

## ORGANISATION, MANAGEMENT AND CONTROL MODEL

adopted by the Board of Directors of  
Chiesi Farmaceutici S.p.A.

under  
Legislative Decree 231/2001  
'CORPORATE ADMINISTRATIVE LIABILITY'

### GENERAL SECTION

# INDEX

DEFINITIONS.....	5
1. INTRODUCTION.....	8
2. FOREWORD.....	11
2.1 Legislative Decree 231/2001.....	11
2.2 The adoption of the Organisation, Management and Control Model as a possible exemption from administrative liability.....	14
3. THE MODEL.....	16
3.1 Aims of the Model.....	16
3.2 Recipients of the Model.....	17
3.3 Preparation of the Model.....	17
3.4 Underpinning elements and principles of the Model.....	19
3.5 The ‘acceptable risk’ approach.....	20
3.6 Approval, amendment and integration of the Model.....	20
3.7 Model Structure.....	21
3.8 Implementation of the Model.....	21
4. THE COMPANY, THE GOVERNANCE SYSTEM AND THE ORGANISATIONAL AND AUTHORISATION SYSTEM.....	22
4.1 The Company.....	22
4.2 The governance system.....	22
4.3 The organisational system.....	23

4.4 The Global Compliance Function .....	24
4.5 The Global Internal Auditing Function.....	26
4.6 The authorisation system .....	28
5. THE CODE OF CONDUCT .....	29
6. THE FINANCIAL RESOURCES MANAGEMENT SYSTEM .....	30
7. COMMUNICATION AND TRAINING .....	32
7.1 Employee Training and Information.....	32
7.2 Communication and dissemination .....	33
8. THE DISCIPLINARY SYSTEM .....	35
9. THE SUPERVISORY BODY .....	36
a. Requirements of the Supervisory Body.....	36
b. Composition of the Supervisory Body .....	38
9.1 The System of Information Flows to and from the Supervisory Body.....	38
a. Reporting by the Supervisory Body to the Corporate Bodies.....	38
b. Information flows to the Supervisory Body.....	39
b.1 Event-driven information flows .....	40
b.2 Periodic information flows.....	41
9.2 Reporting conduct relevant to the Model.....	42
a. Disciplinary sanctions .....	43

10. INTERNAL INVESTIGATIONS.....44

11. THE CONTROLS.....47

11.1 Horizontal control measures .....47

11.2 Vertical controls.....52

REVISIONS TO THE ORGANISATION, MANAGEMENT AND CONTROL MODEL.....53

ATTACHMENTS.....55

## DEFINITIONS

Chief Executive Officer	The chief executive officer of Chiesi Farmaceutici S.p.A.
Sensitive Activities	The activities performed by Chiesi Farmaceutici S.p.A. – and the relative sub-processes – exposed to the potential risk of committing the offences listed under Legislative Decree 231/2001 (“Predicate Offences”)
CASSC	Committee for Social and Community Development Activities
CCNL	The National Collective Labour Agreement currently in force and applied by Chiesi
B.o.D. or Board of Directors	The Board of Directors of the Company
C.C.	Cost centre
CFO	The Chief Financial Officer of Chiesi Farmaceutici S.p.A.
Chiesi or the Company	Chiesi Farmaceutici S.p.A.
Code of Conduct	Code of Conduct adopted by the Company
Collaborators	Anyone who performs their professional activity for Chiesi under contractual forms other than employment (with the exception of Consultants)
Consultants	Any natural person or independent company providing Chiesi with specialist advice or professional services of an intellectual nature
CShare	Indicates the Chiesi intranet area
Decree or Legislative Decree 231/2001	Legislative Decree No. 231 of 8 June 2001, containing 'Regulations on the administrative liability of legal entities, companies and associations, including those without legal personality'
Recipients	Those indicated in section 3.2 of this document
Employees	All employees of Chiesi Farmaceutici S.p.A. (including managers)
Suppliers	Suppliers of goods and professional and non-professional services to the Company (incl. financial services). This definition also includes Consultants
Functions	All functions entrusted with the performance of company activities relevant to this Model
Global Compliance Function	The Global Compliance Function of Chiesi Farmaceutici S.p.A.
Group or Chiesi Group	Chiesi Farmaceutici S.p.A. and all its subsidiaries

<p>Confindustria Guidelines</p>	<p>The Guidelines for the Construction of Organisational, Management and Control Models pursuant to Legislative Decree 231/2001 approved by Confindustria in 2014 and subsequent amendments and integrations</p>
<p>Model Matrix - Company Procedures</p>	<p>The document "MODEL MATRIX - COMPANY PROCEDURES", which lists the main Company procedures applicable to Special Sections and is available in the CShare S.B. area</p>
<p>Model</p>	<p>Organisation, Management and Control Model adopted, pursuant to the Decree, by Chiesi.</p>
<p>Non-conformity</p>	<p>Non-fulfilment of a requirement with respect to an ISO standard and/or the violation or non-application of a company procedure/process detected by a Process Owner following first level checks or by an auditor</p>
<p>O.d.A.</p>	<p>Purchase Order</p>
<p>Supervisory Body, S.B. or Body</p>	<p>Supervisory Body, responsible for supervising the operation of and compliance with the Model and its updating</p>
<p>Corporate Bodies</p>	<p>Members of the Board of Directors and the Board of Statutory Auditors of Chiesi</p>
<p>P.A. or Public Authority/Authority</p>	<p>Public Administration (incl. the relevant officers and persons in charge of a public service) such as the Judicial Authority, Italian and foreign, national and local Institutions and Public Administrations, the Italian Medicines Agency ("AIFA"), Consob, the Competition and Market Authority, the Personal Data Protection Authority, Borsa Italiana S.r.l, the Authority for Electricity, Gas and the Water System and the other Italian and foreign Supervisory Authorities, or private entities equivalent to the same, as well as their officers and internal bodies.</p>
<p>Special Section</p>	<p>Special Sections that the Model comprises. The Special Sections have been subdivided by Processes</p>
<p>Partners</p>	<p>Contractual partners of the Company (natural or legal persons) that the Company enters into any form of contractually regulated cooperation relationship with (temporary business association – ATI, joint ventures, consortia, etc.) and that are to cooperate with the Company in the context of Sensitive Activities</p>
<p>Chairman</p>	<p>The Chairman of the Board of Directors of Chiesi Farmaceutici S.p.A.</p>
<p>Process Owners</p>	<p>The corporate functions that are responsible for the management and control of the Sensitive Processes and Activities mapped within the risk assessment, as also identified in the document "Process Owners" available in CShare</p>
<p>Process(es)</p>	<p>Each of the corporate processes relevant to the Model and mapped in the Risk Assessment. Each Special Section is dedicated to a specific Process</p>
<p>Public Officials</p>	<p>(i) Any person who exercises a legislative, judicial or administrative public function;</p>

- (ii) any person who acts (in an official capacity) for or on behalf of:
  - (a) a Public Administration of a State, whether local, national or federal;
  - (b) an agency, office or body of the European Union or of a Public Administration of a State;
  - (c) an enterprise owned, controlled or participated in by a Public Administration of a State, unless such enterprise operates on a normal commercial basis in the relevant market;
  - (d) a public international organisation, such as the European Bank for Reconstruction and Development, the International Bank for Reconstruction and Development, the International Monetary Fund, the World Bank, or the United Nations or the World Trade Organisation; or
  - (e) a political party, a member of a political party or a candidate for political office, whether Italian or foreign; or
- (iii) any person in charge of a public service, to be understood as a person who, in whatever capacity, performs a public service (i.e., an activity that is regulated in the same way as a public function, but characterised by the lack of powers typical of a public function). The performance of simple orderly tasks and the performance of merely material work are excluded.

**Recommendation**

Observation that may be expressed by a Process Owner following first-level controls and/or by an auditor following an audit with the aim of improving business processes

**R.d.A.**

Purchase Request

**Offence or Predicate Offence**

Any of the offences referred to in Legislative Decree 231/2001

**RSPP**

Chiesi's Prevention and Protection Service Manager under Legislative Decree No. 81/2008

**Disciplinary System**

Disciplinary system forming part of the Model as described in this document

**Subsidiary**

Each of Chiesi's subsidiaries

**SpeakUp&BeHeard or System**

Chiesi Group Whistleblowing System

**TCF**

Tax Control Framework adopted by Chiesi

## 1. INTRODUCTION

Chiesi is part of an international group focused on research, development and commercialisation of innovative therapeutic solutions especially in the fields of neonatology, respiratory diseases and rare diseases. The Chiesi Group is present directly and through its affiliated/subsidiary companies in approx. 30 countries.

The Chiesi Group's production is divided into three sites: (i) the plants in Parma (Italy), divided into the Via Palermo and Via S. Leonardo sites; (ii) the Blois-La Chaussée Saint Victor workshops (France); and (iii) the Santana de Parnaíba plant (Brazil).

The Parma facility is also an international supply centre and the headquarters of the Group's R&D activities. The San Leonardo plant has been successfully inspected several times by the regulatory authorities of numerous countries, including some of the most representative ones such as the US FDA, the Canadian TPP Agency and the Italian AIFA.

The company has implemented environmental and health & safety management systems that have also been subject to external certification in accordance with ISO 14001 and ISO 45001 standards, which are periodically renewed.

The correct application of international Good Manufacturing Practice standards for drug production, interpreted by Chiesi with the use of state-of-the-art technologies (such as a high level of automation and product segregation from the environment), represents the best guarantee also from the perspective of operators' safety and environmental protection.

The ability to guarantee an optimal level of service when supplying products to Subsidiaries and customers is also the result of careful management of the partnership relationship with suppliers, who are called on to provide a service in line with the Company's service, safety and quality standards, with a view to business continuity.

Chiesi considers honesty, integrity and social responsibility to be criteria for evaluating its success on a par with operational results. For this reason, the Company felt the need to adapt its corporate structure to the provisions of the Decree as early as 2002. At the Board of Directors' meeting held on 28 March 2002, the Chairman proposed to the Board of Directors the launch of an internal project called 'Ethics & Integrity', aimed at drawing up an Organisational, Management and Control Model and setting up a specific Company function – the Supervisory Body – with autonomous powers of initiative and control.

The Model was subsequently subject to multiple revisions (see Table REVISIONS TO THE ORGANISATION, MANAGEMENT AND CONTROL MODEL), to adapt it to the growing complexity of Chiesi's structure and activities, new types of offences introduced by Legislative Decree 231/2001 and the latest caselaw and sector Guidelines.

The Model was updated in 2022 – to: (i) incorporate the indications of the Confindustria Guidelines updated in June 2021 and the most recent caselaw guidelines on the administrative liability of entities; and (ii) assess the applicability to the Company of the offences<sup>1</sup> and the relevant legislative amendments introduced in Legislative Decree 231/2001 after 2020 – and lastly in 2023 to integrate the General Section and the Disciplinary System with the provisions governing the management of reports in Legislative Decree 24/2023 "Implementation of Directive (EU)

---

<sup>1</sup> i.e., Arts. 25-*octies*.1 "Crimes relating to non-cash payments", 25-*septiesdecies* "Crimes against cultural heritage" and 25-*duodevicies* "Laundering of cultural assets and devastation and looting of cultural and landscape assets" of the Decree.



2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law and on provisions concerning the protection of persons who report breaches of national laws".

In 2016, the Company obtained its legality rating, which is renewed every 2 years. In 2018, Chiesi adopted the corporate form of a Benefit Company (in accordance with Law No. 208/2015), incorporating in its articles of association an objective to provide a common benefit to society and the environment, alongside the objective of profit generation. In 2019, the Chiesi Group obtained B Corp® certification and formed part of a global movement of companies that maintain high standards regarding social and environmental impact and remain committed to providing an inclusive, fair and regenerative economic environment. This certification was last renewed in 2022.

In 2020, after beginning to create the legal entity of Chiesi Italia S.p.A. and launching new business approaches such as rare diseases, patient centricity, real-world evidence and the reorganisation of important Company areas, it became necessary to distinguish between Chiesi Farmaceutici S.p.A. and Chiesi Italia S.p.A. in relation to the Organisation, Management and Control Model and related aspects.

In 2023, the Model of the company Unikeris Limited (a Chiesi Group company with registered office in the UK and a branch office in Italy) was also drafted based on the structure of this document.

Finally, in 2024 Chiesi obtained certification under the ISO 37001:2016 standard 'Anti-bribery Management System' with the aim of further spreading the culture of compliance across the organization and mitigating potential active and passive bribery risks related to the company's business, as well as certification under the ISO 27001 standard on 'Information Security Management System'.

All the circumstances described above were considered during the current update of the Company's Model. On this occasion, as part of the Risk Assessment activities before updating this Model, the following new Offences introduced by the Decree after the Model's previous update were considered:

- Law Decree No. 105 of 21 September 2019, which introduced the new Offence of 'Violation of the Rules on the Perimeter of National Cyber Security';
- Law No. 157 of 19 December 2019, which inserted the 'tax offences' under Legislative Decree No. 74 of 10 March 2000;
- Legislative Decree No. 75 of 14 July 2020, implementing Directive (EU) 2017/1371 ("BIP Directive"), which introduced new offences within the scope of offences against the Public Administration and tax offences and the smuggling offences under Presidential Decree No. 43 of 23 January 1973).
- Legislative Decree No. 19 of 2 March 2023, which introduced a new predicate offence to Art. 25-ter of Legislative Decree 231/2001 (i.e., the offence of false or omitted declarations for the issuance of the preliminary certificate envisaged under the implementing legislation of EU Directive 2019/2121, of the European Parliament and of the Council, of 27 November 2019);
- Regulation (EU) 2023/966 of 15 May 2023, which replaced the Annex to Regulation (EC) No. 338/97, also referred to in Arts. 1, 2 and 3-bis governing the import, export, possession, use for profit, purchase, sale, display or possession for sale or commercial purposes of protected species, the latter being included among the environmental offences listed under Art. 25-undecies of Legislative Decree 231/2001;
- Law No. 68 of 13 June 2023, which introduced point 1.2.3-bis to Annex 5 to Part III and also amended Table 3 of Annex 5 to Part III (point

- 4) of Legislative Decree 152/2006, listed under Art. 25-undecies of Legislative Decree 231/2001 (see Art. 137 of Legislative Decree 152/2006);
- Law No. 93 of 14 July 2023, which amended Art. 171-ter of Law No. 633/1941, envisaged under Art. 25-novies of Legislative Decree 231/2001;
  - Law No. 137 of 9 October 2023, which introduces the new predicate offences set out in Art. 24 (i.e., disturbance of the freedom of competitive tenders under Art. 353 of the Criminal Code; disturbance of the freedom of the procedure for choosing a contractor under Art. 353-bis of the Criminal Code) and Art. 25-octies.1 of Legislative Decree 231/2001 (i.e., fraudulent transfer of valuables under Art. 512-bis of the Criminal Code);
  - Law No. 137 of 9 October 2023, amending the predicate offences listed under Art. 25-undecies of Legislative Decree 231/2001 (i.e., environmental pollution under Art. 452-bis of the Criminal Code and environmental disaster under Art. 452-querter of the Criminal Code);
  - Law No. 159 of 13 November 2023, amending Art. 73(5) of Presidential Decree No. 309 of 9 October 1990, envisaged under Art. 24-ter of Legislative Decree 231/2001 (see Art. 74 of Presidential Decree No. 309 of 9 October 1990 – association for the purpose of illegal trafficking in narcotic or psychotropic substances);
  - Legislative Decree No. 224 of 6 December 2023, amendment to Art. 2638, para. 3-bis, of the Civil Code (obstruction of the exercise of the functions of public supervisory authorities), under Art. 25-ter of Legislative Decree 231/2001;
  - Law No. 206 of 27 December 2023, which extends the scope of the offence of selling industrial products with misleading signs under Art. 517 of the Criminal Code, envisaged under Art. 25-bis.1 of Legislative Decree 231/2001;
  - Decree of 20 October 2022, Decree of 14 December 2022, Decree of 13 February 2023, Decree of 13 July 2023, Decree of 1 August 2023, Decree of 2 August 2023, Decree of 3 August 2023, Decree of 31 October 2023, Decree of 12 December 2023 amending Table I of Presidential Decree No. 309 of 9 October 1990, under Art. 24-ter of Legislative Decree 231/2001 (see Art. 74 of Presidential Decree No. 309 of 9 October 1990 – association for the purpose of illegal trafficking in narcotic or psychotropic substances);
  - Law No. 6 of 22 January 2024, which amends Art. 518 duodecies of the Criminal Code (destruction, dispersion, deterioration, defacement, defacement for unlawful use of cultural landscape assets) under Art. 25-septiesdecies of Legislative Decree 231/2001;
  - Law No. 56 of 29 April 2024, converting Law Decree No. 19 of 2 March 2024, which introduces para. 2 to Art. 512-bis of the Criminal Code (fraudulent transfer of valuables), under Art. 25-octies.1 of Legislative Decree 231/2001;
  - Law No. 90 of 28 June 2024 ‘Provisions on the strengthening of national cybersecurity and computer crime’, which intervenes on computer crime offences, introducing new predicate offences (e.g., ‘computer extortion’);
  - Legislative Decree 87 of 14 June 2024 ‘Revision of the tax penalty system, under Art. 20 of Law No. 111 of 9 August 2023’, amending Art. 10-querter of Legislative Decree 74/2000 set out as an Offence by Art. 25-quinquiesdecies of Legislative Decree 231/2001.

## 2. FOREWORD

### 2.1 Legislative Decree 231/2001

On 4 July 2001, Legislative Decree No. 231 of 8 June 2001 came into force, containing the 'Regulations on the administrative liability of legal persons, companies and associations, including those without legal personality'.

The Decree aimed to bring domestic legislation on the liability of legal persons into line with several international Conventions that Italy has long since acceded to, such as the Brussels Convention of 26 July 1995 on the protection of the financial interests of the European Communities, the Convention also signed in Brussels on 26 May 1997 on combating bribery involving officials of the European Community or its Member States, and the OECD Convention of 17 December 1997 on combating bribery of foreign public officials in economic and international transactions.

Art. 5 of Legislative Decree 231/2001 sets out the company's liability if the alleged offences are committed in its interest or to its advantage:

- a. by persons **who hold positions of representation, administration or management** of the company or of an organisational unit thereof having financial and functional autonomy, as well as by persons who exercise (incl. de facto) management and control thereof (e.g., directors and general managers); or
- b. by persons **subject to the direction or supervision of any of the persons referred to in the preceding paragraph** (e.g., non-management employees).

Therefore, if a Predicate Offence is committed, the criminal liability of the natural person who materially committed the offence is added – if and to the extent that all the other regulatory prerequisites are fulfilled – to the 'administrative' liability of the company.

These rules therefore aim to involve entities in prosecutions for specific types of offences committed in their interest (with a view to the corporate policy adopted) or to their advantage (in order to obtain a financial benefit from the commission of the offence).<sup>2</sup>

In terms of **penalties**, all offences committed entail financial penalties against the legal person; for more serious offences, the application of prohibitory penalties is also envisaged, such as disqualification from exercising the activity, suspension or revocation of authorisations, licences or concessions, prohibition from contracting with the P.A., exclusion from financing, contributions or subsidies and possible revocation of those already granted, and prohibition from advertising goods and services.

The criminal offences set out under the Decree (**incl. attempted offences**) impose liability on the company under the Decree. More specifically, Art. 26(1) of the Decree envisages that, if any listed offences are attempted, the amount of the financial penalty and the time that the disqualification penalty remains effective for are reduced by between one third and one half. However, imposition of these penalties is excluded if the company, in accordance with Art. 26, 'voluntarily prevents the action from being carried out or the event from taking place'.

Art. 4 of Legislative Decree 231/2001 states that the liability set out by the Decree also applies to entities in relation to **offences committed abroad**.

<sup>2</sup> Recent guidelines of the Supreme Court of Cassation – also referred to by the Confindustria Guidelines – point out that in culpable offences (i.e., health & safety offences and environmental offences) the interest or advantage must arise from the breach of the precautionary rules (e.g., saving safety costs, increasing the speed of performance, increasing productivity, or sacrificing the adoption of accident prevention measures).

The prerequisites for the applicability of Art. 4 cited above are as follows:

- the offence must be committed abroad by the person functionally linked to the entity;
- the entity must have its head office in Italy;
- the entity may be liable in the cases and under the conditions envisaged in Arts. 7, 8, 9 and 10 of the Criminal Code. More specifically:
  - if the following offences are committed on foreign soil:
    1. crimes against the personality of the Italian State;
    2. offences of counterfeiting the state seal and of using that counterfeit seal;
    3. offences of counterfeiting currency that is legal tender in the territory of the State, or in revenue stamps or in Italian public credit cards;
    4. offences committed by public officials in the service of the State, abusing their powers or violating the duties inherent in their functions; and
    5. any other offence for which special legal provisions or international conventions establish the applicability of Italian criminal law.
  - if a political offence is committed on foreign soil that is not included among those indicated in point 1 above, the offender is subject to the penalties set out under Italian law, at the request of the Minister of Justice;
  - if, outside the cases indicated in the two previous points, a crime is committed on foreign soil for which Italian law prescribes life imprisonment, or imprisonment of at least three years. In the case of a crime for which a punishment restricting personal liberty of a lesser term is set, the offender is subject to a criminal penalty at the request of the Minister of Justice or at the request, or on complaint, of the offended person; and
  - if a foreign national, outside the cases indicated in Arts. 7 and 8, commits an offence on foreign territory to the detriment of the State or a citizen for which Italian law prescribes life imprisonment or imprisonment of at least one year, the offender is subject to the penalties under Italian law, at the request of the Minister of Justice or at the instance or on complaint of the offended person;
- if the cases and conditions set out in the preceding point are fulfilled, the entity is liable provided that the State of the place where the offence was committed does not prosecute the offence;
- in cases where the law provides that the offender is punished at the request of the Minister of Justice, proceedings are brought against the entity only if the request is also made against the latter; and
- the offender must be in the territory of the State at the time of prosecution and must not have been extradited.

With regard to the **types of Predicate Offences**, the offences listed below were considered – in the context of the Risk Assessment described in greater detail in section 3.4 below – to be reasonably foreseeable in the performance of corporate activities and therefore considered for the

purposes of preparing the Model:<sup>3</sup>

- a. Misappropriation of funds, fraud to the detriment of the State, a public body or the European Union or for the purpose of obtaining public funds, computer fraud to the detriment of the State or a public body and fraud in public supply (Art. 24 of Legislative Decree 231/2001);
- b. computer crimes and unlawful processing of data (Art. 24-bis of Legislative Decree 231/2001);
- c. organised crime offences (Art. 24-ter of Legislative Decree 231/2001);
- d. embezzlement, extortion, undue induction to give or promise benefits and bribery (Art. 25 of Legislative Decree 231/2001);
- e. offences of counterfeiting money, public credit cards, revenue stamps and identification instruments or signs (Art. 25 bis of Legislative Decree 231/2001);
- f. offences against industry and trade (Art. 25-bis1 of Legislative Decree 231/2001);
- g. corporate offences (Art. 25-ter of Legislative Decree 231/2001);
- h. offences for the purpose of terrorism or subversion of the democratic order under the Italian Criminal Code and special laws (Art. 25-quater of Legislative Decree 231/2001);
- i. offences against the individual (Art. 25-quinquies of Legislative Decree 231/2001);
- j. offences of culpable homicide and grievous or very grievous bodily harm, committed in breach of the rules on accident prevention and the protection of hygiene and health at work (Art. 25-septies of Legislative Decree 231/2001);
- k. receiving, laundering and using money, goods or benefits of unlawful origin, as well as self-laundering (Art. 25-octies of Legislative Decree 231/2001);
- l. copyright infringement offences (Art. 25-novies of Legislative Decree 231/2001);
- m. inducement not to make statements or to make false statements to the judicial authorities (Art. 25-decies of Legislative Decree 231/2001);
- n. environmental offences (Art. 25-undecies of Legislative Decree 231/2001);
- o. employment of third-country nationals whose stay is irregular (Art. 25-duodecies of Legislative Decree 231/2001);
- p. tax offences (Art. 25-quinquiesdecies of Legislative Decree 231/2001);
- q. smuggling (Art. 25-sexiesdecies of Legislative Decree 231/2001); and

---

<sup>3</sup> The Company adheres to the interpretative orientation on the identification of the predicate offence of the crime of criminal conspiracy, according to which the 231 liability of the entity for the offences set out in Legislative Decree 231/2001 must be limited solely to cases in which the challenged case is included in one of the Predicate Offences indicated in the Decree itself (see Criminal Court of Cassation, Section VI, no. 3635 of 24 January 2014). This approach is also adopted by the Company in relation to the assessment of the offence of self money laundering, in line with the information clarified by the Confindustria Guidelines on this point.

r. transnational offences (Art. 10 of Law No. 146 of 16 March 2006).

In contrast, the following offences were not considered in the Risk Assessment because the respective risks were assessed as not being reasonably foreseeable for the Company:

- a. racism and xenophobia (Art. 25-duodecies of Legislative Decree 231/2001);
- b. market abuse (Art. 25-sexies of Legislative Decree 231/2001) (Art. 25-sexies of Legislative Decree 231/2001);
- c. female genital mutilation practices (Art. 25-quater.1 of Legislative Decree 231/2001);
- d. fraud in sporting competitions, gaming or betting and gambling by means of prohibited devices (Art. 25-quaterdecies of Legislative Decree 231/2001);
- e. offences relating to non-cash means of payment (Art. 25-octies.1 of Legislative Decree 231/2001);
- f. offences against the cultural heritage (Art. 25-septiesdecies of Legislative Decree 231/2001); and
- g. laundering of cultural goods and devastation and looting of cultural and landscape heritage (Art. 25-duodevicies of Legislative Decree 231/2001).

## 2.2 The adoption of the Organisation, Management and Control Model as a possible exemption from administrative liability

Art. 6 of the Decree introduces a special form of exemption from the liability in question if the company proves that:

- (a) it has adopted and effectively implemented through its management body, before committing the offence, a model capable of preventing offences of the type committed;
- (b) it has entrusted an internal body – endowed with autonomous powers of initiative and control – with the task of supervising the operation of and compliance with the Model, and ensuring that it remains up-to-date;
- (c) the individuals who committed the offence acted by fraudulently circumventing the above Model; and
- (d) there has been no omission or insufficient supervision by the body referred to under letter (b) above.

The Decree (as amended by Legislative Decree No. 24/2023)<sup>4</sup> also envisages that the Model – in relation to the extent of the delegated powers and the risk of commission of the Offences – must meet the following requirements:

1. identify Sensitive Activities;

<sup>4</sup> Legislative Decree No. 24/2023 'Implementation of Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law and on provisions concerning the protection of persons who report breaches of national laws'.

2. provide for (or refer to) specific protocols governing the definition and implementation of corporate decisions in relation to the offences to be prevented;
3. identify the financial resources suitable for implementing an organisational system to prevent the commission of the Offences;
4. impose duty-to-inform obligations on the body responsible for supervising the operation of and compliance with the Model (i.e., the Supervisory Body);
5. set up an internal disciplinary system capable of penalising breaches of the measures listed in the Model;
6. provide for internal reporting channels and the prohibition of retaliation set out in Legislative Decree 24/2023 ('Decree 24/23'); and
7. provide for penalties under the disciplinary system referred to in point 5 above against all individuals who: (i) violate the measures for the protection of the reporting person, the persons involved and the persons identified in the report under Art. 12 of Decree 24/23; (ii) take retaliatory action against the reporting person (and/or the further persons referred to in Art. 3(5) of Decree 24/23), for reasons directly or indirectly connected with the report; and/or (iii) obstruct or have attempted to obstruct reports.



### 3. THE MODEL

#### 3.1 Aims of the Model

Chiesi is aware of the value that can derive from an internal control system capable of preventing the commission of Offences by its Employees, Corporate Bodies, Consultants, Collaborators, Partners and Suppliers. Also, the Company is aware that the adoption and effective implementation of the Model improves the system of Corporate Governance in that it limits the risk of Offences being committed and allows it to benefit from the exemption envisaged under Legislative Decree 231/2001.

The definition and implementation of the Model have been carried out in the conviction that they – over and above the requirements under the Decree that indicate the Model itself as an optional and non-compulsory element – could amount to, in addition to being an exempting circumstance under the Italian regulations on the liability of entities for administrative offences dependent on crime contained in Legislative Decree 231/2001, a fundamental tool for raising awareness of all those who work in the name and on behalf of Chiesi. This results in them being able to follow, when performing their activities, correct and straightforward conduct (e.g., by ensuring that the Model is not subject to any form of criminal liability). Legislative Decree 231/2001 serves as a fundamental tool for raising awareness among all those who work in the name of and on behalf of Chiesi and thereby ensuring that they follow correct and straightforward conduct when performing their activities and therefore prevent the risk of Offences from being committed.

Therefore, this Model serves to prepare a structured and organic system of prevention, deterrence and control aimed at reducing the risk of Offences from being committed by identifying Chiesi's Sensitive Activities, the principles of conduct that must be complied with by the Recipients of the Model, and specific monitoring activities that need to be carried out also in a preventive manner (ex ante control) to prevent Offences from being committed.

The principles in this Model is aimed at: (i) on the one hand, ensuring that the potential perpetrator of the Offence is fully aware that they have committed an offence (which is strongly condemned by Chiesi because it derogates from its principles and interests, even if the Company were to appear to benefit from it in any way); and (ii) on the other hand, thanks to constant monitoring of activities, enabling Chiesi to prevent the Offence itself from being committed or to react promptly if an Offence is committed.

More specifically, by identifying Sensitive Activities and then setting out their procedures, the Model aims to:

- introduce principles and rules of conduct in the Company aimed at promoting and enhancing, to an even greater extent, an ethical culture within it, with a view to fairness and transparency in the conduct of business;
- prevent the risk of the offences listed under the Decree from being committed while carrying out any activities identified in the map of areas at risk;
- ensure that all those who operate within Chiesi's Sensitive Activities remain aware that – in the event of conduct that breaches the Model and other company rules and procedures (as well as the law) – they would be subject to criminal penalties, and also the Company;
- enable constant monitoring of activities at risk by the entire company organisation and, in particular, by the Supervisory Body responsible for supervising the operation of and compliance with the Model;
- enable the Company to take action to prevent or counteract the commission of the Offences in a timely manner;



- introduce an appropriate Disciplinary System to sanction non-compliance with the measures indicated in the Model; and
- reiterate that Chiesi does not tolerate unlawful conduct of any kind or for any purpose whatsoever because this conduct, in addition to amounting to a violation of the laws in force, is contrary to the ethical principles that the Company adheres to.

### 3.2 Recipients of the Model

The rules in this Model are addressed at:

- (a) persons in positions of representation, administration or management of the Company;
- (b) persons exercising (incl. *de facto*) management and control of the Company itself;
- (c) all employees of the Company subject to the direction or supervision of the persons referred to above; and
- (d) Collaborators, Consultants, Representatives<sup>5</sup>, Partners, Suppliers and, in general, third parties operating in the name of or on behalf of or in the interest of the Company or under the supervision of the apical persons.

The above persons are collectively referred to as the '**Recipients**'.

The Company's Model also represents a collection of principles and a point of reference for the definition of the Model of each possible Subsidiary subject to the provisions of Legislative Decree 231/2001, without prejudice to the full autonomy of the Subsidiary in preparing, adopting and revising its own Model, and its unique characteristics. Without prejudice to this, the preparation and updating of its own Model by each Subsidiary must also consider the indications and implementation methods envisaged by the Company based on the Group's organisational and operational structure. Each Subsidiary, if any, subject to the provisions of Legislative Decree 231/2001 must form an autonomous and independent Supervisory Body.

The representatives appointed by the Company in the corporate bodies of subsidiaries, consortia and joint ventures promote the principles and contents of the Model in the areas of their respective areas of responsibility, and the Company's Supervisory Body monitors this promotion.

### 3.3 Preparation of the Model

In preparing this Model, Chiesi was inspired by the Guidelines drawn up by the main trade associations. The key points identified by the Guidelines can be summarised as follows:

- identifying the Processes, sub-processes and Sensitive Activities, through a detailed assessment of the Company's business, aimed at verifying which area/sector of the Company the Offences in question could foreseeably occur in; and
- setting up a control system capable of preventing risks by adopting appropriate horizontal and vertical controls, and assessing the suitability

---

<sup>5</sup> Anyone acting in the name and/or on behalf of Chiesi under a mandate.

of existing control elements.

More specifically, Chiesi has complied with the indications provided by Farmindustria with the “Document for the identification of Guidelines for the construction of Organisation, Management and Control Models pursuant to Legislative Decree 231/2001 in the pharmaceutical sector”, which identified some important organisational-procedural principles that member companies must adopt in order to reduce the risk of conduct covered by the Decree in the areas considered most at risk in the pharmaceutical sector. These principles are to be integrated into the Special Sections of the Model, whereas when defining the General Section, the Farmindustria Document refers to the Confindustria Guidelines.

The activity described in the previous points is set out in a document (“**Risk Assessment**”) that is maintained by the Company. The activity of preparing and constantly updating the Risk Assessment is the responsibility of the Board of Directors, with the support of the Supervisory Body. The results of the Risk Assessment activity and related controls are subject to a specific periodic assessment by the Supervisory Body, which is sent to the Board of Directors.

The Risk Assessment is carried out as follows:

- through a careful examination of all relevant company documentation (incl. the company organisational chart, articles of association, delegations of powers and company procedures on sensitive issues in relation to the offences listed under the Decree), the main risk areas (the Processes) that characterise the Company’s business are identified;
- within the framework of these Processes, the corporate activities exposed to the risk of the commission of offences under Legislative Decree 231/2001 (i.e., the Sensitive Activities) are identified;
- Sensitive Activities are subsequently associated with the Third Parties involved in the activity and with the respective company controls and procedures;
- as a result of this activity, all the Functions that characterise corporate operations and the relevant managers (“**Process Owners**”) are mapped. This is done in order to match them with the Sensitive Activities previously identified and based on the indications provided by the POs themselves;
- after matching the Sensitive Activities with Process Owners, each of the Sensitive Activities are assessed for risks of all the categories of offences under Legislative Decree 231/2001 that could reasonably be foreseen as being committed when performing each Sensitive Activity, and an illustrative description is provided of the different ways that these offences could be committed;
- in order to calculate the risks relating to individual Sensitive Activities: (i) the parameters for assessing the inherent or foreseeable risks, the level of adequacy of control measures and the residual or concrete risks are set out; (ii) the matrices for calculating the risk levels are prepared; and (iii) the risk acceptability threshold is identified (see Annex 1 ‘Risk Assessment Methodology’);
- the risk calculation is carried out through a self-assessment of the foreseeable risk, the level of adequacy of controls and therefore the concrete risk in relation to each Sensitive Activity and the respective categories of Offences identified above. This is carried out with the involvement of the POs concerned through specific individual interviews or collective workshops;
- the results of the Risk Assessment are also processed and evaluated through a digital system and crystallised in a Risk Assessment matrix that can be consulted by Process, Sensitive Activity, Offence Family and Function;

- the results of the Risk Assessment are analysed to: (i) identify the Sensitive Activities in relation to which the internal control system could be improved; and (ii) identify and plan the related improvement actions to be implemented in order to reduce the risk of commission of the Offences connected to the performance of the above Sensitive Activities. More specifically, depending on the levels of risk encountered, improvement ideas and suggestions are identified in order to:
  - strengthen the control systems in relation to Processes found to be at higher risk;
  - intensify verification and control activities and reshape information flows; and
  - carry out appropriate monitoring activities to intercept any increase in the level of risk associated with corporate processes.

The Risk Assessment is updated also by assessing the results of other risk assessments carried out by the Company that are also relevant for the purposes of Legislative Decree 231/2001 (e.g., risk assessments carried out for the purposes of ISO 37001).

In view of the outcomes of the phases described above, the Special Sections of the Model are prepared.

The method described above is also adopted every time the Model is updated if the interventions are of a substantial nature and therefore require new Sensitive Activities to be identified, new Offences to be assessed or new Special Sections to be prepared.

### 3.4 Underpinning elements and principles of the Model

The following actions form the cornerstones of the Model and are dealt with in specific paragraphs of this General Section:

- the mapping of Chiesi's Sensitive Activities;
- risk prevention, by adopting specific procedural principles aimed at regulating the definition and proper implementation of corporate decisions in relation to the Offences to be prevented;
- the control measures aimed at preventing the risk of Offences being committed (i.e.: (i) verification and documentation of operations carried out in the context of Sensitive Activities; (ii) compliance with the principle of segregating roles in the structuring of corporate procedures and the management of financial resources; (iii) the definition of authorisation powers consistent with the responsibilities assigned and the verification of corporate conduct; and (iv) the functioning of the Model with consequent periodic updating – *ex post* control);
- raising awareness and dissemination at all levels of the Company of the rules of conduct and the procedures established; and
- the assignment of specific supervisory tasks to the Supervisory Body on the effective and correct functioning of the Model.

More specifically, when defining and updating the Model, account was taken of the procedures and control systems existing and already operating within the Company – identified when analysing the Sensitive Activities – to the extent that they were considered suitable to also serve as measures for preventing Offences and monitoring Processes involved in the Sensitive Activities.

The Model is characterised by: (i) effectiveness, i.e., the adequacy of the set of controls put in place to prevent the commission of Offences; (ii) precision, i.e., consideration of the characteristics, size, type of activity and historical events of the Company; and (iii) relevance, i.e., constant

updating.

The Model's design is also based on proportionality, in which rules and controls are maintained in proportion to the size and structure of the Company's organisational structure.

### 3.5 The 'acceptable risk' approach

Essential in the construction of a preventive control system is the concept of 'acceptable risk'. More specifically, successful application of Legislative Decree 231/2001 requires an effective threshold that limits the quantity and quality of the preventive measures to be adopted and implemented to prevent the alleged offences from being committed. Without first calculating the acceptable risk level, the quantity/quality of preventative controls that could be introduced would in fact be virtually infinite, with unforeseeable effects on the company's operations. The same general principle, which can also be applied to criminal law, of the concrete enforceability of conduct amounts to a central point of reference in this regard.

As highlighted by the Confindustria Guidelines regarding the preventive control system to be built in relation to the risk Offences being committed, regarding intentional offences, the conceptual threshold of acceptability is demonstrated by a prevention system that can be circumvented only by acting fraudulently, in line with the logic of the "fraudulent evasion" of the Model as an express exemption for the purposes of the exclusion of the entity's liability (see Art. 6(1)(C) of Legislative Decree 231/2001: "persons have committed the offence by fraudulently circumventing the models...").

As pointed out in caselaw, the 'fraud' referred to in Legislative Decree 231/2001 does not necessarily require actual artifice and deception; at the same time, however, fraud is not only a breach of the Model's provisions. It assumes that the Model is breached by deliberately circumventing the security measures in place to ensure its effectiveness.

However, with regard to culpable offences (e.g., culpable homicide and culpable personal injuries committed in violation of occupational health and safety regulations and culpable environmental offences) the threshold of 'acceptable risk' must be modulated differently, given that fraudulent avoidance of the Model appears incompatible with the subjective element of culpable offences, in relation to which the intention to cause the harmful event is absent. In these cases, the threshold of 'acceptable risk' is reached if an individual breaches the Model (and, in the case of health & safety offences, the underlying mandatory requirements set by prevention regulations) even though the Supervisory Body has fully complied with its supervisory obligations under Legislative Decree 231/2001.

Based on these principles, the Company's Model sets protocols for all Sensitive Activities considered to be 'at risk' of alleged offences. These protocols must: (1) be reasonably capable of preventing all possible intentional offences, unless they are fraudulently circumvented; and (2) provide an adequate system of controls on all obligatory procedures whose omission could lead to culpable offences.

### 3.6 Approval, amendment and integration of the Model

The Model is constantly updated with the legislation in force in order to take into account the new offences included or referred to in Legislative Decree 231/2001 and the related caselaw, as well as the best reference practice (see Annex 1).

Because the Model amounts to – under and for the purposes of Art. 6(1)(a) of the Decree – a formal document issued by the top management, any amendments or additions to the Model remain the exclusive responsibility of the B.o.D., after assessment and/or upon report of the Supervisory Body, for the following matters:

- any changes to the configuration and tasks of the Supervisory Body;
- changes or additions to the Disciplinary System;
- mapping of Sensitive Activities; and
- adaptation of the Model.

Without prejudice to the above, once a year the Board of Directors, supported by the Supervisory Body, deliberates on the requirements for updates to be made to the Model and any possible amendments and additions that are needed.

### 3.7 Model Structure

The Model comprises a General Section and a Special Section.

- a) the General Section describes: (i) the Decree's contents and impacts; (ii) the Model's basic principles and objectives; (iii) the procedures for adopting, disseminating, updating and applying the Model's contents; and (iv) the general principles laid down in the Model;
- b) the Special Sections, each one dedicated to a Process, set out: (i) the Sensitive Activities characteristic of the Process considered; (ii) the Offences whose commission could be reasonable foreseeable when performing the Sensitive Activities; and (iii) all related control protocols.

With specific regard to the Special Sections, the structuring of the Model by single Process (instead of by types of Offence) makes it possible to: (i) guarantee adequate usability – and therefore ease of application – by persons who have no specific legal training; and (ii) structure training courses focused only on the Processes that the individual employee is involved in.

The General Section also contains the following annexes:

- the Risk Assessment Methodology (Annex 1);
- the Statute of the Supervisory Body (Annex 2);
- the Disciplinary System (Annex 3); and
- the SOP 'Use and Management of SpeakUp&BeHeard' (Annex 4).

### 3.8 Implementation of the Model

For the Model's implementation phase, the Board of Directors and the Presidency, supported by the Supervisory Body, are responsible - for their respective areas of responsibility – for the implementation of the various elements of the Model (incl. operational procedures).

In any event, Chiesi highlights that proper implementation and control of compliance with the company provisions – and, therefore, with the rules in this Model – is an obligation and a duty of all the Company personnel but, in particular, each Function Head who is delegated, within the scope of his/her competence, with primary responsibility for controlling these types of activities (especially those that are more at risk).

## 4. THE COMPANY, THE GOVERNANCE SYSTEM AND THE ORGANISATIONAL AND AUTHORISATION SYSTEM

### 4.1 The Company

Chiesi Farmaceutici S.p.A. is an Italian multinational pharmaceutical company focused on the research, development and commercialisation of innovative therapeutic solutions.

The areas that the Company is active in – either directly or indirectly through subsidiaries or affiliates – are mainly respiratory and cardiovascular diseases, anti-inflammatories and painkillers, but also neonatal, musculoskeletal and rare diseases. Chiesi is also active in the bio-pharmaceutical sector.

### 4.2 The governance system

In defining its system of governance, the Company has favoured the so-called traditional system (Shareholders' Meeting, Board of Directors, Board of Statutory Auditors) and has entrusted an auditing company with the task of auditing and controlling the accounts.

#### Shareholders' Meeting

The Shareholders' Meeting passes resolutions, in ordinary and extraordinary meetings, on matters reserved to it by law and by the articles of association and appoints the members of the Board of Directors.

The Assembly is chaired by the Chairman of the Board of Directors.

#### Board of Directors

The Board of Directors is vested with the broadest powers of administration of the Company and with the responsibility for implementing and achieving the company's corporate purpose, to the extent permitted by law and the articles of association.

According to the articles of association, the Chiesi Board of Directors comprises five to nine members elected by shareholders at a Shareholders' Meeting held to decide on the number of board members.

Chiesi's B.o.D. chooses the Chairman and the delegated Directors from among its members and may delegate its powers, in each case setting the limits of their respective powers.

#### Board of Statutory Auditors

The Board of Statutory Auditors comprises three regular members and two alternate members and is appointed – along with its chairman – by shareholders at a Shareholders' Meeting.

The Board of Statutory Auditors ensures the fulfilment of all duties imposed by law and the Statute.

#### External auditing firms

Under Art. 2409-bis et seq. of the Civil Code, the Company has appointed an external auditor, registered in the register maintained by the Ministry of Justice, to audit the company's accounts.

These auditing activities must be recorded in a special book maintained at the company's registered office.

### 4.3 The organisational system

The Company's organisational structure is focused on ensuring the segregation of tasks, roles and responsibilities between the operational and control Functions – as reported in the company's organisational chart and in the job descriptions of the individual company areas, where present, which identify their qualifications and responsibilities.

Also, the adequacy of the organisational system was verified based on the following criteria:

- formalisation of the system of powers, delegations and proxies conferred;
- clear definition of assigned responsibilities and hierarchical reporting lines;
- application of the principle of segregation of duties in defining the processes relevant to this Model; and
- correspondence between the activities currently carried out and those envisaged in the related organisational instruments.

The exact identification of the tasks of each person and their assignment in a clear and transparent way also allows compliance with the principle of 'separation of roles', which is fundamental for curbing potential offences subject to penalties under Legislative Decree 231/2001.

In the context of the Company's organisational structure, the rules aimed at defining the decision-making processes underlying the Company's most significant operational areas are also of particular importance. In this regard, the reorganisations described below – which came into force (for the most part) in January 2024 in order to make the Company's organisation more efficient, simplify processes and outline clear responsibilities – are particularly important. The new organisational model includes:

- (i) **four Commercial Regions**, reporting directly to the Chief Executive Officer (replacing the former 'Chief Commercial Officer' – CCO): Europe Top 5, Mid-size Europe, USA, China & International;
- (ii) the **Strategy, Sustainability & Growth (SSG) Unit**, responsible for defining the "One Chiesi" strategy and resource allocation, with the aim of generating long-term shared value for the Group and its stakeholders. This Function includes: Global Strategy; Shared Value & Sustainability; Business & Corporate Development; Competitive Intelligence; SKAI (R&D – Scientific and External Knowledge Analytics and Insights); Centre of Open Innovation and Competence; and Digital Health;
- (iii) the **Air and Care Franchises**, which manage the overall development and implementation of strategies for each therapeutic area, including growth, pipeline development, portfolio management and resource allocation. The Franchises are organised based on



'development phases': the **Pipeline Development Team** brings innovation and coordinates programme leadership, in close collaboration with R&D; the Commercial **Portfolio Management Team** coordinates commercial and launch activities (incl. Life Cycle Management strategies), with a focus on patient welfare; the global **Medical Affairs, Value & Access** and **Business Excellence & Customer Experience** functions report to the Air Franchise but support both Franchises;

(iv) Chiesi Group's **Global Rare Diseases (GRD)** business unit was established in 2020 to **provide innovative therapeutic solutions to people living with rare diseases** and to ensure equitable access to treatment. GRD works with the rare disease community worldwide, supporting patient advocacy activities to give patients and their families a voice; and

(v) the new **Transformation Office**, comprising: the **Global Post-Merger Integration Office**, which is responsible for managing value-creation plans, and identifying and coordinating integration processes between the various Functions; the **Global Project Management Office**, which leads large-scale strategic transformation projects and processes, monitoring their execution; and the Digital Transformation **Office**, which leads Chiesi's digital transformation, defining the roadmap; and the **Agile Transformation Unit** leads the implementation of the Agile working method.

#### 4.4 The Global Compliance Function

The Global Compliance Function was created by a resolution of the Chiesi Board of Directors in 2015. The purpose of the Function is to ensure increasing adherence to international standards on ethics, anti-bribery and antitrust, as well as more effective coordination at Group level on these issues.

Since its establishment, the structure of the Global Compliance Function has been strengthened and expanded, substantially reaching coverage of the entire Group. More specifically, the Global Compliance Function comprises:

- a Chief Compliance Officer, who reports hierarchically to the Group General Counsel and, functionally, to the top management (i.e., the Chief Executive Officer) and has the hierarchical reporting of all compliance functions of Group companies, which functionally report to the local General Managers; and
- by Compliance Managers (responsible for the Company's different Functions) and Regional Compliance Heads, who – in line with the corporate organisational model – coordinate the Compliance Managers of the Group companies within their respective Regions.

In 2023, the 'Ethics, Transparency & Anti-bribery Compliance' unit was established within the Global Compliance Function. By a resolution of the Board of Directors in November 2023, this unit was assigned the role of Anti-bribery Compliance Function under the ISO 37001:2016 standard.

The Global Compliance Function works in close cooperation with the Global Internal Auditing Function and all corporate structures.

The main tasks of the Function include:

- the definition and adoption of adequate operational and guidance tools (particularly, Policies, Guidelines and Standard Operating Procedures – SOPs) for all Group companies, with a particular focus on anti-bribery and antitrust issues; the main documents prepared in this regard by the Global Compliance Function include:



- (i) the Group Guideline on interactions with healthcare professionals (HCPs) and healthcare organisations (HCOs), the purpose of which is to provide a set of binding general principles applicable across the Group on the management of interactions with HCPs and HCOs;
  - (ii) the SOP on the Management of Transfers of Value to HCPs and HCOs, which defines the processes and general rules to be followed by all Group companies when managing transnational transfers of value to HCPs and HCOs, which ensures correct application of the rules governing this area – particularly the rules set by the European Federation of Pharmaceutical Industries Associations (EFPIA) and the American Sunshine Act;
  - (iii) the Anti-Bribery Policy (approved by the B.o.D. on 22 December 2015 and its subsequent amendments and additions), which provides Employees and anyone acting on behalf of and/or for Chiesi with a set of general principles on how to recognise and deal with issues related to bribery and how to comply with the respective legislation; and
  - (iv) the Guideline and SOP ‘Use and Management of SpeakUp&BeHeard’.
- monitoring the correct application of the Company’s compliance procedures and policies in cooperation with the Global Internal Auditing Function;
  - the adoption of Standard Operating Procedures (SOPs) at corporate level on the subject of interactions with HCPs and HCOs, with a definition of the relevant approval flows;
  - the adoption of corporate tools (incl. IT tools) for the management of compliance issues. In this regard, it is worth mentioning the introduction of the Group’s whistleblowing system in 2016. This system – called SpeakUp&BeHeard – in addition to guaranteeing a coordinated management of all reports (both transmitted by Chiesi Employees and by persons external to the Company) of conduct that could jeopardise Chiesi’s business and/or reputation, is also relevant for the purposes of applying the Decree in Italy. SpeakUp&BeHeard was updated in July 2023 in order to bring it into line with the requirements of Decree 24/23 concerning the way in which reports are handled and the protection of the confidentiality of the person reported, the reporter and the information communicated through the report (see section 9 for further details on SpeakUp&BeHeard); and
  - the handling of reports concerning the Company transmitted through SpeakUp&BeHeard.

The Decree’s implementation remains the responsibility of the Global Compliance Function, who is required to monitor its development and manage updates to the Model – in the light of regulatory and organisational changes that have occurred – and submit these to the Supervisory Body for evaluation.

With specific regard to anti-bribery, in addition to the general management of the issue, the Global Compliance Function (and, in particular, the ‘Ethics, Transparency & Anti-bribery’ unit, which has been assigned the role of Anti-bribery Compliance Function) is also assigned the following tasks, as provided for by the ISO 37001 standard:

- oversee the organisation’s design and implementation of the anti-bribery management system;
- provide advice and guidance to corporate staff on the anti-bribery management system and bribery issues;

- ensure that the anti-bribery management system complies with the requirements of the ISO 37001 standard; and
- prepare periodic reports on the performance of the anti-bribery management system to the Board of Directors, top management and other corporate bodies, as appropriate.

#### 4.5 The Global Internal Auditing Function

In order to ensure the highest standards of control over Processes and to guarantee their continuous improvement, Chiesi has set up a Group Internal Auditing Function.

The Global Internal Auditing Function – established in 2005 – implements audit programmes that take into consideration the Processes and Sensitive Activities relevant to this Model and the results of previously conducted audits. These programmes (normally lasting three years) are submitted (for preliminary sharing) to the Supervisory Body and to the Chairman of the Board of Directors, to whom the Function functionally reports, for relative verification and validation, and are included in the Audit Plan approved annually by the Board of Directors.

The audit activities conducted by the Global Internal Auditing Function are risk-based (i.e., focused on the main risks of the organisation) and must remain reasonable and proportionate to the structure of the Function.

The company maintains documented information as proof of the implementation of the audit programme and the results of each audit.

### CENTRALISED PURCHASING FUNCTIONS

#### Global Procurement

The Global Procurement Function, headed by the Chief Procurement Officer (who reports hierarchically to the CFO) has over the years undergone an important reorganisation process aimed at unifying, centralising and increasingly globalising direct purchases (i.e., purchases of raw materials and production materials, packaging and various materials for production) and indirect purchases (i.e., purchases of generic goods and services that are not connected to the production cycle) made by the Chiesi Group. To this end, the Global Procurement Function is currently organised in the following units:

- **Global Direct Procurement:** manages all purchases of direct materials used in drug production processes for both Chiesi production sites and some CMOs working for Chiesi;
- **Global Indirect Procurement:** manages all purchases of indirect material/service categories, not directly related to the production of the drug, generating central agreements for global use;
- **Global Sustainable Procurement:** defines the global Sustainable Procurement approach, setting out rules and processes for an increasingly sustainable engagement of Chiesi partners with minimal environmental impact;

- **Global R&D Procurement:** manages all purchases related to the core R&D service categories at all Chiesi Group research sites; and
- **Regional Global Category Hubs** (EU Top 5, EU Mid-size, US and China & International) that co-ordinate and support the subsidiaries in the implementation of strategic projects, thus fostering a unified and harmonised approach and methodology in procurement processes.

## INTERNAL COMMITTEES

Over the years, Chiesi has launched a policy to strengthen the structure of internal committees. In this way, the Company intended to pursue the objective of significantly increasing the culture of control within its organisation, representing these committees as the guarantor tool for further application of the principle of segregation of duties.

Below is a list of the main committees active at Chiesi.

- **GOVERNANCE COMMITTEES**

- Group Executive Leadership team (“GELT”): this committee comprises Chiesi’s Chief Executive Officer and his hierarchical first reports. The Committee, in particular, has the role of: (i) assessing and defining (as the “Steering Committee”) important strategic projects, priorities and methods of implementation; (ii) exercising control in the implementation of Group Plans; (iii) assessing investments of corporate relevance and importance; and (iv) discussing and formulating “horizontal policies”, i.e., those rules and principles that concern the Chiesi Group as a whole and must be respected and fulfilled uniformly by all the Group companies.
- Global Public Affairs Review Committee: this committee comprises representatives from the Chiesi Group’s management and performs a steering function for Public Affairs activities at Global level.

- **MONITORING COMMITTEES**

CASSC (Committee for Social and Community Development Activities): this is governed by the “Donations” procedure. The CASSC, established in 2015, has the purpose of defining, promoting and monitoring the development strategy of the local communities where the Group has its offices, with a particular focus on the territory of Parma and its province. The areas of intervention of the activities supported by the CASSC include environmental protection, education of new generations, social development and inclusion, enhancement of culture and attractiveness of the territory, as well as ad hoc interventions in emergency situations. The business-community collaboration and co-planning model promoted by CASSC serves as a reference for the Group’s companies.

## 4.6 The authorisation system

As suggested by the Confindustria Guidelines, authorisation and signature powers must be assigned consistently with the organisational and management responsibilities defined, providing, when required, for a precise indication of the approval thresholds for expenditure, especially in areas considered at risk of offences.

The B.o.D. (directly or through a mandate given to its Chairman and/or Chief Executive Officer) is the body responsible for formally conferring and approving delegated powers and signatory powers, providing for a precise indication of the approval thresholds for expenditure.

More specifically, the system provides for the allocation of:

- **permanent** powers of **representation**, which may be granted through registered powers of attorney in connection with the performance of activities related to the permanent responsibilities set out in the company organisation; and
- powers relating to **individual transactions**, conferred through notarial powers of attorney or other forms of delegation in relation to their content, which must comply with the regulatory requirements of the forms of representation and the types of individual deeds to be executed.

The Company ensures consistency between the authorisation system of signatory powers and corporate representation powers and the organisational and management responsibilities defined, by periodically monitoring and updating it, as well as promptly on occasion:

- the revision of the company's macro-organisational set-up (establishment/development of first-level organisational units, etc.);
- significant changes in responsibility and/or turnover in key positions in the structure; and
- an exit from the corporate organisation of persons with corporate powers or the entry of persons requiring corporate powers.

Each of the proxies may, in turn, provide expenditure proxies to their main reports within the Department that they belong to. The conferral of these proxies is discussed with the Group Legal and Corporate Affairs Function ('GLCA'), which assesses their congruity with the general system, formalises their conferral through a special form and checks that they remain constantly updated.

## 5. THE CODE OF CONDUCT

The adoption of ethical principles relevant to the prevention of offences under Legislative Decree 231/2001 represents an objective of this Model. In this perspective, the adoption of a Code of Conduct as a useful governance tool serves as an essential element of the preventive control system. The Code of Conduct, in fact, aims to recommend, promote or prohibit certain conduct that attracts penalties in proportion to the seriousness of any breaches committed.

The rules of conduct in this Model are integrated with those of the Code of Conduct, although the Model has a different scope from the Code of Conduct in terms of the purposes it intends to pursue in implementing the provisions of the Decree.

In this respect, in fact:

- the Code of Conduct, on the one hand, represents an instrument adopted autonomously that remains valid at Group level and sets out: (i) the principles of “company deontology”; (ii) the commitments that Chiesi identified as its own; and (iii) the standards of conduct that all Employees must adhere to; and
- the Model, on the other hand, responds to specific prescriptions set out in the Decree that are aimed at preventing the commission of Offences (for acts which, if committed in the interest or to the advantage of the company, could entail administrative liability of the company under the Decree).

### Anti-Bribery Policy

On 22 December 2015, the Board of Directors also approved Chiesi’s Anti-Bribery Policy. The Policy, as subsequently amended, is a Group document that sets out a set of common anti-bribery rules applicable to both internal and external stakeholders of the Group.

## 6. THE FINANCIAL RESOURCES MANAGEMENT SYSTEM

The Decree requires that the Models provide for 'methods of managing financial resources suitable for preventing the commission of offences'. The provision finds its rationale in the realisation that most of the offences listed under the Decree can be committed by using companies' financial resources, such as creating extra-accounting funds for engaging in bribery.

The process of managing financial resources refers to all activities related to monetary and financial outflows for the fulfilment of social obligations of various kinds, which in essence can be traced to the following macro-groups:

- ordinary flows: related to current activities/operations, such as purchases of goods & services and licences; and financial, tax and social-security payments, salaries and wages; and
- extraordinary flows: related to financial transactions, such as subscriptions, capital increases and credit allocation.

More specifically, in compliance with the principles of transparency, verifiability and relevance to the company's business, this management process includes the following steps:

- planning, by the individual Functions, of periodic and/or spot financial requirements and communication – duly authorised – to the competent Function;
- provision (by the competent function) of the necessary financial resources by the set deadlines;
- request for a duly formalised payment order; and
- verification that the amount in the relevant document corresponds to the payment order.

The Confindustria Guidelines recommend adopting mechanisms to proceduralise decisions that, by ensuring that the various stages of the decision-making process can be documented and verified, prevent improper management of the entity's financial resources.

Again, based on the principles indicated in the Confindustria Guidelines, the control system relating to the process of managing financial resources is based on the qualifying elements of the separation of roles in the key phases of the process, suitably formalised, and the traceability of all acts and authorisation levels to be associated with the operations.

More specifically, the specific control elements comprise the following:

- existence of different actors operating at different stages/activities of the process;
- request of the payment order to discharge the duly formalised obligation;
- control over making the payment;
- reconciliations on final accounts;
- existence of authorisation levels for both the request for payment and the provision, broken down based on the nature of the transaction (ordinary/extraordinary) and the amount;

- existence of a systematic information flow ensuring continual alignment between powers of attorney, operational proxies and authorisation profiles resident in the information systems;
- systematic reconciliation of both intercompany accounts and accounts with credit institutions; and
- traceability of acts and individual steps in the process (with specific regard to cancellations of documentation that has already resulted in a payment).

In accordance with the criteria described above, the Company has adopted specific procedures to regulate administrative processes (incl. the procedure governing the preparation of financial statements).

## 7. COMMUNICATION AND TRAINING

### 7.1 Employee Training and Information

Internal training serves as an essential tool for effective implementation of the Model and widespread dissemination of the principles of conduct and control adopted by the Company. This is to ensure a reasonable prevention of offences that the Decree imposes administrative liability for.

Already at the start of the 'Ethics & integrity' project in 2003, the Company had set up several training sessions aimed at all managers, middle managers and a wide selection of the Company's employees.

As of 2015, on the other hand, mandatory training on the Model's content is delivered by using a special e-learning platform. The course is divided into training modules, with an assessment questionnaire at the end of each module. Failure to pass the questionnaire implies an obligation to repeat the relevant module. The course content is updated based on the latest approved amendments to the Model.

The definition of the training content concerning Legislative Decree 231/2001 and the application of the Organisation, Management and Control Model, as well as the realisation of the courses and their delivery, remains the responsibility of the Global Compliance Function.

Training programmes must be shared with the Supervisory Body.

The content of all training programmes needs to meet the following requirements:

- comprehensive, effective, clear and adequately detailed;
- appropriate for the activity carried out by the person within the company (risk activities, control activities, non-risk activities, etc.);
- participation in training programmes is mandatory for individuals identified based on pre-defined criteria, and appropriate control mechanisms must be in place to monitor attendance; and
- control mechanisms must be in place to verify the participants' level of learning.

General training - implemented based on the content and methods considered most suitable and effective - must involve all levels of the organisation, in order to enable each individual to become familiar with:

- the precepts in Legislative Decree 231/2001 on the administrative liability of entities and the offences and penalties that it lists;
- the Disciplinary System;
- the control principles in the internal operating procedures and standards of conduct;
- the powers and tasks of the Supervisory Body; and
- the internal reporting system regarding the Supervisory Body.

Based on specific assessments, special training sessions may be organised for the types of recipients who perform particular activities reported as potentially at risk of specific offences under the Decree. Special training, where necessary, must allow the subject to:



- be aware of the potential risks associated with their activities;
- know and activate the specific control mechanisms in order to monitor the activity itself;
- know and apply the rules of conduct detailed in the Special Sections of the Model; and
- be able to detect any anomalies and report them in a way and timeframe useful for implementing possible corrective actions.

The training content is updated based on the evolution of the legislation and the Model: therefore, in the event of significant changes (e.g., extension of the Company's administrative liability to new types of offences), the content is consistently supplemented and their proper use is checked.

The Global Human Resources Function sets out the methods for recording the assignment and completion of the course.

Non-participation in training activities without justification by Employees amounts to a violation of the principles in this Model and, therefore, will result in disciplinary measures under section 8 and in the relevant Annex 3.

The Supervisory Body periodically verifies whether the training plan has been implemented and has the power to request periodic checks on Employees' knowledge of the Decree, the Model and its operational implications.

## 7.2 Communication and dissemination

In line with the provisions of Legislative Decree 231/2001 and the Confindustria Guidelines, the Company fully publicises this Model to ensure that all personnel are aware of its content.

Communication must be widespread, effective, clear and detailed, with periodic updates related to changes in the Model, in compliance with the Confindustria Guidelines.

More specifically, effective communication must:

- be sufficiently detailed in relation to the target hierarchical level;
- use the most appropriate and easily accessible communication channels for the recipients of the communication in order to provide the information in a timely manner, enabling the target personnel to benefit from the communication effectively and efficiently; and
- have high-quality content, include all the necessary and latest information and remain timely, up-to-date and accessible.

Recipients of the communication include:

- all employees;
- new employees, upon hiring; and
- third parties operating in the name or on behalf of the Company in areas that are particularly sensitive for the purposes of the Decree and/or the Model.

More specifically, the Company has from the outset set up an intranet site that is accessible to all head-office staff and provides all the Model's documentation and useful information on the Supervisory Body.

## 8. THE DISCIPLINARY SYSTEM

The definition of a system of penalties – commensurate with each respective violation and serving as an adequate deterrence – applicable in the event of violation of the rules set out in this Model (“**Disciplinary System**”) renders the supervisory action of the Supervisory Body as effective and is intended to ensure that it is implemented.

To this end, the Company has adopted a Disciplinary System for the purposes of Legislative Decree 231/2001 that is aimed at imposing penalties for possible violations both by Employees – managers and non-managers – and by Directors and Statutory Auditors, as well as members of the Supervisory Body, Consultants, Collaborators and third parties.

These violations must result in disciplinary action – regardless of whether criminal proceedings are filed – because they amount to a breach of the respective employee’s duties of diligence and loyalty and could lead to a breach of the relationship of trust established with the employee. The Company must provide for – among other things – disciplinary measures capable of affecting the variable part of remuneration.

The application of the Disciplinary System and its related measures is therefore independent of the conduct and outcome of any criminal proceedings that the judicial authorities have initiated if the conduct also amounts one of the offences listed under Legislative Decree 231/2001. This is because the rules of conduct imposed by the Model are assumed by the Company in full autonomy, regardless of the criminal offence that any conduct amounts to.

The Disciplinary System is therefore autonomous from criminal offences and does not serve to substitute offences under legislation governing the employment relationship, the Workers' Statute (Legislative Decree 300/1970) and the CCNL.

Also, this System must be adequately disseminated as an integral part of the implementation of the Model by providing adequate information and training to the Recipients.

The Disciplinary System adopted by the Company is annexed to this Model and forms an integral part of it (see Annex 3 ‘Disciplinary System’).

## 9. THE SUPERVISORY BODY

Art. 6(1)(B) of Legislative Decree 231/2001 stipulates that one of the prerequisites for exemption from liability arising from any the offences under it being committed is the establishment of an internal body within the Entity – the ‘Supervisory Body’ – with autonomous powers of initiative and control. This has the task of supervising the operation of and compliance with the Model and ensuring that it remains updated.

### a. Requirements of the Supervisory Body

To fulfil the functions laid down by the Decree, the Body must possess adequate requirements of autonomy, independence, professionalism and continuity of action, as well as honourableness and an absence of conflicts of interest (see Annex 2 'Statute of the Supervisory Body'). More specifically:

- **autonomy and independence:** as specified also by the Confindustria Guidelines, the position of the Body within the Entity ‘must guarantee the autonomy of the control initiative from any form of interference and/or conditioning by any component of the Entity’ (incl. the management body).

The Supervisory Body must therefore be placed in the highest possible organisational position, reporting to the Company’s most senior operational management levels. Also, to guarantee its necessary autonomy of initiative and independence, ‘it is essential that the Supervisory Body is not assigned operational tasks that – by making it a participant in operational decisions and activities – would undermine its objectivity when monitoring conduct and the Model’. For the purposes of this Model and the Company's activity, 'operational tasks' means any activity that could affect the strategic or financial aspects of the Company itself (see Confindustria Guidelines on this point).

Autonomy and independence must be understood in more than just a formal sense: in other words, the Supervisory Body must: (i) be endowed with effective powers of inspection and control; (ii) be able to access relevant corporate information on its own initiative; (iii) be provided with adequate resources; and (iv) be able to make use of instrumentation, support and experts when performing its monitoring activities.

More specifically, the management body must ensure this requirement is met by providing additional financial resources. This includes at the suggestion of the Supervisory Body itself, which has the power to authorise these additional resources to guarantee the proper performance of the management body’s duties (e.g., by obtaining specialist consultancy and paying for essential travel expenses).

Independence also assumes that the members of the Supervisory Body: (i) are not in an existing or potential position that gives rise to a conflict of interest with the Company; and (ii) hold no executive functions within the Company that would undermine their objectivity when verifying compliance with the Model.

Finally, to guarantee the requirements of independence and autonomy, from when they are appointed and throughout their term of office, the members of the Body:

- (a) must not hold executive or delegated positions on the Board of Directors of the Company or other Chiesi Group companies;
- (b) must not be direct or indirect owners of shares in the Company or any other companies that would enable them to exercise control or significant influence over the Company;

- (c) must not directly or indirectly entertain with the Company – or companies controlled by or connected to the Company – any form of economic relations that would affect their impartial judgement. This is also assessed based on the subjective financial position of the individual – except for the employment relationship, remuneration as external members of the Supervisory Body or membership of the Board of Statutory Auditors, if any. They also must not engage in any significant business relations with the directors with delegated powers (executive directors) or with any shareholders controlling the Company;
  - (d) must not have economic relations with or be part of the executive directors' household, where household means the spouse not legally separated, cohabiting partner, relatives and relatives-in-law up to the fourth degree of kinship;
  - (e) must not have relationships of kinship, marriage, cohabitation *more uxorio* or affinity up to the fourth degree with any: (i) members of the Board of Directors; (ii) persons who represent, direct or manage the Company; (iii) persons who exercise actual or *de facto* management and control of the Company; (iv) the Company's statutory auditors and representatives of the auditing firm; or (v) any other persons indicated by law;
  - (f) must possess and maintain the requirements of good reputation set out in Annex 2 'Statute of the Supervisory Body'.
- **professionalism:** this requirement refers to the specialised technical skills that the Body needs to be endowed with in order to perform the activity assigned to it by the regulation. More specifically, the members of the Body need to have specific knowledge of all techniques that can be used for performing inspection, consulting, control system analysis and legal activities (particularly in the criminal and corporate sector), as clearly specified in the Confindustria Guidelines. Members of the Body therefore also must have knowledge of risk analysis and assessment techniques, the flow charting of procedures and processes, fraud detection methodologies, sampling and the structure and methods of committing offences.

These characteristics, together with the independence of the Supervisory Body, guarantee its objectivity; its internal members are therefore chosen from among persons with adequate professionalism in corporate risk control and management and in legal matters; also, the external members of the Supervisory Body should preferably be chosen from among persons with expertise in legal matters, corporate organisation, auditing, internal control systems and risk management, accounting, finance and safety at work.

Additionally, the Supervisory Body may also use external professionals to obtain competent expertise in the above matters.

- **continuity of action:** effective implementation of the Model requires a body that is dedicated to supervisory activities and operates continuously.

The Supervisory Body continuously performs the activities necessary for supervising the correct application of the Model with adequate commitment and with the necessary powers of investigation. This is an internal structure of the Company that: (i) guarantees continuity of supervisory activities; (ii) ensures that the Model is implemented and is constantly updated; and (iii) performs no operational tasks that could impair its ability to objectively assess the Company's activities.

## b. Composition of the Supervisory Body

The composition of the Supervisory Body is decided on by the Board of Directors based on the rules set out in the "Statute of the Supervisory Body" attached to this Model, which it forms an integral part of (see Annex 2 "Statute of the Supervisory Body").

For a definition of the aspects relating to the functioning of the Supervisory Body, see the document titled "Statute of the Supervisory Body" mentioned above.

## 9.1 The System of Information Flows to and from the Supervisory Body

### a. Reporting by the Supervisory Body to the Corporate Bodies

The Supervisory Body reports on the Model's implementation, the activities carried out and the emergence of any critical issues.

Two reporting lines are assigned to the Supervisory Body:

- the first, on an ongoing basis, directly to the President of Chiesi; and
- the second, on a periodic basis, as well as whenever the need and/or opportunity arises, towards the Board of Directors, the Board of Statutory Auditors and the Auditing Firm.

These information flows cover, in particular:

1. the activities carried out by the Supervisory Body, including with the support of the corporate functions; and
2. any critical issues (and suggestions for improvement) that have emerged both in terms of conduct or events internal to the Company, and in terms of the Model's effectiveness. If the Supervisory Body detects any criticalities that regard any of the subjects identified above, the corresponding report is to be addressed promptly to one of the other subjects to whom the reporting lines set out in the list above are addressed.

Each year, the Supervisory Body also submits a written report on the implementation of the Model at the Company to the above persons, which contains:

- (a) a summary analysis of all the activities carried out during the year (indicating in particular the specific checks and verifications performed and their outcome, any updates to the mapping of Sensitive Activities, the status of implementation of the improvement actions underway, etc.); and
- (b) a plan of activities envisaged for the next reporting period, taking into account any critical issues that have arisen and reflecting any need to adapt the Model or procedures.

The Board of Directors and the Chairman of the Board of Directors have the right to convene the Supervisory Body at any time, which, in turn, has the right to request, through the competent Functions or persons, that the above body be convened for urgent reasons.

Meetings with the bodies that the Supervisory Body reports to must be minuted, and copies of the minutes must be maintained by the Supervisory

Body.

#### b. Information flows to the Supervisory Body

Art. 6(2)(d) of Legislative Decree 231/2001 requires that the Model imposes obligations to inform the body responsible for supervising the operation of and compliance with the Model.

The obligation to maintain a structured information flow serves as a tool to ensure supervision of the effectiveness and suitability of the Model and for the possible *ex post* verification of how offences listed under the Decree were able to be committed. It also allows control planning activities of the Supervisory Body to be improved.

The obligation to inform the Supervisory Body applies to: (i) all Board Directors and Employees (through their respective Functional Managers) who work within the Company; and (ii) all persons who do not belong to the Company but who work on its behalf. The duty of disclosure is part of the broader duty of diligence and duty of loyalty of the employee under Arts. 2104 and 2105 of the Civil Code.

Also, a person filing a report is responsible for the truthfulness, authenticity and originality of all documentation and information provided to the Supervisory Body in the performance of the supervisory activity falling within its competence.

Additionally, the Supervisory Body must meet periodically, and at least annually, with the following persons:

- the Chairman of the Board of Directors;
- the Corporate HSE Manager and/or the Prevention and Protection Service Manager (RSPP), with the person in charge of managing the environmental aspects at site level and (if necessary) with the persons in charge of verifying the compliance of the activities referred to in the safety and environmental procedures;
- the Supervisory Bodies of the Group Companies (e.g., Chiesi Italia and Unikeris Ltd.) and, depending on the case, a relevant corporate representative (e.g., a member of the Board of Directors and process owners) in order to collect and exchange information on the performance of activities;
- the Board of Auditors;
- auditors;
- the person responsible for managing the system of procedures;
- the Chief Compliance Officer; and
- the Anti-Bribery Compliance Function of the Company.

The above meetings may be held in person or by any other suitable means defined by the Supervisory Body (e.g., acquisition of periodic reports).

The Supervisory Body, as well as any persons whose services the Supervisory Body uses, are obliged not to disclose the news and information acquired in the performance of its functions, ensuring their confidentiality and refraining from seeking and using them for purposes other than

those indicated in Art. 6 of Legislative Decree 231/2001. In any case, all information held by the Body is processed in compliance with the legislation in force on the subject and, in particular, in accordance with Italian and Community legislation on the protection of personal data. Breach of these obligations amounts to just cause for removal from office.

Any information collected and any report received or prepared by the Supervisory Body must be maintained for 10 years in a special file maintained by the Supervisory Body in hard copy or electronic format that access is permitted to only by the structure of the Body.

Communication flows to the Supervisory Body are divided into:

- Event-driven flows; and
- Periodic flows.

### b.1 Event-driven information flows

Event-driven flows must be made in written form through the MESA – Procomp platform; to the Supervisory Body's mailbox: [odvchiesifarmaceutici@chiesi.com](mailto:odvchiesifarmaceutici@chiesi.com); or in any other way considered appropriate by the Supervisory Body. This must be done following any anomalous or unusual events that relate to the implementation of the Model and the company procedures referred to in the Model that relate to any Sensitive Activities that could be considered useful for the performance of the Supervisory Body's duties.

More specifically, for example, we stress the importance of the following communications:

1. any relevant enactment, modification and/or integration of the Company's corporate organisational system and/or corporate structure (extraordinary transactions, etc.), such as modifications and variations to the system of delegated and proxy powers conferred in a way that affects the mapping of Sensitive Activities and the risk assessments associated with corporate processes, the organisational chart, etc;
2. requests for legal assistance made by any Employees who are being prosecuted for an offence under the Decree;
3. results of any first-level controls provided for under the Company's procedures adopted by the Process Owners and/or of the controls carried out on the Processes referred to in the Special Sections (to implement the Model) downstream of which Recommendations were found that were not closed within the agreed timeframe, or Non-conformities;
4. outcomes of investigations (internal and external, including inspections by the Public Authorities which are competent for the concerned Process) that have resulted in: (i) Recommendations that have not been concluded by the agreed deadlines; (ii) Non-conformities; or (iii) penalties;
5. outcomes of audits conducted by external certification bodies for the issue/renewal of certifications relevant to Legislative Decree 231/2001 (e.g., ISO 37001, 14001, 45001 and 27001);
6. measures and/or news coming from judicial police bodies, or from any other authority, that indicates that investigations or proceedings are being carried out (incl. against unknown persons) for offences listed under Legislative Decree 231/2001 and that these investigations



involve the Company or its Employees, Corporate Bodies, Collaborators, Consultants, Partners, and Suppliers, as well as controlled Group companies;

7. any communications from the Board of Statutory Auditors concerning anomalies/criticalities encountered when assessing and controlling the adequacy of the Company's organisational structure and internal control system;
8. any communications from the external auditing firm concerning shortcomings in the system of internal controls, observations on the financial statements and/or reprehensible facts; and
9. (extracts of) Board of Directors resolutions concerning financial/corporate transactions that involve the Company (incl. non-finalised transactions and cross-border or domestic acquisitions, mergers and demergers).

In addition to the above event-driven information flows, the Special Sections of this Model identify the additional circumstances that determine the obligation to send event-driven communication flows to the Supervisory Body.

The Supervisory Body may, however, independently request further periodical information or news concerning specific situations from any corporate Function or structure. The corporate Functions are responsible for ensuring that all documentation relating to information sent to the Supervisory Body remains available.

The Global Compliance and Global Internal Auditing Functions (for their respective areas of competence) provide the Supervisory Body with all necessary support for defining, collecting, managing and analysing information flows (incl. supervising and coordinating the forwarding of these flows by the corporate Functions).

If any of the above persons breach the disclosure obligations referred to in this paragraph, a disciplinary measure must be applied to them. This will vary depending on the seriousness of the breach of the above obligations and must be proposed by the Supervisory Body and defined in accordance with the rules set out in section 8 of this Model.

## b.2 Periodic information flows

In addition to the above event-driven information, all the Functions of the Company – including the Functions outsourced to other Group companies identified in the individual Special Sections of this Model – must send to the Supervisory Body all information acquired as part of the control activities put in place to implement the Model and that are useful for ensuring that the Supervisory Body is provided with effective information for the purposes of its supervisory activities.

Without prejudice to the possibility for the Body to identify additional periodic reporting flows, the information and documentation to be transmitted and/or made available to the Supervisory Body (with the relevant deadlines and information channels to be used) as well as the responsible Functions are identified – for each Sensitive Activity – in the relevant Special Sections.

The information flows referred to in this paragraph must be sent through the Supervisory Body's email box: [odvchiesifarmaceutici@chiesi.com](mailto:odvchiesifarmaceutici@chiesi.com), or through the MESA – Procomp platform, or in any other way considered appropriate by the Supervisory Body. In this communication, the

responsible person must also include a conclusive assessment on the progress of activities and on whether conduct and/or operations in violation of the Model have been detected.

## 9.2 Reporting conduct relevant to the Model

In addition to the information flow system outlined above, which is imperative, anyone who becomes aware, by reason of the functions performed, of unlawful conduct relevant under the Decree or of any violation of this Model is required to immediately report it through SpeakUp&BeHeard. If any reports are unfounded, or made with malice or gross negligence, the measures set out in the Disciplinary System (Annex 3) are applied.

SpeakUp&BeHeard is the communication and reporting management system adopted by Chiesi. This system comprises a web platform (which resides outside the Group's IT system because it is hosted on an independent server) and a voice mailbox. These can be accessed by anyone who wishes to file a report and by any Group company. This system is structured in a way that uses digital methods to guarantee: (i) the highest levels of confidentiality regarding the identity of the person filing the report and the person reported (without prejudice to legal obligations and the protection of the rights of the Company and persons wrongly accused and/or in bad faith); and (ii) confidentiality, security, non-traceability and integrity of the data relating to the report. In the case of reports made in different ways, the Company cannot guarantee the same levels of protection. More specifically, if the report is made by email, anonymity might not be guaranteed.

The process of transmission and management of reports, as well as the roles and responsibilities of those involved in the process, are defined within the SOP 'Use and Management of SpeakUp&BeHeard'.

Coordination between the Global Compliance Function – the body entrusted with the receipt and management of reports made through SpeakUp&BeHeard – and the Supervisory Body is ensured by the participation of the Chief Compliance Officer within the Supervisory Body: if conduct potentially relevant to the application of the Model is reported through SpeakUp&BeHeard, the Global Compliance Function (as the reports' manager) informs the Supervisory Body at any stage of the reporting management process, according to the information flow defined in the SOP.

Additionally, the Global Compliance Function sends the Supervisory Body (as an information flow) all reports that it has prepared – in accordance with the SOP governing reports received and managed through SpeakUp&BeHeard – if these have an impact on the Model or the Decree.

In any case, the Company verifies and ensures that whistleblowers are subject to no form of direct or indirect retaliation, discrimination or penalisation for reasons directly or indirectly connected to the report. More specifically, no individuals may be subjected to any of the retaliatory actions under Art. 17 of Decree 24/23 (such as dismissal, suspension, downgrading, non-promotion, reduction in salary, change of function/place or working hours, negative merit notes, coercion, intimidation, discrimination or in any case unfavourable treatment). This is without prejudice to the application of the measures under the Disciplinary System (Annex 3) that are deployed against individuals who file reports: (i) that are unfounded; or (ii) with malice or serious misconduct.

Adequate information about the existence, methods of use and management of reports – as well as the rights of whistleblowers – is provided based on Decree 24/23, and particularly through: the Company's intranet (C-Share), the Company's website ([www.chiesi.com](http://www.chiesi.com)), and the workplace display.

#### a. Disciplinary measures

With regard to the disciplinary measures to be adopted following the assessment phase of the reports, the area of responsibility of Human Resources remains unchanged. Following the outcome of the investigations carried out on the reports received, penalty procedures under the Model's Disciplinary System may be initiated against the following individuals, in accordance with the corporate procedures in force and with the involvement of the competent corporate Functions:

- any person who is held responsible for the reported fact;
- any person who: (i) breaches any measures that are designed to protect the reporting party, any persons involved or any persons mentioned in the report under Art. 12 of Decree 24/23; (ii) takes retaliatory action against the reporting party (and/or any other persons referred to in Art. 3(5) of Decree 24/23)<sup>6</sup> for reasons directly or indirectly connected with the report; or (iii) obstructs or attempts to obstruct the report; and
- any person who maliciously, or with gross negligence, files a report that is unfounded.

Whistleblowers who believe they have suffered retaliatory conduct because of a previous assessment may file a new report on the retaliation suffered. The timely performance of the related investigations by the competent Functions, with the support of the Functions concerned by the reported facts, is guaranteed.

---

<sup>6</sup> Under Art. 3(5) of Decree 24/23, the measures to protect against retaliatory acts set out in Decree 24/23 apply to: (i) whistleblowers (i.e., persons both internal and external to the company and linked to it by an employment and/or collaboration relationship, as defined in Art. 3 of Decree 24/23); (ii) the facilitators of whistleblowers; (iii) people in the same work environment as the whistleblower and linked to him/her by a stable emotional or kinship relationship up to the fourth degree; (iv) colleagues of the whistleblower who work in the same work environment as the whistleblower and have a habitual and current relationship with him/her; and (v) entities owned by the whistleblower or for which the whistleblower works, as well as entities operating in the same work environment as the whistleblower.

## 10. INTERNAL INVESTIGATIONS

The Company must react in an appropriate way: (i) to any news of criminal investigations or the pending or probable initiation of legal proceedings – such as, in particular, proceedings relating to Predicate Offences – by Italian, foreign or international authorities concerning alleged offences attributed to: (a) Chiesi; (b) its subsidiaries or affiliated companies; (c) members of the corporate bodies of Chiesi or its subsidiaries or affiliated companies; and/or (d) Employees or Collaborators of Chiesi or its subsidiaries or affiliated companies; and (ii) in the event of the emergence, also following internal audits and controls or reports received, of signs of violations of the Model or the possible commission of conduct that Chiesi or its subsidiaries or affiliated companies could be liable for and/or that could damage their reputation.

In these situations, the Company's appropriate reaction could involve carrying out internal investigations.

The need to conduct internal investigations must be assessed against the principles of this Model, as well as against the Company's corporate governance rules.

In the context of this assessment, the newly introduced para. 5-bis of Art. 25 of the Decree must also be taken into account. This envisages a bonus treatment if, before the first-instance decision, the entity has effectively taken steps to: (i) prevent the criminal activity from being carried out to further consequences; (ii) ensure the evidence of the offences and the identification of the perpetrators; or (iii) seize amounts or other benefits transferred, and has eliminated the organisational deficiencies that led to the offence.

Any internal investigations must be aimed at:

- internal or 'restorative' purposes, e.g., to:
  - ensure that the competent bodies have adequate knowledge of the relevant facts;
  - prevent any misconduct or violations from being repeated and/or having further effects;
  - verify the effectiveness of the Model and identify possible improvement actions; or
  - verify the prerequisites for the initiation of possible disciplinary proceedings;
- external or 'procedural' purposes, e.g., to:
  - search for and gather evidence for defence purposes or with a view to possible civil or criminal proceedings; or
  - engage in remedial conduct related to the Decree and other applicable rules.

Therefore, in the cases mentioned at the beginning of this paragraph, Chiesi must carry out a preliminary assessment or preliminary investigation of the facts in question. Following this, if the conditions are met and if it is feasible, Chiesi must also consider the concrete circumstances in compliance with the principles of reasonableness and proportionality and must assess whether to conduct an internal investigation.

If Chiesi considers it necessary to conduct an internal investigation:

- the conduct of internal investigations may be entrusted to the Supervisory Body. In this case it will assume a coordinating and supervisory role and use a corporate Function or a combination of Functions with the above requirements and/or external consultants to carry out investigations;
- appropriate powers and resources must be allocated to the persons entrusted with carrying out the investigations. This performance may be entrusted to a corporate Function – or a combination of corporate Functions – that remains independent and is not involved in any business processes (excluding in any case all persons belonging to the Function under investigation) and/or to external consultants specifically appointed for this purpose;
- investigation activities can include collecting, storing and analysing company data and information, in paper or electronic format, and conducting interviews with employees;
- in any event, the investigation activity must be carried out in a way that amounts to no possible interference with the investigations in progress by the competent authorities and remains in compliance with the limits imposed by the applicable legislation on the secrecy of investigations carried out by these authorities;
- adequate information flows must be ensured and, in particular, the status and results of the internal investigation must in any event be communicated by the persons in charge of carrying out the relevant activities to the Company's competent bodies;
- all investigations must be carried out confidentially, guaranteeing the confidentiality of their results, without prejudice to legal obligations and those arising from orders by the competent authorities;
- if the internal investigation confirms the existence of offences or violations of the Model, the Company must take all consequent measures considered appropriate, which can include the following, depending on the concrete circumstances:
  - disciplinary proceedings filed against the personnel involved and the possible deployment of disciplinary penalties;
  - punitive measures against the business partners involved, such as, depending on the provisions of the relevant contracts, the application of a penalty, termination of the contract or withdrawal from the contract;
  - corrective actions within the meaning of the Decree; or
  - revisions and updates to the Model.

Investigations must be conducted in a way that identifies and collects only relevant material in a way that reduces any processing of personal data to the minimum extent necessary. This must be done in compliance with the principle of minimisation in the collection of personal data and, in any case, in full compliance with company procedures (including the SOP on the use of electronic devices).

For the purposes of its assessments regarding possible internal investigations and measures to be taken following these investigations, it must take into account applicable laws, confidentiality requirements, the protection of all persons involved, security, potential criminal, civil and administrative liability, labour laws and potential financial losses.

With regard to any offences or violations concerning Subsidiaries and associateddc, the autonomy, duties and responsibilities of the respective corporate and supervisory bodies of these companies remain unaffected and unaffected.

## 11. THE CONTROLS

With this Model, the Company intended to implement an updated system of internal controls centred on the principles indicated below and required by the Confindustria Guidelines.

The controls aimed at preventing the risk of the offences listed under Legislative Decree 231/2001 from being committed are structured over two control levels: (1) Horizontal control measures are general control measures that apply to the specific Processes that the Company's business is divided into; and (2) Vertical control measures are specific to the different Processes and Company activities. The degree of control that the Company decides to implement for each activity at risk is connected – in addition to a cost-benefit assessment – to the risk threshold considered acceptable by the Company itself for that specific activity.

### 11.1 Horizontal control measures

The control principles that need to be ensured in all risk activities that emerge from the mapping, as well as in all Processes, are as follows:

- (a) Code of Conduct: the adoption of a Code of Conduct as a useful governance tool is an essential element of the preventive control system. Every business must promote a high standard of professionalism and prohibit conduct that conflicts with legal provisions and ethical and deontological values.
- (b) Sufficiently up-to-date, formalised and clear organisational system: this standard concerns the allocation of decision-making responsibilities and the introduction of hierarchical reporting lines in a way that remains commensurate with the degree of responsibility and authority conferred. The organisational system needs to focus attention on employee reward systems, which are necessary for directing the activities of operational and managerial staff towards the goal of achieving corporate objectives. However, if these are based on manifestly unmotivated and unattainable performance targets, they could amount to a veiled incentive to commit some of the offences envisaged under the Decree (see Special Section "Human Resources").
- (c) Policies and Guidelines: this is based on policies and guidelines that set general principles of conduct. More specifically, policies, on the one hand, represent the Company's vision and mission, are global in nature and are implemented (also locally) through specific procedures. The Guidelines, on the other hand, may also have a local character but contain no elements that are linked to operations and describe Chiesi's standards, minimum requirements and the Company's strategies.
- (d) System of delegated and proxy powers: in principle, the system of delegated and proxy powers needs to: (i) be characterised by elements of "security" for the purposes of preventing Offences (traceability and highlighting of Sensitive Activities); and, at the same time (ii) allow the company's business to be managed efficiently. Delegation is understood as an internal act of attribution of functions and tasks. Power of attorney means unilateral legal powers that the Company assigns to an individual to represent the company in relations with third parties. The holders of a corporate function who need powers of representation to perform their duties are granted a "power of attorney" to the appropriate extent that remains consistent with the functions and management powers attributed to the holder through the "proxy". The System of Delegations and Powers of Attorney give specific powers to clearly identified persons, including – in some cases – the power to represent the company in relations with third parties (public or private). With the support of the GLCA Function, the System of Powers of Attorney and Proxies: (i) remain updated in accordance with all organisational changes (e.g., hirings, terminations and changes in



organisational structures) that could impact it; and (ii) is adequate and consistent with the role and management powers of the persons that the powers of attorney and proxies are attributed to.

Authorisation and signatory powers must be defined (also with the aid of IT tools, such as SAP), correctly assigned and communicated, providing – when required – for a precise indication of the approval thresholds for expenditure in a way that gives no individual unlimited discretionary powers.

- (e) **Roles and responsibilities**: the roles, tasks and responsibilities of each corporate function involved in risk activities must be defined. In particular, the Company identifies the corporate persons in charge of representing the company and of making binding decisions towards it by granting appropriate powers of attorney, respectively.
- (f) **Segregation of Functions**: Process Owners must ensure compliance with the principle of separation of roles in the management of Processes and assign different individuals with the phases that they cover, particularly regarding decision-making, authorisations, executions and control.
- (g) **Document traceability, archiving and preservation**: the document traceability of each relevant step of the process must be ensured, as well as the correct and documented archiving, preservation and verifiability of the related documentation in relation to each process, operation or transaction. To this end, traceability of the activity must be ensured through adequate documentary support that controls can be carried out on at any time. It is therefore appropriate that, for each transaction, it is easy to identify which individuals: (i) authorised the transaction; (ii) materially carried it out; (iii) recorded it; and (iv) carried out a check on it. The traceability of transactions is ensured with a higher level of certainty by using computer systems capable of managing the transaction, which ensures compliance with the above requirements. It is also necessary to ensure the documentability of the controls performed. To this end, the procedures with which the controls are implemented must guarantee the possibility of retracing the control activities carried out, so as to allow an assessment of the consistency of the methodologies adopted (self assessment, sample surveys, etc.) and the correctness of the results that emerged (e.g., audit reports).
- (h) **Controls and monitoring**: verification activities (periodic or ad hoc) are performed on each Process and performance of activities are monitored to ensure they remain compliant with the Model (also in coordination between different corporate Functions) and the deadlines set for performing individual activities (where applicable).
- (i) **Contractual clauses**: specific clauses must be included in the contracts that regulate the performance of Sensitive Activities in order to protect Chiesi from conduct by its contractual counterparts that breaches the Model and the company's procedures that implement it. These clauses must include: (i) a declaration by the counterparty that it is aware of and undertakes to respect the principles of the Anti-Bribery Policy and the Code of Interdependence for Suppliers adopted by the Company; (ii) the Company's right to terminate the respective contract if the other party breaches any of these obligations; and (iii) a reference to any other relevant clauses under the Model (e.g., clauses on the protection of health and safety in the workplace for contracting agreements with risk of interference in work). The GLCA Function is responsible for drafting and updating: (i) contract templates (which are also validated by using IT tools); and (ii) procedures on managing contractual tools.
- (j) **Information flows**: the standard requires each Process Owner of the Sensitive Activity/Process considered from time to time to provide the Body with all relevant information on the specific Activity/Process. This particularly includes all possible knowledge of situations in which



the Sensitive Activity/Process was performed in violation of the corporate guidelines or procedures in force. It also requires: (i) the preparation and updating of periodic summary reports containing relevant information on the Sensitive Activity/Process considered from time to time; as well as (ii) the provision of periodic meetings with the individual Function Managers and with the staff dedicated to the performance of Sensitive Activities.

- (k) **Financial resources management system:** financial management is supported by structured expenditure authorisation processes and dedicated IT tools, set up on workflows consistent with formally defined spending powers and organisational roles (see Special Section 'Administration and Finance').

These systems and processes are inspired by the principles of:

- segregation of duties (the person requesting the expenditure is different from the person authorising it, which is different from the person who materially makes the payment and records it);
- traceability of all financial movements and reconciliation of them with the administrative-accounting system;
- identification of the rationale of the expenditure to be incurred;
- provision of standard forms of payment; and
- identification of the recipients of the flows.

- (l) **Tax Control Framework:** the Company has adopted a TCF, understood as the set of tools, organisational structures, standards and corporate rules that allows – through an adequate process of identification, measurement, management and monitoring of the main tax risks – the company to be managed in a way that minimises the risk of operating in violation of tax regulations or the principles or purposes of the law. The existence of such an instrument requires strict monitoring of the operation and effectiveness of the internal control system in relation to tax management. The Company's TCF has also been judged positively by the Italian Revenue Agency upon admission to the "collaborative compliance" regime (established by Legislative Decree No. 128 of 5 August 2015, under the heading "Provisions on legal certainty in relations between tax authorities and taxpayers, in implementation of Art.s 5, 6 and 8, paragraph 2, of Law No. 23 of 11 March 2014").

As defined in the tax strategy, in accordance with the best international standards on TCF, the framework adopted by the Company is also characterised by:

- **Adaptability to the internal and external environment:** tax risk management processes ensure that the TCF adapts to major changes that affect the business, including changes in tax legislation; and
- **Reporting Flows:** the TCF provides for the preparation, at least once a year, of a summary report with the results of the Tax Risk Management activities carried out, which is addressed to the Management Bodies and a system of information flows to the other Control Functions identified within the TCM (e.g., the Tax Risk Control Committee) as well as to the Supervisory Body in accordance

with the procedures described in the above document.

The adoption of the TCF therefore amounts to an effective tax risk management tool also for the purposes of compliance with the Decree, and, for this reason, the Company manages its coordination and integration with the system of controls dictated by the Model.

- (m) Safeguards aimed at preventing the risk of the Company being involved in an offence committed by one of the Group companies: this safeguard is designed to ensure:
- the independent preparation and revision of its own Model by each Group company subject to the provisions of the Decree;
  - the specific analysis, when drafting the Model, of the activities and processes outsourced by other Group companies;
  - the appointment of an autonomous Supervisory Body by each Group company subject to the provisions of the Decree, possibly with different members, for each Group company, and with possible forms of coordination between the different bodies, but never with the hierarchical predominance of the parent company;
  - evidence of integrated processes involving the activities of several Group companies, as well as activities intended to be merged into a single outcome (e.g., consolidated financial statements) in the parent company model;
  - the performance of management and coordination activities through communications in official form; and
  - the performance of audits by the Company on the activities carried out by other Group companies.
- (n) Communication to and training of personnel: communication must concern the Model, authorisation powers, hierarchical reporting lines, procedures, information flows and everything that contributes to transparency in daily operations. Communication must be widespread, effective, authoritative (i.e., issued from an appropriate level), clear and detailed, and periodically repeated. Also, access to and consultation of the documentation constituting the Model must also be allowed through the corporate intranet. An adequate training programme must also be developed that illustrates the recipients, the content of the training courses, the frequency, the delivery methods, the compulsory nature of participation in the courses, the frequency and quality controls on the content of the programmes, and the systematic updating of the content of the training events in view of the updating of the Model.
- (o) Analyses and supporting information: this refers to analyses and supporting information prepared to summarise with accuracy and precision the summary/actual data relating to the performance of a given business activity and requires that this data be examined and verified in advance by a manager with the necessary skills and qualifications in order to intercept any errors in good time (e.g., SAP extractions, final balances drawn up at the end of specific projects and summary data of clinical studies).
- (p) Certification of performance: documentation on the activities performed for the Company by all third parties involved in the Sensitive Activity from time to time.
- (q) Integrated control systems: the control requires that all operational risks must be considered, particularly those relating to offences that could be committed, in order to provide timely warning of the existence and emergence of general and/or particular critical situations. Appropriate indicators (KPIs) must be defined for the individual types of risk detected, and internal Risk Assessment processes must be defined for the individual corporate functions.

- (r) Controls relating to Sensitive Activities entrusted, in whole or in part, to third parties: if any of the Sensitive Activities are fully or partially entrusted to third parties, the control requires, among other things: (i) a contractual clause to be included that requires the respective third parties to certify that they are aware of and undertake to comply, when carrying out activities on behalf of the company, with the principles in the Supplier Code of Interdependence and the Anti-Bribery Policy; (ii) the company that provides the service to guarantee the truthfulness and completeness of all documentation and information communicated; (iii) the Global Internal Auditing Department to request all information from the company providing the service that it needs to verify its correct performance, where possible; and (iv) the Company to terminate the contracts in question if these obligations are breached.
- (s) SpeakUp&BeHeard: with Law No. 179 of 30 November 2017 (“Provisions for the protection of the authors of reports of offences or irregularities that they have become aware of in the context of a public or private employment relationship”), the Decree introduced the system for regulating and managing reports filed by employees of public and private entities on violations relevant for the purposes of the Decree. This system was amended by Decree 24/23, which: (i) introduced significant innovations concerning the procedures for handling reports (in particular) concerning offences relevant to the Decree or violations of the Model; and (ii) required specific guarantees to protect the identities of the reporter, the reported person and the information communicated through the report, as well as measures to protect the reporter (and the additional persons specified in Decree 24/23)<sup>7</sup> from retaliatory acts.

Chiesi, as early as 2016, equipped itself with a telematic system called Confidential Reporting System (“CRS”), through which all Employees could file reports on violations of the Model, the Decree, the Anti-Bribery Policy and the criminal laws applicable to the Company.

The CRS (defined with the support of a qualified external consultant) was updated in 2022 (with the new name ‘SpeakUp&BeHeard’) and in 2023, following the entry into force of Decree 24/23, in order to: (i) make it a system accessible not only to Employees but to anyone (both internal and external to the Company) who chooses to file a report; (ii) guarantee continuous dialogue between the reports’ manager and the reporting party; and (iii) provide for a system for managing reports at a local level, for Group companies with a Compliance Function, and at a centralised level (with management by the Global Compliance Function) for all reports concerning other Group companies and Chiesi.

The System comprises, in particular:

- of a web platform – accessible via the link [ch-speakupandbeheard.com](http://ch-speakupandbeheard.com) – and a dedicated Chiesi voicemail with which whistleblowers can register their report or request an appointment with the reports’ manager; and
- an SOP regulating its operation (“Use and Management of SpeakUp&BeHeard”), which forms an integral part of this Model (Annex 4).

The Global Compliance Function was entrusted with the management of the reports because it meets the autonomy and professional requirements of Decree 24/23.

---

<sup>7</sup> See footnote 5.

The system is in line with the requirements of Decree 24/23 and the Confindustria Guidelines and is structured in a way that: (i) guarantees the highest standards of protection of the identity of the reporter and the confidentiality of the information communicated; and (ii) provides for clear measures to protect the reporter from possible retaliatory and discriminatory acts. To this end, the SOP governing its operation defines:

- i. the general principles governing the operation of SpeakUp&BeHeard;
  - ii. the type of violations that can be reported through SpeakUp&BeHeard;
  - iii. the persons who can make the report;
  - iv. how to access SpeakUp&BeHeard;
  - v. assessment steps by the Global Compliance Function;
  - vi. reporting to the Supervisory Body; and
  - vii. the involvement of HR for the purposes of taking disciplinary measures in the event of the reported breach being established.
- (t) **Anti-Bribery Policy and ISO 37001:2016 certification**: the Anti-Bribery Policy provides top management and subordinates of the Company – and anyone acting on behalf of the Company and/or for the Company – with a set of general principles on how to recognise and handle bribery-related issues and how to comply with the relevant legislation. The Policy was last updated in 2023 in order to integrate it with the appropriate references to the Anti-bribery Compliance Function and the Anti-bribery Management System adopted by Chiesi and certified according to the ISO 37001:2016 standard (“Anti-bribery Management Systems”); and
- (u) **UNI EN ISO IEC 27001:2017 certification**: the Company obtained UNI EN ISO IEC 27001:2017 certification for the ‘Information Security Management System’.

## 11.2 Vertical controls

In addition to the horizontal control measures described above, each Special Sections of the Model sets out specific rules of conduct aimed at regulating the specific aspects of each of the Sensitive Activities included in each Process.

Additionally, for the purposes of controlling the risk of offences whose commission is identified as being reasonably foreseeable in relation to each Process in the Risk Assessment, the internal organisational tools (i.e., procedures, SOPs and operating instructions) are also of particular importance, which, in relation to the Sensitive Activities considered from time to time, identify the roles and responsibilities of the various figures involved and define the relevant controls in detail.

The Supervisory Body is responsible for assessing and deciding on cases in which a conflict arises between the Model and any other procedural instrument adopted by the Company.

Each Recipient is required to read the relevant Special Section if it is in any way involved in the Process, even if not directly as Process Owners.

## REVISIONS TO THE ORGANISATION, MANAGEMENT AND CONTROL MODEL

N. REV.	DATE	REVISION RATIONALE	RA UPDATE
0	28/02/2003	-	-
Rev. 1	18/12/2006	New offences in Legislative Decree 231/2001 Reorganisation or new business processes	Yes
Rev. 2	12/12/2008	New offences in Legislative Decree 231/2001	Yes
Rev. 3	23/07/2010	New offences in Legislative Decree 231/2001	Yes
Rev. 4	22/07/2013	New offences in Legislative Decree 231/2001 Reorganisation or new business processes	Yes
Rev. 5	22/12/2015	New offences in Legislative Decree 231/2001 Reorganisation or new business processes	Yes
Rev. 6	27/02/2018	New offences in Legislative Decree 231/2001 Reorganisation or new business processes	Yes
Rev. 7	22/12/2020	New offences in Legislative Decree 231/2001 Reorganisation or new business processes	Yes
Rev. 8	15/12/2022	New offences in Legislative Decree 231/2001 Confindustria Guidelines 2021	No, only assessment of relevance of new offences
Rev. 9	25/07/2023	Alignment of the General Section and the Disciplinary System with the provisions on the management of reports contained in Legislative Decree no. 24/2023	No
Rev. 10	19/07/2024	New offences in Legislative Decree 231/2001	No, only assessment of relevance

		Reorganisation of business processes and structures Review of information flows Disciplinary System Update Integration with Risk Assessment 37001	of new offences
--	--	--	-----------------

## ATTACHMENTS

- ANNEX 1 Methodology Risk Assessment
- ANNEX 2 Statute of the Supervisory Body of Chiesi Farmaceutici S.p.A. pursuant to Legislative Decree 231/2001
- ANNEX 3 Disciplinary system adopted in line with the Organisation, Management and Control Model by Chiesi Farmaceutici S.p.A.
- ANNEX 4 SOP 'Use and Management of SpeakUp&BeHeard'