



# Group Guidelines on Ethics & Compliance

EDITION 2015



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## INTRODUCTION

Subsequent to the dramatic increase in the ethical expectation of businesses and professionals, clients, suppliers, patients, regulators and employees are deliberately choosing/giving their preference to those companies which declare and give proper evidence of running their businesses in an ethical, lawful and sustainable manner.

Pharmaceutical manufacturers are not immune to this trend in the market. In the recent past many leading pharmaceutical companies have equipped themselves with transparent compliance plans aiming to align interests with their stakeholders and earn their loyalty.

These Guidelines are of particular interest for the Chiesi Group, and symbolize a desirable achievement for the Group.

On the one hand, these Guidelines are the result of the Chiesi Group's historically deep rooted commitment to complying with the highest standards of conduct. On the other hand, they represent the Chiesi Group's renewed willingness to recognize business ethics and lawful conduct as the fundamental pillars of its reputation and success.



## DEFINITIONS

**Chiesi Group:** Chiesi Farmaceutici S.p.A. and all its subsidiaries and affiliates.

**Company:** any Chiesi Farmaceutici S.p.A. subsidiary or affiliate.

**Chiesi Corporate Compliance Committee:** collegial body in charge of providing support to the Companies as specified in the specific chapter (hereinafter the “Committee”).

It is composed of at least three members appointed by the Board of Directors of Chiesi Farmaceutici S.p.A. among corporate functions meeting adequate requirements of competence and independence.

**Corporate Governance:** the set of processes, practices, policies, laws, and institutions affecting the way a corporation (or company) is directed, administered or controlled. It also includes the relationships among the many stakeholders involved and the goals for which the corporation is governed. In contemporary business corporations, the main external stakeholder groups are shareholders, debt holders, trade creditors, suppliers, customers, authorities, regulators and communities affected by the corporation’s activities; the main internal stakeholders are boards of directors, executives and other employees. Considering sector peculiarities, Chiesi Group stakeholders include: pharma business corporations, patients, hospitals, the scientific community, health officers and taxpayers.

**Internal Control System:** process, performed by an organization’s board of directors, management and other personnel, designed to provide “reasonable assurance” regarding the achievement of objectives in the following categories: effectiveness and efficiency of operations, compliance with applicable laws and regulations, reliability of financial reporting.

**Risk:** a possibility of loss, the loss itself, or any characteristic, object or action that is associated with that possibility.

**Control Activities:** actions, policies and procedures helping to ensure appropriate risk response, including activities such as approval, authorization, verification, reconciliation, review of operating performance, security of assets and separation of duties.

**Separation of Duties (SoD):** the concept of having more than one person required to complete a task. In business the separation by sharing of more than one individual in one single task shall prevent fraud and error. The concept is alternatively called “segregation of duties” or “separation of powers”.

**“Group Code of Ethics and Conduct” or “Group Code”:** document approved on May 17<sup>th</sup> 2010 by the Board of Directors of Chiesi Farmaceutici S.p.A, applicable to all Companies of the Group.

The Group Code expresses the Company’s commitment to operating not only in accordance with the laws and regulations currently in force but also with certain principles and rules of conduct of an ethical nature. It is binding upon all the bodies, employees, consultants, collaborators, agents and, at a more general level, all third parties acting on behalf of the Company.

**Company Code:** local Code issued by Chiesi Companies for the local implementation of the Group Code.



## PURPOSE

The purpose of these Guidelines is to provide a common framework for the ongoing efforts of Company to enforce and implement an integrated, robust governance and compliance structure in terms of ethics, anti-corruption and interactions with healthcare professionals/organizations.

This includes the alignment of common approaches to high priority processes/areas within the Group.

This will not only enable the Company to comply with regulatory requirements in a way that is aligned with stakeholders' interests, but will also allow to identify, assess and manage the key risks inherent in the Company's businesses and processes.

These Guidelines are designed, implemented and enforced to be effective in establishing and maintaining a culture and environment that encourages ethical and lawful conduct. This includes a commitment to compliance with the laws as a fundamental tenet to preventing, detecting and penalizing criminal conduct consistent with current standards set forth in both international and national laws and regulations.

The main objective of the Guidelines is to align the Company's vision with the many regulatory requirements in order to make sure that all key risks are identified and properly managed.

## SCOPE

These Guidelines apply to all the Company.

The contents of these Guidelines apply to anyone who conducts business on behalf and in the name of Chiesi Group – including employees, executive officers, members of the Board of Directors, agents, consultants, contract labor or others, when handling Chiesi Group matters, according to their respective responsibilities.

This version of the Guidelines was approved by the Board of Directors of Chiesi Farmaceutici S.p.A. on November 9<sup>th</sup> 2015 in order to be deployed to the Company.

This constitutes an official Chiesi Group document and as such is binding upon all the Company.



## GENERAL RULES AND RESPONSIBILITIES

Each Company included in the scope as previously defined is expected to conform its organization and its Internal Control System to the contents of these Guidelines.

Should part of these Guidelines not be applicable in a country due to local laws and regulations, the Company Managing Directors/General Managers are responsible for promptly informing the Committee, specifying which part of these Guidelines are inconsistent with the local laws and regulations.

### **Modifiability**

These Guidelines will remain the same regardless of changes that occur to the Company and the environment in which it operates.

## GUIDELINES UPDATES, MODIFICATIONS AND MONITORING

Chiesi Farmaceutici S.p.A. Board of Directors, supported by the Committee, is responsible for updating, correcting and periodically assessing the adequacy of these Guidelines.

In addition Chiesi Farmaceutici S.p.A. Board of Directors, supported by the Committee, is in charge of overseeing and monitoring the implementation and efficacy of the solutions adopted.

## CHIESI CORPORATE COMPLIANCE COMMITTEE

The Chiesi Corporate Compliance Committee is in charge of:

- Providing support to the Board of Directors of Chiesi Farmaceutici S.p.A. in:
  - Reviewing the efficacy of the Guidelines and in case of need proposing up-dates;
  - Overseeing and monitoring the implementation of the solutions adopted through the Guidelines;
  - Adopting the necessary resolutions in case of severe violations of the Guidelines;
- Interpreting the Guidelines for implementation;
- Evaluating and (if possible) approving requests of exceptions to the Guidelines raised by the Company in the event of the impossibility to comply (be aligned) with the Guidelines due to local laws and regulations or other specific circumstances;
- Analyzing cases of violations of the Group Code, Company Codes, rules, procedures or the Guidelines, whenever it is not possible or appropriate to manage it locally, and supporting the decision making regarding the necessary response.

In addition the Committee is responsible for:

- Analyzing the documentation and the notifications sent by the Companies as afore defined in the Guidelines;
- Reporting – on a yearly basis – to the Board of Directors of Chiesi Farmaceutici S.p.A. on the aforesaid activities.

A mailbox to send notifications or requests for support has been established:

[CorporateComplianceCommittee@chiesi.com](mailto:CorporateComplianceCommittee@chiesi.com)

# GOVERNANCE PRINCIPLES





## 1. Group Code of Ethics and Conduct (“Group Code”) and Company Codes

The Company will issue a Local Code of Conduct (hereafter the “Company Code”) based on the Group Code, specifically adapted to specific local requirements or needs.

Company is responsible for guaranteeing the compatibility and alignment of the Company Code to the Group Code and shall notify the Committee of any deviation from the Group Code.

### Communication

The Company Code, by means of appropriate training and other suitable methods of communication, must be brought to the attention of the Corporate bodies, Company employees, field force, consultants and temporary contract collaborators, agents, proxies and any other third party that may act on behalf of the Company, especially in relations with any Public Administrations.

All the aforementioned parties are required to understand its contents, formally accept and substantially comply with its precepts.

The purpose and contents of the Company Code shall be included in the training activities for the field force and, whenever possible, for newly recruited staff in general.

### Notice

All Company employees have to be provided at least with:

- The Company Code;
- Group Guidelines on Ethics & Compliance;
- All other relevant business internal rules;
- Training necessary for them to operate in compliance with local requirements considering their level and specific job description, in accordance with a documented communication and training program.

### Internal reporting

Anyone who becomes aware of violations of the Company Code or other events that might affect the scope and effectiveness of the Company Code is required to promptly report this internally according to the local hierarchy.

Whenever it is not possible or appropriate, this information should be addressed to the Committee.

An Internal Reporting System shall be implemented in order to protect confidentiality of reporting and preserve the anonymity of reporters, in accordance with paragraph “Internal Reporting System”.

## 2. Organizational Structure & System

The Company’s organizational structure shall be tailored on the Company’s objectives and needs. The organizational structure and system shall provide the necessary information flow (upstream, downstream and across all business activities) to manage its activities.

The Company’s organizational structure shall be geared to ensure the separation of duties, roles and responsibilities among the operational and control functions. Whenever it is not possible to apply this principle, appropriate compensation controls should be identified and properly documented.

### Formalization and documentation

The organizational structure of the Company shall be formalized, appropriately documented and made available to employees considering their specific role and position.

Company organization charts and relevant documents shall be defined and documented in order to clearly identify the main responsibilities for each organizational unit/business area and communicated to all personnel.

The formalization of the organizational structure shall include evidence of delegation of authority, evidence of hierarchy lines and a description of roles, and shall reflect a transparent separation of duties and a system of “cross-checks”.

The Company shall document formal written job descriptions identifying competences and responsibilities at least for all key (managerial & technical) roles and, for jobs involving only a few specific tasks, job duties shall be clearly communicated.

The job descriptions specify the knowledge and skills needed, either generally or in terms of the nature and extent of education, training and experience required.

The Company management shall implement a regular process to evaluate the skills required to meet objectives, and to ensure that departments have the right resources, with appropriate qualifications and experience.

Job descriptions shall be used in hiring, training and appraisal processes and decisions. Reward and compensation systems should be clearly and formally connected with roles and positions.

### Disclosure of information

The organizational structure shall be easily accessible to employees considering their specific role and position, by means of publication on the Company intranet (where existing) or other equivalent tools (i.e. company network internal public folders, e-mails).

### Accuracy of documentation

The documentation of the organizational structure shall reflect the actual structure of the organization at all times. Should any change occur in the Company, the organizational structure documentation shall be updated promptly.

### Modifications

The Company Board of Directors or equivalent statutory body supported by the Managing Director/General Manager shall periodically evaluate the Company's organizational structure in the light of changed conditions (i.e. changes in the business and industry) and holds the right to modify or change the organizational structure.

## 3. Powers of Attorney & Delegations of Authority

### Assignment of powers

Powers of Attorney and Delegations of Authority must be assigned coherently with organizational and managerial responsibilities and include, especially in sensitive areas (i.e. considered at risk of crime), accurate indication of thresholds for approval of expenses.

The Company Board of Directors or equivalent statutory body (either directly or through a Chairman mandate) is responsible for approving and formally assigning Powers of Attorney and Delegations of Authority, as well as providing an accurate indication of the thresholds for approval of expenses.

Attribution of absolute ('no limits') or excessive powers is forbidden.

### Communication

A clear description of powers of attorney and delegations of authority (including limits of powers and delegation) shall be communicated to each employee, according to his/her role and position.

### Non-attribution and non-delegation of power to unlawful individuals or organizations

Employees of the Company shall delegate substantial discretionary Company authority to any individual or organization that is known to have an adequate ethics and legal track record.

## 4. Control principles

The control principles which shall be assured in all activities and in all business processes are required to comply with the following:

- Ensure integrity and ethics in every operation, through the provision of an accurate set of rules of conduct which aim to prevent wrongdoings;
- Ensure that all employees are aware that, according to various international conventions and national laws, the granting or acceptance of improper benefits can constitute a criminal offence;
- Formally define duties and responsibilities for each function involved in business activities at risk;
- Assign decision-making responsibilities according to the degree of responsibility and authority conferred;
- Define, assign and communicate Powers of Attorney and Delegation coherently with organizational and managerial responsibilities and include, especially in areas considered at risk of crime, an accurate indication of thresholds for approval of expenses;
- Ensure the principle of separation of duties in the management of processes. This concept should be addressed in technical systems and in information technology in the same way; if the principle cannot be applied, compensation controls should be identified;
- Regulate the activities at risk, ensuring appropriate control tools (checks, reconciliations, information mechanisms, etc.);
- Ensure the accountability, documentation, consistency and appropriateness of any transaction or operation. The traceability of operations should be ensured by a higher level of certainty by the use of computer systems able to manage the operation, allowing the compliance with the requirements described above;
- Ensure the accurate documentation of control activities. To this end, the processes by which controls are implemented must guarantee the possibility to trace back the control activities carried out in such a way as to allow the assessment of the consistency of methodologies (selfassessment, sample surveys, etc.), and fairness of the results (i.e. audit reports);
- Ensure the presence of specific channels of communication with the appropriate personnel in charge to manage information regarding the potential violation of relevant rules (i.e. Supervisory Body, Compliance Officer, etc.);
- Provide for the timely control and monitoring of the correctness of the work of individual functions considered part of the process (compliance, proper use of powers and signing of expenditure, etc.).

## Policies and Procedures

The Company shall implement a set of policies and procedures, both manual and computer based, designed to regulate the Company activities, in accordance with the principles outlined above.

### General principles for policies and procedures

All policies and procedures shall reflect the following principles:

- Every operation, transaction and action must be: verifiable, documented, coherent and relevant;
- No person can autonomously manage an entire process;
- Controls must be documented.

### Written policies/procedures

Written policies, procedures and protocols that document the Company commitment to compliance and address specific areas of potential fraud and abuse, shall be developed and distributed to all interested employees.

### Procedures review and revision

Policies and procedures shall be reviewed and revised periodically with the aim of constantly improving compliance and business activities and to ensure their updating in line with the Company organizational processes and needs.

## 5. Communication & Training

### Communication

Communication shall be up-to-date, comprehensive, effective, clear and detailed.

In particular, for the communication to be effective it must:

- Be sufficiently detailed in relation to the hierarchical level of destination;
- Use the communication channels that are most appropriate and easily accessible to the recipients of the communication so as to provide the information in a timely manner, allowing the recipient to make use of personal communication very effectively and efficiently;
- Be of high quality in terms of content (include all necessary information), be timely, updated (it must contain the latest information) and accessible.

Communication principles shall result in a formalized program properly addressed to:

- All employees;
- New employees upon hiring;
- Third parties acting on behalf of the Company particularly in sensitive areas.

In particular, the Company shall establish an intranet site, accessible to all staff at headquarters and a network, where all relevant documents describing the Company rules and functioning (i.e.: policies and procedures, codes, formalization of the organizational structure, powers of attorney and delegations of authority, etc.) are available.

According to communication program, the Board of Directors (or equivalent statutory body) and all employees, by means of appropriate training and other suitable methods of communication, shall always be properly informed on:

- The objectives of the Company;
- The Company and/or Group's general rules, values and requirements as stated in the Group Code and/or Company Code, policies and procedures;
- Other Company and/or Group compliance and ethics programs, where applicable;
- Responsibilities, powers of attorney and delegations of authority considering their level and specific job description;
- The disciplinary system and its contents;
- Compensation systems and incentives;
- Codes of Practices, sector rules, health & safety measures, Good Practices.

### Training

Training shall be designed to identify areas of potential exposure and prevent any activity not consistent with the Company and /or Group rules and guidelines.

Training programs must be overseen by appropriate personnel. In this regard, training programs must meet the following requirements:

- Training programs must be tailored to the position held by participants (newly hired employees, executives, managers, etc.);
- The content must differ according to the activity of the subject within the Company (risk potential, control activities, activities not at risk, etc.);
- The frequency of training should be functional to the degree of change of the environment in which the Company acts. The frequency of training should also be functional to the ability of the personnel to learn, and the commitment of the management to give authority to the training activities carried out;

- The trainer should be authoritative and competent, to ensure the quality of the content covered;
- Participation in training programs should be mandatory and control mechanisms to monitor participation must be established;
- Training programs should include control mechanisms able to verify the degree of learning of the participants.
- Training on ethical matters and relevant company policies and procedures shall be established.

Training may be delivered via multiple media: online and in-house training, online multiple choice tests to check understanding, etc.

Training must be repeated regularly to make sure employees are informed about reviews, according to positions and roles.

#### **Special conditions for newly hired employees**

Newly hired employees shall be provided by a minimum set of information objects (Company Code, all policies and procedures relevant to their job) and training programs must be tailored.

## **6. Management and control activities**

The degree of control that the Company decides to implement for each activity at risk is a function not only of an assessment in terms of cost-benefit analysis, but it shall also consider the risk threshold deemed acceptable by the Company for that particular task.

#### **Purpose**

Management controls shall be established to assure that the risk of wrongdoing and fraud is minimized.

They help to ensure that those actions identified as necessary for addressing risks to achieving the company's objectives are carried out.

Control activities cover a wide range of policies and the related implementation procedures that help ensure that the management directives are effective.

#### **Applicability**

Control activities are implemented throughout the Company at all levels and functions.

#### **Type of controls**

Control activities include approvals, authorizations, verifications, reconciliations, reviews of operating performance, security of assets and separation of duties.

Control activities cover controls over the IT infrastructure and software security, including legal/contract activities.

Financial and accounting processes should be organized and managed in order to grant the appropriate delegation of authority, separation of duties and traceability of operations, with appropriate periodical reconciliations.

Resources shall be properly managed, ensuring a periodical and documented analysis of budget variations.

#### **Detection of wrongdoing**

A set of "red flag" indicators shall be identified in order to promptly and effectively identify and manage anomalies and potential misconduct.

In any case, in the event of an investigation indicating that there has been criminal wrongdoing, the Company shall report violations and cooperate with any appropriate legal process.

#### **Review**

The Company shall review and revise its internal controls related to any such area in order to prevent any future occurrences.

## **7. Internal Reporting System**

Company shall be equipped with specific control systems designed to verify the application of and compliance with the relevant ethic systems and policies.

An internal reporting system (e.g. Help line, inbox mail) must be put in place to allow employees to ask questions about compliance and ethics issues and report violations. The internal reporting mechanisms shall include:

- The possibility to consult with supervisors, human resources, the legal department and compliance officer;
- E-mails, newsletters, suggestion boxes and other forms of information exchange to maintain open lines of communication.

For this purpose, a specific organizational unit (i.e.: Local Supervisory Body, Compliance Officer or equivalent function), with appropriate professional and independence skills, shall be formally identified in order to manage and oversee these aspects.

The reports/information received by the Local Supervisory Body, Compliance Officer or equivalent must be collected and stored in an archive, which can be accessed only by the Local Supervisory Body, Compliance Officer or equivalent.

The internal reporting system shall report to responsible functions defined at local level.

The system protects the confidentiality of reporting and preserves the anonymity of reporters.

Clear information regarding the functioning and how to access the reporting mechanism is to be made easily available to all employees and independent contractors.

### **Detected Offences**

Once a potential offense has been identified, the Company shall conduct an appropriate investigation. For this purpose, a standardized policy shall be established.

The investigation will evaluate information in terms of credibility and gravity and will initiate an informal inquiry or formal investigation.

In the event that an investigation indicates there has been criminal wrongdoing, the Company shall report violations and cooperate with any appropriate legal process. The Company shall review and revise its internal controls related to any such area in order to prevent any future occurrences.

### **Evidence of investigation**

A detailed log that records all reports, including the nature of investigation, its results and any remedial or disciplinary action taken shall be maintained by the Local Supervisory Body, Compliance Officer or equivalent.

## **8. Disciplinary System**

A Disciplinary System, aligned and consistent with local laws and regulations shall be formally defined at Company level in order to punish any conduct in violation of Company Codes and/or Group Code, rules and procedures, including the ones stated in these guidelines.

The establishment of disciplinary measures, as well as the application of the sanctions indicated below, is not meant to substitute any measure deriving from criminal proceedings, which involve the same conduct relevant to the present disciplinary system, pending under the judiciary system.

For any matters not covered by the disciplinary system the laws and regulations and the provisions of collective bargaining and company regulations will apply, where applicable.

This Disciplinary System, as well as being published in the intranet, shall be posted at the Company premises in an easily accessible place.

The Company Disciplinary System shall include:

- The identification of positions and roles subjected to penalties;
- The identification of conduct potentially subjected to penalties;
- Expected sanctions in case of violation of Company Codes and/or Group Code, rules and procedures;
- Procedures for the application of sanctions.

### **Enforcement**

The Company must be dedicated to the effective implementation of its business conduct guidelines.

New and existing employees shall be informed of the Company standards through the business conduct guidelines or other Company communications.

Performance evaluations will include ethics and compliance criteria. Non-compliance will result in disciplinary measures and penalties on a consistent basis.

The disciplinary measures which may be invoked include, but are not limited to, counseling, oral or written reprimands, warnings, suspension without pay, reductions in salary, termination of employment and applicable fines. Disciplinary measures must always comply with local law and regulations.

Persons subject to disciplinary measures shall include, in addition to the violator, others involved in the wrongdoing such as (i) persons who fail to use reasonable care to detect a violation, (ii) persons who if requested to disclose information withhold material information regarding a violation, and (iii) supervisors who approve or condone the violations or attempt to retaliate against employees or agents for reporting violations or violators.

Responsibilities for enforcing the Company Disciplinary System shall be formally identified.

PRINCIPLES REFERRED TO  
“HIGH PRIORITY” PROCESSES/AREAS



## A. Purchasing of services

Chiesi strives to ensure full and open competition, guarantee the objective performance of the contract and eliminate the possibility for unfair competitive advantages.

Proposals shall be selected on responsiveness to the request, price, quality, deadlines of delivery, warranties, accountability and fulfilment of the service, as well as any other relevant factors.

Separation of duties between purchasing activities and the disbursement process shall be assured.

A formalized approval process as well as clear specification of responsibilities shall be indicated.

Contracts and agreements shall be in a written form, particularly where services are provided by any healthcare professional.

For consultancy services, evidence of the rendered services shall always be made available and archived. As appropriate and applicable, in accordance with the assessment of the inherent risk, the following information shall be available:

- Signed copy of the procurement instrument (e.g., contract or purchase order);
- All amendments to the procurement instrument;
- Copies of all bids and offers;
- All purchase specifications including delivery requirements;
- The cost/price analysis that was the basis for the award cost or price;
- As applicable, a written justification as to why sole source or minimum competition was used;
- A written explanation as to why the winning contractor was selected;
- Upon completion of the contract, written comments regarding the quality of the vendor's services and guidance and recommendations regarding potential future work.

## B. Strategic planning & budgeting

Financial and operational needs shall result in a formal budgeting process.

Budgetary controls shall be integrated in the purchase requisition approval controls.

Whenever possible, budgetary controls shall be integrated through IT workflows and the ERP system.

The General Manager/Managing Directors shall submit a detailed budget to and discuss with Corporate management no later than the year end of the preceding tax year.

## C. Marketing & Promotional expenses

The Chiesi Group advocates honest competition amongst pharmaceutical companies.

The Chiesi Group ensures it will convey truthful scientific information about medicinal products, abstain from deceptive practices, avoid conflicts of interest with members of the health professions and act in accordance with the relevant laws and regulations.

The approval process of marketing & promotional expenses shall be integrated and cannot allow oneman decisions.

The approval process related to marketing & promotional expenses shall be formalized and its results duly documented and archived.

## D. Promotions of prescription-only medicines and Interactions with Healthcare Professionals (HCPs)/Organizations (HCOs)

Promotion of prescription-only medicines and interactions with HCPs/HCOs must comply with the applicable local laws, regulations, Code of Practices and these Guidelines.

In general:

- The independence of HCPs/HCOs, in terms of their political judgement, activities and policies, shall be assured;
- All partnerships and interactions between Company and HCPs/HCOs shall be based on mutual respect with the views and decisions of each partner having equal value;
- The Company shall not request, nor shall HCPs/HCOs undertake, the promotion of a particular prescription-only medicine;
- The objectives and scope of any partnership shall be transparent. Financial and non-financial support provided by the Company shall always be clearly acknowledged;
- Company staff are not permitted to act in any capacity for HCOs, especially their executive bodies. This does not affect the rights of the staff of the Company to become members of HCOs, with the authorization of the Company.

## E. Donations, grants

Donations, grants and benefits in kind to institutions, organizations or associations that are comprised of healthcare professionals and/or that provide healthcare or conduct research are only allowed if:

- They are made for the purpose of supporting healthcare, research or social responsibility;

- They are documented and kept on record by the donor/grantor; and
- They do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Donations and grants to individual healthcare professionals are not permitted.

Donations to private individuals are not possible.

The policy also includes specifications on the documentation required from the potential candidate, limits on the value of the donation/grant and methods of disbursement.

Concerning the allocation of donations, details of the purpose of use are to be given.

As a basic rule, monetary donations to medical institutes or non-profit organizations (“NPOs”) shall be made directly and paid to the account of donation recipient. A receipt for the donation should be provided by the recipient.

A donation in kind must involve the transfer of property to the recipient.

If the donation proposed is for a member of staff of a medical institute, he/she must first present an authorization from the responsible office of his/her employer (using the correct current template).

No one-man decisions shall be allowed in the donations process.

Compliance with tax regulations must be assured.

A written agreement shall always be formalized in the donations process.

## **F. Management of scientific information/scientific information disclosure**

The Company ensures that the information material is in compliance with applicable requirements, according to country and legislation. In general:

- Details included in the information pack must always be up-to-date and researched;
- All-comprehensive statements are not allowed;
- Articles, tables and other explanations extracted from scientific papers or journals must be replicated integrally reporting the source;
- Promotional materials must be approved by the responsible manager prior to distribution.

## **Field Force**

The Company ensures that the Field Force responds to the following requirements:

- They must have a diploma in a scientific subject, unless otherwise disciplined by local laws;
- They must not practice any medical or paramedical profession.

## **Free samples**

Free samples of products distributed by the Field Force should meet the following requirements:

- Every sample distributed must be at no larger than the smallest pack in commerce;
- The pack must be clearly marked “free sample pack”.

Whenever applicable, a written request of a physician shall be collected.

## **Scientific Service**

A manager, with an adequate scientific background, shall be appointed in charge of scientific information.

## **Conferences and Congresses**

The organization ensures the proper management of financial and procedural aspects related to the submission of applications for conferences and congresses.

## **Visit to the company laboratory**

The organization ensures the proper management of visits to the company laboratory. In particular,

- Visits shall not exceed one working day;
- Any costs borne by companies for travel expenses or hospitality should be limited to qualified professionals and cannot be extended to any unrelated persons.

## **G. Relationships with agents and intermediaries**

Contracts and agreements with agents and intermediaries shall be in a written form.

Remuneration of agents/intermediaries shall be based on fair market value.

Evidence of the services rendered by agents and intermediaries shall be always available and maintained.

The approval process of agreements with agents/intermediaries cannot allow one-man decisions.



## H. Relationships with Regulators/Public Authorities

Relationships with Regulators and Public Authorities shall be managed by the people/representative in charge by an appropriate power of attorney/delegation of authority.

A formal procedure related to relationships with sensitive Regulators and Public Authorities shall be established, in order to govern roles and responsibilities, evidence of decisions. Specific procedures shall be documented in order to manage at least tenders with Public Authorities and organize meetings and events.

Conflicts of interests must be avoided and forbidden.

## I. Compensation system and incentives

A formalized performance appraisal process shall be established.

Compensation systems and incentives shall refer to actual responsibilities and shall be based on quantitative and qualitative elements. Among the qualitative elements, ethical behavior should be always considered.

Objectives shall be measurable and reasonable. Therefore no discretionary elements shall be part of the incentive program.

Objectives (including incentive amounts and percentages) shall be structured in order to avoid leading to malpractices to be achieved.

Non-ethical practices shall lead to the reduction or zero heading of the appraisal and rewarding process.

Compensation systems and incentives calculations shall be formally documented and appropriately communicated to relevant employees.

The above principles shall be applied both to internal staff and the Field Force.

## L. Research & Development funding

The approval process related to Research & Development funding shall be formalized and its results duly documented and archived.

Traceability of operations shall be always ensured.

Providers shall be selected according to the principles listed in paragraph "Purchasing of services".

Payments for research services should be of fair market value for legitimate, reasonable and necessary services.





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