



**ORGANIZATION, MANAGEMENT
AND CONTROL MODEL
PURSUANT TO LEGISLATIVE
DECREE NO. 231 OF 8 JUNE 2001**

**Approved by the
Board of Directors on
04 December 2024
IBSA Farmaceutici Italia s.r.l.**



SUMMARY

DEFINITIONS	4
INTRODUCTION.....	7
GENERAL SECTION.....	8
1. CHAPTER - DESCRIPTION OF THE REGULATORY FRAMEWORK	9
1.1. Legislative Decree no. 231/2001 and the relevant legislation	9
1.2. Nature and characteristics of the liability of legal persons	9
1.3. Types of offences identified by the DECREE and subsequent amendments	9
1.4. Objective criteria of assigning liability	12
1.5. Subjective criteria of assigning liability	13
1.6. Crimes committed by Top Management.....	14
1.7. Crimes committed by Subordinates.....	14
1.8. Characteristics of the Organization and Management Model	15
1.9. Offences committed abroad	16
1.10. Attempt of commission of an offence	16
1.11. Sanctions	16
1.11.1. Financial penalties.....	16
1.11.2. Disqualification sanctions	17
1.11.3. Other sanctions	18
1.12. Modifying events of the legal entity	18
1.13. Codes of conduct prepared by associations representing the legal entities.....	20
2. CHAPTER - COMPANY DESCRIPTION - GOVERNANCE AND ORGANIZATIONAL STRUCTURE	22
2.1. The IBSA Group.....	22
2.2. IBSA FARMACEUTICI ITALIA S.R.L.....	23
2.3. Business divisions and support functions	24
2.3.1. Operations.....	24
2.3.2. Commercial	25
2.3.3. Sciences.....	26
Research and Development (R&D)	27
Regulatory Affairs.....	28
2.3.4. Support functions	28
2.3.5. Outsourced services.....	29
2.4. Governance model	29
2.5. Board of Directors	30
2.6. Board of Statutory Auditors	30
2.7. Auditing Company	30
2.8. Organizational structure	31
2.9. Organizational chart and corporate organization	31
2.10. Attribution of powers.....	32
2.11. Decisions by top managers and conflicts of interest.....	33
2.12. Company procedures	33
2.13. Company IT system	34
2.14. Certifications.....	35
2.15. Appointment of the Trusted Advocate and establishment of the Company in case of charges against the legal representative	35
3. CHAPTER - NATURE, SOURCES AND PURPOSES OF THE MODEL AND OF THE CODE OF ETHICS	36



3.1. Purpose of the IBSA ITALIA MODEL.....	36
3.2. Structure of the IBSA ITALIA MODEL	39
4. CHAPTER - WHISTLEBLOWING PROVISIONS	42
5. CHAPTER - METHODOLOGY USED IN DEFINING THE MODEL	44
6. CHAPTER - RECIPIENTS OF THE MODEL	46
7. CHAPTER - TRAINING AND COMMUNICATION PLAN	47
8. CHAPTER - ADOPTION OF THE MODEL - CRITERIA FOR UPDATING AND ADAPTING THE MODEL AND PROCEDURES	49
8.1. Adoption, amendment and updating of the MODEL and PROCEDURES	49
9. CHAPTER - THE SUPERVISORY BODY.....	51
9.1. Identification of IBSA ITALIA’s Supervisory Board.....	51
9.2. Function and powers of the Body	54
9.3. Information flows to the Body	59
9.3.1. Obligations to inform the Body.....	59
9.4. Information flows from the Body to corporate bodies	61
9.5. Collection and storage of information	61
10. CHAPTER - THE DISCIPLINARY SYSTEM.....	63
10.1. Function of the disciplinary system.....	63
10.2. Measures against subordinate employees	63
10.2.1. Violations of the MODEL and related sanctions	65
10.3. Measures against Directors.....	67
10.4. Measures against members of the Board of Statutory Auditors	68
10.5. Measures against consultants, collaborators, and business partners.....	68
SPECIAL SECTION (OMISSIS)	69

DEFINITIONS

M.D.: Managing Director of IBSA FARMACEUTICI ITALIA S.R.L.;

SENSITIVE ACTIVITIES: operations or acts that could expose the COMPANY to the risk of committing one of the crimes listed in the DECREE;

PARENT COMPANY: IBSA INSTITUT BIOCHIMIQUE SA, with registered office in Lugano, Switzerland (hereinafter “IBSA SA”, “IBSA SWITZERLAND” or “PARENT COMPANY”);

BoD: Board of Directors of IBSA FARMACEUTICI ITALIA S.R.L. (hereinafter the “BoD” or “Board”);

SUPPLIER CODE OF CONDUCT: the Supplier Code of Conduct of the IBSA Group, adopted by the Company in its first version, by resolution of the Board of Directors on 11 July 2024, with the objective of guiding the entire Group supply chain in the process of implementing the highest ethical, social, environmental and corporate governance standards;

CODE OF ETHICS: the Code of Ethics of the IBSA Group, adopted by the Company in its first version by resolution of the Board of Directors on 13 June 2018, as amended;

COLLABORATORS: subjects who have the following relationships with the COMPANY (i) project-based work relationships; (ii) agency, representation, commercial distribution relationships; (iii) occasional and continuous consulting; (iv) business partners, professionals and suppliers of goods and services;

DECREE: Legislative Decree no. 231 of 8 June 2001¹;

RECIPIENTS: subjects to whom the provisions of the MODEL apply, including Company Representatives, Employees, Collaborators and any other counterparty that has contractual relations with the COMPANY and agrees to comply with the CODE OF ETHICS and the MODEL;

EMPLOYEES: subjects who have an employment relationship of any grade or any kind with the COMPANY, including temporary workers, those with a reintegration or apprenticeship contract or part-time, as well as seconded workers and those under para-subordinate work contracts (work administration);

IT DOCUMENT: any IT support containing data or information that serves as evidential proof or programs specifically designed to process them;

¹ As amended: this clarification applies to any law, regulation or complex regulation to which reference is made in the MODEL.

COMPANY REPRESENTATIVES: the Chairman and members of the Board of Directors, Board of Statutory Auditors, members of the other corporate bodies of the COMPANY that may be established pursuant to Article 2380 of the Italian Civil Code or special laws, as well as any other person in a top management position pursuant to the DECREE, meaning any person who has functions of representation, administration, or management of the COMPANY or a unit or division of it that has financial and functional autonomy;

SUPPLIERS: any person who provides the COMPANY WITH goods and services;

IBSA GROUP OR GROUP: IBSA INSTITUT BIOCHIMIQUE SA and the companies that it controls worldwide;

ADMINISTRATIVE OFFENCES: administrative offences pursuant to Article 187 - *quinquies* of Legislative Decree 58/1998 (hereinafter the "TUF");

ANTI-CORRUPTION GUIDELINES: the IBSA Group guidelines, adopted by the Company, in its first version, with the resolution of the Board of Directors on 13 June 2018, and subsequent amendments, in order to provide a systematic framework of reference in the fight against corruption and to disseminate within the Group the principles and rules to be followed in order to prevent, in all countries in which the Group operates, the commission of corrupt conduct of any kind, direct and indirect, active and passive, including in the form of instigation, and, more generally, to ensure compliance with applicable Anti-Corruption regulations;

MODEL: this Organization, Management and Control Model as provided for by the DECREE, approved by the Board of Directors of IBSA FARMACEUTICI ITALIA S.R.L. on 15 September 2011, as amended;

CORPORATE BODIES: Board of Directors, CEO, Board of Statutory Auditors;

SUPERVISORY BODY: the internal supervisory body of IBSA FARMACEUTICI ITALIA S.R.L., as described by Article 6, paragraph 1, letter b) of the DECREE, which has supervisory functions on compliance with the MODEL and verification of its effective implementation (hereinafter the "BODY" or "SB");

PA: Public administration;

PROCEDURES: the set of procedures, protocols, policies, guidelines, operating instructions, as well as any document adopted by the Company and which makes up its internal regulatory system;

OFFENCES: the types of offence envisaged by Legislative Decree no. 231/2001 on the



administrative liability of entities;

ABMS: the anti-bribery management system adopted by the **COMPANY**, and certified according to the ISO 37001:2016 standard;

QMS: the quality management system adopted by the **COMPANY**, and certified according to the ISO 13485: 2016 and ISO 9001: 2015 standards;

DISCIPLINARY SYSTEM: the set of applicable sanctions and the related proceeding in the event of violation of the MODEL (and of the CODE OF ETHICS);

COMPANY: IBSA FARMACEUTICI ITALIA S.R.L. (hereinafter “IBSA ITALIA”);

TOP MANAGEMENT: persons who are representatives, directors or managers of the **COMPANY** or a unit or division of it that has financial and functional autonomy, as well as by persons who exercise the management or control of the same, even de facto;

SUBORDINATES: persons subject to the management or supervision of top management (hereinafter “SUBORDINATES” or “PERSONS IN A SUBORDINATE POSITION”).

WHISTLEBLOWING: the system for managing reports of unlawful conduct or violations of the Model, in accordance with the provisions of Legislative Decree 24/2023.

INTRODUCTION

The entry into force of the DECREE introduced the administrative liability of legal entities and legal persons as a result of the commission of certain crimes into the Italian legal system, which are in the interest or to the advantage of the same body, as committed by TOP MANAGEMENT or SUBORDINATES.

This liability can result in penalties for the body that can go as far as the prohibition to carry out its business activities, including in a definitive manner.

IN LINE with the focus that the IBSA Group places on ethical conduct and on the liability of entities for administrative offences that constitute a crime (pursuant to the DECREE), in September 2011 the Company decided to adopt a MODEL and to provide, over time, for the ongoing updating of the same. This MODEL consists of:

- a **General Section**, which provides general information regarding the COMPANY'S organizational profiles, ethical principles and corporate *governance*; the process of defining the MODEL itself and its operating principles, as well as the mechanisms for its actual implementation; the composition and duties of the Supervisory Body; the communication and dissemination system of the MODEL and staff training; the disciplinary system, which provides for disciplinary measures/sanctions against employees, directors, auditors and any other RECIPIENTS;
- a **Special Section**, which identifies the sensitive activities exposed to risk of crime and, for each of them, describes the checks provided for (protocols and procedures), with the particular, though not exclusive, aim of preventing the commission of the crimes referred to in the DECREE;

The COMPANY has adopted the MODEL and updates it on the basis of indications from case law to date on the DECREE. The latter requires that the MODEL stems from a realistic and effective vision of the business phenomena as well as the Guidelines periodically issued by trade associations (namely CONFINDUSTRIA and FARMINDUSTRIA) for the creation of organizational, management and control models.

An integral part of the Model are the GROUP'S CODE OF ETHICS and the ANTI-CORRUPTION GUIDELINES adopted by the Model, as well as the internal regulatory system, which oversees the proper performance of business processes.

More specifically, the CODE OF ETHICS is a summary of the principles followed by the RECIPIENTS in exercising their activities, as well as the framework within which the provisions and requirements of this MODEL FIT; the ANTI-CORRUPTION GUIDELINES, in turn, dictate the principles and rules to be followed to prevent, in all countries in which the GROUP operates, the occurrence of corrupt conduct of any kind.



GENERAL SECTION

1. CHAPTER - DESCRIPTION OF THE REGULATORY FRAMEWORK

1.1. Legislative Decree no. 231/2001 and the relevant legislation

Legislative Decree no. 231 of 8 June 2001 entered into force on 4 July 2001² in order to adapt Italian legislation on the liability of legal persons to certain international conventions to which Italy has long since been a part.³

The DECREE contains regulatory provisions concerning the “*Regulations governing the administrative liability of legal persons, companies and associations, including those without legal status*”.

The DECREE introduces and regulates the liability of the “entities” for administrative offences that constitute a crime: direct responsibility, of a (formally) administrative nature, of the body as a result of the commission of certain crimes by subjects functionally linked to the body itself, which provides for the applicability of administrative sanctions against it.

1.2. Nature and characteristics of the liability of legal persons

The administrative liability of the body deriving from the commission of one of the CRIMES provided for by the DECREE is added, and does not replace, that of the natural person who committed the offence.

The body shall be liable even if the accused has not been identified, or charges for the crime have been dropped against the offender for a cause other than amnesty.

Administrative sanctions against the body are set within five years from the date of commission of the crime. However, if the limitation period is interrupted by one of the acts expressly provided for in the DECREE, this shall not run until the time the judgement becomes final. It may therefore happen that charges for the alleged crime resulting in the body’s liability are dropped over the course of time, since the law establishes maximum limits exist for the criminal liability of the natural person, but does not relieve the responsibility of the body, which remains liable.

1.3. Types of offences identified by the DECREE and subsequent amendments

The liability of the body only arises in the cases and within the limits expressly provided for by law. The body “*cannot be held responsible for a fact that constitutes a crime if its responsibility... in relation to that event and the relative sanctions are not expressly provided for by law*”, which entered into force before the commission of the event.

²It was issued in execution of the delegation pursuant to Article 11 of Law no. 300 of 29 September 2000, published in the Official Journal no. 140 of 19 June 2001.

³Such as the Brussels Convention of 26 July 1995 on the protection of the financial interests of European Communities, the Convention of 26 May 1997, also signed in Brussels, on the fight against corruption involving officials of the European Community and Member States, and the OECD Convention of 17 December 1997 on the fight against corruption of foreign public officials in economic and international operations.

The body cannot be held responsible for the commission of any fact constituting a crime, but only for the commission of CRIMES and ADMINISTRATIVE OFFENCES strictly prescribed by the DECREE, in the formulation resulting from its original text as amended, as well as from laws that expressly reference the governance of the DECREE.

Law no. 146 of 16 March 2006 also assumes relevance for the purposes of identifying the relevant types of offences, which ratified and executed the Convention and Protocols of the United Nations against transnational organised crime, as adopted by the Shareholders' Meeting on 15 November 2000 and 31 May 2001, which identifies the responsibility of the body in the criminal conduct. In reference to a series of crimes committed against the public administration, the original text has been supplemented by subsequent legislative provisions that have expanded the number of offences whose commission can entail the administrative responsibility of the body. Law no. 146 of 16 March 2006 (hereinafter "Law 146/2006"), on the: "Ratification and execution of the Convention and Protocols of the United Nations against transnational organised crime, as adopted by the Shareholders' Meeting on 15 November 2000 and 31 May 2001" provides for the responsibility of the body in the event of commission of certain crimes (so-called Transnational Offences).

The catalogue of alleged offences shall therefore include the following:

- offences committed in relations with the Public Administration (Articles 24 and 25 of the DECREE, supplemented by Law 190/2012 and subsequent amendments and additions, as well as by Law 3/2019, Legislative Decree 75/2020 and by law 137/2023 which has introduced among the offences assumed those referred to in art. 353 c.p. and 353-bis c.p., and, last, Law 112/2024, that has taken note of the repeal of the offence referred to in art. 323 c.p.);
- offences relating to computer crime (Article 24-bis of the DECREE introduced by Law 48/08, and subsequently amended by Law 133/2019, and Law 90/2024, which has introduced as a presupposition offence the crime art. 629 p. 3 c.p.);
- offences related to organised crime (Article 24-ter of the DECREE, included by the so-called Security Law, Law no. 94 of 15 July 2009, partly amended by Law 62/2014);
- crimes related to counterfeit money, public credit cards, revenue stamps and identification tools or signs (Article 25-bis of the DECREE introduced by Law 409/01 and supplemented by Article 15, paragraph 7 of Law no. 99 of 23 July 2009, and lastly with Legislative Decree no. 125 of 21/2016");
- offences against industry and commerce (Article 25-bis.1 of the DECREE introduced by Law no. 99 / 2009);
- corporate crimes and corruption between private individuals (Article 25-ter of the DECREE introduced by Legislative Decree no. 61/2002 and partly amended by Law no. 262/2005 and supplemented by Law no. 190/2012, Law no. 69/2015 and Legislative Decree no. 38/ 2017", which further amended Article 2635 of the Italian Civil Code and introduced Article 2635-bis of the Italian Civil Code, entitled

- “Incitement to corruption among private individuals”; an offence further supplemented by Legislative Decree 19/2023 with the introduction of the crime of “false or omitted declarations for the issuance of the preliminary certificate”);
- crimes related to terrorism or subversion of the democratic order (Article 25-quater of the DECREE introduced by Law 7/2003);
 - practices of female genital mutilation (Article 25-quater¹ of the DECREE introduced by Law 7/2006);
 - offences against the individual (Article 25-quinquies of the DECREE introduced by Law 228/03 and partly amended by Law 38/06, Legislative Decree no. 24/2014, Legislative Decree no. 39/2014 and Law no. 199/2016, which introduced the offence of “Illicit intermediation and labour exploitation”);
 - market abuse (Article 25-sexies of the DECREE introduced by Law 62/2005);
 - crimes of culpable homicide and serious or grave injuries committed in violation of regulations on accident prevention and health and safety in the workplace (Article 25-septies of the DECREE, introduced by Law 123/0207 and subsequently replaced by Article 300 of Legislative Decree 81/2008);
 - offences regarding the receiving, laundering and use of money, goods or benefits of illicit origin, as well as self-laundering (Article 25-octies of the DECREE introduced by Legislative Decree 231/2007 and partly amended by Law 186/2014 and by Legislative Decree 90/2017, and further expanded by Law 137/2023);
 - offences relating to non-cash payment instruments and fraudulent transfer of values (Article 25-octies.1 of the DECREE introduced by Legislative Decree 184/2021) and amended by Law 137/2023, which introduced as a crime the offence referred to in art. 512bis c.p.);
 - offences relating to violation of copyright (Article 25-novies of the Legislative Decree introduced by Law no. 99/2009);
 - crime of inducement not to make statements or make false statements to the judicial authority (Article 25-decies of the DECREE introduced by Law no. 116 /2009);
 - environmental crimes (Article 25-undecies of the DECREE introduced by Legislative Decree no. 121/2011 and amended by Law no. 68/2015 and Legislative Decree no. 21/2018);
 - offence of the employment of third-country nationals whose stay is illegal (Article 25-duodecies of the DECREE introduced by Legislative Decree 109/2012 and amended with Law no.161/2017);
 - crimes of fraud in sports competitions, abusive exercise of gaming or betting and games of chance carried out by means of prohibited machines (Article 25-quaterdecies of Legislative Decree 231/2001 of the DECREE, introduced by Law 39/2019);
 - offences of racism and xenophobia (Article 25-terdecies of the DECREE introduced by Article 5 of Law no. 167 of 20 November 2017, the “European Law 2017”);

- tax offences (Article 25-quinquiesdecies of the DECREE, introduced by Law no. 157/2019 and amended by Legislative Decree no. 75/2020);
- smuggling offences (Article 25-sexdecies of the DECREE, introduced by Legislative Decree no. 75 /2020, amendment by DECREE no. 141/2024, which introduced excise offences ex Decree no. 504/1995);
- crimes against cultural heritage (art. 25-septiesdecies of the Decree, introduced by Law 22/2022);
- crimes of laundering cultural property and devastation and looting of cultural and landscape property (Article 25-duodevicies of the Decree, introduced by Law 22/2022);
- transnational crimes, referred to in Article 10 of Law 146/2006;
- non-observance of disqualification sanctions (Article 23 of Legislative Decree 231/2001).

For details of the individual types of crime for which administrative liability is provided for pursuant to the DECREE, see the catalogue annexed to this MODEL ([Annex 1](#)).

1.4. Objective criteria of assigning liability

The commission of one of the offences indicated by the DECREE constitutes the first condition for the applicability of the discipline dictated by the DECREE itself.

The DECREE provides for further assumptions, some of an objective nature, while others of a subjective nature.

The first fundamental and essential criterion of liability of an objective nature is constituted by the OFFENCE or the ADMINISTRATIVE CRIME being committed "*in the interest or to the advantage of the body*".

This means that the body assumes liability if the unlawful act was committed in the interest of the same or to benefit it, without the actual and concrete achievement of the objective being necessary in any way. It is therefore a criterion that is substantiated in the purpose (even non-exclusive) with which the illicit act has been carried out.

The advantage criterion instead regards the positive result that the entity has objectively obtained from the commission of the crime, regardless of the intention of the person who committed it.

However, the body is not liable if the unlawful act was committed by one of the subjects indicated in the DECREE "*in the exclusive interest of itself or of third parties*". This confirms that, if the exclusivity of the pursued interest prevents the liability of the body from arising, on the other hand the liability arises if the interest is common to the body and to the natural person or is partly attributable to one and in part to the other.

The second criterion of objective liability consists of the type of persons responsible for the unlawful act.

The criminal or administrative offence must have been carried out by one or more qualified subjects, which the DECREE groups into two categories, in particular:

- “by persons who perform functions of representation, administration or management of the body or one of its organizational units, which has financial and functional autonomy”, or by those who “exercise management and control, even *de facto*” of the body (subjects in “Top Management” positions);
- “by persons subject to the direction or supervision of one of the top managers” (“Subordinates”, which do not necessarily coincide with employees).

The perpetrators of the offence from which an administrative liability may arise for the entity can be:

- subjects in “*top management*” positions, such as the legal representative, director, general manager or the director of a head office or branch, as well as the persons who exercise management and control of the body, *even de facto*;⁴
- “*subordinates*” who are typically *employees*, but also external entities to the company, who have been entrusted with a task to be performed under the direction and supervision of the body’s “*top management*”.

If several persons cooperate in the commission of the crime (leading to the participation of multiple people in the offence pursuant to Article 110 of the Criminal Code; the same substantially applies in the case of an administrative offence), it is not necessary for the “qualified” subject to put the typical action provided for by law in place, not even in part: it is necessary and sufficient that it provides a consciously causal contribution to the commission of the crime.

1.5. Subjective criteria of assigning liability

The DECREE provides for a series of conditions of a subjective nature, some described positively, others negatively (in the broad sense, since they are entities) when liability arises, which constitute subjective criteria for liability for the unlawful fact for which the company is accused.

As a whole, the DECREE outlines the direct responsibility of the body, for its own action and guilt.

The liability of the body is excluded, in the event before the commission of the crime, it has adopted and effectively implemented an *Organization and Management Model* suitable for preventing the commission of crimes of the kind in question.

In simple summary, it follows that the body’s responsibility is based on the so-called organizational fault, failure to adopt it in advance, or on the failure to comply with the *standards* on the organization and activity of the body for the purpose of preventing crimes: this fault is attributable to the company’s policy or to structural and prescriptive *faults* in the company organization.

⁴ As is the case for a *de facto* director (see Article 2639 of the Italian Civil Code) or a “sovereign” shareholder.

The adoption of the Organization and Management Model does not constitute a requirement for the body, in the sense that there is no legal obligation for the company to adopt a model compliant with the indications of the DECREE.

If the company does not have an organizational and management model, however, it will be liable for the administrative responsibility established by the DECREE.

There is essentially a presumption of organizational fault in the failure to adopt the Organization and Management Model.

1.6. Crimes committed by Top Management

For offences committed by persons in positions of “*Top Management*”, the DECREE establishes the relative presumption of liability of the body, since it provides for the exclusion of its liability if it proves that (see Article 6 of the DECREE):

- “*Prior to the commission of the act, the governing body has adopted and effectively implemented models of organization and management suitable to prevent crimes of the type that occurred*”;
- “*The task of supervising the operation and observance of the models and ensuring their update has been entrusted to a body with autonomous powers of initiative and control*”;
- “*The persons committed the crime by fraudulently eluding the organization and management models*”;
- “*There was no lack of or insufficient supervision by the body with autonomous powers of initiative and control*”.

The conditions listed above must all apply for the liability of the body to be excluded.

1.7. Crimes committed by Subordinates

For crimes committed by subjects in a “*subordinate*” position, the body can only be liable if it is ascertained that “*the commission of the crime was made possible by non-compliance with the obligations of management or supervision*” (see Article 7 of the DECREE).

In other words, the body’s liability is based on the non-fulfilment of management and supervisory duties, duties attributed *pursuant to law* to top management or transferred to other subjects by means of valid proxies.

The regulation introduces a further presumption in favour of the body: failure to comply with management or supervisory obligations does not apply “*if, before committing the crime, the body has adopted and effectively implemented an appropriate organizational, management and control model to prevent crimes of the type that occurred*”. In a mirror image of that previously observed, the fault due to organization, in terms of a lack of

management or supervision, is not presumed *juris et de jure* and is excluded from the adoption of the *Organization and Management Model*.

The effective and efficient adoption and implementation of an appropriate Organization and Management Model, for the purpose of preventing the OFFENCES, constitute the fulfilment of the duties of management and control and act as exemption of the body from liability.

1.8. Characteristics of the Organization and Management Model

The DECREE does not regulate the nature and characteristics of the Organization Model. It is limited to the dictation of certain general principles that in part vary in relation to subjects who could carry out a crime.

For the prevention of crimes by top management”, the model must:

- “*Identify the activities in which crimes may be committed*” (**risk mapping**);
- “*Provide for specific protocols aimed at planning the formation and implementation of the body’s decisions in relation to the crimes to be prevented*”;
- “*Identify ways of managing financial resources that are suitable for preventing the commission of crimes*”; the express provision as regards financial resources indicates that the DECREE gives prominence to the internal regulation of the management of financial resources, which is crucial in the body’s activities;
- “*Provide for obligations of information to the body in charge of supervising the operation and observance of the models*” (“Information flows” to and from the SUPERVISORY BODY);
- “*Introduce a disciplinary system suitable for sanctioning any failure to comply with the measures indicated in the model*”.

With regard to crimes that can be committed by “subordinates” (to management and supervision: to be understood in a very broad sense), the organization and management model must provide for:

- “*In relation to the nature and size of the organization as well as the type of activity carried out, measures suitable to guarantee the performance of the activity in compliance with law, and promptly discover and eliminate at-risk situations*”.

The following must be provided for with regard to the effective implementation of the Organization and Management Model:

- “*A periodic verification and the eventual modification of the same, when significant violations of the provisions are discovered, or when changes occur in the organization or activity*”;
- “*a disciplinary system suitable for sanctioning any failure to comply with the measures indicated in the model*”.

1.9. Offences committed abroad

Pursuant to Article 4 of the DECREE, the entity may be considered responsible, in Italy, for the commission abroad of certain OFFENCES.

The assumptions on which this responsibility is based are as follows:

- the offence must be committed abroad by a subject functionally linked to the body, as a top management or subordinate subject (in the terms examined above);
- the body must have its main office in the territory of the Italian State;
- the body can only be held liable in the cases and under the conditions set forth in Articles 7, 8, 9, 10 of the Italian Criminal Code (and if the law states that the natural person responsible is punished at the request of the Minister of Justice, the body is only liable if the request is also formulated against the body itself);
- if the cases and conditions provided for by the aforementioned Articles of the Criminal Code exist, the body is liable provided that the authorities of the State of the place where the act was committed do not take action against it.

1.10. Attempt of commission of an offence

The administrative liability of the body arises even if one of the criminal offences (in particular, crimes) provided for by the DECREE as a source of responsibility is attempted (Article 56 of the Italian Criminal Code).

1.11. Sanctions

The sanctioning system provided by the DECREE mainly provides for fines and disqualification sanctions, as well as penalties of forfeiture and publication.

1.11.1. Financial penalties

Unlike the rest of the penal and administrative system, financial sanctions are determined by the judge through a system based on “quotas”. In abstract, each offence provides for a minimum and maximum number: in practice, the actual number is established by the judge, “*taking into account the gravity of the act, the degree of responsibility of the body and the activity carried out to eliminate or mitigate the consequences of the act and prevent the commission of additional offences*”; the monetary value of the single amount is determined by the judge based on the “*economic and asset-based conditions of the body*”, in terms such that “*the effectiveness of the sanction*” is assured.

The administrative sanction for the crime is applied by the criminal judge or the judge competent to sentence the perpetrator of the crime in a criminally relevant manner. In cases where the liability of the body exists for an administrative offence committed “*in its*

interest or to its advantage", said sanction is provided for by the administrative authority. If the liability of the body is affirmed, a financial sanction is applied in all cases.

Some cases of reduction of the pecuniary sanction are foreseen: a) if the perpetrator of the crime has committed the act predominantly in self-interest or that of a third party, and the body has not obtained an advantage, or has obtained a minimum advantage; b) when the damage caused is minimal.

The pecuniary sanction deriving from a crime is reduced from one third to half if, before the declaration of the beginning of the hearing of the first degree: a) the body has fully compensated the damage and eliminated the harmful or dangerous consequences of the crime or has made efforts in this direction; b) an organizational and management model suitable for preventing the commission of additional crimes has been adopted and implemented.

For crimes pursuant to Article 25- *sexies* of the DECREE, if the product or profit obtained by the body is significant, the pecuniary sanction is increased up to ten times the amount of said product or profit.

1.11.2. Disqualification sanctions

Disqualification sanctions apply in addition to pecuniary sanctions and constitute the most significant actions.

Disqualification sanctions provided for by the DECREE are:

- temporary or definitive disqualification from carrying out the activity;
- the suspension or revocation of authorisations, licenses, or concessions based on the commission of the offence;
- the prohibition to contract with the public administration, except to obtain the services of a public service;
- exclusion from benefits, loans, contributions, or subsidies and the potential revocation of those already granted;
- the temporary or permanent ban on advertising goods or services.

Disqualification sanctions are only applied in the cases expressly provided for, provided that at least one of the following conditions occurs:

- the body has made a significant profit from the crime and the crime was committed:
 - a. by top management;
 - b. by a subordinate, if the commission of the crime was determined or facilitated by serious organizational deficiencies;
- in the event of repeated offences.

Disqualification sanctions are normally temporary, but can be applied definitively in

exceptional circumstances.

At the request of the public prosecutor, the judge can apply disqualification sanctions to the body even as a precautionary measure, if there are serious indications of the body's liability and grounds and specific elements exist such as to consider the danger of illegal acts of the same nature high as regards the perpetrator in question.

Disqualification sanctions do not apply (or are revoked, if already applied as a precautionary measure) in cases where the body, before the opening declaration of the first instance hearing:

1. has provided compensation for the damage, or repaired it;
2. has eliminated the harmful or dangerous consequences of the crime (or has at least made efforts in this sense);
3. has made the profit of the crime available to the judicial authority for confiscation;
4. has eliminated the organizational shortcomings that led to the crime, adopting organizational models suitable for preventing the commission of new crimes.

If all of these behaviours occur, which are considered of active repentance, a financial penalty will be applied instead of the disqualification sanction.

1.11.3. Other sanctions

In addition to the pecuniary and disqualification sanctions, the DECREE provides for two other sanctions:

- confiscation, which consists in the acquisition by the State of the price or profit of the crime (or, when it is not possible to directly confiscate the price or profit of the crime, in the seizure of sums of money, goods or other benefits of equivalent value to the price or profit of the crime), without prejudice to compensation for damages;
- the publication of the sentence, which consists of only one publication, in extract or in full, at the expense of the body, in one or more newspapers indicated by the Judge in the sentence, as well as by its posting in the municipality where the body has its main office.

1.12. Modifying events of the legal entity

The DECREE regulates the liability of the body in the event of modifying events (transformation, merger, demerger and transfer of a company).

In general terms, it is established that as regards "*the obligation to pay the pecuniary*"

sanction” imposed on the body, “*only the body shall be liable, with its assets or shared fund*”.

The direct liability of shareholders or associates is therefore excluded, regardless of the legal nature of the body.

The general criteria for the application of the financial penalties imposed on the body are those established by civil laws on the liability of the body being transformed for the debts of the original body.

Disqualification sanctions remain the responsibility of the body where the branch of activity in which the offence was committed remained (or has merged), without prejudice to the right of the body resulting from the transformation to obtain the conversion of the disqualification penalty into a pecuniary sanction when the reorganization process following the merger or division has eliminated the organizational *faults* that made the commission of the crime possible.

The DECREE states that, in the event of “*transformation of the legal entity, responsibility remains for crimes committed before the date on which the transformation took effect*”.

Changes in the legal structure (company name, legal form, etc.) are irrelevant as regards the liability of the body: the new body will be liable for sanctions applicable to the original body and facts committed before the transformation.

With regard to the potential effects of mergers and demergers, the merged body, also by incorporation, is “*liable for the crimes for which the legal entities participating in the merger were responsible*”. When the legal entity resulting from the merger takes over in the legal relations of the merged legal entities and the merge of the related company activities, including those within which the offences were carried out, a transfer of responsibility is given to the body resulting from the merger.

If the merger took place before the conclusion of the assessment of the body’s liability, the judge must take into account the economic conditions of the original body and not those of the body resulting from the merger.

In the event of partial demerger, if the demerger takes place through the transfer of only a part of the assets of the demerged company that continues to exist, the responsibility of the demerged body remains unchanged for the crimes committed before the demerger. The collective legal entities benefiting from the demerger that received the assets (in whole or in part) of the demerged company, are jointly and severally liable for the payment of the financial penalties due by the demerged body for crimes that occurred prior to the demerger. The obligation is limited to the value of the assets transferred: this limit does not apply for beneficiary legal entities to which the branch of activity in which the crime was committed was received, even only partially.

The DECREE also regulates the sale and transfer of a company. In the event of sale or transfer of the company within which the crime was committed, the transferee is jointly and severally liable for the payment of the pecuniary sanction with the transferring body, within the limits of the value of the company sold and subject to the benefit of prior enforcement of the transferring body.

In addition to being limited to the value of the company being sold (or transferred), the

responsibility of the transferee is also limited to the pecuniary sanctions that result from mandatory accounting records, or due to administrative offences of which the transferee was aware.

1. 13. Codes of conduct prepared by associations representing the legal entities

The DECREE states that the organizational and management models can be adopted on the basis of codes of conduct drawn up by the associations representing the institutions and communicated to the Ministry of Justice, which has the right to formulate, together with the competent Ministers, observations on the suitability of the models to prevent crimes within 30 days, provided that they guarantee the needs indicated by Article 6, paragraph 2, of the DECREE.

CONFINDUSTRIA has defined its own *Guidelines* for the construction of organizational, management and control models (hereinafter the “Confindustria Guidelines”). These *Guidelines* suggest the use of *risk assessment* and *risk management* processes, providing for the following phases:

- **identification of potential risks** and the **definition of protocols**: the identification of risks implies “*the analysis of the corporate context to identify in which areas or sectors of activity and according to which methods could abstractly verified events detrimental to the objectives indicated by Decree 231*”. The outcome of this phase is the “Map” “*of the business areas at risk and the relevant crimes*” as well as “*the potential ways of implementing the offences in areas at risk*”. The definition of the **protocols** involves the planning (or only the adaptation, if already existing) of a **control system** that regulates the formation and implementation of the decisions of the body; this phase implies “*the evaluation of the existing system within the body for the prevention of crimes and its possible adaptation, in terms of the ability to effectively counter the identified risks*”, where effective work to combat risks does not necessarily require their total elimination (to be carried out where possible), but could also be limited to their reduction “*to an acceptable level*”;
- the adoption: (a) of a **Code of Ethics**, which contains “*the set of rights, duties and responsibilities of the body towards*” *stakeholders* “*(employees, suppliers, customers, Public Administration, shareholders, financial market, etc.)*”, aimed at “*recommending, promoting or prohibiting certain conduct, regardless of what is provided for by law*”, thus outlining the **general principles** of conduct on which the body bases its conduct when carrying out its business; (b) of a structured **disciplinary system**, which serves to adequately sanction the violation of the provisions of the organization and management model according to the principles of proportionality and cross-examination, which is structured differently according to the RECIPIENT (“top management”, “subordinates”, “third parties”);



- the identification of a **Supervisory Body**, which: (a) is in possession of specific **requirements of a subjective and objective nature** (outlined by the Guidelines themselves based on case law); (b) is the custodian of specific **duties and powers** laid down in Article 6 of the DECREE; and (c) is the fulcrum of a **structured system of information flows**, which includes lines for both periodic reporting and *whistleblowing* and involves all of the RECIPIENTS of the Model itself.

2. CHAPTER - COMPANY DESCRIPTION - GOVERNANCE AND ORGANIZATIONAL STRUCTURE

2.1. The IBSA Group

IBSA FARMACEUTICI ITALIA S.R.L. is controlled by IBSA INSTITUT BIOCHIMIQUE SA with registered office in Lugano, Switzerland.

IBSA INSTITUT BIOCHIMIQUE SA, a company founded in 1945, has undertaken a development program since 1985 to strengthen its position, also opening up to the international market. Continuous growth has allowed us to reach a leading position in specific therapeutic areas.

The IBSA GROUP is mainly engaged in the development of effective treatments and innovative products for the treatment of diseases with a significant social impact.

Over 30 years, a *business* model has been developed based on three fundamental principles:

- vertical integration: most of the products are made internally with direct control on all production phases and processes. This guarantees high qualitative standards on all processing stages, greater flexibility and risk reduction along the *supply chain*;
- focus on effective treatments: research and development on special technologies that qualitatively and significantly improve molecules and therapeutic solutions already available, focus is particularly directed on innovating administration systems;
- international presence.

Production capacities range from oral to high-tech injectable formulations.

The following therapeutic areas are of the greatest interest for the GROUP, where activities are concentrated to offer innovative, reliable and advantageous solutions for patients:

- cardiometabolic;
- consumer health;
- dermatology;
- aesthetic medicine;
- endocrinology;
- reproductive medicine;
- osteoarticular;
- pain and inflammation;
- respiratory;
- uro-gynecology.

To achieve long-term results and ensure a range of quality products and services, the GROUP uses internal resources at each stage of the development process, from basic

research to the use of pharmaceutical techniques and pre-clinical and clinical research, to regulatory service activities.

The IBSA GROUP actively markets its products. The *marketing* approach is based on accurate information and integrated support to meet the needs of the medical class in the treatment of its patients.

2.2. IBSA FARMACEUTICI ITALIA S.R.L.

IBSA FARMACEUTICI ITALIA S.R.L. was founded in March 1992 following the decision of THE IBSA GROUP to directly have a presence on the Italian market, a move considered strategic.

The Company's main activities, carried out within the Lodi and Cassina de' Pecchi industrial centres, as well as in its offices in Rome and its laboratories in Ariano Irpino, are research and development, production, promotion and marketing/sales of medicinal specialities (drugs), food supplements, medical devices and cosmetics.

The main customers of the COMPANY are public and private companies such as hospitals, laboratories, pharmacies, medical offices, wholesalers, other Group companies and third-party companies, in Italy and abroad.

The growth of IBSA ITALIA in the reference market took place over time, both for internal lines through the implementation of new activities by leaning on the resources present in the Group, and for external lines with the acquisition of AMSA S.R.L. in 1996, GELFIPHARMA S.R.L. in 2001, and the BOUTY S.p.A. Group in 2010.

In order to rationalise the corporate structure of the Italian subsidiaries, the AMSA S.R.L. AND GELFIPHARMA S.R.L. companies were merged into IBSA ITALIA in May 2010, and the merger of the Bouty S.p.A. and Corsel Pharma S.r.l. companies took place in 2018.

The COMPANY'S goal is to operate in the healthcare world in an innovative and competitive manner, with proposals that respond to the real needs of its stakeholders, while bearing in mind that the patient is always the COMPANY'S prime focus.

The pillars of IBSA Farmaceutici are: people, innovation, quality and sustainability.

Over the years, the COMPANY has developed a series of niche proprietary technologies (e.g. FILMTEC, PEARLtec, NAHYCO HYBRID), that allow an improvement in the quality of molecules and therapeutic solutions currently available and widely used, whose safety and efficacy have been confirmed over years of use. This choice is accompanied by wide-ranging competence, which involves all of the typical activities of a pharmaceutical company, from basic research to development, quality production, high competence in regulatory matters, to the direct scientific information of its own products by the medical profession through a network of Pharmaceutical Representatives, employees of the COMPANY.

For the distribution of its products on the Italian market, the COMPANY uses dedicated sales networks, also e-commerce, together with a dense network of distributors for the foreign market, as well as the other subsidiaries of IBSA GROUP.

2.3. Business divisions and support functions

The COMPANY has an organizational structure divided into:

a. Primary Activities:

- (i) Production and Operations: Manufacturing, Supply Chain, Quality Control.
- (ii) Commercial: Commercial Direction Italy including Sales, Marketing, Market Access; Dermaoesthetics Division, with role of "Global"; Customer & Business Support, Pharma Distributors &– Business Development.
- (iii) Sciences Area including Medical Affairs; Research and Development; Regulatory Affairs;

b. Support functions:

- (i) Finance & Administration,
- (ii) Information Security (IS) and Information Technology (IT)
- (iii) Corporate Communication & CSR
- (iv) Human Resources & Organization
- (v) Health Safety and Environment
- (vi) Quality Assurance
- (vii) Legal Affairs & Compliance
- (viii) Public Affairs
- (ix) Environmental Social Governance (ESG)

This organizational structure operates, according to a functional report, in coordination with the Swiss parent company IBSA INSTITUT BIOCHIMIQUE SA, consistently and in compliance with the company procedures and control systems defined at Group level.

2.3.1. Operations

The production of IBSA GROUP is directed and coordinated under the guidance of the Chief of Technical Operations, in staff to the parent company IBSA SA.

IBSA ITALY production system consists of two production sites (Lodi and Cassina de' Pecchi) both authorised by AIFA (the Italian Medicines Agency) for the productions of drugs and by the competent authorities of many countries including the United States, for the production of medicines and medical devices.

The two production sites operate in compliance with the Good Manufacturing Practices (hereinafter referred to as "cGMP") regulation and are equipped with Quality Management Systems (QMS) certified according to the ISO 9001 and ISO 13485 standards. The two

sites are subject to periodic checks by the Ministry of Health, AIFA, territorial local health authorities, Notified Bodies and accredited Certification Bodies.

The principles and procedures of the Quality Management System (QMS) are, on the other hand, subject to internal checks on its correct application within the company, through periodic audits based on an annual plan.

All operations related to production processes are formalised and tracked. The related documentation is filed by the organizational units involved and/or the *Quality Assurance* department responsible for setting up, from the preparation of dossiers in line with the current legislation on the subjects and the preparation of documentation supporting the application for marketing authorisation.

Each production site has a Quality Unit consisting of the Quality Assurance and Quality Control departments and of Qualified Persons.

Moreover, the Quality Control and Quality Assurance departments are centrally coordinated.

The activities of the production sites are supported by the Supply Chain function for the procurement of goods and services.

The Supply Chain function is also involved in procurement processes, including related ones, for so-called indirect purchases, i.e. not intended directly for production.

2.3.2. Commercial

IBSA ITALIA sells its own products, those of third parties, in Italy and abroad. The head of the commercial structure is the Chief Commercial Officer ("CCO"), on staff at the parent company IBSA SA, responsible for supervising and guiding all the commercial activities of the IBSA GROUP.

The Commercial Area of IBSA ITALIA comprises the following organizations:

i) Commercial Department Italy, also known as Commercial Operations; ii) Dermoaesthetic Division, also known as the Dermoaesthetic Department or Division; iii) Customer & Business Support; iv) Pharma Distributors & Business Development.

In detail:

i) Commercial Department Italy (also called "Sales": deals only with the Italian territory, for all company products (including aesthetic medicine products).

ii) Dermo-aesthetics Division: deals only with aesthetic medicine products for all countries in the world with the exception of Italian market (which is managed by the Commercial Department Italy); has a corporate role with respect to the Group's subsidiaries with regard to the aesthetic medicine business.

Within both Directorates i) and ii) the following activities are managed:

1) Product marketing

- 2) Direct sales and, in the case of the Dermo-aesthetics Division, also through international distributors/ international branches.
 - 3) Management of sales agents
 - 4) Market Access (only Sales Department Italy): includes access to the local market for new drugs. In the field of Market Access, KRAMs (Key Account Regional Managers) are dedicated to collaborating with regional and local health authorities.
- iv) Pharma Distributors & Business Development,
Manages the following activities:
- 1) Business Development: search for international partners and distributors for licensing agreements in countries where the IBSA Group does not operate directly with its subsidiaries.
 - 2) Licensing in and out: evaluation of opportunities in the reference market both on its own behalf and for the Group in general, and on behalf of third parties, also through the creation of strategic relationships and alliances as well as licensing-in opportunities for the expansion of the product portfolio.

2.3.3. Sciences

The Sciences Area comprises three organizations: Medical Affairs, Research and Development, Regulatory Affairs all of which are under the responsibility of the Chief Scientific Officer, who coordinates the entire scientific area of the IBSA GROUP.

Medical Affairs

The Medical Affairs ensures adequate scientific support to the company's functions by guiding the development and execution of medical strategies as well as correct communication with stakeholders of the products placed on the market.

The Medical Affairs function is divided into two areas: Medical Affairs Italia (with scope extended to all company products excluding products from the therapeutic area of aesthetic medicine) and Dermoaesthetics Medical Affairs (with limited scope of application to products in the therapeutic area of aesthetic medicine).

Medical Affairs Italia manage the following activities:

- Scientific information: the COMPANY performs scientific information activities on its products with healthcare professionals. This activity is carried out by the Pharmaceutical Representatives employees of the COMPANY, with the support of Medical Affairs.

The informational activity and promotion of products, including the evaluation of the scientific contents in occasion of the organization of congresses and sponsorships, is carried out in accordance with specific internal procedures and with the provisions of applicable legislation. It is in line with:

- the Farmindustria Code of Conduct, to which IBSA ITALIA adheres;

- the Guidelines of Farindustria, (see “Reference document for the certification of procedures relating to scientific information activities”), which take into account the requirements regarding the administrative liability of legal persons (pursuant to Legislative Decree no. 231/01 and subsequent amendments and additions);
- the Code of Ethics of Confindustria Dispositivi Medici, of which IBSA ITALIA is a member.

The Head of Medical Affairs guarantees compliance with the provisions on the performance of the activities of scientific informants holding the position of Head of the Scientific Service.

- Scientific training: organization of training aimed at ISFs, Sales Agents, Healthcare Professionals, on the scientific aspects related to the products in the company price list, also with the support of consultants.
- Clinical trials: management of clinical trials related to company products. This activity involves both public and private research centres, Ethics Committees, and Clinical Research Organizations.
- Scientific consultancy: the Medical Affairs function makes use of scientific consultancy for the execution of experimental activities and not related to the products of the company portfolio.

Dermaoesthetics Medical Affairs manages the following activities:

- Product promotion, including the evaluation of the scientific relevance of the content in the context of the organization of conferences and sponsorships. This activity is carried out in accordance with specific internal procedures and in accordance with the provisions of the current legislation and is in line with the Code of Ethics of Confindustria Medical Devices, of which IBSA ITALIA is a member.

The Head of R&D and Medical Affairs ensures that the requirements for carrying out the above activities are met.

- Scientific training: organization of training for sales agents and health professionals on the scientific aspects related to the products in the company’s list, also with the support of consultants.
- Management of clinical studies related to the company’s products in the therapeutic area of aesthetic medicine. This activity involves both public and private testing centres, Ethics Committees, Clinical Research Organizations.- Scientific advice: the Medical Affairs function uses scientific advice for the execution of experimental and non-product-related activities in the company’s portfolio of aesthetic medicine therapeutic area.

Research and Development (R&D)

The study, design and production of new products, as a manufacturer on its own account, for the Group and/or for third parties. The IBSA ITALIA R&D division provides for

the update of the product price list for the domestic market and abroad. An integral part of this structure is the regulatory function that operates in order to develop and update registration documents for medical devices, supplements, cosmetics and production sites, with the exception of pharmaceutical products, designed to satisfy the requests of national authorities.

Each activity is performed in synergy with the Parent Company IBSA SA and is aimed not only at the development of new formulations, but at the refinement, improvement, optimisation and development of existing formulations, providing for the completion of all stages of the process (formulation, confirmation of its technical feasibility, development of the toxicological, pharmacological and clinical parts).

R&D activities are carried out at the Lodi, Cassina De' Pecchi and Ariano Irpino sites (where efficacy studies and biological evaluations of medical devices are conducted).

Regulatory Affairs

The Regulatory Affairs function is responsible for the preparation and submission of the documentation necessary to maintain and obtain the authorisations necessary for the marketing of the products in the IBSA portfolio under its responsibility. In this context, there are interactions with the regulatory bodies that review the aforementioned documentation and during inspection visits.

It is also responsible for verifying the compliance with applicable regulations of promotional materials intended for healthcare professionals and the public for subsequent submission to the Competent Authorities for authorization, where applicable.

2.3.4. Support functions

Primary activities are carried out by IBSA ITALIA with the support of certain functions of Group companies, including those abroad. They are:

- Finance & Administration;
- Corporate Communication & CSR;
- Human Resources & Organization;
- Health Safety and Environment;
- Quality Unit (Quality Assurance + Quality Control);
- Legal Affairs & Compliance;
- Information Security;
- Environmental Social Governance (ESG);
- Pharmacovigilance;
- Management of Information System;
- Travel organization.

2.3.5. Outsourced services

The COMPANY pursues the efficiency and effectiveness of all corporate functions. In this perspective, the COMPANY has managed certain functions for external collaborators (*outsourcers*), some within the Group (compare 2.3.4) and other external parties.

The following activities are outsourced to third-party companies:

- Payroll processing and related obligations;
- Tax compliance consultancy;
- Litigation management;
- Warehouse management of finished products for distribution;
- Conduct of clinical trials;
- Filing of documents.

For each outsourced process and consultancy, a specific contract is drawn up that governs the relations between the parties, with particular reference to the scope of the service, the economic conditions and the related responsibilities, also pursuant to the legislation provided for by the DECREE.

2.4. Governance model

The corporate governance system of IBSA ITALIA, as a set of rules, planning, management and control methods necessary for the operation of the company, was outlined in compliance with current legislation and national and international *best practices* to which the Group adheres.

The elements on which the COMPANY's *governance* model is based are:

- the set of values defined in the CODE OF ETHICS and in the ANTI-CORRUPTION GUIDELINES AND IN THE SUPPLIER CODE OF CONDUCT;
- the central role of the Board of Directors;
- transparency in management;
- the attentive distribution of responsibilities on the management, monitoring and evaluation of the internal control and risk management system;
- employees.

The COMPANY uses a "traditional" type of administration system, which provides for a division of responsibilities between Shareholders, the Board of Directors and the Board of Statutory Auditors. In order to increasingly ensure conditions of correctness and transparency in the management of company activities, IBSA ITALIA has deemed it appropriate to also adopt an Organization, Management and Control Model pursuant to

the DECREE, and establish a SUPERVISORY BODY which, together with the CODE OF ETHICS, the PROCEDURES and other policies and provisions defined by the COMPANY, constitutes the plan to ensure the effective prevention and detection of legal violations, as well as a set of corporate governance tools aimed at permitting a healthy management of the company in a manner that is consistent with the objectives set.

The roles and responsibilities of the bodies on which the “traditional” model is based are provided below:

2.5. Board of Directors

As defined by the Articles of Association, the COMPANY may be alternatively managed, by means of a decision of the Shareholders, by a sole director, a Board of Directors composed of two or more members, or two or more directors with joint or separate powers. The choice made by the Shareholders was to establish a Board of Directors composed of six members, including non-shareholders, who remain in office until revocation or resignation. The Board of Directors, composed as such, has all of the powers of ordinary and extraordinary administration, without any limit whatsoever, without prejudice to that which per law is reserved for Shareholders.

2.6. Board of Statutory Auditors

With a decision of the Shareholders on 6 May 2010, the COMPANY has a Board of Statutory Auditors consisting of three standing auditors and two alternate auditors. The Board of Statutory Auditors supervises compliance with the law and the deed of incorporation, compliance with the principles of proper administration, the adequacy of the organizational structure of the company and the methods of concrete implementation of the rules of corporate governance. It is also called upon to monitor the independence of the auditing company, verifying both compliance with the relevant regulatory provisions and the nature and extent of any non-auditing services provided to the company and its subsidiaries by the auditing firm itself and entities belonging to its network. The Board of Statutory Auditors is also called upon to make a proposal to the Shareholders at the time of assignment and revocation of the statutory auditing mandate.

2.7. Auditing Company

Upon a decision of the Shareholders and given the conditions, an audit firm was appointed to verify the proper keeping of accounting records and the correct recording of management actions in the accounting records, as well as the compliance of the financial statements with the rules governing their preparation and correct and truthful representation of the balance sheet and financial position and the economic result for the year, expressing an opinion on the financial statements and the consistency of the management report with the financial statements. It also carries out the additional checks

required by regulations, including those in the sector, and the additional services entrusted to it, where these are not incompatible with the task of auditing the accounts.

2.8. Organizational structure

The COMPANY defines its organizational structure through:

- the identification of the company functions and the activities they carry out;
- the assignment of functional responsibilities and the definition of hierarchical lines of reporting, as highlighted in the company organization chart;
- the definition of a system of rules that establishes general and specific lines of conduct (PROCEDURES), aimed at regulating company activities;
- the definition of a system of authorisation and signatory powers that guarantees the timely and transparent representation of the company decision-making and implementation process;
- the definition of a control system capable of promptly reporting the existence and occurrence of general and/or specific critical situations.

The aforementioned and that specified in the following paragraphs represents the applicable business practice for IBSA ITALIA.

2.9. Organizational chart and corporate organization

The COMPANY periodically updates its corporate organization chart, which describes the activities, responsibilities and functions of the business divisions and support functions. In drawing up its organizational structure, particular attention is paid to the assignment of functional responsibilities, the definition of hierarchical lines of reporting and the formalisation of authorisation levels necessary for the performance of corporate activities in “sensitive” sectors.

To this end, through a formalised system of delegation of powers, in compliance with the principle of segregation of functions, the spending and signing powers in force within the company organization have been defined, also using schemes that provide for combined signatures, in full compliance with the so-called *four eyes principle*.

For each category of expenditure, an authorisation process has been identified that allows IBSA ITALIA, its employees and its stakeholders to minimise the risks by including several signatories from different areas of the company.

It is understood that the duties and activities of each organizational unit are described in the job descriptions managed by Human Resources and Organization.

Moreover, the COMPANY, sensitive to the need to guarantee correct management of environmental and health and safety requirements in the workplace, as well as to ensure efficient and effective company organization, in line with the concrete functioning of IBSA

ITALIA, has formally identified the Employer, pursuant to Article 2 of Legislative Decree 81/2008, who also holds the position of Environmental Manager.

The latter, in turn, has conferred proxies in the forms and in accordance with the procedures set out in Article 16 of Legislative Decree 81/08 to company managers, invested with the broadest managerial and organizational powers both in the field of safety and the environment.

More specifically, taking into account the structure and size of the company, the identified Employer has conferred powers of function in the field of health and safety in the workplace to the managers in charge of the following area: Production plants, Research & Development, Quality Assurance, Quality Control, Logistics.

In order to supervise the work areas managed by them and the related company activities in a capillary manner, these subjects have conferred the sub-delegation of functions pursuant to Article 16, paragraph 3-bis of Legislative Decree 81/2008 to subjects adhering to the requisites of competence, ability, professionalism and experience required to perform the specific functions transferred.

With particular reference to environmental obligations, the Chief Executive Officer and Environmental Manager has delegated the HSE Manager for a more timely and efficient management of the same.

2.10. Attribution of powers

The Board of Directors may delegate the powers of ordinary or extraordinary administration, in whole or in part, to one or more Managing Directors or an Executive Committee, within the limits established by law.

In order to carry out specific activities, the Board of Directors can confer powers of functions/powers of attorney, equipping various persons with effective powers and instruments, also persons external to the board itself.

In addition, the COMPANY may designate according to policies or procedures functional managers within the organization or external representatives of the COMPANY who are part of the IBSA SA Group through specific procedures, in assigning to them specific tasks and powers.

In the first case, the delegation of function/power of attorney is attributed through deeds to which adequate publicity must be given, thus making it enforceable against third parties (i.e. through resolutions of the Board of Directors or filing with the Register of Companies); the second case is an internal act that can be made operational through the approval of procedures, job descriptions, or documents that regulate organizational, authorisation and procedural aspects referable to single cases.

The system is designed to ensure the balance of powers assigned, the absence of situations of the concentration of liability, assignment of incompatible roles and compliance with the principle of the segregation of duties.

The COMPANY has adopted a delegation system of functions/powers of attorney and procedures with the identification of department managers, which are suitable for guaranteeing the timely and transparent representation of the company decision-making and implementation process and promptly managing any situations of a general and/or particular nature.

In addition, IBSA ITALIA has a *Signature Policy*, which establishes the issuing powers for purchase orders in the ERP management system, excluding bank accounts and payments. The following company figures are given the powers to issue: i) local Buyers; ii) Corporate Buyers; iii) Local Buyer Coordinator; iv) Corporate Buyer Coordinator; v) cost centre managers; vi) Head of Cost Centre.

2.11. Decisions by top managers and conflicts of interest

The formation and implementation of the directors' decisions are governed by the principles and provisions contained in applicable legal provisions, the deed of incorporation, Articles of Association, CODE OF ETHICS, MODEL and the Internal Control system. The Directors are required to promptly notify the Board of Directors, the Board of Statutory Auditors and the BODY in charge of archiving and updating as regards all information relating to roles assumed or securities directly or indirectly held in other companies, as well as their transfers or modifications that, due to their nature or type, may reasonably allow the occurrence of conflicts of interest pursuant to Article 2391 of the Italian Civil Code.

The same obligation of communication referred to in the previous point applies to the Managers who are in senior positions, who must inform the Managing Director, the BODY and representatives of the COMPANY appointed in the corporate bodies of foreign subsidiaries, with reference to the existence of family ties or relationships with members of the local Public Administration and/or suppliers, customers or third party contractors of the COMPANY itself.

The employees of the COMPANY (Directors, General Manager and Executives included) cannot accept any kind of gift/regalia (even the usual Christmas gifts) from suppliers and other external parties. Specifically, after registration in the registry, the gifts/ gifts are donated to charity.

2.12. Company procedures

The COMPANY follows specific **PROCEDURES** in carrying out its business. In order to ensure easier maintenance and updating both of the MODEL as well as of the

PROCEDURES, the procedural body is separated from the Model, although it represents a necessary, essential and therefore explicitly mentioned requirement⁵.

The procedural body of the Company is divided into:

- organization chart and company job descriptions;
- procedures and operating instructions of the Quality Management System (QMS);
- Anti Corruption Management System (SGAC) procedures and operational instructions; procedures, operating instructions and policies identified with the acronym SOP;
- procedures, operating instructions and policies adopted by the Legal Affairs and Compliance;
- the Safety Risk Assessment Document adopted by the COMPANY and the company documentation referred to therein (work sheets, procedures, work instructions, etc.).

2.13. Company IT system

IBSA ITALIA uses the ERP SAP as company information systems to support its activities. The SAP ERP system is used for administrative activities not directly related to production and distribution.

ERP is used to manage and track production processes and product distribution activity on the market, as well as administrative processes.

In addition to supporting the COMPANY'S operations through data collection, processing and archiving for the purpose of producing and distributing information, ERP SAP plays a control role in allowing continuous alignment with the *governance* system as regards the organization, definition and assignment of functional and economic responsibilities. Actions and interventions taken by IBSA ITALIA on the SAP corporate IT system are aimed at supporting the organizational structure and making the assignment of responsibilities and delegated powers effective in order to allow the performance of corporate activities. The system of rules implemented by the COMPANY to regulate corporate activities in "sensitive" sectors finds practical application in SAP ERP, which incorporates and gives effect to the operating powers attributed to individual subjects, both with reference to areas of responsibility and the pre-established individual limits of signature and consequent spending powers.

Utility profiling also enables the computerised traceability of operations carried out.

To ensure security, access controls are provided to the SAP system based on a user name and password, profiled on the basis of the specific tasks of each member of the organization.

Data security is guaranteed by back-up procedures that, when performed periodically, safeguard the availability of data contained in computer archives.

⁵ For details of the Procedures that form an integral part of the Model, please refer to Annex 3 "Table linking sensitive processes - company procedures".

2.14. Certifications

The Company's Quality System is certified in accordance with ISO 9001:2015 and ISO 13485:2016.

The Company has also implemented a management system for the prevention of corruption certified in accordance with the ISO 37001:2016 standard.

2.15. Appointment of the Trusted Advocate and establishment of the Company in case of charges against the legal representative

In application of art. 39 of the DECREE, the COMPANY called to answer in criminal proceedings participates with its legal representative, unless he is suspected or accused of the crime that the administrative offence depends on.

In the latter case, the legal representative cannot provide, due to the incompatibility condition in which he is, for the appointment of a lawyer and the establishment of the body for the general and absolute prohibition of representation laid down by the aforementioned article. For this reason, the MODEL must provide precautionary rules for possible situations of conflict of interest of the legal representative suspected of the crime assumed, valid to equip the institution with a lawyer, appointed by specifically delegated subject, that its interests are protected.

In this case, the COMPANY has overcome this problem by providing - more generally - that the appointment of trusted counsel is always and exclusively the responsibility of the Head of Legal Affairs and Compliance of the Group, who does not have the status of legal representative.

However, as the Head of Legal Affairs and Compliance is also a member of the Board of Directors, it has been provided that, in the event that all members of the Board of Directors are investigated/charged with (and therefore also the Head of Legal Affairs and Compliance) the power to appoint the COMPANY's trusted advocate and to be constituted before the Judicial Authority, which is up to the Senior Compliance Manager of the Group.

3. CHAPTER - NATURE, SOURCES AND PURPOSES OF THE MODEL AND OF THE CODE OF ETHICS

This MODEL, approved by the Board of Directors on 15 September 2011 and subject, over time, to ongoing updates due to the organizational and regulatory changes that have occurred over the years, constitutes the internal regulation of IBSA ITALIA, to which the company is bound. It is understood as the set of operating rules and ethical conduct adopted by the COMPANY according to the specific activities carried out in order to prevent the commission of the OFFENCES listed in the DECREE.

The MODEL is inspired by the Guidelines of trade associations, namely *Confindustria* and *FARMINDUSTRIA*, and based on the results of RISK MAPPING and *risk assessment* activities. The COMPANY intended to comply with the provisions of the law with the adoption of the MODEL, first and foremost in conforming to the principles of the DECREE, the associated Self-Regulation Codes and the Recommendations of the supervisory and control authorities, as well as make its internal control and corporate governance system more effective, with particular reference to the objective of preventing the commission of the CRIMES provided for by the DECREE.

3.1. Purpose of the IBSA ITALIA MODEL

The MODEL has the following objectives:

- knowledge of activities that present a risk of committing crimes relevant to the COMPANY (at-risk activities); knowledge of the rules governing risk activities; adequate and effective information to the RECIPIENTS regarding the methods and procedures to be followed in carrying out the at-risk activities; awareness of the sanctioning consequences that may arise to them or to the COMPANY due to the violation of the law, its rules or internal provisions;
- dissemination, personal acquisition and actual affirmation of a corporate culture based on *legality*, being aware of the express reproach on the part of the COMPANY of any conduct that is contrary to the law, regulations, rules of self-discipline, indications of the supervisory and control authorities, internal provisions and, in particular, the provisions contained in this MODEL;
- dissemination, personal acquisition and concrete affirmation of a culture of *control*, which must preside over the achievement of objectives which, over time, the COMPANY puts into place exclusively on the basis of decisions regularly made by the competent corporate bodies;
- efficient and balanced *organization* of the COMPANY, with particular regard to the clear attribution of powers, the formation of decisions and their transparency and

motivation, preventive and subsequent controls on deeds and activities, as well as the correctness and truthfulness of internal and external information.

In relation to the nature and size of the organization specifically concerned as well as to the type of activity or function performed, measures must be taken that are concretely suitable to improve efficiency in carrying out the activities or functions, ensuring constant compliance with the law and all other rules that intervene to regulate the activity or function, promptly identifying and eliminating situations at risk of the commission of crimes, or at least reducing them to the minimum possible.

For the purposes indicated in the previous paragraph, the COMPANY adopts, enforces, and continuously adapts effective regulatory, organizational and procedural choices:

- to ensure that human resources of all levels are recruited, managed and trained according to the criteria expressed in the CODE OF ETHICS OF THE GROUP, the principles and provisions of the MODEL and in timely compliance with applicable legislation, in particular with Article 8 of the Workers' Statute;
- to foster collaboration with the most efficient, constant and widespread implementation of the MODEL by all subjects that work within or with the COMPANY, always ensuring the protection and confidentiality of the identity of those who provide truthful and useful information to identify conduct that is contrary to that prescribed;
- to guarantee that the distribution of powers, competences, functions, duties and responsibilities of the individual subjects working within the COMPANY and their placement within the corporate organization comply with the principles of transparency, clarity and verifiability, and are always consistent with the activity effectively carried out by THE COMPANY. For this purpose, the system of powers of attorney and proxies must be indicated in a document approved by the Board of Directors and constantly updated, with specific indication of the powers attributed, also as regards expenditure or financial aspects, and the limits of autonomy;
- to punish behaviours that constitute an objective exceeding of the competences, attributions and powers of each subject, as determined by law and the rules that apply to the COMPANY;
- establish that the determination of the objectives of the COMPANY or those set for RECIPIENTS at any organizational level meet realistic criteria and objective feasibility with respect to each organizational sector;
- represent and describe the activities carried out by the COMPANY, its functional



structure, corporate organization, relations with supervisory and control authorities, with other subsidiaries, investee companies, or other entities, in truthful and correct documents that are drawn up under the responsibility of clearly identifiable persons and duly updated;

- implement training and refresher programs with the aim of ensuring effective knowledge of the CODE OF ETHICS and the MODEL by all those who work within the COMPANY or with it, as well as by all those who are directly or indirectly involved in the at-risk activities and operations referred to in the following paragraphs;
- allow the use of IT tools and access to the *Internet* exclusively for reasons and purposes related to the work activity of the employee, in accordance with the corporate regulation adopted in this regard.

3.2. Structure of the IBSA ITALIA MODEL

IBSA ITALIA has prepared a MODEL on the basis of the indications provided for by the codes of conduct and *Guidelines* drawn up by the main representative trade associations and indications deriving from the case matter on the subject, which takes its own business situation and history into account with respect to the Company's *governance* system. Drafting of this MODEL, the COMPANY has also taken into account the standards required by the main voluntary regulations on the subject of management systems, to which IBSA ITALIA conforms its activities. Specifically, the control protocols identified in the Special Part of the Model are based on the compliance with the ISO 37001 standards about the anti-corruption, ISO 45001 standards about the safety at work and ISO 14001 standards about the environment.

The MODEL includes the following **constituent elements**:

- a process of **identifying corporate activities** in which the crimes referred to in the DECREE may be committed ("**Sensitive activities**" or "at risk of crime") defined as "*risk mapping*" activities;
- the provision of **controls, protocols and procedures aimed at planning the formation and implementation of the COMPANY'S DECISIONS** in order to prevent their commission of crimes within the sensitive activities identified;
- a process of identifying the **methods for managing financial resources** as suitable for preventing the commission of crimes;
- the **Code of Ethics**;
- the **Supervisory Body**;
- a structured system of **information flows to and from the Supervisory Body** and specific **information** and **reporting obligations** to the former;
- a **plan of periodic checks** on sensitive activities and related control standards;
- a **disciplinary system** designed to sanction the violation of the provisions contained in the MODEL;
- a **training and communication plan** for all company personnel, from *management* to employees, as well as other subjects that interact with the COMPANY;

- the **criteria for updating and adapting the MODEL.**

This MODEL has also been drafted and updated in compliance with the provisions of the first paragraph of art. 30 of Legislative Decree 81/2008, which, on the subject of health and safety in the place of work, prescribes that the organization and management model referred to in art. 6 of the Decree has been adopted and effectively implemented, ensuring a Corporate System for the fulfillment of all legal obligations relating to:

- the compliance with the technical-structural standards of the law concerning the equipment, plants, places of work, chemical, physical and biological agents
- the activities of risk assessment and preparation of the consequent prevention and protection measures;
- the activities of an organizational nature, such as emergencies, first aid, management of contracts, periodic safety meetings, consultations with safety representatives of the employees;
- the health monitoring activities;
- the information and training of the employees;
- the supervisory activities with reference to compliance with safety procedures and work instructions by the employees;
- the acquisition of documents and certifications required by law;
- the periodic checks on the application and effectiveness of the procedures adopted.

IBSA ITALIA, with the implementation of the **Code of Ethics** has defined, has adopted its own **Code of Ethics**, thus formally defining the criteria of conduct that must govern relations with the market and those who have relations with the COMPANY and the Group. The CODE OF ETHICS of the Company is the essential foundation of this MODEL; the provisions of the latter are integrated with the provisions of the CODE OF ETHICS. It contains a series of legal obligations and moral duties that define the scope of the ethical and corporate responsibility of each participant in the organization; as a whole, these constitute an effective tool aimed at preventing unlawful or irresponsible behaviour by subjects who are called upon to act in the name and on behalf of the company. These general principles create operating rules that give the CODE OF ETHICS immediate applicability in current management, with reference to the relationships that must exist between the company and all the institutional interlocutors, including the PA.

The CODE OF ETHICS can essentially be defined as the “Charter of Values” of the Group: it is a charter of moral rights and duties that defines the ethical-social responsibilities of personnel of all hierarchical levels.

It is also a tool to ensure the fair and effective management of transactions and human relations that is able to sustain and protect the reputation of the company, creating trust externally.



Its adoption is the result of the COMPANY'S desire to establish an effective means of preventing irresponsible or unlawful conduct by those who work in the name and on behalf of the company.

4. CHAPTER - WHISTLEBLOWING PROVISIONS

Article 2 of Law no. 179/2017, which amends Article 6 of the DECREE, inserted the regulation of the protection of the reporting of offences or irregularities of which a person has become aware as part of a private employment relationship into the Decree, which is known as Whistleblowing.

As of 15 July 2023, the provisions of Legislative Decree 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 laying down provisions concerning the protection of persons who report breaches of national legal provisions shall take effect.

To this end, the COMPANY has provided two different alternative channels, one of which is computerized, which allow the submission of reports, guaranteeing the protection of the confidentiality of the whistleblower and the prohibition of any form of discriminatory or retaliatory act against whistleblowers for reasons related, directly or indirectly, to the report. Information on violations must relate to conduct, acts or omissions of which the whistleblower or complainant has become aware in the context of work, understood in its broadest sense as the context in which legal relations have been established with the Company.

Reports must be as detailed as possible and must be clear: (i) the circumstances of time and place in which the event which is the subject of the report occurred; (ii) a description of the act; (iii) personal details or other elements that make it possible to identify the person to whom the reported facts can be attributed.

More specifically, all reports regarding violations of EU law, unlawful conduct relevant to the DECREE or violations of the MODEL of which the Recipients have become aware, must be transmitted through one of the following channels:

- Web: <https://ibsawhistleblowing.whistlelink.com/>;
- Mail to: IBSA Farmaceutici Italia Srl – Via Martiri di Cefalonia, 2 – 26900 Lodi (LO), to the attention of Compliance Office marked «Confidential »

To this end, the COMPANY, sensitive to the protection and confidentiality of whistleblowers and irregularities, has complied with the provisions of current legislation, identifying the Compliance function as the manager of reports.

With exclusive reference to reports relating to offences relevant to 231 purposes , the involvement of the SB is envisaged, for the assessment and possible start of the investigation.

The procedure for assessing reports is based on preliminary investigations, which may also consist – if necessary – in the hearing of the person making the report and/or the person responsible for the alleged violation; any consequent measures shall be applied in accordance with the provisions of the following paragraph.



Anonymous reports that appear prima facie *to be irrelevant, unfounded or unsubstantiated*, as well as those relating to claims of a personal nature or irrelevant to regulatory purposes, will not be taken into consideration.

Those reporting in good faith must be guaranteed against any form of retaliation, discrimination, penalisation, or any consequence deriving from the reports themselves. The confidentiality of the informant's identity will be ensured, without prejudice to legal obligations and the protection of the rights of Company or persons accused wrongly and/or in bad faith.

Please refer to the "Whistleblowing" Policy (Annex 2) for further details on regulatory requirements, the choices made by the Company, as well as the definition of the operating methods that can be used for reporting purposes. In line with best practices, this policy aims to be a guide for internal and external stakeholders who wish to make a report.

5. CHAPTER - METHODOLOGY USED IN DEFINING THE MODEL

Article 6, paragraph 2, letter a) of the DECREE expressly provides that the Organization, Management and Control model of the entity identifies the corporate activities in which the crimes included in the DECREE may potentially be committed.

As a result, the COMPANY has carried out an in-depth analysis of such, both in the first draft and in subsequent updates. As part of this activity, the COMPANY initially analysed its own organizational structure, as represented in the corporate organizational chart, which identifies the Departments/Functions and highlights roles and hierarchical - functional lines of reporting.

This document is kept at the Legal Affairs and Compliance department and is available for viewing.

IBSA ITALIA subsequently analysed its activities based on information gathered by company representatives (i.e. Management/Department Managers) who, by virtue of their role, have the greatest and most profound knowledge of the relative business operations of their corporate sector.

The identification of at-risk activities in company processes was based on a preliminary analysis of:

- the company organization chart;
- the system of powers and proxies;
- the resolutions and reports of the administrative and control bodies;
- the corporate regulatory corpus (i.e. procedures, organizational provisions) and the control system in a broad sense;
- the indications contained in the Guidelines issued by Confindustria,, EFPIA, Medtech, Farindustria and Confindustria Dispositivi Medici;
- the “history” of the COMPANY, or of the prejudicial events that have affected the company in the past.

Subsequently, an analysis of the sensitive activities detected and the control environment was carried out with reference to a "future" Model, i.e. one that complies with the provisions of Legislative Decree no. 231/2001, resulting in the preparation of a Gap Analysis (a summary of the differences between existing control protocols and the "future" Model, containing the identification of proposed adjustments and improvement actions). The results of this activity were collected and formalised in a descriptive form that forms an integral part of the Model, called “Mapping of at-risk activities of crime”, which illustrates the risk profiles of IBSA Italia in detail as relating to the commission of crimes included in the Decree.

In particular, the Mapping of activities above concerning the risk of crime are detailed, for each Company activity with the risk of possible commission of crime (so-called "sensitive activities"), the list of crimes envisaged by the DECREE and regarded as

relevant, the Functions/Company Departments involved, the crimes that can be associated, the procedures and control measures identified for each sensitive activity.

On the basis of the sensitive activities - according to different degrees of risk – risk profiles of commission of the crimes envisaged by Articles 24, 24 bis, 24 ter, 25, 25 bis (in relation to the crimes referred to in paragraph 1, letter f) bis, 25 bis1, 25 ter, 25 quinquies n, Article 603bis of the criminal code, 25 septies, 25 octies, 25octies1, 25 nonies, 25 decies, 25 undecies, 25 duodecies, 25 quinquiesdecies, 25 sexiesdecies of Leg. 231/2001 (offences relating to computer crime, computer extortion, offences committed in relations with the Public Administration, offences related to organised crime, crimes related to counterfeit money, public credit cards, revenue stamps and identification tools or signs, offences against industry and commerce, corporate crimes and corruption between private individuals, offences relating to violation of copyright, crimes committed in violation of the regulations for the protection of health and safety at work, inducement not to make statements or to make false statements to the Judicial Authorities, introduction into the state and trade of products with false signs, offences regarding the receiving, laundering and use of money, goods or benefits of illicit origin, as well as self-laundering, offences relating to non-cash payments and fraudulent transfer of values, computer abuse crimes, environmental crimes and the employment of third country nationals whose stay is irregular, tax offences, customs and excise offences).

Considering the activities actually carried out within the Company, it has been believed that crimes relating to forgery of money, public credit cards and revenue stamps, as well as offences against the individuals (with the exceptions mentioned above), racism and xenophobia and fraud in sport competitions as well as those against cultural heritage cannot be concretely committed and therefore it has not been considered necessary to set up a targeted prevention and control systems.

On the other hand, regarding to terrorist crimes and transnational crimes, as well as market abuse crimes, reference to the principles contained in the Code of Ethics was considered exhaustive.

The Mapping of at-risk activities of crime is kept with the Legal Affairs and Compliance Department, which is responsible for their archiving. The department makes them available for viewing to Directors, Statutory Auditors, members of the SB and anyone authorised by the COMPANY to view it.

6. CHAPTER - RECIPIENTS OF THE MODEL

The rules contained in the MODEL apply:

- to persons who are representatives, directors or managers of the COMPANY or a unit or division of it that has financial and functional autonomy, as well as persons who exercise the management or control of the same, even de facto (COMPANY REPRESENTATIVES);
- to employees of the COMPANY of any grade and under any type of contractual relationship, even if posted abroad for the performance of the activity (EMPLOYEES);
- to those who collaborate with the COMPANY under a quasi-subordinate employment relationship (project collaborators, temporary workers, interim workers, interns, etc.), where applicable.

The MODEL with the related CODE OF ETHICS are essential references for those who contribute to the development of the various activities as suppliers of materials, services, and works, as consultants, *partners* in temporary associations, or companies with which IBSA ITALIA operates.

Compliance with the MODEL is also required through the provision of contractual clauses that oblige external collaborators, agents, consultants, and commercial partners to respect the principles contained in the Code of Ethics, as well as procedures specifically related to the activity performed. Non-compliance entitles the Company to withdraw from the contract or terminate it. RECIPIENTS are required to promptly comply with all of the provisions of the MODEL, also in fulfilment of the duties of loyalty, correctness and diligence that arise from the legal relations established with the COMPANY.

The COMPANY disseminates the MODEL through methods that ensure its effective knowledge by all persons involved.

The COMPANY reproaches and sanctions any conduct that is contrary to the provisions of law, the MODEL and the CODE OF ETHICS, as well as conduct put in place in order to evade the law, MODEL or the CODE OF ETHICS, even if the conduct takes place in the belief that it pursues, even in part, the interest of the COMPANY or with the intention of giving it an advantage.

7. CHAPTER - TRAINING AND COMMUNICATION PLAN

In order to effectively implement the MODEL, **IBSA ITALIA** intends to ensure the proper, extended communication and disclosure of its content and principles within and external to its organization, such that the MODEL becomes a constant reference for Company activities.

Communication and training activities **will be diversified** according to the RECIPIENTS TO whom it is addressed and based on principles of completeness, clarity, accessibility and continuity, in order to allow the various RECIPIENTS to be fully aware of the company provisions that they are required to respect and the ethics on which their conduct must be based.

For the purposes of implementing the MODEL, training and information for personnel is managed by the corporate department in charge in close coordination with Legal Affairs and Compliance Department and with the BODY and the heads of other departments involved in the application of the MODEL.

The contents and principles of the MODEL are brought to the attention of all employees and other subjects who have contractually regulated collaborative relationships with IBSA ITALIA.

The MODEL will be extensively communicated so as to become a constant reference in business activities. Notably, it will be communicated to all EMPLOYEES at the time of approval, revision or update, to new employees at the time of hiring and to employees when upon contract stipulation. EMPLOYEES are also ensured the possibility of accessing and viewing this document (and its annexes) in the shared electronic archives of the COMPANY'S local network and the reception of the individual corporate offices.

In order to facilitate the understanding of the MODEL, the COMPANY organises, through the Legal Affairs and Compliance department, **various training courses** through the training unit, according to the roles played by the different people.

Periodic training will be provided, differentiated according to the different categories, functions and levels of the RECIPIENTS and in consideration of the sensitive areas in which they work. Training activities will be carried out:

- immediately after approval of the MODEL;



- in the event of changes and/or updates;
- in training activities for new hires.

During THESE activities, the COMPANY shall inform employees that they are required to know the principles and content of the MODEL, and to contribute to its implementation in relation to the role and responsibilities held within IBSA Italia, respecting it and reporting any shortcomings.

To the following subjects:

- members of **corporate bodies**;

a paper copy of the full version of the MODEL is provided and a signature is requested upon receipt of the same.

The SB monitors the level of implementation of the MODEL through specific verifications defined in its rules.

For the consultation of the MODEL by COLLABORATORS and third parties (promoters, agents, contract workers, consultants, *outsourcers*, suppliers, business *partners*), the general part, together with the CODE OF ETHICS and the ANTI-CORRUPTION GUIDELINES will be published on the company website. All contracts will also contain the so-called “clause 231” which constraints the contractual relationship to comply with the MODEL.

In addition, IBSA ITALIA shall arrange suitable measures with *partners*, *outsourcers* and agents that prevent acts and/or conduct such as to determine a violation of the MODEL on behalf of their employees.

8. CHAPTER - ADOPTION OF THE MODEL - CRITERIA FOR UPDATING AND ADAPTING THE MODEL AND PROCEDURES

8.1. Adoption, amendment and updating of the MODEL and PROCEDURES.

The Board of Directors, except as expressly provided below, has exclusive jurisdiction for **the adoption** and **modification** of the MODEL in order to prevent the commission of crimes and the OFFENCES and ADMINISTRATIVE CRIMES referred to in the DECREE. In particular, the Board of Directors promptly modifies the MODEL if significant breaches or evasion of the provisions contained therein by the BODY, by another Function of the COMPANY or any other person of the same, which highlight its inadequacy, even if only partial, to guarantee the effective prevention of the crime.

Moreover, the Board of Directors promptly updates the MODEL in whole or in part on the proposal of the BODY, if changes or modifications occur:

- a) to the regulatory and legislative system, inclusive of self-governance, which governs the COMPANY'S activity;
- b) in the corporate structure or organization of the COMPANY;
- c) in the business of the COMPANY or with respect to the goods or services offered to customers;
- d) with reference to other elements and circumstances essential for the outcome of risk mapping.

The functional units involved process and promptly make changes to the procedures within their competence as soon as these changes appear necessary for the effective implementation of the MODEL, and do so according to the provisions of the previous letters a), b), c) and d).

Proposals for amendments to the MODEL as referred to in the aforementioned letters a), b), c) and d) are communicated beforehand to the BODY, which must promptly express an opinion. If the Board of Directors deems that it does not meet the approval of the BODY, it must provide adequate proof.

The MANAGING Director of the Company can make purely formal changes to the MODEL or PROCEDURES if such are necessary for increased clarity or efficiency. The changes are immediately communicated to the BODY and the Board of Directors for ratification.

THE BODY must promptly report the facts that suggest the need or the opportunity to modify or revise the MODEL in writing to the Chairman of the Board of Directors. In this case, the Chairman of the Board of Directors must convene the Board of Directors, so that it may make resolutions of its competence.

Insofar as it is compatible, the above is applied by the adoption of new procedures or for the modification of the pre-existing procedures by the functional units involved, as necessary for the implementation of the MODEL. New procedures and changes to those existing must be promptly communicated to the BODY.



9. CHAPTER - THE SUPERVISORY BODY

9.1. Identification of IBSA ITALIA's Supervisory Board

The DECREE identifies the “*body of the entity*” to be entrusted with the “*autonomy and powers of initiative and control*” as the body to:

- **continuously monitor** the functioning and observance of the MODEL, its widespread and effective implementation, compliance with the provisions contained therein by employees, corporate bodies, service companies and other third parties and its consequent effective capacity to prevent the commission of crimes;
- **handle** the timely and constant **updating** of the MODEL, where it is necessary to adapt it in relation to modified company and regulatory conditions.

This “Body” must meet the requirements of stability, hierarchical autonomy with respect to the other bodies and subjects, and expenditure, neutrality, interests, professionalism, integrity, operational efficiency and continuity of action.

The requirement of *autonomy* and *independence* presupposes that the SB:

- possesses autonomous powers of initiative and control;
- has adequate financial resources;
- responds to the highest hierarchical body in the performance of its functions, that is, to the Board of Directors;
- is not controlled by and operates under the directives of any other function, top management or decision-making body;
- is not subject to any form of interference or conditioning by parties internal or external to the COMPANY;
- is not in situations (even only potential) of conflict of interest of a personal, family or professional nature for any reason;
- does not have duties connected directly or indirectly with the formation and implementation of COMPANY decisions;
- does not assume operational/management roles.

The SB carries out its functions by encouraging a rational and efficient cooperation with the bodies and control functions existing in the COMPANY TO THE EXTENT POSSIBLE.

The requirement of *professionalism* presupposes that the SB, as a whole:

- possesses adequate specialist skills, in particular (also alternatively): **(i)** legal, with specific reference to criminal law, to crimes in the economic field (such as financial crimes and corporate crimes) and the administrative liability of institutions pursuant to the DECREE; **(ii)** internal control and *compliance*; **(iii)**

pharmaceutical; **(iv)** accounting and data analysis;

- is equipped with specialised tools and techniques to carry out the activity assigned to it, also using specialised internal and/or external aids.

The requirement of *integrity* implies the absence of **causes of ineligibility**: with respect to each member of the SB there must be no sentence of condemnation or plea bargain, even if not final, relating to crimes provided for by the DECREE or the other causes of ineligibility for directors and statutory auditors of listed companies.⁶

In particular, **Article 2 paragraph 1 of Ministerial Decree no. 162/2000** provides that the following persons cannot hold the office of statutory auditor (or director) in listed companies:

- the person is in the **situations provided for by Article 2382 of the Italian Civil Code** (that is, a legally incapacitated person, one who has been disqualified, bankrupt or sentenced to a penalty that involves the interdiction to hold public offices or the inability to exercise management roles);
- the person has been subjected to a **preventive measure** (see Law no. 1423 of 1956, Law no. 575 of 1965 and Law no. 646 of 1982, repealed and replaced by Legislative Decree no. 159 of 2011, the Antimafia Code), subject to the effects of rehabilitation;
- the person has been given a **final sentence**, unless **rehabilitation** has taken place, or has taken a **plea bargain**, unless charges for the **crime** have been dropped:
- **imprisonment** for an offence provided for by **special legislation** governing the **insurance, banking, financial and credit sector**, legislation on **markets and financial instruments, payment instruments and tax matters**;
- under penalty of **imprisonment** for a **corporate offence** (book V title XI of the Italian Civil Code) or **bankruptcy crime** (Royal Decree no. 267 of 1942, the Bankruptcy Law);
- imprisonment of not less than 6 months for a **crime against the public administration, public order, public faith, heritage, and public economy**;

⁶ Pursuant to Article 147-quinquies and 147 of the TUF (Legislative Decree no. 58/1998) and Article 2 of Ministerial Decree no. 162 of 30 March 2000.

- **imprisonment of not less than 1 year** for any **non-negligent crime**.

To guarantee the requirement of *stability* and *continuity of action* and taking into account the characteristics of its organizational structure, IBSA ITALIA deems it appropriate to identify its SUPERVISORY BODY (hereinafter the “BODY” or “SB”) in a **board comprised *ad hoc***, called upon to **exclusively** and **continuously** perform the functions established by Article 6 of the DECREE and briefly referred to herein. The number of members of the BODY is determined as **three members, two external** - an expert in legal matters and an expert in pharmaceutical *compliance* - **and one internal one** - identified in the Compliance Manager - to the COMPANY, in possession of the prescribed characteristics of *professionalism, integrity* and *autonomy of action*, which must be identified with a specific **resolution of the Board of Directors**.

The **appointment** and **revocation** of the members of the **Body** (such as in the event of violation of their duties deriving from the MODEL) are reserved to the competence of the **Company’s** BOARD OF DIRECTORS, after informing the Board of Statutory Auditors, with a motivated provision with respect to each member.

In selecting the members, the only relevant criteria are those - already set forth - which refer to the specific **professionalism** and competence required for the performance of the functions of the BODY, to be of good **repute** - to be assessed based on the **requirements** established for the directors and auditors of listed companies ⁷ - and, for members external to the COMPANY, to absolute independence with respect to same.

The **term of office** of the BODY is established as **three financial years**, with the possibility of **renewal** only once for an additional three years, while **remuneration** is defined upon appointment. Upon expiration of the mandate, the “outgoing” BODY will temporarily continue to carry out its duties until the effective takeover of the new BODY.

Revocation, which is the competence of the COMPANY’S Board of Directors, is only allowed for **just cause** (e.g. unfaithfulness, inefficiency, negligence, inexperience, serious breach of duties as defined in the MODEL, breach of confidentiality obligations provided by the MODEL, lack of participation at more than three consecutive meetings without a justified reason) and may be ordered after informing the Board of Statutory Auditors. In the event of revocation, the Board of Directors shall promptly **replace** the revoked member, redefining the composition of the BODY by appointing a new member whose mandate expires together with that of the remaining members.

With reference to the individual members of the BODY, the following constitutes a cause for **forfeiture**:

- the unexpected impossibility of performing his/her task properly;
- the loss of the requirements of independence, impartiality, autonomy, as well as the requirements of integrity and eligibility;

⁷ Pursuant to Article 147-quinquies and 147 of the TUF (Legislative Decree no. 58/1998) and Article 2 of Ministerial Decree no. 162 of 30 March 2000.

- the occurrence of conflicts of interest, such as from having significant business relations with the COMPANY, the parent company, or any associates, and familial relations with corporate bodies and top management;
- for internal members, termination of the relationship of employment/collaboration with the COMPANY;
- the assumption of executive, operational or delegated positions.

The Board of Directors is entitled to verify the presence of a cause of forfeiture. Each member of the BODY must promptly notify the Secretary and the other members as to the loss of objective and subjective requirements.

The BODY as a whole is considered **invalid** if the majority of its members are absent due to resignation or other causes. The BODY is also deemed to have lapsed if the COMPANY receives a **sentence of condemnation** or makes a plea bargain (*pursuant to* Articles 444 and following of the Criminal Code) which has become final for an administrative offence due to a crime pursuant to the DECREE, following an verified inadequacy or omission of supervisory activity. In such cases, the Board of Directors shall promptly appoint a new BODY. Until such time, the “invalid” BODY remains in office to exercise its functions.

The BODY will regulate the rules of its operation (method of calling, time schedule of meetings, scheduling of activities etc.) as well as methods of managing the necessary information flows through its own specific **regulation**.

The BODY internally appoints a **President** to which specific functions can be delegated, by choosing a Secretary **from members external** to the COMPANY, who will be entrusted with the filing and preservation of documents concerning the activity of the BODY, ensuring that the documentation itself cannot be modified or altered. Minutes will be **recorded** for the meetings of the BODY. All **documentation** will be kept at the COMPANY in a specific *database*, access to which is exclusively granted to the BODY and persons specifically identified in its regulation BODY.

Taking the special nature of the responsibilities attributed to the BODY into account and the specific professional contents requested of them, in carrying out their supervisory and control duties, the BODY is supported by the structures of the various company departments according to the rules and principles laid down in its own regulations. It can make use of the support of other external subjects whose contribution is necessary or opportune.

9.2. Function and powers of the Body

The BODY has autonomous powers of initiative, intervention and control, which extend to all sectors and functions OF THE COMPANY, including the decision-making body and its members, external collaborators and consultants. These powers may be exercised for the sole purpose of effectively and promptly performing the functions provided for by the MODEL and the rules for its implementation, or overseeing:

- 1) the *effectiveness* and adequacy of the MODEL with reference to the corporate structure and effective capacity to prevent the commission of crimes. For this purpose, and according to the time frame deemed appropriate by the BODY itself, the BODY proceeds to:
 - interpret the relevant legislation;
 - conduct surveys on corporate activities for the purpose of updating the map of at-risk activities and the related sensitive processes;
 - coordinate with the department in charge of defining and implementing training programs for all COMPANY personnel, aimed at providing the necessary awareness and basic knowledge of 231 legislation;
 - monitor initiatives for the dissemination of knowledge of the MODEL within and external to the COMPANY;
 - prepare and continuously update the relevant information in order to allow full and aware acceptance of the COMPANY'S rules of conduct;

- 2) on *compliance* with the MODEL by the corporate bodies, staff and other third parties; the BODY thus proceeds to:
 - periodically carry out targeted checks on certain operations or specific acts performed by the company in the context of sensitive processes, according to the time intervals deemed appropriate by the BODY ITSELF, which may be without prior notice;
 - coordinate with the corporate functions for the best monitoring of the activity, also through special meetings. To this end, the BODY has free access to all company documentation that it deems relevant, and must be constantly informed by the corporate bodies and employees:
 - a) on aspects of business activities that may expose the COMPANY to the risk of committing one of the crimes;
 - b) on relations with *service* companies and other third parties that operate on behalf of the COMPANY within sensitive areas and operations;
 - c) on extraordinary operations of the COMPANY;
 - collect, process and store relevant information regarding compliance with the MODEL and update the list of information that must be sent or made available to the BODY itself;
 - arrange internal inquiries, connecting with the company departments concerned to acquire further elements for evaluation;

- 3) on the *opportunity* to update the MODEL and its monitoring, where there is a need to adapt the same in relation to modified company and/or regulatory conditions. To this end, the BODY proceeds to:
- based on the results emerging from the verification and control activity, periodically express an assessment of the adequacy of the MODEL with respect to the provisions of the DECREE, as well as on its operations;
 - present the Board of Directors with a specific report relating to the aforementioned periodic assessments on the adequacy and effectiveness of the MODEL;
 - according to the time frame deemed appropriate by the BODY and at least every six months, to periodically verify the implementation and effective functionality of the proposed solutions/corrective actions;
 - coordinate with the heads of the competent corporate functions to assess the adoption of any disciplinary sanctions, without prejudice to the competence of the corporate body/function for the imposition of the sanction and the related disciplinary procedure.

The BODY has **autonomous spending powers** on the basis of an annual budget for the allocation of an adequate amount of financial resources, approved by the Board of Directors in the context of the formation of the corporate *budget* on the proposal of the BODY itself. The BODY may make use of its own financial resources for every need necessary for the correct performance of the tasks (e.g. specialist consulting, travel, etc.).

Moreover, the BODY can autonomously commit resources that exceed its spending powers if the use of these resources is necessary to handle exceptional and urgent situations. In such cases, the BODY must immediately inform the Board of Directors at the next meeting. The BODY does not have the power to grant powers of management, decision-making, organizational or disciplinary intervention, even as substitutes, even if related to subjects or questions relating to the performance of the BODY'S activities. The activity of control and verification carried out by the BODY is strictly functional to the objectives of effective implementation of the MODEL, and cannot substitute or replace the institutional control functions of the COMPANY.

Members of the BODY, as well as the subjects of which the BODY uses in any capacity are bound to the **obligation of confidentiality** on all information that may become known in the exercise of their functions or activities. Specifically, the BODY, as part of its activities aimed at monitoring the effective and efficient implementation of the MODEL, retains the following **powers of initiative and control**, which it exercises in constant compliance with the laws and individual rights of workers and persons involved:

1. it carries out periodic inspection and control activities, including random ones, whose minimum time frame is predetermined by the BODY itself, in consideration of the various sectors of intervention or types of sensitive activities and their critical

- points. It meets at least quarterly and draws up minutes and keeps copies;
2. it has access to all information, held by anyone, as regards at-risk activities;
 3. it may, even without prior notice, request information or exhibit documents, including those digital, relevant to at-risk activities, managers of the COMPANY, as well as employees who at any time or occasionally carry out at-risk activities, or supervise them;
 4. it may request information or the presentation of documents pertinent to at-risk activities from Directors, the Board of Statutory Auditors, the auditing company, collaborators, consultants, agents and representatives external to the COMPANY and, in general, to all the external subjects held to comply with the MODEL; the obligation of the latter to comply with the request of the BODY must be included in the individual contracts;
 5. the meetings with the various internal bodies of the COMPANY must be recorded, and a copy of the minutes must be kept both by the BODY and by other bodies;
 6. it can also carry out inspections in coordination with any security services of the COMPANY of which it may avail itself;
 7. it may request information or documents relating to subsidiaries or investee companies, through a request addressed exclusively to the SB of the individual company or equivalent body;
 8. according to a predetermined frequency by the BODY itself, periodically receives reports and information from the managers of functional areas in which the at-risk activities are located or affected by them, even if in part;
 9. it can directly make use of personnel belonging to the various company Functions, potentially identifying dedicated *staff*, and agreeing in advance on the use of personnel with the Head of the Function, provided that there is no reason for urgency. The provisions concerning the organic endowment, assignment to another position and the adoption of disciplinary measures for *Internal Audit* (if present) are made with the favourable opinion of the BODY;
 10. after having informed the Managing Director, it can contact external consultants, if necessary; the communication to the Managing Director may be omitted, under the responsibility of the BODY, due to the particular sensitivity of the investigations or their subject;

11. it submits reports to the Managing Director and Human Resources Director for the potential adoption of sanctioning procedures, without prejudice to the fact that the adoption of the measures remains the responsibility of the departments in charge of it;
12. it submits the Model and the procedures adopted for its concrete implementation to periodic verification, according to the time frame deemed appropriate by the BODY at least once a year anyway, and proposes the update to the decision-making body, according to the provisions of this MODEL;
13. unless critical aspects are found that require greater timeliness in reporting, it periodically draws up a written report, at least every six months on the activity carried out, sending it, together with a justified report of the expenses incurred, to the Chairman of the Board and the Chairman of the Board of Statutory Auditors. The reports, reported in the minutes book, also contain any proposals to integrate and modify the Model and the procedures for its implementation;
14. it may request the convocation and the meeting with the Board of Statutory Auditors, the Board of Directors or the Managing Director; these, in turn, may require direct discussion with the BODY;
15. it must draw up an annual plan for the activities of the following year to be submitted to the Board of Directors and to the Board of Statutory Auditors for their knowledge, and *budget* forecasts within 90 days from the end of the financial year;
16. it must coordinate with the Managing Director and the Head of Personnel Management for the definition of training programs, distribution channels and the content of periodic communications.

In summary, **periodic reports** prepared by the BODY must at a minimum contain, carry out or report:

- any problems arising regarding the implementation of the MODEL or the procedures adopted in implementation or in function of the MODEL and the CODE OF ETHICS;
- the recording of reports received from internal and external subjects regarding the implementation of the MODEL and the PROCEDURES;
- the disciplinary procedures and sanctions as may be applied by the COMPANY'S functions, with exclusive reference to the at-risk activities;
- an overall assessment of the implementation and effectiveness of the MODEL, with potential indications for additions, corrections or modifications, with particular attention to the additions to the management systems of financial resources both inbound and outbound necessary to introduce suitable measures to detect the

- existence of atypical financial flows that have greater margins of discretion;
- a revision of all reports received during the year and information sent to the Body by company structures as well as employee awareness-raising activities.

9.3. Information flows to the Body

9.3.1. Obligations to inform the Body

The correct and efficient performance of the functions of the BODY is based on the availability of all the information relating to at-risk areas and all data on conduct serving to commit a crime. For this reason, the BODY must be given access to all of the data and information mentioned above relating to IBSA ITALIA.

They must be sent to the BODY **by top managers, their subordinates and by the other control bodies:**

- the **periodic results** of the control activities carried out by the same, insofar as they pertain to this MODEL, in order to implement the MODEL itself (**summary reports of the activity, checks and/or monitoring results, final indicators**, etc.), especially for activities assessed as at-risk;
- **anomalies or atypical items** found in the context of the information available and all conduct that is in contrast with or not in line with the provisions of this MODEL;
- all relevant information in relation to the **actual implementation** of the MODEL at all company levels, including all information relating to changes in the corporate organization that could lead to changes in at-risk activities as regards committing the crimes provided for by the DECREE;
- any other information or information relating to the COMPANY'S activity in the areas at risk, which the BODY retains to acquire.

In addition to the reports of violations of the *type* described above, information concerning the following must be compulsorily and immediately sent to BODY:

- significant transactions that fall within the areas defined as at-risk, as identified and described in the *Special Section* of this MODEL;
- any unlawful or suspicious proposal or request made by members of the PA or qualified individuals;
- measures and/or news from judicial police bodies, or any other authority, from which it is inferred that investigations are carried out for the OFFENCES, even against unknown persons, if such investigations involve the COMPANY or its EMPLOYEES, CORPORATE BODIES, COLLABORATORS, or PARTNERS;

- requests for legal assistance or other reports forwarded by EMPLOYEES in the event of the initiation of judicial proceedings against them for the OFFENCES referred to in the DECREE;
- the reports prepared by the managers of other company functions of the COMPANY AS part of their control activities, from which facts, acts, events or omissions of a critical nature with respect to compliance with the provisions of the DECREE could emerge;
- the news concerning the sanctioning procedures carried out and any measures imposed (including measures against EMPLOYEES) or the filing of such proceedings with the related reasons, if they are related to the commission of OFFENCES or violation of the rules of conduct or procedural rules of the MODEL;
- periodically, any other information which, although not included in the list above, is relevant for the purposes of correct and complete supervision and updating of the MODEL.

If necessary, based on the progress of its supervisory activity and the related findings, the BODY proposes to the Board of Directors for any modifications/additions to be made to the list indicated above.

The reporting obligations of COLLABORATORS and other third parties in relation to the COMPANY will be specified in specific clauses included in the contracts that bind these subjects to the COMPANY.

The information obligations on any conduct contrary to the provisions contained in MODEL are part of the broader duty of care and obligation of loyalty of the employee referred to in Articles 2104 and 2105 of the Italian Civil Code. The failure by the employee to fulfil the information obligation may give rise to the application of disciplinary sanctions, as described in Chapter 10.

Moreover, in relation to each sensitive activity and Function concerned, the Supervisory Board agrees with the Managers of the various Company Functions on further, specific and detailed information flows, requesting the periodic transmission of information and documents, the examination of which enables the Supervisory Board to punctually ascertain the constant application of the procedures and compliance with the Company controls, as described in the Model.

All the reports indicated must be addressed to the attention of the SB and sent

- via email addressed to: odvibsa@gmail.com
- or by mail, with the indication of “Confidential - Reserved” to the address:

Supervisory Body
IBSA FARMACEUTICI ITALIA S.r.l.
Via Martiri di Cefalonia, 2
26900 Lodi, Italy

9.4. Information flows from the Body to corporate bodies

In carrying out its activities, the SUPERVISORY BODY reports **on a periodic basis at least annually** to the Board of Directors and to the Board of Statutory Auditors of the COMPANY as regards the activities that it carries out, the implementation of the MODEL, the emergence of any critical aspects and any need for modifications, presenting a **written report**.

The IBSA ITALIA BODY may also be convened by the aforementioned bodies whenever it is deemed appropriate by them, to report on specific facts or events or to discuss topics deemed of particular importance in the context of the crime prevention function.

Moreover, at any time where there is a need for timely information on specific facts or events, the BODY informs the Board of Directors without delay.

9.5. Collection and storage of information

The BODY's verification activities are supported by appropriate documentary evidence. The following is required for each intervention:

- definition of a detailed work plan for the individual activities included in the annual audit program. The work plan serves as a guide in carrying out the checks and is archived at the end of the work together with all the documentation relating to what has been done up to that point;
- formulate requests in writing to the organizational units involved;
- accurately archive all the documentation produced and received in chronological order, in such a way as to allow the traceability of the activities. A similar procedure is provided for the storage of material in electronic format;
- at the end of each intervention, produce a report describing the work performed and the evidence that has emerged;
- update the activity register.

The BODY has the task of establishing a *dossier* for documentation of the activities carried out. In particular, it holds a chronological register in which the activities of the BODY are summarised. This register contains documentation:

- of the training activities undertaken and related results, broken down by category and hierarchical level;
- of verification activities carried out, indicating the duration, reasons for the verification, the organizational units involved and any suggestions;
- of reports received, organised by sensitive activity and indicating the number of reports that have been managed and the structures involved;
- of periodic updating activities of the MODEL, indicating the main actions taken;
- it will be the Secretary's responsibility to keep a book of minutes of the BODY's meetings.

All information, reports, *reports* provided in this MODEL are KEPT by the BODY in a special *database* (computer and paper) for a period of 10 years, subject to compliance with the provisions on the confidentiality of personal data and the rights guaranteed to the persons involved.

Access to the *database* is allowed only to the BODY and to persons specifically identified in the ORGANIZATIONAL regulation.

10. CHAPTER - THE DISCIPLINARY SYSTEM

10.1. Function of the disciplinary system

Article 6, paragraph 2, letter e) and Article 7, paragraph 4, letter b) of the DECREE indicate the introduction of a disciplinary system suitable to sanction the failure to comply with the measures indicated in the MODEL itself as a **condition** for the effective implementation of the MODEL.

The definition of an adequate disciplinary system thus constitutes an essential prerequisite of the “exonerating” value of the MODEL with respect to the administrative responsibility of the legal entities outlined by the DECREE.

The sanctions provided for by the disciplinary system will be applied to every violation of the provisions contained in the MODEL, regardless of the commission of an offence and the conduct and/or outcome of the criminal proceeding possibly initiated by the judicial authority, in the event that the illicit conduct contains the details of a relevant offence pursuant to the DECREE.

This system must be differentiated for employees - or those who are subject to management and supervision by managers - for the managers themselves - in relation to the different type of contract that links them to the COMPANY - and for Directors.

The application of the sanctioning measures does not prejudice or further modify any eventual civil or other consequences (penal, administrative, tax) that may derive from such act.

Any violation or avoidance of the MODEL or of the procedures for its implementation, by anyone, must be immediately communicated in writing, to the BODY, without prejudice to the disciplinary procedures and provisions, which remain the exclusive competence of the holder of the disciplinary power.

All RECIPIENTS of the MODEL have the duty to make the reports referred to in the previous point.

The BODY must be immediately informed of the application of a sanction, for violation of the MODEL or of the procedures established for its implementation, ordered with respect to any person required to comply with the MODEL and the procedures referred to above.

10.2. Measures against subordinate employees

Compliance with the provisions and rules of conduct set forth in the MODEL constitutes the fulfilment by IBSA ITALIA employees of the obligations provided for by Article 2104, paragraph 2, of the Italian Civil Code. The content of the MODEL therefore represents a substantial and integral part of the aforementioned obligations.

Violation of the individual provisions and rules of conduct referred to in the MODEL by IBSA ITALIA employees is always a disciplinary offence.

It should be noted that within the scope of these **employees**, those of **non-managerial qualifications** are subject to **the National Collective Bargaining Agreement** for employees in the chemical, chemical-pharmaceutical, chemical fibre and ceramic, abrasive, lubricating and LPG sectors (hereinafter the “**NCBA**”) and those with **managerial qualifications** are subject to the National Legislative and Economic Contract for Confindustria and Confapi for Industry executives (hereinafter the “**NCBA for Industry Executives**”).

The provisions indicated in the MODEL, whose non-compliance is intended to be sanctioned, are communicated through an internal circular to all employees, posted in a place accessible to all persons and is binding for all employees of the COMPANY.

Disciplinary measures are applicable to employees of IBSA ITALIA in compliance with the provisions of Article 7 of Law no. 300 of 20 May 1970 (“Workers’ Statute”) and any applicable special regulations.

For non-managerial level employees, the sanctions that can be applied are those provided for by law as well as by the sanctioning apparatus of employment contracts, in compliance with the provisions of Article 7 of the Workers’ Statute and any applicable special regulations.

At each notice of violation of the MODEL, a disciplinary action will be taken in order to ascertain the violation itself. In the assessment phase, the employee will appeal the charge in advance and will also be guaranteed an adequate reply period for his/her defence. Once the violation has been ascertained, a disciplinary sanction will be imposed on the perpetrator that is proportionate to the gravity of the violation committed and any recurrence.

It is understood that the procedures, provisions and guarantees provided for by Article 7 of the Workers’ Statute and, as for non-managerial qualification workers, also by the law on the subject of disciplinary measures.

In particular:

- no disciplinary measure can be taken against the worker without having previously disputed the charge or heard his/her story in relation to his/her defence;
- for more serious disciplinary measures than a verbal warning, a written notice must be made to the worker, with the specific indication of the facts constituting the infraction;
- the disciplinary measure cannot be issued unless 8 days have elapsed from such dispute, during which the worker can present his/her justifications. If the provision is not issued within the following 8 days (i.e. within 16 days of the dispute), these justifications will be deemed accepted;
- the provision must be issued within 16 days of the dispute, even if the employee does not present any justification;
- in the event that the alleged infringement is of such gravity as to lead to dismissal, the worker may be suspended from work until the moment that the disciplinary measure is imposed, without prejudice to the right to remuneration for the period in question;

- the application of any disciplinary measure must be motivated and communicated in writing;
- the worker can also present his/her justifications verbally;
- disciplinary measures other than dismissal may be challenged by the employee in trade unions, according to contractual rules.

With regard to the assessment of infringements concerning this MODEL, the disciplinary procedures and the imposition of sanctions, the powers already conferred to IBSA ITALIA Management remain valid within the limits of the respective delegations and powers. These disciplinary sanctions are also provided in the event that employees do not comply with the obligations on whistleblowing.

It is specified that each act relating to the proceeding must be communicated to the SB for an assessment of competence.

10.2.1. Violations of the MODEL and related sanctions

In compliance with the provisions of the relevant legislation and in compliance with the principles of typical violations and typicality of sanctions, IBSA ITALIA intends to make its employees aware of the provisions and behavioural rules contained in the MODEL, the violation of which constitutes a **disciplinary offence**, as well as the applicable **sanctions**, taking the gravity of the infringements into account.

Without prejudice to IBSA ITALIA'S obligations deriving from the Workers' Statute, the following conduct constitutes a violation of the MODEL, which is accompanied by the relative sanctions:

- the provision of **“verbal warning”** shall apply to the worker who violates one of the internal procedures provided for by the MODEL (e.g. does not observe the prescribed procedures, fails to give notice to the SUPERVISORY BODY of the prescribed information, fails to carry out checks, etc.) or who in the performance of activities in sensitive areas, adopts a conduct that does not comply with the provisions of the MODEL itself. This conduct constitutes a failure to comply with the instructions given by the COMPANY;
- the provision of **“written warning”** shall apply to the worker who is a repeat offender in violating the procedures provided by the MODEL or who in carrying out activities in “sensitive” areas (or “at risk”), adopts a conduct that does not comply with the requirements of the MODEL. This conduct constitutes a repeated failure to comply with the instructions given by the COMPANY;
- the provision of a **“fine”, not exceeding the amount of 3 hours of normal remuneration**, shall apply to the worker who violates the internal procedures provided for by the MODEL, or who by adopting a conduct that does not comply with the provisions of the MODEL in carrying out activities in sensitive areas, exposes the integrity of company assets to an objectively dangerous situation. This conduct, along with the failure to comply with the instructions given by the COMPANY, determines a

- situation of danger for the integrity of the COMPANY'S assets and/or constitute acts contrary to its interests;
- the provision of **“suspension” from service and from receiving a remuneration for a period not exceeding 3 days**, shall apply to the worker who violates the internal procedures foreseen by the MODEL, or who by adopting conduct not conforming to the prescriptions of the MODEL in the performance of activities in sensitive areas, causes damage to the COMPANY by performing acts contrary to its interest, or the worker who has re-offended more than three times as regards to the provisions referred to in points 1, 2 and 3. This conduct, along with the failure to comply with the instructions given by the COMPANY, determines damage to the COMPANY'S assets and/or constitute acts contrary to its interests;
 - the provision of **“dismissal with notice”**, shall apply to the worker who adopts, in carrying out the **activities** in sensitive areas, a conduct that does not comply with the provisions of the MODEL and is directed univocally to the fulfilment of an offence provided for and sanctioned by the DECREE. This conduct constitutes a serious failure to comply with the instructions given by the COMPANY and/or a grave violation of the employee's obligation to cooperate in the interest of the COMPANY;
 - the provision of **“dismissal without notice”**, shall apply to the worker who adopts a conduct in the performance of activities in sensitive areas in violation of the prescriptions of the MODEL, such as to determine the effective application against the COMPANY of the measures provided for by the DECREE, as well as the worker who is a repeat offender, consisting of three times in the two-year period in which the deficiencies referred to in point 4 took place. This conduct radically lessens the trust of the COMPANY towards the worker, which constitutes serious moral and/or material damage to the company.

The aforementioned measures will be taken by the **employer** in relation to the extent of the violations and their circumstances, in full compliance with the principle of gradualness and proportionality of the offence committed and the sanction imposed, in accordance with the provisions of Article 7 of the Workers' Statute.

The type and extent of each of the penalties mentioned above will also be applied by taking the following into account:

- the intentional nature of the conduct or the degree of negligence, imprudence or inexperience with regard to the predictability of the event;
- the overall conduct of the worker, with particular regard to the existence of any previous disciplinary measures, within the limits permitted by law;
- the worker's duties;
- the functional role of the persons involved in the facts constituting the violation;
- the potential reiteration of that done within the previous two-year period;
- the extent of the injury or danger as a result of the violation for the COMPANY and for all employees and stakeholders of the COMPANY;
- any other particular circumstances that accompany the disciplinary offence.

IBSA ITALIA's prerogative to request compensation for damages deriving from the violation of the MODEL by an employee is reserved. Any compensation for damages will be commensurate with:

- the level of responsibility and autonomy of the employee who committed the disciplinary offence;
- the possible existence of previous disciplinary measures against the worker;
- the degree of intentionality of his/her behaviour;
- the seriousness of the effects of the same, meaning the level of risk to which the Company reasonably believes to have been exposed following the conduct pursuant to and for the purposes of the DECREE - as a result of the conduct complained of.

The Managers in charge of the actual application of the disciplinary measures described above are the Human Resources Manager and the Manager of the department in which the employee works.

The aforementioned subjects will impose sanctions after hearing the opinion of the SB, as well as the opinion of the hierarchical manager of the person who committed the crime.

The SB must receive timely information of every act concerning the disciplinary procedure against a worker for violation of this MODEL from the moment of the disciplinary dispute. In collaboration with the Human Resources Manager, the SB is assigned the task of verifying and assessing the suitability of the disciplinary system pursuant to and for the purposes of the DECREE.

In the event of violation of the provisions and rules of conduct contained in the MODEL by managers, once the responsibility of the person who committed the violation has been ascertained, the COMPANY adopts the measure deemed most appropriate in accordance with the provisions of the applicable National Collective Labour Agreement.

If the violation of the MODEL causes an overall lack of trust between the COMPANY and manager, the sanction is deemed as **dismissal for just cause**.

10.3. Measures against Directors

Upon notice of violation of the provisions and rules of conduct of the MODEL and failure to comply with the regulations on the protection of whistle-blowers in the context of a working relationship by members of the Board of Directors, the BODY must promptly inform of the Chairman and the entire Board of Directors and the Board of Statutory Auditors in writing as to what happened.

In accordance with the provisions of the Articles of Association, the recipients of the ORGANIZATIONAL REPORT may, take the appropriate measures, including, for example, a written complaint in the minutes, suspension of the right to attendance fees or charge for up to a corresponding maximum to three meetings of the body, the convocation of the

Shareholders' Meeting in order to adopt the most suitable measures provided for by law (**revocation for just cause**, exercise of the **liability action**, etc.).

This is without prejudice to compensation for any damage caused to the COMPANY.

10.4. Measures against members of the Board of Statutory Auditors

Upon notice of violation of the provisions and rules of conduct of the Model by one or more members of the Board of Statutory Auditors and failure to comply with the regulations concerning the protection of reporting illegal acts in the context of a working relationship, the BODY must promptly inform the entire Board of Statutory Auditors and the Board of Directors of the occurrence.

The recipients of the ORGANIZATIONAL REPORT may take or propose that Members to take appropriate measures (**revocation for just cause**, exercise of the **liability action**, etc.) in accordance with the provisions of the Statute, and will provide for the additional duties provided for by law.

This is without prejudice to compensation for any damage caused to the COMPANY.

10.5. Measures against consultants, collaborators, and business partners

The violation by consultants, external collaborators and business partners, or other subjects having contractual relationships with the COMPANY, of the provisions and rules of conduct provided for by the MODEL applicable thereto, or the possible commission of the crimes provided for by the DECREE on their behalf will be sanctioned in accordance with the **specific contractual clauses** included in the relative contracts (or other specific negotiating formulas).

In making explicit reference to compliance with the provisions and rules of conduct set forth in the MODEL, these clauses may include, for example, the obligation of third parties not to adopt acts or conduct themselves in such a way as to determine a violation of the MODEL by IBSA ITALIA. In the event of violation of this obligation, **termination of the contract** may take place with the potential application of penalties.

This is without prejudice to IBSA ITALIA'S right to request compensation for damages deriving from the violation of the provisions and rules of conduct provided for the MODEL by the aforementioned third parties.

If the BODY becomes aware of a violation of the MODEL or the Procedures for its implementation by the RECIPIENTS or contractual counterparts, it informs the manager of the competent department and the Head of the Area to which the contract or report refers, by means of a written report.



SPECIAL SECTION (OMISSIS)