

**Revision 09** 



# FIDIA FARMACEUTICI S.p.A.

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#### ORGANISATIONAL AND MANAGEMENT MODEL PURSUANT TO LEGISLATIVE DECREE No. 231 of 8 JUNE 2001

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# CHAPTER 1

# DESCRIPTION OF THE REGULATORY FRAMEWORK

#### 1.1 The regimen of administrative liability of Entities

Legislative Decree no. 231 of 8 June 2001 containing the "Discipline of the administrative liability of legal persons, companies, and associations, even those without a legal status, pursuant to Art. 11 of Law no. 300 of 29 September 2000, "(hereinafter, the "**Decree**"), introduced into the Italian legal system a regimen of administrative liability (essentially referable to criminal liability) for entities (to be understood as companies, associations, consortia, etc., hereinafter referred to as "Entities") for some types of crimes committed, in the interest or to the advantage of the latter, by:

- Natural persons who perform functions of representation, administration or management of the Entities themselves or of one of their organisational units with financial and functional autonomy;
- natural persons who exercise, even de facto, the management and control of such Entities;
- natural persons under the direction or supervision of one of the aforementioned parties.

#### Such liability is in addition to the (criminal) liability of the natural person who materially committed the crime.

With the adoption of the Decree, Italy has adapted the internal legislation on the liability of legal persons to the international conventions to which Italy adheres<sup>1</sup>.

#### 1.1.1 Sanctions

The sanctions envisaged<sup>2</sup> against the Entity, as a consequence of the commission or attempted commission of the aforementioned crimes, are:

- Pecuniary sanctions (up to 1.5 million euros);
- disqualification sanctions, such as disqualification from exercising the activity, suspension or revocation of licenses or concessions, prohibition on contracting with the Public Administration, exclusion or revocation of loans and contributions, prohibition on advertising goods and services;
- confiscation (and preventive seizure as a precautionary measure) of the profit that the Entity has drawn from the crime, even for equivalent assets;
- publication of the sentence (an additional punishment in case of application of a disqualification<sup>3</sup>).

# 1.1.2 Types of crimes

The types of crimes relevant for the purposes of the Decree and subsequent additions may be included in the following categories:

- crimes against the Public Administration<sup>4</sup>;
- computer crimes and unlawful processing of data<sup>5</sup>;
- offences of organised crime<sup>6</sup>;
- crimes against public trust <sup>7</sup> in matters of forgery of money, public credit cards, revenue stamps and identification instruments or marks;
- crimes against industry and commerce<sup>8</sup>;
- corporate crimes<sup>9</sup>;
- crimes of terrorism or subversion of the democratic order<sup>10</sup>;
- mutilation of female genitals<sup>11</sup>;

<sup>2</sup> Art. 9 et seq., Chapter I, Part II "Sanctions in general" of the Decree.

<sup>&</sup>lt;sup>1</sup> Such as, for example: 1) The *Brussels Convention of the European Community of 26 July 1995* on the protection of financial interests; 2) the *Convention of 26 May 1997*, also signed in Brussels, on the fight against corruption in which officials of the European Community or of the Member States are involved; and 3) the OECD Convention of 17 December 1997 on Combating Bribery of Foreign Public Officials in Business and International Transactions.

<sup>&</sup>lt;sup>3</sup> Art. 18, Part II mentioned.

<sup>&</sup>lt;sup>4</sup> Articles 24 and 25, Chapter I, Part III "Administrative liability for a crime" of the Decree.

<sup>&</sup>lt;sup>5</sup> Art. 24-bis, aforementioned Part III.

<sup>&</sup>lt;sup>6</sup> Art. 24-ter, aforementioned Part III.

<sup>&</sup>lt;sup>7</sup> Art. 25-bis, aforementioned Part III. <sup>8</sup> Art. 25-bis 1, aforementioned Part III.

<sup>&</sup>lt;sup>9</sup> Art. 25-ter, aforementioned Part III.

<sup>&</sup>lt;sup>10</sup> Art. 25-guater, aforementioned Part III.

<sup>&</sup>lt;sup>11</sup> Art. 25-quater 1, aforementioned Part III.



- crimes against the individual, such as the exploitation of child prostitution, child pornography also via the Internet, solicitation of minors, human trafficking and reduction and maintenance in slavery;<sup>12</sup>;
- market abuse<sup>13</sup>;
- manslaughter and serious and very serious negligent injuries, committed in violation of accident prevention regulations and the protection of hygiene and health in the workplace<sup>14</sup>;
- receiving stolen goods, laundering and use of money, goods or benefits of criminal origin; self-laundering<sup>15</sup>;
- offences relating to breaches of copyright<sup>16</sup>;
- crime of incitement to not testify or to bear false testimony before a Court Authority<sup>17</sup>;
- environmental crimes<sup>18</sup>;
- crime of employment of citizens of third countries whose stay in Italy is irregular, if it constitutes a crime<sup>19</sup>;
- transnational crimes<sup>20</sup>;
- crimes of procured illegal entry and aiding and abetting the illegal stay;<sup>21</sup>;
- racism and xenophobia<sup>22</sup>;
- crimes of fraud in sports competitions and the abusive exercise of gaming or betting activities<sup>23</sup>;
- tax crimes;<sup>24</sup>;
- smuggling offences<sup>25</sup>.

#### 1.1.3 Crimes committed abroad

The liability envisaged by the aforementioned Decree also occurs in relation to crimes committed abroad in the cases envisaged by the criminal code in Articles 7, 8, 9 and 10 and on condition that the State of the place where the crime was committed does not lodge proceedings for the same.

1.2 The adoption of the "Organisational and Management Model" as a duty of the company in order to prevent, as far as possible, the commission of the offences envisaged by the Decree

Article 6 of the Decree introduces a particular form of exemption from liability in question if the Entity demonstrates:

- a) To have adopted and effectively implemented through its management body, before the commission of the fact, organisational and management models suitable for preventing crimes of the type that occurred;
- b) to have entrusted to an internal body, endowed with autonomous powers of initiative and control, the task of supervising the functioning and observance of the models, as well as ensuring their updating;
- c) individuals who commit the crime have acted by fraudulently ignoring the organisational and management models adopted by the entity
- d) there was no omission of or insufficient supervision by the body mentioned in the previous subparagraph b).

The Decree also envisages that the models referred to in letter a) must meet the following requirements:

- 1. Identify the areas at risk of committing the crimes envisaged by the Decree;
- 2. prepare specific protocols in order to plan the formation and implementation of the entity's decisions in relation to the crimes to be prevented;
- 3. provide for procedures for identifying and managing the financial resources of the company suitable for preventing the commission of such offences;
- 4. provide for obligations to inform to the body responsible for supervising the functioning and observance of the model;
- 5. introduce an internal disciplinary system suitable for sanctioning the non-observance of the measures stated in the model.

- <sup>16</sup> Art. 25-octies, aforementioned Part III. <sup>16</sup> Art. 25-novies, aforementioned Part III.
- <sup>17</sup> Art. 25-decies, aforementioned Part III. <sup>17</sup> Art. 25-decies, aforementioned Part III.
- <sup>18</sup> Art. 25-undecies, aforementioned Part III.

- <sup>20</sup> Law n. 146, 16 March 2006.
- <sup>21</sup> Art. 25-duodecies, aforementioned Part III.
- <sup>22</sup> Art. 25-terdecies, aforementioned Part III.
- <sup>23</sup> Art. 25-quaterdecies, aforementioned Part III.
- <sup>24</sup> Art. 25-quinquiesdecies, aforementioned Part III.
   <sup>25</sup> Art. 25-sexiesdecies, aforementioned Part III.

<sup>&</sup>lt;sup>12</sup> Art. 25-quinquies, aforementioned Part III.

<sup>&</sup>lt;sup>13</sup> Art. 25-sexies, aforementioned Part III.

<sup>&</sup>lt;sup>14</sup> Art. 25-septies, aforementioned Part III. <sup>15</sup> Art. 25-octies, aforementioned Part III.

<sup>&</sup>lt;sup>19</sup> Art. 25-duodecies, aforementioned Part III.



The same Decree envisages that the organisational and management models may be adopted, guaranteeing the above requirements, based on guidelines drawn up by the representative trade associations and deemed suitable by the competent ministries.

## 1.3 Guidelines drawn up by Confindustria and by Farmindustria

In 2002 Confindustria - representative association of reference of the company Fidia Farmaceutici S.p.A. - Issued its own "Guidelines for the construction of organisational, management and control models pursuant to Legislative Decree 231/01" ("Guidelines"), subsequently updated over the years, which may be summarised according to the following fundamental points:

- identification of risk areas, aimed at verifying in which company area/ sector it is possible to carry out the offences envisaged by the Decree;
- preparation of a control system capable of preventing the risks of committing the aforementioned offences through the adoption of specific protocols.

Furthermore, in March 2009, Farmindustria issued the "Document for the identification of Guidelines for the construction of organisational, management and control models pursuant to Legislative Decree 231/01 in the pharmaceutical sector" ("Farmindustria Guidelines") with the aim of identifying a series of *best practices* to be followed in the many opportunities for interaction between pharmaceutical companies and representatives of the Public Administration.

Both the Confindustria Guidelines and the Farmindustria Guidelines therefore constitute the essential starting point for the correct construction of the Model.



# CHAPTER 2

# DESCRIPTION OF THE COMPANY SITUATION - ELEMENTS OF THE GOVERNANCE MODEL

## 2.1 Activities of the Company

Fidia Farmaceutici S.p.A. (the "Company" or "Fidia") is a company incorporated under Italian law with registered office in Abano Terme (PD), operating in the pharmaceutical sector, dedicated to production and marketing, in Italy through its own commercial network and abroad through licensees, medicinal products, medical devices, and food supplements.

The Company has a factory in Abano Terme, where the production of medicines, medical devices, food supplements are concentrated; of two adjoining factories in Paderno Dugnano (MI), where research and production of transcutaneous patches, impregnated matrices and medical devices are carried out for the administration of active ingredients, including of natural origin, via the dermal and oral routes, cosmetics; a plant in Noto, for research and production of proteins and enzymes.

The Company is at the top of the group by the same name, made up of companies operating on the national and international markets for the production and marketing of pharmaceutical products and medical devices.

#### 2.2 Brief description of the company structure

#### 2.2.1 Organisational structure

The organisational structure of the Company is shown in the attached organisational chart (Annex 1). The most important functions for the purpose of identifying the *process owners* are analysed below.

#### CHAIRMAN - CHIEF EXECUTIVE OFFICER

This function is vested with specific powers of legal representation, signatory powers, and banking powers attributed to the latter by resolution of the board of directors. The Chief Executive Officer presides over the performance of company activities, coordinating the operational functions of the Company.

#### CORPORATE, LEGAL M&A COMPLIANCE

This function is responsible for the legal and *compliance* aspects of the Fidia Farmaceutici Group and for the activities related to the possibility of acquisitions. In particular, "Legal", which deals with corporate, contractual and legal issues is part of this function.

#### CORPORATE R&D - BUSINESS DEVELOPMENT

This function is responsible for identifying possible channels, products, production processes and business growth processes and for the supervision and coordination of research and pharmacovigilance activities. In detail, this function presides over the Research and Development process of new products/processes. In particular, this function carries out the following activities:

- Use of existing scientific, technological, commercial knowledge and skills in order to develop innovative chemicalphysical processes and/ or characteristics;
- carrying out tests, trials and experiments necessary to obtain authorisations for the marketing of products or the use of processes;
- management and protection of confidential information on processes and products (know-how);
- preparation of the documentation necessary for the recognition of patents at national and international level;
- management of patents and know-how.

# CORPORATE CFO - Administration, Finance and Control - IT Services

This function ensures administrative and financial coordination for the companies of the Fidia Farmaceutici Group. The Administration, Finance and Control Department is responsible for this function, which oversees the correct keeping of the compulsory accounting and corporate books in compliance with national corporate and tax regulations and international accounting principles. In particular, this function deals with the following activities:

- Preparation of the annual financial statements;



- preparation of budgets and three-year plans;
- preparation of periodic economic and financial reports;
- preparation of periodic and annual tax returns;
- management of the treasury.

The IT Services function also fulfils this function, which ensures the *information technology* service, both internal to the company and external communication; in particular, the function performs the following tasks:

- Ensuring the proper functioning of hardware and software;
- supervising the process control system activities;
- guaranteeing the correct functioning of internal and external communication systems;
- overseeing the development activities of new IT projects

#### COMMUNICATIONS

The function is responsible for managing relations with third parties and preparing materials, websites and events, aimed at institutional communication, its products and the progress of scientific research.

#### CORPORATE HR

The function presides over personnel policies, in compliance with laws, agreements, and regulations in force. In detail, this function deals with:

- Guaranteeing the outsourced processing of wages and contributions;
- maintaining trade union relations;
- presiding over the search and selection of new personnel;
- promoting professional career activities and related incentives.

#### PROCUREMENT

This function is responsible for the procurement process of raw materials and technical materials used in the production process and the provision of services, after selecting the relevant suppliers.

#### CORPORATE OPERATIONS

This function is responsible for the management and coordination process of the management lines of the individual plants in compliance with the production processes and applicable regulations, as well as compliance with the corporate quality requirements of products and processes. The plant managers (Abano Plant, Paderno Dugnano Plant) and Quality Assurance fulfil this function.

#### REGULATORY AFFAIRS

This function is responsible for preparing the documents and documentation necessary to obtain the authorisations for the production and marketing of products. The function oversees compliance with national and international regulations on the production of pharmaceutical products. The employees belonging to this function are involved in the development of global regulatory strategies for new products and discoveries, collaborating with national and international regulatory Entities to define standards for new technologies, supporting clinical development activities, submitting applications to the regulatory authorities control and ensuring compliance with regulations throughout the life of the product, as well as other aspects of critical importance.

#### PHARMA ITALY

The function manages the process of promotion, sale and the adoption of adequate market policies, as well as participation in public and private tenders in Italy.

#### PHARMA INTERNATIONAL

This function oversees the marketing process of Fidia products on international markets.



# CHAPTER 3

# ORGANISATIONAL, MANAGEMENT AND CONTROL MODEL AND METHODOLOGY FOLLOWED FOR ITS PREPARATION

#### 3.1 Methodology

The adoption of an organisational, management and control model pursuant to the Decree (hereinafter also the "Model"), together with the simultaneous presence of the Code of Ethics of the FIDIA Group (Annex 2, hereinafter also the "Code") as well as representing a reason for the exemption from liability of the Company with reference to the commission of some types of crime, is an act of social responsibility of the FIDIA Group, which gives rise to benefits for all stakeholders: to shareholders, users, employees, creditors and all the other parties whose interests are linked to the fate of the Company.

The introduction of an additional control system, together with the establishment and dissemination of ethical principles, improving the already high *standards* of behaviour adopted by the Company, on the one hand increases the trust and the excellent reputation that the FIDIA Group enjoys towards third parties (an increasingly valuable "*asset*" for companies) and, above all, performs a regulatory function. These tools, in fact, help to regulate the conduct and decisions of those who are called to operate on a daily basis in the name or in favour of the Company in compliance with the aforementioned ethical principles and *standards* of conduct.

Fidia therefore intended to launch a series of activities aimed at making its organisational model compliant with the requirements of the Decree and consistent with both the principles already rooted in its *governance* culture and with the indications contained in the Confindustria and Farmindustria Guidelines. To this end, a process has been activated aimed at revising and updating the Model (hereinafter the "Project"), taking into account the evolution of legislation, practices, as well as the company situation and the organisational structure.

The methodology chosen to implement the Project, in terms of organisational, definition of operating procedures, structuring in phases, assignment of responsibilities among the various company functions, has been elaborated in order to ensure quality and authoritativeness of the results. The Project was divided into the phases summarised below:

Phases	Activity
Phase 1:	Launch of the Project and identification of the processes and activities within which the offences may have been committed, which are referred in Legislative Decree 231/01 Collection and analysis of the documentation, and preliminary identification of the processes/activities within which the crimes referred to in the Decree may abstractly be committed (so-called "sensitive" processes/activities).
Phase 2:	<i>Identification of key officers</i> Identification of the key officers, or the people of the Company who, based on their functions and responsibilities, have an in-depth knowledge of the sensitive areas/ activities, as well as of the control mechanisms currently in place, in order to determine the areas of intervention and a plan of detailed interviews.
Phase 3:	Analysis of processes and sensitive activities Identification and analysis of sensitive processes and activities and control mechanisms in place, with particular attention to preventive controls and other <i>compliance</i> elements/activities.
Phase 4:	<i>Identification of control protocols</i> Identification of the organisational requirements characterising a suitable organisational, management and control model pursuant to the Decree and of the control protocols with a criminality-preventive function, taking into account the procedures already existing in Fidia.
Phase 5:	<b>Defining of Organisational, Management, and Control Model</b> . Defining of the organisational, management, and control model pursuant to the Decree, articulated in all its components and operating regulations.



# 3.2 Purpose and structure of the Model: General part and special parts according to different crime hypotheses

The Model pursues the objective of configuring a structured and organic system of procedures and control activities, aimed at preventing, as far as possible, conducts that may involve the offences contemplated by the Decree.

By identifying sensitive activities and their consequent proceduralisation, the aim is, on the one hand, to bring about full awareness in all those who work in the name and on behalf of Fidia of being able to incur an offence subject to sanction; on the other hand, thanks to constant monitoring of the activity, allowing Fidia to intervene promptly to prevent or combat the commission of the crimes themselves.

The Model is divided into this "General Part," which contains a descriptive part of the activity carried out by the Company and the definition of the structure necessary for the implementation of the Model such as the functioning of the Supervisory Body and the sanction system, and in "Special Parts" whose content consists of the identification of the activities that may be at risk for the commission of the offences envisaged by the Decree, with the provision of the related control protocols. In particular, the structure of the Model with the provision of "Special Parts" allows for timely updating, through any appropriate additions, where Legislators intend to add further relevant criminal offences.

Within each of the macro areas considered, the sensitive activities and control tools adopted for prevention are described. These tools are binding for the recipients of the Model, as defined below, and consist of obligations to do something (compliance with procedures, reports to supervisory bodies) and obligations not to do something (compliance with prohibitions), which are also expressly specified. Compliance with these obligations has a precise legal value; in fact, in the event of a breach of these obligations, Fidia will react by applying the disciplinary and sanctioning system referred to above.

The Special Parts must also be related to the behavioural principles contained in the company procedures and in the Code which guide the behaviour of the recipients in the various operational areas, with the aim of preventing incorrect behaviour or behaviour not in line with Fidia's directives. The Special Parts are as follows:

- > Special Part A Crimes in relations with the Public Administration;
- Special Part B Computer Crimes;
- > Special Part C Crimes relating to counterfeiting and infringement of copyright;
- Special Part D Corporate Crimes;
- > Special Part E Negligent crimes in violation of regulations on health and safety in the workplace;
- > Special Part F Money laundering, receiving stolen goods, and self-laundering crimes;
- Special Part G Crimes related to immigration;
- Special Part H Environmental Crimes;
- Special Part I Market Abuse Crimes;
- Special Part J Tax crimes;
- Special Part K– Smuggling Crimes;
- Special Part L Instrumental Processes.

With reference to the other "predicate crimes" of the administrative liability of entities pursuant to the Decree, such as counterfeiting currency, crimes against the individual (slavery and child pornography), crimes with the purpose of terrorism or subversion of the democratic order, the transnational crimes, associative crimes, organised crime offences, crimes against industry and trade, the crime of inducing not making or making false statements to the judicial authorities, crimes of racism and xenophobia, crimes of fraud in sports competitions and the abusive exercise of gaming or betting activities; it is considered appropriate to specify that in relation to the same, although taken into consideration in the preliminary analysis phase, sensitive activities have not been identified (following subsequent analyses and considerations and interviews with key officers), as it is believed that the risk of committing such crimes may be negligible and, therefore, no specific rules and/or dedicated procedures are envisaged, subject to, in any case, the provision for referral to conduct in compliance with the relevant regulations and the principles contained in the Code.

In the event that it becomes necessary to issue further Special Parts, relating to new types of offences relating to the Company's business area which in the future fall within the scope of application of the Decree, the Board of Fidia is delegated the power to supplement this Model by means of a specific resolution.



#### 3.3 Recipients of the Model

The Model and the related General Part and Special Parts are addressed to the directors, managers, and employees (hereinafter referred to as "Company Representatives") of Fidia in sensitive activities, as well as to external Collaborators and Partners (hereinafter all referred to as "Recipients"). In particular, the objective of the Special Parts is that all the Recipients as identified above adopt rules of conduct that comply with the provisions within each Part, in order to prevent the occurrence of the offences envisaged in the Decree.



# CHAPTER 4

# THE SUPERVISORY BODY PURSUANT TO LEGISLATIVE DECREE 231/01

# 4.1 Identification of the Supervisory Body

Based on the provisions of the Decree (Article 6, paragraph 1, letters a) and b)), the entity may be exempted from liability resulting from the commission of crimes by qualified persons (pursuant to the Decree), if the management body, inter alia, entrusted the task of continuously supervising the operation and compliance with the model, and of updating it, to a body endowed with autonomous powers of initiative and control, whose requirements (as also suggested by the Guidelines) are:

# <u>Autonomy and independence:</u>

- Absence of conflicts of interest, even potential ones, with Fidia;
- possession of autonomous powers of initiative and control;
- non-assignment of operational tasks within Fidia;
- placement in a position of direct reference to the BoD;
- professionalism understood as:
  - Possession of adequate specialist skills;
  - provision of specialised tools and techniques to be able to carry out the activity, also making use of the consultancy of external parties;
- <u>continuity of action</u> understood as:
  - duration of the mandate independent from that of the other corporate bodies;
  - frequency of audits.

# 4.2 Establishment, appointment, and replacement of the Supervisory Body

The Supervisory Body (hereinafter also referred to as the "**SB**") of Fidia is established by resolution of the BoD and remains in office for the period established at the time of appointment: it may be single-person or multi-person. The SB expires on the date established in the appointment, while continuing to perform its functions *ad interim* until the new appointment. The BoD has the right to convene the SB at any time.

The appointment as a member of the SB is conditioned by the presence of the subjective requirements of honour, integrity, and respectability, as well as the absence of causes of incompatibility with the appointment itself, and potential conflicts of interest with the role and tasks that would be performed. It follows that at the time of the appointment, each person designated to hold the position of member of the SB must issue a statement in which the latter certifies the absence of reasons for incompatibility, with respect to the requirements listed in the previous paragraph. These regulations also apply in the event of the replacement of a member of the SB itself.

The revocation of powers and the attribution of the same to different subjects may take place, in addition to the natural expiry of the mandate, only for just cause, also linked to objective interventions of organisational restructuring of the Company, through a specific resolution of the Board of Directors. "Just Cause" for the revocation of the powers connected with the position of member of the Supervisory Body, means, by way of example, but not limited to:

- Gross negligence in carrying out the tasks connected with the assignment such as: failure to prepare the annual summary report on the activity carried out; failure to draw up the supervisory plan;
- "omitted or insufficient supervision" by the SB in accordance with the provisions of Art. 6, paragraph 1, lett. d), Decree
   resulting from a conviction, even if not finalised, issued against Fidia pursuant to the Decree or from a sentence applying the penalty requested (the so-called plea bargain);
- in the case of an internal member, the assignment of operational functions and responsibilities within the company organisational structure that are incompatible with the requirements of "autonomy and independence" and "continuity of action" of the SB. In any case, any provision of an organisational nature that concerns him/her (e.g. termination of the employment relationship, transfer to another position, dismissal, disciplinary measures, appointment of a new manager) must be brought for acknowledgement of the BoD;
- in the case of an external member, serious and ascertained reasons for incompatibility that undermine his/her independence and autonomy;
- failure of even one of the eligibility requirements.



Any decision regarding individual members or the entire SB relating to revocation or replacement is the exclusive responsibility of the BoD.

# 4.3 Economic resources assigned to the Supervisory Body

Every year, the BoD assigns an expense budget to the SB taking into account the requests of the latter. The assignment of the budget allows the SB to operate autonomously and with the appropriate tools for an effective performance of the task assigned to the latter by this Model, in accordance with the provisions of the Decree.

#### 4.4 Functions and powers of the Supervisory Body

In carrying out the tasks entrusted to it, the SB may take advantage, under its direct supervision and responsibility, of the collaboration of all the functions and structures of the Company, or of external consultants. This ability allows the SB to ensure a high level of professionalism and the necessary continuity of action.

The SB has autonomous powers of initiative, intervention and control, which extend to all sectors and functions of Fidia, and which must be exercised in order to effectively and promptly perform the functions envisaged in the Model and by the rules for implementing the same.

In particular, the SB is entrusted with the following tasks and powers for the performance and exercise of its functions:

- Supervising the operation of the Model both with respect to the prevention of the commission of the crimes referred to
  in the Decree and with reference to the ability of bringing to light the occurrence of any illegal conduct;
- carrying out periodic inspection and control activities, of a continuous nature with a frequency and methods
  predetermined by the supervisory activities plan and surprise audits, in consideration of the various sectors of
  intervention or types of activities and their critical points in order to verify the efficiency and effectiveness of the Model;
- freely accessing any Fidia management and units without the need for any prior consent to request and acquire information, documentation and data deemed necessary for the performance of the tasks envisaged by the Decree, from all employees and managers. In the event that justified reasons for denying access to documents are given, the SB draws up a report that is forwarded to the BoD, wherever it does not agree with such challenge;
- requesting relevant information or the presentation of documents, including IT documents, pertinent to risk activities, from the Directors, the supervisory bodies, the independent auditors, collaborators, consultants and in general all persons required to comply with the Model;
- overseeing, develop and promote the constant updating of the Model, formulating, where necessary, proposals to the
  management body for any updates and adjustments that may become necessary as a result of: i) significant violations
  of the provisions of the Model; ii) significant changes in Fidia's internal structure and/or in the methods of carrying out
  business activities; iii) regulatory changes;
- monitoring compliance with the provisions of the Model, in relation to the various types of crimes contemplated by the
  Decree and subsequent laws that have extended its scope, verifying compliance with the procedures envisaged by
  the Model and detecting any behavioural deviations that may emerge from the analysis of information flows and reports
  received;
- ensuring the periodic updating of the mapping and identification of sensitive areas;
- maintaining a link with the auditing company as well as with other consultants and collaborators involved in the implementation of the Model;
- managing relations and ensuring the relevant information flows to the BoD;
- promoting communication and training interventions on the contents of the Decree and the Model, on the impacts of the legislation on the company's activity and on behavioural rules, also establishing frequency controls and possibly different plans for those who work in the various sensitive activities;
- ensuring the implementation of an efficient internal reporting system for the notification of significant information as addressed by the Decree, also guaranteeing the protection of the privacy of the reporting party;
- providing clarifications regarding the meaning and application of the provisions contained in the Model;
- formulating and submitting for approval of the BoD, the expense budget required for the proper performance of the
  tasks entrusted in total autonomy. The SB may autonomously commit resources that exceed its spending powers, if
  the use of such resources is necessary to deal with exceptional and urgent situations. In these cases, the SB must
  inform the BoD immediately at the next meeting;



- promptly reporting to the management body, for the appropriate measures, the violations ascertained of the Model that may lead to the onset of liability on the part of Fidia;
- promoting the activation of any disciplinary proceedings and proposing any sanctions referred to in chapter 7 of this Model;
- verifying and evaluating the suitability of the disciplinary system pursuant to and for the effects of the Decree.

# 4.5 Functions of the SB: Reporting to corporate bodies

The Supervisory Body, upon the emergence of any critical aspects for the implementation of the Model, reports the need for modifications, and to this end prepares *inter alia*:

- i) Annually, a summary report of the activity carried out in the current year and a plan of the activities planned for the following year, to be presented to the Board of Directors;
- ii) immediately, any communication relating to the occurrence of extraordinary situations (for example: significant violations of the principles contained in the Model, legislative innovations regarding the administrative liability of entities, etc.) and in the case of reports received which are of an urgent nature, to be presented to the Chief Executive Officer and the Chairman of the BoD.

The meetings with the Fidia bodies must be documented by means of specific reports.

#### 4.6 Collection and retention of information

All information, notifications, reports, and statements envisaged by the Model are kept on record by the Supervisory Body in a special archive (computerised or on paper) for a period of at least 10 years.



# CHAPTER 5

# INFORMATION FLOWS TO THE SUPERVISORY BODY

# 5.1 Information obligations towards the Supervisory Body refer to:

Information obligations towards the Supervisory Body refer to:

- Information, data, news, documents that allow the SB to be able to carry out its control activity in an informed manner;
- reports on events that could give rise to the Company's responsibility pursuant to the Decree.

All Recipients of the Model are subject to such obligations.

# 5.1.1 Information flows

The Supervisory Body, also through defining of a procedure, may establish the types of information that the managers involved in the management of sensitive activities must transmit together with the frequency and methods with which such communications are forwarded to such Body.

The corporate functions that operate within the context of sensitive activities must transmit to the Supervisory Body the information concerning:

- The periodic results of the control activities carried out by such functions in implementation of the Model, also upon request (summary reports of the activity carried out, etc.);
- any anomalies or atypicalities found in the information available.

The information may concern, as an example but not limited to:

- Transactions that fall within sensitive activities (for example: periodic summary statements on agreements stipulated with public entities, information relating to new personnel recruitment or use of financial resources for the purchase of goods or services or other investment activities, etc.);
- measures and/or news from judicial police bodies, or from any other authority, from which it is clear that investigations are being carried out, including against unknown persons, for the crimes contemplated by Legislative Decree no. 231/2001 and which may involve Fidia;
- requests for legal assistance made by employees in the event of judicial proceedings against them and in relation to the crimes referred to in the Decree, unless expressly prohibited by the judicial authority;
- reports prepared by the heads of other corporate functions within their supervisory activities, which may reveal facts, acts, events or omissions which are critical for compliance with the provisions laid down by the Model;
- notifications relating to disciplinary proceedings implemented and any sanctions issued (including measures taken against employees) or measures taken to dismiss such proceedings jointly with the related reasons;
- Any other information that, although not included in the aforementioned list, is relevant for the purposes of correct and complete supervision and updating of the Model.

In any case, the SB defines and communicates a detailed scheme of Information Flows intended for the latter.

The information flows must be sent to the SB by sending the documentation to the dedicated E-mail address.

# 5.1.2 Reporting - *Whistleblowing*

The obligation to provide information on any conduct contrary to the provisions contained in the Model falls within the broader duty of diligence and obligation of loyalty of the employee. With regard to consultants or external collaborators, etc., there is a contractual obligation of immediate disclosure for them in the event that they receive, directly or indirectly, from an employee/representative of Fidia a request for behaviour that could lead to a violation of the Model.

Therefore, all company personnel, both with reference to top management and subordinates, as well as the external recipients of this document, are obliged to communicate directly with the Supervisory Body to report cases of commission of crimes, circumstances of unlawful conduct relevant under the Decree and based on precise and consistent factual elements, any violations of the Model, as well as any episode of deviation from the principles of conduct provided for by the Model and the Code of Ethics, of which they have become aware due to the functions performed, through multiple alternative



communication channels suitable for guaranteeing, with IT methods, the confidentiality of the identity of whistleblowers as required by Art. 6, paragraph 2-bis, lett. b) of the Decree.

#### Content of reports

For the aforementioned purposes, the whistleblower is required to provide all the elements known to him/her, useful for ascertaining, with due verifications, the reported facts. In particular, the report must contain the following essential elements:

<u>Subject</u>: a clear description of the facts to be reported is required, with an indication (if known) of the circumstances of time and place in which the facts were committed/omitted.

<u>Reported party</u>: the whistleblower must indicate the personal details or in any case other elements (such as the corporate function/role) that allow easy identification of the alleged perpetrator of the illegal behaviour.

Furthermore, the whistleblower may indicate the following additional elements: (i) His/Her personal details, in the event that he/she does not intend to avail himself/herself of the right to keep his/her identity confidential; (ii) the indication of any other parties who may report on the facts stated; (iii) the indication of any documents that may confirm the validity of such facts.

Reports, even when anonymous, must always have a relevant content pursuant to the Decree. Anonymity may in any way represent a tool to vent any disagreements or conflicts between employees. The following is equally prohibited:

- Use of insulting expressions;
- forwarding of reports with purely defamatory or libellous purposes;
- the forwarding of reports relating exclusively to aspects of private life, without any direct or indirect connection with company business. These reports will be considered even more serious when they refer to sexual, religious, political, and philosophical habitual behaviour and orientations.

In a nutshell, each report must have as its sole purpose the protection of the integrity of the Company or the prevention and/or repression of illegal conduct as defined in the Model.

#### Communication channels

The communication channels with the Supervisory Body that follow, in compliance with the legislation on *Whistleblowing*, also guarantee the confidentiality and protection of whistleblowers from any retaliation; furthermore, the Company monitor to ensure that career advancements of any whistleblowers do not incur discriminatory-type treatment, and issues disciplinary sanctions to this effect based on the seriousness of the facts, and in any case in view of the criteria set out in Chapter 7 of the Model, for whistleblowers who by wilful misconduct or gross negligence report facts that later prove to be unfounded.

#### The channels envisaged are the following:

Internal confidential mail: using the appropriate mailboxes. The envelope must clearly state the words "Strictly confidential. Employee information," in order to ensure maximum confidentiality.

E-mail address: segreteria@3pgo.com

Additional channels identified and activated in compliance with the provisions of Art. 6, 2-bis lett. D of the Decree.

#### Handling of reports

The Supervisory Body adopts suitable measures to guarantee the confidentiality of the identity of whoever transmits information to the Supervisory Body. However, behaviours aimed exclusively at slowing down the activity of the Supervisory Body must be appropriately sanctioned. The Company protects whistleblowers in good faith against any form of retaliation, discrimination or penalizing and, in any case, the confidentiality of the whistleblower's identity is ensured, subject to legal obligations and the protection of the rights of the Company or of persons wrongly accused or in bad faith.



For the aforementioned purposes, the Supervisory Body collects and stores the reports received in a special archive (computer and/or paper), which only allows access to members of the Body. At its discretion and under its own responsibility, the Supervisory Body assesses the reports received and the cases in which it is required to take action; the findings of the verification must be made in writing together with justifications for the same.



# **CHAPTER 6**

# TRAINING AND COMMUNICATION PLAN

#### 6.1 Introduction

In order to effectively implement the Model, Fidia intends to ensure correct disclosure of its contents and principles inside and outside its organisation, communicating the contents and principles of the Model not only to its employees, but also to subjects who, while not having the formal qualification of employee, work - on an ongoing basis - to achieve the objectives of Fidia.

Fidia, in fact, intends to do the following:

- Determine, in all those who operate in its name and on its behalf in sensitive activities, the awareness of being able to incur, in the event of violation of the provisions contained therein, an offence subject to sanctions;
- inform all those who work in any capacity in its name, on its behalf or in any case in its interest that the violation of the provisions contained in the Model will result in the application of appropriate sanctions or the termination of the contractual relationship as it involves a loss of the duties of loyalty, fairness, and diligence that arise from the legal relationships established by Fidia;
- reiterate that Fidia does not tolerate unlawful conduct, of any kind and regardless of the purpose, as such conduct (even if Fidia were apparently in a position to take advantage of it) are in any case contrary to the ethical principles which Fidia intends to abide by.

The communication and training activity must be diversified according to the recipients to whom it is addressed and must, in any case, be based on principles of completeness, clarity, accessibility and continuity in order to allow the various recipients to be fully aware of those provisions companies that they are required to comply with and the ethical rules that must inspire their behaviour.

The communication and training activity is supervised by the SB, as it is part of its duties. Training initiatives may also take place remotely through the use of computer systems (e.g.: videoconferencing, e-learning).

# 6.2 Making the Model and Code available

In order to ensure an effective and rational communication and training activity, Fidia promotes awareness for every employee, that is to say both executive personnel/ personnel with managerial functions, and non-executive personnel, and every external collaborator with stable relationships (hereinafter "stable external collaborators") of the contents and principles of the Model and of the implementation procedures, with a different degree of detail according to the position and role covered.

The Code is made available to employees (including new hires) and external collaborators on the Company's website, or through alternative means (for example, attaching to the pay slip or posting it on company notice boards). A copy of the Model is made available to the members of the corporate Entities and to persons with Fidia representative functions at the time of acceptance of the office. Suitable communication and training tools will be adopted to update them regarding: i) any changes to the Model; ii) significant procedural, regulatory or organisational changes.

Third parties external to Fidia (for example, Consultants and Partners) are provided with a specific information letter on the successful adoption of the Model, on the consequences of non-compliance with the Model, upon request to view the copy available on the website.

Where possible, specific clauses aimed at regulating these consequences are included in the respective contractual texts.



# **CHAPTER 7**

# DISCIPLINARY SYSTEM

#### 7.1 General principles

Article 6, para. 2, lett. e) and article 7, para. 4, lett. b) of the Decree require, as a condition for the efficient implementation of the organisational, management and control model, the introduction of an appropriate disciplinary system that punishes failure to comply with the measures set forth in the Model itself. Therefore, the definition of an adequate disciplinary and sanctioning system is an essential prerequisite for the effectiveness of the organisational, management and control model pursuant to the Decree.

The sanctions set out by the disciplinary system will be applied to all violations of the provisions of this Model, regardless of the outcome of any criminal investigation instigated by law enforcement agencies in the event that the behaviour to be sanctioned falls within the scope of crimes identified pursuant to the Decree.

The assessment and application of disciplinary sanctions takes place in compliance with the procedures envisaged by Art. 7 of Law no. 300, 30/5/1970 ("Workers' Statute") and any applicable special regulations, and must take into account the principles of proportionality and adequacy with respect to the alleged violation. In this regard, the following circumstances are relevant:

- Type of the alleged offence;
- actual circumstances in which the offence took place;
- methods by which the conduct took place;
- seriousness of the violation, also taking into account the subjective attitude of the agent;
- possible commission of multiple violations within the context of the same conduct;
- possible participation of more than one person in the commission of the violation
- possible recurrence of the author of the violation.

#### 7.2 Parties

All employees, directors, collaborators of Fidia, as well as all those who have contractual relationships with the Company, within the context of the relationships themselves, are subject to the sanctioning and disciplinary system referred to in this Model.

The procedure for the issuing of sanctions subject to this chapter takes into account the particulars deriving from the legal status of the party involved.

In any case, the SB must be informed of the procedure for imposing disciplinary sanctions. The Corporate HR function is responsible for the actual application of the disciplinary measures, which will impose the sanctions on any report by the SB, also having heard the non-binding opinion of the hierarchical superior of the perpetrator of the prohibited conduct. In any case, the SB, in collaboration with the Corporate HR function, is assigned the task of assessing the adequacy of the disciplinary system to the requirements established by the Decree.

The SB also ensures, in agreement with the Corporate HR function, that specific procedures are adopted to inform all the above-mentioned subjects, from the beginning of their relationship with the company, about the existence and content of the sanctioning apparatus herein.

#### 7.3 Sanctions against blue-collar workers, office workers, and managers

The National Collective Labour Agreement of the Chemical Industry ("CCNL Chimica") applies to the employees of the Company classified as blue-collar workers, office workers, and executives.

Conduct by non-managerial personnel in violation of the individual behavioural rules set out in this Model will constitute disciplinary offences, also in compliance with and in application of the provisions of the Chemical National Collective Labour Agreement, the Workers' Statute and any applicable special regulations.



The sanctions envisaged therein are: verbal warning, written warning, fine not exceeding the amount corresponding to 4 hours of pay, suspension from work and pay for a period not exceeding 8 days, termination of the employment relationship with or without notice.

The type and extent of each of the aforementioned sanctions will be determined in relation to:

- The intent of the behaviour or the level of negligence, imprudence or lack of foresight shown, with regard also to whether the event could have been foreseen;
- the worker's overall behaviour with particular regard to whether or not there have been previous disciplinary measures against them, within the limits permitted by law
- the employees' tasks;
- the functional position of the persons involved in the facts;
- other particular circumstances accompanying the disciplinary violation.

In detail, the disciplinary sanctions are applied as follows:

1) Verbal warning, applicable if the worker violates one of the internal procedures provided for by the Model (for example, does not comply with the prescribed procedures, fails to notify the Supervisory Body of the required information, fails to carry out checks, ...) or adopts behaviour in carrying out activities in sensitive areas that does not comply with the provisions of the Model;

2) a written warning, applicable if the worker is repeatedly violating the procedures envisaged by the Model or in adopting, in carrying out activities in sensitive areas, a behaviour that does not comply with the provisions of the Model itself;

3) a fine of up to 4 hours of remuneration and suspension from service and remuneration (not exceeding 8 days), applicable, if the worker in violating one of the internal procedures envisaged by the Model or in carrying out activities in sensitive areas adopts a conduct that does not comply with the provisions of the Model causing damage or creating a situation of potential danger to the Company, or if the worker has repeatedly committed the violations referred to in point 2);

4) termination of the employment relationship with notice, applicable if the worker adopts behaviour in carrying out activities in sensitive areas that does not comply with the provisions of the Model and constitutes a significant direct non-fulfilment in an unequivocal manner to the commission of a crime sanctioned by Decree or which determines the actual application by the Company of the measures envisaged by the Decree;

5) termination of the employment relationship without notice, applicable if the worker adopts a behaviour in carrying out activities in sensitive areas that does not comply with the provisions of the Model and constitutes a very serious direct, unequivocal non-fulfilment to the commission of a crime sanctioned by Legislative Decree 231/01 or which results in the actual application by the Company of the measures envisaged by the Decree, as well as the worker who has repeatedly committed the deficiencies referred to in point 3).

The Company reserves the right to request compensation for damages caused by an employee infringing the Model.

#### 7.4 Measures against managers/personnel with managerial functions

The National Collective Labour Agreement for Executives in the Chemical Industry is applied to the personnel classified as Executives.

In carrying out their professional activities, Fidia's managers are obliged both to respect and to ensure that their collaborators comply with the provisions contained in the Model. In the event of a violation of the internal procedures envisaged in this Model or of the adoption in carrying out activities within the Sensitive Activities of a behaviour that does not comply with the provisions of the Model itself, the most suitable measures will be applied to the managers in compliance with the provisions required by law and by the applicable CCNL [National Collective Labour Agreement].

Finally, it is emphasised that the adherence of executives to the principles and rules contained in the Model will constitute an element of professional evaluation that may have repercussions on the career path.



The unlawful behaviours of executives for violation of the provisions contained in the Model are to be considered punishable for the following behaviours:

- Failure to supervise personnel hierarchically dependent on him/her, so that compliance with the provisions of the Model is ensured for carrying out activities in the areas at risk of crime and for activities instrumental to operational processes at risk of crime;
- failure to report non-compliance and/or anomalies inherent to the fulfilment of the obligations under the Model, if he/she becomes aware of them, such as to render the Model ineffective with consequent potential danger for Fidia to the imposition of sanctions pursuant to the Decree;
- failure to report to the SB any critical issues relating to the performance of activities in the areas at risk of crime, found during monitoring by the authorities in charge;
- where the executive incurs one or more violations of the provisions of the Model such as to involve the commission of the offences contemplated in the Model, thus exposing Fidia to the application of sanctions according to the Decree.

In the event of a violation of the provisions and rules of conduct contained in the Model by a manager, the Company adopts the measure deemed most appropriate for the latter in compliance with the provisions of law and the applicable national collective bargaining agreement. In general, particular attention will be paid to any damage to the particular relationship of trust between the Company and the manager that could originate from violation of the Model.

#### 7.5 Measures against Directors and Statutory Auditors

In case of violation of the Model by one or more directors and/or auditors, the SB will inform the board of statutory auditors and the Chairman of the BoD, who, based on their respective competences and in accordance with the powers provided by law and/or by the Articles of Association, will take the appropriate measures including, if necessary, convening of a shareholders' meeting in order to adopt the most suitable measures.

#### 7.6 Measures against consultants and external collaborators

The adoption by consultants or external collaborators (both in the case of permanent and occasional collaboration relationships), however named, or other subjects having contractual relationships with Fidia, of behaviours in contrast with the precepts contained in the Decree, in the Model, or with the Code, it will be sanctioned in accordance with the provisions of the specific contractual clauses that will be included in the relative contracts.

By said clauses, the third party undertakes to adopt and effectively implement company procedures and/or maintain suitable conduct to prevent the commission, even attempted, of the offences to which the sanctions apply, as set out in the Decree. The non-fulfilment, even partial, of such obligation is sanctioned with the right of Fidia to suspend the execution of the contract and/or to unilaterally withdraw from it, even in the course of execution, which possibly envisages penalties, or to terminate said contract, subject in any case to Fidia's right to compensation for any damages incurred. These sanctions must be communicated to the SB.

# 7.7 Measures in application of the Whistleblowing discipline

In compliance with the provisions of Art. 2-bis, paragraph 1, lett. d) of the Decree, the sanctions referred to in the preceding paragraphs, in compliance with the principles and criteria set out therein, are applied to those who violate the protection measures of the whistleblower, as well as those who make unfounded wilful misconduct or gross negligence reports.

In detail, the carrying out of retaliatory acts against the author of the report made in good faith constitutes a serious disciplinary violation that will be sanctioned according to the procedures set out in the previous paragraphs. The adoption of discriminatory measures against parties who make the reports may be reported to the National Labour Inspectorate in respect of the measures falling within its competence, as well as by the whistleblower and by the trade union organisation indicated by the latter. Retaliatory or discriminatory dismissal of the whistleblower is null and void. Changing their duties is also null and void pursuant to Article 2103 of the Civil Code, along with any other retaliatory or discriminatory measure adopted against the whistleblower.

It is the employer's responsibility, in the case of disputes related to the imposition of disciplinary sanctions, or to demotions, lay-offs, transfers, or subjection of the whistleblower to another organisational measure with negative effects, direct or indirect, on their working conditions, subsequent to submitting the report, to demonstrate that these measures are based on reasons unrelated to the report itself.



Any unauthorised use of the reporting channels is also prohibited. Protection of the identity of the whistleblower ceases, in the case of reports that are patently unfounded and deliberately preordained with the aim of damaging the reported person or the company. Also in this case, such behaviour constitutes a serious disciplinary violation and is sanctioned according to the aforementioned procedures.

Organisational, management and control model pursuant to Legislative Decree No. 231/01



# CHAPTER 8

# ADOPTION OF THE MODEL - CRITERIA FOR UPDATING AND ADAPTATION OF THE MODEL

# 8.1 Audits and inspections on the Model

The SB must draw up an annual supervisory program through which it plans, in principle, its activities by providing: a schedule of activities to be carried out during the year, the determination of the timing of the checks, the identification analysis criteria and procedures, the possibility of carrying out unscheduled audits and inspections.

In carrying out its activities, the SB may avail itself of both the support of Fidia internal functions and structures with specific skills in the company sectors subject to control from time to time and, with reference to the execution of the technical operations necessary for the performance of the function control, external consultants. In this case, the consultants must always report the results of their work to the SB.

The SB is granted the broadest powers in the course of audits and inspections in order to effectively carry out the tasks entrusted to it.

#### 8.2 Update and adaptation

The BoD resolves on the updating of the Model and its adaptation in relation to changes and/or additions that may become necessary as a result of:

- i) Significant violations of the provisions of the Model adopted;
- ii) changes to the internal structure of Fidia and/or the methods of carrying out business activities;
- iii) regulatory changes;
- iv) results of audits;
- v) ascertainment of serious criminal offences committed even prior to the approval of the Model.

The BoD has exclusive competence in this area.

Once approved, the changes and instructions for their immediate application are communicated to the SB, which, in turn, will, without delay, make the same changes operational and ensure the correct communication of the contents internally and externally to Fidia.

The SB will also, by means of a specific report, inform the BoD about the outcome of the activity undertaken. The SB retains, in any case, specific duties and powers regarding the care, development and promotion of the constant updating of the Model. To this end, it formulates observations and proposals, relating to the organisational and the control system, to the corporate structures responsible for this or, in cases of particular importance, to the Board of Directors. In particular, in order to ensure that the changes to the Model are carried out with the necessary timeliness and effectiveness, without at the same time incurring any lack of coordination between the operational processes, the provisions contained in the Model and the dissemination of the same, the Chairman of the BoD has the task of periodically making changes to the Model that pertain to descriptive aspects, promptly informing the Board and the Supervisory Body. The Board must ratify the changes at its earliest meeting. It should be noted that the expression "descriptive aspects" refers to elements and information that do not affect the substantial contents of the Special Parts of the Model and/or that derive from acts approved by the corporate Entities of Fidia (such as, for example, amendments to the by-laws, etc.) or by corporate functions with specific powers (such as the redefinition of the organisational chart, etc.).

In any case, the Model will be subject to periodic review procedures at least every three years.



# Annex 1 - Organisational chart

The company organisational chart in its current version is attached.



# Annex 2 - Code of Ethics

The Code of Ethics of the FIDIA Group is attached.



#### THE SPECIAL PARTS OF THE MODEL

#### 1 SENSITIVE ACTIVITIES AND THE CONTROL SYSTEM

Art. 6, paragraph 2, lett. a) of the Decree indicates, as one of the essential elements of the organisational and management models envisaged by the Decree, the identification of the so-called "sensitive" or "at risk" activities, i.e. those company activities within which the risk of commission of one of the offences expressly referred to in the Decree (hereinafter "Sensitive Activities").

Consequently, for each special section dedicated to the macro-categories of crime potentially at risk, the Sensitive Activities, the related *process owners*, the crimes that can be committed and the penal-preventive controls to be applied are identified.

In this regard, the control system perfected by Fidia based on the indications provided by the main trade associations, such as the Confindustria Guidelines, envisages the adoption of:

- General principles of behaviour;
- "specific" control protocols applied to individual Sensitive Activities.

The control protocols are based on the following general rules, valid for each special part, which must be respected in the context of each sensitive activity identified:

- Segregation of duties: preventive and balanced distribution of responsibilities and provision of adequate levels of
  authorisation, suitable for avoiding the mixing of potentially incompatible roles or excessive concentrations of
  responsibilities and powers in the hands of individual parties. In particular, the separation of activities and
  responsibilities between who authorises, who executes and who controls a specific operation in sensitive activities,
  must be guaranteed.
- **Regulations**: existence of corporate provisions and/or formalised procedures suitable for providing principles of conduct, operating methods for carrying out sensitive activities as well as methods for filing relevant documentation.
- Authorisation and signatory powers: the authorisation and signatory powers must be: i) consistent with the
  organisational and managerial responsibilities assigned, providing, where required, an indication of the approval
  thresholds for expenses; ii) clearly defined and known within Fidia.
- Traceability:
  - Every operation relating to the sensitive activity must be, where possible, adequately recorded;
  - the process of deciding, authorising and carrying out the sensitive activity must be verifiable *ex post*, also through specific documentary supports;
  - in any case, the possibility of cancelling or disposing of the registrations made must be regulated in detail.

In the individual Special Parts below, the related specific control protocols are identified for each Sensitive Activity and the general principles of conduct are listed.



# SPECIAL PART "A" CRIMES AGAINST PUBLIC ADMINISTRATION

#### 1 CRIMES AGAINST PUBLIC ADMINISTRATION

The Decree exhaustively lists the crimes against the Public Administration that involve liability on the part of the Entities. They are defined as follows:

- Embezzlement to the detriment of the State, another public or community body<sup>26</sup>: failure to allocate contributions, subsidies or similar to the purposes for which they were intended;
- undue receipt of contributions, loans or other disbursements by the State, by another public body or by a Community body<sup>27</sup> through the use of false documents or the issuance of statements certifying things that are not true, or through the omission of due information;
- fraud in public supplies<sup>28</sup>: the alteration of the execution and non-fulfilment of supply contracts concluded with the State or with another public body, or with a company providing public services or of public need;
- aggravated fraud to obtain public funds<sup>29</sup>: receipt of contributions, loans or other disbursements by the State, by another public body or by a community body by means of artifices or deceptions other than the use of false documents, false statements or omission of due information;
- aggravated fraud to the detriment of the State or other public body<sup>30</sup>: the use of artifices and deceptions to
  obtain an unfair profit to the detriment of the State or other public body;
- Computer fraud against the State or other public body<sup>31</sup>: the alteration of the functioning of a computer or telematic system, or the intervention without right on data, information or programs contained in a computer system, to obtain an unfair profit to the detriment of the State or other public body;
- extortion<sup>32</sup>, that is, the case in which the public official or the person in charge of a public service, by abusing his/her role or his/her powers, forces someone to give or unduly promise, to the latter or to a third party, money or other benefits;
- corruption for the exercise of the function<sup>33</sup>, the case in which the public official or the person in charge of a
  public service, for the exercise of his/her functions or powers, unduly receives, for himself/herself or for a third
  party, money or other benefits or accepts a promise thereof;
- corruption for an act contrary to official duties<sup>34</sup>, that is the case in which the public official or the person in charge of a public service, for omitting or delaying or for having omitted or delayed an act of his/her office, or for carrying out having performed an act contrary to the duties of office, receives, for himself/herself or for a third party, money or other benefits, or accepts a promise thereof;
- corruption in court documents<sup>35</sup>: in both cases of corruption defined above, the hypothesis of who receives (or agrees to receive) for himself/herself or for others money or other benefits in order to favour or damage a party in civil, administrative or criminal proceedings;
- undue inducement to give or promise benefits<sup>36</sup>: that is, the case in which the public official or the person in charge of a public service, by abusing his/her quality or his/her powers, induces someone to unduly give or promise money or other benefits to him/her or to a third party; criminal liability also extends to anyone who gives or promises money or other benefits;
- incitement to corruption<sup>37</sup>: in both cases of corruption defined above, the hypothesis that a public official does not accept to receive or a private party refuses to give money or other benefits;
- embezzlement<sup>38</sup>: i.e. diversion for one's own profit or that of others, of money or other movable property belonging to others, committed by a public official who has possession of it by reason of his office, when the fact goes against the financial interests of the European Union;

<sup>26</sup> Art. 316-bis Criminal Code

<sup>&</sup>lt;sup>27</sup> Art. 316-ter Criminal Code

 <sup>&</sup>lt;sup>28</sup> Art. 356 Criminal Code
 <sup>29</sup> Art. 640-bis Criminal Code

 <sup>&</sup>lt;sup>29</sup> Art. 640-bis Criminal Code
 <sup>30</sup> Art. 640, paragraph 2, no. 1 Criminal Code

<sup>&</sup>lt;sup>30</sup> Art. 640, paragraph 2, no. 1 Criminal Co <sup>31</sup> Art. 640-ter Criminal Code

<sup>&</sup>lt;sup>32</sup> Art. 317 Criminal Code

<sup>&</sup>lt;sup>33</sup> Art. 318 Criminal Code

<sup>&</sup>lt;sup>34</sup> Art. 319 Criminal Code

<sup>35</sup> Art. 319-ter Criminal Code

<sup>36</sup> Art. 319-quater Criminal Code

<sup>&</sup>lt;sup>37</sup> Art. 322 Criminal Code

<sup>38</sup> Art. 314 Criminal Code



- embezzlement by profiting from the error of others<sup>39</sup>: i.e. the case in which the public official or the person in charge of a public service, who, in the exercise of his/her functions or service, taking advantage of the error of others, unduly receives or retains, for himself or for a third party, money or other benefits, going against the financial interests of the European Union;
- embezzlement, extortion, undue inducement to give or promise benefits, bribery and incitement to bribery of members of the International Criminal Court or of the Entities of the European Communities and of officials of the European Communities and of foreign states<sup>40</sup>: the hypothesis envisaged by legislators is that of the crimes contemplated under the heading against foreign officials;
- trafficking in illicit influences<sup>41</sup>: i.e. the case of those who, apart from cases of participation in the crimes referred to in articles 318, 319, 319-ter and in the corruption offences referred to in article 322-bis, exploiting or boasting existing or alleged relationships with a public official or a person in charge of a public service or one of the other subjects referred to in article 322-bis, unduly makes the latter give or promise, to himself/herself or to others, money or other benefits, as the price of his/her illicit mediation towards a public official or a person in charge of a public service or one of the other parties referred to in article 322-bis, or to remunerate him/her in relation to the exercise of the latter functions or powers;
- fraud against the European Agricultural Guarantee Fund and the European Agricultural Fund for Rural Development<sup>42</sup>: the use of tricks and deceptions to obtain aid, bonuses, allowances, refunds, contributions or other payments at full or partial expense from the European Agricultural Fund guarantee and the European Agricultural Fund for Rural Development;
- abuse of office<sup>43</sup>: i.e. the case in which the public official or the person in charge of a public service, in carrying out the functions or the service, in violation of laws or regulations, or by failing to abstain in the presence of a personal interest or of a close relative or in other prescribed cases, intentionally procures an unfair financial advantage for himself or others, going against the financial interests of the European Union.

In order to better understand the terminology used in this paragraph, it is clarified that:

- All those parties, public or private, who perform a *public function* or a *public service are considered* "Public Administration" ("PA");
- "public function" means the activities governed by public law regulations that pertain to the legislative (State, Regions, Provinces with special statute, etc.), administrative (members of state and territorial administrations, law enforcement agencies, members of supranational administrations, members of the Authorities, Chambers of Commerce, etc.), judicial (judges, judicial officers, auxiliary bodies of the Administration of Justice such as bankruptcy trustees or liquidators, etc.). Public function is characterised by the exercising of:
  - Authoritative power, that is, the power that allows the PA to achieve its goals through real commands, which
    the private individual is subject to. This is the activity in which the so-called power of authority, which includes
    both the power of coercion (arrest, search, etc.) and of disputing violations of the law (ascertaining fines,
    etc.), and the powers of hierarchical supremacy within public offices;
- certification power is that which gives the certifier the power to certify a fact with evidential effectiveness;
- public service means activities:
  - governed by public laws;
  - characterised by the lack of authoritative or certification powers typical of public function;
  - with the exclusion of the performance of simple order tasks and the performance of merely material work;
- "public official" means someone who "exercises a legislative, judicial or administrative public function."

#### 2 Sensitive Activities and protocols to adopt

The analysis of Fidia's business processes made it possible to identify the activities within which the types of crimes referred to may abstractly occur, and the processes that may be considered "instrumental" to the commission of the crimes or so-called "precondition."

<sup>&</sup>lt;sup>39</sup> Art. 316 Criminal Code

<sup>&</sup>lt;sup>40</sup> Art. 322-bis Criminal Code

<sup>&</sup>lt;sup>41</sup> Art. 346-bis Criminal Code

<sup>&</sup>lt;sup>42</sup> Art. 2 of Law no. 898, 23 December 1986

<sup>&</sup>lt;sup>43</sup> Art. 323 Criminal Code



#### The Instrumental Processes relating to the commission of the crimes referred to in this section are as follows:

- Granting of donations and donations of goods;
- Transfer of free samples of products;
- Granting of gadgets and gifts;
- > Sponsorship and administrative management of medical-scientific congresses;
- Procurement of goods and services
- Management of monetary and financial flows;
- > Reimbursement of expenses, use of credit cards, company assets;
- Entertainment expenses;
- Selection and recruitment of personnel;
- Bonus and benefit management;
- Management of agents;

For identification of the control protocols to be adopted, please refer to the specific Special Part L.

Listed below are: i) Sensitive Activities; ii) the functions/organisational units involved; iii) offences that may be potentially committed; iv) the specific protocols to be adopted.

Management of relations with public entities, with particular reference to the Ministry of Health, AIFA [Italian Medicines Agency], for obtaining authorisations, licenses, concessions for the exercise of company activities: these are activities aimed at obtaining recognition by the authorities (Ministry of Health, AIFA) for the marketing of products (Authorisation for Marketing) and subsequent updates, the authorisation of materials for advertising and scientific information.

## Main Parties, Functions, and Organisational Units involved:

CEO, Corporate Operations, Plant, Quality Assurance, Regulatory Affairs, Legal

#### Potential crimes:

- Corruption in exercising a function (Art. 318, Criminal Code)
- Corruption for an act contrary to official duties (Art. 319, Criminal Code)
- Undue induction to give or promise benefits (Art. 319-quater, Criminal Code)
- Incitement to corruption (Art. 322, Criminal Code)
- Fraud to the detriment of the State or other public body (Art. 640, paragraph 2, no. 1, Criminal Code)
- Illicit traffic in influence (Article 346-bis, Criminal Code)

#### Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- Identify the roles and responsibilities of the persons authorised to maintain relations with the competent public bodies;
- envisage a clear segregation of roles between those who prepare the documentation and those who verify their correctness, authorising its sending to the Public Administration;
- only persons with a special power of attorney are authorised to sign the supporting documentation and participate in meetings with officials, not less than two;
- proceed with the ex post traceability and verifiability of transactions made with the Public Administration through adequate documentary/information supports;
- the outsourcers, consultants, partners and collaborators possibly employed by the Company to assist the latter during the process in question must be chosen with transparent methods and must meet the requirements of professionalism and competence;
- periodically send to the Supervisory Body a list of requests made to the Public Administration.

Management of relations with Committees or Technical Commissions of the Public Body, at the time of submitting the request, transmission of information and documentation aimed at adding a medicinal product of the



Company within the therapeutic handbooks (Regional Therapeutic Handbook - PTR - and Hospital Therapy Handbook - PTO).

Main Parties, Functions, and Organisational Units involved: Chief Executive Officer, Regulatory Affairs, Pharma Italy

# Potential crimes:

- Corruption in exercising a function (Art. 318 Criminal Code)
- o Corruption for an act contrary to official duties (Art. 319 Criminal Code)
- o Undue induction to give or promise benefits (Art. 319-quater Criminal Code)
- Incitement to corruption (Art. 322 Criminal Code)
- Fraud to the detriment of the State or other public body (Art. 640, paragraph 2, no. 1, Criminal Code)
- Illicit traffic in influence (Article 346-bis, Criminal Code)

#### > Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- Identify the roles and responsibilities of the persons authorised to maintain relations with the competent public bodies;
- envisage a clear segregation of roles between those who prepare the documentation and those who verify their correctness, authorising its sending to the Public Administration;
- only persons with a special power of attorney are authorised to sign the supporting documentation and participate in meetings with officials, in a number no less than two;
- proceed with the ex post traceability and verifiability of transactions made with the Public Administration through adequate documentary/information supports;
- the outsourcers, consultants, partners and collaborators possibly employed by the Company to assist the latter during the process in question must be chosen with transparent methods and must meet the requirements of professionalism and competence;
- periodically send to the Supervisory Body a list of requests made to the Public Administration.

Management of sales activities to the PA (e.g. hospitals, direct sales to pharmacies and/or pharmacy cooperatives, etc.) or to persons in charge of public service (health facilities affiliated with the NHS, pharmacists, etc.), and participation in public tenders: these are sales activities of its pharmaceutical products to the main customers of the Company, which have a public nature.

Main Parties, Functions, and Organisational Units involved: Chief Executive Officer, Pharma Italy

# > Potential crimes:

- o Corruption in exercising a function (Art. 318 Criminal Code)
- Corruption for an act contrary to official duties (Art. 319, Criminal Code)
- Undue induction to give or promise benefits (Art. 319-quater, Criminal Code)
- Incitement to corruption (Art. 322, Criminal Code)
- Fraud to the detriment of the State or other public body (Art. 640, paragraph 2, no. 1, Criminal Code)
- Illicit traffic of influence (Article 346, Criminal Code)

# ➢ Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- Identify the roles and responsibilities of the persons authorised to maintain relations with the competent public bodies;
- envisage a clear segregation of roles between those who prepare the documentation and those who verify their correctness, authorising its sending to the Public Administration;
- only persons with a special power of attorney are authorised to sign the supporting documentation and participate in meetings with officials, in a number no less than two;



- verify the correct application of the procedure for participation in calls for tenders (also through RTI/ATI) both
  with reference to the phase of receiving information about the nature of the call to which you wish to participate
  also in associated form (i.e. the way in which they became aware of the call), both with reference to the
  evaluation of the call to tender itself, to its approval, and to the preparation and forwarding of the documentation
  to the Body issuing the pertaining call to tender;
- verify the existence of any conflicts of interest with reference also to the possibility of participating in the tender or not;
- carry out checks on the documentation certifying the existence of essential conditions for participating in the tenders (authorising resolutions to participate in the tender, verification of the integrity of the envelope accompanying the documentation necessary to participate in the tender);
- proceed with the ex post traceability and verifiability of transactions made with the Public Administration through adequate documentary/information supports;
- monitor the powers also with reference to the verification of the authorising signatures for the tenders awarded and for those in which participation is carried out;
- the party who signs communications to public entities must ensure the traceability of the related sources and information elements;
- the party who maintains relations or carries out negotiations with the Public Administration cannot, alone and freely, stipulate the contracts he/she has negotiated;
- the contracts stipulated with the PA must contain the specific clauses envisaged by Law no. 136/2010 where specifically required;
- comply with procedure "SOPCO002/04 Customer Order Management";
- periodically send to the Supervisory Body a list of public tenders in which the Company has participated.

Management of Scientific Information activities, PR and market access activities with the Public Administration (e.g. opinion leaders, pharmacists, medical specialists): these are, in particular, the activities carried out by medical and scientific representatives, which ensure the widespread distribution of the products throughout the territory. The Medicinal Product Sales Representatives carry out scientific information activities relating to medicinal products, medical specialities, medical surgical aids and medical devices; moreover, for the purpose of promoting its products, the Pharma Italy Department carries out PR and market access activities through opinion leaders, doctors, etc.

Main Parties, Functions, and Organisational Units involved: Chief Executive Officer, Pharma Italy

# > <u>Potential crimes:</u>

- Corruption in exercising a function (Art. 318 Criminal Code)
- o Corruption for an act contrary to official duties (Art. 319, Criminal Code)
- Undue induction to give or promise benefits (Art. 319-quater, Criminal Code)
- Incitement to corruption (Art. 322, Criminal Code)
- Aggravated fraud to the detriment of the State or other public body (Art. 640, paragraph 2, no. 1, Criminal Code)
- Illicit traffic in influence (Article 346-bis, Criminal Code)

# > Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- In the Medicinal Product Sales Representatives field, each sales representative must behave in line with the provisions of current legislation, the Confindustria Medical Devices Code of Ethics and the provisions of the Code of Ethics; specifically, the latter must:
  - Respect the scientific nature of the information on the medicinal product, which must be professional, objective, and complete for a correct therapeutic application, based on the indications and dosages approved by the competent authorities;
  - use only information material authorised by the competent authorities in the meeting with healthcare professionals;



- ensure that the contents of the information, even if only verbal, are always documented and documentable, refraining from exaggerated statements and hyperbolic statements;
- deliver free samples of medicinal specialities only to persons authorised to prescribe, in compliance with the provisions of the applicable laws in force;
- ensure that the information material prepared by the Company on its products and used in providing information to doctors refers to the official documentation provided to AIFA at the time of registration or subsequently approved by said Agency in accordance with the applicable laws in force;
- in the information and presentation of medicinal products carried out in front of doctors or pharmacists, it is prohibited to grant, offer or promise prizes, monetary advantages or benefits in kind;
- the promotional material concerning drugs and their use, sponsored by the Company, has negligible value, is
  not fungible and in any case linked to the activity carried out by doctors and pharmacists and is purchased
  directly by the company at a central level;
- only the parties previously identified and authorised by the Company may have relations with the Public Administration.

Moreover, it is compulsory to respect the procedure "for the management of relations with scientific societies, medical associations, and patients."

**Management of collaboration relationships with Universities for research projects**: these are the agreements stipulated by the Company with the University, in order to commission specific research activities, also through the assignment of scholarships.

Main Parties, Functions, and Organisational Units involved: Chief Executive Officer, Corporate R&D - Business Development

## Potential crimes:

- Corruption in exercising a function (Art. 318, Criminal Code)
- Corruption for an act contrary to official duties (Art. 319, Criminal Code)
- o Undue induction to give or promise benefits (Art. 319-quater, Criminal Code)
- Incitement to corruption (Art. 322, Criminal Code)
- Aggravated fraud to the detriment of the State or other public body (Art. 640, paragraph 2, no. 1, Criminal Code)

# > Protocols

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With reference to this sensitive area it is necessary to follow the protocols below:

- Identify the roles and responsibilities of the subjects authorised to decide on collaborative relationships with universities and to maintain the related relationships;
- only persons with a special power of attorney are authorised to sign the supporting documentation and participate in meetings with officials, in a number no less than two;
  - research projects must be documented by means of specific contracts/agreements, which expressly indicate:
    - The purpose of research in a field/speciality relating to the Company's core business;
    - the amount paid, including through a scholarship;
    - the availability/ownership of the results of the research carried out.
- comply with the rules expressly envisaged by the Code of Ethics;
- comply with the procedure "for the management of scholarships";
- periodically send a list of the research projects activated to the Supervisory Body.

*Management of visits to company laboratories by the Public Administration*: These are organised visits for general practitioners, pharmacists, specialist doctors, etc. at the Company's plants.

- Main Parties, Functions, and Organisational Units involved:
  - Chief Executive Officer, Pharma Italy.
- Potential crimes:



- Corruption in exercising a function (Art. 318 Criminal Code)
- o Corruption for an act contrary to official duties (Art. 319, Criminal Code)
- Undue induction to give or promise benefits (Art. 319-quater, Criminal Code)
- Incitement to corruption (Art. 322, Criminal Code)
- o Aggravated fraud to the detriment of the State or other public body (Art. 640, paragraph 2, no. 1, Criminal Code)

# > Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- The organisation of visits to company laboratories and the relative program are agreed and authorised by the competent managers, appropriately authorised and delegated;
- the fundamental requirements of visits to company laboratories are defined and formalised in compliance with the cost-effectiveness criteria defined by the Company, existing regulations and internal procedures and policies relating to safety in the workplace, compliance with good manufacturing practices, good practice standards laboratory, etc.;
- the doctor's participation in the visit is subject to the completion and signature of a specific form, in which the doctor certifies the absence of conflicts of interest and provides consent to the processing of personal data;
- the internal manager for the implementation of the operation ensures the traceability and correct archiving of the process documentation including the initiative project, approvals, final plan, list of participants, authorisation forms for data processing for each participant, estimates and final accounts.

It is compulsory to comply with the procedure "for managing congresses, medical-scientific refresher courses and visits to company laboratories."

Management of relations with the Public Administration (e.g. Opinion leaders, doctors involved, any inspectors of the Ministry of Health, etc.) for clinical trial activities also in the context of investigator's meeting ("IM"): these are the activities of clinical trials for the launch of new medicinal products through the collaboration/supervision of public officials.

Main Parties, Functions, and Organisational Units involved: Chief Executive Officer, Corporate R&D - Business Development

# Potential crimes:

- Corruption in exercising a function (Art. 318 Criminal Code)
- Corruption for an act contrary to official duties (Art. 319, Criminal Code)
- Undue induction to give or promise benefits (Art. 319-quater, Criminal Code)
- Incitement to corruption (Art. 322, Criminal Code)
- o Aggravated fraud to the detriment of the State or other public body (Art. 640, paragraph 2, no. 1, Criminal Code)
- o Illicit trafficking of influence

# > Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- Guarantee the traceability of the scientific and economic evaluation process of the clinical trial;
- guarantee the traceability of the internal authorisation process and the subsequent signing of the contract relating to the clinical trial;
- guarantee the traceability of the process of requesting authorisations from public bodies for the implementation of the clinical trial;
- the internal manager for the implementation of the operations ensures that the organisational of the "investigator's meetings" ("IM") is carried out in compliance with the operating procedures defined by the Company and that these are in line with the provisions of law;
- the internal manager for the implementation of the operation ensures the correct filing of the process documentation, including by way of example: material presented and distributed during the IM, documentation relating to the organisational, detailed final program, list of sites invited to participate, list/ register of participants with relative signature collected during the IM, copy of the appointment letter signed for acceptance by each investigator;



- comply with the provisions of the procedure "for the management of Investigator Meetings";
- comply with the rules expressly envisaged by the Code of Ethics;
- periodically send a list of ongoing clinical trials to the Supervisory Body.

**Management of audits and inspections by the PA**: these are activities related to the management of inspections and/or investigations by public entities and/or persons in charge of public service (e.g. INAIL, INPS, the Revenue Agency, Guardia of Finance, Fire Service, etc.).

- Main Parties, Functions, and Organisational Units involved:
  - Chief Executive Officer, Corporate HR, CFO-Administration, Finance and Control, Regulatory Affairs, Corporate Operations, Plant, Quality Assurance

#### > <u>Potential crimes:</u>

- Corruption in exercising a function (Art. 318 Criminal Code)
- Incitement to corruption (Art. 322, Criminal Code)
- Undue induction to give or promise benefits (Art. 319-quater, Criminal Code)
- Illicit traffic in influence (Article 346-bis Criminal Code)

# > Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- Provide a clear segregation of roles between those who manage relations with the Public Administration, during the inspection phases and those who have the task of supervising their performance (e.g. inspection report audit);
- adopt procedures governing the methods of participation by the persons in charge, in judicial, fiscal, administrative and/or supervisory inspections and the methods of managing relations with public bodies during inspections/controls;
- ensure that only persons with a special power of attorney are authorised to sign the reports, the documentation required during the performance of the verification and control activities;
- verify that, during any judicial, tax and administrative inspections, the parties expressly delegated to do so (at least two) participate. The appropriate reports must be drawn up and retained for the entire procedure relating to the inspection. In the event that the final report highlights critical issues, the SB must be informed with a written note by the manager of the Function/Organisational Unit involved;
- verify the existence of any conflicts of interest with reference to the personal, property, legal or other relationships existing with the physical/ legal entities of the PA with which Fidia personnel should entertain relations with reference to the sensitive activity in question;
- proceed with the ex post traceability and verifiability of transactions made with the Public Administration through adequate documentary/information supports;
- choose the outsourcers, consultants, partners and collaborators, possibly employed during the verification/inspection process with transparent methods and according to a specific company procedure;
- periodically send the SB a list of the checks/visits carried out.

**Management and acquisition of public funding / grants:** these are the activities of preparing the documentation necessary for obtaining grants, managing them and reporting on related expenses, grants disbursed by the MISE, the Region, the European Union, tax credits recognised by the Revenue Agency.

- Main Parties, Functions, and Organisational Units involved: Chief Executive Officer, Corporate HR, CFO-Administration, Finance and Control, Corporate R&D - Business Development, Plant
- > Potential crimes:
- o Undue receipt of funds by the State (Article 316-ter, Criminal Code)
- o Fraud to the detriment of the State or other public body (Art. 640, paragraph 2, Criminal Code)
- o Embezzlement to the detriment of the State (Art. 316-bis, Criminal Code)



- Aggravated fraud for obtaining of public funds (Article 640-bis, Criminal Code)
- Trafficking of illicit influences (Article 346-bis Criminal Code)

#### > Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- identify the roles and responsibilities of the parties authorised to maintain relations with the competent public Entities, whether they are of national or Community importance;
- envisage a clear segregation of roles between those who prepare the requests for financing/reporting of
  expenses and those who verify their content, transmitting them to the Providing Body/Instructing Body;
- ensure that the person who signs the statements/communications for obtaining loans/contributions/tax credits has a specific power of attorney;
- ensure that the information or documents provided are verified, where possible, by the Managers responsible for the subject of the loan/ contribution/ tax credit or, in their absence, by the direct subordinates previously identified and, where possible, signed upon delivery;
- provide that the person designated to manage relations with national or EU public bodies documents the
  activity carried out, keeping track of the information or documents provided also to the other departments
  involved in the procedure for obtaining the loan/ contribution/ tax credit and indicating the subjects who may
  have had relations with the public body involved, so as to always be able to reconstruct the characteristics and
  reasons of the operations ex post, with the possibility of always identifying the subjects involved ("traceability");
- provide that the exchange of information, preliminary or relating to obtaining the loan/contribution/ tax credit, always takes place in writing and, as regards Fidia, through the person or function expressly authorised to do so;
- provide that the delegated Manager, or a person designated by the latter, compiles a specific periodic report
  relating to the requests made by the national or community public body, to be sent via information flows to the
  SB at the intervals indicated by the same. The information flow has the purpose of allowing the SB of the
  Company to be informed about potential situations at risk of crime and to supervise the application of the Model
  and the Code. If in the performance of the activities in question any critical issues of any nature should emerge,
  the SB must be promptly informed;
- ensure that all reporting activities to the national and/or community body connected to the destination of the loans/ contributions, contain absolutely truthful elements and are consistent with the purpose for which they were requested. To this end, all the reporting activities produced by Fidia must be filed in a specific file with the signature of the manager of the department/ organisational unit involved;
- ensure that the outsourcers, consultants, partners and collaborators who participate in the process in question are chosen with transparent methods, compliant with the procedure for obtaining the loan in question, and according to a specific company procedure.

**Management of judicial and extrajudicial disputes against the PA:** this is the activity relating to the management of judicial and extrajudicial disputes arising from Fidia's relations with the PA or other public Entities (including credit recovery activities).

- Main Parties, Functions, and Organisational Units involved: Chief Executive Officer, CFO-Administration, Finance and Control, Legal
- Potential crimes:
- Corruption in legal proceedings (Article 319-ter, Criminal Code)
- Corruption in exercising a function (Art. 318, Criminal Code)
- o Incitement to corruption (Art. 322, paragraph 1-4, Criminal Code)
- Undue induction to give or promise benefits (Art. 319-quater, Criminal Code)
- o Trafficking of illicit influences (Article 346-bis Criminal Code)
- Protocols



With reference to this sensitive area it is necessary to follow the protocols below:

- Clearly define the roles and tasks of the Functions/Organisational Units responsible for the management of active and passive judicial and extrajudicial disputes;
- verify the existence of any conflicts of interest;
- proceed with the traceability and ex post verifiability of the various stages of disputes;
- periodically send the SB a list of active and passive disputes with indication of the related subject.

## 3 General principles of behaviour prescribed in sensitive activities

## This Special Part envisages the express obligation for the Recipients to:

- 1. Implement strict observance of all laws and regulations governing company activity, with particular reference to activities that involve contacts and relations with the Public Administration for the activities related to the performance of a public function or a public service;
- 2. establish and maintain any relationship with the PA based on criteria of maximum fairness and transparency;
- establish and maintain any relationship with third parties in all activities relating to the performance of a public function or a public service based on criteria of fairness and transparency that guarantee the good performance of the function or service and impartiality in carrying out the same;
- 4. comply with the corporate principles and procedures set out in this section.

### As part of the aforementioned behaviours, it is prohibited in particular:

- To engage in, cooperate or cause the commission of acts which either individually or collectively result in, whether directly or indirectly, in the crimes falling within those considered above (Art. 24 and 25 of Legislative Decree);
- make donations in cash or equivalent/comparable securities to Italian or foreign public officials;
- distribute gifts and presents outside of the provisions of normal company practice (i.e. any form of gift offered that
  exceeds normal commercial practice or courtesy or aimed at acquiring favourable treatment in the conduct of any
  company activity). In particular, any form of gift is prohibited to Italian and foreign public officials (or persons in
  charge of a public service) (even in those countries where the giving of gifts is a widespread practice), or to their
  family members, which could influence their discretionary choices or independent opinion or induce ensuring any
  advantage for the company; the provisions of the Code of Ethics apply in any case;
- grant other advantages of any nature (such as, by way of example, promises of direct recruitment or recruitment close relatives) in favour of representatives of the PA, which may have the same consequences as provided for in the previous point;
- pay remuneration or perform services in favour of consultants, suppliers, customers that are not adequately justified in the context of the contractual relationship established with them and the practices in force in the local area;
- submit untruthful statements to national or foreign public Entities, in order to obtain public funds, contributions or subsidized loans;
- allocate sums received from national or community public Entities as disbursements, contributions or loans for purposes other than those for which they were intended.

The general conduct described above supplements and does not replace the principles set out in the Code of Ethics, as well as any procedures for greater protection envisaged within Fidia and relating to sensitive activities.

## 3.1 The Power of Attorney System

For this particular area, the power of attorney system adopted by the company is of fundamental importance, which corresponds to the following fundamental requirements:

- it is the responsibility of the Head of Function/ Organisational Unit to ensure that all his/her collaborators, who represent the Company even occasionally towards the PA, have a written power of attorney;
- The power of attorney contains:
  - the delegating party (party to whom the delegate reports hierarchically);
  - o name and duties of the delegate, consistent with the position held by the same;
  - o scope of the power of attorney (e.g. project, duration, product, etc.);
  - o date of issue.



The Supervisory Body may periodically check, with the support of the other competent functions, the system of proxies and powers of attorney in force and their consistency with the entire system of organisational communications (such are those internal documents of the company with which power of attorneys are conferred) recommending any changes in the event that the management power and/or the qualification does not correspond to the powers of representation conferred on the attorney or there are other anomalies.



## SPECIAL PART "B" COMPUTER CRIMES

## 1 Computer crimes and unlawful processing of data

Legislative Decree no. 48 of 4 April 2008, ratifying and executing the Budapest Convention of the Council of Europe on cybercrime, introduces the following types of crime within the scope of the Decree:

- Falsehood in electronic documents (Article 491-bis, Criminal Code);
- Illegal access to a computer or telecommunications system (Art. 615-ter, Criminal Code);
- Unlawful possession and distribution of access codes to computer or telecommunication systems (Art. 615quater, Criminal Code);
- Distribution of computer equipment, devices or programs intended to damage or interrupt a computer or telecommunication system (Art. 615-quinquies, Criminal Code);
- unlawful interception, prevention or interruption of computer or electronic communications (Art. 617-quater, Criminal Code);
- Installation of equipment designed to intercept, impede or interrupt computer or telecommunication transmissions (Art. 617-quinquies, Criminal Code);
- damage to information, data and computer programs (Art. 635-bis, Criminal Code);
- Damage to information, data and computer programs used by the State or other public body or in any case of public utility (Article 635-ter, Criminal Code);
- damage to computer or telecommunications systems (Art. 635-quater, Criminal Code);
- damage to public utility computer or telecommunications systems (Art. 635-quinquies, Criminal Code);
- Cyber fraud by the provider of electronic signature certification services (Art. 640-quinquies, Criminal Code)

Legislative Decree no. 93 of 14 August 2013 on: "Urgent provisions on security and the fight against violence in general, as well as on civil protection and the provincial commissioner," introduces the crime of cyber fraud, committed with replacement of digital identity, within the scope of the Decree to the detriment of one or more subjects (Article 640-ter, third paragraph of the Criminal Code).

## 2 Sensitive Activities and protocols to adopt

The analysis of Fidia's business processes made it possible to identify the activities within which the types of offences referred to may abstractly occur.

Listed below are: i) Sensitive Activities; ii) the functions/organisational units involved; iii) offences that may be potentially committed; iv) the specific protocols to be adopted.

**Management of information systems**: i.e. the management of information systems, databases and computer networks with particular reference to:

- Compliance with the safety measures required to comply with the provisions of Legislative Decree No. 196/03 and EU Regulation No. 2016/679.
- verifying the presence of access codes to software protected by intellectual property rights and programs likely to cause damage (*malicious software*, data flow capture systems);
- the protection data from the risk of intrusion or use by third parties and management of mailing lists.
- Main Parties, Functions, and Organisational Units involved: All functions and people who use an electronic device, Chief Executive Officer, CFO-Finance Administration and Control-IT Services.
- > <u>Potential crimes:</u>
- o Unauthorised access to a computer or telecommunications system (Art. 615-ter Criminal Code)
- Unlawful possession and distribution of access codes to computer or telecommunication systems (Art. 615quater, Criminal Code)
- Damage to information, data and computer programs (Art. 635-bis, Criminal Code)



- Damage to information, data and computer programs used by the State or other public body or in any case of public utility (Article 635-ter, Criminal Code)
- o Damage to computer or telecommunications systems (Art. 635-quater, Criminal Code)
- o Damage to public utility computer or telecommunications systems (Art. 635-quinquies, Criminal Code)

## > Protocols

The Company must fulfil the following obligations:

- Provide the Recipients with adequate information/training regarding:
  - Correct use of company IT resources;
  - o risk of commission of computer crimes;
  - importance of keeping your access codes (username and password) confidential, and the prohibition of disclosing them to third parties;
  - need not to leave computer systems unattended and the advantages of blocking them, should they leave the workstation;
- limit as far as possible the use of IT systems and access to them (also from and to the outside through the connection to the internet), by the Recipients, exclusively for the purposes related to the uses made by the latter;
- carry out, in compliance with the privacy legislation, the trade union agreements in place and the Workers' Statute, periodic checks on the corporate IT network in order to identify abnormal behaviour
- prepare and maintain adequate physical defences to protect the servers and all other corporate IT systems;
- ensure compliance with the policies adopted by the Company and in particular with the "IT systems management" procedure;
- set up the IT systems themselves in such a way that, if they are not used for a certain period of time, they are automatically blocked;
- equip the data processing centre with a lockable door;
- protect, as far as possible, every computer system of the Company in order to prevent the unlawful installation
  of hardware devices capable of intercepting communications relating to a computer or telematic system, or
  between multiple systems, or capable of preventing or interrupting them (keylogger, backdoor, malicious
  software, etc.);
- provide each computer system with adequate firewall and anti-virus software and ensure that, where possible, these cannot be deactivated;
- prevent the installation and use of software not approved by the Company or not related to the professional activity carried out for the same;
- limit access to particularly sensitive areas and websites as a vehicle for the distribution and dissemination of
  infected programs (so-called "viruses") capable of damaging or destroying computer systems or data contained
  in these contents (for example, e-mail sites or sites for disseminating information and files);
- if wireless connections are used to connect to the Internet network (i.e. wireless, through routers equipped with a WiFi antenna), protect them by setting an access key, in order to prevent third parties from illegally connecting to the network via the routers and performing offences attributable to employees of the Company;
- provide, where possible, an authentication procedure using a username and password which corresponds to a limited profile of the management of system resources, specific for each Recipient or category of Recipients.

**Management of physical access to sites where there are IT platforms for transmitting and sharing data:** this is the management of data transmission operations to Public Authorities such as AIFA, the Ministry of Health, Public Entities such as INPS, INAIL, public structures/ companies, by accessing digital platforms, portals, available on the related websites.

## > Main Parties, Functions, and Organisational Units involved:

Chief Executive Officer, Corporate Operations, Plant, Regulatory Affairs, CFO-Administration, Finance and Control, Corporate HR, Corporate R&D - Business Development

#### Potential crimes:

Unauthorised access to a computer or telecommunications system (Art. 615-ter Criminal Code)



 Unlawful possession and distribution of access codes to computer or telecommunication systems (Art. 615quater Criminal Code)

## Protocols

- The Company must fulfil the following obligations:
- Envisage a clear segregation of the roles and duties of the Functions responsible for managing the various phases of the sensitive process; and, in particular, the management of Fidia's access methods to the IT and telematic systems of third parties, with which Fidia has relations in the context of its business;
- envisage controls in order to prevent unauthorised access, damage and interference at Fidia and third parties, with which Fidia has relations in the context of its business;
- envisage clear and precise rules in order to prevent the possession and/or unauthorised use of codes, keywords
  or other means suitable for accessing a computer or telematic system of third parties, with which Fidia maintains
  relationships within the scope of its activities;
- monitor access to information, information systems, the network, operating systems, applications from third
  parties with whom Fidia has relations in the context of its business;
- define adequate procedures for dealing with incidents and problems relating to IT security.

**Management of documentation in digital format**: this is the management of the operations of transmission of documents to the Public Administration by means of a digital signature.

Main Parties, Functions, and Organisational Units involved: CEO, Plant, Regulatory Affairs, CFO-Administration, Finance and Control, Pharma Italy

### > Potential crimes:

 Falsification of a public IT document or document with evidential value (Article 491-bis of the Italian Criminal Code)

## > Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- Define criteria and methods for the generation, distribution, revocation and storage of keys (smart cards);
- formally regulate any management of smart cards by third parties;
- define the controls for the protection of the keys from possible modifications, destruction and unauthorised use;
- ensure traceability and adequate archiving of supporting documentation for activities carried out with the use of smart cards.

## 3 General principles of behaviour

In carrying out their respective activities/functions, in addition to knowing and respecting the rules governed by the Company's Articles of Association, the principles laid down by the Code, the operating procedures and any other internal regulations relating to the *Corporate Governance* system, the Recipients must comply with the rules of conduct contained in this Special Part which envisages the express prohibition of engaging in conduct such as to integrate the types of offences considered above (pursuant to Article 24-bis of the Decree) or conduct which, although not in themselves constitutes a crime, could potentially integrate one of the offences under consideration herein.

In particular, the following **is absolutely prohibited**:

- Introducing computers, peripherals, other equipment or software into the company without the prior authorisation of the CFO-Administration, Finance and Control-IT Services function and in any way, modifying the configuration issued by such function of fixed or mobile workstations;
- acquiring, possessing or using software and/or hardware tools that could be used to evaluate or compromise the security of IT or telematic systems (such as systems for identifying passwords, identifying vulnerabilities, decrypting encrypted files, intercepting traffic in transit, etc.);
- obtaining credentials for accessing company, customer or third party IT or telematic systems with methods or procedures different from those authorised for this purpose by the Company;
- disclosing, transferring or sharing with personnel internal or external to the Company their access credentials to



the systems and to the company network, of customers and third parties - each account holder is responsible for the actions carried out through his own account on the systems and on the company network;

- distorting, obscuring, replacing ones' identity, and sending anonymous emails or E-mails bearing a false identity;
- tampering with, stealing or destroying the corporate, customer or third party IT assets, including archives, data and programs;
- carrying out tests or attempt to compromise the security controls of company IT systems, unless it is explicitly envisaged in their work duties;
- exploiting any vulnerabilities or inadequacies in the security measures of corporate IT or telematic systems, of
  customers or of third parties, to obtain access to resources or information other than those to which one is
  authorised to access, even if such intrusion does not causes damage to data, programs or systems;
- communicating to unauthorised persons, internal or external to the company, the controls implemented on the information systems and the ways in which they are used;

#### In addition, the **following general protocols** must be observed:

- use of the company e-mail service in compliance with the Code of Ethics, using only one's own account;
- each account holder must take care of the execution/ daily/ weekly/ biweekly (depending on the type of database
  to be copied, for example accounting and management, mail, staff personal folders) of the backup copies of the
  databases processed, in collaboration with the operator or operators in charge of the management and
  maintenance of the electronic tools, in order to ensure the integrity of the data against the risk of destruction or
  loss;
- non-public data and information relating to customers and third parties (commercial, organisational, technical) including remote connection methods must be managed as confidential data;
- in transmissions, pay the utmost attention both in the drafting phase and in the memorization/ storage phase, so that the information is accessible only to those who are authorised to know it and that there is no risk of alteration.



# SPECIAL PART "C" COUNTERFEITING AND COPYRIGHT INFRINGEMENT CRIMES

## 1 Crimes against industry and commerce; Crimes relating to copyright infringement

Law No. 99 of 23 July 2009, "Provisions for the development and internationalization of companies, as well as in the field of energy," which entered into force on August 15, 2009, introduces the following types of crimes into the body of the Decree:

- Counterfeiting, alteration or use of trademarks or distinctive marks and i.e. patents, models and designs/drawings (Art. 473 Criminal Code);
- Introduction into the State and trade of products with false markings (Article 474 of the Criminal Code);
- Interference with freedom of industry or commerce (Art 513 Criminal Code);
- Unlawful competition with threat or violence (Art. 513-bis Criminal Code);
- Fraud against domestic industries Art. 514 (Criminal Code);
- Fraud in trade (Art. 515 of the Italian Criminal Code);
- Sale of adulterated food as natural food (Art. 516 Criminal Code);
- Sale of industrial products with misleading marks (Art 517 Criminal Code);;
- Manufacture and sale of goods made by usurping industrial property rights (Art. 517-ter of Criminal Code);
- Counterfeiting of geographical indications or denominations of origin of agri-food products (Art. 517-quater Criminal Code);
- Copyright offences (171, first paragraph, letter a-bis, and third paragraph, 171-bis, 171-ter, 171-septies and 171octies of Law no. 633 of 22 April 1941).

### 2 Sensitive Activities and protocols to adopt

The analysis of Fidia's business processes made it possible to identify the activities within which the types of offences referred to may abstractly occur.

Listed below are: i) Sensitive Activities; ii) the functions/organisational units involved; iii) offences that may be potentially committed; iv) the specific protocols to be adopted.

**Marketing of goods**: this involves the management of marketing strategies and activities, including regulatory ones, together with the management of the marketing process of pharmaceutical products.

- Main Parties, Functions, and Organisational Units involved: CEO, Procurement, Pharma Italy, Pharma International, Factory, Regulatory Affairs
- > <u>Potential crimes:</u>
- o Introduction into the State and trade of products with false markings (Article 474 Criminal Code);
- Fraud in trade (Art. 515 of Criminal Code);
- o Sale of industrial products with misleading marks (Art 517 Criminal Code);;
- o Manufacture and sale of goods made by usurping industrial property rights (Art. 517-ter of Criminal Code).

## > Protocols

The regulation of the described activity must:

 Provide that the Recipients ensure that the subjects in charge of verifying the possible existence of identical trademarks or patents or the possible existence of similar patents that could potentially conflict with the one to



be registered, have not expressed a negative opinion on the filing and the consequent use of a trademark or patent on the Italian market;

- provide for the preparation of a dossier necessary for any patent registration;
- provide for specific controls to be implemented on products and their packaging, with analysis of the composition of the product up to the monitoring of the environment of the production line, aimed at guaranteeing the quality, safety and integrity of the products and their packaging.

In addition, specific and concrete controls are envisaged including, for example:

- carrying out verifications on the rights of pre-existing third parties in order to ensure that the same or similar
  patents are not already filed / registered and that the rights of third parties are not violated;
- defining of specific powers of attorney for the management and filing of trademarks;
- carrying out specific competitor patent surveillance analyses and research activities;
- implementation of specific controls on products and their packaging, with analysis of the composition of the product up to the monitoring of the environment of the production line, aimed at guaranteeing the quality, safety and integrity of the products and their packaging;
- preparation of product conformity declarations;
- presence of a specific validation process for product labels;
- presence of a specific complaints management process;
- presence of a specific process for managing the collection and archiving of product documentation;
- provision of company procedures relating to the quality management system;
- presence of a specific dispute management process.

With specific reference to marketing and promotion activities, the following protocols are current:

- guarantee the traceability of the authorisation process and signing of contracts relating to all promotion and marketing initiatives;
- provide that the promotion and marketing activities are authorised, verified by the Pharmaceutical General Management, by the Chief Executive Officer, as envisaged in the internal proxies, in the powers of attorney, so that the truthfulness of promotional or other communications is ensured;
- comply with procedure "SOP AR 017/01 Approval process for health advertising and scientific information."

**Management of licenses and computer software**: this is the activity relating to the control of the conditions for access, use and protection of the IT resources used within Fidia.

Main Parties, Functions, and Organisational Units involved: Chief Executive Officer, Procurement, CFO-Finance Administration and Control-IT Services

## > Potential crimes:

 Duplication, transformation, distribution, illegal communication of programs protected by copyright (Art. 171, Law 633/1941).

## > Protocols

It is necessary:

- provide for the obligation to comply with the provisions of the law to protect the authorship of computer
  programs and databases protected by copyright (the "Works"), as well as the limitations envisaged for the right
  of duplication of computer programs and reproduction, transfer, distribution and/or communication of the
  contents of databases;
- provide for the authorisation mechanisms for the use, reproduction, processing, duplication and distribution of Works or parts thereof;
- provide for the adoption of protection tools (e.g. access rights) relating to the storage and archiving of Works, ensuring their inventory;
- provide for the formalised verification when receiving supports containing computer programs, databases, phonograms or videograms of musical, cinematographic or audiovisual works and/or sequences of moving



images - of the presence on them of the mark by the authorities in charge the supervision of copyright, or the exemption of the media in question from such obligation.

The regulation of the described activity must envisage:

- The installation of programs, which have not already been acquired centrally, must be authorised by each individual department Manager;
- all computer media disposed of (PC, floppy disk, CD or DVD) must be preventively and appropriately rendered illegible in order to avoid the involuntary dissemination of protected programs and/or databases.

## 3 General principles of behaviour

In carrying out their respective activities/functions, in addition to knowing and respecting the rules governed by the Company's Articles of Association, the principles laid down by the Code, the operating procedures and any other internal regulations relating to the *Corporate Governance* system, the Recipients must comply with the rules of behaviour contained in this Model.

This Special Part envisages the express prohibition of engaging in conduct such as to result in the types of crimes considered above (pursuant to Article 25-bis, letters f-bis, 25-bis 1 and 25-novies of the Decree) or which, although they do not in themselves constitute crimes, may potentially result in one of the crimes under consideration herein.

### More specifically, it is compulsory to:

- Manage relationships with customers by ensuring high quality standards, in compliance with the regulations for the protection of competition and the market and providing truthful, precise and exhaustive information about the origin and quality of the products offered for sale;
- carry out control activities on the supply of finished products both in the preventive phase and in the marketing phase;
- verify, or have the competent Entities verify, before registering any trademark, logo or any distinctive sign, or
  patenting inventions, designs and models or, in any case, any other intellectual work, that they have not already
  been registered or patented both at national, international and community level;
- obtain, for each distinctive sign or intellectual work used by the Company, of which it is not the owner, a regular license agreement;
- purchase, create, place online only content (photographs, video sequences, poems, comments, reviews, articles
  and other written content, files containing music in any format) with a license for use or in any case in compliance
  with the legislation on law copyright and other rights related to their use;
- verify (by one or more managers expressly delegated to do so) in advance, where possible, or by means of
  specific control activities, including periodic ones, with the utmost rigour and timeliness, that the contents on the
  network comply with the regulations in force regarding copyrights and rights related to the use of protected
  intellectual property;
- verify that for all the above contents that are placed on the network by third parties or purchased by the Company
  and placed on the network, there is an express assumption of responsibility by the third parties themselves in
  order to comply with copyright regulations and other rights related to the use of intellectual property;
- likewise, verify that the placing on the network of all the aforementioned contents by users takes place after identification (registration and authentication) of the users themselves and express assumption of responsibility by the latter with regard to the placing on the network of contents protected by rules on copyright and other rights related to their use;
- use only software with a license for use and within the limits and conditions envisaged by current legislation and by the license itself, with the exception of those computer programs available for download and free use, always under the conditions and within the limits established by law or by the owner of the copyright and other rights related to its use;
- use only databases with a license for use and within the limits and conditions provided for by current legislation
  and by the license itself, with the exception of those that can be freely consulted, always under the conditions and
  within the limits established by law or by the owner of copyright and others rights connected to its use, also with
  regard to the research, extraction, processing, re-processing and publication of the data contained therein.

#### Furthermore, the following is prohibited:



- Engaging in, collaborating with, or causing the carrying out of behaviours such as to result in the crimes considered above (Article 25-bis letter f-bis, 25-bis 1 and 25-novies of the Decree);
- engage in, collaborate with or cause the carrying out of behaviours which, although as such, do not to constitute in themselves crimes falling within those considered above, could potentially become so;
- reproduce, promote or sell designs or models, such as to cause confusion as to the identification or origin of the
  product, as well as to use evocative names or distinctive signs of third party products in the absence of a valid
  license or outside the limits defined by related agreements;
- carry out any form of intimidation or harassment against other competitors operating in the same sector (for example, through boycott, transfer of employees, refusal to contract, etc.);
- counterfeit or alter national or foreign brands or distinctive signs of industrial products, being able to know of the
  existence of the industrial property title or make use of counterfeit or altered trademarks or distinctive signs;
- counterfeit or alter national or foreign patents, industrial designs or models, or make use of such counterfeit or altered patents, designs or models;
- introduce industrial products with trademarks or other distinctive signs, national or foreign, counterfeited or altered, into the State in order to profit from them.
- deliver to the buyer a movable thing for another, or a movable thing, by origin, provenance, quality or quantity, different from that declared or agreed;
- place for sale or otherwise put into circulation intellectual works or industrial products, with national or foreign
  names, trademarks or distinctive signs, capable of misleading the buyer as to the origin, provenance or quality of
  the work or product;
- manufacture or use industrially objects or other goods made by usurping an industrial property title or in violation
  of the same, being able to know of the existence of the industrial property title;
- introduce into the territory of the State, hold for sale, put up for sale with a direct offer to consumers or in any case
  put into circulation objects or other goods made by usurping an industrial property title or in violation of it, in order
  to profit from it;
- illegally duplicate computer programs, for profit or for the same purposes import, distribute, sell, hold for commercial or business purposes or lease programs contained in media not unmarked by the Italian Society of authors and publishers (SIAE).
- reproduce, in order to make a profit, on media not marked SIAE, or transfer to another medium, distribute, communicate, present or demonstrate in public the content of a database in violation of the provisions of articles 64-quinquies and 64- sexies of Law no. 633/1941, or perform the extraction or reuse of the database in violation of the provisions of articles 102-bis and 102-ter of the same law, or distribute, sell or rent a database.

The general conduct described above supplements and does not replace the principles set out in the Code of Ethics, as well as any procedures for greater protection envisaged within Fidia and relating to sensitive activities.



## SPECIAL PART "D" CORPORATE CRIMES

#### 1 Corporate crimes

As part of the corporate law reform, Legislative Decree No. 61 of 11 April 2002, in force since 16 April 2002, introduced the new Art. 25-ter of the Decree, extending the administrative liability regimen of Entities to so-called "corporate crimes." The types of corporate crimes considered are:

- False corporate communications and minor facts (Articles 2621 and 2621-bis of the Civil Code): knowingly expose, in order to obtain an unfair profit for oneself or for others, in financial statements, reports or other corporate communications addressed to shareholders or public, provided for by law, material facts that do not correspond to the truth or omit material facts whose disclosure is required by law on the economic, patrimonial or financial situation of the company or group to which it belongs, in a concretely suitable way to induce others in error. In this regard, it should be noted that Law no. 69 of 27 May 2015, published in the Official Gazette no. 124 of 30 May 2015, introduced significant changes to the criminal provisions on false corporate communications, contained in the Civil Code; in detail, the main changes concerned (i) the official prosecution of the crime, (ii) the psychological element, represented by the specific malice, aimed at "obtaining an unfair profit for oneself or for others," but it is no longer characterised by any element of deceptive intentionality, (iii) the partial revision of the typical conduct, (iv) the elimination of the quantitative thresholds of criminal relevance of the conduct;
- undue return of contributions (Article 2626 of the Civil Code): return contributions to the shareholders or release them from the obligation to make them;
- illegal distribution of profits and reserves (Article 2627 of the Civil Code): distributing profits or reserves that cannot be distributed by law;
- illegal operations on stocks or shares of the company or of the parent company (Art. 2628 of the Civil Code): purchase or subscribe shares also of the parent company, damaging the share capital;
- operations to the detriment of creditors (Art. 2629 of the Civil Code): reduce the share capital, carry out mergers or demergers that cause damage to creditors;
- failure to communicate a conflict of interest (Art. 2629 bis of the Civil Code): the violation of the
  obligations imposed to communicate a situation of conflict of interest with prejudice to the company or to third
  parties;
- fictitious formation of capital (Art. 2632 of the Civil Code): fictitiously increase the capital, mutually
  subscribe to shares and overestimate contributions or assets in the event of transformation;
- undue distribution of company assets by liquidators (Art. 2633 of the Civil Code): distribution of company assets before payment of creditors or before setting aside the sums necessary to satisfy them;
- obstructing an audit (Art. 2625, paragraph 2, of the Civil Code): concealing documents suitable to prevent the carrying out of auditing activity of shareholders, of the other corporate bodies;
- bribery between private individuals (Art. 2635, paragraph 3 of the Civil Code) and instigation to bribery between individuals (Art. 2635 bis of the Civil Code): offering, even following solicitation, or promising undue money or other benefits (as briber) in favour of directors, general managers, executives in charge of preparing corporate accounting documents, auditors and liquidators, as well as in favour of those who exercise managerial functions other than the previous ones, to perform or omit an act, in violation of the obligations inherent in their office or of the obligations of trust (in the quality of corrupt subjects); liability pursuant to Legislative Decree 231/2001 concerns the briber and also applies if the offer or promise of money or other undue benefits is not accepted;
- unlawful influence on the shareholders' meeting (Art. 2636 of the Civil Code): performing simulated or fraudulent acts aimed at determining unlawful quorum at the shareholders' meeting;
- insider trading (Art. 2637 of the Civil Code): disseminating false information or carrying out simulated operations capable of causing an alteration in the price of unlisted financial instruments;
- impeding the exercising of functions of public supervisory authorities (Article 2638, paragraphs 1 and 2, of the Civil Code): in order to impede the exercising of supervisory functions, expose false material facts, although subject to evaluation, on the economic, equity or financial situation of the supervised parties or, for the same purpose, concealing with other fraudulent means facts that must be communicated.



### 2 Sensitive Activities and protocols to adopt

The analysis of Fidia's business processes made it possible to identify the activities within which the types of offences referred to may abstractly occur and the processes that may be considered "instrumental" to the commission of the crimes or so-called "precondition."

The Instrumental Processes relating to the commission of the crimes referred to in this section are as follows:

- Granting of donations and donations of goods;
- Transfer of free samples of products;
- Granting of gadgets and gifts;
- Procurement of goods and services
- > Sponsorship and administrative management of medical-scientific congresses;
- > Management of monetary and financial flows;
- Reimbursement of expenses, use of credit cards, company assets;
- Entertainment expenses;
- Selection and recruitment of personnel;
- Bonus and benefit management;
- Management of agents;

For identification of the control protocols to be adopted, please refer to the specific Special Part L.

Listed below are: i) Sensitive Activities; ii) the functions/organisational units involved; iii) potentially committing offences; iv) the specific protocols to be adopted, distinguishing between Sensitive Activities relating to corporate crimes in general and Sensitive Activities relating to corruption between individuals.

#### Sensitive Activities - corporate crimes

**Drafting of the financial statements, the management report and other corporate communications:** concerns the operations relating to the recognition, registration and representation of the business activity in the accounting records, in the financial statements, in the reports and in any other prospectus relating to the economic situation, equity and financial position of Fidia required by legal provisions and legislative obligations related to the keeping of accounting records and company books.

> Main Parties, Functions, and Organisational Units involved:

Chief Executive Officer, CFO-Administration, Finance and Control

#### > <u>Potential crimes:</u>

- False corporate communications (Art. 2621-2621-bis, Civil Code)
- Obstructing an audit (Article 2625, paragraph 1, Civil Code)
- Unlawful influence on the shareholders' meeting (Art. 2636, Civil Code)
- o Insider trading (Art. 2637, Civil Code)
- o Impeding the exercise of the functions of the public supervisory authorities (Art. 2638, Civil Code)

#### Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- Clearly define the roles and tasks of the Functions/Organisational Units responsible for the management of active and passive phases of the sensitive process;
- disseminate to the personnel involved in the preparation of the aforementioned documents, regulatory
  instruments that clearly define the accounting principles to be adopted for defining information and data on
  the economic, equity, and financial situation of Fidia and the operating procedures for their accounting.
  These rules must be promptly supplemented/ updated by the information provided by the competent office
  based on the novelties in the field of primary and secondary legislation and disseminated to the recipients



indicated above;

- prepare and disseminate instructions, addressed to the various Functions/ Organisational Units, indicating
  the data and information that must be provided to the Administration, Finance and Control function,
  responsible for the process of preparing the financial statements on the occasion of the annual and interim
  closings, as well as the methods and timing of transmission of the same (e.g. preparation of the schedule
  of accounting closures);
- make changes to the accounting data only with the authorisation of the Function / Organisational Unit that generated them;
- comply with the policies, operating protocols adopted by the Company in relation to accounting;
- carry out one or more meetings, with relative drafting of minutes, between the auditing company and the SB
   before the meetings of the BoD and the shareholders' meeting called to approve the financial statements
   which concern the draft financial statements if any critical issues in the performance of auditing activities;
- carry out, in addition to training for those who work in the Administration, Finance and Control function, basic training activities (regarding the main legal and accounting concepts and issues) for Functions/ Organisational Units involved in the defining of the valuation items of such documents;
- envisage periodic meetings and/or exchanges of information with any accounting, tax, etc. outsourcers in
  order to verify the regular and constant professionalism in the management of the service and in the
  preparation of accounting documents;
- provide for formalised regulations relating to the keeping, retention and updating of the financial statements and other corporate accounting documents from their establishment, and possible approval by the BoD, to the filing and publication (including computerized) of the same and the relative archiving.

**Management of corporate operations**: these are operations of an extraordinary nature, such as distribution of reserves, reductions in share capital, mergers, demergers, contributions, which can lead to changes in share capital.

Main Parties, Functions, and Organisational Units involved: Board of Directors, Chief Executive Officer, CFO-Administration, Finance and Control

## Potential crimes:

- o Obstructing an audit (Article 2625, paragraph 1, Civil Code)
- Undue restitution of contributions (Article 2626, Civil Code)
- o Illegal distribution of profits and reserves (Art. 2627 Civil Code)
- Unlawful transactions involving shares or quotas of the company or of the parent company (Article 2628, Civil Code)
- o Transactions prejudicial to creditors (Article 2629, Civil Code)
- Failure to disclose a conflict of interest (Art. 2629-bis, Civil Code)
- Fictitious establishment of capital (Art. 2632, Civil Code)
- Unlawful influence on the shareholders' meeting (Art. 2636, Civil Code)
- Insider trading (Art. 2637 Civil Code)
- Impeding the exercise of the functions of the public supervisory authorities (Art. 2638 Civil Code)

## Protocols

With reference to this sensitive area, it is necessary to follow these protocols:

- Clearly define the roles and tasks of the Functions/Organisational Units responsible for the management of corporate operations, providing for checks on the completeness and truthfulness of the information necessary for taking decisions and executing corporate transactions;
- identify the function and the person appointed to manage corporate transactions of an extraordinary nature on behalf of Fidia, to whom a specific proxy and written power of attorney should be conferred;
- prepare suitable documentation to assess the feasibility and strategic and economic convenience of the



transaction, including, where applicable:

- ✓ qualitative-quantitative description of the target (feasibility study, financial analysis, studies and statistics on the reference market, comparisons between different alternatives for carrying out the operation);
- ✓ characteristics and subjects involved in the transaction;
- ✓ technical structure, main guarantees and collateral agreements and financial coverage of the transaction;
- ✓ methods for determining the economic conditions of the transaction and indication of any external consultants/intermediaries/advisors involved;
- ✓ impact on the prospective economic, financial, and equity situation;
- ✓ assessments on the adequacy and consistency with the interest of the Company of the transaction to be resolved.
- file, store and retain (in paper and electronic format) the relevant documentation (the agenda, calls to convene, resolutions, and minutes);
- record the meetings of the Board of Directors and the Shareholders' Meeting in the Company Books;
- allow access to all persons appointed to carry out auditing activities of the Company Books in accordance with the provisions of the relevant legislation.

It is also necessary to monitor powers also with reference to the verification of the signatures of documents relating to corporate transactions.

Management of the relationship with the Independent Auditors, with the Board of Statutory Auditors: these are relationships with the independent auditors with reference to the control activities that may be exercised by the latter by virtue of the provisions of the law.

> Main Parties, Functions, and Organisational Units involved:

Chief Executive Officer, CFO-Administration, Finance and Control

## > Potential crimes:

- Obstructing an audit (Article 2625, paragraph 1, Civil Code)
- Corruption between private parties (Art. 2635, paragraph 3, Civil Code)
- Unlawful influence on the shareholders' meeting (Art. 2636, Civil Code).

## > Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- Envisage a clear segregation of roles between those responsible for preparing the documentation to be
  provided to the Board of Statutory Auditors, the independent auditors, and those who authorise their sending;
- clearly define the roles and tasks of the Functions/Organisational Units responsible for managing the various
  phases of the sensitive process (e.g. collection or provision of information to be sent to the Board of Statutory
  Auditors, to the auditing firm, control over the accuracy of the documentation/information collected);
- select the auditing firm with transparent methods and in compliance with the provisions of Art. 13 of Legislative Decree no. 39/2010;
- carry out one or more meetings, with relative drafting of minutes, between the auditing company and the SB
   - before the meetings of the BoD and the shareholders' meeting called to approve the financial statements which concern the draft financial statements should any critical issues arise in the performance of auditing
   activities;
- disseminate to the personnel involved in the preparation of the aforementioned documents, regulatory
  instruments that clearly define the accounting principles to be adopted for defining information and data on
  the economic, equity, and financial situation of Fidia and the operating procedures for their accounting. These
  regulations must be promptly supplemented/ updated by the information provided by the competent office
  based on the novelties in the field of primary and secondary legislation and disseminated to the recipients
  indicated above;



 document and file the main relationships with the Board of Statutory Auditors, the independent auditors, as well as any requests for documentation or findings at the Administration, Finance, and Control function.

#### Sensitive Activities - Corruption between private parties

**Management of relations with third parties**: these are activities aimed at promoting one's business, with private third parties (non-profit institutions, associations, foundations, etc.), the management of relations with suppliers, as well as the procurement of new customers, loyalty of the relationship with customers, the stipulation of new contracts, as well as any other activity carried out for the promotion of business activities with potential customers or acquired customers, when they are purely private in nature (wholesalers, Italian and foreign distributors, private clinics, etc.).

#### Main Parties, Functions, and Organisational Units involved:

CEO, Legal, Quality Assurance, Procurement, CFO-Administration, Finance and Control, Corporate R&D -Business Development, Plant, Corporate HR, Pharma Italy, Pharma International, Regulatory Affairs, Communication

#### > <u>Potential crimes</u>:

- o Corruption between private parties (Art. 2635, paragraph 3, Civil Code)
- o Investigation of corruption between private individuals (Art. 2635-bis Civil Code)

#### Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- Clearly define the roles and tasks of the Functions/Organisational Units responsible for managing the various
  phases of the sensitive process (identification of the counterparty, management of the relationship,
  contractual proposal, signing of the agreement);
- dealing with customers, institutions, suppliers, third parties in general, who meet the moral and professional requirements established by the Company, also taking into account the creditworthiness analysed by the competent function;
- respect the principle of traceability of the process adopted to reach the stipulation of the agreement;
- exclusively use contract models prepared by the competent function and submit any significant changes with respect to the aforementioned models for approval by the same function;
- define contracts in coordination with the competent functions;
- conclude contracts in writing and using contractual standards; if necessary, ad hoc clauses or customer contractual standards may be used, provided that they are validated by the competent functions;
- carry out anti-bribery and conflict of interest training activities;
- trace all forms of contributions to non-profit organisations, with an indication of the relative motivation;
- identify general and transparent criteria for determining a maximum offer price for each product or service, so that any anomaly may be easily detected;
- determine general regulations especially on terms and conditions of payment;



- plan benchmarking activities (comparison with economic market values);
- prepare adequate company protocols for: purchases of goods and services; assignment of consultancy and other professional services;
- comply with procedure "SOP CO001/03 Definition of contractual agreements and review of the contract";
- Moreover, it is compulsory to respect the procedure "for the management of relations with scientific societies and patients";
- communicate to the SB with a written note:
  - Sales transactions exceeding a given amount which may represent the risk threshold;
  - sales transactions higher than a given percentage with respect to the average price of the product, as resulting from the aforementioned general criteria;
  - all collection operations below the standard payment terms (for example, invoices paid on demand).

#### **3** General principles of behaviour prescribed

#### Corporate crimes;

#### **Prohibitions**

This Special Part envisages the express prohibition - for the Company Representatives, directly, and for the External Collaborators and Partners, through specific contractual clauses - to:

- Engage in, collaborate with or cause the carrying out of behaviours such as to result in the crimes considered above (Article and 25-novies of the Decree);
- engage in, collaborate with or cause the carrying out of behaviours which, although they are not such as to constitute in themselves crimes falling within those considered above, may potentially become so.

As part of the aforementioned behaviours, the following are specifically prohibited:

- Warrant or transmit false, incomplete data or, in any case, data not corresponding to reality, on the economic, equity and financial situation of the Company for drafting and representation in financial statements, budgets, reports or other corporate communications;
- omit communication of data and information required by law on the economic, equity, and financial situation of the Company;
- return contributions to shareholders or release them from the obligation to make them, except in cases of legitimate reduction of share capital, in any form not specifically included among those described below;
- distribute profits or advances on profits not actually achieved or destined by law to reserves;
- make reductions in the share capital, mergers or demergers, in violation of the provisions of law protecting creditors;
- proceed to establish or fictitiously increase the share capital, assigning shares for a value lower than their nominal value when setting up companies or increasing the share capital;
- divert the corporate assets, during the liquidation of the Company, from their destination to the creditors, dividing
  them in favour of the shareholders before paying the creditors or setting aside the sums necessary to satisfy the
  latter;
- engaging in conduct which materially prevents, through the concealment of documents or the use of other fraudulent means, or which in any case constitutes an obstacle to the performance of the control or auditing of corporate management by Independent Auditors;
- determine or influence the adoption of the resolutions of the shareholders 'meeting, putting in place simulated or fraudulent acts aimed at altering the regular procedure for establishing the shareholders' intent.

### <u>Duties</u>

This section provides for the express obligation of the aforementioned subjects to:

• Behave correctly, transparently, and collaboratively, in compliance with law, in all activities aimed at the accounting, drafting and preparation of the financial statements of Fidia;



- strictly observe all the regulations set by law, to protect the integrity and effectiveness of the Company's share capital;
- refrain from carrying out simulated or otherwise fraudulent transactions, capable of causing a significant distortion of the economic/equity and financial results achieved by the Company;
- manage documents, reports and other annotations in a correct and sufficiently detailed manner, maintaining documentation of the activities and guaranteeing their storage through archiving;
- promptly and correctly, in a true and complete manner, make the communications required by the law in force at the time;
- report to their hierarchical manager or company management and, together with the Supervisory Body, both the
  existence of errors or omissions in the accounting process of management events and behaviours that are not
  in line with the provisions of this Special Part;
- carry out training activities on accounting standards and accounting principles for the personnel of the Administration, Finance, and Control function.

#### **Corruption between Private parties**

#### **Prohibitions**

This Special Section envisages the express prohibition - for the Company Representatives, directly, and for the External Collaborators and Partners, through specific contractual clauses - to:

- Give or promise money or other benefits in favour of directors, general managers, managers in charge of
  preparing corporate accounting documents, auditors and liquidators, as well as in favour of those who exercise
  managerial functions other than the previous ones, of client or potential client companies, or partners in general,
  belonging to the private sector;
- engage in behaviours which, although as such do not constitute in themselves a type of crime pursuant to Art. 2635 and 2635-bis of the Civil Code, may potentially become one;
- find themselves or cause any situation of conflict of interest towards their partners, customers or potential customers in relation to the provisions of the aforementioned crime;
- submit offers not subjected to the approval process required by company practice;
- stipulate contracts with conditions established according to non-objective parameters and/or in violation of the provisions of company practice;
- produce untrue documentation and data in order to obtain acceptance of an offer by a private counterpart.

## <u>Duties</u>

For the purposes of implementing the aforementioned behaviours:

- Company Representatives must not accept or solicit gifts, acts of courtesy, such as gifts or forms of hospitality, or other utilities exceeding the normal courtesy practices and such as to be considered usual in relation to the recurrence and not be interpreted by an impartial observer, as aimed at acquiring advantages in an improper manner. It is not permitted to offer, promise, give gifts, acts of courtesy, such as gifts or forms of hospitality, or other benefits, exceeding normal courtesy practices. In any case, these expenses must always be authorised, documented, and in compliance with the budget limits;
- during a business negotiation, request or commercial relationship with a private subject, the following actions
  must not be taken (directly or indirectly):
  - examining or proposing employment and/or commercial opportunities that may benefit employees of private entities;
  - soliciting or obtaining of confidential information that may compromise the integrity or reputation of both parties;



## SPECIAL PART "E"

## NEGLIGENT CRIMES IN VIOLATION OF REGULATIONS ON HEALTH AND SAFETY IN THE WORKPLACE

**1** Manslaughter, serious, and very serious negligent injuries in violation of accident prevention regulations and the protection of hygiene and health in the workplace.

Law no.123 of 3 August 2007<sup>44</sup>, introduces Art. 25-septies in the Decree, subsequently amended by the Consolidated Law on safety: the body is also responsible in instances of:

- Manslaughter (Article 589, Criminal Code) and
- Serious or very serious personal injury through negligence (Article 590, Criminal Code).

where the crime of manslaughter has been committed in violation of accident prevention regulations and the protection of hygiene and health in the workplace.

The reference regulations are contained in the Consolidated Law on safety.

Moreover, it should be specified that any violation of the employer's obligation to guarantee the safety of the place where the work is performed (Article 2087, Civil Code) - Resulting in at least a serious injury - involves the ex officio opening of proceedings against the company. Case law has, in fact, established that any violation of the regulations concerning work safety aggravate the crime of manslaughter, and serious and very serious negligent injuries and, therefore, make Art. 25-septies of the Decree applicable.

Serious or very serious injury (Article 583 of the Criminal Code) means an injury that causes:

- A life-threatening illness or leaves the injured party unable to work for a period over forty days;
- permanent weakening of a sense or organ; a disease that is certainly or probably incurable; the loss of a sense; the loss of a limb, or a mutilation that renders the limb unusable, or the loss of the use of an organ or the ability to procreate, or a permanent and serious difficulty speaking; deformation, or permanent scarring of the face.

It must be emphasised that, in these cases, the offence is punished as mere negligence: unlike the other predicate offences which require awareness and voluntary nature of the action.

#### 2 Sensitive Activities and protocols to adopt

The analysis of Fidia's business processes made it possible to identify the activities within which the types of offences referred to may abstractly occur.

Listed below are: i) Sensitive Activities; ii) the functions/organisational units involved; iii) offences that may be potentially committed; iv) the specific protocols to be adopted.

**System attributing responsibility and organisation of safety**: these are the activities aimed at the correct identification of roles and responsibilities regarding safety in the workplace, with consequent identification of the various figures: Employer ("DL"), Employer Delegate ("DDL"), Head of the Prevention and Protection Service ("RSPP"), Workers' Safety Representative ("RLS"), Company Doctor, managers and supervisors.

#### > Main Parties, Functions, and Organisational Units involved:

CEO, Plant, Pharma Italy, Corporate R&D - Business Development, Quality Assurance, Procurement

#### Potential crimes:

- Manslaughter (Article 589, Criminal Code)
- Personal injury due to negligence (Article 590, Criminal Code)

#### Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

<sup>&</sup>lt;sup>44</sup> Published in the Official Gazette n. 185, 10 August 2007, and entered into force on 25 August 2007.



- Define by the DL (natural person to whom, as detectable by official company documentation, who is
  attributed responsibility of the company organisation also for the purposes of health and safety legislation in
  force from time to time) and by these to communicate to the BoD and to the SB the organisational structure
  responsible for overseeing safety in the workplace, as well as any subsequent modification thereof;
- the organisational structure must ensure a clear identification of the DL and a formalised system of delegation of functions in the field of health and safety prepared according to the following principles of jurisprudential orientation: (i) effectiveness - existence and coexistence of decision-making and financial autonomy of the delegate; (ii) technical and professional suitability of the delegate; (iii) supervision of the delegate's activity, non-compliance, non-interference; (iv) certainty, specificity and awareness;
- confer the delegation of functions by the DL in accordance with the requirements envisaged by Art. 16 of Legislative Decree. 81/2008. The system of proxies must be documented and traceable;
- carry out the assignment of the roles of RSPP, Company Doctor, the election or designation of the Workers' Safety Representative; the identification of the executive and supervisor functions must be carried out in compliance with the legislation in force from time to time and in such a way as to ensure compliance with the principles of correctness, transparency, traceability; in detail it is necessary to: (i) verify the existence of the specific requirements in line with the provisions of the law in force on the subject matter; (ii) ensure traceability of the checks carried out in relation to possession of the specific requirements envisaged by the relevant legislation; (iii) carry out the *assessment* of personnel to understand their capacities and temporal availability in order to cover these specific roles; (iv) provide for a formal designation and assignment of offices; (v) ensure the traceability of the formal acceptance of the issued assignments;
- ensure, if the Prevention and Protection Service is outsourced, that the relationship between the Service
  and the Company is contractually formalised and the addition of specific clauses that require the *outsourcer*to comply with the principles contained in the Model and in this Special Part and regulate the consequences
  deriving from the violation of the provisions contained therein.

*Risk identification and assessment*: these are activities aimed at assessing business risks in accordance with the provisions contained in Legislative Decree no. 81/2008.

- Main Parties, Functions, and Organisational Units involved: CEO, Plant Pharma Italy, Corporate R&D - Business Development, Quality Assurance, Procurement
- > Potential crimes:
- Manslaughter (Article 589, Criminal Code)
- Personal injury due to negligence (Article 590, Criminal Code)

# Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- Clearly define roles and tasks in order to identify: (i) responsibilities for checking, approving and updating the contents of the Risk Assessment Document (DVR); (ii) the methods and criteria for reviewing the hazard identification and risk assessment processes; (iii) the traceability of the involvement of the Company Doctor in the process of identifying hazards and assessing the risks;
- provide for the identification of workers' duties;
- provides for the explicit definition of the assessment criteria adopted for the various categories of risk in compliance with the applicable legislation and regulations;
- draw up the DVR in accordance with the provisions of the law, which must contain at least: (i) the
  assessment procedure, with the specification of the criteria adopted and the names of the persons who
  participated in the assessment; (ii) the identification of the prevention and protection measures and of the
  individual protection devices, of the procedures for the implementation of the measures resulting from the
  assessment; (iii) the program of measures deemed appropriate to ensure the improvement of safety levels



- over time; (iv) the identification of the tasks that expose workers to specific risks that require recognised professional skills and specific experience, education and training;
- promptly update the DVR in the presence of a change in company risks or new regulatory provisions or accidents or significant events that suggest a change;
- make the DVR available to the SB and inform the same about any possible update.

**Process of definition and management of protection and prevention procedures**: these are the activities of identification, preparation, application and dissemination of procedures aimed at preventing accidents at work both in ordinary conditions and in emergency conditions.

## Main Parties, Functions, and Organisational Units involved:

CEO, Plant Pharma Italy, Corporate R&D - Business Development, Quality Assurance, Procurement

### > <u>Potential crimes:</u>

- o Manslaughter (Article 589, Criminal Code)
- Personal injury due to negligence (Article 590, Criminal Code)

### Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- Comply with the procedures adopted by the establishments;
- define methods for acquiring, evaluating and managing the provisions relevant to the organisational in order to comply with the applicable technical-structural standards;
- define plans and periodically carry out training and information sessions aimed at making safety procedures of both managerial and operational nature known and disseminated;
- carry out a review of the safety procedure that may have been violated in the event of accidents or nearaccidents or emergencies, carry out an analysis of the incident if necessary;
- keep under control through preventive and scheduled maintenance, all machines, systems, work environments, guaranteeing the functionality of all safety and alarm devices;
- organise the procedures for managing emergencies and evacuations, also carrying out the appropriate simulations;
- involve in the process of definition, implementation, dissemination and monitoring of prevention and
  protection procedures each of the figures involved in the organisational structure overseeing safety at work
  (DL, Head of the Prevention and Protection Service, Workers' Safety Representative, Company Doctor,
  managers and supervisors), each in compliance with their roles and skills.

In particular, for the purposes of the correct implementation of the above:

- the DL, in compliance with Art. 17, and 29 of Legislative Decree no. 81/2008, defines and maintains the criteria and methodologies for identifying company and specific risks;
- The Manager for Prevention and Protection Service: (i) reports to the Legislative Decree at least every six months on the state of effectiveness and efficiency of the system for protecting the health and safety of workers in Fidia's workplaces. This report highlights any critical issues also connected to significant changes in the organisational of work or in relation to the degree of development of the technique, prevention and protection or following significant accidents and referring to the contrast and mitigation strategies already planned and/or adopted (solution/ manager) and situations not yet taken care of; (ii) verifies the adequacy of company legislation on safety in the workplace; (iii) supervises the activities of the Protection and Prevention Service; (iv) convenes the annual meeting with the figures concerned;
- the Company Doctor reports at least annually to the DL on the activity carried out and the criticalities encountered. If the Company Doctor verifies non-compliance by the DL with assessment of temporary or permanent unfitness relating to a specific task of one or more workers, the latter promptly reports this to the Supervisory Body;



- the RLS collaborates with the DL, reporting any irregularities found and proposing appropriate solutions. Said RLS, in compliance with the law, has the right to access workplaces, even during inspections, as well as the company documentation concerning risk assessment and related prevention measures;
- the RSPP meets at least annually with the RLS, the Company Doctor and the DL or his/her representative pursuant to Art. 35 TUS [Safety Act]. A copy of the report is forwarded by the DL to the SB;
- at the end of the activity, a specific report is drawn up containing the results connected to the evaluation made. Based on the findings that emerged during the activity and the results noted, the actions to be implemented in order to remove the non-conformities found are defined.

### **3** General principles of behaviour

This Special Part, in compliance with the provisions of Art. 30 of Legislative Decree. no. 81/2008, requires:

- Compliance with technical-structural standards concerning equipments, plants, workplaces and chemical, physical and biological agents;
- · Risk assessment activities and provision of consequent prevention and protection measures;
- Organisational activities, such as emergencies, first aid, contract management, periodical safety meetings, consultations with workers' representatives on safety;
- carrying out health monitoring activities;
- carrying out information and training activities for workers;
- monitoring of activities in reference to worker's compliance with procedures and instructions on safety at work;
- acquisition of documentation and certifications required by law;
- periodic verifications of the application and effectiveness of the adopted procedures.

In accordance with the legal requirements, in order to pursue the above, Fidia adopts and implements at the Abano Terme plant, in Paderno Dugnano, and in a simplified form in the Noto plant, its own Occupational Safety Management System (SGSL), compliant with British Standard OHSAS 18001, in accordance with the provisions of Art. 30, paragraph 5 of Legislative Decree. 81/2008.

#### **Prohibitions**

This Special Part envisages the express obligation for the Recipients to:

- Implement behaviours such as to expose Fidia to one of the crimes envisaged by Art. 25-septies of the Decree;
- implement behaviours such as to expose Fidia to one of the crimes envisaged by Art. 25-septies of the Decree;
- omit the updating of prevention measures, in relation to organisational changes that have relevance for the purposes of health and safety in the workplace;
- omit the adoption of fire-fighting and prompt evacuation measures in case of serious and immediate danger.

## **Obligations**

This Special Part envisages the express obligation of the aforementioned subjects to:

- Use machinery, apparatus, equipment, dangerous substances and preparations, means of transport, tools, and safety devices securely and correctly;
- make appropriate use of the protection equipment available;
- immediately report to the Head of the Prevention and Protection Service the deficiencies of the means and devices referred to in the preceding two points, as well as any other dangerous conditions of which they become aware, acting directly in case of urgency;
- not remove or modify safety, signalling or control devices, without prior authorisation;
- not carry out on their own initiative, operations or manoeuvres that are not within their competence or which
  may jeopardise their safety or that of other workers;
- comply with the provisions contained in the Emergency and Evacuation Plan;



• comply with the prescriptions given by the safety signs as well as the contents of the emergency safety procedures transmitted by the RSPP also through classroom training.



## PART SPECIAL "F"

## MONEY LAUNDERING, RECEPTION OF STOLEN GOODS, SELF-LAUNDERING CRIMES

#### 1 Receiving stolen goods, laundering and use of money, goods or benefits of criminal origin

Legislative Decree of 16 November 2007<sup>45</sup>, introduces the hypotheses envisaged in articles 648 (receiving stolen goods), 648-bis (money laundering) and ter (use of money, goods or benefits of criminal origin) of the criminal code within the scope of application of the Decree.

Legislators aim to prevent that, once a crime has occurred (so-called crime or predicate offence), persons other than those who committed the crime ("Outside instances of accomplices ...") become interested in the things that originate from the crime itself. The core of the three crime hypotheses, therefore, is found in activities subsequent to the commission of a crime, activities which, in any case, involve the aggression of the legal asset of equity (as regulations aimed at preventing any economic advantage obtained with goods of criminal origin) and of juridical benefit in the administration of justice (since, in any case, goods of illicit origin, through said criminal conduct, risk being dispersed, thus creating an obstacle for the authority in ascertaining and repressing the predicate offences activities).

The differences between articles 648, 648-bis and 648-ter of the Criminal Code, on the other hand, lie essentially in the conduct (material element) and in the subjective element (generic or specific fraud). Regarding the material element:

- Receiving stolen goods: it is punishable to purchase, receive, conceal or intervene to purchase, receive or conceal money or things deriving from a crime.
- Money laundering: it is punishable to replace, transfer, carry out other transactions in such a way as to hinder the identification of the criminal origin of money, goods or other benefits deriving from a crime.
- Use of money, goods or benefits of criminal origin: it is punishable to use money, goods or utilities of criminal origin in economic or financial activities.

Regarding the subjective element:

- Receiving stolen goods: punishable as a conduct carried out in order to obtain a profit for oneself or for others (specific fraud).
- Money laundering: the type of crime is generic wilful misconduct.
- Use of money, goods or benefits of criminal origin: the type of crime is generic wilful misconduct.

Among these three criminal cases, in the context of corporate criminal law, money laundering is certainly the most relevant case and, therefore, the most important risk to be considered (US legislation calls it "money laundering" or "washing of money").

This constantly evolving legislation envisages limitations on the use and transfer of cash, obligations to identify customers, to register for financial intermediaries and to report suspicious transactions, as well as operational rules for the prevention of criminal activities (*know your customer rule* and quantitative analysis of transactions) capable of guiding the contents of the compliance model.

It should be noted that in 2013, within the implementation of the Decree, the crime of improper use or alteration of credit or payment cards, or any other similar document enabling the withdrawal of cash or the purchase of goods or the provision of services, was added.

#### Self-laundering crime

Art. 3 of Law no. 186 of 15 December 2014 "Provisions regarding the emergence and return of capital held abroad as well as for strengthening of the fight against tax evasion. Provisions on self-laundering" introduced, inter alia, within the Italian legal system the crime of self-laundering which punishes "whoever, having committed or contributing to committing a crime without intent, employs, replaces or transfers in economic, financial,

<sup>&</sup>lt;sup>45</sup> In implementation of directive 2005/60/EC of 26 October 2005, and of directive 2006/70/EC of 1 August 2006.



entrepreneurial or speculative activities, the money, goods, or other benefits deriving from the commission of such crime, so as to concretely hinder the identification of their illicit origin."

The crime of self-laundering occurs as a multi-offensive case, capable of consolidating the damage to the assets of the victim of the predicate crime and also harming the administration of justice and the public economy as a whole. Those who self-recycle with investments and purchases of various kinds prevent or make the victim's restoration operations more difficult, negatively impact credit and price trends and, ultimately, the whole system of economic relations.

Self-laundering is an actual crime, in that the perpetrator must necessarily be the one who participated in the commission of the non-culpable crime, from which the income subject to reinvestment derived. As far as the material element is concerned, the typical conduct of the crime follows three different factual models: replacement, transfer and use in economic or financial activities of money, goods or other utilities, deriving from the commission of the culpable crime.

The determination of the punishable conducts is limited to those behaviours which, although not necessarily artificial in themselves (integrating, that is, the artifices and deceptions, typical of fraud), make it objectively difficult to identify the criminal origin of the asset.

In particular, the concept of replacement of the money, goods or of other benefits of criminal origin, include all the activities aimed at the so-called "laundering" of the criminal product, separating it from any possible connection with the crime (the replacement, therefore, may be carried out in the most varied ways, for example by exchanging cash for other banknotes, depositing in the bank and subsequent withdrawal). The transfer, on the other hand, consists of a specification of the replacement and concerns all the conducts that involve a shift of the assets of criminal origin from one subject to another or from one place to another, so as to lose all traces of ownership, origin, and the actual destination. The transfer or replacement of illicit proceeds must concern financial, economic or speculative entrepreneurial activities, as required by paragraph 4 of Art. 648 ter.1 of the Criminal Code. In any case, the crime is not punishable if there is a destination for the personal use or enjoyment of money, goods or other utilities of illicit origin.

The objective element of the offence will therefore not be included if there is a destination for personal use or enjoyment of money, goods or other benefits of illicit origin.

As regards the subjective element, the crime is punishable as generic wilful misconduct, which consists in the conscience and will to carry out the replacement, transfer or other operations concerning money, goods or other utilities, together with the awareness of the suitability of the conduct to create an obstacle to the identification of such origin.

The main categories of predicate offences of the crime of self-laundering may be:

- Tax offences;
- Crimes against property (for example usury, extortion, theft, embezzlement, robbery);
- Crimes against the Public Administration;
- Crimes against the administration of justice;
- Organised crime.

Therefore, as a result of the crime in question, a predicate crime may also be a crime not included in the scope of application of Legislative Decree 231/2001.

#### 2 Sensitive Activities and protocols to adopt

The analysis of Fidia's business processes made it possible to identify the activities within which the types of offences referred to may abstractly occur and the processes that may be considered "instrumental" to the



commission of the crimes or so-called "precondition."

The instrumental processes relating to the commission of the offence referred to in this section are as follows:

- Procurement of goods and services;
- Management of monetary and financial flows.

For identification of the control protocols to be adopted, please refer to the specific Special Part L.

Listed below are: i) Sensitive Activities; ii) the functions/organisational units involved; iii) offences that may be potentially committed; iv) the specific protocols to be adopted.

*Management of investments:* these are activities relating to management of the investments made by the Company.

## > Main Parties, Functions, and Organisational Units involved:

Chief Executive Officer, Plant, CFO-Administration, Finance and Control, Procurement, Corporate R&D -Business Development, Legal

### > Potential crimes:

- Money laundering (Art. 648-bis, Criminal Code)
- Use of money, goods or benefits of illegal origin (Art. 648-ter, Criminal Code)
- Self money-laundering (Article 648-ter-1, Criminal Code)

## > Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- Clearly define the roles and tasks of the Functions/Organisational Units responsible for the management of active and passive phases of the sensitive process;
- ensure traceability of the decision-making process, through the preparation and filing of the related supporting documentation;
- guarantee that each investment is supported by (i) a clear economic analysis of cost-benefit evaluation, (ii) clear identification of the counterparty;
- comply with the authorisation procedures for investments adopted by the Company through the final approval
  of the Chief Executive Officer and/or the Board of Directors, in compliance with the system of powers of attorney
  adopted;
- promptly notify the Supervisory Body of any operation that presents any anomaly indices such as:
  - absence of plausible justifications, for carrying out transactions that are clearly not usual, not justified or not proportionate to the normal exercising of the activity;
  - execution of transactions that use available funds that appear excessive with respect to the economic and equity profile of the Company;
  - ✓ execution of transactions that do not appear to have economic and financial justifications;
  - ✓ acquisitions for various reasons of availability of goods, including luxury goods, of high value, not justified by the company's turnover;
  - conclusion of agreements in favour of third parties, agreements for a party to be appointed or registrations to a trust, concerning rights on real estate, without any plausible motivation.

*Management of intra-group transactions*: these are all activities concerning relations with companies belonging to the FIDIA group and with the subsidiaries of the Olon Group

## Main Parties, Functions, and Organisational Units involved:



Chief Executive Officer, CFO-Administration, Finance and Control

### Potential crimes:

- o Receipt of stolen goods (Art. 648, Criminal Code)
- Money laundering (Art. 648-bis, Criminal Code)
- o Use of money, goods or benefits of illegal origin (Art. 648-ter, Criminal Code)
- Self money-laundering (Article 648-ter-1, Criminal Code)

### Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- Always evaluate the purposes, profitability and interest of the Company in carrying out an intra-group transaction;
- formalise the contractual terms and conditions governing relations and transactions between companies belonging to the same group; in detail, a contract must be stipulated in writing for each intra-group transaction, which contains respectively:
  - ✓ an indication of the parties to the contract;
  - ✓ the description of the object (provision of services, purchase/sale of goods, provision of loans) of the contract;
  - the indication of the consideration (price, commission, royalties, interest rate) or at least the criterion for determining the relative consideration;
  - $\checkmark$  the duration of the contract;
- ensure that the consideration for intra-group transactions is at market values in accordance with the indications contained in Art. 110, paragraph 7 of Presidential Decree no. 917 of 22 December 1986, and in the OECD Guidelines on Transfer Pricing;
- respect the following operating protocols:
  - ✓ an original copy of the contract signed by the parties is adequately filed and kept at the Company's registered office;
  - the services covered by the contract are effectively fulfilled by the various parties involved according to the agreed methods, terms, and conditions;
  - adequate documentary trace is kept of the purchases or sales, of the services rendered or acquired, by the person in charge concerned, with filing of the relative documents at the headquarters of the Company;
  - ✓ payments made or received by way of consideration comply with: (i) the sales/services actually rendered/received as well as (ii) the agreements contained in the relative contract;
  - ✓ all payments are made against the issue of an invoice or equivalent document, where required by law;
  - ✓ all payments are duly accounted for in accordance with the applicable legal provisions;
- carry out reconciliations through the SAP system;
- use the dedicated accounts of the Chart of Accounts for intra-group transactions.

*Customer and supplier master data management*: this is the process of acquiring information on customers and suppliers in order to evaluate their merit, reliability, and credibility.

- Main Parties, Functions, and Organisational Units involved: CEO, Plant, Procurement, Pharma Italy, Pharma International
- Potential crimes:
- Receipt of stolen goods (Art. 648, Criminal Code)
- Money laundering (Art. 648-bis, Criminal Code)
- Use of money, goods or benefits of illegal origin (Art. 648-ter, Criminal Code)
- Self money-laundering (Article 648-ter-1, Criminal Code)



### Protocols

With reference to this sensitive area it is necessary to follow the protocols below:

- Acquire information on customers and suppliers (for overall amounts on an annual basis exceeding € 100,000) according to the internal procedures adopted by the Procurement and Administration, Finance, and Control functions;
- promptly notify the SB by the proposed functions of the cases in which:
  - The supplier refuses or is unjustifiably reluctant to provide the information necessary to declare the activity carried out, to present accounting or other documentation, to provide any other information that, under normal circumstances, is acquired in the performance of normal business activities;
  - ✓ the supplier refuses to or raises objections to provide the account number to which the payment has been or will be credited;
  - the supplier provides information that is clearly inaccurate or incomplete, such as to manifest the intent to conceal essential information;
  - ✓ the supplier uses identification documents that appear to be counterfeit;
  - ✓ the supplier uses the services of a frontman without plausible justifications.

Cash pooling management: these are activities related to the management of the Group's cash pooling.

- Main Parties, Functions, and Organisational Units involved: Chief Executive Officer, CFO-Administration, Finance and Control
- > <u>Potential crimes:</u>
- Money laundering (Art. 648-bis, Criminal Code)
- Use of money, goods or benefits of illegal origin (Art. 648-ter, Criminal Code)
- Self money-laundering (Article 648-ter-1, Criminal Code)

#### Protocols

With reference to this sensitive area, the following protocols must be observed:

- Formalise the *cash pooling* relationship by means of a specific agreement;
- carry out monthly bank reconciliations;
- manage relations with participating companies in a transparent manner that ensures the traceability of flows;
- archive banking documentation in an exhaustive and complete manner.

Management of corporate transactions: these are activities aimed at carrying out extraordinary transactions.

- Main Parties, Functions, and Organisational Units involved: Board of Directors, Chief Executive Officer, CFO-Administration, Finance and Control, Legal
- Potential crimes:
- Money laundering (Art. 648-bis, Criminal Code)
- Use of money, goods or benefits of illegal origin (Art. 648-ter, Criminal Code)
- Self money-laundering (Article 648-ter-1, Criminal Code)

#### ➢ Protocols

With reference to this sensitive area, the following protocols must be observed:

 Provide for the transmission of data and information, including extraordinary corporate transactions (acquisitions, mergers, demergers, etc.) to the responsible function and the Supervisory Body, through a system (including IT) that allows the tracking of individual steps also with reference cash inflow and outflow in



order to verify, for example, the existence of some anomaly indicators, such as by way of example but not limited to:

- Carrying out of operations financed with international telegraphic payments, in particular from foreign countries known as off-shore centres or characterised by privileged regimes in terms of taxation or banking secrecy or indicated by the International Financial Action Group (FATF) as non-cooperative;
- operations characterised by an unjustified use of payment techniques by offsetting or by elements such as the agent's domicile with third parties, the presence of post office boxes or postal addresses other than tax or professional domicile;
- ✓ settlement of payments by checks with progressive serial numbers or several checks of the same amount with the same date or by checks without indicating the beneficiary.
- ✓ carrying out transactions with counterparties in unusual locations for the same;
- sending and receiving money to/from numerous and recurring foreign counterparties in locations that are not geographically distant;
- ✓ transactions involving counterparties established in foreign countries known as off-shore centres or characterised by privileged regimes from a fiscal point of view or banking secrecy or indicated by the FATF as non-cooperative, and which are not justified by the customer's economic activity or other circumstances:
- Transactions relating to the establishment and transfer of real rights on properties, carried out with means
  of payment from the aforementioned countries;
- search for loans based on guarantees, also represented by securities or certificates, certifying the existence of large deposits with foreign banks, particularly if such deposits or loans are held with or disbursed by parties established in these countries.

Fiscal and tax management and related obligations: these are activities aimed at preparing tax documents, paying taxes, etc.

Main Parties, Functions, and Organisational Units involved: Chief Executive Officer, CFO-Administration, Finance and Control

## > Potential crimes:

- Money laundering (Art. 648-bis, Criminal Code)
- Use of money, goods or benefits of illegal origin (Art. 648-ter, Criminal Code)
- Self money-laundering (Article 648-ter-1, Criminal Code)

# > Protocols

Management of the sensitive area identified must include:

- Segregation as part of the process with separation of roles between whoever carries out the accounting of economic events, whoever supervises the control of the surveys, and whoever is in charge of tax management;
- traceability of the decision-making process through documentation and archiving (telematic and/or paper) of each activity of the process by the structure involved;
- use of a dedicated computer system for recording active and passive invoices, as well as any other economic event;
- regulation and monitoring of access to the computer system;
- accounting by the responsible office only of the active/ passive invoices that have received the approval for
  registration and their payment/ collection only after having received the approval of the manager who requested
  the purchase/ sale;
- detection of all corporate administrative facts that have an economic and equity effect;
- regular keeping and storage of compulsory accounting records for the purposes of income tax and value added tax;



- calculation and determination of the taxes due with the assistance of a third party consultant, under a specific
  written agreement with the latter including standard clauses on the unconditional acceptance by the consultant
  of the Model referred to in the Decree;
- periodic training meetings on tax issues and related obligations by a third party consultant;
- periodic review of the correct execution of tax obligations;
- compliance with the rules envisaged at group level for the purposes of tax consolidation; for these purposes it
  is necessary to prepare a specific written agreement between the companies adhering to the consolidation;
- verification with a third party consultant of any tax implications deriving from the execution of an operation of an ordinary or extraordinary nature;
- compliance with the policies, operating protocols adopted by the Company in relation to accounting. The protocols envisaged in Special Part J Tax offences are also applicable.

# 3 General principles of behaviour

## **Prohibitions**

This Special Part envisages the express prohibition for Recipients to:

- Engage in, collaborate with or cause the carrying out of behaviours such as to result in the crimes considered above (Article and 25-octies of the Decree);
- engage in, collaborate with or cause the carrying out of behaviours which, although not such as to constitute crimes falling within those considered above, may potentially become so.

### **Duties**

This section envisages the **express obligation** of the aforementioned parties to:

- Know and comply with all the measures aimed at guaranteeing the correct management of liquidity, and, therefore, of collections and payments;
- verify the commercial and professional reliability of suppliers and customers;
- verify the regularity of payments, with reference to the full coincidence between recipients/ payers of payments, and counterparties actually involved in commercial transactions;
- implement formal and substantial audits on corporate cash flows, with reference to collections from third parties, payments to third parties and intra-group transactions. Such audits must take into account, inter alia, the registered office of the counterparty company (e.g. tax havens, countries at risk of terrorism, etc.), the credit institutions used (registered office of the banks involved in the transactions and institutions that do not have physical settlements in any country).

The general conduct described above supplements and does not replace the principles set out in the Code of, as well as any procedures for greater protection envisaged within Fidia and relating to sensitive activities.



## PART SPECIAL "G" CRIMES RELATED TO IMMIGRATION

## 1 The offences envisaged by Art. 25-duodecies of the Decree

### Employment of third-country nationals without a valid residence permit is irregular

Legislative Decree 109/2012, on: "Implementation of Directive 2009/52/EC which introduces minimum standards relating to sanctions and measures against employers who employ illegally staying third-country nationals" refers to Art. 25-duodecies of the Decree the crime referred to in Art. 22 paragraph 12 bis of Legislative Decree no. 286/1998 (employment of citizens of third countries whose stay in Italy is irregular).

### Crimes of procured illegal entry and aiding and abetting the illegal stay;

Art. 30, paragraph 4 of Law no. 161 of 17 October 2017, containing "Amendments to the code of anti-Mafia laws and preventive measures, as per Legislative Decree no. 159, of 6 September 2011, to the Criminal Code and the implementing, coordination and transitional legislation of the Criminal Code of Procedure and other provisions. Delegation to the Government for the protection of work in seized and confiscated companies" has included among the predicate offences of the Decree, at Art. 25-duodecies, the offences of procured illegal entry, referred to in Article 12, paragraphs 3, 3-bis, 3-ter of Legislative Decree no. 286, of 25 July 1998, and of aiding and abetting the clandestine stay, pursuant to Art. 12, paragraph 5 of Legislative Decree No. 286 of 25 July 1998, on the subject matter of illegal immigration.

### 2 Sensitive Activities and protocols to adopt

The analysis of Fidia's business processes made it possible to identify the activities within which the types of offences referred to may abstractly occur.

Listed below are: i) Sensitive Activities; ii) the functions/organisational units involved; iii) offences that may be potentially committed; iv) the specific protocols to be adopted.

**Entrusting of assignments for work and services:** this is the activity relating to the management of selecting and entrusting of assignments, to self-employed workers, relating to a work or service that they undertake to render in person, "independently" and "without a bond of subordination," therefore outside an employment relationship.

# > Main Parties, Functions, and Organisational Units involved:

CEO, Plant, Legal, Procurement

#### > <u>Potential crimes:</u>

Use of third-country nationals whose stay is irregular (Article 22, paragraph 12-bis of Legislative Decree no. 286, of 25 July 1998)

## Protocols

With reference to this sensitive area, the Company prepares:

- A specific procedure/check list for the stipulation of contracts for the administration of work, performance, and contracts;
- appropriate system of delegations and proxies for the conclusion of contracts involving the employment of a workforce by the counterparty;
- authorisation procedures for purchases; in particular, it is mandatory to comply with procedure "SOP SA001/03 Purchase of materials, goods and services";
- appropriate request to suppliers or business partners of a specific commitment to comply with the legislation in question.



**Recruitment of personnel**: is the activity relating to the methods of selecting people to be recruited with an employment contract.

Main Parties, Functions, and Organisational Units involved: Chief Executive Officer, Corporate HR

## Potential crimes:

- Employment of third-country nationals whose stay is irregular (Article 22, paragraph 12-bis of Legislative Decree no 286, of 25 July 1998)
- crime of procured unlawful entry, pursuant to Art. 12, paragraphs 3, 3-bis, 3-ter of Legislative Decree no. 286 of 25 July 1998;
- crime of aiding and abetting the illegal stay, pursuant to Art. 12, paragraph 5 of Legislative Decree No. 286 of 25 July 1998, on the subject matter of illegal immigration

### > Protocols

Respect for protocol no. 9 is referenced, as envisaged in Special Part L - Instrumental Processes. In addition, the following protocols must be observed:

- carry out preventive checks with prior information also to the competent Authorities regarding the validity of
  residence permits and the possession of the requirements in general for the job by non-EU candidates vying
  for recruitment;
- carry out periodic subsequent checks on the continuing validity requirements of the residence permits of non-EU foreigners hired and employed by the Company;
- comply with procedure "SOP HR002 Search, selection, personnel addition and monitoring of trial period."

## 3 General principles of behaviour

In carrying out their respective activities/functions, in addition to knowing and respecting the regulations governed by the Company's Articles of Association, the principles laid down by the Code, the operating procedures and any other internal regulations relating to the *Corporate Governance* system, the Company Representatives, directly, and external collaborators and partners, through specific contractual clauses, must comply with the rules of conduct contained in this Model.

This Special Part envisages the express *prohibition* to:

- Engage in conduct such as to integrate the types of offences considered above (pursuant to Article 25duodecies of the Decree) or conduct which, although not in themselves constituting a crime, could potentially result in one of the offences under consideration herein;
- violate the principles and procedures existing in the company and relating to the hiring of foreign workers and/or envisaged in this Special Part.

Consequently, this Special Part envisages the express *obligation* of the aforementioned parties to:

- Behave correctly, transparently, and collaboratively, in compliance with the law relating to the employment of third country nationals;
- carrying out all communications required by law and regulations to the Public Supervisory Authorities in a timely, accurate, and complete manner, without placing any obstacles in the way of the performance of any functions exercised by them.
- carry out the necessary training and information courses.



## SPECIAL PART "H" ENVIRONMENTAL CRIMES

## 1 Environmental crimes

Some "Environmental Crimes" have been introduced among the crimes within the scope of application of the Decree, including:

- killing, destruction, capture, taking, possession of specimens of protected wild animal or plant species (Art. 727-bis, Criminal Code);
- destruction or deterioration of habitats within a protected site (Art 733-bis, Criminal Code);
- trade in specimens of species listed in Annex A, Appendix I, and Annex C, Part 1 of Regulation (EC) no. 338/97 (Art. 1 of Law No. 150 of 7 February 1992);
- trade in specimens of species listed in annex A, appendix I and III, and annex C, part 2 of Regulation (EC) no. 338/97 (Art. 2 of Law No. 150 of 7 February 1992);
- prohibition of possession of specimens constituting a danger to public health and safety (Art. 6 of Law no. 150 of 7 February 1992);
- waste water discharges (Art. 137, paragraph 2, 3, 5, 11, 13 Legislative Decree no. 152 of 3 April 2006);
- discharges onto the soil (Article 103 of Legislative Decree no. 152 of 3 April 2006);
- discharges into the subsoil and groundwater (Article 104 of Legislative Decree no. 152 of 3 April 2006);
- discharges into sewer networks (Article 107 of Legislative Decree no. 152 of 3 April 2006);
- discharges of dangerous substances (Article 108 of Legislative Decree no. 152 of 3 April 2006);
- unauthorised waste handling activities (Article 256, paragraph 1, 3, 5, 6, and Articles 208, 209, 210, 211, 212, 214, 215, 216 of Legislative Decree no. 152 of 3 April 2006);
- prohibition of abandonment of waste (Article 192 of Legislative Decree no. 152 of 3 April 2006);
- prohibition of mixing hazardous waste (Article 187 of Legislative Decree no. 152 of 3 April 2006);
- electrical and electronic waste, medical waste, end-of-life vehicles and products containing asbestos (Article 227 of Legislative Decree no. 152 of 3 April 2006);
- site remediation (Article 257 paragraphs 1 and 2, of Legislative Decree no. 152 of 3 April 2006);
- violation of the obligations of communication, keeping of mandatory registers and forms (Article 258, paragraph 4, 2nd sentence of Legislative Decree no. 152 of 3 April 2006);
- ideological falsehood committed by a private individual in a public act (Article 483, Criminal Code);
- temporary storage of hazardous medical waste (Article 256, paragraph 6, first sentence, letter a) of Legislative Decree no. 152 of 3 April 2006);
- Illegal waste traffic (Article 259, paragraph 1, of Legislative Decree no. 152 of 3 April 2006);
- organised activities for illegal waste trafficking (Article 452-quaterdecies, Criminal Code);
- IT system for monitoring the traceability of waste (Article 260-bis of Legislative Decree no. 152 of 3 April 2006);
- violation of the emission limit values (Article 279, paragraph 5, Legislative Decree 152/06).
- material forgery committed by a public official in certificates or administrative authorisations (Article 477, Criminal Code);
- material forgery committed by a private individual (Article 482, Criminal Code);
- cessation and reduction of the use of ozone-depleting substances (Article 3 of Law No. 549 of 28 December 1993);
- intentional pollution caused by ships (Article 8 of Legislative Decree no. 202 of 6 November 2007);
- negligent pollution caused by ships (Article 9 of Legislative Decree no. 202 of 6 November 2007);
- Environmental pollution (Art. 452-bis, Criminal Code);
- Environmental disaster (Art. 452-quater, Criminal Code);
- Negligent offences against the environment (Art. 452-quinquies, Criminal Code);
- Aggravated associative crimes (Article 452-octies, Criminal Code);
- Trafficking and abandonment of highly radioactive material (Art. 452-sexies, Criminal Code)



## 2 Sensitive Activities and protocols to adopt

The analysis of Fidia's business processes made it possible to identify the activities within which the types of crimes referred to may abstractly occur.

Listed below are: i) Sensitive Activities; ii) the functions/organisational units involved; iii) crimes that may be potentially committed; iv) the specific protocols to be adopted.

*Waste management:* this system concerns the management of environmental protection systems and in particular:

- The waste management process (collection, transport, recovery, disposal and brokerage) and the related legislative and authorisation requirements;
- the selection, evaluation, and management process of relations with the company in charge of disposal;
- the process of preparing the certificate of analysis and characterisation of waste;
- the management process of the temporary storage of hazardous waste;
- the waste traceability process.
- Main Parties, Functions, and Organisational Units involved: CEO, Plant, Procurement

#### > <u>Potential crimes:</u>

- Unauthorised waste handling activities (Article 256, paragraph 1, 3, 5, 6, and Articles 208, 209, 210, 211, 212, 214, 215, 216 of Legislative Decree no. 152 of 3 April 2006);
- Violation of communication obligations, keeping of mandatory registers and forms (Art. 258, of Legislative Decree no. 152 of 3 April 2006);
- o Illicit waste traffic (Article 259 of Legislative Decree no. 152 of 3 April 2006);
- Temporary storage of hazardous medical waste (Article 256, paragraph 6, first sentence, letter a) of Legislative Decree no. 152 of 3 April 2006);
- o organised activities for illegal waste trafficking (Article 452-quaterdecies, Criminal Code);
- IT system for monitoring the traceability of waste (Article 260-bis of Legislative Decree no. 152 of 3 April 2006).

## Protocols

The following principles must be observed, to be integrated with the system procedures and process, operational control and emergency instructions provided for within each plant.

Specifically, the operational procedures for waste management adopted by the Company in accordance with the provisions of Legislative Decree 152/06 as well as the administrative waste management procedures applicable to the various types of waste produced by the Company, with particular reference to the communication requirements, the keeping of mandatory registers and forms and/or the obligations prescribed by the current protempore legislation on traceability of waste.

In addition, the following protocols must be observed:

- Identify all the categories of waste and the correct methods of temporary storage of the same, including the regulation of those produced by contractors within the Company's sites;
- identify administrative and operational responsibilities for waste management;
- define the administrative procedures for the delivery of waste to the collection, storage and disposal companies, including the criteria for prior verification and during the execution of the contract for the presence of the necessary authorisations therein;
- provide for information activities for all workers;
- provide for information and training activities for workers who, within the company organisation, operate



- within the operational activities at risk of crime;
- check the records (as an example, but not limited to, the register of loading and unloading the waste produced, the waste transport forms, etc.) of the environmental management system;
- acquire and store documentation relating to compliance with laws, regulations and environmental protection standards;
- keep the documentation relating to the authorisation procedures, authorisations, certifications and any inherent documentation, as well as any additional or amendment documents;
- implement internal audits
- keep the documentation relating to internal company regulations;
- perform constant monitoring of company procedures, ensuring an adequate and timely review of the same, particularly in the event of any worsening of the risk or in the event of an emergency;
- monitor environmental legislation and the obligations required by the same;
- periodically verify compliance with the administrative requirements envisaged by the relevant environmental legislation;
- comply with procedures "HSE-A-02 Waste-management of storage and temporary storage" and "SOP MC 014/01 Management of waste from production areas and laboratories."

Protection of the soil, subsoil and water (e.g. spillage of substances in the groundwater, spills from purification plants): concerns the management of environmental protection systems with particular reference to:

- The management of process and waste water and related legislative obligations, including authorisations, prescriptions, and limits;
- the management of plants that generate water discharges;
- the implementation of legislative obligations regarding the remediation of polluting sites;
- pollution of the soil, subsoil, surface water or groundwater in the absence of reclamation.
- Main Parties, Functions, and Organisational Units involved: CEO, Plant

## > <u>Potential crimes:</u>

- o Environmental pollution, including through negligence (Article 452-bis and 452-quinquies, Criminal Code);
- Site remediation (potentially feasible contravention: (i) upon entering the land purchased by a previous owner who had already polluted the site (ii) through his own polluting activity, when the risk threshold concentrations are exceeded) (Article 257 paragraphs 1 and 2, Legislative Decree no. 152 of 3 April 2006);
- o Environmental disaster, including negligent (Art. 452-quater and 452-quinquies, Criminal Code);
- Violation of the regulations on waste water discharges (Article 137, paragraph 2, 3, 5, 11, 13 of Legislative Decree no. 152 of 3 April 2006).

## Protocols

The following principles must be observed, to be integrated with the system procedures and process, operational control and emergency instructions envisaged within each:

Define and strictly observe specific protocols relating to the adoption of prevention measures, under normal
operating conditions and emergency safety measures that may be necessary in the hypothesis of events
suitable for determining situations of potential contamination of soil, subsoil, water surface or underground
and/or potentially impacting flora and fauna, as well as the adoption of remediation interventions that may
be necessary pursuant to articles 239 et seq. of Legislative Decree 152/2006.

In addition, the following protocols must be observed:



#### For industrial waste water management:

- Identify the discharging points present in each plant;
- comply with the prohibition of discharging waste water into the soil, subsoil and groundwater;
- obtain the necessary authorisations for the discharge of industrial waste water;
- maintain and renew the authorisations for discharges of industrial waste water within the terms established by current legislation;
- submit a new application for authorisation in the event of a change in discharges;
- periodically check the chemical-physical parameters prescribed in the authorisation in order to comply with the emission limits;
- comply with the requirements set out in the authorisations issued by the competent authorities;
- comply with the prohibitions imposed by current legislation, including the prohibition of dilution, since the emission limit values cannot in any case be achieved by diluting with water taken exclusively for the purpose;
- equip each drain with an inspection pit positioned upstream of the drain itself;
- sample the waters to check if the table limits have been exceeded, immediately before discharging into the receiving body;
- verify that all workers have received adequate information/training on environmental issues and pollution prevention;
- make all drains accessible, except domestic ones and those similar to domestic ones, for sampling by the competent control authority;
- periodically check the correct implementation of the previous obligations.

### For the management of soil and subsoil protection and remediation activities

- Upon the occurrence of an event that is potentially capable of contaminating the site, take the necessary
  measures to prevent the spread of any contamination within 24 hours following the event, as well as
  immediately notify the relevant Bodies;
- carry out a preliminary investigation in order to identify the concentrations of the parameters subject to
  potential pollution. in case of ascertaining the presence of contamination, immediately communicate to the
  Bodies in charge with a description of the emergency prevention and safety measures adopted;
- submit, within the time-frame required by current legislation, to the Bodies in charge the characterisation plan of the polluted site to be submitted for their authorisation;
- after the approval of the characterisation plan, submit to the results of the site-specific risk analysis to the region, performed based on the results of the characterisation, within the time limits established by current legislation. In this case, the procedure below is followed:
- Following the evaluation and validation of the aforementioned analysis, the site is declared polluted or unpolluted. In the latter case, the responsible Bodies declare the procedure concluded, possibly prescribing a monitoring program, which plan must be presented by the person responsible for the pollution; in the event that the site is declared polluted, within six months from the approval of the risk analysis document, it is necessary to present the operational project for remediation or operational or permanent safety (and, where necessary, the additional measures of environmental repair and restoration);
- the Bodies in charge approve the project possibly with measures and additions (the term may be suspended only once to request additions or further details and starts again from the presentation of the integrated plan)
- the Bodies in charge ascertain and certify the completion of the remediation, permanent safety and operational safety measures, as well as their compliance with the plan.
- identify the applicable environmental requirements, define how these requirements apply to the environmental aspects of the specific plant and periodic assessment of compliance therein;
- prepare a specific environmental register, showing the significant areas for identifying and assessing the environmental impacts associated with the activities carried out by the plant;
- prepare operating instructions on environmental protection that also include methods for monitoring the limits



- set by the applicable legislation or authorisations;
- verify that all workers have received adequate information/training on environmental issues and pollution prevention;
- identify potential emergency situations and potential accidents that may have an impact on the environment and how to respond.

Furthermore, procedures "DO009 Sampling waste water" and "IO PM030/ 01 Disposal of special liquid waste from the raw material production service areas" must be respected.

Air emissions: concerns the management of environmental protection systems with particular regard to:

- Implementation of legislative obligations regarding the management of air emissions, including the relative authorisations, measures, and limits.
- Main Parties, Functions, and Organisational Units involved: CEO, Plant

#### > <u>Potential crimes:</u>

- Violation of emission limit values (Article 279 of Legislative Decree no. 152 of 3 April 2006);
- Cessation and reduction of the use of ozone depleting substances (Article 3 of Law no. 549 of 28 December 1993)

## > Protocols

The following principles must be observed, to be integrated with the system procedures and process, operational control and emergency instructions envisaged within each plant:

- Define and strictly observe specific protocols relating to the adoption of prevention measures, under normal operating conditions and emergency safety measures that may be necessary in the hypothesis of events capable of causing situations of potentially exceeding the limits of emissions into the air;
- strictly prohibit the use and possession of the substances listed in table A attached to Law no. 549 of 28
  December 1993, and adequately control the substances considered to be harmful to the ozone layer;
- verify, in relation to the provisions of current legislation, the need to obtain the authorisation for atmospheric emissions, issued with reference to the entire plant;
- obtain the authorisation within the time limits envisaged by the legislation in force and, for plants not yet authorised, implement the controls envisaged in the legislative provisions applicable therein;
- implement the provisions of the authorisation regarding: collection and conveyance methods (for emissions that are technically conveyable), compliance with emission limit values and requirements, sampling and analysis methods, periodicity of the relevant checks;
- maintain and renew the emission authorisations within the terms established by current legislation;
- submit a new application for authorisation in the event of a substantial change in the plant;
- periodically check the correct implementation of the previous obligations.

In addition, the following protocols must be observed:

- prepare operating instructions on environmental protection that also include methods for monitoring the limits set by the applicable legislation or authorisations;
- verify that all workers have received adequate information/training on environmental issues and pollution prevention;
- identify potential emergency situations and potential accidents that may cause limits to be exceeded and have an impact on the environment and the relative methods of response;
- ensure that preventive actions are carried out on machines and systems, with particular reference to abatement systems, on a regular basis, through the planning, at scheduled times, of maintenance



interventions.

*Management of prevention and containment systems*: this concerns the management of the prevention and containment systems, implemented in each plant.

- Main Parties, Functions, and Organisational Units involved: CEO, Plant
- > Potential crimes:
- o Environmental pollution (Art. 452-bis, Criminal Code)
- o Environmental disaster (Art. 452-quater, Criminal Code)
- Negligent offences against the environment (Art. 452-quinquies, Criminal Code)

#### > <u>Protocols</u>

With reference to this sensitive area it is necessary to follow the protocols below:

- Define adequate planning policies for the adoption, improvement, intervention on the prevention and containment systems of any liquid or gaseous flows, which may be spilled or emitted into the atmosphere, if accidents occur;
- Perform periodic audits on the quality, reliability of prevention and containment systems by parties specialised in environmental matters;
- carry out a periodic check of the containment systems and equipment (containment basins, fire extinguishing systems, etc.), also by means of tests that simulate the occurrence of accidents;
- plan and carry out maintenance activities of the systems and equipment used to contain liquid spills or gaseous emissions following accidents;
- perform in-depth analyses on the action and reaction mechanisms of the prevention and containment systems in the presence of near-misses, in order to detect any weaknesses, shortcomings, with the consequent definition of a development and improvement plan;
- comply with procedures "SOP PG 019/02 Removal of accidentally spilled chemicals" and "PM 003/02 Emergency interventions in the raw material production area outside normal working hours."

#### 3 General principles of behaviour prescribed

This Special Part envisages the express prohibition of engaging in conduct such as to result in the types of crimes considered above (pursuant to Article 25-undecies of the Decree) or behaviour which, although not in itself constituting a crime, may potentially result in one of the crimes under consideration herein.

In particular, there is an express *prohibition* for the Recipients to:

- Engage in, collaborate with or cause the carrying out of behaviours which, although as such do not constitute crimes falling within those considered above, may potentially become so;
- perform services in favour of *outsourcers*, consultants, partners and collaborators in general that are not
  adequately justified in the context of the contractual relationship established with them, or in relation to the
  type of assignment to be carried out and the local practices in force;
- make cash donations or grant advantages of any kind (for example the promise of employment) to public
  officials also in charge of checks in the field of environmental regulations;
- engage in any behaviour that is an obstacle to the exercise of supervisory functions, including during
  inspections by public authorities (GdF, Labour Inspectorate, Arpa, Fire Service, etc.) such as: express
  opposition, spurious refusals, or even obstructive or non-cooperation behaviours, such as delays in
  communications in making documents available, or delays in meetings organised on time.

This Special Part consequently envisages the express *obligation* of the Recipients:

• To behave correctly, promptly, transparently and collaboratively, in compliance with the law and internal



company procedures, in all activities aimed at protecting the environment;

- to strictly observe all the regulations set by law to protect environmental matters and to always act in compliance with the internal company procedures that are based on such regulations;
- manage relations with the PA in a unitary manner with reference to the Authorities responsible for supervising environmental regulations for the areas of activity at risk, identifying the person responsible for each operation or plurality of operations (in the case of particular repetition of the same) carried out in the areas of activity at risk;
- prepare internal environmental protection standards appropriate to environmental risks.



Revision 09

## SPECIAL PART "I" MARKET ABUSE CRIMES

#### 1 *Market Abuse* crimes

- Market abuse crimes, governed by Law no. 62 of 18 April 2005, referred to by Art. 25-sexies of the Decree, are:
- Abuse of privileged information (Article 184 of Legislative Decree no. 58/1998), a crime that is committed to those who, by reason of a position of "privilege" (as a member of the administrative, management or control of the issuer, or participates in the issuer's capital) uses this information to operate on financial markets;
- **manipulation of the markets** (Article 185 of Legislative Decree no. 58/1998) a crime involving anyone who disseminates false information or implements artifices capable of causing a significant alteration in the price of financial instruments.

The core of the crime hypotheses, object of this Special Part, may be found in activities consisting in the illicit use of privileged information or in the dissemination of untrue information capable of causing a significant alteration in the price of financial instruments.

According to the provisions of Art. 181 of Legislative Decree no. 58/1998 ("TUF"), information having the following characteristics (hereinafter "Privileged Information") is considered to be of a privileged nature:

#### ✓ Of a precise nature, in the sense that:

i) it must be information relating to existing or occurred circumstances or events or to circumstances or events that can reasonably be expected to come into existence or to occur (the reference is to cases in which the news is being formed and concerns events not yet occurred, think of the case characterised by the news that a listed company is about to launch a takeover bid, or the case concerning a strategic plan for the productive repositioning of a company issuing securities listed on Italian regulated markets);

ii) it must be specific information, that is to say that the information must be sufficiently explicit and detailed, so that whoever uses it is placed in a position to believe that the effects on the price of the financial instruments may actually occur from the use;

- ✓ <u>not yet made public;</u>
- concerning, directly or indirectly, one or more issuers of financial instruments listed on Italian regulated markets or one or more financial instruments traded on the capital market (the reference concerns both the so-called corporate information, i.e. information relating to facts generated by or originating from the issuing company relating, for example, to the economic and financial situation or organisational events of the issuer, and the so-called market information, i.e. information relating to facts generated outside the sphere of the issuer and which have a significant impact on the market position of the issuer );
- <u>price sensitive</u> according to reasonable investors, in the sense that it must be information that, if made public, would presumably be used by a reasonable investor as one of the elements on which to base their investment decisions.

#### 2 Sensitive Activities and protocols to adopt

The analysis of Fidia's business processes made it possible to identify the activities within which the types of offences referred to may abstractly occur.

Listed below are: i) Sensitive Activities; ii) the functions/organisational units involved; iii) crimes that may be potentially committed; iv) the specific protocols to be adopted.

Management and use of news acquired as a result of business activities: this is the correct management in



confidential form of information and news, on economic-financial data, business models, products, etc. acquired in the context of business activities, as well as the activities of issuing press releases and information to the market.

#### > <u>Main Parties, Functions, and Organisational Units involved:</u>

Chief Executive Officer, Pharma Italy, Pharma International, Communication, Corporate R&D - Business Development

#### > Potential crimes:

- Abuse of privileged information (Art.184 and 187-bis TUF)
- Market manipulation (185 and 187-ter TUF)

#### > <u>Protocols</u>

The following protocols must be observed:

- Privileged information acquired in the course of their work by all directors, employees, collaborators, for whatever reason they operate in Fidia, must be handled with the utmost confidentiality and in accordance with the strictest rule of sound and prudent management of confidential information; to this end, specific confidentiality commitment clauses are included in the contracts with employees and collaborators;
- the directors, employees, collaborators, may communicate the privileged information they have come into
  possession, in the exercise of their work, exclusively (i) to parties internal to Fidia who need to know it for
  reasons also pertaining to the normal exercise of their work, highlighting the confidential nature of the
  information; (ii) to third parties, external to Fidia, who need to know them for a reason relating to the
  performance of their work, profession, function or office;
- the dissemination to the public of official statements, as well as any relationship with the press and other means of communication, aimed at the dissemination of documents and the dissemination of information on relevant facts concerning Fidia, require the prior authorisation of the contents by the Chief Executive Officer

## 3 General principles of behaviour prescribed

#### **Prohibitions**

This section envisages **the express prohibition on Fidia's Corporate Representatives** from engaging in, assisting or causing the carrying out of behaviours which, taken individually or collectively, directly or indirectly integrate the crimes of market manipulation. and abuse of privileged information.

#### **Obligations**

This section envisages the express obligation of the aforementioned parties to:

- Behave correctly, transparently and collaboratively, in compliance with the law and Fidia procedures, in all
  activities aimed at managing and communicating privileged information and confidential information to the
  outside world;
- avoid publishing or disseminating false information or engaging in simulated transactions or other behaviours of a fraudulent or deceptive nature concerning listed or unlisted financial instruments capable of significantly altering their price.

## SPECIAL PART "J" TAX CRIMES



#### 1 Tax Crimes

Law no. 157 of 19 December 2019, of conversion with amendments to Legislative Decree no. 124, 26 October 2019, containing "Urgent provisions on tax matters and for non-postponable needs," introduced the following types of crimes in the body of the Decree, at Art. 25-quinquiesdecies:

- Fraudulent returns through the use of invoices or other documents for non-existent transactions (Article 2 of Legislative Decree no. 74/2000): a crime is the conduct of those who, in order to evade income or value added taxes, using invoices or other documents for non-existent transactions, indicate fictitious passive elements in one of the declarations relating to said taxes. The offence is considered committed by making use of invoices or other documents for non-existent transactions when such invoices or documents are recorded in the compulsory accounting records, or are held for the purpose of evidence against the financial administration.
- Fraudulent returns with the use of other devices (Art. 3, Legislative Decree 74/2000): the conduct of those who, in order to evade income or value added taxes, by carrying out objectively or subjectively simulated transactions or by making use of false documents or other fraudulent means capable of hindering the assessment and mislead the tax authorities, indicates in one of the declarations relating to said taxes active elements for an amount lower than the actual amount or fictitious passive elements or credits and deemed fictitious, when, jointly: a) the tax evaded is higher, with reference to one of the individual taxes, to € 30,000.00; b) the total amount of the active elements subtracted from taxation, also through the indicated in the return, or in any case, exceeds € 1,500,000.00, or if the total amount of receivables and fictitious withholdings as a reduction of the tax is greater than five percent of the amount of the tax itself or in any case to € 30,000.00. The offence is considered committed by making use of false documents when these documents are recorded in the obligatory accounting records or are held for evidence purposes against the financial administration.
- unfaithful statement in case of serious cross-border VAT fraud (Article 4, Legislative Decree 74/2000): the conduct of those who, in order to evade the value added tax for a total amount of not less than 10 million euros, in the context of cross-border fraudulent systems, carrying out objectively or subjectively simulated transactions is criminally relevant. or using false documents or other fraudulent means capable of hindering the assessment and misleading the financial administration, indicates in the VAT return active elements for an amount lower than the actual amount or fictitious passive elements or credits and deemed fictitious.
- omitted statement in case of serious cross-border VAT fraud (Article 5, Legislative Decree 74/2000): the conduct of those who, in the context of cross-border fraudulent systems, fail to submit the annual VAT return in order to evade the value added tax for a total amount of not less than 10 million euros is criminally relevant.
- Issue of invoices or other documents for non-existent transactions (Article 8 of Legislative Decree 74/2000): the criminally relevant conduct consists in the issue or release of invoices or other documents for non-existent transactions, in order to allow third parties to evade income or value added taxes.
- Concealment or disposal of accounting documents (Art. 10 of Legislative Decree 74/2000): the criminally
  relevant conduct consists in the concealment or disposal, in whole or in part, of the accounting records or
  documents that must be kept, so as not to allow the reconstruction of income or turnover, in order to evade
  income or value added taxes, or to allow third parties to evade them.
- undue compensation in the event of serious cross-border VAT fraud (Article 10-quater of Legislative Decree 74/2000): the conduct of those who, in the context of cross-border fraudulent systems, do not pay the sums due by using in compensation credits not due or non-existent, in order to evade the value added tax for an amount total not less than 10 million euros.
- fraudulent evasion of the payment of taxes (Article 11, Legislative Decree 74/2000): the conduct of those who: (i), in order to avoid the payment of income or value added taxes or interest or administrative penalties relating to said taxes for a total amount exceeding € 50,000.00, simulates disposal or carries out other fraudulent acts on its own or on others assets capable of rendering the compulsory collection procedure totally or partially ineffective; (ii) in order to obtain for himself or for others a partial payment of taxes and related accessories, indicate in the documentation submitted for the purposes of the tax settlement procedure active



elements for an amount lower than the actual one or fictitious passive elements for a higher total to  $\in$  50,000.00.

#### 2 Sensitive Activities and protocols to adopt

The analysis of Fidia's business processes made it possible to identify the activities within which the types of offences referred to may abstractly occur.

As regards the **Instrumental Processes** relating to the commission of the offence referred to in this section, they are as follows:

- Procurement of goods or services;
- > Sponsorship and administrative management of medical-scientific congresses and events;
- > Management of monetary and financial flows;
- Entertainment expenses;
- > Reimbursement of expenses, use of credit cards, company assets.

For identification of the control protocols to be adopted, please refer to the specific Special Part L.

Listed below are: i) Sensitive Activities; ii) the functions/organisational units involved; iii) offences that may be potentially committed; iv) the specific protocols to be adopted.

**Preparation of tax returns and related obligations:** This is the process of drafting tax returns, based on the accounting documentation and related obligations, such as submission of returns, payment of related taxes, etc.

- Main Parties, Functions, and Organisational Units involved: Chief Executive Officer, CFO-Administration, Finance and Control, HR Corporate
- > <u>Potential crimes:</u>
- Fraudulent returns through the use of invoices or other documents for non-existent transactions (Article 2 of Legislative Decree 74/2000);
- Fraudulent returns with the use of other devices (Art. 3, Legislative Decree 74/2000).
- > Protocols



It is necessary to:

- Provide for a clear separation of roles and responsibilities between those who preside over the accounting
  and recording of company operations, whoever calculates taxes and prepares tax returns and the related
  payments;
- provide for control mechanisms that ensure that an invoice or any other documentation certifying the existence of the transaction is attributable to each cost/revenue item;
- ensure that increases and/or decreases reported in the tax returns (IRES and IRAP) must be supported by adequate documentation and motivation compliant with the applicable tax legislation;
- ensure that the data and information contained in the VAT returns are compliant and consistent with the VAT registers and with payments made;
- ensure that the taxes paid (IRES, IRAP, VAT, withholding taxes) are compliant and consistent with the data
  and information reported in the tax returns;
- ensure compliance with the requirements of the legislation on direct and indirect taxes;
- provide for periodic training meetings on tax issues and related obligations by a third party consultant;
- provide for periodic review mechanisms for the correct execution of tax obligations;
- if a third party consultant is used in the preparation and submission of tax returns, sign a specific contract in which to insert standard clauses regarding the consultant's unconditional acceptance of the principles referred to in Legislative Decree 231/2001 and the Code of Ethics.

**Recognition, accounting and recording of passive transactions:** this is the management of the operations of the passive cycle (purchase of goods and services), which feed into the related fiscal and accounting records, based on contractual and fiscal documentation.

## Main Parties, Functions, and Organisational Units involved:

Chief Executive Officer, CFO-Administration, Finance and Control, Procurement, HR Corporate

## Potential crimes:

- Fraudulent returns through the use of invoices or other documents for non-existent transactions (Article 2 of Legislative Decree 74/2000);
- Fraudulent returns with the use of other devices (Art. 3, Legislative Decree 74/2000).

## > Protocols

It is necessary to provide:

- compliance with the control protocols on accounting records provided for in Special Part D Corporate Offences, sensitive process "Preparation of the financial statements, the management report and other corporate communications";
- compliance with the control protocols provided for in Special Part F Money laundering, receiving stolen goods, self-laundering crimes, sensitive processes "Customer and supplier master data management" and "Management of infra-group transactions";
- compliance with the control protocols provided for in Special Part L Instrumental Processes, "Purchase of goods and services" process;
- traceability of the decision-making process through documentation and archiving (telematic and/ or paper)
  of each activity of the passive cycle; in particular, each purchase of goods and / or services must be
  accompanied by a duly authorised purchase request, a purchase order, a contract, documentation certifying
  the existence of the supplier, the relative competence, the execution of the transaction (Chamber of



Commerce registration, latest balance sheet, identification for VAT purposes, delivery note, transport documents, time-sheets, reports, reports, etc.);

- clear and traced identification of the contact person responsible for the supplier (role covered, email address, company references, headquarters/office);
- ascertaining the relationship between the person who performed the services/sale of goods and the holder of the invoices received;
- mechanism for checking the economic validity of the transaction and its objectively and subjectively substantial effectiveness;
- control mechanism on the value/ price of goods/ services in line with that normally practised in the reference market;
- use of the dedicated computer system for recording payable invoices, as well as any other economic event, capable of tracing each entry;
- regulation and monitoring of access to the computer system;
- accounting by the responsible office in the accounting entries and VAT registers only of the passive invoices that have received approval for registration and their payment only after having received the approval of the function manager, who certifies the execution of the transaction;
- detection of all passive corporate administrative events that have an economic and equity impact.
- periodic verification of the correspondence between salaries paid to employees and the relative amounts indicated in the certifications/pay slips;
- detailed verification of expense reports by analysing authorisations and related expense receipts.

**Detection, accounting, and recording of active transactions:** this is the management of the active cycle transactions (sale of goods and services), which feed into the related fiscal and accounting records, based on contractual and fiscal documentation.

## > Main Parties, Functions, and Organisational Units involved:

Chief Executive Officer, CFO-Administration, Finance and Control, Pharma Italia, Pharma International

#### > <u>Potential crimes:</u>

- Fraudulent returns through the use of invoices or other documents for non-existent transactions (Article 2 of Legislative Decree 74/2000);
- Fraudulent returns with the use of other devices (Art. 3, Legislative Decree 74/2000);
- o Issue of invoices or other documents for non-existent transactions (article 8 of Legislative Decree 74/2000);
- o fraudulent evasion of the payment of taxes (Article 11, Legislative Decree 74/2000).

## > Protocols

- It is necessary to provide:
- compliance with the control protocols on accounting records provided for in Special Part D Corporate Offences, sensitive process "Preparation of the financial statements, the management report and other corporate communications";
- traceability of the decision-making process through documentation and archiving (telematic and/ or paper)
  of each activity of the active cycle; in particular, a purchase order sent by the customer, a contract,



documentation certifying the execution of the transaction (delivery note, transport documents, time-sheet, reports, etc.);

- ascertaining of the relationship between the person who has received the provision of services/ sale of goods and the holder of the invoices issued;
- mechanism for checking the economic validity of the transaction and its objectively and subjectively substantial effectiveness;
- use of the dedicated computer system for recording active invoices, as well as any other economic event, capable of tracing each entry;
- regulation and monitoring of access to the computer system;
- accounting by the responsible office in the accounting records and VAT registers only of the active invoices that have received the approval for registration and their payment only after having received the approval of the function manager, who certifies the execution of the transaction;
- verification of the correspondence between the VAT resulting from the issued invoices and the VAT actually collected;
- detection of all active corporate administrative events that have an economic and equity impact;
- verification with a third party consultant of any tax implications deriving from the execution of an operation
  of an ordinary or extraordinary nature, which involves the transfer of the Company's assets, especially in
  the presence of a tax dispute.

Accounting documentation management and archiving process: deals with the management and storage of accounting records and documents which must be kept.

#### > Main Parties, Functions, and Organisational Units involved:

Chief Executive Officer, CFO-Administration, Finance and Control

#### > Potential crimes:

• Concealment or disposal of accounting documents (Art. 10, Legislative Decree 74/2000)

## > Protocols

- It is necessary to provide:
- regular keeping and storage of compulsory accounting records for the purposes of income tax and value added tax;
- compliance with the requirements of the legislation on direct and indirect taxes, regarding the terms and conditions for the conservation of accounting and tax documentation;
- adoption of a transparent, effective and efficient system for filing accounting and tax documentation;
- truthful and correct indication and related communications of the place of keeping and conservation of the accounting records;
- control and monitoring mechanism of the transfer to a remote archive and / or disposal of documentation, admissible only when the terms of forfeiture of the tax assessment have expired.

*Management of corporate transactions*: these are activities aimed at carrying out extraordinary transactions.

## Main Parties, Functions, and Organisational Units involved:

Board of Directors, Chief Executive Officer, CFO-Administration, Finance and Control

- > <u>Potential crimes:</u>
- Fraudulent returns through the use of invoices or other documents for non-existent transactions (Article 2 of Legislative Decree 74/2000);
- Fraudulent returns with the use of other devices (Art. 3, Legislative Decree 74/2000);



- issue of invoices or other documents for non-existent transactions (article 8 of Legislative Decree 74/2000);
- o fraudulent evasion of the payment of taxes (Article 11, Legislative Decree 74/2000).
- Concealment or destruction of accounting documents (Art. 10, Legislative Decree 74/2000).

#### > Protocols

With reference to this sensitive area, reference is made to the protocols provided for in Special Part D - Corporate crimes and in Special Part F - Money laundering, receiving stolen goods, self-laundering, with reference to the same sensitive area.

Furthermore, for each operation it is necessary to analyse with the support of a third party consultant any elusive profiles for tax purposes of the transactions to be carried out.

#### 3 General principles of behaviour

This Special Part envisages the express prohibition of engaging in conduct such as to integrate the types of crimes considered above (pursuant to Article 25-quinquiesdecies of the Decree) or conduct which, although not constituting a crime, could potentially result in one of the crimes under consideration herein.

More specifically, it is compulsory to:

- Submit tax returns within the legal deadlines;
- proceed with the payment of taxes on due dates or through recourse to the institute under a voluntary correction of errors procedure;
- fill in tax returns with absolutely truthful data and information;
- record the invoices supported by documentation proving their existence in the VAT Registers;
- proceed with monthly VAT payments in compliance with the legal terms;
- organise training and information sessions on tax obligations and deadlines;
- provide for reconciliation mechanisms between accounting and fiscal data;
- cooperate fully in the event of visits, inspections, accesses by the Revenue Agency or the Finance Police;
- respond with truthful data and information to questionnaires notified by the Revenue Agency.

#### Furthermore, it is prohibited to:

- indicate fictitious passive elements in tax returns;
- carry out simulated operations;
- request, prepare invoices or other documentation for non-existent transactions;
- put in place false documents to alter tax results and reduce the tax burden;
- conceal and / or destroy all or part of the accounting records or documents which must be kept;
- dispose of assets to make compulsory collection for tax purposes fruitless (e.g. making payments for the benefit
  of suppliers and third parties in order not to interrupt the business continuity, consequently hiding resources
  from the correct fulfilment of the taxes due);
- submit false documents, data and information as part of a tax transaction.



## SPECIAL PART "K" SMUGGLING CRIMES

## 1 Smuggling crimes

Legislative Decree n. 75, 14 July 2020, issued in Implementation of Directive (EU) 2017/1371, relating to the fight against fraud affecting the financial interests of the Union through criminal law, introduced in the body of the Decree, Art. 25-sexiesdecies, entitled "Contraband"; such crime, as envisaged by the Customs Consolidation Act DPR 43/1973, consists of "the conduct of those who introduce into the territory of the State, in violation of the provisions on customs matters, goods that are subject to border rights." Specifically, the types of smuggling offences envisaged by the Decree are:

- Smuggling in the movement of goods across land borders and customs spaces (Article 282 of Presidential Decree no. 43/1973);
- Smuggling in the maritime movement of goods (Article 284 of Presidential Decree No. 43/1973);
- Smuggling in non-customs areas (Article 286 of Presidential Decree no. 43/1973);
- Smuggling for improper use of imported goods with customs facilities (Article 287 of Presidential Decree no. 43/1973);
- Smuggling in cabotage and circulation (Art. 289 DPR n. 43/1973);
- Smuggling in the export of goods eligible for restitution of rights (Article 290 of Presidential Decree No. 43/1973);
- Smuggling in the import or temporary export (Art. 291 DPR n. 43/1973);
- Smuggling in the movement of goods in the border lakes (Art. 283 DPR n. 43/1973);
- Smuggling in the movement of goods by air (Article 285 of Presidential Decree No. 43/1973);
- Smuggling in customs warehouses (Article 288 of Presidential Decree no. 43/1973);
- Smuggling of foreign manufactured tobacco (Art. 291-bis DPR n. 43/1973);
- Association to commit crime with the aim of smuggling foreign tobacco (article 291-quater Presidential Decree no. 43/1973)

#### 2 Sensitive Activities and protocols to adopt

The analysis of Fidia's business processes made it possible to identify the activities within which the types of offences referred to may abstractly occur.

As regards the **Instrumental Processes** relating to the commission of the crime referred to in this section, they are as follows:

- Procurement of goods or services;
- Management of monetary and financial flows;

For identification of the control protocols to be adopted, please refer to the specific Special Part L.

Listed below are: i) Sensitive Activities; ii) the functions/organisational units involved; iii) crimes that may be potentially committed; iv) the specific protocols to be adopted.

**Management of customs operations:** deals with the management of import-export operations that involve the execution of customs formalities (declarations, payment of duties and VAT, etc.), also through freight forwarders.

#### > Main Parties, Functions, and Organisational Units involved:

CFO - Finance and Control Administration, Corporate Operations, Pharma International, Plant Director.



#### Potential crimes:

- Smuggling in the movement of goods across land borders and customs areas (Article 282 of Presidential Decree no. 43/1973);
- o Smuggling in the maritime movement of goods (Article 284 of Presidential Decree No. 43/1973);
- Smuggling in non-customs areas (Article 286 of Presidential Decree no. 43/1973);
- Smuggling for improper use of imported goods with customs facilities (Article 287 of Presidential Decree no. 43/1973);
- Smuggling in cabotage and circulation (Art. 289 DPR n. 43/1973);
- Smuggling in the export of goods eligible for restitution of rights (Article 290 of Presidential Decree No. 43/1973);
- Smuggling in the import or temporary export (Art. 291 DPR n. 43/1973);
- o Smuggling in the movement of goods by air (Article 285 of Presidential Decree No. 43/1973);

#### > <u>Protocols</u>

It is necessary to:

- comply with the practices and procedures in place at the Company;
- provide for a clear separation of roles and responsibilities between those who preside over import-export
  operations and those who manage customs operations;
- make and prepare customs declarations, including through third-party forwarding agents, filling them in with absolutely truthful data and information (for example tariff code, origin, value, quantity, etc.) and proceed with the payment of duties and VAT, where due;
- select the shippers according to the internal procurement procedures, after verifying the integrity and professionalism requirements;
- define the relationship of representation with the shippers by means of specific contracts that define terms and conditions, as well as the relative profiles of responsibility;
- include clauses in contracts with shippers whereby suppliers undertake to respect the organisational model and the code of ethics of the Company;
- provide for control mechanisms on customs operations carried out by shippers in the name and on behalf of the Company;
- ensure compliance with the requirements of customs legislation;
- provide for periodic training meetings on customs issues and related obligations by a third party consultant, also with the aid of informative and explanatory circulars.

## 3 General principles of behaviour

This Special Part provides for the express prohibition of engaging in conduct such as to result in the types of offences considered above (pursuant to Article 25-sexiesdecies of the Decree) or behaviours that although not crimes, may potentially result in one of the crimes under consideration herein.

More specifically, it is compulsory to:

- behave correctly, transparently and collaboratively, in compliance with the law and internal company
  procedures, in all activities aimed at drafting the documents required by customs legislation, in import-export
  operations, in order to provide the Agency with Customs truthful and correct information on the Company's
  customs obligations;
- observe the rules laid down by the national legal system on customs matters;
- cooperate fully in the case of visits, inspections, accesses by the Customs Agency;
- reply with truthful data and information to questionnaires notified by the Customs Agency;

## Furthermore, it is prohibited to:

- engage / collaborate / cause the carrying out of behaviours that may fall within the crimes considered for the purposes of Legislative Decree 231/2001;
- to introduce into the territory of the State goods in violation of the provisions on customs matters;



- indicate false and / or erroneous data and information in customs declarations, using invoices or other incorrect documents;
- take advantage of undue customs relief;
- take advantage of undue customs relief;
- issue or release invoices or other false documents, in order to circumvent customs obligations.



## SPECIAL PART "L" INSTRUMENTAL PROCESSES

#### **1** Instrumental Processes

The analysis of Fidia's business processes also identified a series of Instrumental Processes for committing the crime, or those processes which contain the instrument through which the crime could be committed. For this reason, the control system on these processes must be particularly stringent.

The instrumental processes and the crime classes (and the Special Parts) to which they are connected are listed below:

	Art. 24: Crimes against Public Administration S.P. A	Art. 25-ter: Corporate Crimes S.P. D	Art. 25-octies: Money laundering, receiving stolen goods, self- laundering S.P. F	Art. 25- quinquiesdeci es Tax Crimes S.P. J	Art. 25- sexiesdecies Smuggling Crimes S.P. K
Instrumental process					
Granting of donations and donations of goods	~	~			
Transfer of free samples of products	~	~			
Granting of gadgets and gifts	~	<b>~</b>			
Procurement of goods or services	~	~	~	~	~
Sponsorship and administrative management of medical- scientific congresses and events	<b>&gt;</b>			~	
Management of monetary and financial flows	~	~	~	~	~
Entertainment expenses	~	~		~	
Reimbursement of expenses, use of credit cards, company assets	~	~		~	
Recruitment and hiring of personnel	~	~			
Management of bonuses and benefits	~	~			
Management of agents	~	~			

#### 2 Control system - Specific control standards

The specific control protocols relating to the individual Instrumental Processes identified are listed below:

#### 1) Granting of donations and donations of goods

With reference to this sensitive area it is necessary to follow the protocols below:

- comply with the procedure "for the management of free loans, donations, gifts";
- carefully examine the donations and donations in order to verify the existence of the purposes of pure donation, justified by the scientific or humanitarian purpose;



- define the prerequisites for making a donation. Each request must contribute to supporting a project of scientific, educational, social or humanitarian importance and must not refer to the products of the group and / or to the promotion of the prescriptions;
- make "one-off" donations, i.e. do not repeat the donation, during the same year or in subsequent years if the project is always the same;
- not allocate donations to an individual (natural person) or to a private commercial company (S.p.A., S.r.I., S.n.c., S.c.a.r.I., etc.);
- in the case of donations intended for associations, these must be associations with legal personality, "ONLUS," non-profit organisations or foundations;
- Company personnel cannot in any way express commitments or agreements, even verbal, regarding the acceptance or availability of requests for donations or donations;
- annually budget for the total amount allocated to donations;
- if the recipient is a University or a research facility within a Public Body, check the possibility of stipulating a research contract, in place of the donation;
- comply with the rules expressly envisaged in the Code of Ethics.

#### 2) Granting of free product samples

With reference to this sensitive area it is necessary to follow the protocols below:

- the internal manager for the implementation of the operation must ensure that any activity of distribution of free samples is carried out according to processes organised and kept under control and in line with the provisions of current legislation;
- the internal manager for the implementation of the operation must ensure that each sample provided to the Medicinal Product Sales Representative (ISF) is graphically identical to the smallest package on the market and that the packaging and primary packaging of the product is indelibly marked the indication "free sample - sale prohibited" or other similar statement;
- free samples of medicinal products must be delivered only to doctors and upon written request bearing the date, stamp and signature of the recipient written requests from doctors regarding samples are withdrawn by the ISF;
- free samples of a medicinal product for human use can only be given to doctors authorised to prescribe it and must only be delivered through the ISF;
- the deliveries of the samples must be carried out in compliance with the quantities and timing provided for by the relevant legislation;
- guarantee the traceability and archiving of all process documentation;
- comply with the procedure "for the management of free loans, donations, gifts."

#### B) Granting of gadgets and gifts

With reference to this sensitive area it is necessary to follow the protocols below:

- all gifts intended for doctors and pharmacists must be purchased directly from the company centrally;
- gadgets and gifts granted must be of modest value and directly and exclusively connected to the company
  activity and aimed at increasing and promoting the image of the Company, in compliance with the rules of
  the Code of Ethics;
- all concessions of gadgets and gifts must be authorised, justified and documented, as well as aimed at lawful and ethical activities;
- guarantee the traceability and archiving of all process documentation;
- establish a register of gifts;
- comply with the procedure "for the management of free loans, donations, gifts."

#### I) Sponsorship and administrative management of medical-scientific congresses

## With reference to this sensitive area it is necessary to follow the protocols below:

sponsorships in favour of political groups and / or parties are prohibited;



- sponsorships must be exclusively motivated and connected to the company activity and aimed at increasing
  and promoting the image and culture of the Company;
- all forms of sponsorship must be, in addition to being aimed at lawful activities, justified and documented, authorised, verified and signed by the Directors / heads of functions indicated in the internal delegations / powers of attorney;
- all activities relating to the organisational and / or participation in congress events and any related communications to Public Entities must take place in accordance with the applicable regulatory provisions and must be carried out according to processes organised and kept under control in line with the promotion and information plans corporate scientific;
- the operations must be directly and exclusively connected to issues relating to the use of medicines / medical devices / food supplements and must be, in addition to being aimed at lawful and ethical activities, also authorised, justified and documented;
- all information relating to the drug must be checked and authorised in advance in order to ensure that it is accurate, up-to-date, verifiable and complete;
- the internal manager for the implementation of the operation must ensure (i) that all requests for activation
  / participation in events are in line with the provisions of current regulations; (ii) the correct filing of the
  documentation of all the request and authorisation procedures for congress events including the AIFA
  authorisation and final balance, complete with the event expense report and / or copy of the related invoices;
- comply with the procedure "for the management of congresses, medical-scientific refresher courses and visits to company laboratories;
- comply with the rules expressly provided for in the Code of Ethics.

#### The online purchase of goods or services

With reference to this sensitive area it is necessary to follow the protocols below:

- comply with procedure "SOP SA001 / 03 Purchase of materials, goods and services";
- provide for a clear segregation of roles between those who formulate the purchase request, those who
  authorise and execute it, who makes the payment, subject to verification of receipt of the good or service;
- verify the existence of any conflicts of interest with reference to personal, patrimonial, legal or other relationships existing with the physical / legal subjects of the counterparties with which Fidia personnel should entertain relations with reference to the sensitive activity in question;
- no payment may be made in cash and in case of derogation the same payments must be appropriately authorised. In any case, payments must be made within the framework of specific administrative procedures, which document the traceability and traceability of the expenditure.

#### Management of monetary and financial flows

With reference to this sensitive area it is necessary to follow the protocols below:

- clearly define the roles, tasks and responsibilities of the functions / organisational units involved during the various stages of the process;
- the person who signs the declarations / communications for obtaining loans / contributions must have a special power of attorney;
- prepare an evidence sheet containing the type of contribution / financing / facilitation, the granting public entity, the head of the Function / Organisational Unit involved, the external collaborators / partners involved, progress status;
- proceed with the traceability and verifiability of the phases of the process with adequate filing of the documents used;
- the documentation drawn up and in general any other formalised information must contain only absolutely truthful elements;



- any changes to the accounting data must be made only with the authorisation of the Function / Organisational Unit that generated them;
- prepare a periodic report to be sent to the SB;
- all reporting activities to the national and / or community body connected to the destination of the loans / contributions / tax credit must contain absolutely truthful elements and must be consistent with the purpose for which they were requested. To this end, all the reporting activities produced by Fidia must be filed in a specific file with the signature of the manager of the department/ organisational unit involved;
- the *outsourcers*, consultants, partners and collaborators who participate in the process in question must be chosen with transparent methods and according to a specific company procedure;
- periodically send the SB a list of the loans / contributions obtained.

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With reference to this sensitive area it is necessary to follow the protocols below:

- comply with the internal policies that regulate the recognition of expense reimbursements and the assignment of company assets;
- the SB must be informed with a written note of any criticality or conflict of interest;
- any changes to the accounting data must be made only with the authorisation of the Function / Organisational Unit that generated them;
- for each documentation prepared, the traceability of the relative sources and information elements must be ensured;
- periodically send the SB a list of the activities carried out;
- comply with the procedure "P010 Travel and expense reimbursement regulations."

#### 8) Entertainment expenses

With reference to this sensitive area it is necessary to follow the protocols below:

- the employee, collaborator, CEO, who incurs entertainment expenses, directly or by credit card, prepares the Expense Note, indicating the reason for incurring the expense and the third beneficiary; the Expense Note is endorsed for acceptance by one's department manager or by the Chief Executive Officer;
- all entertainment expenses, subject to reimbursement or incurred by using a credit card, together with the Expense Note, must be documented on a monthly basis with the originals of the invoices or receipts and sent to both the Human Resources function and the Administration, Finance and Control function for the related accounting; the Administration, Finance and Control function sends the monthly statement of payments made with the credit card and a copy of the relative documentation to the Human Resources function;
- verify the existence of any conflicts of interest with reference to personal, patrimonial, legal or other relationships existing with external physical / legal subjects (private or public) with which Fidia personnel should entertain relations with reference to the sensitive activity under exam;
- the SB must be informed with a written note of any criticality or conflict of interest that arises;
- periodically send the SB a list of the entertainment expenses incurred;
- no payment can be made in cash and in case of derogation, the same payments must be appropriately authorised;
- comply with the procedure "P009 Entertainment expenses";
- comply with the provisions of the Code of Ethics.

9) Recruitment and hiring of personnel



With reference to this sensitive area it is necessary to follow the protocols below:

- comply with procedure "SOP HR002 Search, selection, personnel addition and monitoring of trial period."
- operate in full compliance with laws, regulations in force, the Code of Ethics and principles of loyalty, correctness, clarity and transparency;
- verify that the new hires fall within the approved budget limits and that the hiring is approved according to the internal authorisation process;
- carry out the selections according to methods designed to ensure that the choice of candidates is made based on objective considerations of the professional and personal characteristics necessary for the execution of the work to be performed, avoiding favouritism of any kind;
- operate in compliance with the criteria of meritocracy and equal opportunities, without any discrimination based on sex, racial and ethnic origin, nationality, age, political opinions, religious beliefs, state of health, sexual orientation, economic and social conditions, in relation to the real needs of the Company;
- guarantee the segregation of the selection process, also ensuring the traceability of the candidate's evaluation process by filing the relevant documentation;
- ensure that the verification of the existence of possible conflicts of interest and the possible status of a
  former public employee of the candidate is carried out, in order to guarantee compliance with the provisions
  of Legislative Decree165/2001, Art. 53, paragraph 16-ter (introduced by Law 190/2012 on "Anticorruption");
- recruit personnel only and exclusively with a regular employment contract and with remuneration consistent with the Collective Agreement applied;
- ensure that the contracts are signed by subjects with suitable powers;
- ensure that the definition of the economic conditions is consistent with the position held by the candidate and the responsibilities / tasks assigned;
- ensure that at the time of hiring, the employee is given a copy of the Code of Ethics and this Model and that the latter formally undertakes to fully comply with the principles contained therein;
- verify that the working hours are applied in compliance with current legislation;
- ensure that working conditions respectful of personal dignity, equal opportunities and an adequate working environment are ensured within the Company, in compliance with the collective contractual regulations of the sector and with social security, tax and insurance regulations;

guarantee an adequate training process on the Model and the Code of Ethics.

#### **10)** Management of bonuses and benefits

With reference to this sensitive area it is necessary to follow the protocols below:

- periodically monitor the remuneration systems;
- ensure the tracking of reward mechanisms, through the use of adequate IT systems;
- the SB must be informed with a written note of any criticality or conflict of interest;
- periodically send the SB a list of the activities carried out;
- the assessment of individual behaviour for the purposes of a career within the company is carried out by
  expressly considering the requirements of honesty and compliance with the protocols, procedures, as well
  as the principles contained in the Code;
- no payment may be made in cash and in case of derogation the same payments must be appropriately authorised. In any case, payments must be made within the framework of specific administrative procedures, which document the traceability and traceability of the expenditure.

#### 11) Management of agents

With reference to this sensitive area it is necessary to follow the protocols below:

- the agents that Fidia intends to use to carry out marketing activities must be selected and in any case evaluated using transparent methods;
- agency contracts must guarantee: a) the definition and explanation of responsibilities, operational, control, supervisory activities, etc. between the contractors; b) the definition and sharing of the methods and procedures with which the service is provided; c) the inclusion of standard clauses to be used for the purpose



of preventing the crimes referred to in the Decree, with the agent's commitment to comply with the Model and the Fidia Code of Ethics;

 adopt a commercial policy that defines the *fees* applicable to agents; the *fees* must be reported in the contracts; any deviations must be adequately justified and reported to the SB.