

**Code of Ethics**  
**JULY 21, 2015**

# **Code of Ethics**

## **Lofarma**

*July 21, 2015*

**Code of Ethics**  
**JULY 21, 2015**

*Dear Partner,*

*Your business dealings and relationships with physicians, pharmacists, patients and the employees of public and private entities, and whenever you supply goods and services, all influence the image of Lofarma.*

*Being aware of your role should be a constant point of reference for conduct based not only on professionalism, but also the ethical values and principles of the code of conduct described in this Code of Ethics of the Lofarma Group.*

*The creation and application of this document testifies to the commitment of the Lofarma Group to achieve high quality standards in terms of efficiency and ethics.*

*We are all conscious and convinced of the fact that the success of Lofarma Group is increasingly dependent on an efficient, healthy, correct and loyal organisation.*

*Rubens Vaglio*  
*President*

*January 27, 2011*

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## **COMPANY MISSION**

Lofarma is a European company that has been operating in the pharmaceutical industry for many years, with a special focus on allergic diseases. Its business operations include the research, development, production and marketing of products in accordance with the company's mission:

*"Lofarma's goal is to provide a concrete contribution to the health of people and improve their quality of life."*

## **1. PREFACE**

The Code of Ethics (hereinafter the "Code"), has been prepared by Lofarma S.p.A., the parent company of the Lofarma Group, to define and enforce within the Lofarma Group all the ethical principles and rules of conduct with which all employees and professionals collaborating with the group must comply as they conduct their business activities.

The intention of the Lofarma Group is to ensure that its employees, executives, partners and anyone acting on behalf of the Lofarma Group (hereinafter the "Addressees") in "relationships with various contacts, amongst whom the Italian and foreign Public Administrations figure prominently" do not commit offences that could not only discredit the image of Lofarma Group, but also lead to financial penalties or disqualification as per Legislative Decree 231/01, "Regulation of the administrative liability of legal entities".

This Code represents the only basis of binding principles that characterise all the companies belonging to the Lofarma Group. Every company within the Lofarma Group may adapt its code of conduct to the local context, but they may not deviate from the principles sanctioned by law and the Code itself.

The Code is an integral part of the "Organisation, management and control model" set forth by art. 6 of Legislative Decree 231/2001; both are based on the Codes of Ethics of Farmindustria and Assobiomedica, to which the parent company Lofarma S.p.A. belongs, and the Farmindustria Guidelines for the certification of procedures associated with scientific information activities.

The Code must be applied to all the business activities of the Lofarma Group and should serve as a constant point of reference for all the procedures, policies and contractual relations of the company.

In the case of conflict, the Code will prevail over instructions provided by the internal hierarchy and over internal procedures.

Failure of the Addressees to comply with the Code or act contrary to the law in the belief that they are pursuing the interests of the Lofarma Group is never justified.

## **2. GENERAL PRINCIPLES**

### **2.1 OBSERVANCE OF THE LAW**

An essential principle of the Lofarma Group is to observe the laws and regulations in effect in all the countries where it operates, so Lofarma will not initiate or continue collaborating with anyone who does not intend to adopt and observe these principles.

### **2.2 IMPARTIALITY AND NON-DISCRIMINATION PRINCIPLE**

In its relations with internal, external and institutional contacts in general, the Lofarma Group avoids discrimination of any kind based on the age, gender, sexual preference, state of health, race, nationality, political opinions and religious beliefs of its contacts.

### **2.3 RESPECT FOR THE INDIVIDUAL AND FOREIGN WORKERS**

The Addressees must respect the dignity of people and their private life, both in internal and external relationships. Harassment or offences of any kind will not be tolerated.

All Addressees must personally help create and maintain a climate of mutual respect, collaboration and support, being sensitive towards their colleagues.

All Addressees must work to guarantee the precise respect for the rules stated in immigration matters with particular reference to the disposition relative to the employment procedures, with regards to full time or part time work of foreign workers.

### **2.4 INTEGRITY**

Lofarma Group will not tolerate any form, active or passive, of bribery or colluding, laundering and self-laundering, blackmail or any other similar corruption.

### **2.5 CONFLICT OF INTEREST AND TRANSPARENCY PRINCIPLE**

The Addressees must avoid conflict of interest situations; in particular they must:

- Undertake operations and activities only in the interests of the Lofarma Group and in a legal, transparent and correct manner;
- Avoid conflicts of interest between financial, personal and family activities and their responsibilities within the company;
- Immediately notify the Supervisory Board of any situation that may constitute or lead to a conflict of interest, and refrain from any such activity.

### **2.6 COMPLETENESS AND CONFIDENTIALITY OF INFORMATION**

The Addressees must provide truthful, complete and accurate information so that all interested parties can make independent and informed decisions.

In accordance with the law, the Lofarma Group safeguards the confidentiality of information in its possession, respecting the people and confidentiality requirements set forth by the Code.

The Addressees are prohibited from using confidential information for purposes not strictly connected with their professional activity.

### **2.7 PRIVACY PROTECTION**

The Lofarma Group pledges to treat the personal data and confidential information gathered and managed within the scope of its business activities in accordance with the law on confidentiality. To this end, the Addressees must act in accordance with the Lofarma Group's data protection management policy.

### **2.8 ENVIRONMENTAL PROTECTION**

Lofarma Group considers protecting the environment as a primary asset, and pledges to safeguard its operating territory by developing low impact industrial solutions.

### **2.9 GIFTS AND GRATUITIES**

Gifts, gratuities or free services of any kind are not permitted, with the exception of the customary forms of courtesy practiced in the country of the addressee.

Addressees are therefore not permitted to request or accept directly, indirectly or through an intermediary money, gifts or favours of any kind, with the exception of goods of a negligible value. If this is or could potentially serve as compensation for a service connected to the business relationship with companies in the Lofarma Group, or if it is not possible to refuse or return the gift, the recipient of the gift must immediately notify his/her direct supervisor and the Supervisory Board (hereinafter the S.B.). Similarly, if the addressee is in a management position, he/she must notify the S.B.

### **2.10 CONTROL AND PROTECTION OF COMPANY ASSETS**

The parent company Lofarma S.p.A. uses a control system to protect the company's assets.

Each employee is responsible for the company assets assigned to him/her to do his/her job. Addressees may not improperly use, or allow others to improperly use, their assigned assets or the resources of the Lofarma Group.

### **2.11 TRANSPARENCY OF ACCOUNTING INFORMATION**

The Lofarma Group condemns the conduct of anyone who alters the accuracy and truthfulness of the data and information contained in the financial statements, reports or other business communications provided for by the law.

Everyone who is responsible for creating these documents must diligently verify the accuracy of the data and information that will be included in the preparation of the above documents.

All operations must be documented and the original versions (or certified copies) of the documents stored in accordance with the law, so that for each action taken during the various phases, the authors and the reasons for these actions where stated, can always be identified.

## **2.12 RELATIONS WITH PARTNERS AND CORPORATE BODIES**

The Lofarma Group expects the executives, functional managers and employees to conduct themselves appropriately and transparently in the course of their business duties, particularly when responding to requests from Partners, the Board of Statutory Auditors, other Corporate Bodies and auditing companies as they perform their respective corporate functions.

## **2.13 COMPETITION AND ANTI-TRUST**

The Lofarma Group respects the principles and laws that protect competition in the markets where it does business, and refrains from any conduct that may distort competition.

The Addressees must comply with these laws and to ask the S.B. for advice in case of doubt.

## **2.14 ANTI- MONEY LAUNDERING**

The Lofarma Group aims for the utmost transparency in business transactions to prevent money-laundering and self-laundering and dealing in stolen goods.

This principle must be adhered to in relation to all contractual counterparties, including those belonging to the Lofarma Group.

# **3. SPECIFIC PRINCIPLES**

## **3.1 EMPLOYEES**

### **3.1.1. SELECTION AND RECRUITMENT OF EMPLOYEES**

Employee candidates are evaluated based on how closely their profiles and specific skills match the job and company requirements as they have been described by the requesting Department, and they are always evaluated in accordance with equal opportunities for all parties involved.

The information requested is strictly in order to verify the professional and psycho-aptitudinal requirements, and with respect for the private life and personal opinions of the candidate.

During the selection and recruitment phase, the Lofarma Group avoids any form of partiality, nepotism or favoritism.

All personnel have to be employed with a regular contract according to the provisions of the law, including the rules regarding foreign workers.

### **3.1.2. BONUS SYSTEM AND INCENTIVES**

The Lofarma Group makes every effort to ensure that the overall and individual fixed annual targets (contemplated or otherwise in a bonus system) of the managers and employees in its organisation do not lead to illegal actions, and are instead focused on a possible, specific, concrete and measurable result that is achieved within a specific timeframe.

The S.B. must be immediately notified of any problems or situations that conflict with the above principle so that it can implement the necessary corrective measures.

With respect to the performance evaluation of the Sales Force (hereinafter the SF), the quality of the scientific information must be taken into account, through training and testing by the company's Scientific Department.

### **3.1.3. EMPLOYEE RIGHTS (HARASSMENT – HEALTH AND SAFETY)**

The Lofarma Group pledges to safeguard the workplace and moral integrity of its employees and partners, ensuring their right to working conditions that respect the dignity of the individual.

The Lofarma Group pledges to infuse and establish a culture of safety, developing the awareness of the risks and familiarity with and respect for the relevant laws in effect, promoting responsible conduct by all employees.

### **3.1.4. DUTIES OF EMPLOYEES**

All employees must work in accordance with the laws, the principles of the Code and other rules and internal procedures, in addition to other requirements of the employment contract.

## **3.2 CLIENTS**

### **3.2.1. CODE OF CONDUCT WITH CLIENTS**

As they conduct their relationships with clients, Addressees should promote the utmost impartiality and avoid any form of discrimination, encouraging full collaboration and availability, providing clear, truthful information about each product in order to allow informed, rational decision-making.

### **3.2.2. QUALITY OF PRODUCTS AND SERVICES**

The Lofarma Group pledges to achieve and maintain the high quality standards of the products and services offered, in order to fully satisfy and protect its clients.

## **3.3 SUPPLIERS**

The Lofarma Group intends to establish and maintain business relations with suppliers who guarantee the greatest level of correctness and ethical conduct, and

will contractually require the suppliers to observe the laws, and be familiar with and adhere to the principles of the Code.

The Lofarma Group also contractually reserves the right to take any appropriate measure (including cancelling the contract) if the above supplier violates the requirements of the law or the principles of the Code while acting in the name and/or on behalf of the Company.

Supplies are selected only on the basis of competitiveness, quality, affordability and price, without any discriminatory practices.

Employees of the Lofarma Group or anyone acting on its behalf may not enter into a relationship with a supplier if he/she has an interest, including non-financial or indirect interests, in the business activities of the supplier.

Supplier relationships are characterized by correctness and good faith and must be documented and be traceable.

Employees responsible for the purchasing process must:

- observe the principles of impartiality and independence as they perform their assigned tasks and functions, and act only on the basis of objective and documentable criteria;
- abstain from personal obligations towards suppliers; the relevant supervisor must be notified of any personal relationships between employees and/or consultants and suppliers before entering into any negotiations;
- immediately inform the S.B. about any attempted or actual change in the normal business relations.

### **3.4 PUBLIC ADMINISTRATION**

Addressees who act on behalf of Lofarma in relationships with the Italian and/or foreign Public Administration (hereinafter P.A.), will base their conduct on respect for *impartiality* and the *principle of sound administration* to which the P.A. is bound.

#### Relationships with the P.A.

Relations with the Italian and/or foreign Public Administration in the name and on behalf of the Lofarma Group are restricted to those individuals who have been specifically appointed by the Lofarma Group to negotiate or have contact with these administrations, public officials, bodies, organisations and/or institutions.

The people appointed by Lofarma to conduct business negotiations, requests or relationships with the Italian and/or foreign P.A. must not attempt for any reason to influence the decisions of the Public Officials or Civil Service employees who are negotiating and making decisions on behalf of the Italian and/or foreign P.A.

Based on this principle, the following examples are therefore not permitted (by way of example and not exhaustive):

- offering in any way opportunities of employment and/or business that may benefit the Public Officials and/or Civil Service employees personally or through a third party;
- offering money or any other benefits;
- providing false information that may induce or change the P.A.'s ability to analyse and make decisions;
- performing any other act intended to induce Italian or foreign Public Officials to do or omit something in violation of the laws of their department.

#### Funding and contributions

The purpose for which contributions, subsidies or funds are obtained from the state or any other public body or from the European Community must be respected, even if it is of little monetary value or import.

#### Management of audits

Whenever the relevant Public Authorities, Corporate Bodies and their members conduct audits and inspections, the employees, consultants, collaborators, agents, attorneys and any third party acting on behalf of Lofarma must make themselves available and cooperate with the inspectors and auditors.

It is forbidden to obstruct in any way the functions of the Public Vigilance Authorities that come into contact with the Lofarma Group through their institutional positions.

### **3.5 HEALTHCARE PROFESSIONALS, SCIENTIFIC BODIES**

#### **3.5.1. SCIENTIFIC INFORMATION**

With regard to scientific information and other promotional activities involving Lofarma products, company employees must act in accordance with the law in effect, the regulations of the Codes of Ethics of Farindustria and Assobiomedica, and with internal company procedures.

The content of the information must always be documented and be documentable; exaggerated claims and comparisons that cannot be demonstrated are not permitted.

Sales force representatives must present themselves to healthcare professionals stating their function.

The sales force periodically receives training from the Scientific Department.

### **3.5.2. PROMOTIONAL AND INFORMATIONAL MATERIAL**

Whilst presenting drugs and providing information to healthcare professionals, it is not permitted to offer or promise rewards, monetary benefits or fringe benefits.

The promotional material about drugs and their use must be of negligible value and connected to the activity performed by the healthcare professional. This material must also clearly indicate the name of the product and the sponsoring company. All promotional material is acquired directly from the main headquarters.

The informational material provided by the parent company Lofarma S.p.A. about its products authorized to market, and which it uses to provide information to healthcare professionals, must reference the official documents submitted to AIFA.

Informational material for scientific or professional use that does not specifically refer to the drug may be supplied free of charge only if it is of negligible value, as set forth by the Code of Ethics of Farindustria.

### **3.5.3. CONGRESSES, CONVENTIONS, COURSES AND SCIENTIFIC MEETINGS**

Participation in congresses, conventions and scientific meetings must take place in accordance with the laws in effect, the principles of the Codes of Ethics of Farindustria and Assobiomedica and internal company procedures, and must be based on the principles of ethical conduct, scientific information and affordability.

### **3.5.4. VISITS TO COMPANY LABORATORIES**

Visits to company laboratories are permitted provided that appropriate training-information sessions take place during the visit, that they do not exceed the time required to conduct the sessions, and that hospitality is limited to the time stipulated by the Code of Ethics of Farindustria.

### **3.5.5. INVESTIGATOR MEETINGS**

Investigator meetings (i.e. investigator study meetings) organised by the Lofarma Group must:

- include the appropriate number of participants with respect to the centre(s) involved;
- aim to formulate or discuss a specific protocol to be deposited at the centre/s;
- not be for promotional purposes.

The duration of the meeting must comply with the work schedule and exclude tourist events and hospitality for companions at any level.

The location must be chosen using the same criteria for conventions and congresses.

### **3.5.6. ADVERTISING IN NEWSPAPERS AND MAGAZINES**

Advertisements in newspapers and magazines must ensure that there is a clear distinction between information and publicity so that the reader can immediately recognise the promotional message whatever its form (editorial or advertising page).

### **3.5.7. SCIENTIFIC CONSULTING AND BURSARIES**

Scientific collaborations must always be conducted in accordance with the law in effect, the principles of the Codes of Ethics of Farmindustria and Assobiomedica and internal company procedures. Scientific collaborations may also be enacted through bursaries and scientific consultancies, provided that the initiative is adequate, appropriate and can be documented.

### **3.5.8. RELATIONSHIPS WITH SCIENTIFIC BODIES**

The Lofarma Group may enter into collaborative relationships with Scientific Societies and Medical Associations, provided that they are aimed at disseminating scientific knowledge and increasing professional knowledge, and conducted in conjunction with reliable national organisations whose mission is well-known.

## **3.6 PROFESSIONAL ASSOCIATIONS, TRADE UNIONS, POLITICAL, SOCIAL AND CULTURAL ORGANISATIONS**

If the Lofarma Group decides to join a professional association, it pledges to participate in the association's activities in full compliance with the rules shared and set forth by the association itself.

The Lofarma Group deals with Trade Unions with a sense of responsibility and constructively, and encourages an atmosphere of mutual trust and dialogue.

The Lofarma Group does not support politically motivated demonstrations or initiatives, and refrains from providing financial or other means of support to political parties and politicians, trade unions and/or their representatives.

The Lofarma Group may promote or participate in initiatives that are consistent with the above aims when pursuing institutional, cultural and social affairs initiatives.

## **4. IMPLEMENTATION AND CONTROL OF THE CODE OF ETHICS**

### **4.1 KNOWLEDGE AND UNDERSTANDING OF THE CODE**

The Code is disseminated to the internal and external parties involved through the appropriate means of communication and distribution.

Internally, adequate knowledge and understanding of the Code is ensured through information and training programs, defined in accordance with the Organisation, Management and Control Model.

### **4.2 REPORTING VIOLATIONS**

The Addressees must immediately notify the S.B. of any violation they become aware of during the course of their duties. The S.B. may also be notified by email at the following address:

organismodivigilanza@lofarma.it

Anyone reporting a violation in good faith will be protected against any form of retaliation, discrimination or penalisation, and his/her identity will remain confidential, without prejudice to the legal obligations and protection of the Lofarma Group, or to the people who have been accused in bad faith.

### **4.3 SUPERVISORY BOARD**

#### **4.3.1. Identification**

The Supervisory Board is responsible for controlling and updating the Organisation, Management and Control Model and the Code of Ethics.

This board must be within the Lofarma Group, perform special activities that require the knowledge of instruments and *ad hoc* techniques, and be characterised by continuity of action.

The S.B. reports directly to the top operational and control management levels of the Lofarma Group to ensure full independence and autonomy in the execution of its duties.

Lofarma has formed its own S.B., which:

- reports directly to the board of directors;
- acts autonomously within its scope of responsibilities. For this purpose, the Board uses internal personnel and/or external consultants to ensure that the adequacy and appropriateness of the Model is verified on a continuous basis;
- has its own "work plan" which it has created, and which is approved by the Board of Directors.

In order to protect its autonomy and independence, the S.B. may propose changes to its organisation, authoritative powers and the way it functions, but these may only be officially approved by the Board of Directors if they are justified. They may be revoked only for just cause.

#### **4.3.2. Requisites**

The requisites for the S.B. are as follows:

- a) Autonomy and independence: to ensure that the S.B. is not directly involved in the management activities that it controls and, most importantly, the ability to perform its work without being directly or indirectly influenced by the subjects controlled. These requisites can be achieved by ensuring that the S.B. is hierarchically independent and reports directly to the top management of the company, i.e. the Board of Directors.
- b) Professionalism: the S.B. is a body with technical, professional and specialised expertise that is appropriate for the functions it needs to perform. These characteristics, and its independence, ensure objectivity of judgement.
- c) Continuity of action: the S.B. is a body within the company, with an appropriate organisation and dedicated resources, and is not encumbered by operational tasks that may constrain the efforts required to perform its assigned functions.

Information flows to and from the S.B. have been established in the Model in order to provide the board with adequate access to information and thus be able to act effectively with respect to the company's organisation.

#### **4.3.3. Functions and powers**

Generally, the S.B. is responsible for monitoring the following:

- a) compliance of the Addressees with the Model regarding the various types of violations provided for by the Decree;
- b) the actual effectiveness of the Model within the company structure and its actual ability to prevent the violations provided for by the Decree;
- c) updating the model, if necessary, based on changes in the company's conditions;
- d) the adequacy, application and effectiveness of the penalty system.

Operationally, the S.B. is responsible for the following:

- monitoring the company's activities in order to update the company procedures;
- periodically auditing certain operations or specific actions;
- developing training programs for the employees and collaborating with the Department heads to implement them;
- monitoring the initiatives taken to disseminate the knowledge and understanding of the Model and preparing the internal documentation necessary for the functioning of the Model, containing instructions, clarifications or updates; the S.B. must also prepare and apply operational procedures for best practices on a continual basis;
- gathering, developing and storing the relevant information required to comply with the Model, and updating the list of information that must be submitted or made available to the board, and which constitutes the "formal" database of its internal control activities;
- collaborating with all the company departments as it performs the monitoring activities within the scope of its responsibilities and those in the procedures;
- verifying the adequacy of the internal control system with respect to the law in effect;
- verifying that the elements required to implement the Model (adoption of standard clauses, completion of procedures, etc.) are adequate and meet the requirements to be observed as stipulated by the Decree, by adopting or otherwise recommending the adoption of updated elements;
- verifying the requirements to update the Model;

- periodically reporting to the Board of Directors regarding the implementation of company policies to implement the Model;
- engaging external consultants, if necessary, to accomplish the above activities.

The S.B. must be constantly kept informed by the operational structure and has free access to data, company information and all relevant company documentation in order to perform its activities.

The social bodies and their members, employees, consultants and contractors, sales representatives, lawyers and third parties who act on behalf of the Lofarma Group in their relations with the P.A. must cooperate fully so that the V.B. can perform its functions.

#### **4.3.4. Modality and periodicity of reporting to corporate bodies**

The S.B. of Lofarma S.p.A. operates along three reporting lines.

- One: on a continuous basis, directly with the President of the Board of Directors;
- Two: periodically through its control report documents;
- Three: contingently, by preparing an informative report about its activities for the Board of Directors and the Board of Statutory Auditors.

The above functional reports, even in bodies without operational tasks and thus free of managerial activities, ensure that the S.B. can act with guaranteed independence.

The S.B. may be convened by the above bodies at any time, or it may request a meeting to report on the functioning of the Model or specific situations.

Furthermore, the S.B. may communicate with the Board of Directors whenever it deems it necessary or opportune, and nonetheless must periodically submit a report to the Board of Directors containing the following information:

- the monitoring activities performed by the Board during the relevant period;
- comments on internal conduct or events in Lofarma S.p.A. and the efficacy of the Model;
- the corrective and improvement measures planned and their status

The meetings with the above subjects and bodies must be recorded in minutes and copies of the meeting minutes kept by the S.B. and the bodies involved.

#### **4.4 DISCIPLINARY MEASURES**

Failure to observe the principles contained in this Code will lead to disciplinary measures.

These measures will be applied regardless of the institution or outcome of any criminal proceedings, because the addressees are bound by the organisation models and internal procedures, and violations must be penalised regardless of whether a

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crime has actually been committed or is punishable, in order to comply with the requirements of the above Legislative Decree.

The employee disciplinary measures will be commensurate with the seriousness of the offence and will be in accordance with art. 7 of the law 300/1970 and the National Labour Chemical Pharmaceutical Contract for Italy, or any contract in the relevant member countries of Lofarma Group.

Disciplinary measures for Addressees who are not employees must be included in the contract or decided upon by the industry bodies that govern the business relationship.

#### **4.5 EFFECTIVENESS**

The present Code of Ethics was approved for the first time by the Board of Directors on the 27<sup>th</sup> January 2011, then on the 25<sup>th</sup> January 2012, and on the 8<sup>th</sup> May 2013 and lastly presented and approved on the 21<sup>th</sup> July 2015.