



**IBSA Institut Biochimique SA**

**COMPLIANCE PROGRAMME**

**Pursuant to Italian Legislative Decree 231 of 8 June 2001  
and Article 102 of the Swiss Criminal Code**

Approved by the Board of Directors  
on 24 June 2019

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## **GENERAL SECTION**



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## DEFINITIONS

**IBSA** or the “**Company**”: IBSA Institut Biochimique SA.;

“**Advisory Services**”: the support services in relation to technical, scientific, tax, legal and other matters provided by third-party professionals to IBSA.;

“**Anti-Corruption Guidelines**”: the guidelines adopted by the Group that set out the rules for ensuring compliance by the third parties operating for or on behalf of the Group Companies with the Anti-Corruption regulations and the main principles contained therein.;

“**Code of Ethics**”: the internal code of conduct of the IBSA Group prepared and approved by the management body of the Company, containing the set of ethical principles that those who work for the Company and for the entire Group are required to adhere to in order to ensure compliance with the law in all the countries where they operate.;

“**Collaborators**”: those who provide their work services on a continuous basis to the Company, and in coordination with it, but without being subject to an employment relationship.;

“**Compliance Programme**”: this compliance programme, drawn up, adopted and implemented in accordance with Italian Legislative Decree 231/2001 and the Swiss Criminal Code, including the Code of Ethics, the Anti-Corruption Guidelines, and any procedures, protocols, policies and/or rules, internal guidelines, and company memos, as well as the system of delegated responsibilities and powers, etc. referred to therein.;

“**Confindustria Guidelines**”: the Guidelines adopted by Confindustria (Confederation of Italian Industry) on 7 March 2002 (as amended) for the preparation of compliance programmes in accordance with Article 6, paragraph 3, of Italian Legislative Decree 231/2001.;

“**Corporate Functions**”: the individual organisational units of IBSA responsible for managing and conducting the Company’s operations.;

“**Crimes**”: the crimes envisaged in Italian Legislative Decree 231/2001 in relation to the corporate liability of entities and in the Swiss Criminal Code.;



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“**Decree**” or “**Italian Legislative Decree 231/01**”: Italian Legislative Decree 231 of 8 June 2001 as amended;

“**Document**”: this Compliance Programme, in all its parts;

“**Employees**”: those who have an employment relationship with the Company, including the executives;

“**Entity**”: the legal persons subject to criminal liability under the Decree and the SCC;

“**General Section**”: the introductory section of the Document, which provides information to the Senior Managers and the Subordinates and contains the rules regarding the main provisions of the Decree, the principles adopted by IBSA as the basis for the construction of the Compliance Programme, and the Penalty System;

“**Group**”: means all the companies controlled by IBSA;

“**Management Body**”: the Board of Directors of the Company or any other system of management that may be adopted by the Company;

“**Partners**”: the counterparties with which the Company enters into some form of contractually regulated relationship (e.g. dealers, distributors, agents, professionals, advisory firms in general, etc.), aimed at cooperation with the Company;

“**Penalty System**”: the disciplinary system and the related penalty mechanism to be applied in the event of violation of the Compliance Programme;

“**Procedures**”: the set of procedures, protocols, guidelines and operating instructions adopted by the Company and constituting its system of internal rules;

“**Public Authorities**” or “**PAs**”: the Public Authorities and, in particular, national and foreign public officials and public service officers that IBSA has dealings with;

“**Recipients**”: the Senior Managers, Subordinates and Third Parties that are subject to the provisions of the Compliance Programme;

“**SCC**”: the Swiss Criminal Code of 21 December 1937 as amended;

“**Senior Managers**”: the individuals that hold senior positions (representation, administration or management of the Entity or one of its organisational units that has financial and functional



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independence, or individuals that are responsible, on a *de facto* basis, for the management or control of the entity);

“**Sensitive Activities**”: the company activities and processes within which there is a theoretical risk of committing the offences envisaged in Italian Legislative Decree 231/01, as well as the crimes envisaged in Article 102 of the Swiss Criminal Code;

“**Special Section**”: the section of the Compliance Programme containing the description, for each of the categories of crimes, of the Sensitive Activities of the Company within which the crimes envisaged in the Decree and envisaged in the SCC may be committed, together with details of the corrective measures adopted to prevent those crimes from being committed;

“**Subordinates**”: the individuals managed or supervised by one of the Senior Managers;

“**Supervisory Body**”: the internal control body, made up of a single individual, responsible for supervising the functioning and observance of the Compliance Programme adopted by the Company;

“**Suppliers**”: the suppliers of non-professional goods and services to the Company that do not meet the definition of Partners;

“**Third Parties**”: by way of non-limiting example, suppliers, consultants, contractual counterparties and third parties in general, that do not meet the definition of Subordinates due to the absence of a subordinate relationship;

“**Violation**”: the adoption or omission of actions or conduct, not in compliance with the law and with the provisions of the Compliance Programme and the related Procedures, which results in the commission of one of the crimes envisaged by Italian Legislative Decree 231/01 and/or by the SCC; and the adoption or omission of actions or conduct, governed by the Compliance Programme and the related Procedures, or required by the law, which expose the Company even solely to the mere risk of the commission of one of the crimes envisaged by the applicable legislation.



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## **INTRODUCTION**

At IBSA Institut Biochimique SA (referred to below also just “**IBSA**” or the “**Company**”) we are fully aware of the need to ensure that our business activities are conducted in compliance with the laws and regulations of the countries where we operate and accordingly we have decided to adopt our own Compliance Programme in line with the provisions of Italian Legislative Decree 231/2001 and the Swiss Criminal Code.

The Compliance Programme has been drawn up based on the recent regulatory updates and the recommendations from the legal literature and case law and has been approved by the Board of Directors of the Company.

### **1. THE SWISS CRIMINAL CODE**

The Federal Law of 21 March 2003 (Terrorist Financing), in force since 1 October 2003, has added Title VII, headed “Corporate Criminal Liability”, to the Swiss Criminal Code, which, in Article 102, provides for the possibility of imposing a fine of up to 5,000,000 francs, on an entity (legal entity under private and public law, except for local authorities and sole-proprietor companies and firms) in relation to the commission of a crime, irrespective of the criminal liability of any natural persons, if - in the same way as envisaged by the Italian Legislation - the organisation is found to be at fault.

Specifically, the Swiss Criminal Code introduces two separate types of liability:

- “vicarious criminal liability” (Article 102.1, SCC), according to which the company is liable for the crime or offence committed, in the exercise of business activities in accordance with the corporate purpose, if it is not possible to identify the person who committed it due to “*inadequate internal organisation*”.

The lack of specification of the crime that could give rise to the entity’s liability means that specific measures need to be adopted to combat the commission of crimes related to negligence, such as, for example, those relating to the environment or safety at work.

- “concurrent criminal liability” (Article 102.2, SCC), according to which the undertaking is punished “*irrespective of the criminal liability of any natural persons*”, provided the “*undertaking has failed*”



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*to take all the reasonable organisational measures that are required in order to prevent one of the crimes”<sup>1</sup>*  
specifically envisaged in the Code.

This refers in particular to the crimes of:

- criminal organisation;
- financing terrorism;
- money laundering;
- bribery of Swiss public officials and granting of advantages;
- bribery of foreign public officials;
- bribery of private individuals.

The common thread between the two forms of liability is without doubt the concept of fault of the organisation, which means that all reasonable and necessary organisational measures need to be adopted to avoid the commission of a particular crime, and includes not only the notions of corporate governance and risk management, but also company customs and practices.

Unlike the provisions of the Italian legislation, the Swiss Criminal Code does not provide indications on the measures that companies must adopt and implement to ensure the prevention of the commission of the crimes and guarantee the correct identification of those responsible for the management of all the company processes.

Accordingly, in the absence of specific indications available from the Swiss legislation, we have drawn up our Compliance Programme on the basis of the Confindustria guidelines issued on 7 March 2002, updated in March 2014 and approved by the Italian Ministry of Justice, as well as the Code of Conduct of Farindustria, in view of the specific nature of our industry sector and our geographical areas of operations.

## **2. ITALIAN LEGISLATIVE DECREE 231 OF 8 JUNE 2001**

### **2.1. The Corporate Liability of Entities**

The Decree introduced the notion of corporate liability into the Italian legislation, arising from a crime committed by Entities (understood as companies, associations, consortia, etc.), which forms part of a

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<sup>1</sup> The crimes in question are envisaged in and punished by Articles 260ter, 260quinquies, 305bis, 322ter, 322quinquies, 322septies paragraph 1 or 322octies of the Swiss Criminal Code, details of which are provided in Appendix 1 “Catalogue of predicate crimes for liability of the entity”.



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broader legislative process designed to combat corruption and adapt the related national legislation to the international conventions signed by Italy (including the Brussels Convention of 26 July 1995 on the protection of the European Communities' financial interests, the Brussels Convention of 26 May 1997 on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, and the OECD Convention of 17 December 1997 on combating bribery of foreign public officials in international business transactions).

This liability, which is additional to the (“criminal”) liability of the individual who actually committed the crime, only exists when an individual, who is functionally linked to the entity in accordance with Article 5, paragraph 1 of the Decree, has committed one of the crimes contemplated in Articles 24 and following of the Decree, in the interest and to the advantage of the Entity.

The Perpetrators of the Predicate Crime can only be (i) individuals who hold representative, administrative or management positions in the Entities, or in one of their financially and functionally independent organisational units, or individuals who exercise management and control (also on a *de-facto* basis) over the Entities (“**senior managers**”), as well as (ii) individuals managed or supervised by one of the aforementioned persons (“**subordinates**”).

The list of relevant crimes for the purposes of the Decree has been extended over time and now includes offences in the following categories:

- *crimes in relations with Public Authorities* (such as corruption, misappropriation of funds from the State, undue receipt of funds, fraud against the State, computer fraud against the State, and inducement to give or promise benefits, referred to in Articles 24 and 25 of Italian Legislative Decree 231/2001);
- *cybercrime and unlawful data processing* (such as computer fraud, malicious hacking of an information or computer system, installing and distributing equipment designed to intercept, prevent or interrupt communications relating to an information or computer system, unauthorised possession and distribution of access codes to information and computer systems, and damaging information or computer systems, referred to in Article 24-bis of Italian Legislative Decree 231/2001);
- *organised crime* (e.g. mafia-type associations, including foreign organisations, mafia vote-buying, and kidnapping for extortion, referred to in Article 24-ter of Italian Legislative Decree 231/2001);
- *crimes against public trust* (such as, for example, forgery of distinctive signs and instruments, referred to in Article 25-bis of Italian Legislative Decree 231/2001);



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- *crimes against industry and trade* (such as disruption of freedom of trade and commerce, illegal competition with threats and violence, fraud against national industries, fraudulent trading, sale of industrial products with misleading signs, and manufacture and trade of goods made by misappropriating industrial property rights, referred to in Article 25-bis.1 of Italian Legislative Decree 231/2001);
- *corporate crimes* (such as false company statements, impeding company controls, unlawful influence on the shareholders' meeting, and private-to-private corruption, referred to in Article 25-ter of Italian Legislative Decree 231/2001, as last amended by Italian Legislative Decree 38/2017);
- *crimes relating to terrorism and subversion of democracy* (referred to in Article 25-quater of Italian Legislative Decree 231/2001);
- *crimes against the individual* (such as trafficking in persons, enslaving and holding in slavery, and unlawful intermediation and exploitation of labour, referred to in Article 25-quater.1 and Article 25-quinquies of Italian Legislative Decree 231/2001);
- *market abuse crimes* (insider dealing and market manipulation, referred to in Article 25-sexies of Italian Legislative Decree 231/2001);
- *crimes relating to health and safety at work* (manslaughter and serious personal injury through negligence referred to in Article 25-septies of Italian Legislative Decree 231/2001);
- *crimes of receiving, laundering and using money, goods or assets of unlawful origin, as well as self-laundering* (referred to in Article 25-octies of Italian Legislative Decree 231/2001);
- *copyright infringement and related crimes* (Article 25-nonies of Italian Legislative Decree 231/2001);
- *crime of inducement to refrain from making statements or to make false statements to Legal Authorities* (Article 25-decies of Italian Legislative Decree 231/2001);
- *environmental crimes* (Article 25-undecies of Italian Legislative Decree 231/2001);
- *crimes of employment of illegally staying third-country nationals, as well as of illegal entry and aiding and abetting of illegal immigration* (Article 25-duodecies of Italian Legislative Decree 231/2001);
- *racism and xenophobia* (Article 25-terdecies of Italian Legislative Decree 231/2001);
- *fraud in sports competitions, illegal gambling or betting* (Article 25-quaterdecies of Italian Legislative Decree 231/2001);
- *transnational crimes* (such as criminal association and crimes of obstruction of justice, provided the crimes are “transnational” in nature);



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- *non-compliance with prohibitory penalties* (Article 23 of Italian Legislative Decree 231/2001)<sup>2</sup>.

## **2.2. Adoption of the Compliance Programme as a Condition of Exemption from Corporate Liability**

Article 6 of the Decree establishes that the Compliance Programme adopted by the Entity can be a condition for exemption from the Decree.

Specifically, if a crime is committed by a senior manager, corporate liability is excluded if the Entity demonstrates that:

- a) before the act was committed, it had adopted and effectively implemented Compliance Programmes, through its management body, designed to prevent the type of Crimes committed;
- b) it had assigned an internal unit, vested with independent powers of initiative and control, the task of ensuring the functioning and observance of the compliance programmes, as well as overseeing their updating;
- c) the individuals who committed the crime did so by fraudulently ignoring the aforementioned Compliance Programmes;
- d) there was no lack or absence of supervision by the unit referred to in point b) above.

Where the crime is committed by individuals in senior managers, there is a presumption of guilt of the Entity. Therefore, in order to benefit from the above-mentioned exemption, the Company needs to provide proof of its lack of involvement in the acts concerned, by demonstrating that the conditions listed above have been met and that, consequently, the crime is not the result of its “organisational fault”.

For crimes committed by subordinates subject to management or supervision by a senior manager, the Entity is only liable if the commission of the offence was made possible by the violation of the management or supervision obligations imposed on the Company. For the entity to be liable for the offence, the accusation must prove the failure to adopt and effectively implement a Compliance Programme capable of preventing crimes of the same nature as those committed.

However, the adoption of the Compliance Programme is not sufficient in itself to exclude the corporate liability of the Entity. Indeed, Italian Legislative Decree 231/2001 also requires the Compliance Programme to be efficient and effective.

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<sup>2</sup> The examples of the crimes listed above are provided in the appendix



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In accordance with Article 6, paragraph 2 of Italian Legislative Decree 231/2001, in order to be effective, the Compliance programme must meet the following requirements:

1. identifying the areas at risk of commission of the crimes envisaged by the Decree;
2. setting up specific protocols to assist management in formulating and implementing the entity's decisions in relation to the crimes to be prevented;
3. establishing procedures for identifying and managing the financial resources necessary for preventing such crimes;
4. establishing obligations for sending information to the unit responsible for supervising the functioning and observance of the compliance programme;
5. introducing an internal disciplinary system capable of penalizing the failure to comply with the measures set out in the compliance programme.

Lastly, in order for the Compliance Programme to be effective, it must be implemented effectively.

Article 7, paragraph 4 of Italian Legislative Decree 231/2001, identifies the requirements for the effective implementation of the Compliance programme as:

- periodic verification, with modification of the compliance programme where necessary, when significant violations of the regulations are discovered or when the organisation or its activities undergo changes;
- imposition of penalties in the event of violation of the provisions of the Compliance Programme.

### ***2.3. Penalty System***

The penalties applicable to the entity responsible for an administrative offence are specifically identified in Articles 9 and following of Italian Legislative Decree 231/2001 as:

- financial penalties;
- prohibitory penalties;
- confiscation;
- publication of the judgement.

The *financial penalty* is applied in all cases in which the liability of the Entity is ascertained. This type of penalty is determined by the court through a system based on “units”, of a number of not less than one hundred and not more than one thousand and of an amount ranging from a minimum of €258.22 to a maximum of €1,549.37. In setting the financial penalties the court determines:



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- the number of units, based on the seriousness of the act, the extent of the Entity's liability, and what has been done to eliminate or mitigate the consequences of the act and prevent the commission of additional offences;
- the amount of the single unit, based on the economic and financial situation of the Entity.

The *prohibitory penalties*, listed in Article 9, paragraph 2 of Italian Legislative Decree 231/2001, may consist of:

- a ban on carrying out the activity;
- the suspension or withdrawal of authorisations, licences or permits enabling the commission of the offence;
- a ban on contracting with public authorities, other than to obtain a public service;
- the exclusion from concessions, loans, grants and subsidies and possible revocation of those granted;
- a ban on advertising goods or services.

This type of penalty only applies for the administrative offences for which it is specifically envisaged, provided at least one of the following conditions apply:

- a) the Entity has gained a substantial profit from the commission of the Crime and the Crime was committed by senior managers, or by individuals subject to the management of another individual if, in the latter case, the crime resulted from or was facilitated by serious organisational deficiencies;
- b) the crime is a repeat offence.

The Court determines the type and duration of the prohibitory penalty, which cannot be less than three months and not more than two years, based on the suitability of the individual penalties for preventing offences of the type committed and, if necessary, can apply them jointly (Articles 14, paragraph 1 and paragraph 3 of Italian Legislative Decree 231/2001). In the case of conviction for the crimes indicated in Article 25, paragraphs 2 and 3 of Italian Legislative Decree 231/2001, the prohibitory penalties are raised to a duration of not less than four years and not more than seven years, if the crime was committed by one of the persons referred to in Article 5, paragraph 1, sub-paragraph a), and to a duration of not less than two years and not more than four years, if the crime was committed by one of the persons referred to in Article 5, paragraph 1, sub-paragraph b)<sup>3</sup>.

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<sup>3</sup> In accordance with Article 25, paragraph 5-bis of Italian Legislative Decree 231/2001, “*if, before the first instance sentence, the entity has effectively taken steps to prevent the criminal activity from having further consequences, to secure the evidence of the crimes and to identify the persons responsible or to seize the sums or other benefits transferred and has eliminated the organisational deficiencies that led to the crime by adopting and*



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In the most serious cases, the penalties of the ban on carrying out the activity, the ban on contracting with Public Authorities and the ban on advertising goods or services may be applied on a permanent basis<sup>4</sup>.

In addition (instead of the imposition of the penalty) the activity of the Entity may also be carried out by an administrator appointed by the Court in accordance with and under the conditions set out in Article 15 of Italian Legislative Decree 231/2001<sup>5</sup>.

The prohibitory penalties can also be applied as a precautionary measure upon request by the Public Prosecutor, provided there is strong evidence of the Entity's liability and there is a real danger that other offences of the same nature as the one being prosecuted will be committed. The court orders the application of the penalties by means of an ordinance.

In accordance with Article 19 of Italian Legislative Decree 231/2001, the conviction always involves the *confiscation* - also by means of equivalent - of the price (money or other economic benefit given or promised to induce or cause another person to commit the crime) or the profit (immediate economic benefit derived) from the crime, except for the part that can be returned to the injured party and subject to the rights acquired by third parties in good faith.

The *publication of the conviction* judgement in one or more newspapers, as an excerpt or in full, may be ordered by the court together with the posting of a public notice in the municipality where the entity has its head office, when a prohibitory penalty is imposed. The publication is carried out by the clerk of the competent court and paid for by the Entity.

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*implementing compliance programmes capable of preventing crimes of the type that have occurred, the prohibitory penalties shall have the duration set by Article 13, paragraph 2".*

<sup>4</sup> See, in this regard, Article 16 of Italian Legislative Decree 231/2001, according to which: "1. An entity can be permanently banned from carrying out an activity if the entity has obtained a significant profit from the crime and has been sentenced, at least three times in the last seven years, to temporary ban on carrying out the activity. 2. The court may permanently ban the entity from contracting with the public administration or advertising goods or services if the entity has already been sentenced to the same penalty at least three times in the last seven years. 3. If an entity or one of its organisational units is permanently used for the single or prevalent purpose of enabling or facilitating the commission of crimes for which it is liable, the ban on carrying out the activity is always permanent and the provisions contained in Article 17 do not apply".

<sup>5</sup> "Court-appointed administrator – If the conditions exist for applying a prohibitory penalty that results in the interruption of an entity's activities, the judge, when applying the penalty, will arrange for the entity's activities to continue under a court-appointed administrator for a period equal to the duration of the prohibitory penalty applied, provided at least one of the following conditions applies: a) the entity provides a public service or an essential public service which if interrupted could cause serious harm to the general public; b) interruption to the entity's activity could cause significant repercussions on employment, as a result of the size of the activity and the economic conditions in the area where it takes place. In the judgement allowing the activity to continue, the court specifies the responsibilities and powers of the court-appointed administrator, taking into account the specific activity in which the entity committed the offence. Under the responsibilities and powers indicated by the court, the court appointed administrator is entrusted with implementing compliance programmes capable of preventing the commission of crimes of this type. The court-appointed administrator cannot carry out special administration operations without the authorisation of the court. Any profit deriving from the continuation of the activity is confiscated. Continuation of the activity by a court-appointed administrator cannot be ordered if the prohibitory penalty is permanent".



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#### ***2.4. Attempted Crime***

When the Predicate Crimes are committed in attempted form<sup>6</sup>, the financial penalties (in terms of amount) and the prohibitory penalties (in terms of duration) are reduced from one third to a half (Articles 12 and 26 of Italian Legislative Decree 231/2001).

No liability is incurred by the Entity if it voluntarily prevents the completion of the action or the occurrence of the event (Article 26 of Italian Legislative Decree 231/2001). In this case, the exclusion of penalties is justified by the removal of any relationship of association between the entity and the parties that assume they are acting in its name and on its behalf.

#### ***2.5. Crimes Committed Abroad***

Article 4 of Italian Legislative Decree 231/2001 establishes that the corporate liability of the entity may also exist when the crimes envisaged in Italian Legislative Decree 231/2001 are committed abroad<sup>7</sup>, provided that the individual and objective conditions for liability envisaged by the Decree are met.

Article 4 in fact establishes that the entity is only liable when:

- a) the crime is committed by a person functionally linked to the entity, in accordance with Article 5, paragraph 1, of the Decree;
- b) the entity has its head office in the territory of the Italian State;
- c) the government of the place where the crime was committed has not already taken action against the entity;
- d) the conditions established in Articles 7, 8, 9 and 10 of the Italian Criminal Code apply.

#### ***2.6. Criminal Liability in Groups of Companies***

Italian Legislative Decree 231/2001 does not expressly address the aspects related to the liability of an Entity belonging to a group of companies, despite the fact that this is a common situation.

Given that a group cannot be considered a direct centre of imputation of liability for a crime and cannot be classed as one of the parties indicated in Article 1 of Italian Legislative Decree 231/2001, we need to consider how Compliance Programmes work in relation to crimes committed by entities belonging to these kinds of aggregations of companies.

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<sup>6</sup> Article 56 Criminal Code envisages that “Whoever carries out acts, aimed unequivocally at committing a crime, is liable for an attempted crime, if the action does not take place or the event does not occur”.

<sup>7</sup>Article 4 of Italian Legislative Decree 231/2001 establishes the following: “1. In the cases and under the conditions envisaged in Articles 7, 8, 9 and 10 of the Italian Criminal Code, entities that have their head offices in Italy are also liable to prosecution for crimes committed abroad, provided the State where the act was committed does not intend to prosecute. 2. In cases where the law provides for the offender to be punished on request from the Minister of Justice, the entity in question will only be prosecuted if the request is also made with respect to the latter”.



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As also highlighted in the latest updated version of the Confindustria (Confederation of Italian Industry) Guidelines, *a holding/parent company may be held liable for a crime committed within the operations of its subsidiary* when:

- a predicate crime has been committed in the immediate and direct interest or advantage not only of the subsidiary but also of the parent company;
- individuals functionally connected to the parent company have *participated* in the commission of the predicate crime by making a causally significant contribution (Supreme Court, Criminal Division, ruling no. 24583 of 2011), which has been substantively and specifically proven.

### **3. IBSA'S GOVERNANCE MODEL AND ORGANISATIONAL STRUCTURE**

#### ***3.1. IBSA Institut Biochimique SA***

IBSA Institut Biochimique SA is a pharmaceutical company founded in 1945, which, since 1985, has embarked on a process of development to strengthen its position and expand into the international market. Steady growth has enabled it to achieve a leading position in specific therapeutic areas. Currently, IBSA, as a Parent Company, with a network of companies operating worldwide, employs around 1,400 people and has a portfolio of products for 9 therapeutic areas with numerous active patents.

IBSA has developed an efficient business model based on three fundamental principles:

- vertical integration: most of the products are manufactured in-house with direct control of all the production phases and processes. This ensures high quality standards in all the processing phases, as well as greater flexibility and reduced risk throughout the supply chain;
- focus on effective therapies: research and development on special technologies that significantly improve the quality of existing molecules and therapeutic solutions, with particular emphasis on developing innovative delivery systems;
- an international presence.

The Company has cutting-edge production facilities where most of the products marketed by IBSA are manufactured. It also establishes synergistic relationships with the staff functions of the other companies controlled by it, which are governed by detailed intercompany agreements, in order to pursue the achievement of the strategic and business objectives set at Group level.



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### ***3.2. IBSA's Corporate Governance System***

IBSA adopts a management system that divides responsibilities between Shareholders, the Management Body, the Executive Committee and the external auditors and is designed to ensure conditions of fairness and transparency in the management of company operations.

The executive bodies and officers of the Company are:

- a) the Board of Directors;
- d) the Chief Executive Officer of the Company;
- e) the Executive Committee.

#### **Board of Directors**

The Board of Directors is self-appointed and consists of one or more members who are elected for a period of one year by the shareholders' meeting.

The Board of Directors is responsible for the ultimate management and overall supervision of the Company as well as the supervision and control of the activities of the Chief Executive Officer.

It sets the principles of the company strategies and policies and performs its function in accordance with the Law, the Articles of Association and the Organisational Rules adopted by the Company.

#### **Chief Executive Officer**

The CEO is responsible for the day-to-day executive management of the Company, as well as the management of the company operations and the functions that report to the CEO.

The CEO reports directly to the Board of Directors, informing it promptly of any significant extraordinary events and on an ongoing basis regarding market penetration activities, as well as the Company's business developments.

#### **Executive Committee**

The Executive Committee is composed of the Company's Chief Officers and the Heads of the Company's respective operating units (the "Executive Directors") appointed by the Board of Directors on proposal by the CEO, who chairs the committee, and it is responsible for managing the Company's operations and overall business activities.



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The Executive Committee implements the strategic company policy along the lines indicated by the Board of Directors or the CEO - except for decisions of extraordinary importance which require approval by the Board of Directors - and discusses and draws up the annual financial plan of the department concerned to be submitted to the Board of Directors for approval.

### **Independent Auditors**

By decision of the shareholders' meeting, a firm of independent auditors was engaged to audit the proper keeping of the accounts, the correct recording of the operating events in the accounting records, the compliance of the financial statements with the rules governing their preparation, and the correct and truthful representation of the financial position and cash flows and the operating earnings, and to provide an opinion on the financial statements and on the consistency of the report on operations with the financial statements.

### ***3.3. Organisational Framework***

IBSA has an organisational structure consisting of:

- Primary Activities: (i) Technical Operations, (ii) Manufacturing; (iii) Medical Affairs, (iv) R&D Scientific Affairs, (v) Fertility and Endocrinology, (vi) Pharmaceutical Research and Development, (vii) International Business Operations, and (viii) Swiss Business Operations
- Support Functions, including: (i) Finance & Administration, (ii) Information Technology, (iii) Human Resources, (iv) Legal Affairs, (v) Quality Control, (vi), (vii) Global Supply Chain, (viii) Regulatory Affairs; and (ix) Communication

These functions are represented within the company Organisation Chart, which describes the activities, responsibilities and functions of the various company functions and which is an integral part of the Compliance Programme. The specific characteristics of the functions listed above and their responsibilities are formalised in specific job descriptions, which are continuously updated and archived by the Human Resources function and are also adopted to ensure compliance with the provisions of the Swiss Criminal Code.



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In allocating the duties and responsibilities, IBSA pays particular attention to defining the hierarchical reporting and formalising the authorisation levels necessary for carrying out the “at risk” activities. In particular, the Company uses a system of Signature Policies to set the authorisation limits, which, in compliance with the principle of segregation of functions, require joint signatures of the personnel with signing powers and the Company’s representatives.

### *3.3.1. Primary Activities*

#### **Technical Operations and Manufacturing**

The Ticino production sites operate in compliance with the Good Manufacturing Practices (GMP) according to the rules of the Quality Management Systems (QMS) adopted by the Company.

The production process is carried out under the direction of the Manufacturing Director, in compliance with the production plans, established by the Technical Department based on the technical and personnel availability.

The correct implementation within the company of the principles and procedures of the QMS is monitored through periodic audits based on an internally-established annual audit plan. All operations related to the production processes are formalised and recorded. The related documentation is archived by the organisational units involved and/or by the Quality function.

#### **Medical Affairs**

This function is responsible for the scientific support activities for all the company products, except for the hormones area, which handled by the Fertility and Endocrinology.

More specifically, this involves the organisation, management and control of activities connected with the definition and planning of scientific communication, provided both directly and in support of the marketing, commercial and medical functions of distributors and affiliates (including Group entities); the planning and implementation of corporate events (e.g. conventions, marketing meetings, stand-alone meetings, and press conferences); and the management of contacts with industry opinion leaders and communication activities at international congresses organised by IBSA, directly and/or in collaboration with R&D, and upon consultation with Legal Affairs.

All the activities related to the function are formalised and recorded.

#### **R&D Scientific Affairs**



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This function designs and implements scientific research projects and clinical studies (pre- and post-marketing) in compliance with the GPC, the operating procedures, and the industry-sector rules and regulations.

The activities are carried out in close coordination with the Legal Affairs function for the compliance checks and are governed by specific internal procedures.

### **Fertility and Endocrinology**

This function is responsible for the analysis and market positioning of products in the “hormones” category, manufactured by IBSA.

This function also coordinates the marketing initiatives, at group level, particularly in relation to cost and sales management/analysis/control in the related markets, calculating and controlling the profitability of the products under management.

### **Pharmaceutical Research and Development**

This function handles the research and development aimed at creating new pharmaceutical formulations and producing GMP lots for clinical trials.



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### **International Business Operations**

This function is responsible for managing the business operations of all the IBSA distributors located in the 5 continents. It promotes the Company's economic growth through the continuous monitoring and stimulation of the revenues of its business partners. It analyses and researches the accuracy of the budgets and margins, monitors the achievement of targets by the distributors, and assesses new business opportunities and commercial agreements in new markets.

### **Swiss Business Operations**

This function is responsible for all the business operations in Switzerland, including marketing, direct sales, promotion and scientific information.

#### *3.3.2. Support Functions*

The support functions for IBSA's core business are responsible, on the one hand, for the direct and independent management of the Parent Company's activities and, on the other hand, for the coordination and supervision of the same functions set up within the Group Companies.

The following are managed by other Group Companies:

- Finance and Administration
- Legal Affairs
- Information Technology
- Supply Chain, for the supplies for the organisation of travel and major events

The following activities are outsourced to third-party companies:

- Tax compliance advisory services
- Litigation management

For each outsourced process, and for the advisory services, a specific agreement is drawn up that governs the relations between the parties and, in particular, the purpose of the service, the financial terms and conditions, and the related responsibilities, also pursuant to the provisions of the Decree.



## 4. IBSA'S COMPLIANCE PROGRAMME

### *4.1 Introduction*

At IBSA we are aware of the need to ensure fairness in the conduct of our business and the operations carried out both in Switzerland and in all the countries where we operate. Accordingly, in line with our company policies, we have decided to adopt a Compliance Programme that meets the requirements of organisational efficiency established by the Swiss Criminal Code and the Decree.

For us, the development of the Compliance Programme is not only an instrument for the prevention of Crimes, but, above all, a strategic instrument for the continuous improvement of our governance system and for the pursuit of correct and transparent conduct, in compliance with current regulations and in line with the ethical-social values enshrined in the Group's Code of Ethics, which underpin the Company's approach to conducting our business.

In keeping with the Code of Ethics and the Anti-Corruption Guidelines, the Compliance Programme adopted by the Company is the instrument for reaffirming our complete condemnation of any conduct of an illegal nature, as well as the instrument designed to ensure that all company activities are carried out according to uniform and controlled procedures.

The Compliance Programme therefore performs the following functions:

- making all those who work in the name and on behalf of IBSA aware of the need for strict adherence to the Compliance Programme, the violation of which results in severe disciplinary penalties;
- punishing any conduct, inspired by a misguided company interest, that is in conflict with laws, regulations or, more generally, with the principles of fairness and transparency;
- providing information about the serious consequences that could arise for the Company (and therefore for all its employees, executives and senior managers) from the application of the penalties (financial and prohibitory) envisaged by the applicable regulations and the possibility that they may also be ordered on a precautionary basis;
- enabling the Company to constantly control and carefully supervise sensitive processes in order to be able to act promptly when risks arise.



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#### ***4.2 Applicable Guidelines***

In view of the absence of regulatory parameters defined by the Swiss legislation, the Company has drawn up the Compliance Programme in accordance with the Guidelines for the construction of Compliance Programmes in accordance with Italian Legislative Decree 231/2001 issued by the Italian representative body Confindustria on 7 March 2002, as updated, which are an undisputed and authoritative benchmark at European level and require the following activities:

- identification of the risk areas, i.e. the company area or sector concerned by the risk of the crime being committed;
- establishment of a control system reasonably capable of preventing or reducing the risk of committing crimes through the adoption of specific protocols. Of particular importance in this regard, are the organisational structures, activities and rules implemented by the management and the company personnel, within the internal control system, aimed at ensuring:
  - effective and efficient operations;
  - reliability of company information, both towards third parties and internally;
  - compliance with laws, regulations, rules and internal policies.

In drawing up the Compliance Programme, the Company has also taken into account the provisions of the Farindustria (Italian association of pharmaceutical companies) Guidelines and its Code of Conduct, as the reference for the conduct of all the activities carried out by the Company in Italy or in favour of its Italian subsidiaries.

In any event, any deviations from the content of the Guidelines, due to the Company's specific characteristics and geographical scope of operations, do not undermine the validity of the Compliance Programme, because it corresponds to the Company's specific circumstances and may well therefore deviate from the Guidelines - which are general in nature - due to specific protection and prevention needs.

#### ***4.3 The Project for the Development of IBSA's Compliance Programme***

The Compliance Programme has therefore been constructed according to the following methodological steps.

##### ***Step 1 - Organisational Analysis and Identification of Sensitive Processes***

This step consisted of the analysis of the Company, to identify the processes and activities within which the crimes specifically identified by Italian Legislative Decree 231/2001 and the SCC may be



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committed and to identify the persons responsible, i.e. the key officers with in-depth knowledge of these processes/activities and the control mechanisms currently in place.

This analysis was carried out by examining the documentation relating to the Company (organisation chart, job descriptions, procedures adopted, organisational provisions, etc.) and conducting interviews with the key officers, in order to identify the activities performed by them, as well as the company processes comprising these activities and their actual and effective implementation.

### ***Step 2 - As-Is Analysis***

After having identified the areas and activities potentially at risk, the following were identified, analysed and formalised for each sensitive process:

- the main phases;
- the functions and roles/responsibilities of the internal and external parties involved;
- the existing controls;

in order to verify within which sensitive process or activity and how the crimes envisaged in the Decree and the SCC could theoretically be committed.

### ***Step 3 - Gap Analysis***

The results of the analysis described above were then used to identify any vulnerabilities and the related actions to improve the internal control system needed to ensure that the Compliance Programme is capable of preventing the crimes envisaged.

### ***Step 4 - Drafting of the Compliance Programme***

Based on the results of the previous steps and the comparison with applicable best practices, as well as the strategic policies choices made by the Company's decision-making bodies and the degree of synergistic alignment with the existing internal control system, the Company's Compliance Programme was drafted, which is divided into the following sections:

- **General Section**, containing a description of the regulatory landscape, the activity carried out by the Company and its functioning, together with the details of the structure necessary for the implementation of the Compliance Programme such as the functioning of the Supervisory Body and the disciplinary system;
- **Special Section**, divided into the categories of crimes, which identify the corporate activities carried out by the Company where the predicate crimes envisaged by the Decree and the SCC may be committed, together with the related control protocols established.



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#### ***4.4 Identification of the Sensitive Processes***

Following the analysis of the organisational structure and based on the information acquired during the interviews with the Key Officers and their staff, the sensitive processes and the related activities were identified where the commission of the crimes envisaged by the Decree may be possible.

The results of this activity were collected and set out in a fact sheet called “Risk Assessment - Mapping of the At-Risk Activities” which is an integral part of the Compliance Programme and which provides a detailed description of the risks relating to the commission of the crimes envisaged by the Swiss Criminal Code and the Decree.

The Mapping of the At-Risk Activities details the categories of crimes considered relevant within the Company’s business organisation, as well as the business activities at risk of possible commission of the crimes (“sensitive activities”) and the processes whose execution, again in principle, may create the conditions and/or means for the commission of those crimes (“instrumental/functional processes”), the Business Functions/Departments involved, the associated crimes, the examples of how and why they may be committed, and the control procedures and safeguards established for each sensitive activity. Specifically, the Mapping of the At-Risk Activities identifies the potential areas of direct liability of IBSA connected to the performance of functional and support activities, for the subsidiaries, that may have an impact for the purposes of application of the Decree.

The Mapping of the At-Risk Activities is kept by the Legal Affairs Function, which takes care of its archiving, making it available - for consultation - to the Board of Directors, the members of the Supervisory Body, and anyone authorised by the Company to view it.

In view of the crimes envisaged by the Swiss Criminal Code and Italian Legislative Decree 231/2001 and taking into account the type of activity carried out by IBSA, directly and on an outsourcing basis in favour of other companies of the Group, and in particular IBSA Farmaceutici Italia S.r.l., the Company has identified the following categories of crimes: i) crimes against Public Authorities and private-to-private corruption; ii) organised crime; iii) crimes of receiving, laundering and reusing money; and iv) inducement to refrain from making statements or to make false statements to legal authorities.

The Special Section contains a specific Sub-Section for each category of crime considered relevant within the company, which sets out:

- the “General rules of conduct” that all the Recipients are required to adopt when carrying out sensitive activities and the related instrumental/functional processes;



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- the “Specific prevention protocols” designed to direct the formulation and implementation of the Company’s decisions in relation to the crimes to be prevented, in addition to the “General prevention protocols” identified in the introduction to the Special Section.

#### ***4.5 IBSA’s Internal Control System***

The Compliance Programme does not replace IBSA’s existing control system, but instead runs alongside it - together with the Group Code of Ethics, which is an integral and complementary part of the system - clearly steering the Company towards the objective of lawfulness and transparency that it pursues throughout all its areas of operations.

The internal control system is made up of:

- the corporate governance rules set out in the Articles of Association and the Organisational Rules;
- the system of internal authorisations and the system of delegated powers;
- a detailed organisation chart, describing the roles of each area and identifying the persons responsible for them;
- the job descriptions of each Function;
- the internal body of rules (operating instructions, guidelines and procedures);
- the Group Anti-Corruption Guidelines;
- the company information system that controls the proper and correct use of the information technology tools, preventing any type of abuse and applying the national and European privacy regulations.

Although they have not been issued in compliance with the provisions of Italian Legislative Decree 231/2001, the main purposes of the rules of conduct and procedures listed above include the control of the propriety, diligence and lawfulness of the conduct of those who represent or are employees of the Company and, therefore, contribute to ensuring the prevention of the predicate crimes envisaged by Italian Legislative Decree 231/2001 and the SCC, including those that have not been specifically addressed in the special sections of the Compliance Programme, because their risk of commission “in the interest or to the advantage of the Entity” is considered to be minimal.



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#### ***4.6 Code of Ethics***

The Compliance Programme constitutes a separate and autonomous document with respect to the Group's Code of Ethics, although both documents share IBSA's explicit desire to operate both internally and externally in full compliance with the principles of legality and fairness.

Although distinct, the two documents are clearly complementary: the Code of Ethics clarifies what is required and what is prohibited in order to avoid charges of organisational inefficiency - a condition for the liability of the entity both in Switzerland and Italy - and the commission of any crime envisaged by or referred to in the Decree and the SCC, other than just those that are specifically addressed in the Compliance Programme, due to their association with the activities carried out by the Company.

In fact, the Code of Ethics contains the set of values that the Company recognises, adheres to and shares with specific categories of legitimate stakeholders. The rules of conduct, which ensure their implementation, govern the principles of conduct to be adopted in the performance of the corporate activities to guarantee the proper functioning, reliability and good reputation of the Company, and are an effective tool for the prevention of unlawful conduct by all those who find themselves acting in its name and on its behalf.

#### ***4.7 Recipients of the Compliance Programme***

The rules contained in this Compliance Programme apply to the members of the company bodies and all those who perform management, administration, executive or control functions in the Company, as well as all the employees, and in general all those who act under the management and/or supervision of the persons indicated above (below all collectively referred to as the "Recipients").

The control principles contained in the Compliance Programme and in the Code of Ethics also apply, within the limits of the existing contractual relationship, to those who, although they do not belong to the Company, operate under its mandate or on its behalf or are in any case connected to the Company by significant legal relationships, such as suppliers, consultants, and business partners. These parties undertake, within the relationships established with the Company and by virtue of specific contractual clauses, to behave correctly and in compliance with the provisions of the applicable regulations and in particular to prevent the commission of the crimes for which the penalties established by the Decree and the SCC apply.

## **5. SUPERVISORY BODY**



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### ***5.1. Introduction***

Under the provisions of the Decree, the Company can be exempted from liability resulting from the commission of Crimes, in its interest or to its advantage, by senior managers or subordinates subject to their supervision and management, if the management body - in addition to having adopted and effectively implemented the Compliance Programme capable of preventing the crimes - has assigned the task of supervising the functioning and observance of the Compliance Programme to a body with independent powers of action and control (below the “**Supervisory Body**”).

In compliance with the provisions of the Decree, taking into account the characteristics of its organisational structure and the recommendations in the applicable Guidelines, IBSA has decided to establish a Supervisory Body with a single member, represented by a person external to the Company with independent powers of action and control.



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#### ***4.2 Requirements of the Supervisory Body***

The main requirements of the Supervisory Body indicated by the Confindustria Guidelines are:

- professional expertise, since the Supervisory Body must have the necessary expertise in legal and financial matters, as well as the techniques for the analysis and assessment of legal risks;
- independence, since the Supervisory Body must be guaranteed self-determination in its controls free of any form of interference or influence. To protect and guarantee its objective judgement the Supervisory Body is not assigned any operational tasks and does not participate in operational decisions and activities. The Supervisory Body must also be provided adequate financial resources necessary for the proper performance of its activities. Lastly, the rules for the internal functioning of the Supervisory Body are defined and adopted by it in the Rules of the Supervisory Body;
- continuity of action, since the Supervisory Body is required to continuously monitor the actual and effective implementation of the Compliance Programme in accordance with the provisions of the Decree.

In addition, the appointment as member of the Supervisory Body is subject to the satisfaction of the individual eligibility requirements.

In particular, the persons designated to hold the office of member of the Supervisory Body must issue a declaration in which they certify the absence of:

- *conflicts of interest*, including potential conflicts of interest, with the Company that could prejudice the independence required by the role and duties of the Supervisory Body;
- direct or indirect *ownership of shares* of an amount enabling them to exercise significant influence over the Company;
- *management functions* - in the three financial years prior to appointment as a member of the Supervisory Body - in companies subject to bankruptcy or other insolvency procedures;
- *conviction*, even if not yet final, in Switzerland, Italy or abroad, for crimes affecting professional morality.

If any of the above grounds for ineligibility are established in relation to a person already appointed, they will automatically be removed from office. In this case, the Board of Directors shall arrange their replacement by resolution of the Board.



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#### ***4.1 Appointment, Term of Office, and Termination***

The Company's Supervisory Body, appointed by resolution of the Board of Directors, remains in office for three financial years or for a different period established at the time of appointment, but not less than one financial year.

At the end of the term, the Supervisory Body remains in office until the new appointment or re-election by subsequent decision by the Board of Directors.

The termination of office may also occur by resignation, forfeiture or death. In the event of resignation from the office, the Supervisory Body must notify the Board of Directors in writing, so that it can promptly replace it.

The termination of office may also occur by revocation by the Board of Directors. However, in order to guarantee the necessary freedom and independence of the Supervisory Body, the revocation can only take place for just cause through a specific resolution of the Board of Directors.

By way of example, the "just cause" for revocation of the tasks and powers connected with the office of member of the Supervisory Body may be:

- serious negligence in the performance of the tasks connected with the engagement;
- "*absence or lack of supervision*" - in accordance with the provisions of Article 6, paragraph 1, subparagraph d) of the Decree, which may also result from a conviction, even if it has not become final, issued against the Company pursuant to Italian Legislative Decree 231/2001, or from a sentence of application of the penalty on request (so-called plea bargaining);
- conflicts of interest, including potential conflicts of interest, with the Company that could prejudice the independence required by the role and duties of the Supervisory Body.

In any case of renunciation, termination, revocation or death, the Board of Directors shall promptly appoint the new Supervisory Body.

#### ***4.2 Financial Resources Assigned to the Supervisory Body***

In order to operate independently and have the most appropriate tools to ensure the effective performance of the task assigned to it by this Compliance Programme, in accordance with the provisions of the Decree, the Supervisory Body must have adequate financial resources at its disposal.

To this end, the Board of Directors approves an allocation of financial resources, proposed by the Supervisory Body, which the latter will have at its disposal for all the requirements necessary for the proper performance of the tasks assigned to it.



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The remuneration of the sole member of the Supervisory Body is set by the Board of Directors at the time of appointment.

#### ***4.3 Functions and Powers of the Supervisory Body***

The Supervisory Body shall adopt a set of rules aimed at regulating the performance of its activities.

The Supervisory Body is assigned the task of supervising:

- adherence to the provisions of the Compliance Programme, in relation to the crimes applicable under the Decree and the SCC;
- the effectiveness of the Compliance Programme in relation to the company structure and the effective ability to prevent the commission of the crimes;
- the need to update the Compliance Programme, when it requires adaptation to changes in business and/or regulatory conditions.

In particular, the Supervisory Body is assigned the following powers for the performance of its functions:

- verifying the efficiency and effectiveness of the Compliance Programme also in terms of consistency between the operating methods actually adopted and the protocols formally established by the Compliance Programme;
- verifying the continued satisfaction over time of the requirements of efficiency and effectiveness of the Compliance Programme;
- promoting the updating of the Compliance Programme, where necessary, making proposals for any updates and adjustments to be made through amendments and/or additions that may be needed as a result of: i) significant violations of the provisions of the Compliance Programme; ii) significant changes to the Company's internal structure and/or how the business activities are conducted; and iii) regulatory changes;
- promptly reporting verified breaches of the Compliance Programme that may give rise to liability for the Company to the management body, for the adoption of the appropriate measures;
- promoting initiatives for the dissemination of the Compliance Programme, as well as for the training of personnel and raising their awareness regarding adherence to the principles contained in the Compliance Programme;
- promoting communication and training initiatives on the details of the criminal liability of the entities envisaged by the Swiss and Italian legislation, the related impacts on the Company's operations, and the rules of conduct;



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- providing clarifications regarding the meaning and application of the provisions contained in the Compliance Programme;
- promoting the implementation of an effective internal communication channel enabling the transmission of information relevant to the effectiveness of the Compliance Programme, while ensuring the protection and confidentiality of the reporting person;
- producing the forecast of the expenditure necessary for the correct performance of the assigned tasks and submitting it to the Board of Directors for approval;
- having unrestricted access, in accordance with the applicable regulations, to any department of the Company in order to request information, documentation and data considered necessary for the performance of the tasks assigned to it;
- requesting material information from collaborators, consultants and external collaborators of the Company, however designated;
- promoting the activation of any disciplinary proceedings as a consequence of identified violations of this Compliance Programme.

#### ***4.4 Functioning of the Supervisory Body***

The Supervisory Body carries out its supervision and checks on a quarterly basis or whenever deemed necessary, in accordance with the Internal Rules to be adopted by the Supervisory Body following its establishment.

The Chief Executive Officer, heads of corporate functions, and external consultants may be called to attend the meetings if their presence is necessary for the performance of its activities.

In view of the specific nature of the Supervisory Body's duties and the related professional requirements, it may be supported by dedicated personnel in the performance of its supervisory and control tasks. It may also use the aid of the functions within the Company as necessary and may also use external advisory functions when this is necessary for the more effective and independent performance of its functions.

In any event, the Supervisory Body remains directly responsible for the proper fulfilment of the supervisory and control obligations arising from the Decree.

#### ***4.5 Reporting to the Company Bodies***

The Supervisory Body is required to report the results of its work to the Board of Directors of the Company.



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In particular, the Supervisory Body reports on (i) the work carried out; (ii) any breaches of the Compliance Programme, and (iii) any critical issues in terms of its efficiency and effectiveness.

The Supervisory Body liaises continuously with the Board of Directors and prepares an information report for the management body, at least once a year, on the supervisory work carried out, the results of this work, and the implementation of the Compliance Programme within the Company.

The Supervisory Body may also consult with the Board of Directors whenever it deems it appropriate for the effective and efficient performance of the tasks assigned to it.

Formal meetings with the bodies that the Supervisory Body reports to must be recorded in their respective minute books, and copies of the minutes and any written reports must be kept by the Supervisory Body and by the bodies involved from time to time.

The work of the Supervisory Body cannot be challenged by any company body, structure and function, subject to the requirement for the Board of Directors to verify the adequacy of the Supervisory Body and its work, due to its responsibility for the functioning and effectiveness of the Compliance Programme.

### ***4.6 Information to be Sent to the Supervisory Body***

To facilitate and ensure the effectiveness of the work by the Supervisory Body, all information considered useful for this purpose must be sent by the Recipients to the Supervisory Body, including:

- any critical issues that may be significant for the correct application of the Compliance Programme, identified in the first and/or second level controls;
- measures and/or information originating from Criminal Investigation bodies or any other national or foreign Authority from which it can be gathered that investigations are being conducted, including against unknown persons, for the crimes envisaged by the Decree or the SCC;
- internal and external communications concerning any circumstance that may be connected with the crimes envisaged by the Decree and the SCC (e.g. disciplinary measures initiated/implemented against employees);
- requests for legal assistance made by employees who are being prosecuted by the Judiciary for the crimes envisaged by the Decree and the SCC;
- information regarding the effective implementation of the Compliance Programme, at all company levels, with details - within the disciplinary proceedings carried out - of any penalties imposed or the decisions to abandon the proceedings with the reasons why, if they are linked to the commission of any of the crimes envisaged in the Decree or relate to the Disciplinary System;



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- suspected or confirmed cases of breach or incorrect application of a procedure or rule by an employee or consultant, with a detailed report on the measures adopted to ensure compliance with the procedure and/or in any case to prevent the person from committing a Crime (for example, temporarily relieving that person of the task of dealing with parties on behalf of the Entity).
- information related to the organisational changes implemented;
- updates of the powers and significant internal authorisations or atypical transactions within which there is a potential risk in relation to any of the Crimes;
- decisions relating to the application for, disbursement of, or use of public funds;
- changes in the situations of risk or potential risk in relation to any of the crimes envisaged in the Decree;
- visits, inspections and investigations initiated by the competent bodies and any findings and penalties imposed upon their conclusion;
- a copy of any communications made to the Supervisory Authority;
- results of internal audits in general and, in particular, those aimed at verifying compliance with the Compliance Programme and the Code of Ethics.

In relation to each sensitive process and Function concerned, the Supervisory Body also agrees with the Heads of the various company functions on additional, specific and detailed information flows. These consist of information and documents sent periodically to the Supervisory Body that enable it to determine the continuous application of procedures and compliance with the company controls, as described in the Compliance Programme.

All the reports indicated must be addressed to the attention of the Supervisory Body, by post, marked “*personal confidential*” to the following address:

Supervisory Body  
c/o IBSA Institut Biochimique  
Via del Piano, 29  
6915 – Pambio-Noranco, Lugano



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The information provided to the Supervisory Body is intended to facilitate and improve the planning of the controls and does not require it to conduct a systematic and detailed check on the circumstances reported. It is therefore up to the Supervisory Body to decide when and how to act.

In compliance with Article 6, paragraph 2 bis, of Italian Legislative Decree 231/2001, which establishes that the Compliance Programme must include one or more channels through which employees or collaborators can send detailed and precise reports of illegal conduct or breaches of the Compliance Programme identified by them, the Company has set up channels aimed at protecting the confidentiality of the authors of the reports and has identified the Legal Affairs function as the body responsible for managing those reports, which will be required to promptly inform the Supervisory Body for it to adopt the most appropriate measures.

The reports can be sent to the following e-mail address

[compliance@ibsa.ch](mailto:compliance@ibsa.ch)

or, by post, marked “*personal confidential*” to the following address

Legal Affairs  
c/o IBSA Institut Biochimique  
Via del Piano, 29  
6915 – Pambio-Noranco, Lugano

Any retaliatory conduct committed against the reporting person or in any case aimed at breaching protection measures for the reporting person and adopted by the management bodies or by persons acting on behalf of the Company shall be penalised, based on the seriousness of the conduct, according to the procedures set out in the chapter below.

The conduct of those who make reports intentionally or through gross negligence that prove to be unfounded shall also be punished.

## **5. DISCIPLINARY AND PENALTY SYSTEM**



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### ***5.1 The Function of the Disciplinary System***

The establishment of a system of penalties (which must be commensurate with the type of violation and be designed to act as a deterrent) to be imposed in the event of a breach of the rules of conduct set out in the Compliance Programme is intended to ensure the effectiveness of the Compliance Programme and is an essential part of it.

The Disciplinary System is based on the following principles:

1. it is structured differently according to the recipients (where the strictly disciplinary part is aimed at the employees, whereas the part with the penalties is aimed at third parties; together, the two parts are called the “**disciplinary and penalty system**”) and take into account any repeat offending;
2. it precisely identifies the penalties to be imposed on the recipients for cases of violation, breach or circumvention, by the latter, of the provisions of the Compliance Programme or the internal procedures referred to by the Compliance Programme, all in compliance with the applicable regulatory provisions and the internal company regulation “Rights and Duties of Employees” adopted by the Company and known by all its collaborators;
3. it includes a procedure for determining the above-mentioned violations, breaches, circumventions, imperfect or partial applications, as well as a specific procedure for imposing the applicable penalties, identifying the person responsible for their application and, in general, for supervising the observance, implementation and updating of the disciplinary system.

In particular, this Disciplinary System is aimed at:

1. individuals who hold the position of representative, director or manager of the Company;
2. individuals subject to the management or supervision of one of the individuals referred to above and, in general, all employees;
3. all those who, for whatever reason and at whatever level of responsibility, work within the Company, contributing, through their actions, to the conduct of the Company’s overall business, including consultants and other external collaborators, however designated.

This Disciplinary System is divided into sections, each referring to the particular category of recipients, taking into account the legal status of the different parties concerned.

The application of disciplinary or contractual penalties does not depend on the outcome of any criminal proceedings against the offender, because the rules imposed by the Compliance Programme are adopted completely independently by the Company, irrespective of the type of offence that violations of the Compliance Programme may cause.



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The Supervisory Body is assigned the task of monitoring the observance and correct application of the Disciplinary System in the event of significant violations, as well as informing the Board of Directors for it to update, modify and/or supplement the Disciplinary System, when it considers this is necessary to improve the effectiveness of the Compliance Programme.

### ***5.2 Disciplinary System for Employees***

The violation, infringement, circumvention, or imperfect or partial application of the individual rules of conduct set out in this Compliance Programme by Company employees constitutes a disciplinary offence punishable as detailed below.

For the purposes of this Disciplinary System, disciplinary measures are imposed on employees, including senior managers, in compliance with the IBSA Company Rules, the procedures envisaged by the related regulations, and any specific regulations, including agreements, applicable.

More specifically, for the purposes of this Disciplinary System, the disciplinary measures that can be imposed, under the Company Rules, consist of:

1. a verbal reprimand;
2. a written warning;
3. a fine of up to three hours;
4. suspension from work and pay for 1 to 3 days;
5. dismissal.

Subject to the Company's obligations arising from national legislation and any specific applicable regulations, as well as any applicable internal regulations, the following conduct constitutes a violation of the Compliance Programme, accompanied by the related penalties:

1. A “**verbal reprimand**” shall be issued to a worker who violates one of the internal procedures referred to in the Compliance Programme (for example, who does not observe the required procedures, fails to communicate the required information to the Supervisory Body, fails to carry out due checks, etc.), or adopts conduct that does not comply with the Compliance Programme's requirements in the performance of activities in sensitive areas. Such conduct constitutes a failure to comply with the instructions given by the Company.
2. A “**written warning**” shall be issued if the worker repeatedly violates the procedures referred to in the Compliance Programme or, when carrying out activities in sensitive areas, behaves in a manner that does not comply with the provisions of the Compliance Programme. Such conduct constitutes a repeated failure to comply with the instructions given by the Company.



3. A “**fine of up to three hours**” is imposed if the worker who, by violating the procedures referred to in the Compliance Programme, or by adopting conduct that does not comply with the provisions of the Compliance Programme when carrying out activities in sensitive areas, exposes the company assets to a situation of objective danger. Such conduct, adopted through failure to comply with the instructions given by the Company, results in a situation of danger for the Company’s assets and/or constitutes behaviour contrary to the Company’s interests.
4. The measure of “**suspension**” from work with the related reduction in remuneration from one to three days shall be imposed on a worker who, in violating the procedures referred to in the Compliance Programme, or in adopting conduct when carrying out activities in sensitive areas that does not comply with the provisions of the Compliance Programme, is a repeat offender for more than three times in the calendar year in relation to the breaches referred to in points 1, 2 and 3. Such conduct, adopted through failure to comply with the instructions given by the Company, causes damage to the Company and, in any case, constitutes conduct objectively contrary to its interests.
5. The measure of “**dismissal with notice**” shall apply to any worker who, in carrying out activities in sensitive areas, adopts conduct that does not comply with the provisions of the Compliance Programme and is clearly aimed at the commission of a crime envisaged by the Decree and the SCC. Such conduct constitutes a serious failure to comply with the instructions given by the Company and/or a serious violation of the worker’s obligation to cooperate in the growth of the Company.
6. The measure of “**dismissal without notice**” shall apply to a worker that, in carrying out activities in sensitive areas, adopts conduct in violation of the provisions of the Compliance Programme, which results in the imposition on the Company of the measures provided for by the Decree and the SCC, as well as to a worker that is a repeat offender more than three times in the calendar year in relation to the breaches referred to in point 4. Such conduct severely undermines the Company’s trust in the worker and constitutes serious non-material and/or material damage for the Company.

In any event, the penalties are commensurate with the employee’s level of responsibility and independence, and the intentionality of the conduct and its seriousness, which refers to both the significance of the obligations violated and the effects that the Company can reasonably be considered exposed to, also pursuant to and for the purposes of the Decree and the SCC. Where several offences are committed by a single act and are punished by different penalties, the most serious penalty shall apply. Repeat offences over three years automatically result in the application of the next most serious



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penalty.

The person responsible for the application of the disciplinary measures described above for non-executive employees is the Human Resources Director, who will impose the penalties in response to any report by the Supervisory Body, after having consulted the hierarchical superior of the perpetrator of the penalised conduct.

In any event, the Supervisory Body is promptly informed of any act involving the disciplinary procedure against a worker for violation of this Compliance Programme, from the time when the disciplinary charge is made.

The Supervisory Body is also responsible for verifying and assessing the suitability of the Disciplinary System pursuant to and for the purposes of the Decree and the SCC.

The Supervisory Body is also notified of any decisions to abandon the disciplinary proceedings referred to in this chapter.

Workers are given immediate and extensive information about the introduction of any new provisions, through internal communications explaining the reasons for their adoption and summarising their content.

### ***5.3 Measures for Directors***

The Company rigorously assesses breaches of this Compliance Programme committed by those who represent the Company's senior management and are therefore an expression of its image towards the institutions, employees, shareholders and the public. Indeed, to create and consolidate a company ethic sensitive to the values of propriety, fairness and transparency, these values must be adopted and respected by the company decision-makers, so that they set an example and act as inspiration for everyone who works for the Company at all levels.

If Directors violate the internal procedures envisaged by the Compliance Programme or adopt measures, in exercising their powers, that conflict with the provisions or principles of the Compliance Programme, the Supervisory Body shall promptly and formally inform the Board of Directors, which shall take all the necessary actions required by the applicable regulations.

If the violation involves several members of the Board of Directors, the Supervisory Body shall promptly inform the Shareholders' Meeting of the Company.



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#### ***5.4 Penalties for Third Parties***

For the purposes of this Disciplinary System, the following conduct is punishable for third parties that have dealings with the Company (e.g. suppliers, distributors, agents, consultants):

1. breaches, infringements, or imperfect or partial applications of the contractual provisions which have not produced consequences or which, even though they do not constitute a criminal offence, constitute infringements of IBSA's Code of Ethics;
2. breaches, infringements, circumventions, or imperfect or partial applications of the contractual provisions clearly aimed at committing a crime penalised by the Decree or the SCC;
3. breaches, infringements, circumventions, or imperfect or partial applications that have led to the prosecution of the Company.

In particular, for the purposes of this Disciplinary System, the penalties imposed on the persons referred to in this paragraph are:

- written reminder of the requirement for strict compliance with the rules of conduct violated, to be recorded in the register of suppliers or by other means that keeps a record for the future (always applicable);
- implementation of the specific clauses included in the related contracts through which the consequences of such offences are regulated, also with regard to the damage suffered by the Company as a result of the act.

With regard to the procedure for determining such violations and the subsequent written reminder or implementation of the aforementioned clauses, the Supervisory Body verifies that the reporting Function has notified the perpetrator of the violation with specific details of the acts alleged, accompanied by the issuance of a written reminder of the requirement for strict compliance with the rules of conduct violated by formal notice and with an invitation to remedy the violation identified, or by the termination of the contractual relationship.

The Company retains the right in any event to compensation for the damage suffered by the Company as a result of such violations.

In this regard, the Company shall include specific clauses in the contracts that acknowledge the third party's awareness of the Compliance Programme and require the third party and its employees and collaborators to make a commitment to refrain from conduct likely to violate the provisions set out above.



## 6. EDUCATION AND TRAINING

To guarantee the effectiveness of the Compliance Programme, the Company ensures appropriate awareness and dissemination of the rules of conduct contained in the programme among the members of the company bodies and all employees, external collaborators and third parties that have relations, of any nature, with the Company.

This objective concerns all the staff included in the above categories, both those already present in the company and those who will be added in the future. The level of training and information is provided using specific methods appropriate to the function performed by the Recipients.

Participation in training activities in accordance with the procedures and timing established by the Company is mandatory and failure to comply with the obligation is subject to disciplinary assessment.

In particular, the training and education will be provided in accordance with the following procedures.

### *6.1 Training of Internal Company Personnel*

The adoption of the Compliance Programme shall be communicated to the Recipients of this document by making this document available in the most suitable manner (e.g. appropriate distribution on the website, posting on notice boards, provision of paper copies of the Compliance Programme, specific information notices).

The Human Resources function is required to provide new hires/new collaborators, when they sign the recruitment/collaboration contract, with a declaration certifying that they have read the Compliance Programme and the Code of Ethics and their commitment to comply with them.

All the declarations of acknowledgement and commitment to comply with the Compliance Programme shall be kept by the Function.

All updates of the Compliance Programme are duly communicated to the personnel with a reminder to the Heads of each Function to disseminate the updated version of the Compliance Programme.

The Company's personnel and collaborators are also provided appropriate training on the contents of the Compliance Programme.

This training is divided into the following two phases:

- general training aimed at informing the Recipients of the legislative requirements and the contents of the Compliance Programme adopted by the Company;



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- specific training for those who work in sensitive areas, aimed at informing the Recipients in particular about the specific risks the area in which they operate is exposed to and the principles of conduct and company procedures that they must follow in carrying out their activities.

The formulation of the training courses, their timing and methods of delivery, is the responsibility of the Administration Department, with the aid of the Supervisory Body in defining the forms of control over course attendance and the quality of the content of the training programmes.

The Heads of each Function are required to inform their staff about the Compliance Programme, in addition to ensuring participation in the training courses.

The education and training activity actually carried out is duly documented and the related documentation is kept by the Human Resources function.

The education and training system is continuously checked and, where necessary, modified by the Supervisory Body, in collaboration with the Human Resources function or other Heads of Function for the aspects under their responsibility.

### ***6.2 Third Party Recipients of the Compliance Programme***

The communication of the contents and principles of the Compliance Programme is also aimed at the third parties that have a contractually governed collaboration relationship with the Company or that represent the Company but are not subject to an employment relationship (e.g. business partners, consultants and other external collaborators, however designated).

The Company assesses the methods (e.g. publication on its website according to the different types of external collaborators and partners) used to inform these parties about the policies and procedures followed by IBSA as a result of the adoption of the Compliance Programme and the Code of Ethics, in addition to including appropriate contractual clauses that require them to comply with the provisions of the Compliance Programme, subject to the application of penalties or termination of the relationship.

## **7. CRITERIA FOR UPDATING AND ADAPTING THE COMPLIANCE PROGRAMME**

The Compliance Programme is an “*instrument issued by the Management Body*” and, accordingly, in compliance with the provision of Article 6, paragraph 1, letter a) of the Decree, its adoption and subsequent amendments and additions are the responsibility of the Board of Directors of the Company or the Chief Executive Officer, subject to subsequent ratification by the Board of Directors as the holder of the power of disposition in relation to the Compliance Programme.



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In the event of changes or updates made by the Chief Executive Officer, the latter shall promptly inform the Board of Directors of such.

In any event, the Supervisory Body can assess and express an opinion on the proposals for updating and/or revising the Compliance Programme before they are actually adopted.

For example, the Company assesses the updating of the Compliance Programme and its adaptation in relation to changes and/or additions that may become necessary as a result of:

- changes in the Company's internal structure and/or in the methods of carrying out its business activities;
- changes in the business areas;
- information on attempts to commit or the commission of the crimes considered by the Compliance Programme;
- information on possible new ways of committing the crimes considered by the Compliance Programme;
- regulatory changes;
- results of the checks;
- significant violations of the provisions of the Compliance Programme.

The audits carried out are formal and the records of these activities are kept.