

# ORGANISATION, MANAGEMENT AND CONTROL MODEL pursuant to Legislative Decree No. 231/2001

approved by OPOCRIN S.P.A. on 24 October 2024

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#### **Definitions**

Terms indicated with a capital letter shall have the meaning specified below in this Model, regardless of their gender and number:

- "Regulatory authorities": all the national and international regulatory authorities operating in the field of the regulation of medicines for human use, such as AIFA (Agenzia Italiana del Farmaco), FDA (Food and Drug Administration), PMDA (Pharmaceuticals and Medical Devices Agency), etc.
- "Code of Ethics": Opocrin's code of ethics, approved by the Board of Directors, containing the set of ethical principles and *standards* of conduct that persons working for the Company are required to adopt, also in relation to activities that may constitute the types of offences envisaged by Legislative Decree 231/2001
- "Co-workers": those who work on a continuous basis for the Company, in coordination with it, without being subordinate to it
- "Consultants": persons who, by reason of their professional skills, provide their intellectual work for or on behalf of the Company on the basis of a mandate or other professional relationship
- "Decree" or "Legislative Decree 231/2001": Legislative Decree No. 231 of 8 June 2001, as amended and supplemented
- "Addressees": all persons required, pursuant to paragraph 3.5 of the General Section, to comply with the provisions of the Model
- "Employees" or "Personnel": persons having a subordinate or para-subordinate employment relationship with the Company, including managers
- "Entity": legal persons, companies and associations, including those without legal personality, subject to administrative liability under the Decree (including private law companies performing a public service and those controlled by public administrations)
- 'Model': this organisation, management and control model, drawn up, adopted and implemented pursuant to Legislative Decree 231/2001 (in its subdivision into General Section and Special Section)
- "Opocrin" or "Company": Opocrin S.p.A.
- "Supervisory Body" or "SB": the internal control body responsible, pursuant to Article 6, c. 1, lett.
   b) of the Decree, for supervising the operation of and compliance with the Model adopted by the Company, as well as for updating it



- 'Public Administration' or 'PA': the public administration and, with reference to offences against the
  public administration, public officials and persons in charge of a public service (e.g. public service
  concessionaires)
- "Offence": the offence underlying the administrative liability of the Entity referred to in Legislative Decree No. 231/2001
- "Report": communication transmitted to the Supervisory Board, even anonymously, through the channels set up for this purpose by Opocrin, containing any information relevant to Legislative Decree 231/2001 or relating to violations of the Model and the Code of Ethics
- "Senior Persons": natural persons holding top management positions (representation, administration or management of the Company or of one of its organisational units with financial and functional autonomy or persons exercising de facto management and control)
- "Subordinates": natural persons subject to the direction or supervision of one of the Senior Persons;
   Subordinates include Employees and all those employees who, although not employees of the
   Company, have continuous and stable relations with it
- "Workers' Statute": Law No 300 of 20 May 1970
- "Third parties": parties not belonging to Opocrin, i.e. by way of example but not limited to, Collaborators, Consultants, suppliers, customers and third parties in general with whom the Company has, directly or indirectly, relations or relationships



#### INTRODUCTION

Opocrin is a company that has been operating for years in accordance with consolidated operating rules and procedures; this Model aims to reconcile the purposes of control and prevention, through effective and incisive measures, with the opportunity of not excessively burdening the corporate structure and organisation.

The Recipients of the Model, in the performance of their respective activities, must comply not only with this Model and the Code of Ethics, but also with the provisions of legislative decree 231/2001 and internal regulations.

The Supervisory Board, appointed by the Company and endowed with autonomous powers of initiative and control, is entrusted with the responsibility of supervising the operation of and compliance with the Model, also ensuring that it is constantly updated in line with regulatory and legal developments, as well as with organisational and operational changes to the corporate structure.

## (I) ADOPTION OF THE ORGANISATION, MANAGEMENT AND CONTROL MODEL. AIMS AND OBJECTIVES

Although the adoption of an organisational, management and control model *pursuant to* Legislative Decree 231/2001 is an option and not an obligation, Opocrin has decided to adopt its own Model and Code of Ethics, as well as to appoint a Supervisory Board, as it is aware that this choice, in addition to representing an opportunity to strengthen and improve its internal control system, is also an important safeguard in the perspective of the amended Article 2086 of the Italian Civil Code, which provides for the duty to establish (among others) an organisational structure appropriate to the nature and size of the company; in this perspective, there is no doubt that the Model is a real tool for *risk management* and strengthening of *corporate governance* mechanisms.

Moreover, Opocrin's decision to adopt a Model and Code of Ethics (as well as to ensure that they are constantly updated) is part of the Company's broader business policy, which considers these documents to be a true instrument of Corporate Social Responsibility in the broadest sense, as well as the foundation of its governance system.

In fact, the Company believes that the adoption of the Model, together with the Code of Ethics, constitutes - over and above the provisions of the law - a valid tool for raising the awareness of all the Recipients and, more generally, of all the Company's *stakeholders* so that, in the performance of their activities, they behave correctly and transparently in line with the ethical-social values that inspire Opocrin in the pursuit of its corporate purpose and that, in any case, prevent the risk of commission of Offences.



With the adoption of the Model and the Code of Ethics, the Company has also set itself the objective of equipping itself with a structured and organic system, comprising a set of general principles of conduct as well as control procedures and activities, which meets the above-mentioned aims, as well as the purposes and prescriptions required by Legislative Decree No. 231/2001, both in terms of preventing the Offences referred to therein (preventive controls), and in terms of controlling the implementation of the Model and the possible imposition of sanctions (*ex post* controls).

The judgement of suitability outlined by the Decree is in fact carried out by means of a structured internal control system, capable of ensuring the development of a coherent framework, modulated on the specific preventive needs of the corporate system, which, together with the definition of protocols 'suitable for preventing Offences', must respond to the function, provided for by the legislation, of separating the Entity's administrative liability from that of the Senior Executives or Subordinates deriving from the Offences committed, in cases where the Entity has adopted adequate measures to prevent the commission of such Offences.

In view of the above and in compliance with the provisions of the Decree, by resolution of the Board of Directors of 2 April 2012, Opocrin adopted and approved for the first time its own Organisation, Management and Control Model pursuant to Legislative Decree 231/2001.

The Model was subsequently updated and adapted to the evolution of the Company and the relevant legislation.

In particular, also due to the effect of the introduction of additional Offences under the Decree and in order to be able to avail itself of a prevention and control tool that is always capable of fully satisfying the suitability assessment outlined in Legislative Decree 231/2001, Opocrin's Board of Directors, by resolution of 31 March 2015, approved a new edition of the Model, as well as the Code of Ethics.

In the conviction that a Model can only be considered adequate if it is effectively implemented, the Company has been in constant and continuous contact with the Supervisory Board over the years in the context of the activity carried out by the latter pursuant to Article 6(2)(b) of the Decree, in order to verify the continued suitability of the complex internal control system implemented by Opocrin for the purposes of Legislative Decree 231/2001.

During 2019, following the introduction of new Offences under Legislative Decree 231/2001 and in order to re-evaluate all the types of Offences potentially relevant to the Company, Opocrin proceeded to further update the Model and the Code of Ethics, which were approved by resolution of the Board of Directors on 30 March 2020.

This update, in particular, resulted in the deletion from the risk analysis, and thus from the prevention and control measures, of certain offences that were irrelevant with respect to the activity carried out



by the Company and the regulation of which would have been a source of an overall weighting of the Model to the detriment of its immediate comprehension, implementation and consequent effectiveness.

Therefore, the Company, in agreement with the Supervisory Board, updated and partially revised the Model and the Code of Ethics in order to further enhance their usability and intelligibility by the Recipients, as well as to take into account the regulatory changes that have occurred since their last approval, which resulted in a specific *risk assessment* activity in relation to the newly introduced individual offences.

In 2024, in view of the merger by incorporation by Opocrin of the company Laboratori Derivati Organici S.p.A. ., the Company started a further project to revise its Model.

As required by law and by the *best practices* on the subject, this updating and revision activity was accompanied by a detailed "risk mapping" exercise and an assessment of any corrective actions to be implemented, in order to include in the Model also the activities and risks arising therefrom of the Trino Vercellese plant of Laboratori Derivati Organici S.p.A., although almost identical to those of the Company, given the same specific sector of operation.

The update was also aimed at incorporating and analysing the new offences provided for by Legislative Decree 231/2001, as well as acknowledging the activation of the procedures necessary to obtain certification of the Company's Safety and Environment Management System, a system that also includes worker health, prevention of major accidents and fire prevention, as well as energy and environmental sustainability issues.

When drafting the update of the Model, it was then reaffirmed, taking up values and concepts that are now an asset of the Company, that the overall system should aim at

- make all Addressees of the Model aware that any unlawful conduct may result in criminal and administrative sanctions for both the individual and the Company;
- ensure the correctness of the conduct of the Company and of the persons representing it, in full compliance with the law and the procedures adopted by Opocrin;
- strengthen control, monitoring and sanctioning mechanisms to counter the commission of offences.

Over the years, Opocrin has also implemented an effective and permanent internal control system - fundamental to ensuring the effectiveness of the Model - whose scope extends across all the different organisational levels and consists *inter alia* of procedures and regulations governing significant administrative and operational activities.

These procedures and regulations have been drawn up and are constantly updated, starting from



certain general principles and founding criteria dictated by the Model itself and by the Code of Ethics and consisting, in particular, of the separation of roles in the performance of activities inherent to the various processes, the 'traceability' of choices, aimed at enabling their constant transparency (e.g. by means of appropriate documentary evidence) and the identification of clear responsibility criteria. This version of the Model - to be considered a replacement for the previous versions - therefore represents the set of principles, rules, tools and procedures aimed at providing the Company with an effective organisational, management and control system, capable of identifying and preventing conduct that is criminally relevant under the Decree.

## (II) PREPARATION OF THE MODEL

The Model was drafted taking into consideration, in addition to the activity concretely carried out by the Company and the context of reference, the provisions of the Decree, the accompanying ministerial report, the general principles of an adequate internal control system, inferable from international best practice, and the 'Guidelines for the construction of organisation, management and control models *pursuant to* Legislative Decree 231 of 2001', drawn up by Confindustria on 7 March 2002 and last updated in June 2021.

For the drafting of this edition of the Model, the Company has also reviewed its operating and organisational methods, making use of the experience gained over the years of implementation of the Model, also in the light of the awareness, on the part of all the Recipients, of the importance of a punctual application of the prevention measures in all the areas of application of the provisions of Legislative Decree No. 231/2001.

In this context, the structure of the Model - in the version most recently approved by the Board of Directors on 30 March 2020 - based on a detailed analysis of the individual processes and the relevant corporate functions involved, measuring the exposure of each of them to the risk of occurrence of each individual criminal offence envisaged as an Offence under Legislative Decree No. 231/2001, has been maintained and - on this basis - two levels of intervention have been confirmed and maintained, depending on the results that have emerged.

A first level, common to all functions, regardless of their degree of permeability to the risk of commission of the Offence, represented by the Code of Ethics, addressed to all Addressees, containing sanction provisions in the event of violation of the relevant provisions.

A second level, individualised and calibrated to the individual function or process that has been found to be particularly exposed to the risk of an Offence occurring, containing corrective mechanisms in the individual process that, if duly observed, make it possible to prevent Offences from being



committed, reducing the degree of risk to an acceptable or physiological level for the type of activity and the type of function.

For this reason, the essential features of the Model can be identified in the following phases:

- 1. the identification of *risks* (*risk assessment*), i.e. the mapping and analysis of processes at risk and of the corporate functions involved in order to identify where (in which area/sector of activity) and in what manner the commission of the offences provided for by Legislative Decree No. 231/2001 may occur;
- 2. the design of the control system, i.e. the assessment of the existing control system within the company (the procedures and regulations in place) and its suitability and effectiveness in order to effectively counter the identified risks, as well as the assignment of the residual risk for each process at risk and the identification of further prevention measures to be adopted, also in relation to the management of financial resources.

The components of an internal control system preventing offences, which must be implemented at company level to ensure the effectiveness of the Model, are therefore identified as follows:

- adoption of a Code of Ethics identifying the principles of conduct capable of preventing the offences considered;
- adoption of a sufficiently formalised and clear organisational system, especially with regard to the allocation of roles and responsibilities;
- adoption of operational and IT procedures;
- adoption of a system of authorisation and signature powers;
- adoption of an appropriate internal control system;
- adoption of a communication and training system for personnel.

The above-mentioned components must be inspired by the following principles:

- every operation, transaction, action must be verifiable, documented, consistent and congruous;
- no one (with due exceptions) can independently manage an entire process;
- the control system must document the performance of controls.
- 3. Appointment of the Supervisory Body, i.e. the body entrusted with the task of supervising the operation of and compliance with the Model and ensuring that it is updated, in relation to which appropriate information flows must be established;
- 4. The provision of a disciplinary system and/or sanctioning mechanisms for violations of the provisions of the Code of Ethics, the Model and the procedures relevant to the Model.

Based on these business organisation principles, the set of corrective processes necessary to contain the risk in cases of 'medium' or 'high' exposure was outlined.



In essence, Opocrin has been equipped for years with a first level of control represented by the introduction of the Code of Ethics and the appointment of the Supervisory Board, and has introduced the operating procedures referred to in Annex A) of this Model in order to 'specify' and detail the prevention measures specified herein.

The offences that the Company, in agreement with the Supervisory Board, has deemed may affect, even marginally, the Company's activities are specifically dealt with in the Special Section of the Model, with an analysis of their configurability in the Company's life together with the degree of risk calibrated on the basis of the suitability/sufficiency of the company processes involved and the subsequent corrective actions taken by the Company.

## (III) CODE OF ETHICS

Opocrin has adopted its own Code of Ethics - approved for the first time by the Company with a resolution of the Board of Directors on 2 April 2012 and subsequently amended on 31 March 2015 and 30 March 2020 - aimed at defining the fundamental principles and ethical-social values that the Company recognises, accepts and shares and which it requires all Addressees to observe, in the conviction that ethics in the conduct of business is to be pursued as a condition of success for the company.

In fact, the Code of Ethics expresses ethical principles and fundamental values (such as, for example, honesty, non-discrimination, fairness, transparency, protection of health and safety at work) which, permeating every process of the Company's daily operations, constitute essential and functional elements for the correct performance of the Company's activities at every level.

The Code of Ethics establishes, as a mandatory principle of the Company's operations, compliance with the laws and regulations in force and with the ethical values commonly recognised in the conduct of business, and sanctions the principles to which (i) all Addressees must adhere - in the daily performance of their work activities and/or their duties or functions - and (ii) operations, conduct and relations, both internal and external to the Company, must be oriented. Following its adoption and subsequent amendments, the Code of Ethics was adequately disseminated to the Addressees, informing them that failure to comply with the essential principles set out therein may constitute a breach of contractual obligations undertaken with the Company.

In this perspective, the principles contained in the Code of Ethics - although representing a tool endowed with its own autonomy and of general scope - constitute the first safeguard on which the Model is based, as well as a useful interpretative reference in the concrete application of the same in



relation to the dynamics of the company, also with a view to making the exemption provided for in Article 6 of Legislative Decree No. 231/2001 operative.

The importance of the Code of Ethics for the Company and its binding effect are demonstrated by the provision of appropriate sanctions in the event of violation of the Code.

## (IV) STRUCTURE OF THE MODEL

This Model is made up of a 'General Section' and a 'Special Section', prepared in relation to the different categories of Offences contemplated in Legislative Decree 231/2001 and considered at risk for Opocrin.

The General Part has the function of:

- retrace the development of legislation on the administrative liability of the Entity;
- deal with the general principles on the subject;
- define a sort of 'identity card' for the Company, briefly describing its history, the characteristics
  of its *business* and organisational set-up, paying particular attention to the analysis and
  description of the main internal processes through which the business develops;
- define the principles of conduct and general prevention protocols common to all identified sensitive activities;
- Define the methodological approach used to prepare the Model and the provisions relating to its transposition and implementation;
- define the powers and tasks of the Supervisory Board, as well as the information flows concerning it;
- Outline the information and training plan to be adopted in order to ensure awareness of the measures and provisions of the Model;
- define the disciplinary system and the relevant sanctioning apparatus;
- indicate the criteria for updating and adapting the Model.

The Special Section has the function of:

- identify potentially verifiable offences, compile and update the risk matrix (*risk assessment*) and draw up any preventive and/or corrective measures in respect of existing processes;
- define the principles of conduct to be implemented and the specific prevention protocols referring to each sensitive activity identified.

The Opocrin Model is also supplemented by the following components of the internal control system, which contribute to strengthening the system pursuant to the Decree:

• company management systems (Quality and Environmental Safety Management System),



certified in compliance with *the cGMP* and BS OHSAS 18001:2007 (UNI ISO 45001:2018 from 2020) and UNI EN ISO 14001:2015 standards and, for the Corlo site, also with Legislative Decree 105/2015, the so-called Seveso III Directive;

• *policies*, operating procedures and internal regulations adopted by the Company, which constitute implementation of the contents of the Model.



## **GENERAL PART**



## 1. THE NORMATIVE

## 1.1. LEGISLATIVE DECREE No. 231/2001 ON THE ADMINISTRATIVE LIABILITY OF ORGANISATIONS

Legislative Decree No. 231 of 8 June 2001, containing the 'Regulations on the administrative liability of legal persons, companies and associations, including those without legal personality, pursuant to Article 11 of Law No. 300 of 29 September 2000', introduced for the first time in our legal system a system of administrative liability - substantially comparable to criminal liability - against the Entity, in addition to that of the natural person who materially committed the offence.

The Entity's administrative liability arises from the commission of one or more offences (even in the form of an attempt) expressly indicated in the Decree (or in regulations that expressly refer to the same), in the interest or to the advantage of the Entity itself, by Senior Executives or Subordinates. More precisely, if the Offence is committed by Senior Persons of the Entity, a presumption of liability is established against the latter. This is in view of the fact that the natural person expresses, represents and implements the management policy of the Entity. Conversely, there is no presumption of liability of the Entity where the perpetrator of the Offences is a Subordinate, so that in such a case the fact of the Subordinate entails the liability of the Entity only if it turns out that its commission was made possible by the failure to comply with the obligations of management and supervision of the Subordinate.

The configuration of the Entity "s liability as an administrative offence implies that the offence committed by the natural person remains conceptually distinct from the administrative offence committed by the Entity, so much so that the Entity "s liability remains unaffected even where the offence committed by the natural person exists, but a cause of extinction of the offence has occurred or the author of the offence has not been identified.

The broadening of liability aims to involve in the punishment of certain criminal offences the assets of the Entity and, ultimately, the economic interests of the shareholders, who, until the entry into force of the law under review, did not suffer any consequences from the commission of offences committed, to the advantage or in the interest of the Entity, by its directors and/or employees. In fact, the principle of personal responsibility for criminal liability left the Entity immune from sanctions other than compensation for damages, if and insofar as they existed.

The regulatory innovation is of no small importance, given that the Entity can no longer be said to be extraneous to the commission, to its advantage or in its interest, of Offences by its Senior Executives or Subordinates.



### 1.2. OFFENCES

The Offences in relation to which the administrative liability of the Entity is envisaged are exhaustively indicated in Section III of the Decree.

Legislative Decree No. 231/2001, in its original text, referred exclusively to a series of offences committed in relations with the Public Administration (such as, inter alia, the undue receipt of funds to the detriment of the State, embezzlement to the detriment of the State, fraud committed to the detriment of the State or another public body, computer fraud to the detriment of the State, extortion and bribery, *etc.*).

The original text has been supplemented by subsequent legislative measures that have progressively broadened the list of offences whose commission may give rise to the administrative liability of the Entity.

In addition, Law No. 146 of 16 March 2006, concerning the 'Ratification and implementation of the United Nations Convention and Protocols against transnational organised crime, adopted by the General Assembly on 15 November 2000 and 31 May 2001' provides for the Entity's liability in the event of the commission of certain so-called '*transnational organised crime*' offences (such as, for example, criminal conspiracy, mafia-type conspiracy, migrant trafficking, *etc.*).

Therefore, the Entity's administrative liability exists where one or more of the Offences peremptorily identified in the Decree in the following provisions are committed:

- Article 24, with reference to the offences of 'misappropriation of funds, fraud to the detriment of the State of a public body or the European Union or for the purpose of obtaining public funds, computer fraud to the detriment of the State or a public body and fraud in public procurement':
  - Misappropriation of public funds (Article 316-bis of the criminal code) [Article amended by Decree-Law No. 13/2022];
  - Undue receipt of public funds (Article 316-ter of the Criminal Code) [Article amended by Law no. 3/2019 and Decree-Law no. 13/2022];
  - fraud to the detriment of the State or other public body or the European Communities (Article 640(2)(1) of the Criminal Code);
  - Aggravated fraud to obtain public funds (Article 640-bis of the criminal code) [Article amended by Decree-Law No. 13/2022];
  - computer fraud to the detriment of the State or other public body (Article 640-ter of the criminal code);



- Fraud in public supply (Article 356 of the Criminal Code) [introduced by Legislative Decree
   No. 75/2020];
- Fraud to the detriment of the European Agricultural Fund (Article 2. L. 23/12/1986, no. 898)
   [introduced by Legislative Decree no. 75/2020];
- Disturbing the freedom of tenders (Article 353 of the criminal code) [Article introduced by Law No. 137/2023];
- Disturbance of the freedom to choose a contractor (Article 353-bis) [Article introduced by Law no. 137/2023].
- Article 24-bis (introduced by Law No. 48 of 18 March 2008 when ratifying and executing the Council of Europe Convention on Cybercrime, drafted in Budapest on 23 November 2001, and subsequently amended by Decree-Law No. 105 of 21 September 2019, converted by Law No. 133 of 18 November 2019, containing 'Urgent provisions on the perimeter of national cyber security and the regulation of special powers in sectors of strategic importance'), with reference to 'computer crimes' and 'unlawful processing of data':
  - computer documents (Article 491-bis of the criminal code);
  - Unauthorised access to a computer or telecommunications system (Article 615-ter of the criminal code);
  - Unlawful possession, dissemination and installation of equipment, codes and other means of accessing computer or telecommunication systems (Article 615-quater of the criminal code)
     [Article amended by Law No. 238/2021];
  - Unlawful possession, dissemination and installation of computer equipment, devices or programmes intended to damage or interrupt a computer or telecommunications system (Article 615-quinquies of the criminal code) [Article amended by Law No. 238/2021];
  - Unlawful interception, obstruction or interruption of computer or telematic communications
     (Article 617-quater of the criminal code) [Article amended by Law No. 238/2021];
  - Unlawful possession, dissemination and installation of equipment and other means of intercepting, impeding or interrupting computer or telematic communications (Article 617-quinquies of the criminal code) [Article amended by Law No. 238/2021];
  - damaging computer information, data and programmes (Article 635-bis of the criminal code);



- damaging computer information, data and programmes used by the State or other public body or in any case of public utility (Article 635-ter of the Criminal Code);
- damaging computer or telecommunications systems (Article 635-quater of the criminal code);
- damaging computer or telecommunication systems of public utility (Article 635-quinquies of the criminal code);
- computer fraud of the electronic signature certifier (Article 640-quinquies of the criminal code);
- Violation of the rules on the National Cybersecurity Perimeter (Article 1, paragraph 11,
   Decree-Law No. 105 of 21 September 2019).
- Article *24-ter* (introduced by Law No. 94 of 15 July 2009, containing 'Provisions on public security' and amended by Law 69/2015), with reference to '*organised crime offences*':
  - Mafia-type association, including foreign ones (Article 416-bis of the criminal code) [Article amended by Law No. 69/2015];
  - criminal conspiracy (Article 416 of the criminal code);
  - political-mafia electoral exchange (Article 416-ter of the Criminal Code) [as replaced by Article 1, paragraph 1 of Law no. 62 of 17 April 2014, as from 18 April 2014, pursuant to the provisions of Article 2, paragraph 1 of the same Law 62/2014);
  - kidnapping for the purpose of extortion (Article 630 of the criminal code);
  - Association aimed at the illegal trafficking of narcotic or psychotropic substances (Article 74 of Presidential Decree No. 309 of 9 October 1990) [Paragraph 7-bis added by Legislative Decree No. 202/2016];
  - all offences if committed by availing oneself of the conditions provided for in Article 416-bis of the criminal code in order to facilitate the activities of the associations provided for in the same article (Law 203/91);
  - unlawful manufacture, introduction into the State, sale, transfer, possession and carrying in a public place or a place open to the public of weapons of war or warlike weapons or parts thereof, explosives, clandestine weapons as well as more common firing weapons, excluding those provided for in Article 2(3) of Law No. 110 of 18 April 1975 (Article 407(2)(a)(5) of the Code of Criminal Procedure).



- Article 25 (subsequently amended by Law No. 190 of 6 November 2012, Law No. 3 of 9 January 2019, Legislative Decree No. 75/2020, Law No. 112/2024 and Law No. 114/2024), with reference to the crimes of 'embezzlement, extortion, undue induction to give and promise benefits and bribery':
  - extortion (Article 317 of the Criminal Code) [Article amended by Law No. 69/2015];
  - corruption for the exercise of the function (Article 318 of the Criminal Code) [amended by Law No. 190/2012, Law No. 69/2015 and Law No. 3/2019];
  - bribery for an act contrary to official duties (Article 319 of the Criminal Code) [Article amended by Law No. 69/2015];
  - aggravating circumstances (Article 319-bis of the criminal code);
  - bribery in judicial proceedings (Article 319-ter of the criminal code) [Article amended by Law No. 69/2015];
  - Undue induction to give or promise benefits (Article 319-quater of the Criminal Code)
     [Article added by Law no. 190/2012 and amended by Law no. 69/2015];
  - bribery of a person in charge of a public service (Article 320 of the criminal code);
  - penalties for the corruptor (Article 321 of the Criminal Code);
  - incitement to corruption (Article 322 of the criminal code);
  - embezzlement, extortion, undue inducement to give or promise benefits, bribery and incitement to bribery of members of international courts or bodies of the European Communities or of international parliamentary assemblies or international organisations and of officials of the European Communities and of foreign States (Article 322-bis of the Criminal Code) [amended by Law No. 190/2012 and Law No. 3/2019];
  - Trafficking in unlawful influence (Article *346-bis* of the Criminal Code) [amended by Law 3/2019];
  - Embezzlement (limited to the first paragraph) (Article 314 of the Criminal Code) [introduced by Legislative Decree No. 75/2020];
  - Misappropriation of money or movable property (Article 314-bis of the Criminal Code)
     [introduced by Decree-Law No. 92 of 4 July 2024 and amended by Conversion Law No. 112 of 8 August 2024];
  - Embezzlement by profiting from another person's error (Article 316 of the Criminal Code)
     [introduced by Legislative Decree No. 75/2020].



- Article 25-bis (introduced by Article 6 of Law No. 409 of 23 November 2001 and subsequently amended by Law No. 99 of 23 July 2009 and by Legislative Decree No. 125/2016), with reference to the offences of 'counterfeiting money, public credit cards, revenue stamps and identification instruments or signs':
  - alteration of currency (Article 454 of the criminal code);
  - counterfeiting of currency, spending and introduction into the State, in concert, of counterfeit
     currency (Article 453 of the criminal code);
  - spending and introduction into the State, without concert, of counterfeit money (Article 455 of the criminal code);
  - spending of counterfeit money received in good faith (Article 457 of the criminal code);
  - Forgery of revenue stamps, introduction into the State, purchase, possession or putting into circulation of forged revenue stamps (Article 459 of the Criminal Code);
  - counterfeiting watermarked paper in use for the manufacture of public credit cards or stamps
     (Article 460 of the criminal code);
  - manufacture or possession of watermarks or instruments intended for the counterfeiting of money, revenue stamps or watermarked paper (Article 461 of the criminal code);
  - use of counterfeit or altered stamps (Article 464 of the Criminal Code);
  - counterfeiting, alteration or use of trademarks or distinctive signs or of patents, models and designs (Article 473 of the criminal code);
  - introduction into the State and trade in products with false signs (Article 474 of the Criminal Code).
- Article 25-bis.1 (introduced by Law No. 99 of 23 July 2009), with reference to 'offences against industry and trade':
  - unlawful competition with threats or violence' (Article <u>513-bis</u> of the criminal code);
  - disturbing the freedom of industry or trade (Article 513 of the criminal code);
  - fraud against national industries (Article 514 of the criminal code);
  - fraud in the exercise of trade (Article 515 of the criminal code);
  - sale of non-genuine foodstuffs as genuine (Article 516 of the criminal code);
  - sale of industrial products with misleading signs (Article 517 of the Criminal Code);
  - manufacture of and trade in goods made by usurping industrial property rights (Article 517-ter of the criminal code);



- counterfeiting of geographical indications or designations of origin of agri-food products
   (Article 517-quater of the criminal code).
- Article 25-ter (introduced by Article 3 of Legislative Decree No. 61 of 11 April 2002, subsequently amended by Law No. 262 of 28 December 2005, Law No. 190 of 6 November 2012, Law No. 69 of 27 May 2015, Legislative Decree No. 38 of 15 March 2017, Law No. 3 of 9 January 2019 and, most recently, by Legislative Decree No. 19/2023), with reference to 'corporate offences':
  - false corporate communications (Article 2621 of the Civil Code) [Article amended by Law No. 69/2015];
  - minor facts (Article 2621-bis of the Civil Code);
  - false corporate communications by listed companies (Article 2622 of the Civil Code) [Article amended by Law No. 69/2015];
  - impeded control (Article 2625(2) of the Civil Code);
  - undue return of contributions (Article 2626 of the Civil Code);
  - illegal distribution of profits and reserves (Article 2627 of the Civil Code);
  - unlawful transactions involving shares or quotas in the company or its parent company (Article 2628 of the Civil Code);
  - transactions to the detriment of creditors (Article 2629 of the Civil Code);
  - failure to disclose a conflict of interest (Article 2629-bis of the Civil Code) [added by Law No. 262/2005];
  - fictitious capital formation (Article 2632 of the Civil Code);
  - undue distribution of company assets by liquidators (Article 2633 of the Civil Code)
  - bribery between private parties (Article 2635 of the Civil Code) [added by Law No. 190/2012;
     amended by Legislative Decree No. 38/2017 and Law No. 3/2019];
  - incitement to bribery among private individuals (Article 2635-bis of the Civil Code) [added by Legislative Decree No. 38/2017 and amended by Law No. 3/2019];
  - unlawful influence on the assembly (Article 2636 of the Civil Code);
  - agiotage (Article 2637 of the Civil Code);
  - obstructing the exercise of the functions of public supervisory authorities (Article 2638(1) and (2) of the Civil Code);



- false or omitted declarations for the issue of the preliminary certificate (Article 54 of Legislative Decree No. 19/2023) [added by Legislative Decree No. 19/2023].
- Article 25-quater (inserted into the original body of the Decree by Article 3 of Law No. 7 of 14 January 2003), which refers to 'offences with the purpose of terrorism or subversion of the democratic order':
  - subversive associations (Article 270 of the Criminal Code);
  - associations for the purposes of terrorism, including international terrorism or subversion
     of the democratic order (Article 270 bis of the criminal code);
  - Aggravating and mitigating circumstances (Article 270-bis.1 of the Criminal Code)
     [introduced by Legislative Decree No. 21/2018];
  - assistance to associates (Article 270b of the Criminal Code);
  - recruitment for the purposes of terrorism, including international terrorism (Article 270 quater of the criminal code);
  - transfer organisation for terrorist purposes (Article *270-quater*.1) [introduced by Decree-Law No. 7/2015, converted, with amendments, by Law No. 43/2015];
  - training in activities for the purposes of terrorism, including international terrorism (Article
     270 quinquies of the criminal code);
  - financing of conduct with the purpose of terrorism (Law No. 153/2016, Article 270 *quinquies*.1 of the Criminal Code);
  - misappropriation of seized goods or money (Article 270d.2 of the criminal code);
  - conduct for the purposes of terrorism (Article 270 sexies of the criminal code);
  - attempt for terrorist or subversive purposes (Article 280 of the criminal code);
  - acts of terrorism with deadly or explosive devices (Article 280 bis of the criminal code);
  - acts of nuclear terrorism (Article 280b of the criminal code);
  - kidnapping for the purpose of terrorism or subversion (Article 289 bis of the criminal code);
  - Kidnapping for the purpose of coercion (Article 289-ter of the Criminal Code) [introduced by Legislative Decree 21/2018];
  - incitement to commit any of the offences provided for in Chapters 1 and 2 (Article 302 of the criminal code);
  - political conspiracy by agreement (Article 304 of the Criminal Code);
  - political conspiracy by association (Article 305 of the Criminal Code);



- Armed gang: formation and participation (Article 306 of the criminal code);
- assistance to participants in conspiracies or armed gangs (Article 307 of the criminal code);
- seizure, hijacking and destruction of an aircraft (Law No. 342/1976, Article 1);
- damage to ground installations (Law No. 342/1976, Art. 2);
- sanctions (Law No. 422/1989, Art. 3);
- diligent repentance (Legislative Decree No. 625/1979, Art. 5);
- New York Convention of 9 December 1999 (Art. 2).
- Article 25-quater.1 (introduced by Article 8 of Law No. 7 of 9 January 2006), with reference to 'practices of female genital mutilation':
  - female genital mutilation practices (Article 583-bis of the criminal code).
- Article 25-quinquies (introduced by Article 5 of Law No. 228 of 11 August 2003, subsequently supplemented by Law No. 38 of 6 February 2006, Legislative Decree No. 39 of 4 March 2014 and, most recently, by Law No. 199 of 29 October 2016), which aims to repress certain 'offences against the individual':
  - reduction to or maintenance in slavery or servitude (Article 600 of the criminal code);
  - child prostitution (Article 600-bis of the criminal code);
  - child pornography (Article 600-ter of the criminal code);
  - Possession of or access to pornographic material (Article 600-quater) [Article amended by Law No. 238/2021];
  - virtual pornography (Article 600-quater.1 of the Criminal Code) [added by Article 10, Law
     No. 38 of 6 February 2006];
  - tourist initiatives aimed at exploiting child prostitution (Article 600-quinquies of the criminal code);
  - Trafficking in persons (Article 601 of the Criminal Code) [amended by Legislative Decree 21/2018];
  - purchase and sale of slaves (Article 602 of the criminal code);
  - Illegal brokering and exploitation of labour (Article 603-bis of the criminal code);
  - solicitation of minors (Article 609-undecies of the criminal code) [Article amended by Law No. 238/2021].



- Article 25-sexies (introduced by Law No. 62 of 18 April 2005, the so-called Community Law of 2004, in transposition of Community Directive 2003/6/EC), with particular reference to market abuse offences:
  - Market manipulation (Article 185 of Legislative Decree No. 58/1998) [Article amended by Legislative Decree No. 107/2018 and Law No. 238/2021];
  - Abuse or unlawful communication of inside information. Recommending or inducing others to commit insider trading (Article 184 of Legislative Decree no. 58/1998) [Article amended by Law no. 238/2021].
- Article 25-septies (introduced by Law No. 123 of 3 August 2007, as amended by Legislative Decree No. 81 of 9 April 2008 on the protection of health and safety at work), with reference to the hypotheses of 'manslaughter and serious or very serious culpable lesions, committed in violation of the rules on accidents and on the protection of health and safety at work':
  - culpable personal injury (Article 590 of the Criminal Code);
  - manslaughter (Article 589 of the Criminal Code).
- Article 25-octies (introduced by Legislative Decree No. 231 of 21 November 2007, amended by Law No. 186 of 15 December 2014 and by Legislative Decree No. 195/2021), with reference to the offences of "receiving stolen goods, money laundering, use of money, goods or benefits of unlawful origin as well as selflaundering":
  - Receiving stolen goods (Article 648 of the criminal code) [Article amended by Legislative Decree 195/2021];
  - money laundering (Article 648-bis of the criminal code) [Article amended by Legislative
     Decree 195/2021];
  - Use of money, goods or benefits of unlawful origin (Article 648-ter of the Criminal Code)
     [Article amended by Legislative Decree 195/2021];
  - Self-laundering (Article 648-ter.1 of the Criminal Code) [Article amended by Legislative Decree 195/2021].
- Article 25-octies.1 (article added by Legislative Decree No. 184/2021 and amended by Law No. 137/2023) concerning "offences relating to non-cash payment instruments and fraudulent transfer of values":



- misuse and falsification of non-cash payment instruments (Article 493-ter of the Criminal Code);
- possession and dissemination of computer equipment, devices or programmes aimed at committing offences involving non-cash payment instruments (Article 493-quater of the Criminal Code);
- computer fraud aggravated by the carrying out of a transfer of money, monetary value or virtual currency (Article *640-terc.*p.);
- Fraudulent transfer of valuables (Article *512-bis*) [Article introduced by Law No. 137/2023 and amended by Decree-Law No. 19/2024].
- Article 25-octies.1 paragraph 2 (article added by Legislative Decree 184/2021) concerning other offences relating to non-cash payment instruments;
- Article 25-novies (introduced by Law no. 99 of 23 July 2009 and amended by Law no. 93/2023), which extends the Entity's administrative liability to the offences covered by Law no. 633/1941 concerning "copyright infringement":
  - making available to the public, in a system of telematic networks, by means of connections of any kind, a protected intellectual work, or part of it (Article 171, Law No. 633/1941, paragraph 1, letter a) bis);
  - offences referred to in the preceding paragraph committed on other people's works not intended for publication if their honour or reputation is offended (Article 171, Law No. 633/1941, paragraph 3);
  - unauthorised duplication, for profit, of computer programs; import, distribution, sale or possession for commercial or entrepreneurial purposes or rental of programs contained in media not marked by the SIAE; preparation of means to remove or circumvent protection devices for computer programs (Article 171-bis L. No. 633/1941 Paragraph 1);
  - reproduction, transfer to another medium, distribution, communication, presentation or demonstration in public, of the contents of a database; extraction or re-use of the database; distribution, sale or rental of databases (Article 171-bis L. No. 633/1941 Section 2);
  - unauthorised duplication, reproduction, transmission or dissemination in public by any process, in whole or in part, of intellectual works intended for the television, cinematographic circuit, sale or rental of records, tapes or similar supports or any other



support containing phonograms or videograms of musical, cinematographic or audiovisual works assimilated or sequences of moving images literary, dramatic, scientific or educational, musical or dramatic-musical, multimedia works, even if included in collective or composite works or databases; reproduction, duplication, transmission or unauthorised dissemination, sale or trade, transfer for any reason or unauthorised importation of more than fifty copies or specimens of works protected by copyright and related rights; entering into a system of telematic networks, through connections of any kind, of an original work protected by copyright, or part of it (Article 171-ter of Law no. 675 of the Italian Republic); and *171-ter* L. No 633/1941) [amended by L. No 93/2023];

- failure to notify the SIAE of the identification data of the media not subject to the mark or false declaration (Article 171-septies of Law No. 633/1941);
- fraudulent production, sale, import, promotion, installation, modification, use for public and private use of equipment or parts of equipment for the decoding of audiovisual transmissions with conditional access made over the air, by satellite, by cable, in both analogue and digital form (Article 171-octies of Law No. 633/1941).
- Article 25-decies (introduced by Legislative Decree No. 116 of 3 August 2009 and subsequently amended by Legislative Decree No. 121 of 7 July 2011), with reference to the offence of 'inducement not to make statements or to make false statements to the judicial authorities':
  - inducement not to make statements or to make false statements to the judicial authorities (Article *377-bis* of the criminal code).
- Article 25-undecies (introduced by Legislative Decree No. 121 of 7 July 2011, implementing Directives 2008/52/EC and 2009/123/EC on environmental protection, as amended by Law No. 68 of 22 May 2015, Legislative Decree No. 21/2018 and Law No. 137/2023), with reference to "environmental offences":
  - environmental pollution (Article 452-bis of the criminal code) [Article amended by Law No. 137/2023];
  - environmental disaster (Article 452-quater of the criminal code) [Article amended by Law No. 137/2023];
  - culpable offences against the environment (Article 452-quinquies of the Criminal Code);



- trafficking in and abandonment of highly radioactive material (Article 452-sexies of the criminal code);
- aggravating circumstances (Article 452-octies of the Criminal Code);
- The killing, destruction, capture, taking or possession of specimens of protected wild animal
   or plant species (Article 727-bis of the criminal code);
- destruction or deterioration of habitats within a protected site (Article 733-bis of the criminal code);
- import, export, possession, use for profit, purchase, sale, display or possession for sale or commercial purposes of protected species (Law No. 150/1992, Art. 1, Art. 2, Art. 3-bis and Art. 6);
- discharges of industrial waste water containing hazardous substances; discharges to the soil,
   subsoil and groundwater; discharges into the sea from ships or aircraft (Legislative Decree
   No 152/2006, Article 137);
- unauthorised waste management activities (Legislative Decree No. 152/2006, Article 256);
- pollution of the soil, subsoil, surface water or groundwater (Legislative Decree No. 152/2006, Article 257);
- illicit trafficking in waste (Legislative Decree No. 152/2006, Article 259);
- breach of reporting obligations, the keeping of compulsory registers and forms (Legislative Decree No. 152/2006, Article 258);
- Organised activities for the illegal trafficking of waste (Article 452-quaterdecies of the Criminal Code) [introduced by Legislative Decree No. 21/2018];
- computerised waste traceability control system (Legislative Decree No. 152/2006, Art. 260-bis);
- sanctions (Legislative Decree No. 152/2006, Art. 279);
- malicious pollution caused by ships (Legislative Decree No. 202/2007, Art. 8);
- negligent ship-source pollution (Legislative Decree No 202/2007, Art. 9);
- cessation and reduction of the use of harmful substances (Law No. 549/1993 Art. 3).
- Article 25-duodecies (introduced by Legislative Decree No. 109 of 16 July 2012, as amended by Law No. 161 of 17 October 2017 and Decree-Law No. 20/2023), with regard to the offence of "employment of third-country nationals whose stay is irregular" and other offences relating to illegal immigration:



- Provisions against clandestine immigration (Article 12, paras. 3, 3 bis, 3 ter and 5,
   Legislative Decree no. 286/1998) [Article amended by Decree-Law no. 20/2023];
- employment of third-country nationals whose stay is irregular (Article 22(12a) of Legislative Decree No 286/1998).
- Article 25-terdecies (introduced by Law No. 167 of 20 November 2017 as amended by Legislative Decree No. 21/2018), with regard to the offences of racism and xenophobia:
  - propaganda and incitement to commit racial, ethnic and religious discrimination (Article *604-bis* of the Criminal Code) [added by Legislative Decree No. 21/2018].
- Article 25-quaterdecies (introduced by Article 5 of Law No. 39 of 3 May 2019), with reference to the offences of "fraud in sporting competitions, unlawful gaming or betting and gambling exercised by means of prohibited devices":
  - fraud in sporting competitions (Article 1, Law No. 401/1989);
  - abusive exercise of gambling or betting activities (Article 4, Law No 401/1989).
- Article 25-quinquiesdecies (introduced by Article 39, paragraph 2 of Decree-Law No. 124 of 26 October 2019, converted with amendments by Law No. 157 of 19 December 2019 and Legislative Decree No. 75/2020), with reference to "tax offences":
  - fraudulent declaration using invoices or other documents for non-existent transactions (Article 2 of Legislative Decree No. 74/2000);
  - fraudulent declaration by means of other devices (Article 3 of Legislative Decree No. 74/2000);
  - issue of invoices or other documents for non-existent transactions (Article 8 of Legislative Decree No. 74/2000);
  - concealment or destruction of accounting documents (Article 10 of Legislative Decree No. 74/2000);
  - fraudulent evasion of tax payments (Article 11 of Legislative Decree No. 74/2000);
  - False declaration (Article 4 of Legislative Decree no. 74/2000) [introduced by Legislative Decree no. 75/2020];
  - omitted declaration (Article 5 of Legislative Decree no. 74/2000) [introduced by Legislative
     Decree no. 75/2020];



- Undue compensation (Article 10-quater of Legislative Decree No. 74/2000) [introduced by Legislative Decree No. 75/2020].
- Article 25-sexies decies (added by Legislative Decree No. 75/2020) concerning smuggling:
  - smuggling in the movement of goods across land borders and customs areas (Article 282
     Presidential Decree No. 43/1973);
  - smuggling in the movement of goods in border lakes (Article 283 Presidential Decree No. 43/1973);
  - smuggling in the maritime movement of goods (Article 284 Presidential Decree No. 43/1973);
  - smuggling in the movement of goods by air (Article 285 Presidential Decree No. 43/1973);
  - smuggling in non-customs zones (Article 286 Presidential Decree No. 43/1973);
  - smuggling for undue use of goods imported with customs facilities (Article 287 Presidential Decree No. 43/1973);
  - smuggling in customs warehouses (Article 288 Presidential Decree No. 43/1973);
  - smuggling in cabotage and traffic (Article 289 Presidential Decree No. 43/1973);
  - smuggling in the export of goods eligible for duty drawback (Article 290 Presidential Decree No. 43/1973);
  - smuggling on temporary import or export (Article 291 Presidential Decree No. 43/1973);
  - smuggling of foreign manufactured tobacco (Article *291-bis* Presidential Decree No. 43/1973);
  - Aggravating circumstances of the offence of smuggling foreign manufactured tobacco
     (Article 291-ter Presidential Decree No. 43/1973);
  - conspiracy to smuggle foreign manufactured tobacco (Article 291-quater of Presidential Decree No. 43/1973);
  - other cases of smuggling (Article 292 Presidential Decree No 43/1973);
  - aggravating circumstances of smuggling (Article 295 Presidential Decree No. 43/1973).
- Article 25-septiesdecies, (added by Law no. 22/2022 and amended by Law no. 6/2024) concerning offences against cultural heritage:
  - theft of cultural goods (Article 518-bis of the criminal code);
  - Misappropriation of cultural goods (Article 518-ter of the criminal code);



- Receiving stolen cultural goods (Article 518-quater of the criminal code);
- forgery in private contracts relating to cultural goods (Article 518-octies of the criminal code);
- violations concerning the alienation of cultural goods (Article 518-novies of the Criminal Code);
- unlawful importation of cultural goods (Article 518-decies of the criminal code);
- unlawful removal or export of cultural goods (Article 518-undecies of the criminal code);
- destruction, dispersal, deterioration, defacement, defacement and unlawful use of cultural or landscape heritage (Article 518-duodecies of the criminal code);
- counterfeiting of works of art (Article 518-quaterdecies of the criminal code).
- Article *25-duodevicies*, (added by Law No. 22/2022), concerning the laundering of cultural goods and the devastation and looting of cultural and landscape assets:
  - laundering of cultural goods (Article 518-sexies of the criminal code);
  - devastation and looting of cultural and landscape heritage (Article 518-terdecies of the criminal code).
- Article 10, Law 146/2006, on transnational offences:
  - provisions against clandestine immigration (Article 12, paragraphs 3, 3-bis, 3-ter and 5, of the Consolidated Text of Legislative Decree No. 286 of 25 July 1998);
  - association for the purpose of illicit trafficking in narcotic or psychotropic substances
     (Article 74 of the Consolidated Text of Presidential Decree No 309 of 9 October 1990);
  - criminal association for the purpose of smuggling foreign manufactured tobacco (Article
     291-quater of the Consolidated Text of Presidential Decree No. 43 of 23 January 1973);
  - inducement not to make statements or to make false statements to the judicial authorities (Article 377-bis of the criminal code);
  - personal aiding and abetting (Article 378 of the Criminal Code);
  - criminal conspiracy (Article 416 of the criminal code);
  - mafia-type association, including foreign ones (Article 416-bis of the criminal code).

Then there is a particular case of administrative liability dependent (not on a crime, but) on an administrative offence and provided for outside Legislative Decree No. 231/2001. This is the case



governed by Articles 187-quinquies et seq. of Legislative Decree No. 58 of 24 February 1998, no. 58 of 24 February 1998 ("Consolidated Law on Financial Intermediation"), which provide for administrative pecuniary sanctions (in addition to the confiscation - also for equivalent amounts - of the product or profit of the offence and of the assets used to commit it) against the Entity in whose interest or to whose advantage the administrative offences of insider trading and market manipulation set out in Articles 187-bis and 187-ter of the same Consolidated Law have been committed.

The Entity's administrative liability also arises in the event that the Offences (with the exception of culpable offences) are committed in the form of an attempt. In such cases, however, the pecuniary and disqualification penalties are reduced by between one third and one half.

The Entity's liability also extends to offences committed abroad, provided that the State of the place where the offence was committed does not prosecute them, and provided that the particular conditions set out in Legislative Decree No. 231/2001 are met.

Pursuant to Article 26 of the Decree, the Entity is not liable when it voluntarily prevents the performance of the action or the realisation of the event.

## 1.3. SANCTIONS UNDER THE DECREE

The ascertainment of the Entity's liability, as well as the determination of the *anter* and *quantum* of the penalty, are assigned to the criminal court competent for the proceedings relating to the Offences on which the administrative liability depends.

In the event that a Senior Management Person or a Subordinate Person commits one of the offences provided for in Articles 24 et seq. of the Decree or those provided for in the special regulations referred to, the Entity may be subject to the imposition of serious and detrimental sanctions.

The penalty system provided for by Legislative Decree 231/2001 is divided into four types of sanctions, to which the Entity may be subject in the event of conviction under the Decree:

• pecuniary administrative sanction: this is governed by Articles 10 et seq. of the Decree and applies in all cases in which the judge holds the Entity liable.

The pecuniary sanction is calculated through a system based on quotas, the number and amount of which are determined by the judge: the number of quotas, to be applied between a minimum and a maximum that varies according to the case, depends on the seriousness of the offence, the degree of liability of the Entity, the activity carried out to eliminate or mitigate the consequences of the offence or to prevent the commission of further offences.



The amount of the individual tranche, on the other hand, is to be set between a minimum of  $\in$  258.23 and a maximum of  $\in$  1,549.37, depending on the economic and patrimonial conditions of the organisation.

Article 12 of the Decree provides for a number of cases in which the fine is reduced.

- Disqualification sanctions: these are governed by Articles 13 et seq. of the Decree and are applied, in addition to the pecuniary sanctions, only if expressly provided for the offence for which the Entity is convicted and only in the event that at least one of the following conditions is met:
  - the Entity has derived a relevant profit from the offence and the offence was committed by a Senior Management Person or a Subordinate Person if the commission of the offence was made possible by serious organisational deficiencies;
  - in the event of repeated offences.

The prohibitory sanctions provided for in the Decree are:

- ✓ disqualification;
- ✓ suspension or revocation of authorisations, licences or concessions functional to the commission of the offence;
- ✓ prohibition of contracting with the Public Administration, except to obtain the performance of a public service;
- ✓ exclusion from facilitations, financing, contributions or subsidies and/or revocation of those already granted;
- ✓ ban on advertising goods or services.

Exceptionally applicable with definitive effects, the prohibitory sanctions are temporary, with a duration ranging from three months to two years (with the exception of the provisions of Article 25(5) of Legislative Decree No. 231/2001), and relate to the specific activity of the Entity to which the offence refers. They may also be applied as a precautionary measure, prior to the conviction, at the request of the Public Prosecutor, if there are serious indications of the Entity's liability and well-founded and specific elements indicating a concrete danger of the further commission of offences of the same nature as the one for which proceedings are being taken.

In any case, disqualification sanctions shall not be applied when the offence was committed in the predominant interest of the perpetrator or of Third Parties and the Entity obtained a minimal or no advantage or the pecuniary damage caused is of particular tenuousness.

The application of prohibitory sanctions is also excluded if the Entity has carried out the remedial conduct provided for in Article 17 of Legislative Decree No. 231/2001.



- Confiscation: pursuant to Article 19 of the Decree, the conviction shall always order the confiscation of the price or profit of the Offence (ordinary confiscation) or of goods or other utilities of equivalent value (confiscation for equivalent), except for the part that can be returned to the injured party and without prejudice to the rights acquired by third parties in good faith.
- publication of the conviction: may be ordered when the Entity is sentenced to a disqualification sanction.

It consists of the publication of the conviction on the website of the Ministry of Justice, as well as by posting in the municipality where the entity has its head office, and is executed at the expense of the entity.

Administrative sanctions against the Entity are time-barred at the end of the fifth year from the date of commission of the offence.

The Entity's final conviction is entered in the national registry of administrative offence sanctions.

## 1.4. THE EXEMPTING CONDITION

Article 6 of Legislative Decree 231/2001 envisages the possibility for the Entity to be exonerated from administrative liability if it proves that it has adopted and effectively implemented, prior to the commission of the offence, an appropriate organisation and management model to prevent the commission of criminal offences of the kind that occurred. The system provides for the establishment of a control body within the Entity with the task of supervising the actual effectiveness of the Model. Accordingly, a specific form of exemption from liability is obtained if the entity proves that

- (a) has adopted and effectively implemented, prior to the commission of the offence, an organisational and management model capable of preventing offences and offences of the kind that have occurred;
- (b) the task of supervising the functioning of and compliance with the model as well as ensuring that it is updated has been entrusted to a body of the Entity endowed with autonomous powers of initiative and control;
- (c) the persons who committed the Offences acted by fraudulently circumventing the aforementioned model;
- (d) there has been no or insufficient supervision by the body referred to in (b) above.

The Entity's exoneration from liability therefore passes through the judgement of the suitability of the internal organisation and control system, which the criminal judge is called upon to formulate during the criminal proceedings against the material author of the offence. This particular perspective



therefore requires the Entity to assess the adequacy of its procedures with respect to the requirements mentioned above.

The Decree stipulates that organisation and management models must meet the following requirements:

- 1. identify the so-called 'potential risks', i.e. identify in the corporate context the areas or sectors of activity in the context of which the offences provided for in the Decree could in abstract terms be committed ('areas of activity at risk of offence');
- 2. provide for specific protocols aimed at planning the formation and implementation of the Entity's decisions in relation to the offences to be prevented, with the intention of effectively countering i.e. reducing to an acceptable level the identified risks;
- 3. identify ways of managing financial resources suitable for preventing the commission of such Offences;
- 4. provide for information obligations vis-à-vis the body in charge of supervising the functioning of and compliance with the model;
- 5. introduce an appropriate disciplinary system to sanction non-compliance with the measures indicated in the model.

Moreover, according to the provisions of Law no. 179 of 30 November 2017 ("Provisions for the protection of the authors of reports of offences of irregularities of which they have become aware in the context of a public or private employment relationship"), as well as Legislative Decree no. 24/2023 ("Implementation of Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law and on the protection of persons who report breaches of national laws"), the organisation and management models must provide for channels through which the persons indicated in Art. 5, paragraph 1, letters a) and b) of the Decree may make (including by computer), in order to protect the integrity of the Entity, "circumstantiated reports of unlawful conduct", relevant under Legislative Decree no. 231/2001, "and based on precise and concordant factual elements, or of violations of the organisation and management model of the entity, of which they have become aware by reason of the functions performed", guaranteeing in any case the confidentiality of the identity of the reporter in the management of such Reports.

With particular reference to risks arising from the commission of offences in the area of occupational health and safety, Article 30 of Legislative Decree No. 81/2008 also provided for a presumption of compliance with the requirements expected for corporate organisation models defined in accordance with *British Standard* OHSAS 18001:2007 (now UNI ISO 45001:2018). It should be noted that



Opocrin has obtained, and maintains active, said certification for its pre-merger sites and is currently in the process of obtaining it also for the Trino Vercellese production site.

Finally, with reference to the presumption of conformity of the organisational model in relation to the Offences referred to in Article *25-undecies* of the Decree, it should be noted that, although this presumption has not been expressly stated, given the technical nature of such Offences fully comparable to the Offences relating to health and safety in the workplace, it should also be applied analogously to the UNI ISO 14001:2015 certification, as widely supported in doctrine.



## 2. THE SOCIETY A'

## 2.1. THE COMPANY. BRIEF INTRODUCTION: COMPANY OBJECT, HISTORY, ARTICULATION AND TARGET MARKET

Opocrin is an Italian company dedicated since 1964 to the research, production, processing and marketing of raw materials for pharmaceutical use, mainly derived from animal organs and tissues, and of synthetic products.

Opocrin consists of three production units located respectively in Corlo di Formigine (MO), production and registered office, in Nonantola (MO) and in Trino Vercellese (VC) production sites, as well as an administrative office located in Modena.

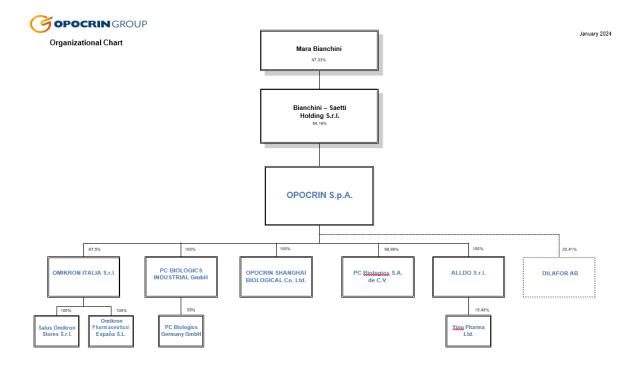
In February 2020, the Company finalised the acquisition of Laboratori Derivati Organici S.p.A., a company operating in the same market sector consisting of the production and sale of active ingredients based on heparins and heparinoids, with its main production site in Trino (VC).

In December 2023, Opocrin and Laboratori Derivati Organici S.p.A. signed the deed of merger by incorporation of this company by Opocrin, in execution of the merger plan approved by the resolutions of their respective Shareholders' Meetings of September 2023. As of 1 January 2024, Opocrin has, therefore, assumed the rights, obligations, liabilities, reasons and actions of the merged company Laboratori Derivati Organici S.p.A., continuing in all its relationships, including those of a procedural nature, prior to the merger, in accordance with the provisions of Article 2504-bis of the Italian Civil Code. From that date, therefore, the Trino Vercellese (VC) plant became Opocrin's third Italian production plant.

Opocrin also holds 67.5% of the capital of Omikron Italia S.r.l., a company active in research, development, production, registration and marketing in Italy and abroad of medicinal specialities, medical devices, food supplements, cosmetics and foodstuffs for special medical purposes, intended for the ophthalmic and vascular sector. In view of the special nature of Omikron Italia S.r.l.'s *business*, it has adopted its own Model 231 and Code of Conduct.

As can be seen from the Group organisation chart below, there are also a number of foreign production and sales offices.





The reference market, within which the Company operates, is essentially made up of major Italian and foreign pharmaceutical companies to which the so-called active ingredients produced through the prior procurement of the raw materials necessary for their manufacture are sold.

Pharmaceutical companies then produce the finished drug to be placed on the market.

Thus, Opocrin, although operating in the pharmaceutical sector, has only a marginal direct presence in the 'end' market, but is an essential component in the production chain of certain drugs and active ingredients.

Below are the active ingredients produced by the Company as at the date of updating the Model, broken down by plant.



OPOCRIN - STABILIMENTI PRODUTTIVI								
	PRODOTTI	CATEGORIA PER CIASCUN PRODOTTO (INTERMEDIO O API)	FINALITA' TERAPEUTICA PER CIASCUN PRODOTTO					
CORLO	SULODEXIDE	API	ANTITROMBOTICO					
SURFATTANTE		API	TRATTAMENTO RDS					
PARNAPARINA		API	ANTICOAGULANTE					
	EPARINA SODICA API		ANTITROMBOTICO, ANTICOAGULANTE					
NONANTOLA	CATALASE	INTERMEDIO	ANTIFIAMMATORIO CICATRIZZANTE					
	EPARINA CALCICA	API	ANTICOAGULANTE					
	PROTEINA FERRICA	INTERMEDIO	ANTIANEMICO (USO NON PHARMA)					
	FERRO SACCARATO	API	ANTIANEMICO (USO PHARMA)					
	CARBOSSIMALTOSIO FERRICO	API	ANTIANEMICO (USO PHARMA)					
	COLLAGENE	INTERMEDIO	PREPARAZIONE DI PRODOTTI EMOSTATICI E COADIUVANTE DELLA RIPARAZZIONE TISSUTALE (USO NON PHARMA)					
TRINO	SULODEXIDE	API	ANTITROMBOTICO					
	MESOGLICANO	API	ANTITROMBOTICO					
·	EPARINOIDE JP	API	TROMBOFLEBITI					
	EPARINOIDE ALTA ATTIVITA'	API	ANTIFIAMMATORIO, ANTIESSUDATIVA, ANTICOAGULANTE					
	EPARINA SODICA	API	ANTITROMBOTICO, ANTICOAGULANTE					
	EPARAN SOLFATO	INTERMEDIO	DERMA REPAIR (USO COSMETICO)					

An important core of Opocrin's activities is the specialised research group (R&D) focused on research areas where contemporary (and future) therapeutic needs are combined with the risks associated with new drug development, thanks also to fruitful collaborative relationships with the academic world. The reference sector makes relations with regulatory authorities and ministerial authorities extremely important, since the Company's production plants, located in Corlo di Formigine (MO), Nonantola

Opocrin has obtained *Good Manufacturing Practices* (GMP) certification, Integrated Environmental Authorisation for all plants, as well as, for the Corlo and Nonantola plants, Certification of conformity to BS OHSAS 18001:2007 (UNI ISO 45001:2018 from 2020) and UNI EN ISO 14.001:2015 *standards* of its Integrated Safety and Environment Management System (SGSA), which also complies with the requirements of Legislative Decree 105/2015 for the Prevention of Major Fires, where applicable. These UNI ISO 45001:2018 and UNI EN ISO 14.001:2015 compliance certifications are also being obtained for the Trino Vercellese plant.

## 2.2. I OPOCRIN'S MAIN INDUSTRIAL AND BUSINESS PROCESSES

(MO) and Trino Vercellese (VC), are certified by them.

## 2.2.1 THE PRODUCTION PROCESS

FROM PRODUCT TO CERTIFICATION



Opocrin is active in the production of active pharmaceutical ingredients and the import of raw materials and intermediates for pharmaceutical use.

In particular, productive activities result in:

- extraction of active ingredients from animal organs;
- purification of crude products;
- import of raw materials and intermediates;
- batch quality control;
- packaging.

As a pharmaceutical company, Opocrin operates in full compliance with very high quality *standards*. For this reason, the control of raw materials, as well as the control and verification of all processes involved in the production process, are subject to pre-established quality criteria that comply with the cGMP (*current Good Manufacturing Practices*).

The Quality System adopted by Opocrin, which fully complies with the guidelines contained in the above-mentioned regulatory references, is applicable to and extends, with reference to the production cycle, to all the processes that make up the cycle itself and that are expressed in

- 1) identification of incoming and outgoing materials;
- 2) verification that the finished product corresponds to the established specifications;
- 3) carrying out in-process and end-of-process tests and checks;
- 4) customer relationship management;
- 5) order processing and delivery.

Opocrin's Quality System, which oversees the entire production cycle, has been defined, documented and implemented by means of:

- Quality System procedures;
- Quality Registration documents;
- quality plans (Training Planning, V.I. Planning, etc.).

As part of the production cycle, the technical product documents, i.e. the DMF (*Drug Master File*) / ASMF (Active *Substance Master File*) relating to active ingredients, form an integral part of the Quality documentation.

These documents are prepared for each product and contain a description of the production processes and controls carried out on the raw materials and the finished product.

The documents are filed with the relevant regulatory authorities and the production of the products is carried out as described in them.



These Authorities have the task of verifying the aforementioned documentation, inspecting the production site to verify the conformity of what has been declared by the Company, issuing authorisations/certifications and taking related/consequential measures as a result of what has been found (sanctions, withdrawal of authorisations/certifications, *etc.*).

In the pharmaceutical sector, the *Qualified Person* (QP) is the professional figure who has the burden of certifying that the protocols (*Good Manufacturing Practices*) in accordance with legislative decree 219/2006 have been respected. Opocrin has appointed three *Qualified Person*, respectively for the Corlo di Formigine production site, the Nonantola production site and the Trino production site.

The purpose of the affidavit, in short, is to assure the purchaser that all the rules governing the production of the various active ingredients by the company have been complied with.

This is because, as mentioned, the Regulatory Authorities, by authorising the production site where the products are manufactured, certify the individual production processes (on the basis of the *dossier* submitted previously by the company at the start of production) and set the traceability limits on which the final products must be manufactured.

On the subject of equipment conformity, it should be noted that the regulatory authorities have the power to review the adequacy of equipment to ensure product conformity.

Unlike other types of industrial facilities, in the case of Opocrin the plant and machinery must meet a *standard* approved by the Regulatory Authorities and the Public Administration. Therefore, the Company is required to constantly verify the proper maintenance of all plants and to promptly adapt them to any indications that may be received from the Regulatory Authorities and the Public Administration.

The installed equipment is subject to qualification and subject to periodic preventive maintenance programmes as well as the necessary maintenance interventions in case of failure.

Responsibility for the maintenance, calibration and qualification of installations lies with the Industrial Engineering Function.

All work performed on installations is subject to timely documentation.

With particular reference to the production cycle of active ingredients, the main document that regulates the entire process is the *Batch Record*, otherwise known as the processing sheet.

The *Batch Record* is a step-by-step document that regulates the individual production process by strictly stating:

- the raw materials to be used;
- the equipment to be used;
- the premises where the process itself is to take place;



• the detailed modalities of the steps in the production process.

The document, which effectively translates into an operating instruction, regulates and traces each stage of production (production methods and process control, identification of equipment, description of critical parameters, process efficiency, references to product safety requirements) allowing traceability of the products and raw materials used in order to guarantee product quality.

The Production Manager, Quality Assurance and the *Qualified Person* of the relevant production site participate in the preparation of the *Batch Record*.

Each figure involved in the individual *steps in* the formation of the *Batch Record* initials the results of their work and/or the controls performed. All Quality documentation collected (processing sheet, status labels, analysis requests and process documentation) is handed over to Quality Assurance (QA) for initial verification and is then forwarded to the relevant QP for final approval and product release. The final responsibility for the product remains with the QP of reference, in accordance with the provisions of legislative decree 219/2006, which has the task of verifying, certifying and signing that the batches sold to its customers have been produced in full compliance with all the regulations governing the entire production cycle. QP therefore affixes its signature to guarantee the successful outcome of all the processes involved in the production cycle.

All product documentation - certified by QP - is made available to customers and regulatory authorities.

Production is planned on the basis of a production schedule (often at the beginning of the financial year) which - in line with company policy - aims to minimise stocks of raw materials and finished products and consequently to produce 'on demand', i.e. strictly according to orders received.

Such a strategy significantly reduces, on the one hand, the business risks arising from problematic accumulations of unsold stock and, on the other hand, the corresponding risk of commission of Offences related to the urgency of any rapid disposal of stock.

The raw materials used in the production cycles are purchased exclusively from a limited number of qualified suppliers, subject to periodic verification.

All products that become part of the production cycle, whether raw materials or intermediate products, refer to a specification that precisely defines their quality specifications and the methods used to control them.

The analytical documentation relating to the checks performed is reviewed and checked according to the procedures laid down for the product release *process*. In the event of non-compliance, procedures are activated in which the criteria for 'Rejected' are established and regulated.



Any process and/or control deviations are also handled according to the dictates of specific procedures.

Certain phases of the production process can be outsourced through subcontracting; in these cases, the delegated activity is contractually regulated with the subcontractor's commitment to guarantee the same quality *standard* as that guaranteed by Opocrin, which, as mentioned above, has the possibility of checking the subcontractor's work at any time through scheduled *audits*.

Quality Assurance periodically supervises production *processes* by conducting inspections (*internal audits*) within the company itself. This form of 'self-control', the results of which are communicated to top management, aims to guarantee - in an even more stringent manner - the correctness and good outcome of all the processes that make up the production process.

#### RELATIONS WITH THE PUBLIC ADMINISTRATION IN THE PRODUCTION PROCESS

In addition to the aforementioned relations with the Regulatory Authorities, the Company maintains relations with the Public Administration, in particular with the local territorial bodies responsible for issuing the necessary authorisations that are indispensable for regular company operations.

#### THE SAFETY AND HEALTH PROTECTION OF WORKERS IN THE PRODUCTION PROCESS

ORGANISATION OF THE SECURITY FUNCTION

The Employer has appointed a figure to whom, pursuant to Article 16 of Legislative Decree No. 81/2008, as amended and supplemented, has been entrusted with the delegation of safety and environment matters, with unlimited spending power (the Safety and Environment Function Delegate).

Opocrin has also established, pursuant to Article 31 of Legislative Decree 81/2008, as amended, an internal Company Prevention and Protection Service (SPP), consisting of a Manager (RSPP) and an Employee (ASPP) for each region in which the Company's production plants are located, therefore, Emilia-Romagna and Piedmont. The SPPs are coordinated by the Environmental Safety Manager, in order to ensure a consistent and uniform approach to the issues arising in the various plants.

There is also an additional Safety and Environment officer to support the previous functions.

The company's SPP is supported by external consulting companies for specialised risk assessments. Each plant has a Workers' Safety Officer (RLS), elected by the employees, who receives appropriate training and regular updates.



Health surveillance has been entrusted to a Competent Doctor (external professional) for each region where the Company's production plants are located, pursuant to Article 41 of Legislative Decree 81/2008 and the Company's internal procedures.

A number of workers in charge of implementing emergency management measures (including fire prevention, first aid and major accident prevention) have been designated and regularly receive adequate education, information and training.

#### HEALTH SURVEILLANCE

The Competent Doctor, appointed pursuant to Legislative Decree 81/2008 and subsequent amendments and additions, draws up an annual health protocol, highlighting the frequency and types of checks to which employees are subjected in view of the specific risk assessments drawn up.

At the periodic safety meeting, the Competent Doctor prepares an anonymous annual report on the progress of health surveillance, the organisational arrangements for which are governed by a specific company procedure.

## RISK ASSESSMENT

The company SPP, also assisted by external consultants, carries out risk assessments as provided for in Articles 28 and 29 of Legislative Decree 81/2008.

Following these assessments, the SPP submits to the Employer and, through him, to the Functional Delegate for Safety and Environment, a programme of appropriate measures to ensure a progressive improvement of safety levels in order to further reduce residual risks.

The document is submitted to the plant's RLS and is also drafted with the cooperation of the Medical Officer.

The risk assessment is regulated by a special company procedure and is updated when there are changes in the production process or work organisation:

- significant for the health and safety of workers;
- in relation to the degree of development of technology, prevention or protection;
- as a result of significant injuries;
- when the results of health surveillance show it to be necessary;
- as a result of regulatory changes.

The risk assessment document (D.V.R.), the contents of which are to be considered herein as fully referred to in the latest updated version (also with regard to the actions and conduct required to be



observed in connection with the offences provided for in Articles 589 and 590 of the Criminal Code) mainly covers the following specific risks

- chemical and carcinogenic risks (hazardous substances);
- biological risk;
- fire and explosion risk;
- risk of manual handling of loads;
- risk from physical agents (noise, vibration, radiation, electromagnetic fields);
- risk of major accidents *pursuant to* Legislative Decree 105/2015, for the Corlo di Formigine site only.

#### REGULAR MEETING AND REVIEW

A periodic meeting is organised annually, subdividing the production plants according to the region in which they are located, which is attended by the Employer or his delegate, the SPP, the Competent Doctor, RLS, in accordance with the provisions of Article 35 of Legislative Decree 81/08 and subsequent amendments and supplements.

At this meeting, the SPP submits the following to the participants for their consideration:

- updates in risk assessment;
- trends in accidents, occupational diseases and health surveillance (by the Competent Doctor);
- selection criteria, technical characteristics and effectiveness of personal protective equipment;
- information and training programmes.

Also on an annual basis, a review of the Environment and Safety Management System is organised, according to the provisions of the individual reference standards and in accordance with the specific procedure:

- results of internal audits and conformity assessments;
- results of any external audits and inspections by the competent authorities and/or bodies;
- results of participation and consultation;
- performance;
- comparison with set targets and safety improvement objectives;
- dangerous occurrences, preventive and corrective actions;
- status of authorisations, etc.

HEALTH AND SAFETY EDUCATION, INFORMATION AND TRAINING



An annual training, information and instruction plan is prepared for personnel, including supervisors and managers.

In the case of new recruits, the PPS organises first-entry training as well as general and/or specific training in accordance with the regulations, within the first 60 days of the worker's employment.

The Safety and Environment Function, among its various information/training initiatives, also delivers quarterly internal circulars to Personnel aimed at informing and updating workers on issues of interest to the Company concerning safety and the environment and the prevention of major accidents *pursuant to* Legislative Decree 105/2015 (the so-called Seveso III Directive).

#### EXTERNAL COMPANIES

The activities of external companies for the execution of works or service contracts are regulated by means of a DUVRI (single document for the assessment of interference risks) or simple information, pursuant to Article 26 of Legislative Decree 81/2008 and subsequent amendments and additions, as per the specific company procedure.

Where necessary, the Company shall train, inform and educate, with regard to the specific risks present, workers employed in the performance of works or service contracts at its production sites. When falling under Title IV (Construction Sites), a Safety Coordinator is appointed during the design and execution phases (external consultants) and a Safety and Coordination Plan is drawn up and a notification made to the competent bodies.

# THE ENVIRONMENTAL FUNCTION AND RELATED PROCESSES

The Company has adopted all appropriate measures for the prevention of environmental offences by regulating them in specific internal company procedures - SGSA certified according to the UNI ISO 14001:2015 *standard* - and has obtained and maintains active for all its plants the Integrated Environmental Authorisation (AIA), to which it is subject as an industrial complex that uses a chemical and biological process for the manufacture of basic pharmaceutical products (point 4.5 Annex VIII to Part Two of Legislative Decree 152/2006, as amended and supplemented).

On the occasion of each change, Opocrin first submits a request for authorisation to the competent regional authority (to ARPAE for Emilia-Romagna and to the Province for Piedmont).

The Functional Delegate for Safety and Environment also holds the title of manager with specific reference to the provisions of Legislative Decree 152/2006, as well as Legislative Decree 105/2015 (the so-called Seveso III Directive) for the Corlo production site.



#### **WASTE**

The company's production activity involves the generation of both hazardous and non-hazardous waste.

The waste is entrusted to authorised and qualified suppliers, in tankers or packaged appropriately.

The company, as required by the AIA, performs the necessary analyses annually for waste characterisation purposes.

The amount of waste produced and subsequently disposed of is recorded in a loading and unloading register, according to the type of waste, as well as on forms at the time of disposal.

#### WATER DISCHARGES

The Company has a purification plant at which the production effluents of the Corlo site and part of the effluents of the Nonantola site are treated (as provided for in the Integrated Environmental Authorisation of the Corlo site) and discharged in compliance with applicable regulations.

Waste water from the Nonantola site, in addition to the above, is disposed of through authorised external companies or discharged into the public sewerage system, in accordance with applicable regulations.

Wastewater from the Trino plant is first treated at a purification plant and then discharged into the receiving water body.

The Environmental Safety Function arranges for periodic analyses, conducted both internally by the Company's QC laboratory and externally by authorised laboratories, of the plant's functionality, as well as official analyses at least every six months by external laboratories as required by the AIA.

#### ATMOSPHERIC EMISSIONS

Each emission listed in the AIA is numbered and uniquely identified near the point of emission.

The AIA identifies the most significant emission points to be subjected to self-monitoring at the Corlo, Nonantola and Trino sites.

The date, time, results of the measurements and the production load during the sampling are recorded in a special register ('self-monitoring register').

Between the months of April and May each year, the Company submits to the competent authorities an environmental *report* for each plant, which includes, for the Corlo and Trino plant, also a solvent management plan, showing the amount of diffuse emissions for the previous year.

#### EMISSIONS TO SOIL



The Functional Delegate for Safety and the Environment, as manager, within the scope of its production controls, carries out - through internal technicians - monitoring of the state of preservation of all structures and containment systems of any warehouse, keeping them in a fully efficient condition at all times, in order to avoid soil contamination.

For each plant, the company submitted the 'baseline report' for the management of emissions into the soil and subsoil.

#### SOUND EMISSIONS

The Delegate of Functions for Safety and Environment, as manager, must intervene promptly if deterioration or breakage of installations or parts thereof causes obvious noise pollution.

It must also periodically carry out a noise impact assessment and a new preventive noise impact prediction/assessment in the case of changes to installations that alter the noise emissions of the production facility.

Opocrin complies with the noise zoning limits of the municipalities where the plants are located.

#### MONITORING PLAN

The company has set up a monitoring plan for all plants, as required by the AIA.

#### 2.2.2 THE PURCHASING PROCESS

The four macro-areas of procurement can be briefly identified as follows:

- 1. Purchases of consumables;
- 2. Purchases of durable goods;
- 3. Purchases of raw and ancillary materials;
- 4. Entrustment of services.

All acts aimed at the purchase or supply of goods and/or services must be authorised through the approval of the purchase request (RdA) issued, in electronic format, by Opocrin's operational/management system.

The transaction for the creation of the RoA must be filled out in all its mandatory parts (supplier, description, code of the good and/or service, quantity requested, price, cost centre, delivery date and destination warehouse) in an exhaustive and correct manner by the requesting function, with the aim of guaranteeing the exact passage of information to the functions that have the task of assessing the validation of the document and of issuing the consequent authorisation to purchase. The electronic



form must, therefore, contain all the information necessary for a correct, precise and clear identification of the good and/or service requested.

The person proposing the purchase draws up the RoA document which must be sent to the head of function or to his direct manager (or, more generally, to the head of the cost centre) for approval of the purchase request.

The SAP management authorisation process provides for the verification of the availability of the expenditure for the requested purchase with the approved *budget*, since each expenditure commitment for the purchase of goods and/or services must be undertaken in full compliance with the approved *budget* for each cost centre. The approving manager is also responsible for verifying the consistency of the expenditure item with the approved *budget*. Each relevant function must have full knowledge of the approved *budgets* - related to the functions under its responsibility - and the possibility of verifying them accurately at any time.

The RdA document approved by the person in charge of the cost centre is automatically transmitted by the management system to the Procurement Office, which has the task of preliminarily verifying the formal correctness of the document received and, if it detects inaccuracies and/or omissions, of referring it back to the function that transmitted it with a request for clarification of the content or with an indication of the changes to be made.

The Procurement Office, having completed the preliminary checks on the RoA document, proceeds with the acceptance of the purchase request received and the selection of the supplier, where applicable, by acquiring a number of quotations; it being understood that, in the event that the peculiarities of the goods and/or services requested are such as to entail specific technical skills for the identification of the supplier, the Procurement Office coordinates with the requesting function to select the most appropriate supplier and to request quotations.

Purchases of raw and ancillary materials are made on the basis of production planning derived from a sales projection provided by the sales function.

Once the process of selecting the supplier of the good and/or service has been completed, following any evaluation of the commercial offers received, the Procurement Department proceeds to send the purchase order.

The sending of the order to the supplier represents acceptance of the offer made by the supplier; with the sending of the order, the contract for the purchase or supply of the goods and/or services requested is therefore finalised, and to all intents and purposes binding on the Company.

The order must be marked with all the essential and identifying elements necessary for the correct completion of the supply contract; it must therefore bear a clear and correct indication of the supplier,



the good and/or service to be purchased and all further references useful to better define the agreement reached (quantity, price, delivery terms and conditions, payment terms and conditions, *etc.*).

The contractual conditions agreed for the purchase or supply of a good and/or service must be known and knowable by all those involved in the purchasing process itself, so that there is a clear understanding and identification of the responsibilities of each.

In the event the order is issued in execution of a contract already entered into with one or more suppliers, contractors and/or consultants - including technical supply specifications relating to raw materials - that regulates *ex ante* the supply relationship by providing for the terms and conditions of purchase of a good and/or service, explicit reference must be made to these in the order request document and in the order itself; this obligation must be observed even in the event that a contract is not formalised with the supplier, but supply conditions have however been previously agreed upon, of which the order is in any case a fulfilment.

If there are no specific contracts regulating the purchase or supply of a good and/or service, but agreements are made to regulate the purchase or supply - at the contracting stage - by means of e-mail and/or fax communication, these must be retained and forwarded together with the RoA and the order document, in the same way as the documentation relating to the entire procedure.

Documentation referring to the RoA is stored in the SAP management system and made available for checks and verifications. Supply contracts are archived by the Legal Affairs Office, while *technical/quality agreements* are archived by the QP of the plant to which the supply refers.

In the case of purchase requirements on the cost centre, which exceed the *budget* limit and for which it is necessary to allocate additional sums, the extra *budget* request will be handled and approved by different parties depending on the total of the extra sum requested, within the SAP management system:

- amount less than and/or equal to € 50,000.00: the approval involves not only the Head of the cost centre but also the Head of the relevant Directorate;
- amount greater than € 50,000.00 and less than and/or equal to € 200,000.00: the approval involves not only the head of the cost centre but also the Head of the relevant Department and the CFO;
- amount exceeding € 200,000.00: the approval involves not only the head of the cost centre but also the Head of the relevant Department, the CFO and the Managing Director.

The request and approval of extra *budgets* within CAPEX will instead follow an approval *workflow* outside the SAP system, and the request must be submitted to the Management Control department.



#### 2.2.3 THE SALES PROCESS

## COMMERCIAL FUNCTION STAFF

The Commercial Function carries out activities related to the sale of products, while the *Operation* Function and the purchasing of certain strategic raw materials, in particular heparins and heparinoids (Strategic Raw Materials Purchasing Department).

The Commercial Services Department coordinates sales and pricing policies for the various customers in line with the indications given by the Commercial Director and in the light of the *forecasts/commitments* received from customers.

Raw materials are mainly purchased in dollars, while customer invoicing is almost always in euros. As a result, there is a potential exchange rate risk, which is contained through the implementation of hedging policies that take the form of forward currency purchases made at the same time as the order is received by the customer.

#### THE STANDARD PROCESS OF NEGOTIATION AND SALE

The sales process begins with contact with potential or established customers following their requests for supplies, followed by a commercial offer drawn up by the Company detailing quantity, price, delivery times and payment terms; in some cases, depending on the complexity of the commercial relationship and/or the economic importance of the agreement, it is incorporated within a structured contract

Following successful negotiations, the Company receives the purchase order from the customer (by e-mail) and subsequently forwards the final confirmation of the order to the customer.

At this point, the sales activity can be considered completed and the material execution of the requested supply is delegated to the production and technical departments, which work on the realisation of the product to be shipped to the customer.

Transport and insurance costs related to the delivery of the product to the customer are usually included in the sales price, unless specific cases of different INCOTERMS apply

## 2.2.4 ADMINISTRATIVE MANAGEMENT AND BUDGETING PROCESS

The Director of Finance and Control is responsible for and coordinates the Administration, Finance and Control activities of the Opocrin Group Companies and ensures their proper functioning in accordance with the defined policies and the statutory, fiscal and management deadlines of the same. He is responsible for the preparation of the statutory financial statements, the management of the *report* for the Board of Directors and attends the Board of Directors by invitation.



The activities carried out relate to management control, tax compliance, accounts receivable and payable, VAT invoicing, general accounting and management of relations with credit institutions.

#### ACTIVE BILLING

Active invoicing is the final step in the sales process.

Following acceptance of the Company's sales offer, the Sales Department enters the order confirmed by the customer and/or the provisions of the relevant commercial contract into the system.

Once the order is processed in production and the goods are prepared for shipment by the Logistics Function, the issue of the Transport Document (DDT) by the management system takes place.

As the last step in the process, the administration prepares the sales invoice on the basis of the information contained in the system.

With the entry into force from 1 January 2019 of the electronic invoicing obligation for the supply of goods and services performed between persons resident, established or identified in the national territory, the Company issues invoices in electronic format, which are subsequently sent to the Interchange System of the Italian Revenue Agency via a dedicated *provider*.

## CASH MANAGEMENT

As far as Italian customers are concerned, receipts are always handled by means of bank transfers such as bank transfers or bank receipts (Ri.Ba).

With regard to the collection of invoices from foreign customers, the medium used is the international bank transfer. No letters of credit are currently used.

In any case, the Company uses and accepts only traceable means of payment.

# PASSIVE INVOICING

Passive invoicing is the final step in the purchasing process, whether for goods or services.

The function requesting the good and/or service enters into the system a RoA approved by the function manager on the basis of the authorised *budgets*; this RoA is subsequently transformed into an order to the supplier by the Procurement Department.

The authorised function will accept the goods/services (EM goods entry) for accrued cost recognition, after checking whether they conform to the order.

Invoices received in electronic format through the Interchange System are printed by the administration and registered in the management system.



If the supplier's invoice shows conformity problems with the order, a 'stop payment' indication is placed on it.

To solve the problems encountered, the Administration contacts the requesting function/department that entered the RDA in the system for goods, and the Procurement Department for services.

Invoices that are not handled electronically are forwarded to the administration by the Procurement Department, and for strategic matters by the relevant department.

In relation to incidental expenses, management is not preventive but occurs ex post: when entering the purchase requirement into the system, the applicant does not have to enter any reference to these incidental expenses.

When registering the invoice, any additional value of ancillary expenses is added by the administration by means of a dedicated line in the system, on the basis of the amount already stated in the accounting document.

Accounting therefore takes place directly at the invoice view, without blocking the entry in the case of final values that differ from those entered when entering purchase requirements and without the need for further approval by the cost centre managers.

Incidental expenses that are accounted for directly on the invoice are as follows:

- collection charges;
- CONAI contribution;
- revenue stamps;
- miscellaneous expenses (e.g. administrative expenses, management fees, etc.);
- packaging costs;
- management charges.

In relation to transport costs, there is a different management method depending on the amount of the costs.

In the case of transport costs whose amount exceeds the threshold of EUR 200.00, contrary to the process for ancillary costs, the applicant and/or the Procurement Department (depending on the type of negotiation, internal or centralised) initiate a dialogue with the supplier to request an estimate in advance, so that they are made explicit and quantified in the relevant commercial offer.

In relation to invoices for telephone costs, car rental and maintenance, energy consumption, canteens, customs clearance, disposals, clothing, office rental and temporary workers, the accounting is direct invoice view.

# PAYMENT MANAGEMENT



Payments of supplier invoices are normally made by traceable payment methods.

The banking proxy is issued to the Managing Director.

Payments through the *Remote Banking* service are made as follows:

- the Treasury Specialist prepares the payment order on the system;
- the Head of Human Resources and Personnel Administration prepares monthly payment orders for employees' salaries in the system;
- the Managing Director authorises the payment on the electronic system, after having initialled an appropriate paper bill prepared by the Administration or, in the case of salaries, by the Director of Finance and Control.

Payments can also be made in cash, using the money in the 'cash box', only for small current expenses. The cash is replenished by direct withdrawals from banks by bank cheque and bank proxy, under the sole signature of the Managing Director.

Further payments (e.g. online purchases, consumables at shops, *etc.*) can be made by company credit card.

During business trips in Italy and abroad, the Company also makes credit cards or rechargeable cards available to the company departments from time to time requesting them, to be used in accordance with the provisions of the internal company regulations "Employee Travel".

#### STOCK ACCOUNTING

The company is obliged to keep tax records of the warehouse.

The handling of goods is tracked through loading and unloading operations on the management system.

The inventory is taken at the end of the semester (interim inventory) and at the end of the year.

During the inventory verification phase, all internal stock movements are stopped until the inventory is completed. During the year-end inventory, the physical count is carried out under the control of the auditor.

#### PREPARING FINANCIAL STATEMENTS

The Company performs interim accounting closures to assess the economic, asset and financial situation during the year, in order to inform the Board of Directors of the company's performance on a frequent and timely basis.

At the end of the accounting year (1/1 - 31/12), the Administration is responsible for the preparation of the Company's final statutory financial statements.



On this aspect, it should be noted that the Company is subject, by law, to the control of the Board of Statutory Auditors, composed of professionals duly enrolled in the competent professional registers, and to the auditing of its financial statements by the Auditing Company.

The steps according to which the process of preparing the annual financial statements is developed are as follows:

- 1. Preparation of draft accrual-based financial statements as at 31/12 *before* taxation, by the Director of Finance and Control;
- 2. tax calculation carried out by the external professional appointed by the Company, assisted by the Director of Finance and Control;
- 3. Preparation of the financial statements in final form, taxed and in accordance with EEC reporting by the Director of Finance and Control.

The financial statements are prepared taking into account the regulatory changes introduced by Legislative Decree 139/2015, in compliance with the rules contained in Articles 2423 et seq. of the Italian Civil Code, and in particular with the valuation criteria set out in Article 2426 of the Italian Civil Code, interpreted and supplemented by the accounting standards issued by the Italian Accounting Body.

It consists of: Management Report, Balance Sheet, Income Statement, Cash Flow Statement and Notes to the Financial Statements;

- 4. presentation, discussion and approval of the budget by the Board of Directors;
- 5. presentation and approval by the Shareholders' Meeting.

The auditing company follows all process steps in order to complete the audit activities within the deadlines set for the approval of the financial statements by the Board of Directors and the Shareholders' Meeting.

At the end of the accounting year (1/1 - 31/12), the Company's Management Control is also responsible for the preparation of the consolidated financial statements of the Opocrin Group.

The consolidated financial statements include the financial statements of Opocrin S.p.A. and its subsidiaries.

In this regard, it should be noted that the Company prepares consolidated financial statements on a voluntary basis, as it is exempt from the obligation to prepare them pursuant to Article 27, paragraph 3 of Legislative Decree 127/1991.

The steps according to which the process of preparing consolidated financial statements is developed are as follows:



- 1. aggregation of the accounting data of the separate accrual-based financial statements as at 31 December of the various companies belonging to the Group;
- 2. preparation of consolidation entries;
- 3. preparation of the consolidated financial statements on an accrual basis as at 31/12, by the Director of Finance and Control.
  - The consolidated financial statements are prepared in accordance with *International Financial Reporting* Standards (IFRS Standards);
- 4. presentation, discussion and approval of the consolidated financial statements by the Board of Directors.

Starting with the financial statements for the financial year 2025, Opocrin will also be obliged to disclose non-financial information and report on its ESG performance in a transparent and measurable manner, by means of the sustainability report. Through this document, the company will have to carry out a self-analysis in order to identify any shortcomings, choosing corrective actions and communicating the strategies to be activated in order to increase value creation.

In order to comply with regulations concerning sustainability reporting and *disclosure* relating to ESG factors, attention must be paid to cases that could integrate the commission of relevant offences, also from a 231 perspective.

Among them, an abstractly configurable offence could be that of false corporate communications under Articles 2621 and 2622 of the Civil Code, which punishes untrue declarations concerning financial, economic and/or asset information of the company.

While it is true that non-financial information does not directly concern the Company's economic, equity or financial situation, what is certain is that such information will take on an increasingly central value, and this circumstance could have consequences given that the sustainability report containing information of an ESG nature, i.e. environmental, social and *governance*, will become an integral part of the financial statements as a specific section of the management report pursuant to Article 2428 of the Italian Civil Code, thus assuming economic-financial relevance itself.

## 2.3 CORPORATE GOVERNANCE AND ORGANISATIONAL STRUCTURE OF OPOCRIN

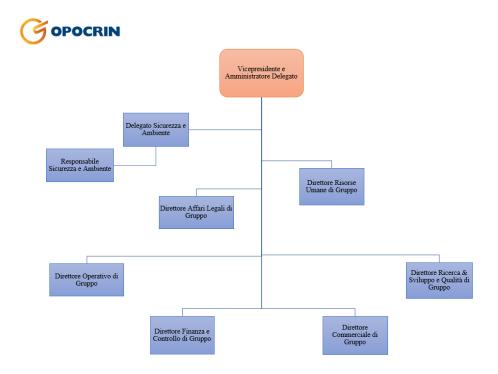
Opocrin's corporate organisation is based on the so-called 'traditional model' founded on the following corporate bodies: the Shareholders' Meeting, the Board of Directors (chaired by the Chairman of the Board of Directors and with two Managing Directors) and the Board of Statutory Auditors, in addition to the Auditing Company.



The *corporate governance* model is completed by the set of powers and proxies, the procedures and regulations for internal control, the Code of Ethics and the Model *pursuant to* Legislative Decree 231/2001, all approved by the Board of Directors, with which directors, auditors, employees and, in some cases, those who enter into contractual relations with the Company (Collaborators, Third Parties, etc.) must comply.

The company's organisational chart presents a substantially traditional organisational structure with the classic functions of a manufacturing company: Research and Development and Quality Management, Human Resources Management, Legal Affairs Management, Commercial Management, Operations Management, and Finance and Control Management.

The first-level functions report directly to the Vice-Chairman of the Board of Directors and Chief Executive Officer, as shown in the General Organisation Chart of the Company.



## 2.4 INTEGRATED COMPLIANCE

In order to ensure greater efficiency of the *governance* system, it is advisable to adopt an integrated approach that allows the rationalisation of risks related to business processes and the activation of synergies in their management and control.

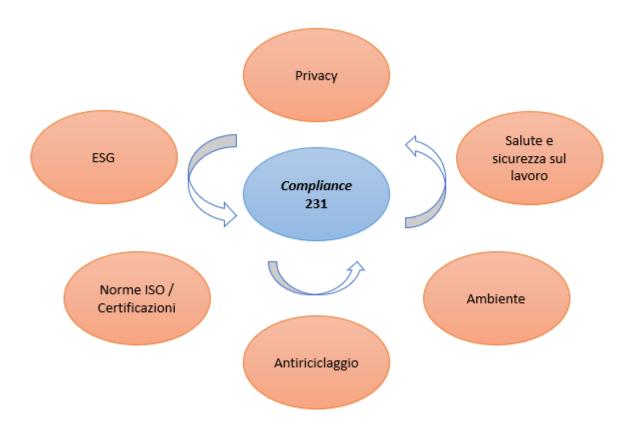
As pointed out by Confindustria, in its Guidelines for the construction of Models 231, "the transition to integrated *compliance* could allow [...] Entities to":

i. rationalise activities (in terms of resources, people, systems, etc.);



- ii. improve the effectiveness and efficiency of *compliance* activities;
- iii. facilitate information sharing through an integrated view of different needs.

The adoption of an integrated *compliance* system is also appropriate because of the many and considerable interaction between the regulations in force. Below are some of the sector regulations that directly intersect with the regulations of Decree 231.



## **2.4. 1PRIVACY**

During 2023, the company embarked on a project to overhaul the Group's privacy department.

With a view to continual self-analysis and ever-increasing improvement, the Company has in fact decided, also with the support of external professionals, to comprehensively review the privacy documentation in use at the Company, as well as to sensitise and train even more thoroughly all personnel who could potentially come into contact with personal data, to process them correctly and in compliance with the applicable regulations.

To this end, the register of data processing operations carried out by the company was updated and refined, a co-ownership agreement was signed between Opocrin Group companies in relation to some



of them, privacy notices addressed to the different categories of data subjects were revised and updated, as well as the appointments of data processors and authorised persons.

The company also drew up the privacy organisation chart, updated its website and appointed a Group DPO, who can be contacted at opocringroup-dpo@opocrin.it and opocringroup-dpo@pec.it.

As far as company personnel are concerned, all employees were provided with a special training session, customised in relation to the Group companies and the functions they concretely hold; on this occasion, the main principles of the GDPR were illustrated, the figures of data controller, data processor, data subject and authorised person were described, and some practical cases were analysed; at the end of the training, participants were given an assessment test, which was mostly positive.

#### 2.4.2 BENEFICIAL OWNER

On 9 October 2023, the Decree of 29 September 2023 of the Ministry of Enterprise and Made in Italy was published in the Official Gazette, certifying the operation of the system for reporting data and information on beneficial ownership.

From the date of publication in the Official Gazette, the obliged parties would have had 60 days, i.e. until 11 December 2023, to send the communication about the beneficial owner to the territorially competent Chamber of Commerce, as provided for in Article 3, paragraph 6, of the Decree of the Ministry of Economy and Finance No. 55 of 11 March 2022 ('DM 55/2022').

As the deadline approached, however, due to the critical issues highlighted in particular in the area of privacy and wide-ranging access to data, a number of fiduciary associations had lodged an appeal with the Lazio Regional Administrative Court requesting the annulment, subject to suspension of the effectiveness, of the decree on the operation of the Register of beneficial owners, as set out in Ministerial Decree No. 55/2022.

The precautionary petition for the suspension of the decree had been preliminarily granted, with suspension of the deadline for sending notifications; however, on 9 April 2024, the Lazio Regional Administrative Court rejected the appeals filed, resulting in a new start of the deadline for communications.

Following the appeal of the judgments by some of the plaintiff associations, on 17 May 2024 the Council of State ordered the suspension of the enforceability of the judgments of the Regional Administrative Court of Lazio of 9 April, and set the hearing for discussion for 19 September 2024, resulting in a new suspension of the communication deadlines.

Notwithstanding the changes that are affecting the operation of the Register of beneficial owners, given the relevance of the issue potentially also from a 231 perspective, on 21 December 2022, the



Company had formally identified the beneficial owner in accordance with the criteria set forth in the regulations through a specific resolution of the Board of Directors.

The advisability of making such an identification at the board meeting had, moreover, been considered as a *best practice* to be undertaken with a view to *accountability* aimed at making explicit the assessments underlying the identification of the beneficial owner prior to the relevant disclosure to the Chamber of Commerce.

Following the interpretation of Article 20, Paragraph 2, of Legislative Decree 231/2007 (the so-called AML Decree - *Anti Money Laundering*) and applying it to the Company's shareholding structure, it was inferred that shareholdings in excess of 25% are held by two shareholders: Bianchini-Saetti Holding S.r.l. and Chiesi Farmaceutici S.p.A.

Starting from the aforementioned legal persons, the chain of participation was then moved up the chain to the natural persons concerned.

# 2.4.3 CERTIFICATIONS

The Company has obtained and maintains active UNI ISO 45001:2018 (ex 18001) and UNI EN ISO 14001:2015 compliance certifications for its Corlo and Nonantola plants since 2016 and 2022, respectively.

These UNI ISO 45001:2018 and UNI EN ISO 14.001:2015 conformity certifications are also being obtained for the Trino Vercellese plant.

## <u>UNI ISO 45001:2018</u>

The 2018 UNI ISO 45001 standard is an international standard concerning the occupational health and safety management system.

Compliance with the international standard ensures compliance with the requirements for Occupational Health and Safety Management Systems and enables an organisation to better assess risks and improve its performance, considering its context and stakeholders.

The aim of the standard is to make it systematic for a company to control, know, be aware of and manage all possible risks inherent in situations of normal and extraordinary operations in the workplace.

The UNI ISO 45001 standard also requires the management of an organisation to commit itself and its workers directly to the identification and management of the system, thus creating a virtuous circle of improvement in workers' health and safety.



ISO 45001 certification is based on occupational health and safety management and requires organisations to continuously improve, thus providing all stakeholders with the assurance of compliance with specified safety policies.

# <u>UNI EN ISO 14001:2015</u>

The 2015 UNI EN ISO 14001 is a voluntary international standard that specifies the requirements for an environmental management system.

To define the ISO 14001-compliant management system, it is necessary:

- carry out an analysis of the environmental aspects (emissions, resource use, etc.) that an organisation actually has to manage, understand the legislative framework and requirements applicable to the company and assess the significance of the impacts;
- define a company policy on environmental issues;
- define specific environmental responsibilities;
- define, implement and maintain the activities, procedures and records required by the requirements of the standard.

A UNI EN ISO 14001:2015 certified environmental management system allows, among other things:

- the control and maintenance of legislative compliance and the monitoring of environmental performance;
- the reduction of waste (water consumption, energy resources, etc.);
- to ensure a systematic and prearranged approach to environmental emergencies;
- the implementation of defined methods for the prevention of environmental crimes.

#### Legislative Decree 105/2015, so-called SEVESO DIRECTIVE III

The Company's Corlo site also complies with Legislative Decree 105/2015, the so-called Seveso III Directive, which aims to prevent and control major-accident hazards involving hazardous substances and to improve the safety of industrial activities using such substances by imposing strict risk management, emergency planning and public information requirements.

#### UNI PDR 125:2022

In 2024, the Company also obtained gender equality certification under the UNI/PdR 125:2022 guidelines for its management system.

Any non-compliance found with respect to Gender Equality can be reported:

- by e-mail to the Human Resources Department;



- via the internal Whistleblowing reporting channel available at https://opocringroupopocrin.integrityline.com/;
- by means of a hard copy communication, possibly also in anonymous form, to the Human
   Resources Department to be filed in the document collection boxes at each company site.

#### 2.4.4 OPOCRINAID COMMITTEE

In March 2023, the Company set up the OpocrinAID Committee, aimed at managing sponsorships, donations and other acts of generosity made by Opocrin Group Companies to third parties.

The Committee, a non-profit organisation, is chaired by the Chairman of Opocrin S.p.A., and stems from the Group's desire to direct internal synergies to the best of its ability in order to achieve common objectives of cultural, charitable, social and humanitarian value, pursuing purposes of common benefit for the various stakeholders, also considering the impact of sustainability aspects of the same.

The Committee focuses on various projects, activating solidarity initiatives such as funding, concrete aid and whatever is needed to support foundations, associations, hospitals, schools, universities, public and private institutions.

The Committee operates in full compliance with the principles of voluntariness, independence, neutrality, objectivity, transparency, impartiality and in accordance with the provisions of Legislative Decree 231/2001, as well as the Confindustria Guidelines and the Company's Model and Code of Ethics.

The Committee also works to safeguard the principles of diversity and inclusion already inherent in Opocrin Group companies, and to respect gender equality according to the UNI PdR125:2022 standard.

#### 2.4.5 POSSIBLE SYNERGIES BETWEEN THE MODEL AND ESG FACTORS

On 25 September 2024, Legislative Decree 125/2024 came into force, with which Italy transposed the *Corporate Sustainability Reporting* Directive - *CSRD*, (Directive 2022/2464/EU), replacing the *Non Financial Reporting Directive - NFRD* (Directive 2014/95/EU), which concerns the obligation for companies to disclose non-financial information and report on their ESG (*Environmental*, *Social*, *Governance*) *performance* in a transparent and measurable manner. For Opocrin, this obligation will be in force as of the financial statements for the financial year 2025.

The CSRD requires companies to:

• measure and monitor their impact on the environment, society and governance;



- publish information on this impact in an easily accessible sustainability report;
- follow a common reporting framework to ensure comparability of data.

Under this directive, companies will therefore be required to report not only on financial aspects, but also on sustainability issues and impacts on operations, the environment and people, specifying the risks and opportunities arising from sustainability factors that influence company performance.

ESG issues may also be connected with certain types of offences relevant under Legislative Decree 231/2001.

These connections are manifested *first and foremost* in the strong affinities between the Decree's areas of interest and the *Sustainable Development* Goals (SDGs) agreed upon by the UN member states as part of the Global Agenda for Sustainable Development, which are expressed in 17 macro-objectives and 169 targets identified by the UN to achieve sustainable development by 2030.

#### I 17 MACRO-OBIETTIVI (AGENDA 2030)

- 1. Sconfiggere la povertà
- 2. Sconfiggere la fame
- 3. Salute e benessere
- 4. Istruzione di qualità
- 5. Parità di genere
- 6. Acqua pulita e servizi igienico-sanitari
- 7. Energia pulita e accessibile
- 8. Lavoro dignitoso e crescita economica
- 9. Imprese, innovazione e infrastrutture
- 10. Ridurre le disuguaglianze
- 11. Città e comunità sostenibili
- 12. Consumo e produzione responsabili
- 13. Lotta contro il cambiamento climatico
- 14. Vita sott'acqua (salvaguardia degli oceani)
- 15. Vita sulla terra (salvaguardia degli ecosistemi terrestri)
- 16. Pace, giustizia e istituzioni solide
- 17. Partnership per gli obiettivi

It is, in fact, possible to identify a convergence between the *Sustainable Development Goals* of the United Nations' Agenda 2030 and the general interests protected by the Decree: in fact, the internal control system implemented with Model 231, by impacting sensitive activities also on the ESG front, can contribute to the general pursuit of many of the sustainability objectives.



	ESG	Reati presupposto d.lgs. 231/2001	SDGs
_	E	Reati Ambientali (art. 25-undecies)	3. Salute e benessere 6. Acqua pulita e servizi igienico-sanitari 11. Città e comunità sostenibili 12. Consumo e produzione responsabili 13. Lotta contro il cambiamento climatico 14. Vita sott'acqua (salvaguardia degli oceani)
			15. Vita sulla terra (salvaguardia degli ecosistemi terrestri)
	s	<ul> <li>Delitti contro la personalità individuale (art. 25-quinquies)</li> <li>Delitti di omicidio colposo e lesioni gravi o gravissime commesse con violazione delle norme antinfortunistiche e sulla tutela dell'igiene e della salute sul lavoro (art. 25-septies)</li> <li>Impiego di cittadini di paesi terzi il cui soggiorno è irregolare (art. 25-duodecies)</li> <li>Razzismo e xenofobia (art. 25-terdecies)</li> </ul>	3. Salute e benessere 5. Parità di genere 8. Lavoro dignitoso e crescita economica 10. Ridurre le disuguaglianze 11. Città e comunità sostenibili 12. Consumo e produzione responsabili
	G	<ul> <li>Indebita percezione di erogazioni, truffa in danno dello Stato, di un ente pubblico o dell'Unione europea o per il conseguimento di erogazioni pubbliche, frode informatica in danno dello Stato o di un ente pubblico e frode nelle pubbliche forniture (art. 24)</li> <li>Peculato, concussione, induzione indebita a dare o promettere utilità, corruzione e abuso d'ufficio (art. 25)</li> <li>Reati Societari (art. 25-ter)</li> <li>Delitti contro l'industria e il commercio (art. 25-bis.1)</li> <li>Reati di abuso di mercato (Art. 25-sexies)</li> <li>Ricettazione, riciclaggio e impiego di denaro, beni o utilità di provenienza illecita, nonché autoriciclaggio (art. 25-octies)</li> <li>Reati Tributari (art. 25-quinquiesdecies)</li> </ul>	12. Consumo e produzione responsabili 16. Pace, giustizia e istituzioni solide 17. Partnership per gli obiettivi

In this perspective, Model 231 can be a significant starting point for *governance* that supports the company in terms of sustainability and, at the same time, a useful *compliance* tool to strengthen the implementation of corporate procedures also in terms of ESG.

The 231 Model, in fact, contains principles, rules, prohibitions and rules of conduct necessary to regulate corporate conduct that could even hypothetically give rise to the commission of Offences in the interest and to the advantage of the Company. From this point of view, enriching and supplementing it by introducing ESG rules of conduct not only makes 231 risk prevention more



effective,	but also	avoids	a potential	negative	impact	on	sustainability	to t	he o	detriment	of the
Company	and its s	takeholde	ers.								



# 3. THE ORGANISATION, MANAGEMENT AND CONTROL MODEL OF OPOCRIN

Opocrin - within the framework of the already existing internal control system and in order to best ensure the conditions of efficiency, fairness, loyalty and transparency in the conduct of business - has implemented all the activities deemed necessary to ensure the adequacy of its own Model to the provisions of Legislative Decree 231/2001 and, also in consideration of the legislative innovations that have occurred from time to time, of the consequent expansion of the predicate offences as well as of the progressive interventions of case law on the matter, has proceeded to subsequently update and revise the Model.

Pursuant to the provisions of Article 6(1)(a) of the Decree, the Company - by means of a risk mapping process, as well as an assessment of the activities, existing controls and the corporate context in which it operates (so-called *risk assessment*) - has identified the corporate activities exposed to risk in the context of which Offences may potentially be committed (so-called sensitive activities).

In relation to the areas identified as 'sensitive', in order to prevent or mitigate the risk of such offences being committed, Opocrin has therefore formulated a number of principles of conduct and general prevention protocols applicable to all sensitive activities, as well as specific prevention protocols for each of the identified risk activities.

The types of Offence considered relevant for the Company's liability will be analysed and described in the Special Part of the Model and the sensitive activities will be identified in relation to them, i.e. the activities in which it is theoretically possible for an Offence to be committed, as identified at the outcome of the *risk assessment* carried out. Furthermore, the principles and rules of conduct for the organisation, performance and control of the operations performed within the various sensitive activities will be dictated and specific prevention procedures will be identified.

## 3.1 OFFENCES THAT MAY AFFECT THE COMPANY

The Company has identified, among the cases contemplated in the Decree, the Crimes potentially relevant for its administrative liability at the outcome of the *risk assessment* activity better described in the Special Part of the Model, for the purposes of which it took into consideration - *inter alia* - the activity carried out by the Company and the socio-economic context of reference, as well as the corporate 'history' and the relations that the Company establishes with Third Parties.

With reference to the Crimes envisaged by the Decree as a cause of the Entity's administrative liability and not contemplated in the Special Part of the Model, after careful analysis and risk assessment, it was decided not to envisage prevention and control measures in the Special Part, since they were



deemed to be wholly irrelevant in view of the nature, characteristics and the way in which Opocrin's *business is* actually conducted and the existing external controls of the Model.

In any case, the Company considers that the set of behavioural principles set out in the Code of Ethics and the principles and rules of *corporate governance* defined by the Company constitute an effective prevention system.

The Company itself and the Supervisory Board are required to monitor the Company's activities and to supervise the adequacy of the Model, also identifying any new prevention requirements that require updating.

#### 3.2 THE PRINCIPLES OF CONDUCT AND GENERAL PREVENTION PROTOCOLS

All the Recipients of the Model, as identified in paragraph 3.5 of the General Section, are required to adopt rules of conduct in compliance with the law, with the provisions contained in this Model, with the principles contained in the Code of Ethics and in the instruments implementing the Model itself, in order to prevent the occurrence of the Offences envisaged by the Decree.

In particular, the principles identified in the Code of Ethics, to be understood as fully referred to herein, referring to the various types of Recipients, constitute a prerequisite for and an integral part of the general prevention protocols indicated below.

For the purposes of the adoption and effective implementation of the Model, in the context of all operations concerning sensitive activities, better identified in the Special Section of the Model, the Company also implements the general prevention protocols indicated below:

- Only persons who have been previously identified by means of delegations, powers of attorney, organisation charts, *job descriptions*, procedures or any organisational provisions are authorised to perform sensitive activities;
- the system of delegation of powers and the conferral of powers to sign externally is consistent with the responsibilities assigned to each person;
- the formation and implementation of the Company's decisions comply with the principles and prescriptions contained in the provisions of the law, the Articles of Association, the Code of Ethics and the instruments implementing the Model;
- levels of hierarchical and functional dependency are formalised and the different tasks within the company are described;
- the formation phases and authorisation levels of the Company's acts are documented and reconstructible;



- the allocation and exercise of powers within a decision-making process are congruent with the positions of responsibility and the relevance and/or criticality of the underlying economic transactions;
- there is no subjective identity between those who take or implement decisions, those who must give an accounting record of those decisions, and those who are required to carry out the controls provided for by law and by the procedures laid down in the internal control system;
- documents concerning the formation of decisions and their implementation are archived and stored by the competent function. Access to archived documents is permitted only to authorised persons according to the company's operational procedures, as well as to the Board of Statutory Auditors, the Auditing Company and the Supervisory Board;
- the handling of personal data by the Company complies with EU Regulation 2016/679 and Legislative Decree No. 196 of 30 June 2003, as amended or supplemented, including regulations;
- the choice of any external consultants is justified and is made on the basis of requirements of professionalism, independence and competence;
- Employee reward systems respond to realistic objectives consistent with the tasks, activities performed and responsibilities entrusted;
- the Company's financial flows, both incoming and outgoing, are constantly monitored and always traceable;
- all forms of donations aimed at promoting the image and activity of the Company must be authorised, justified and documented;
- the Supervisory Board verifies that the company operating procedures governing sensitive activities fully implement the principles and prescriptions contained in the Special Section, and that they are constantly updated, also at the proposal of the Board itself, in order to ensure the achievement of the purposes of this document.

#### 3.3 THE CONSTRUCTION OF THE MODEL

This Model, also in this new edition, has been drafted taking into account Opocrin's corporate reality, its organisational structure, specific activity and the economic and social context of reference.

The Company has arrived at the identification of principles and general rules for the organisation, performance and control of its activities, through the work methodology described below:

- 1) acquisition and verification of company documentation;
- 2) confrontation with the Staff;



- 3) elaboration of the risk matrix on the so-called *risk assessment* model, preceded by an analysis of business processes, and consequent *gap analysis*;
- 4) Identification of processes and functions at principal risk of offence.
- 5) identification of specific control protocols and possible enforcement procedures.

## 3.3.1 THE ACQUISITION AND EXAMINATION OF COMPANY DOCUMENTATION E

During the drafting of the Model, a preliminary acquisition and thorough examination of all company documentation relevant to the analysis for the drafting and updating of the Model was carried out, including, by way of example, the following

- company organigram
- proxies and powers of attorney
- active and passive invoice register (on a sample basis)
- accident register
- relevant occupational health and safety and environmental documentation.

This provided a picture of the company's organisational structure and the distribution of functions and powers within the company, how it functions, and who interacts with it on a daily or periodic basis.

## 3.3.2 COMPARISON WITH THE STAFF OF A COMPANY

Following the documentary analysis, numerous discussions were initiated with the heads of the corporate functions, and if necessary also with certain employees belonging to those functions, identified on the basis of the corporate organisational chart and the powers attributed to them and who, by virtue of the role they hold, have the broadest and deepest knowledge of the operations of the corporate sector of relative competence.

Alongside the in-depth examination of the issues crucial to the drafting of the Model, as mentioned above, the documental compliance with the Company's concrete operations was first verified.

In these comparisons, the following information was acquired:

- function and role of the contact person in the Company;
- description of the activity carried out by the function;
- area of activity at risk: definition of the area at risk Offence;
- specific protocols implemented and/or to be adopted relating to the area of activity at risk;
- formalised internal procedures;
- separation of roles, allocation of responsibilities, management of information flows and archiving;



- control/monitoring: existence and documentation of control and monitoring activities;
- public bodies involved: list of any public bodies involved in carrying out its activities.

# 3.3.3 IDENTIFICATION OF RISKS, CRITERIA FOR ASSESSMENT AND ELABORATION OF THE RISK MATRIX ON THE MODEL OF THE SO-CALLED "RISK ASSESSMENT". RISK ASSESSMENT

On the basis of the results of the previous two *steps*, the risk of offence occurrence was analysed.

The criteria used to assess the magnitude of each individual function and process to the risk of an offence occurring are as follows:

- extent of the penalty envisaged;
- type of sanction (pecuniary and/or prohibitory);
- social disvalue of the alleged offence in relation to the impact on the Company's commercial reputation.

Risk is the degree of likelihood of occurrence of the predicate offence. It is assessed in different terms (high, medium or low) depending on the:

- I. degree of probability (plausibility) of occurrence of the individual case;
- II. specific degree of organisation of the individual business function and its processes aimed at counteracting the abstract possibility of verification (control);
- III. concrete, post-conviction consequences if the individual case (impact) occurs.

The synergic application of these criteria to the corporate processes, by assigning a score from 1 to 5, has led to the drafting of a risk matrix, the elaboration of which - we repeat - is consequent to the analysis of the risk of occurrence of a predicate offence in relation to the corporate macro-functions abstractly concerned, with the further clarifications that follow.

The risk analysis carried out took into account the documentation provided by the Company itself, but above all the specific nature of the activity carried out by Opocrin (production of active ingredients for drugs) and the discussions held with Personnel on the practices, processes and critical situations noted in the past.

The Special Section summarises the summary results for each of the corporate functions for each type of Offence potentially relevant under Legislative Decree 231/2001 for the administrative liability of the Company.



#### 3.4 APPLICATION AND VERIFICATION OF THE EFFECTIVE IMPLEMENTATION OF THE MODEL

This Model - adopted by special resolution of the Company's Board of Directors - is binding on the Company and all Recipients, and the provisions contained herein are binding on them, as are the prescriptive and sanctioning provisions and the principles of conduct set out in the Code of Ethics.

Any breach of the provisions set out in the Model and the Code of Ethics will be sanctioned in accordance with the provisions and procedures described therein.

It is the Company's responsibility to apply the Model in relation to the activities it actually performs. To this end, Opocrin's Board of Directors - in compliance with the provisions of Article 6, first paragraph, letter b) of the Decree - has appointed a Supervisory Board, independent and autonomous, endowed with autonomous powers, with the task of supervising the operation of and compliance with the Model.

The Supervisory Board is entrusted with the task of boosting and coordinating on a general level the control activities on the application of the Model to ensure its correct and uniform implementation, as well as carrying out specific control actions in particular cases.

In accordance with the aforementioned criteria, the Model is implemented as explained in the following chapters.

## 3.5 THE ADDRESSEES OF THE MODEL

The Addressees of the Model are:

- all directors and those who have representative, administrative or management functions in the Company, as well as those who exercise, also de facto, the management and control of the Company;
- all employees of the Company, even if they are abroad for the performance of activities.

The Model also applies to those who, although not functionally linked to the Company by a subordinate or para-subordinate employment relationship, act under the direction or supervision of the Company's top management, as well as to Third Parties linked in some form of collaboration or cooperation with the Company, to the extent that they may perform sensitive activities.

Finally, the Recipients of the Model are the Statutory Auditors and Auditors of the Company.

All the Addressees thus defined are obliged to respect and enforce, with the utmost diligence, the provisions contained in the Model and its implementing procedures, as well as the Code of Ethics.

Each Addressee of the Model is required to know and comply with the principles and rules of the Model.



The Company makes the purposes and contents of the Model known both through the *Zucchetti* internal corporate platform, to which Company employees have access, and through the website https://opocrin.it/csr/, which can be accessed by other Addressees.

The adoption of the Model is also made known to third party contractors - where possible - within the framework of the contracts signed with them.



# 4. <u>SUPERVISORY BODY</u>

Article 6(1)(b) and (d) of the Decree, in making the Entity's exemption from liability conditional upon the adoption and effective implementation of an organisational, management and control model, suitable for preventing the commission of the Offences, provides for the mandatory establishment of a body of the Entity, endowed with both an autonomous power of control (to supervise the operation of and compliance with the Model) and an autonomous power of initiative, to ensure that it is constantly updated.

Therefore, Opocrin, in order to benefit from the exemption from administrative liability under Article 6 of Legislative Decree No. 231/2001, in addition to having adopted this Model, which is suitable for preventing the commission of offences potentially relevant to the Company, has entrusted the task of supervising the operation of and compliance with the Model and of updating it to a body of the Company itself with autonomous powers of initiative and control, the Supervisory Board, which has been granted expenditure autonomy up to an amount of €15,000 per year.

The entrusting of these tasks to the Supervisory Board and their correct and effective performance are indispensable prerequisites for exemption from liability, whether the offence has been committed by Senior Management or by Subordinates.

Finally, the regulation of the Model reiterates that the effective implementation of the Model itself requires, in addition to the establishment of a disciplinary system, its periodic verification by the Supervisory Board appointed for this purpose.

#### 4.1. PROCEDURES FOR THE APPOINTMENT AND DISMISSAL OF THE SUPERVISORY BOARD

The Supervisory Board is appointed by Opocrin's Board of Directors, assessing the professionalism and skills of the persons proposed and, if necessary, indicating the term of the appointment and the procedures for revocation. Revocation, as well as appointment, is decided by the Board of Directors. In relation to the size and characteristics of the Company's activities, as well as the support that the Supervisory Board receives from corporate functions, it was deemed appropriate to configure the Supervisory Board in a monocratic form. Should the Company opt for a collegial composition in the future, the role of Chairman of the SB must in any case be entrusted to an external member.

The members of the Supervisory Board must have and maintain the required qualities of professionalism, competence, and specific experience and must not be in a position of conflict or conflict with the functions to be performed. With regard to the requirements of professionalism and competence, members must preferably be chosen from (i) Chartered Accountants who have been



practising their profession for at least ten years; (ii) Lawyers who have been practising their profession in leading law firms for at least five years; (iii) professionals who have previously held the position of *internal auditor* for at least three years or have worked in leading auditing firms for at least three years; (iv) professionals who hold or have held the same position as a member of the Supervisory Board in other companies or groups of companies.

The Supervisory Board may make use of the Legal Affairs Department for the performance of its supervisory activities. It is up to the Supervisory Board, within the framework of its own regulations, to establish the modalities and timing of the supervisory activity to be carried out in the company. In accordance with the principles laid down in Legislative Decree No. 231/2001, the Supervisory Board is allowed to outsource (to third parties with the specific skills necessary for the best performance of the task) tasks of a technical nature, the overall responsibility for supervising the Model remaining with the Supervisory Board itself.

The Supervisory Board normally meets quarterly or, in any case, whenever one of its members deems it necessary.

Minutes of each meeting are drawn up and signed by all members. The meetings of the Supervisory Board are validly constituted with the presence of its members. The Supervisory Board validly takes its decisions by majority vote, if it is a collegial body.

The Supervisory Board may appoint a secretary, who may also be chosen from outside its members.

## 4.2. TASKS OF THE SUPERVISORY BOARD

The activities that the Supervisory Board is called upon to perform, by virtue of the task entrusted to it, also on the basis of the indications contained in Articles 6 and 7 of Legislative Decree No. 231/2001, can be summarised as follows:

- (i) supervision of the effectiveness of the Model, which takes the form of verifying the consistency between the concrete conduct and the established Model;
- (ii) Examination of the adequacy of the Model, i.e. of its real (and not merely formal) capacity to prevent, in principle, unwanted conduct;
- (iii) analysis of the maintenance of the soundness and functionality requirements of the Model over time;
- (iv) taking care of the necessary updating of the Model in a dynamic sense, in the event that the analyses carried out make it necessary to make corrections and adjustments.

In particular, the Supervisory Board is entrusted with the following tasks:

supervise the operation of and compliance with the Model;



- verify the actual suitability of the Model to prevent the commission of the offences referred to in Legislative Decree 231/2001;
- analysing the persistence of the Model's soundness and functionality requirements over time;
- taking care of, developing and promoting, in cooperation with the corporate functions concerned, the constant updating of the Model and the system of supervision of its implementation, suggesting, where necessary, to the Company's governing body the necessary corrections and adjustments;
- maintaining relations and ensuring the flow of information within its competence to the Board of Directors and the Board of Auditors;
- carry out audits and inspections in order to ascertain possible violations of the Model;
- ensure the preparation of reports on the results of the interventions carried out;
- Define and promote initiatives for the dissemination of knowledge and understanding of the Model, as well as the training of Personnel and the awareness of the Addressees of the principles contained in the Model;
- provide clarification on the meaning and application of the provisions contained in the Model;
- set up an effective internal communication system to enable the transmission and collection of relevant information for the purposes of Legislative Decree No. 231/2001, guaranteeing the protection and confidentiality of the reporter;
- solicit the competent bodies and coordinate with them in relation to any disciplinary proceedings against the Addressees;
- report established violations to the competent body for the initiation of disciplinary proceedings;
- verify that violations of the Model are effectively and adequately sanctioned.

It should be specified from the outset that the Board of Directors, even with the establishment of the Supervisory Board *pursuant to* Legislative Decree No. 231/2001, retains all the powers and responsibilities provided for by the provisions of the code, to which is added that relating to the adoption and effectiveness of the Model, as well as the establishment of the Supervisory Board (Article 6, c. 1, letters a) and b) of the Decree).

Moreover, the Board of Statutory Auditors, owing to its considerable professional affinity and the tasks assigned to it by law, is one of the SB's 'institutional' interlocutors. The auditors, in fact, being entrusted with the responsibility of assessing the adequacy of the internal control systems, must always be informed of the possible commission of Offences, as well as of any deficiencies in the Model.



The duties of the Supervisory Board are also specified analytically for the predicate offences considered to be at greater risk of occurrence. For all matters not expressly provided for herein, reference is therefore made to the provisions for individual offences in the Special Part of the Model.

#### 4.3. REQUIREMENTS AND POWERS OF THE SUPERVISORY BOARD

The main requirements to be met by the Supervisory Board are:

### 1. Autonomy and independence

The position of the Supervisory Board within the Company must guarantee it autonomy of initiative and control from any form of interference and/or conditioning by any component of the Company.

These requirements are ensured by the inclusion of the Supervisory Board in the highest hierarchical position, with its direct 'reporting' to the Board of Directors as a whole.

The Supervisory Board is not entrusted with managerial or operational tasks which, by making it a participant in corporate decisions and activities, would undermine its objectivity of judgement when verifying conduct and the Model.

The members of the Supervisory Board, in addition to the professional skills described, must therefore meet the subjective requirements of honourableness, absence of conflicts of interest and kinship relations with corporate bodies and members of the Board of Directors; these requirements further guarantee the autonomy and independence required by the task.

#### 2. Professionalism

The Supervisory Board must possess a background of knowledge and techniques such as to enable it to adequately and effectively perform the assigned activity. These are specialised techniques peculiar to those who carry out 'inspection' activities, but also consultancy in the analysis of control systems and legal and, more specifically, criminal law.

Therefore, knowledge of the structure and implementation methods of the Offences is essential, and can be ensured through the use of company resources or external consultancy. With regard to issues concerning the protection of health and safety at work, the Supervisory Board must make use of all the resources activated for the management of the relevant aspects, including those provided for by sector regulations.

#### 3. Continuity of action



In order to guarantee the effective and constant implementation of the Model, the presence of a structure dedicated to the activity of supervision of the Model is envisaged without, as mentioned, managerial and operational tasks that could lead it to take decisions with economic and financial effects.

## 4. Other Requirements

The activities carried out by the SB cannot be reviewed by any other corporate body or structure, it being understood that the Board of Directors is in any case called upon to supervise the adequacy of its intervention, since the ultimate responsibility for the functioning and effectiveness of the Model lies with the management body itself.

In addition, the Supervisory Board has free access to all the functions of the Company - without the need for any prior consent - in order to obtain any information or data deemed necessary for the performance of its duties under the Decree.

The Supervisory Board, should it deem it appropriate, may avail itself - under its direct supervision and responsibility - of the assistance of all the structures and functions of the Company or of external consultants.

# 4.4. REPORTS OF VIOLATIONS AND MISCONDUCT RELEVANT UNDER LEGISLATIVE DECREE 231/2001

The Supervisory Board must receive, in addition to the information and documentation indicated in the Special Part of the Model and any indications that may be necessary during the performance of monitoring activities, any Report concerning the implementation of the Model, the commission of Offences provided for by the Decree in relation to Opocrin's activity, or in any case to conduct not in line with the rules of conduct adopted by the Company.

If an Employee, Consultant or Collaborator, in the performance of his or her working activity and/or assignment or function, on the basis of precise and concordant factual elements, becomes aware of violations of the Code of Ethics and/or the Model (and/or of the company procedures that refer to it) or of unlawful conduct that is relevant pursuant to Legislative Decree No. 231/2001, he or she may report such situations to the Supervisory Board.

These Reports, as well as the mandatory communications pursuant to this Model, may be sent to the Supervisory Board e-mail address (odv231@opocrin.it) or by ordinary mail to the address 'Organismo di Vigilanza, c/o Opocrin S.p.A., Strada Scaglia Est n. 5, 41126, Modena (MO)'. A special mailbox has also been set up for the Secretariat of the Supervisory Board: segreteriaodv231@opocrin.it.



Also other categories of Addressees (such as, for example, suppliers, contractors, customers, *etc.*) may, in any case, contact the Supervisory Board to report a violation of the Code of Ethics and/or the Model or unlawful conduct relevant under the Decree, always using the above-mentioned communication channels.

These Reports, which may therefore be received both by Company Personnel and by Third Parties, may relate to any violation or suspected violation of this Model and of the procedures related to it, conduct that is inconsistent with Opocrin's ethical principles, or anomalies or atypicalities encountered in the performance of activities.

The Company's Supervisory Board shall assess, at its reasonable discretion and responsibility, each Report received and any appropriate consequent measures to be taken, hearing, if necessary, the author of the Report and/or the person responsible for the alleged violation, and giving reasons in writing for any refusal to proceed with an internal investigation.

The Supervisory Board shall act in such a way as to guarantee whistleblowers against any form of retaliation, discrimination or penalisation, also ensuring the confidentiality of the whistleblower's identity, without prejudice to legal obligations and the protection of the rights of the Company or of persons wrongly accused and/or in bad faith.

The Supervisory Board will report to the Board of Directors any violations of the Organisational Model that emerge with reference to the above-mentioned Reports.

All Reports are kept, by the Supervisory Board, in a special file, in accordance with the procedures defined by the Supervisory Board itself and such as to ensure the confidentiality of the identity of the person making the Report.

#### 4.5. INFORMATION FLOWS TO AND FROM THE SUPERVISORY BOARD

In accordance with the provisions of Article 6(2)(d) of the Decree, the corporate bodies are required to communicate to the Supervisory Board any information useful for carrying out the control activity and verifying compliance with the Model, its functioning and its proper implementation. These obligations to inform the Supervisory Board are also considered by Confindustria - in the latest version of the Guidelines for the construction of Models 231 - as a further tool to facilitate the activity of monitoring the effectiveness of the Model and of ascertaining *ex post* the causes that made it possible for the offence to occur.

The same reporting obligations apply to the heads of the functions concerned by sensitive activities, as identified in the relevant corporate procedures, as well as to any Employee or external party (Collaborator, Consultant, supplier, *partner*, *etc.*) who is aware of such information.



The Company has therefore shared with the Supervisory Board the opportunity to implement the following periodic information flows:

- on a six-monthly basis, the Human Resources Function, together with the Safety and Environment Function Head, must communicate to the Supervisory Board information on accidents or *near misses*, by means of a summary report also including any accidents with a prognosis of less than 40 days;
- On a six-monthly basis, the Human Resources Department must notify the Supervisory Board of updates on personnel management (e.g. new hirings, terminations, disciplinary measures);
- on a six-monthly basis, the Human Resources Department must provide the Supervisory Board with an update on any reports concerning gender equality;
- On a six-monthly basis, the Secretary of the OpocrinAID Committee communicates to the Supervisory Board the list of sponsorships, donations and other acts of liberality granted to third parties;
- On an annual basis, the Quality Department must report to the Supervisory Board on inspections received from regulatory bodies and/or authorities, as well as on reports and deviations that should be brought to its attention;
- on an annual basis, the Health, Safety and Environment Function must report to the Supervisory Board on inspections received by Bodies and/or Authorities, concerning HSE.

Furthermore, all Opocrin functions - through their managers - must inform the Supervisory Board:

- ✓ on a periodic basis, the additional information identified by the Supervisory Body and requested by it from the individual corporate functions of Opocrin. This information must be transmitted at a time and in a manner to be defined by the Supervisory Board;
- ✓ on an occasional basis, any other information, of any kind, coming from Personnel or even from Third Parties and pertaining to the implementation of the Model in the areas of activity at risk and compliance with the provisions of the Decree, which may be deemed useful for the performance of the tasks of the SB.

In particular, information must be compulsorily and promptly (i.e. on an eventual basis) forwarded to the Supervisory Board about

any measures and/or news coming from judicial police bodies or any other authority, from
which it can be inferred that investigations are being carried out on persons, companies or
third parties that have relations with Opocrin for the Crimes relevant to Legislative Decree
No. 231/2001;



- any requests for legal assistance made by directors and/or employees of the Company in the event of legal proceedings being commenced for the relevant offences under Legislative Decree No. 231/2001;
- any reports prepared by the heads of the various corporate functions from which facts, conduct, events or omissions may emerge with profiles of criticality and responsibility with respect to the relevant offences under the Decree;
- information on the actual implementation, at all levels of the company, of the Model, with evidence of disciplinary proceedings carried out and any sanctions imposed (including measures against Employees) or measures to dismiss such proceedings with the relevant reasons;
- Substantial changes made to the risk assessment document *pursuant to* Legislative Decree 81/2008 as amended;
- any accident resulting in a prognosis of more than 40 days.

The transmission of the above-mentioned information must take place via confidential internal mail, at the above-mentioned address, or via the above-mentioned dedicated mailbox.

As part of the information flows to the corporate bodies, the Supervisory Board prepares:

- annually, a report summarising the activities carried out during the current year, to be submitted to the Board of Directors and the Board of Auditors:
- periodically sharing the minutes of the Supervisory Board meetings with the Board of Auditors;
- immediately, a communication concerning the occurrence of extraordinary situations (e.g. news of significant violations of the contents of the Model, legislative innovations on the subject of the administrative liability of the Entity, *etc.*) and in the event of Reports received that are of an urgent nature, to be submitted to the Board of Directors.

#### 4.6. THE WHISTLEBLOWING SYSTEM

Whistleblowing is a tool aimed at preventing conduct, acts or omissions that harm the public interest or the integrity of the public administration or private entity.

The term *whistleblower* refers to a person, an employee of a body or administration, who reports violations or irregularities committed to the detriment of the public interest and the administration to which he or she belongs to the bodies empowered to intervene.

In relation to the Company, whistleblowing occurs when an employee or a stakeholder of the Company reports unlawful conduct of which he/she has become aware in the course of his/her work.



The Company had adopted the so-called *Whistleblowing* System already in previous editions of the Model,

through the establishment of dedicated reporting channels that allowed any interested party to submit reports of unlawful conduct of which he/she had become aware by reason of his/her duties, guaranteeing the confidentiality of the reporter's identity and prohibiting any retaliatory or discriminatory act against him/her for reasons related to the report.

However, following the entry into force of Legislative Decree No. 24 of 10 March 2023, transposing Directive 2019/1937/EU of the European Parliament and of the Council of 23 October 2019, it became necessary to revise the pre-existing *Whistleblowing* System in order to better ensure:

- the confidentiality of the information received, the protection of the identity of the reporter
   and reported person, as well as of all other actors involved;
- the provision of a dual reporting channel, in written and oral form;
- the implementation of efficient encryption systems;
- the correct application of the principle of data minimisation;
- compliance with the principles of data retention, with data retention periods proportionate to
   each individual case reported;
- identification of the roles attributed to the various actors involved in the procedure and management of the relations between them (identification of the internal figure receiving the reports, Supervisory Board and/or other functions);
- management of external relations and identification of the relevant tasks entrusted to data processors *under* Article 28 GDPR;
- organisational and technical security measures based on an adequate risk assessment;
- an impact assessment pursuant to Article 35 GDPR.

In the light, therefore, of the above-mentioned more stringent requirements, also of a technical nature, imposed by the new legislation, the Company implemented the pre-existing *Whistleblowing* System with some additional measures, by means of a reporting platform provided by an external *provider*. This reporting platform, active since December 2023 and available at <a href="https://opocringroup-nature">https://opocringroup-nature</a>.

opocrin.integrityline.com/, is rather intuitive, both from the point of view of the reporter, who is guided in filling in a *form in* order to better circumscribe and frame the scope and subject of the report, and from the point of view of the figure in charge of its management, who is given the opportunity to involve any further persons who may be useful in analysing the report, including *first and foremost* the Supervisory Board, while respecting the absolute confidentiality of the reporter and the reported



person and the response timeframes laid down by the legislation, including by means of an *alert* system.

This application also provides for the possibility, even though this is not an obligation imposed by law, of allowing whistleblowers to transmit whistleblowing reports anonymously; however, the Company has decided, at present, to exclude this possibility, in order to make potential whistleblowers more accountable and to carry out appropriate and effective checks on the reports themselves. However, any anonymous reports will also be assessed by the Company, outside the internal *Whistleblowing* channel, given the anonymity of the whistleblower.

The platform also guarantees full compliance with the security requirements of Legislative Decree 24/2023: all reports are, in fact, encrypted and stored in ISO 27001-certified European high-security data centres (certification that monitors, among other things, the organisation for IT Security, IT Security incident management capability; information security aspects of business continuity), as well as GDPR-compliant.

As regards the management of the platform, the Company has decided to set the Legal Affairs and Compliance Function as the manager of any reports received, also in order to identify *ex ante* the scope of relevance of the offence being reported, and to involve, depending on the circumstance, the corporate function concerned, in the case of violations that do not have relevance under the Decree, or, otherwise, the Supervisory Board, which may directly access the report of interest and take any initiative deemed appropriate.

This choice, moreover, is in line with what emerged from the AODV position paper of 10 October 2023, which, with regard to the role of the SB in the context of Whistleblowing, suggests avoiding the coincidence between the manager of (all) Whistleblowing reports and the SB, in order to optimise the management of Whistleblowing reports, should a different corporate function be involved, and to avoid potential conflicts of interest and participation in management activities that could undermine the independence of judgement and autonomy of the SB.

With regard to the characteristics of the report, it must be as detailed as possible, in order to allow the platform operator to analyse the facts.

In particular, they must be clear:

- the circumstances of time and place in which the event reported occurred;
- description of the fact;
- personal details or other elements enabling identification of the person to whom the reported facts can be attributed.

Information on reported violations must be truthful.



Mere suppositions, unreliable indiscretions (so-called rumours), as well as news in the public domain, erroneous information (with the exception of genuine error), manifestly unfounded or misleading, or if merely harmful or offensive shall not be considered such.

It is also useful for the whistleblower to provide documents that may provide evidence of the facts being reported, as well as an indication of other persons potentially aware of the facts.

The identity of the whistleblower may not be disclosed, without the whistleblower's express consent, to persons other than those responsible for receiving or following up whistleblowing reports, who are expressly authorised to process such data pursuant to Articles 29 and 32(4) of Regulation (EU) 2016/679 and Article 2-quaterdecies of the Personal Data Protection Code set out in Legislative Decree No 196 of 30 June 2003, as amended.

The Company shall protect the identity of the persons involved and of the persons mentioned in the report until the conclusion of the proceedings initiated as a result of the report, in compliance with the same guarantees provided for in favour of the reporter.

Adequate protection and support measures shall also be applied to the aforementioned persons in order to avert the risk of direct or indirect retaliation, such as, but not limited to, dismissal, suspension or equivalent measures, downgrading or non-promotion, or change of function.

Acts taken in violation of the prohibition of retaliation are null and void.

Pursuant to Article 17 et seq. of Legislative Decree No. 24 of 10 March 2023, in the context of judicial or administrative proceedings or in the case of out-of-court disputes concerning the ascertainment of the conduct, acts or omissions prohibited against the whistleblower, it is presumed that the same have been put in place as a result of the whistleblowing.

The burden of proving that such conduct or acts are motivated by reasons unrelated to the report lies with the person who has carried out the retaliatory acts.

The whistleblower may inform the ANAC of the retaliation he/she believes he/she has suffered, whether attempted or contemplated.

With regard to the support measures put in place in favour of the whistleblower, he/she may turn to third sector entities on the list published on the ANAC website.

These are bodies that carry out activities in the general interest for the pursuit, on a non-profit basis, of civic, solidarity and socially useful purposes and that have entered into agreements with ANAC.

The support measures provided consist of information, assistance and advice free of charge on how to report and on the protection from retaliation offered by national and EU legislation, on the rights of the person concerned, and on the terms and conditions of access to legal aid.



The disciplinary system adopted by the Company pursuant to Article 6(2)(e) of the Decree provides for sanctions to be applied against those whom the Company ascertains to be responsible for offences relating to

-retaliation or proposed adoption, obstruction of reporting (even attempted) or breach of confidentiality obligations,

-failure to establish reporting channels, failure to adopt procedures for handling them, or procedures that do not comply with the requirements of the decree, or failure to verify and analyse reports;

-civil liability of the reporting person for defamation or slander in cases of wilful misconduct or gross negligence, unless he/she has already been convicted, also at first instance, of the offences of defamation or slander; as well as against anyone who violates this procedure.

For the same offences, ANAC may intervene with the application of administrative pecuniary sanctions (from  $\[ \in \]$  500 up to  $\[ \in \]$  50,000) in the event of their detection.

The Company informs Employees of how to use the internal *Whistleblowing* reporting channel both through a *vademecum* and through the specific procedure distributed to all corporate functions.

A direct *link* to the reporting platform can also be found on the Company's website https://opocrin.it/csr/, which can be accessed by other Addressees.



## 5. TRAINING OF RESOURCES AND DISSEMINATION OF THE MODEL

#### 5.1. TRAINING AND INFORMATION DE L PERSONNEL

For the purposes of implementing this Model and the Code of Ethics, Opocrin ensures that both the Staff already present in the company and those to be hired are properly acquainted with the rules of conduct contained herein, with different degrees of detail depending on the different level of involvement of resources in sensitive processes.

The information and training system is supervised and supplemented by the activity carried out in this field by the SB in cooperation with the heads of the functions involved in the application of the Model from time to time: in fact, the organisation of periodic interviews with the aforesaid heads allows the SB to perform the tasks and functions entrusted to it, being able, on that occasion, to count on the direct acquisition of information from the persons interviewed and, thus, to concretely assess the effective implementation of the Model.

Opocrin's Code of Ethics is made available to the public and can be viewed by *stakeholders* in the *Corporate Social Responsibility* section of the company website (www.opocrin.it).

#### 1. The initial communication

The adoption of this Model is communicated to all Personnel (including members of corporate bodies) present in the company at the time of its adoption, and the document is uploaded and consultable by all Personnel on the company portal. All subsequent amendments and information concerning the Model will be communicated through the same information channels.

New employees are given a *set of* information (Code of Ethics, internal company regulations, *etc.*), with which they are assured the knowledge they consider of primary importance.

#### 2. Training

The training activity aimed at disseminating knowledge of the regulations set forth in Legislative Decree No. 231/2001 is differentiated, in terms of content and delivery methods, according to the Recipients' qualification, the risk level of the area in which they operate, and whether or not they have functions of representation of the Company.

In particular, Opocrin envisages different levels of information and training through dissemination tools such as, for example, periodic targeted seminars, update e-mails, internal information notes, *etc.*, guaranteeing in any case that training is of a proportionate intensity and continuity character



## 5.2. COLLABORATORS, CONSULTANTS AND SUPPLIERS

External parties must be informed of the contents of the Model and the Code of Ethics, as well as of Opocrin's requirement that their conduct comply with the provisions of Legislative Decree No. 231/2001.

With regard to Third Parties (Co-workers, Consultants, Suppliers, Contractors, *etc.*), acting *on* behalf of or in the interest of Opocrin, the relevant contracts must:

- be set out in writing, in all their terms and conditions;
- contain *standard* clauses in order to comply with Legislative Decree 231/2001;
- contain a declaration by the same to the effect that they are aware of the regulations set out in Legislative Decree No. 231/2001 and that they undertake to behave in accordance with the regulation;
- contain an appropriate clause regulating the consequences of their breach of the rules set out in Legislative Decree 231/2001, the Model and the Code of Ethics adopted by the Company (e.g. express termination clauses, penalties, *etc.*).



# 6. <u>DISCIPLINARY SYSTEM</u>

Pursuant to Article 6(1)(e) and Article 7(4)(b) of Legislative Decree No. 231/2001, the provision of an effective system of sanctions is an essential requirement of the Model for the purposes of exemption from administrative liability of the Company.

The Model adopted by Opocrin, therefore, provides for an adequate disciplinary system applicable in the event of violation of the Model itself, of the Code of Ethics and of the relevant company implementing procedures and regulations.

The provision of a penalty system makes the action of the Supervisory Board efficient and is intended to ensure the effectiveness of the Model itself.

The application of the disciplinary system and of the relevant sanctions is independent of the conduct and outcome of any criminal proceedings initiated by the judicial authorities in the event that the conduct to be censured also constitutes a relevant offence under Legislative Decree No. 231/2001.

The disciplinary measures and related sanctions, which make up the disciplinary system, are identified by the Company on the basis of the principles of proportionality and effectiveness, taking into account the different qualifications of the persons to whom they apply (employees or managers, directors, auditors, collaborators).

#### **6.1.** MEASURES AGAINST EMPLOYEES

Violation by employees subject to the CCNL Industria Chimica (excluding, therefore, managers) of the individual rules of conduct set out in this Model, the Code of Ethics and the relevant internal implementing procedures and regulations, constitutes a breach of the primary obligations of the employment relationship and constitutes a disciplinary offence.

Opocrin's corporate disciplinary system consists of the provisions of the Civil Code and the special laws on the subject, as well as the provisions of the collective bargaining agreement for the sector (CCNL Chemical Industry).

With specific reference to the sanctions that can be imposed on such employees, they fall within those provided for by the sanctions system set out in the special rules contained in the applicable collective bargaining agreement (CCNL Industria Chimica), in compliance with the procedures set out in Article 7 of the Workers' Statute and any special and/or sector regulations applicable.

Violation of the Model, the Code of Ethics, as well as of the relevant implementing company procedures and regulations, by the Employees in question, entails the adoption of the disciplinary measures outlined below, as provided for by collective bargaining and applicable law:



- 1. Verbal warning: in the event of minor non-compliance with the principles and rules of conduct laid down in this Model or in the Code of Ethics, or of violation of the internal procedures and rules laid down and/or referred to, or of adoption, within the sensitive areas, of a conduct that does not comply with or is not appropriate to the prescriptions of the aforementioned rules.
- **2.** Written reprimand: in the event of non-compliance with the principles and rules of conduct laid down in this Model or in the Code of Ethics or violation of the internal procedures and rules laid down and/or referred to, or adoption, within the sensitive areas, of a conduct that does not comply with or is not appropriate to the prescriptions of the aforementioned rules, to an extent that can be considered, even if not minor, not serious.
- **3.** Fine in an amount not exceeding the amount of 4 hours of normal pay: in the event of noncompliance with the internal procedures laid down in this Model or in the Code of Ethics or in the adoption of a conduct that repeatedly fails to comply with the provisions of the Model itself or of the Code of Ethics, in the performance of activities in areas at risk, in the event that each failure has not been previously ascertained, contested and sanctioned.
- **4.** Suspension from pay and from service for a maximum of 8 days: in the event of non-compliance with the principles and rules of conduct laid down in this Model or in the Code of Ethics or violation of the internal procedures and rules laid down and/or referred to, or adoption, within the sensitive areas, of a conduct that does not comply with or is not appropriate to the prescriptions of the aforementioned rules, to an extent to be considered of greater seriousness, even if dependent on recidivism.
- **5. Dismissal for misconduct**: in the event that the worker adopts, in the performance of activities in areas at risk, a conduct clearly in breach of the provisions of this Model or of the Code of Ethics and such as to determine the concrete application against the Company of the measures laid down in the Decree, such conduct being deemed to constitute the performance of "acts such as to radically undermine the Company's trust in him/her", or the occurrence of the misconduct referred to in the preceding points, resulting in serious prejudice to the Company.

In relation to the above, the Model refers to the sanctions apparatus defined in the sector's CCNL in force at the time of the act (current Articles 38-40 of the current CCNL for the Chemical Industry).



Infringements, in addition to the provisions of the CCNL, may be sanctioned - depending on their seriousness and intensity - also through the curtailment of rewards, incentives and bonuses and, more generally, through the reduction of the variable part of remuneration, so as to further discourage any conduct in violation of the Model, the Code of Ethics and/or in contrast with company rules.

Pursuant to Article 7 of the Workers' Statute and the applicable sectoral CCNL, in relation to disciplinary measures that are more serious than a verbal warning, a written reprimand must first be made to the employee with a specific indication of the facts constituting the infringement.

Infringements are ascertained and the ensuing disciplinary proceedings are initiated by the Head of the Human Resources and Personnel Administration Function, in compliance with current legislation and with the disciplinary rules contained in the CCNL from time to time applicable. The head of the corporate function involved may be called upon to collaborate in drafting the dispute.

Any disciplinary measures are taken by the Board of Directors (or a member delegated by it), in accordance with the provisions of the law and the applicable collective bargaining agreement (CCNL Industria Chimica).

The disciplinary measure must be justified and communicated to the employee in writing by registered letter by hand or by return receipt.

In the event that the adoption, in the performance of activities in the areas at risk, of a conduct that does not comply with the provisions of the Model and the Code of Ethics or the violation of the relevant internal implementation procedures is carried out by a manager of the Company, also in consideration of the special fiduciary bond and the position of guarantee and supervision of compliance with the rules established in the Model that characterises the relationship between the Company and the same, Opocrin shall be entitled to take the most appropriate measures against such person, in compliance with the provisions of the laws in force and of the applicable National Collective Labour Agreement for Managers of Goods and Services Manufacturing Companies, and taking into account the seriousness of the breach(es) and any repetition thereof (in the most serious cases, dismissal with notice or for just cause may be envisaged, or for less serious breaches, less severe sanctions may be imposed, in accordance with the principle of gradual sanctions).

Provision is made for the necessary involvement of the Supervisory Board in the procedure for ascertaining violations and imposing sanctions for violations of the Model, the Code of Ethics or the internal implementing procedures and rules, in the sense that disciplinary proceedings may not be closed or a disciplinary sanction imposed for such violations without prior information and opinion of the Supervisory Board.



In accordance with the principles of proportionality and effectiveness, the type and extent of each of the above-mentioned sanctions will be determined in relation:

- the type of offence alleged and the seriousness of the infringement;
- the intentionality of the conduct or degree of negligence, recklessness or inexperience with regard also to the foreseeability of the event;
- the overall conduct of the employee with particular regard to the existence or otherwise of disciplinary precedents of the same, to the extent permitted by law;
- to the worker's duties;
- the functional position of the persons involved in the facts constituting the fault;
- other special circumstances accompanying the disciplinary infringement (concurrence of several persons, etc.);
- to any episodes of recurrence or repetition.

In any event, when determining the severity and incisiveness of the penalty, the criteria laid down in the Criminal Code and in the relevant CCNL may be borrowed, with regard to the personality of the offender and to the comparison of the circumstances of the act.

#### **6.2.** MEASURES AGAINST DIRECTORS

In the event of a breach of the Model and the Code of Ethics by one or more members of the Board of Directors, the Supervisory Board must inform the Board of Auditors and the entire Board of Directors so that they may take the appropriate measures (formal written warning, total or partial revocation of any delegation, *etc.*).

In the event of the commission of serious violations pursuant to Legislative Decree No. 231/2001, the Chairman of the Company's Board of Directors shall proceed to convene the Shareholders' Meeting to resolve on the revocation of the mandate and any liability action.

#### **6.3.** MEASURES AGAINST MAYORS

In the event of violation of the Model and the Code of Ethics by one or more auditors, the Supervisory Board must inform the entire Board of Auditors and the Board of Directors so that appropriate measures can be taken.

#### 6.4. MEASURES AGAINST THIRD PARTIES

Any breach by third parties of the rules set forth in the Code of Ethics and the Model adopted by Opocrin, applicable to them, or the commission of the offences set forth in Legislative Decree no.



231/2001 shall be sanctioned in accordance with the provisions of the law and in the specific clauses that Opocrin inserts - where possible - in the contracts, also regulating the civil law consequences of the breaches and providing for specific termination clauses or the right to withdrawal, without prejudice to compensation for damages.

This is without prejudice to any claim for compensation if such conduct causes damage to the Company, as in the case of the application to it by the judge of the measures provided for by Legislative Decree No. 231/2001.

# 6.5. SANCTIONS PURSUANT TO ARTICLE 6(2-BIS) OF LEGISLATIVE DECREE NO. 231/2001

With reference to the system of sanctions relating to the proper handling of Reports of Offences *pursuant to* Article 6, paragraph *2-bis* of Legislative Decree No. 231/2001, the following are provided for:

- (i) sanctions for those who engage in direct or indirect retaliatory or discriminatory acts against the whistleblower for reasons directly or indirectly linked to the Whistleblowing;
- (ii) sanctions against those who, with malice or gross negligence, make reports that turn out to be unfounded.

The sanctions are defined in relation to the role of the recipient of the sanctions, as set out in the preceding paragraphs.



# 7. <u>UPDATING AND ADAPTING THE MODEL</u>

In accordance with Article 6(1)(b) of Legislative Decree No. 231/2001, the Supervisory Board is entrusted with the task of updating the Model.

To this end, the Supervisory Board, also availing itself of the support of the corporate functions, identifies and reports to the Board of Directors the need to proceed with the updating of the Model, also providing indications as to how to proceed with the implementation of the relevant measures.

The Board of Directors assesses the need to update the Model reported by the Supervisory Board and decides on the updating of the Model in relation to amendments and/or additions that may become necessary as a result of

- regulatory changes in the area of the administrative liability of entities and significant innovations
   in the interpretation of the relevant provisions;
- identification of new sensitive activities, or variation of those previously identified, also possibly connected with the start-up of new business activities, changes in the internal structure of the Company and/or in the way in which business activities are carried out (e.g. listing on the stock exchange, change of corporate purpose, change of corporate governance system, etc.);
- issuing and amending guidelines by the relevant trade association notified to the Ministry of
  Justice pursuant to Article 6 of Legislative Decree No. 231/2001 and Articles 5 et seq. of
  Ministerial Decree No. 201 of 26 June 2003;
- commission of offences relevant to the administrative liability of entities by the recipients of the
   Model's provisions or, more generally, of significant violations of the Model;
- detection of deficiencies and/or gaps in the Model's provisions following audits of its effectiveness.

However, the Chairman of the Board of Directors and the Managing Director of Opocrin have the power to make any amendments or additions of a purely formal nature to the Model.

Amendments, updates or additions to the Model adopted by the Board of Directors must always be communicated to the Supervisory Board.

Amendments affecting the company procedures supporting the Model are adopted directly by the company departments concerned, which inform the Supervisory Board thereof.

