the participants in structures such as: Resorts, Ships, Castles, which are outside the city, Farms, Holiday Farm Houses, Golf Clubs, thermal structures or structures having as main activity services dedicated to Wellness or SPA resorts.

Invitations issued to physicians to attend conferences and congresses are subject to the condition that the topic of the congressional meeting shall relate to the specialisation of the attending physicians.

The main objective of the participation in or organisation of international, national and regional conferences and congresses shall be to promote scientific cooperation between physicians.

In no event may scientific initiatives be organised that also serve tourist purposes.

As concerns the choice of venue for meetings organised directly or indirectly by the Company, the latter shall provide sound scientific, organisational and logistic reasons for the choice of the venue, with the exception of catering locations, and such venue shall be characterised by a qualifying scientific programme. The participants invited to meetings shall be chosen on an international, national or at least regional basis. Exclusively touristic places are strictly prohibited in the following periods:

- from 1 June to 30 September as concerns seaside places;
- from 1 December to 31 March and from 1 July to 31 August as concerns mountain places.

The purpose of scientific meetings at the local level is to complete drug scientific information

activities. They may not last longer than 12 hours. The number of participants invited to meetings is lower at the regional level.

*(b) INTERNATIONAL, NATIONAL AND REGIONAL EVENTS*

MALESCI's involvement in the hospitality offered to participants in congressional events may not have characteristics such as to overshadow the technical-scientific characteristics of the event.

At least 10% of the physicians participating in such events shall be under 40 years of age. Said percentage shall in any event be guaranteed at least on an annual basis. Furthermore, the time of the hospitality offered to participants may not exceed a 12-hour time period prior to and immediately after the Congress.

Any hospitality costs during events shall not regard general practitioners, unless these events are conventions that have acquired CME credits.

As regards conference meetings in or outside Italy it is forbidden to arrange or sponsor autonomous initiatives with social, cultural or tourist purposes, including gala dinners. Social dinners organised by the Congress for the participants as a whole are allowed and shall be included in the registration fees.

No hospitality of any kind or form can be offered to companions of the persons invited.

Non-CME conference events organised at a national level shall not last less than six hours per day. The provision of this paragraph shall not apply to events organised directly by national or international scientific companies.

Hospitality offered during congress events shall be limited to travel, accommodation and payment of the Congress registration fees. During the days of the congress the hospitality offered may also include meals and drinks up to a threshold of 60 euro per each Professional per meal for all events held in Italy. As for events held abroad, referral shall be made to the amounts and thresholds mentioned in the relative country's Code of Professional Conduct, where applicable. In any other case, the limit remains fixed at 60 euro also for events held abroad. The respect of the principle of sobriety shall, however, be guaranteed and the meal shall be offered preferably in the same hotel where the guests are staying or in contiguous structures.

Furthermore, no hospitality of any kind or form can be offered to companions of the persons invited.

*(c) PROMOTIONAL MATERIAL USED AT CONGRESSES*

During congresses gadgets of negligible value and relevant to the physician or pharmacist profession may be distributed with the exception of objects that graphically recall packaging of medicinal products. The name of the proprietary medicinal products and/ or the name of the active ingredient and /or the

name of the Company may be written on the gadgets.

*(d) ONLINE REFRESHER COURSES AND TRAINING*

The medical-scientific training and refresher courses through the electronic tools such as web meetings, e-meetings or FAD and similar events shall not provide any form of hospitality and shall not be subject to any restriction in terms of the duration of the work.

*(e) LOCAL SCIENTIFIC MEETINGS*

Scientific meetings at the local level may be sponsored only if the event is CME accredited. Such events shall be held in locations such as hospitals, universities, scientific foundations and conference rooms that ensure scientific dignity.

Local scientific meetings may entail limited participation by physicians, who shall predictably be selected on a basis below the regional level. Such meetings shall not last more than 12 hours in total. Participants in a local scientific meeting shall only be offered a coffee break. If the event lasts longer than six hours they may be offered a small business breakfast between the morning and afternoon sessions.

*(f) INTERREGIONAL EVENTS*

The interregional events are characterised by a balanced representation of physicians from at least three regions and shall not require more than an overnight stay. These initiatives follow the same rules laid down in Farmindustria's Code of Professional Conduct for national events.

*(g) REFRESHER COURSES*

The rules set forth for scientific congresses, conventions and meetings also apply to the medical-scientific refresher courses organised at any territorial level.

The Company is prohibited from organising or sponsoring the participation of professionals in refresher courses that do not have a medical or scientific character, such as foreign language, IT, or tax courses or similar initiatives.

The sponsorship of initiatives directed at healthcare professionals' training (i.e. the various medical staff, pharmacists, health managers, technical and administrative personnel of public and private healthcare facilities) and relating to topics associated with the healthcare management directly related to the drugs is instead allowed, provided that they are held in Italy, are organised by qualified entities,

take place in hospital or university venues or venues that are at least capable of ensuring scientific dignity and are completed within the course of a day with a forecast actual work of at least 6 hours. In these cases, companies shall not bear any hospitality costs except for a light lunch.

The sponsorship of initiatives whose duration is more than one day is only allowed in the case of national level events organised by companies qualified in relation to the subject matter. In this case, pharmaceutical companies may also bear the participants' travel and accommodation costs for a maximum of one night stay.

#### (h) SATELLITE SYMPOSIA

If companies organise satellite symposia held simultaneously with conference events in Italy or abroad, it shall be necessary to comply with current regulations and professional rules on Conferences and Meetings and, where applicable, the rules of Continuing Education in Medicine. These initiatives shall be held either as part of the main event or in the half day before the start or following the end of the same. If it starts in the afternoon, the satellite symposium shall be held in the morning of the same day or in the afternoon of the last day in the event that the main event shall end at midday.

#### (i) VISITS TO COMPANY LABORATORIES

MALESCI organises physicians' visits to company laboratories. However, the organisation of such visits takes into account the following rules of conduct:

- the duration of the visit shall not exceed the time strictly necessary for it to be held;
- the hospitality offered shall be limited to the period of time laid down in FARMINDUSTRIA's Code of Professional Conduct (in particular, it is included between the twelve hours prior to and immediately following the end of the initiative);
- the nature of the visit shall not be such as to compromise the technical purposes thereof;
- costs may be reimbursed solely for economy-class air travel and stays in maximum four-star hotels.
- no hospitality of any kind or form shall be offered to companions of the persons invited.

Under no circumstances shall the organisation of visits to company laboratories, including for tourism purposes, be allowed.

#### (l) INVESTIGATORS' MEETINGS

The term *Investigators' meetings* refers to study meetings called by investigators for the purpose of pre-clinical, clinical or observational studies organised by the Company. Such meetings shall comprise a

number of participants proportionate to the number of Centres involved in the study, aim to the draft of a protocol to be filed at the local Ethical Committee or be attested to by the existence of a specific protocol filed with the local Ethical Committee, and have no promotional implications.

The duration of the initiative shall comply with the meeting programme excluding tourism or recreation aspects as well as hospitality for companions of any type.

The choice of the venue shall be made in compliance with the criteria identified for the choice of conferences and congresses as well as the identification of the limits of the hospitality offered.

The organisation or sponsorship of initiatives that take place abroad and concern studies involving mostly Italian centres or mainly the participation of Italian physicians shall not be allowed.

If, in order to get to the Investigator meetings' venue, intercontinental flights longer than 6 consecutive hours are necessary, it shall be possible to provide participants with business class travel. This possibility is not applicable to Investigators' Meetings related to observational studies.

#### (m) THE INITIATIVES OF PROFESSIONAL RELATIONS

PR initiatives with Healthcare Operators (such as business lunches and dinners) may be carried out only if the following conditions are met:

- a number of Operators generally no higher than 6;
- company directors, possibly accompanied by an Area Manager or similar role, peremptorily excluding territorial operational roles.

Such initiatives shall, moreover, be inspired by the principles of sobriety and shall not be of a repetitive nature.

### ***III.2.f) Relations between the industry, the scientific and healthcare sector and patients' associations***

#### ***(a) SCIENTIFIC CONSULTANCY AND SCHOLARSHIPS***

Within the scope of scientific cooperation activities between the Company and the scientific world, the Personnel are required to comply with current regulations, with the provisions of FARMINDUSTRIA's Code of Professional Conduct and with the applicable company procedures.

The collaboration can also be performed through scholarships and scientific consultancy, as long as the consistency, adequacy and traceability of the initiative are observed.

The decision-making aspect of such initiatives shall be reserved for operational top management and is of a joint nature in compliance with applicable company procedures.



(b) *RELATIONS WITH SCIENTIFIC COMPANIES*

Cooperation with Scientific Companies and Medical Associations aims at disclosing scientific knowledge and improving professional knowledge and is undertaken with entities of proven reliability and national standing, and whose mission is well known.

(c) *CLINICAL TRIALS AND DRUG-RELATED STUDIES*

In the phase immediately following the issue of authorisation to market proprietary medicinal products, only clinical trials authorised pursuant to the law governing such activities shall be allowed. Clinical studies, post marketing surveillance studies and surveys conducted after the marketing of a drug shall be exclusively conducted for scientific purposes.

The performance of so-called 'Drug-related studies' – also referred to as 'Non-Interventional Clinical Trial', 'Observational Study' or 'Epidemiologic Study' – is subject to compliance with the provisions laid down in the circular of the Ministry of Health 2 September 2002, no. 6 "*Activities of the Ethical Committees established pursuant to Ministerial Decree 18.3.98*" and the resolution of AIFA of 20.3.08 setting out the guidelines for the classification and management of drug observational studies.

In any event, the Company undertakes to meet the following conditions:

- a written contract shall be drawn up with the entities involved in the study, which shall contain the detail of its characteristics and the nature of the services offered;
- the Study Protocol shall be approved by the company Medical Department which shall also ensure that the Study is conducted through *clinical monitors*;
- any remuneration provided for participating in the Study shall meet cost-effective criteria and reflect the market value of the work performed;
- pharmaceutical sales representatives shall not be involved in aspects of a business-financial nature and their involvement, if any, shall only take place in a logistical capacity under the supervision of the Medical Department and shall be subject to appropriate prior training.
- the Study shall not contain elements such as to encourage or suggest the prescription or purchase of a particular medicinal product.

In the event that, for purposes of study or training initiatives undertaken directly or indirectly by the Company, recourse is made to the use of instruments exclusively for the foregoing studies or initiatives, the distribution to physicians of the relevant instruments shall take place through an Entity or Entities involved in the study (local health offices, universities, hospital agencies and Institutes for

Treatment and Research) and their use shall be regulated by the application of a specific Agreement between the Company and the foregoing Entities.

In every case, it shall be specified that the instruments can be used for a determined period and exclusively for the purpose of completing the study or the training initiative, that they shall be withdrawn at the conclusion of the study or initiative and that they cannot be used again for immediately successive enquiries to be conducted by the Company with the same Entities.

The withdrawal shall be specifically documented.

In all cases the use of IT instruments is expressly forbidden (such as notebook or desktop computers, handhelds and similar products).

*(d) INTERNET SITES*

The internet site opened by the Company and addressed to the general public, in addition to complying with the requirements laid down under the regulations and the relevant laws in force, shall also guarantee that the source of all information set forth in the site, the designated recipients of such information and the objectives of the site are all clearly identified. The Company guarantees that access to sections containing promotional information on drugs which cannot be advertised to the general public shall be exclusively reserved to pharmacists and physicians. The Company also guarantees that any promotional messages relating to the drugs advertised to the general public shall be included on the Internet site in compliance with current regulations.

*(e) RELATIONS WITH PATIENTS' ASSOCIATIONS*

Any form of economic support, whether direct or indirect towards a Patients' Association shall comply with the following criteria:

- a specific and preliminary agreement aimed at regulating the amount of financing and the reasons for its disbursement shall be entered into in compliance with company procedures;
- the public use by the Company of the logo or material owned by the Patients' Association shall be authorised in advance by the association;
- any form of sponsorship regarding Patients' Associations shall be transparent and without promotional objectives;
- the Company shall not - under any circumstances - include a clause aimed at requesting to be the sole sponsor of a given Patients' Association;
- in all cases in which journeys or other forms of hospitality are provided, the provisions set

out on conferences and congresses shall apply;

- the list of any supported Patients' Associations shall be included on the Company's Internet site.

Only contracts between the Company and Patients' Associations providing Services to companies shall be allowed for the sole purpose of supporting Healthcare or Research. Patients' Associations representatives may be engaged as experts and consultants for Services such as participation in advisory board meetings and speakers. A written contract or agreement shall be agreed in advance which specifies the nature of the Services to be provided and the basis for payment of those Services. A legitimate need for the Services shall be clearly identified and documented in advance of requesting the Services. The compensation for the Services shall be reasonable and not exceed the fair market value of the Services. Pharmaceutical companies shall make publicly available each year a list of Patients' Associations that they have engaged to provide contracted Services.

#### ***III.2.g) Participation in tenders***

As regards the participation in tender procedures, it is necessary to adopt the following conduct:

- to act in accordance with the principles of fairness, transparency and good faith;
- to assess, in the examination of the tender notice, the appropriateness and feasibility of the services required;
- to provide all data, information and updates required in the selection of participants and officials for the purposes of awarding the tender;
- in the event of public tenders, to entertain, with the public officials in charge, clear and fair relations, thereby avoiding any conduct that might compromise the freedom of judgment of the relevant officials.

In the event of the tender being awarded, in the relations entertained with clients it is necessary:

- to ensure the performance of the negotiations and business relations in a clear and transparent manner;
- to ensure the diligent fulfilment of contractual obligations.

#### ***III.2.h) Professional update obligation***

In the fulfilment of their duties on behalf of MALESCI, all employees are required to maintain a high degree of professionalism at all times.

Moreover, all employees, in relation to their specific areas of responsibility, are required to be constantly updated on a professional level.

### **III.2.i) Confidentiality**

The personnel are required to process all data, information and updates in their possession with the utmost confidentiality, including after the termination of the employment relationship. In particular, it is necessary to prevent the dissemination of such information or its use for one's own speculative purposes or those of third parties.

The personnel shall also process the information and data relating to strategic roles, functions and sensitive processes with absolute confidentiality, especially when they are functions and processes exposed to any form of external solicitation.

The personnel are required to process the information regarding the goods and services procurement process with the utmost confidentiality.

Any other information, data or document which employees become aware of during the performance of their duties shall be the Company's exclusive property, including, but not limited to, every idea, formula, technique, invention, programme, business plan, marketing and sales plan and similar information, which shall constitute confidential information and the exclusive property of MALESCI S.p.A.

It is therefore prohibited to disclose such information externally without express permission and to use it for one's own personal advantage. Without prejudice to the prohibition to disclose information concerning the company's organisation and production methods or use it in such a way as to cause damage to it, all employees, in particular, are required to:

- acquire and process only the necessary and appropriate data for purposes directly related to the function performed;
- acquire and process such data only within the scope of specified procedures;
- store the data in such a way as to prevent any unauthorised entities from acquiring knowledge thereof;
- communicate the same data within the scope of predetermined procedures and/or upon explicit authorisation from superiors;
- ensure that there are no absolute constraints or constraints relating to the possible

disclosure of information concerning third parties bound to the Company by virtue of a contract of whatsoever nature and, where appropriate, obtain their consent.

Information of a confidential nature may be disclosed only to the Supervisory Body or the judicial authorities.

#### ***III.2.j) Diligent use of the company's assets***

The Personnel shall protect and preserve any valuables and assets belonging to the Company that has been entrusted to them, and contribute to the protection of the Company's assets in general, avoiding situations that might adversely affect the integrity and safety of such assets.

In any event, the Personnel shall refrain from using the Company's resources, goods or materials for their own personal advantage or, in any event, for any unlawful purposes.

#### ***III.2.k) Protection of the share capital and creditors***

The Corporate Bodies, the Management, employed Personnel and external Collaborators are required to:

- adopt at all times a correct, transparent and cooperative approach, in compliance with the rules of law and with internal company procedures, in all the activities targeting preparation of the financial statements and of the other corporate reports required by the law and directed at shareholders or the general public, in order to provide a true and fair view of the Company's profit and loss, balance sheet and cash flow;
- strictly observe the legal provisions aimed at protecting the integrity and effectiveness of the share capital (e.g.: mergers, acquisitions of companies, distribution of profits and reserves, etc.) and to always act in compliance with internal company procedures, upon which those rules are based, in order not to jeopardise the rights of creditors and third parties in general;
- conduct any Company liquidation transactions focusing on the corporate creditors' best interests; it is therefore prohibited to divert corporate assets from their allocation to creditors, distributing them among shareholders before issuing payment to the entitled creditors, or setting aside the sums necessary to meet such payments.

Moreover, MALESCI S.p.A. ensures the proper operations of its corporate bodies, guaranteeing and supporting any form of control over the company's management required by the law as well as the free and correct manifestation of the shareholders' will; it is therefore mandatory to ensure strict compliance with the internal procedures prepared for this purpose by the Company and/or, in any case, the adoption of conduct in line with this principle.

With specific reference to the preparation of the financial statements, the Company considers the truthfulness, fairness and transparency of the financial statements, reports, and other corporate communications required by law and addressed to the shareholders or the general public as essential principles in the conduct of the business and guarantee of fair competition. This calls for an in-depth analysis into the validity, accuracy, and completeness of the basic information required for the accounting records.

Consequently, it is not permitted to conceal any information or allow the management and the entities subject to their direction and control to provide a partial or misleading representation of the profit and loss, balance sheet and cash flow data. Therefore, all collaborators - both inside and outside the Company - engaged in producing, processing and recording this information are responsible for the transparency of the Company's accounts and financial statements. Each profit and loss, balance sheet and cash flow transaction shall be adequately recorded and accompanied by appropriate supporting documentation in order to conduct, at any time, inspections aimed at verifying the characteristics and reasons behind the transaction and identifying who authorised, completed, recorded and checked the same transaction.

All transactions recorded are accompanied by appropriate supporting documentation of the activities carried out, so as to allow:

- easy accounting entries;
- the identification of the different levels of responsibility;
- the accurate reconstruction of the transaction, also in order to reduce the likelihood of any material or interpretative errors.

The Company demands full dedication from its Personnel to ensure that all operations and transactions carried out within the scope of their activities are correctly and promptly recorded in the accounts.

Each record shall reflect exactly what is shown by the supporting documentation.

Any negligence, omission or falsification which employees might become aware of shall be promptly reported to the Supervisory Body.

### ***III.2.1) Health and safety and the environment***

MALESCI looks to the future having as its primary values policies for workers' safety and environmental protection. The long-term goal is to reach zero operational incidents, accidents at work and the impact on the environment.

The Company, in keeping with its technological development and progress, shall adopt the most appropriate measures to eliminate the risks associated with the performance of its business activities thereby ensuring healthy premises and selecting equipment, processes and materials aimed at mitigating any risks that they pose on workers' health and safety. In any event, the Company is committed to carefully evaluating any existing residual risks in order to mitigate their potential consequences as much as possible.

Moreover, the MENARINI Group promotes a culture based on accident prevention and the awareness of the risks to which workers are exposed through a specific educational and training plan.

The Company, independently and in accordance with legal provisions, or upon receipt of the reports coming from any other source, shall take all the necessary measures to ensure and improve the working environment also and above all with reference to hygiene and safety controls, as well as the procedures designed to constantly improve the business climate.

The Company undertakes to encourage the Management and employed Personnel to comply with the wide regulatory framework started with Laws 626/94 and 494/96 and incorporated and re-codified in Legislative Decree 81/08.

Any third parties otherwise coming into contact with the Company shall cooperate to the best of their skills and responsibilities in order to promote practices intended to ensure workers' health and safety.

In order to comply with the provisions laid down in Legislative Decree 81/08, and as amended and supplemented, the Company constantly monitors its systems and devices wherever they are located or in operation beyond the legal obligations and the prevention of imminent risks to ensure the highest safety and quality of its services. The Manager of the Risk Prevention and Protection Service (hereinafter, "RSPP"), who collaborates with the Employer, identifying the risks associated with the work activity and providing the same with the appropriate technical guidance to eliminate them or, should this not be possible, minimise them. The Personnel and Company Collaborators ensure the widest possible cooperation in respect of the Company or any entity performing inspections and checks on behalf of INPS, INAIL, the Ministry of Health, Labour and any other sector of the relevant

Public Administration.

It is mandatory for all Company members to inform without delay the employer, the manager or the person in charge of any anomalies and irregularities on the subject of health and safety at work.

In the performance of their duties and as part of the relations entertained with the Workers' Representatives for Health, Safety and the Environment (RLSSA), the RSPD shall be considered a qualified consultant of the Employer.

In relation to the environment, the Company is strongly committed to addressing and managing the environmental instances and issues in a structured manner, with medium-term policies and formalised programmes. In this respect, the objectives are, on the one hand, the continued improvement of the company's conduct and corporate assets with a view to increasing compliance with existing legislation and, on the other hand, the coordinated development of a management system and an environmental sustainability report highlighting both the current outstanding performance and the further progress that shall be achieved over time. To this end, the Company has obtained voluntary integrated certifications both in terms of health and safety at work, and the environment.

All the Company's personnel, as part of their duties, participate in the process of risk prevention, environmental protection and the protection of health and safety with respect to themselves, their colleagues and third parties.

### ***III.2.m) Anti-money laundering/receipt of stolen goods***

In order to ensure transparency and fairness of business transactions, the Personnel are required to adopt all the means and appropriate precautions.

In particular, the Company requires to:

- draw up in writing - with details of the content and financial conditions agreed - the tasks assigned to service companies and/ or individuals managing the Company's economic/financial interests;
- ensure that the relevant functions check that payments to all counterparties have been made regularly, also by checking the correspondence between the subject to which the order is made out and the subject collecting the related sums;
- check the financial flows concerning any dealings (payments/intragroup transactions) with the Group companies;
- carefully comply with the minimum standards and requirements for the selection of the



- bidders of any goods and/or services that the Company intends to acquire;
- establish the criteria for evaluating bids based on the commercial and professional reliability of the suppliers and partners as well as request and obtain all the necessary information;
  - ensure the utmost transparency in the event of entering into any agreements/ joint ventures aimed at making investments.

### ***III.2.n) Use of IT systems***

In the performance of their professional duties, the Personnel are required to use the IT or telecommunications tools and services in compliance with the regulations currently in force (and in particular, in relation to computer crimes, cyber security, privacy and copyright) as well as internal procedures.

The Personnel are prohibited to load borrowed or unauthorised software on to the company's systems, and they are also prohibited from making unauthorised copies of programmes licensed for personal, corporate or third-party use.

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

Furthermore, the Personnel are also prohibited to send threatening or injurious e-mail messages, and to resort to linguistic expressions that do not conform to the Company's style, or otherwise use inappropriate language.

### ***III.2.o) Bribery among individuals***

The Personnel are prohibited from engaging in all forms of inducement, promise, donation, offer of money or other benefits, whether direct or indirect, of any kind to a private entity (suppliers, clients, agencies, business partners, consultants etc.) for the performance (or lack thereof) of an act of their official duties, in breach of their professional and loyalty obligations, in order to receive a benefit of any kind for the company and/or for themselves and/or third parties, regardless of whether such act of their official duties is actually performed or not.

Similarly, they are prohibited from accepting money or other compensation, whether of an economic or any other nature, for the company and/or for themselves and/or third parties if this is intended to influence the performance of an act of their official duties.

It is possible to donate/accept gifts of modest value, provided that this is done in compliance with company procedures and where the conduct is not intended to influence the recipient.

### **III.3 Rules of conduct for Third-Party Recipients**

This Code of Ethics also applies, in addition to the Corporate Bodies and the Personnel, also to Third-Party Recipients. These are understood to mean entities outside the Company operating, directly or indirectly, for the Company (including but not limited to agents, collaborators in any capacity, consultants, suppliers, business partners) or the Independent Auditors.

Third-party recipients, like other entities, are required to comply with the provisions of the Model and Code of Ethics and in particular with reference to the ethical standards and rules of conduct laid down for the personnel, to the extent applicable.

To this end, it shall be necessary to include in the letters of appointment and/or negotiation agreements, special clauses differentiated depending on whether the third party acts in the name and on behalf of MALESCI S.p.A. (attorneys, agents, collaborators, etc.) compared to cases where the third party does not act in the name and/or on behalf of the Company (e.g. suppliers of goods and/or services), as detailed in the Disciplinary System.

For any contractual relationships already in place at the time of entry into force of the Code of Ethics, MALESCI S.p.A. shall have the Third-Party Recipient sign a specific supplementary agreement including the abovementioned provision.

### **III.4 Reporting obligations to the Supervisory Body**

The members of the Corporate Bodies, the Personnel and Third-Party Recipients are required to give timely notice to the Supervisory Body of any violations, including of a potential nature, of laws or regulations, of the Model, of this Code of Ethics, of the Internal procedures which they may become aware of in the fulfilment of their tasks and duties.

In any event, the Supervisory Body shall be necessarily:

- A. and immediately notified of any information that may be related to any breaches, including of a potential nature, of the Model, including, but not limited to:
  - 1) any orders received by one's superior and deemed to be contrary to the law, the internal regulations, or the Model;
  - 2) any requests or offers of money, gifts (exceeding a modest value) or other benefits originating from, or destined to, public officials or persons in charge of a public service or private entities;

- 3) any significant departures from the budget or spending anomalies emerged from authorisation requests in the final balance phase by the Management Control function;
- 4) any negligence, omission or falsification in book-keeping or in the storage of the documentation upon which the accounting records are based;
- 5) any measures and/or reports coming from the judicial police or any other authority which indicate that investigations are being conducted which involve, even indirectly, the Company, employees or corporate body members;
- 6) any requests for legal assistance put forward by employees under the national collective bargaining agreement, in the event of the start of criminal proceedings against the same;
- 7) any reports related to ongoing disciplinary proceedings and any sanctions applied or the reasons for their filing;
- 8) any reports, not promptly detected by the competent functions, concerning any shortcomings or inadequacies in work stations, work equipment, or the protection devices made available to the Company, or any other situation that may constitute a hazard associated with workplace health and safety;
- 9) any breach, including of a potential nature, of environmental regulations as well as of the relevant procedures issued by the Company;
- 10) any departure detected during bid evaluations from company procedures or predetermined criteria;
- 11) information relating to the existence of an actual or potential conflict of interests with the Company.
- 12) any critical issues with regard to tenders, whether public or of public significance, at the national / local level in which the Company participated; as well as any critical issues with respect to any orders obtained as a result of private negotiations;
- 13) any communications from the auditing firm regarding issues that may indicate a lack of internal controls;

- 14) any injuries or illnesses that may cause an employee's inability to carry out ordinary activities at least for a period of forty days;
  - 15) the critical issues arising from the first-level control activities carried out in areas exposed to the risk of crime;
  - 16) reports following the inspections carried out by external control bodies (e.g. AIFA, ASL, etc....);
- B. periodically, as set out below, the information relating to the Company's business, which may be relevant to the Supervisory Body's fulfilment of the duties assigned to it, including, but not limited to:
- 17) information related to any organisational changes or changes in the current company procedures (on a four-month basis);
  - 18) updates to the system of powers and delegations (on a quarterly basis);
  - 19) the agenda of the minutes of the Board of Directors' meetings (on a quarterly basis);
  - 20) list of tenders with regard to tenders, whether public or of public significance, at the national/local level, in which the Company participated (on a quarterly basis);
  - 21) decisions relating to the request, issue and use of public funds (on a quarterly basis);
  - 22) the list of donations and gratuities issued to public entities (on a quarterly basis);
  - 23) periodic reporting relating to workplace health and safety, and in particular the minutes of the regular meeting pursuant to art. 35 of Legislative Decree No. 81/2008 (on an annual basis), as well as all the data on accidents at work occurred on the Company's sites (on a quarterly basis); the information on the annual expense/investment budget prepared in order to make the necessary and/or appropriate improvements in the health and safety sector (on an annual basis); any updates to the DVR, the reports, by the company physician, of any irregular situations found during periodic or scheduled visits (on a quarterly basis);

- 24) the annual financial statements, together with the notes, as well as the six-monthly (annual) balance sheet;
- 25) the duties conferred upon the independent auditors other than the auditing appointment (on a quarterly basis);
- 26) communications by the Statutory Board of Auditors and the independent auditors, relating to each critical issue emerged, even if resolved (on a six-monthly basis);
- 27) the reports prepared by the Corporate Internal Audit and Compliance Department in relation to the monitoring activities carried out in relation to company processes and activities mapped as risk or instrumental areas in the Model (on a quarterly basis);
- 28) annual copy of the MUD (*Modello Unico Dichiarazione Ambientale*).

Reports to the Supervisory Body may be forwarded, including anonymously, both via e-mail (ODVMALESCI@MALESCI.IT), and in writing to the address: Organismo di Vigilanza, Malesci Istituto Farmacobiologico S.p.A, Via Lungo l'Ema, 7, 50012 Bagno a Ripoli (FI).

In any case, the Supervisory Body shall ensure that the entity submitting the report, if identified or identifiable, is not the subject of any retaliation, discrimination or, in any case, penalties.

#### **IV. THE TRANSPARENCY OF TRANSFERS OF VALUE AMONGST PHARMACEUTICAL COMPANIES, HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS**

##### **IV.1 Obligation of transparency**

On an annual basis, the Company shall document and disclose, by using a special template, all transfers of value carried out directly or indirectly to Healthcare Professionals and Organisations.

Data shall be published on the company's website. The Company is required to keep the appropriate documentation for at least 3 years where it states that consent to the disclosure of data has been requested from the Healthcare Professional.

The exclusion of the obligation to disclosure applies on transfers of value connected to OTC medicines and those related to promotional material referred to in point 2.13 of the Farindustria's Code of Professional Conduct, to meals and drinks and to drug samples.

As regards the methods of disclosure of the data associated with transfers of value and the related frequency, reference is made to the provisions laid down in Farindustria's Code of Professional Conduct.

#### **IV. 2 Disclosure of data on an individual and aggregate basis**

The Company shall disclose, on an individual basis for every recipient, the amount of the transfers of value carried out during the previous year with reference to:

- a) expenses for the participation in conferences and congresses regarding registration fees, travel and accommodation (excluding meals and drinks);
- b) expenses for consultancy and professional activities not otherwise covered in letter a), resulting from a specific contract between the company and individual Healthcare Professionals where the type of service is stated.

To this end, the Company shall do the utmost possible to obtain consent from the Healthcare Professionals to data disclosure.

If the Healthcare Professional does not give their consent to data processing, the Company shall disclose the data on an aggregate basis, in accordance with the methods laid down by Farindustria's Code of Professional Conduct.

The Company shall disclose the amount of the transfers of value carried out for each Healthcare Organisation in the previous year with reference to:

- a) donations and grants (including gratuitous loans for use) both in cash and in kind;
- b) direct or indirect contribution to congress events carried out through healthcare facilities or third parties, including the sponsorship of physicians to conferences and congresses with the payment of the registration fees and the travel and accommodation costs;
- c) financial transactions related to consultancy and professional activities resulting from a written contract between pharmaceutical companies and Institutions, Organisations or Associations that provide any type of service not covered under points a) and b).

#### **IV. 3 Research and development costs**

The annual costs that pharmaceutical companies incur for research and development activities shall be disclosed in aggregate form. These include those related to planning and performance of:

- a) non-clinical studies, as defined in the Good Laboratory Practices;
- b) clinical studies, as defined in the Directive 2001/20/EC;

c) observational prospective studies, according to point 4.4 of this Code, that involve the gathering of data on patients by individual physicians or groups of physicians.

Costs related to Investigators' Meetings, Advisory Boards or hospitality where they are connected to the activities according to letters a) b) and c) above, as well as a note summarising the methodology used for the preparation of the data with reference to information concerning VAT, the currency or any other tax aspects associated with the transfer of value on an individual or aggregate form shall also be disclosed on an aggregate basis.

## **V. IMPLEMENTATION AND SUPERVISION OF COMPLIANCE WITH THE CODE OF ETHICS**

### **V.1 Duties of the Supervisory Body**

The supervision over the implementation and compliance of the Model and Code of Ethics is entrusted to the Supervisory Body, for the identification and appointment of which reference is made to the Model.

Except as provided in the specific document referred to as "Supervisory Body's Articles of Association" (which forms an integral part of the Model), with specific reference to this Protocol, some typical duties incumbent upon the Supervisory Body are set out below. Said Body is required, among other things:

- to monitor compliance with the Model and the Code of Ethics, in order to mitigate the risk of committing the offences under the Decree;
- to express opinions both in terms of any ethical issues that may arise in the context of the company's decisions, and in terms of any alleged breaches of the Model or the Code of Ethics which it may become aware of;
- to provide all possible tools for understanding and clarifying the correct interpretation and implementation of the provisions contained in the Model or the Code of Ethics;
- to monitor the updating of the Code of Ethics, including through its own adaptation and/or update proposals;
- to promote and monitor the implementation, by the Company, of the communication and training activities relating to the Model and, in particular, to the Code of Ethics;
- to report to the relevant corporate bodies any breaches of the Model or the Code of Ethics, ensuring the effective implementation of any measures imposed.

## **V.2 Breaches of the Code of Ethics and related sanctions**

Compliance with the rules of the Code of Ethics shall be considered an essential part of the duties incumbent on the Corporate Bodies and the Company's Personnel, as well as an essential part of the contractual obligations undertaken by the so-called Third-Party Recipients.

Any breach of the rules of the Code of Ethics shall result in the application of the sanctions provided for in the Disciplinary System (to which reference is made) and/or, in relation to the Third-Party Recipients, in the clauses included in their contracts.

With reference to the Top Managers, different penalties are applicable, from written reprimand to the revocation of the appointment.

So-called employed individuals may be given several types of sanctions ranging, from the least serious to the most serious, from verbal warning to written reprimand, to suspension from work or pay not in excess of three days, to dismissal in compliance with the provisions laid down in the applicable National Collective Bargaining Agreement, as set out in further detail in the Disciplinary System to which reference is made.

With specific reference to Third-Party Recipients, there are special sanctions of a contractual nature of different degrees on the basis of a specific clause included in the contract or letter of appointment, as detailed in the Disciplinary System to which reference is made.

## **V.3 Reporting of any breaches of the Code of Ethics**

If an entity required to comply with the Model and this Code of Ethics becomes aware of a fact and/or circumstance that may put it at risk of committing a breach, it is required to promptly inform the Supervisory Body.

The Company has set up the appropriate communication channels in order to support the process of reporting to the Supervisory Body.

More specifically, a special mailbox (ODVMALESCI@MALESCI.IT) has been activated, to which it is possible to send any reports concerning non-compliance with the Model or this Code, and which shall also be used for receiving reports of an anonymous nature, or those for which it is not possible to trace the sender's identity.

In addition, reports may be made in writing, by sending a special communication, even anonymously,



to the following address: Organismo di Vigilanza, Malesci Istituto Farmacobiologico S.p.A, Via Lungo l'Enza, 7, 50012 Bagno a Ripoli (FI).

In any event, the Supervisory Body ensures that those who submitted reports shall not be the subject of retaliation, discrimination or, in any case, penalties, thereby guaranteeing the appropriate confidentiality of such persons.