

Novartis Vaccines and Diagnostics Srl
Organisation, Management and Control Manual
Statutory Decree 231/2001

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INTRODUCTION: THE MANUAL STRUCTURE

The manual consist of a series of interlinked and organised documents that may be recorded as a single body.

The interlinking of a “central” document and a series of annexes meets the requirements for more efficient updating (the various documents can be updated individually, each will be identified by an edition number that will allow them to be traced) and protection for the confidentiality of certain of them (e.g. the detailed risk statements per job which will be distributed only to those responsible for them and to the corporate organisations and the Board). The manual breaks down as follows in detail:

- Descriptive part; second edition, contains a general part and several special parts (A, B, C)
- Annex “A”; Schedule of Risks – second edition. Consisting of a text and diagram for each job associated with sensitive activities. Distributed to heads of department.
- Annex “B”; List of guidelines and procedures (“Protocols”). The internal rules and provisions are listed that the company has adopted to prevent or rapidly discover the existence of crime “231” circumstances.
- Annex “C”; Code of Conduct for companies of the Novartis Group
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Organisation, management and control model

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GENERAL PART

CHAPTER 1: THE STATUTORY DECREE OF 8 JUNE 2001, No. 231: GENERAL DETAILS

The Statutory Decree of 8 June 2001, No. 231 (hereinafter briefly called “the Decree”) introduced a particular form of liability within our system, nominally administrative but essentially of a criminal or semi-criminal nature imposed on organisations, companies and associations, even those without legal personality.

According to these rules, organisations may be considered directly liable, and consequently sanctioned, for certain crimes, attempted or committed by directors or staff in the interests or to the advantage of the organisation concerned.

The liability of the organisation is added to that of the private person essentially responsible for the crime, without substitution.

By Statutory Decree No. 231 of 8 June 2001 headed “Rules for the administrative responsibility of legal persons, companies and associations, including those without legal personality” (hereinafter called “the Decree”), issued following the instructions contained in Art. 11 of the Act of 29 September 2000, No. 300, it was decided to adjust the internal rules concerning the liability of legal persons to the International Conventions that Italy adopted some time ago, such as

- The **Brussels Convention of 26 July 1995** concerning protection of financial interests of the European Community;
- The **Convention of 26 May 1997**, also signed in Brussels, concerning the fight against corruption in which officers of the European Community or of Member States are concerned and
- The **OECD Convention of 17 December 1997**, concerning the fight against corruption amongst foreign public officials in economic and international operations.

Art. 5 (1) of the Decree introduced a system of administrative liability into the Italian legal system (essentially concerning criminal liability) imposed on organisations (which means companies, associations, consortiums, etc., hereinafter called “organisations”) when certain organisational requirements apply that may be summarised in the following points:

- a) the organisation must be included in the category to which the Decree applies;
- b) when a crime has been committed included amongst those listed in the said Decree, in the interests or to the advantage of the organisation;
- c) the person committing the crime must be a senior employee of the organisation or a person hierarchically or operationally answerable to the latter;
- d) failure by the organisation to adopt or implement an organisational model suitable to prevent the committing of crimes of the type that has occurred;
- e) as an alternative to the above point, only where the crime is committed by a senior person, also the failure to assign independent powers of initiative and control to an appropriate body within the organisation (or insufficient supervision on the part of the latter).

It follows from the combination of all these conditions that the organisation is subject to sanctions of varied nature, having in common a particularly serious nature, which include amongst those of particular importance financial and prohibitive sanctions, in various forms (up to forced termination of business).

The circumstances to which the Decree attributes the particular form of criminal liability requires the simultaneous existence of a whole series of **positive elements** (a combination of which is therefore necessary) and the associated absence of certain **negative elements** (whose possible existence may in turn imply exemption).

1.1 Positive elements of the circumstances

With regard to the positive elements, it should be noted first of all that the Decree applies to **any company or association, including those without legal personality, and any other organisation possessing legal personality**, except for the State and organisations discharging constitutional functions, the territorial public bodies, and other non-economic public organisations.

This being so, the liability as laid down by the Decree on the organisation is involved if a crime has been committed that:

- a) falls amongst those indicated by the Decree in the appropriate list (briefly called a **crime**);
- b) has been committed also or exclusively in the **interests or to the advantage of the organisation**, unless in the latter case the Crime was committed in the exclusive interests of the guilty person or of third parties;
- c) has been committed by a **private person**:
 - 1) **in a senior position** (or a private person who discharged his duties of representation, administration or directing of the organisation or of one of its

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organisational units possessing financial and operational independence or by a private person undertaking, also de facto, management and control of the organisation concerned); or

- 2) **subordinate persons** (or a person answerable to the management or supervised by a Senior Person).

In the case of a crime committed by a subordinate person, the combination of each of the above circumstances will be subject to a specific burden of proof which must be discharged by the Public Prosecutor; on the other hand, in the case of a crime committed by a senior person, the combination of each of the conditions referred to in items (d) and (e) will be the subject of simple presumption (*juris tantum*), made subject to the rights of the organisation to provide proof to the contrary (i.e. reversal of the burden of proof).

1.1.1 The circumstances of crime

The circumstances of crime relevant for the purposes of the Decree and subsequent additions thereto fall within the following categories:

Crimes against the Public Authorities (Art. 24; Art. 25)
Embezzlement from the state
Improper receipt of matters issued to the detriment of the State
Fraud to the detriment of the State or other public bodies
Aggravated fraud in connection with the public issue of matters
Data fraud to the detriment of the State or a public body
Extortion, corruption or instigation towards corruption concerning an official act ¹
Corruption and instigation to corruption through an act contrary to official duties
Corruption in legal acts

The crimes of forgery (Art. 25a)
Forgery of the currency
Alteration of the currency
Counterfeiting of watermarked paper
Production or holding of watermarks, etc.
Distribution of forged currency received in good faith
Use in good faith of forged notes
Forgery of stamp duties

¹ The sanctions for the crimes of corruption and extortion applied to the organisation even if they were committed by (or against) any of the following subjects:

- a) Members of the Commission of the European Communities, the European Parliament, the Court of Justice and the Court of Accounts of the European Communities;
- b) Officers or agents employed under contract in the position of servants of the European Communities or under the scheme applicable to agents of the European Communities;
- c) Persons instructed by member states or by any public or private body within the European Communities who discharge duties corresponding to those of officers or agents of the European Communities;
- d) Members or employees of organisations formed on the basis of the Treaties establishing the European Communities;
- e) Those who within the scope of other member states of the European Union discharge duties and similar activities to those of public officers and those entrusted with a public service.

The persons referred to above are regarded as similar to public officers if they discharge similar duties and as instructed by a public service in other cases.

Corporate crimes (Art. 25 b)

Communication of false company details (crime)
Communication of false company details (misdemeanour)
Falsity in prospectus (crime)
Falsity in prospectus (misdemeanour)
Falsity in reports or communications by audit companies (crime)
Falsity in reports or communications by audit companies (misdemeanour)
Obstruction of an audit
Fictitious formation of capital
Improper refunding of contributions
Illegal distribution of profits and reserves
Unlawful operations concerning shares or shareholdings in the company or the controlling company
Operations to the prejudice of creditors
Improper distribution of the company's assets by liquidators
Unlawful influence on a general meeting
Speculation
Obstruction to the discharge of the duties of the public supervisory authorities

Crimes aimed at terrorism or the upsetting of the democratic order including funding for such purposes (Art. 25 c)

Practices concerning the mutilation of the female genital organs (Art. 25 c (1))

Crimes against the personality of the individual, such as enjoyment of the proceeds from prostitution, pornography for minors, trading in persons and the subjection to or maintaining in slavery (Art. 25 d)

Market abuses (Art. 25 e)

Misuse of privileged information
Manipulation of the market

Culpable homicide and culpable serious or very serious injury committed in breach of the accident-prevention rules and those protecting health and safety at work (Art. 25 f)

Other crimes (Act of 16 March 2006, No. 146)

Complicity to commit a crime, of a simple nature or of mafia type

Complicity aimed at contraband in tobacco worked abroad or unlawful traffic in narcotics or psychotropic substances

Laundering and the use of money, assets or other useful matters of unlawful origin

Trafficking in migrants

Inducing not to make declaration or to make untruthful declarations to the legal authorities.

Personal favouring

In the Special Part we shall proceed to investigate the crimes that might be committed in theory at Novartis such as crimes against the Public Authorities, corporate crimes and crimes committed in breach of the accident prevention regulations and those protecting health and safety at work.

1.1.2 Crimes committed abroad

On the basis of the provisions of article 4² of the Statutory Decree 231/01, the liability as stated in the said Decree also applies to crimes committed abroad, provided that the State of the place where the crime was committed does not proceed against them and that

- the crime was committed abroad by a person operationally associated with the organisation;
- the organisation will be liable only in cases where the law provides that the guilty person – a private person – will be punished at the request of the Ministry of Justice. In such cases, proceedings will take place against the organisation only if the request is made and aimed at the organisation itself.

1.1.3 Sanctions

The sanctions for which the Decree provides against the organisation are:

- a) **financial** sanction;
- b) **prohibitive** sanctions;
- c) **publication of the sentence**;
- d) **confiscation**.

² **Art. 4: Crimes committed abroad** (text: effective from 4.7.2001):

1. In the cases and under the conditions provided by articles 7, 8, 9 and 10 of the Criminal Code, organisations having their principal place of business in the territory of the State will also be liable for crimes committed abroad if the State of the place where the act was committed does not proceed against them.

2. In cases where the law provides for the guilty party to be punished on application by the Minister of Justice, proceedings will be brought against the organisation only if the application is also made against the latter.

The said sanctions will be applied on completion of a set of proceedings.

Prohibitive sanctions may be applied also as a precaution, but never jointly, at the request of the Public Prosecutor to the Court, if both of the following conditions apply:

- a) the existence of **serious indications** that the organisation is liable in terms of the Decree;
- b) the existence of established, specific elements specifically indicating the **risk of unlawful acts being committed of the same nature** as that for which proceedings are brought³.

In imposing precautionary measures, the Court will take account of the specific suitability of each in relation to the nature and degree of the precautionary requirements to be met in a specific case, and the necessary proportion between the extent of the offence and the sanction that it is considered can be finally applied to the organisation.

It is understood that a ban on the conduct of business may be imposed as a precaution only when every other measure proves inadequate.

a) The financial sanction

The financial sanction consists of the payment of a sum of money to the extent laid down in the Decree (so-called “per quota” system), by multiplying the number of quotas decided by the Court on the basis of the seriousness of the offence and the organisation’s liability, in the unit value of the quota fixed on the basis of the economic and asset conditions of the organisation.

b) Prohibitive sanctions

From the aspect of the person sanctioned, it will be noted that in the case of unlawful acts committed, the financial administrative sanction will in each case be applied to the organisation, while prohibitive sanctions are provided only in the case of crimes of some substance or in the case of repeated unlawful acts, given the largely penalising nature of this sanction.

The prohibitive sanctions consist of

1. a **ban**, final or temporary, on the conduct of the business⁴;
2. **suspension or withdrawal** of authorisations, licences or concessions instrumental in committing the unlawful act;
3. a **ban, temporary or final, on contracting with a public authority**⁵, except when obtaining services from a public authority; the exclusion of benefits, funding, contributions or subsidies and the possible withdrawal of those already granted; or a ban, temporary or final, on publicising goods or services.

³ Instead of a precautionary measure, the Court may appoint a Judicial Commissioner for a period equal to that of the measure that would have been applied.

⁴ This implies suspension or withdrawal of authorisations, licences or operational concessions to conduct the business.

⁵ Also limited to certain types of contract or certain authorities.

Temporary prohibitive sanctions apply for a period **of not less than 3 months and not more than 2 years**. The type and duration will be decided by the court in the light of the specific activity to which the organisation's unlawful act relates, on the basis of the economic and asset conditions of the organisation for the purpose of ensuring the effectiveness of the sanction, in the light of the seriousness of the offence, the degree of the organisation's liability and the action taken to eliminate or attenuate the consequences of the offence and to prevent the committing of further unlawful acts, and also taking account of the suitability of the individual sanctions in preventing unlawful acts of the type of that committed.

A final ban on activities will be imposed under the following conditions, provided that the imposition of other prohibitive sanctions proves inadequate:

1. at the discretion of the Court, if the organisation has drawn **profits to a relevant extent** from the crime and has **already been sentenced**, at least three times in the past seven years, a temporary ban on conducting the business;
2. necessarily, also if conditions evidently apply for the application of a prohibitive measure, if the organisation or one of its organisational units is **permanently used** for the sole or predominant purpose of permitting or facilitating the committing of Crimes.

If the basis exists for applying a prohibitive sanction that results in an interruption of the organisation's business, the Court will instead of applying the sanction provide for the business of the organisation to be continued by a **Commissioner** for a period equal to the duration of the prohibitive sanction that would have been applied if at least one of the following conditions applies:

1. the organisation discharges a **public service or a service of public necessity** to suspend which could cause serious harm to the community;
2. the interruption of the organisation's business may, having regard to its size and the economic conditions in the territory where it is located, **have relevant repercussions on employment**.

Profit obtained from the conduct of the business will be confiscated.

An order for the business to be continued by the commissioner will not be made if the interruption in business follows the final application of a prohibitive sanction.

c) Publication of the sentence

The sentence will be published once only, in excerpt or full form, by the office of the clerk of the Court, at the expense of the organisation on the basis indicated in the sentence concerned.

Publication of the sentence may be ordered if a prohibitive sanctions is applied to the organisation.

d) Confiscation

Confiscation (and preventive seizure on a precautionary basis) consists of the enforced acquisition by the State of the price and profit from the Crime except for the part that may be refunded to the victim and subject in all cases to the vested rights of third

parties in good faith. If confiscation cannot be made in kind, it may be the subject of a sum of money, goods or other benefits in value equivalent to the price or profit from the Crime.

1.2 The negative nature of the circumstances

Only when all the positive features mentioned above are combined liability as imposed by the Decree on the organisation will not apply if the Crime has been committed

- I) by a **senior employee**, if the **organisation** proves that:
 - a) the directing organisation has adopted and effectively implemented a **model for organisation and management suitable to prevent Crimes of the kind of that committed** (hereinafter called the “Model”)
 - b) the task of the operation and observance of the Model and to ensure it is updated has been entrusted to a **State body possessing independent powers of initiative and control** (hereinafter briefly called the Supervisory Body or OdV). In small-sized companies, these tasks may be undertaken directly by the directing Organisation.
 - c) persons who have committed the crime have **fraudulently** evaded the organisational and management models;
 - d) supervision by the OdV has not been lacking or insufficient.

- II) By a **subordinate person** unless the Public Prosecutor proves that the committing of the Crime was made possible by **failure to observe the obligations of direction or surveillance**. In either case, failure to observe the obligations of direction or supervision will not apply if the organisation, prior to the crime being committed, has adopted and effectively implemented a **Model**.

CHAPTER 2: THE MODEL ADOPTED BY NOVATIS VACCINES AND DIAGNOSTIC SRL (hereinafter called “Novartis” or “The Company”

2.1 Introduction

The Decree⁶ introduces a **special form of relief from liability** applicable if the organisation demonstrates that

- a) at has adopted and effectively implemented through its governing body organisational and management models prior to the committing of the offence that are suitable to prevent crimes of the kind that have occurred;
- b) it has entrusted the task of overseeing the operating and observance of the models and of ensuring their updating to an internal organisation possessing autonomous powers of initiative and control;
- c) that the persons who have committed the crime acted fraudulently to evade the organisational and management models;
- d) that vigilance on the part of the body referred to in paragraph (b) above has not been lacking or insufficient.

The Decree further provides that, with regard to the extension of delegated powers and the risk of the offences being committed the organisational, management and control models must meet the following requirements⁷

- a) to identify the areas at risk where the crimes referred to in the Decree might be committed;
- b) to lay down specific protocols for programming the making and implementation of the organisation’s decisions in relation to the crimes to be prevented;
- c) to identify means for identifying and managing financial resources that are suitable to prevent the committing of such crimes;
- d) to lay down obligations for the providing of information to the organisation appointed to supervise the functioning and observance of the Model;
- e) to introduce a disciplinary system suitable for sanctioning failure to observe the measures set out in the Model.

The Decree provides that the organisational, management and control models may be adopted providing the above requirements are met on the basis of the codes of conduct (e.g. the Guidelines) drawn up by associations representing the industry and advised to

⁶ Art. 6 (1) of the Decree.

⁷ Art. 6 (2).

the Ministry of Justice which, in consultation with the appropriate Ministries, may comment (within 30 days) on the suitability of models for preventing the crimes⁸.

Finally, provision is made for the task of vigilance in small-sized organisations to be undertaken directly by the directing body.⁹

2.2 The guidelines issued by Confindustria

Confindustria has approved the final text¹⁰ of its own “Guidelines for the construction of organisational, management and control models under Statutory Decree 231/2001”, which may be summarised in accordance with the following **fundamental points**”:

- to identify areas of risk with a view to verifying in which area/sector of the company prejudicial events as provided by the Decree may arise;
- to set up a system of control able to prevent risks by adopting appropriate protocols.

The **more relevant components of the control system** set out by Confindustria as a means of reasonably preventing the committing of the crimes referred to in the Decree are:

- a Code of Conduct (or Ethical Code);
- an organisational system;
- manual and data procedures;
- authorised and signatory powers;
- control and management systems;
- communication to personnel and their training.

The **components of the control system** must be uniformly established in accordance with the following **principles**:

- means for verifying and recording every operation and its cohesion and congruence;
- application of the principle of the separation of functions (e.g. no-one can manage an entire process independently);
- recording of checks;
- setting up of an adequate system of sanctions for breach of the rules and procedures set out in the Model;
- identification of the requirements of the Supervisory Body, summarised as follows:

⁸ Art. 6 (3).

⁹ Art. 6 (4).

¹⁰ On 7 March 2002 and subsequently updated on 18 May 2004

- autonomy and independence;
- professionalism;
- continuity of action;
- obligations to provide information on the part of the controlling body.

It should be noted that failure to observe the specific points of Confindustria's guidelines will not in itself invalidate the Model. The individual Model may, in fact, depart from the Guidelines, which by their nature are of general application, and be drawn up with regard to the specific realities of the organisation concerned.

This comment also applies to the appendix to the Guidelines, drawn up by Confindustria with reference to the introduction to art. 25 b of the Decree, with regard to company crime, which will also be taken into account when drawing up the present Model.

2.3 The methodological approach

In line with the objective of adopting the organisational model under Statutory Decree No. 231/2001, the logical and methodological approach adopted by the Company concerns:

- identifying the areas exposed to the risk of crimes being committed (so-called sensitive areas);
- “risk assessment” or identifying and drawing up the processes inherent in the risk area, with a description of the relative critical points that may exist;
- identification of action plans aimed at overcoming and mitigating the critical points found;
- the drafting of protocols and organisational procedures containing binding provisions aimed at preventing the irregularities referred to in the said Decree;
- the introduction of an adequate disciplinary system (further to the provisions made by the CCNL) to sanction the failure to observe the measures indicated in the model in order to guarantee their effectiveness on the part of all personnel employed and other workers (consultants, etc.) of the company.

2.4 Adoption and approval of the Model by NOVARTIS

Although parliament has provided for a “right” on the part of the addressees of the decree to adapt to the provisions introduced by it, NOVARTIS has in line with its own company policy decided to adopt a “Organisational, Management and Control Model”

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to ensure the best conditions at all times for correctness and transparency in conducting the company's business.

NOVARTIS considers that over and beyond the requirements of the law, adoption of this Model constitutes a further, valid instrument for ensuring awareness on the part of all staff and those working with NOVARTIS. It has done so to confirm its own desire and determination to adopt correct and transparent conduct in the pursuit of its own activities in line with the ethical-social values whereby the company has always been inspired and also in due course to adjust the capacity of the existing model to prevent the risk of the crimes referred to in the decree from being committed. The present manual, consisting of a General Part, a Special Part "A" – Crimes relating to the Public Authorities, a Special Part "B" – Company Crimes, and a Special Part "C" – Crimes against Health and Safety, was approved by the NOVARTIS VACCINES AND DIAGNOSTICS SRL board of directors by resolution of 16 November 2007, and has replaced the model in force up to that date (previously approved on 27 May 2005) in line with the need to guarantee maximum consistency between the model and the circumstances concerned and its ongoing improvement).

The Model's **principal objective** is to set up a structured and organic system of procedures, standards for conduct, and an auditing activity aimed at preventing, as far as possible, not only the committing of actions likely to facilitate the crimes covered by the Decree but also behaviour out of keeping with the actions and ethics that characterise the NOVARTIS Group worldwide.

It will in fact be remembered that NOVARTIS has always adopted a culture of control not repressive at any time but, above all, as an opportunity for continuous improvement of its business in the pursuit of both economic and ethical objectives.

The group's codes, as laid down and applied in Italy as well, that affect the ethics and the correctness of the company's conduct and that of its staff and workers and that form an integral part of the present model form a natural combination in this context.

The ever-present need to guide and monitor the company's activities towards ensuring observance of the principles set out above has allowed it to set up an efficient, permanent system of internal controls in the course of time, in addition to a system of procedures to regulate important operational and administrative activities. The present model, which is the result of a complex and extensive activity of identifying the activities exposed to the risk of crime ("sensitive activities") and their subsequent procedural implementation forms part of this highly sensitive and progressive context with regard to controls, with a view to

- rendering uniform the instruments used by the Company to prevent breach of the company's procedures and standards of behaviour and to respond to the committing of unlawful actions in conflict with the provisions adopted by the company;
- to confirm in due course the Company's position for the purpose of always maintaining a lively awareness amongst all those working for and on behalf of NOVARTIS of the risk they may incur through an unlawful act, the committing of which is clearly sanctioned by the Company as contrary to its interests and its

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principles, even if it may apparently have obtained a direct or even indirect economic advantage from it;

- acting quickly to prevent and eliminate the committing of crimes by constant monitoring of the company's business.

Cardinal points of the Model in addition to the principles set out above are:

- the mapping of activities at risk, or those activities within the scope of which the committing of the crimes referred to in the Decree is potentially most probable, the "sensitive activities" in point of fact.
- attribution to the Supervisory Body of the specific tasks of surveillance of the effectiveness and correct functioning of the Model;
- verification of every operation considered sensitive;
- application and observance of the principle of separation of functions, on the basis of which no-one can manage an entire process independently;
- attribution of powers consistent with organisational responsibilities;
- the *ex post* verification of company conduct, and of the functioning of the Model, with consequent periodic updating;
- the distribution of and the involvement of all levels of the company in implementing rules of behaviour, procedures and company policies;
- coordination of the elements of the Model with the system of internal control already existing in the company.

In order to ensure the widest understanding of the instructions contained in the Model, it is divided into

1. **A general part**, which contains the elements comprising the Model and in addition sets out to illustrate the operational rules of the Supervisory Body and the system of sanctions.
2. One or more **special parts**, the contents of which consist of analyses and procedures comparing the various types of crime laid down in the Statutory Decree 321/2001 and which are considered relevant with a view to the responsibilities of the organisation in accordance with the mapping out of the areas at risk. The special parts may be added to the present model by the same procedure as provided for approval of the model itself in the light of the requirements and needs that may prove necessary following the trend in the company's business and legislative developments.

Each of the annexes and the special parts form an integral part of this model.

The rules contained in the Model apply to those who discharge, even *de facto*, management, administrative, directing or control duties within NOVARTIS and to all

employees; and further to those who while not belonging to the Company work under its mandate or are tied to the company by relations of the type referred to in the paragraph “Disciplinary System” below.

The distribution and knowledge of the contents of the Model to all addressees will be undertaken by the company by whatever means it considers most suitable.

The addressees are required to observe all the provisions, also in discharge of their duties of loyalty, correctness and diligence resulting from the legal relations set up with the Company.

NOVARTIS dissociates itself from and condemns any kind of behaviour conflicting with the law and the provisions of the Model.

2.5 Changes to and updates of the Model

As permitted by the Decree, the Model is “an instrument issued by the governing body”.

Consequently, the subsequent modifications and any substantial additions, that may also be requested by the Supervisory Body, are subject to the authority of and approval by the NOVARTIS Administrative Body – in each case with prior information to the Supervisory Body.

CHAPTER 3: ELEMENTS OF THE NOVARTIS MODEL

The elements specific to the Model adopted by NOVARTIS will be considered in detail below.

3.1 AREAS AT RISK, PROCEDURES AND PROTOCOLS

Following the investigation made into areas and activities that prove potentially sensitive, the result of which is set out in Annex “A” “Schedule of Risks”, the Company has proceeded to verify the adequacy of the existing procedures and already covered by the previous model applying and has decided – where it considered it necessary – to integrate them to guarantee their effectiveness in preventing the anticipated risks contained in Statutory Decree 231/01 from being committed.

The activities submitted to regulation by the procedures and protocols are many, and it has been considered desirable to attach to the model (Annex “B”) only the procedures relating to areas and activities that are especially sensitive in terms of Decree 231/2001, although the model refers explicitly to the system of existing procedures and those available on the intranet database, which has been distributed to employees and workers and with which they are expected to be familiar.

The system of procedures is governed by **SOP (NFCM/231/QAIS) – Master** approved by the board of directors on 16 November 2007. The Sop attributes to the Executive Committee the responsibility of approving all procedures issued in connection with the Decree 231/01 sub-systems and Certification of the Scientific Information activities.

3.2 NOVARTIS CODE OF CONDUCT

The Code of Conduct meets the requirements for the crimes commission laid down in the Decree with the inclusion of rules and general principles of conduct to be advised as soon as possible.

The Code of Conduct attached to this Manual (Annex “C”), maintained by NOVARTIS for years and well before the issue of Statutory Decree 231/2001, is intended to introduce the principles and general rules of conduct, including those made for reasonable prevention of the crimes indicated in the Statutory Decree No. 231.2001 and making them binding within NOVARTIS.

The Code, therefore, is aimed at recommending, promoting or prohibiting certain behaviour independently of the provisions at legal level and is an embodiment of the principles that have always inspired NOVARTIS’ activities throughout the world.

The Code of Conduct is one of the Company’s official documents. It is aimed at employees, consultants, project workers, agents, representatives and third parties working on account and on behalf of the Company. The Code of Conduct, while we are aware that it cannot meet all possible infringements that could arise despite its existence, is aimed at illustrating the conduct in line with the ethical principles and values whereby NOVARTIS is infused.

The conduct of employees and management, of those who act as consultants or with powers of representation for the company, and other contracting counterparties of NOVARTIS, such as e.g. possible partners in a joint venture, the Temporary Industrial Association, etc. must comply with the rules of conduct – both general and specific – laid down in the Model and related documents.

To ensure that neither its own employees nor persons in a senior position nor otherwise any of those acting on behalf or in favour of the Company might commit the kind of crime that would not only discredit the image of the Company itself but also result in the application of one of the financial and/or prohibitive sanctions referred to in Statutory Decree No. 231.2001, the Company in due course instituted the position of Compliance Officer. This position is held in all companies belonging to the NOVARTIS group, with the specific task of ensuring adherence to and observance of the Code of Conduct; the tasks of the Compliance Officer are detailed in a job description.

3.3 THE SUPERVISORY BODY

3.3.1 Identification and appointment of the Supervisory Body

The Administrative Body at NOVARTIS considered it desirable that the Company should have a Supervisory Body of the collegiate type.

The Supervisory Body (or “Odv”), in implementing the provisions of the Decree, will have the specific task of monitoring its operation, the efficiency and observance of the

Model itself, and its updating, as required by the Supervisory Body's Rules attached to this Manual.

3.3.2 Responsibility attributed to the Supervisory Body

For the purpose of discharging its tasks, the Supervisory Body has been assigned specific functions including the following by way of example.

a) Verification and auditing procedures for the business

- To monitor the company's business activities with a view to establishing the areas at risk of a crime in accordance with Statutory Decree 231/2001 and to suggest updates and additions where this seems necessary;
- on the basis of the results obtained, to activate the company's appropriate departments to introduce operating and monitoring procedures that will properly regulate the discharge of the business, with a view to identifying and implementing a suitable model for organisation, management and control;
- to verify, also on the basis of any added areas at risk, the true effectiveness of the said model in connection with the company's departments and its effective ability to prevent the committing of the crimes referred to in the said Statutory Decree 231/2001, suggesting – where it is considered necessary – any updates to the model, with particular reference to the trends and changes in the organisational structure and operations of the company and/or the applicable law;
- to make periodic checks on the company's departments considered at risk of a crime, to ensure that the business is conducted in accordance with the organisational, management and control model adopted, also coordinating the appropriate company departments for this purpose;
- to provide internal organisational documentation containing the instructions, clarifications and updates required to update the model.

In order to permit discharge of the duties described above, the Supervisory Body will have free access to all of the company's documentation.

b) Training of personnel

- The OdV will ensure that a suitable training programme is introduced for employees, based on suitable initiatives for the distribution of knowledge and understanding of the model and to verify its implementation.

c) Sanctions

- to promote the process associated with the application of the sanctions and disciplinary provisions provided in the event of breach of the model within the appropriate company department and to verify its implementation, without prejudice to the latter's competence with regard to decision-making procedures and the choice of the most suitable measures to be introduced.

In fact, the Supervisory Body, as indicated in the Decree, will have independent powers of initiative and control in order to ensure that the Model is observed but will have no enforcing and/or sanctioning powers regarding employees (in all categories), consultants, and the company's governing bodies, which are entrusted to the appropriate areas within the company.

d) Updates

- To provide for the analysis, interpretation and follow-up of rules for the company's administrative responsibilities under the Statutory Decree 231/2001, and to assess the suitability of the Model for the provisions made therein;
- To assess the need for updating the Model, also by means of appropriate meetings with the various sections of the company concerned;
- To monitor updating of the company's organisation chart where it describes the organisation of the undertaking as a whole, specifying the areas, departments and offices and appropriate functions.

3.3.3 Reporting by the Supervisory Body to the company's governing bodies and the top management

The Supervisory Body will ensure implementation of the Model and deal with any critical points arising from it.

In particular, the ODV will with regard to implementation of the model, the application of the rules contained in it, and any critical points arising in this connection in periodic, half-yearly and annual reports.

The addressees of the periodic report are the Executive Committee, the Board of Directors, the Audit Committee and the Compliance Officer. Where necessary, in relation to critical points arising, the Audit Company and the General Meeting called to approve the balance sheet for the year may be included as well.

The Administrative Body is required to consider the periodic report and to enquire into the action taken and its outcome, where appropriate areas exist for improvement of criticality of the system.

Meetings with the company bodies and the reports with information should be minuted in the appropriate book, endorsed and kept by the ODV.

The ODV may be called at any time by the above bodies and may in turn submit a request for this purpose, with reference to the operation of the model or specific situations.

3.3.4 Information flow towards the Supervisory Body

Art. 6 (2) d. of the Statutory Decree No. 231/01 requires the "Organisational Model" to include a duty to inform the body appointed to monitor the operation and observance of the model itself.

For this purpose, the OdV will set up an efficient information flow which will permit it to be periodically updated by the company departments concerned on the activities considered at risk of a crime and to lay down suitable means of communication in order to obtain knowledge at an early date of any breaches of the model and the procedures, and which will enable it to refer them to the appropriate bodies within the company.

The obligation of a structured information flow is intended as an instrument to guarantee the activity of monitoring the effectiveness and efficiency of the Model and for any subsequent investigation of the reasons that made it possible for crimes covered by the Decree to be committed.

The information provided to the Supervisory Body is intended to improve control planning activities and lay down no obligation as to a prompt and systematic verification of all the aspects represented.

For this purpose, an appropriate electronic mailbox will be set up, accessible only to members of the ODV and protected by a password system.

The organisation will ensure that persons submitting reports are protected against any form of retaliation, discrimination or penalisation, also ensuring that the identity of a person reporting is kept confidential, except as required by law or for protection of the Company's rights, and the reputation of the person(s) reporting and those concerned.

The obligation to provide information applies primarily on the departments considered potentially at the risk of crime, but any person who obtains possession of details relating to the committing of crimes or to behaviour out of keeping with the provisions of the model is required to notify the Supervisory Body accordingly immediately. All employees, workers, consultants and members of the governing bodies, affected by provisions, enquiries or requests for information relating to a suspected crime on the part of the Public Security Organisations, the judicial police or control bodies must necessarily report to the Supervisory Body immediately in writing.

Provision must also be made for an information flow between the Supervisory Body, the Audit Committee and the Audit Company.

3.3.5 Collection and safekeeping of information

All information, notifications and reports for which this Model provides will be kept by the ODV in a database or paper file for a period of five years. The period of safekeeping will be suspended in the event of proceedings or action or audits in progress and will recommence from the point when these are finished.

3.4 Training and communication

With a view to the effectiveness of the present Model, the Company is required to guarantee correct knowledge and distribution of the rules of conduct contained therein amongst all employees and all persons engaged on management, administrative, directing and auditing duties and persons cooperating with the company and all those acting for it and on its behalf.

The level of training and communication will be applied at different degrees of depth in accordance with the various levels of involvement of the resources concerned in “sensitive activities”.

Training for personnel to implement the model will be undertaken by the Human Resources Department in close cooperation with the Legal department and the Supervisory Body and will be broken down as follows:

- management staff and those with representative positions in the Organisation;
- other personnel;
- third parties and external workers.

Specific, programme training will be provided for newcomers. Subsequent to their introduction, communication activities will be continuous and consistent through annual updating seminars, free access to the company’s Internet site dedicated to the subject, and updating by the Supervisory Body, the despatch of updating emails, etc.

3.5 DISCIPLINARY SYSTEM

3.5.1 General principles

The disciplinary system, which forms an integral part of the Model (Annex “D”), is addressed to employees, management, directors, auditors, consultants and workers in various respects with the Company, providing for appropriate sanctions, also of a financial nature. Breach of the rules of behaviour as provided by the Model by workers employed by the Company and/or its management will constitute failure to observe the obligations under a working relationship under Arts. 2104¹¹ Civil Code and 2106¹² Civil Code.

The application of disciplinary sanctions, leaving aside the outcome of any criminal proceedings, since the rules of conduct and internal procedures are binding on the addressees, independently of the actual committing of a crime as a consequence of conduct adopted.

3.5.2 Measures against Employees (non-management)

Breach by employees covered by the CCNL of the conduct provisions contained in this Manual is a disciplinary offence.

¹¹ **Art. 2104 - Care taken by the work provider**

1. The work provider will show the care required by the nature of the service required, the company’s interests and the special demands of national production.
2. The provisions will also be observed for execution and control of labour laid down by the employer and by the latter’s staff to which they are hierarchically answerable.

¹² **Art. 2106 – Disciplinary sanctions**

Failure to observe the provisions contained in the two above articles may result in the application of disciplinary sanctions according to the seriousness of the offence and in line with corporate standards.

Art. 2104 Civil Code, which sets out the duty of “obedience” on the part of the worker, states that the employee must in discharging his particular duties observe the provisions both legal and contractual imposed by the employer. On failure to observe these provisions, the employer may impose disciplinary sanctions, graded according to the seriousness of the offence, while observing the provisions contained in the CCNL for the pharmaceutical industry.

In particular, the disciplinary system must be shown to conform to the following principles:

1. the system must be properly published by posting up a notice in a place accessible to employees and be the subject of specific updating and information courses where necessary;
2. the sanctions may include definitive changes to the contract of employment and comply with the principle of proportionality to the offence, specification of which will be entrusted to the collective agreement for the industry in accordance with Art. 2106 Civil Code;
3. the rights of defence of a worker accused of a shortcoming must be secured.

The disciplinary provisions imposed on such workers are those laid down under the sanctioning system of the CCNL, in particular:

- a) admonishment or reprimand stated verbally;
- b) censure or admonishment stated in writing;
- c) a fine, in a sum not exceeding three hours’ basic pay;
- d) suspension of the service and of pay for not more than 15 days;
- e) dismissal.

All the provisions of the Act No. 300 of 1970 (the so-called “Workers’ Statute”) and of the collective agreement for the industry continue to apply and are incorporated herein, both with regard to sanctions imposed and to the form in which these powers are exercised.

The disciplinary system further provides for a relationship between earnings (the variable part associated with the incentives system) and conduct considered relevant with regard to observance of the organisational Model.

3.5.3 Measures against employees of managerial status

On breach by management of the internal procedures laid down in this Manual or the pursuit of conduct, when undertaking “sensitive activities” in areas regarded as at risk, not conforming to the requirements of the present document, the company may decide to apply the most suitable measures against those responsible having regard to the provisions of the regulations.

Without prejudice to the Company's obligations arising from the Collective Agreement and the applicable internal Rules, the behaviour subject to sanctions and comprising a breach of the present Manual is as follows:

- a) breach of the internal procedures laid down in this Manual (e.g. failure to observe the prescribed procedures, failure to provide the ODV with the prescribed information, failure to make checks, etc.) or the adoption in the discharge of sensitive activities of behaviour not conforming to the provisions of the Model;
- b) breach of internal procedures laid down herein or adoption in the discharge of sensitive activities of conduct not conforming to the requirements thereof which places the Company in an objective position where one of the Crimes may be committed.

With regard to the confirmation of breaches and the imposition of the sanctions, the powers already vested, within the limits of their respective authority, in the company's governing bodies and the appropriate departments will remain unchanged.

Sanctions and a possible request for damage to be made good will be measured at the level of responsibility and independence of the employee and manager, the possible existence of disciplinary precedents affecting the employee, the intentional nature of behaviour and the seriousness thereof, which means the level of risk to which the Company may reasonably consider itself exposed – in terms and for the purposes of the Statutory Decree 231/01 – as a result of the impugned conduct.

The system of sanctions is subject to ongoing verification and assessment by the ODV and by the staff and head of Human Resources, the latter remaining responsible for the correct application of the disciplinary measures set out herein, possibly on instructions from the ODV.

3.5.4 Measures against directors

In the case of a breach of the current rules or the Model by Directors of NOVARTIS, the Supervisory Body will advise the Managing Director and the Audit Committee, which will take steps to institute the appropriate initiatives laid down in the current rules and a specific sanction under the NOVARTIS sanctioning system, including by way of example:

- calling a meeting of shareholders in order to adopt the most suitable measures laid down by law and/or
- withdrawal of powers that may have been conferred on the Director
- dismissal of the director.

3.5.5 Measures against associated workers, consultants and other third parties

Any conduct adopted by workers, consultants or other third parties associated with NOVARTIS in a contractual relationship other than that of an employee, in breach of the provisions of the Model, may result in cancellation of the contractual relationship as provided by the specific clauses of contract inserted in the letter of appointment or, if

none, by the disciplinary system adopted by NOVARTIS, subject to any request for compensation if such conduct causes damage to the company, even independently of cancellation of the contractual relationship.

CHAPTER 4: SYSTEM OF INTERNAL CONTROL

4.1 Organisational system

The first element to be examined was the extent of the adequacy of the internal organisation system. This was assessed on the basis of the following criteria:

- formal status of the system
- clear definition of responsibilities and assigned and lines of hierarchical seniority;
- existence of conflict of tasks;
- correspondence between activities effectively pursued and those provided under the appointments and responsibilities described in the Company's organisation chart.

The organisational system at NOVARTIS is based on the following documents:

- company organisation chart;
- job description/detailed job listing, clearly for each section of the organisation chart setting out
 1. hierarchical answerability;
 2. any functional answerability;
 3. tasks, with a precise indication of their scope and the limits to independent decision-making;
- authorisation powers with a precise indication of the thresholds of approval for expenses and requirements for joint signature;
- signing powers with an indication of the range of authority to make arrangements with persons abroad.

The organisation system is defined through the issue of Organisational Service Orders signed by the Managing Director and the Director of Human Resources.

Organisational Service Orders are drawn up and distributed by the Human Resources Department, which also arranges for the distribution of a report which on a fixed date will include the updated organisation chart for the Company and the responsibilities of each department.

4.2 Authorisation and signatory system

The analysis concerns a review of the system of powers of authorisation and signature consistent with the organisational and managerial responsibilities assigned and/or specifically pursued. Confirmation was obtained by examination of the authorisations granted and the internally delegated management powers, in the light of the company's organisation chart.

It is a general rule at NOVARTIS that only persons with formal, specific powers may make commitments towards third parties for and on behalf of the Company.

The following are therefore provided:

- signing powers relating to authorisation of expenses, negotiation and payments, attributable by means of internal documents and/or conferred by notarised powers of attorney;
- powers of "permanent representation", granted by notarised powers of attorney recorded in connection with the exercise of permanent responsibilities within the company organisation;

4.3 SAP data system

The Company's activities are administered on an ERP system which is based on the SAP data processing application, the processes within which can be modified only with the prior authorisation of the person responsible.

The system forms a full part of the existing system of audits as it permits all phases of company management to be verified and monitored, especially those considered more sensitive for the purposes of Statutory Decree 231/2001.

Furthermore, updated reports can be provided through the application in question, concerned with the activity of auditing and control undertaken by all persons appointed for this purpose, including ODV.

The SAP system further allows the entire flow to be monitored from the authorisation stage to conclusion of the procedure and therefore any action considered "anomalous" to be identified and examined.

4.4 Management control system

The management control system current at NOVARTIS provides for the following stages:

- processing of the annual Budget and any amendments thereto;
- expense analysis.

The system is capable of quickly providing and detecting the existence and occurrence of generally and/or especially critical situations.

Management control at NOVARTIS is undertaken at the various points officially provided during the year by the Group Budget and Control system.

4.5 *System and compliance with the Sarbanes Oxley Act (Sox)*

The global dimensions of the economy have in recent years resulted in national and international laws being ever more stringent in terms of transparency and stringency.

Legislation such as the Sarbanes Oxley Act (known as Sox) on internal controls which the Sec (US Security Exchange Commission) applies to all companies listed in the USA, have therefore started to have an impact on the businesses of many Italian companies.

In fact, Sox applies in cascade to the companies associated with it even if located in and subject to the laws of other countries, e.g. their Italian subsidiary.

In essence, Sox is concerned with the safeguards that the companies can set up to ensure correctness and completeness in their balance sheet data.

NOVARTIS, being the true head of the NOVARTIS AG group of companies listed on the New York Stock Exchange, quickly took the opportunities offered by the Sox controls and, in this connection, has proceeded to map out and describe all the operating processes contributing towards the production of the balance sheet and at the same time to ensure that all key checks on the correctness of processes are effective and recorded.

Implementation of the system to comply with the Sox rules at NOVARTIS proved a further opportunity to take yet more formalised and verifiable account of the processes used to produce data for the balance sheet.

Verification of SOX compliance, furthermore, is entrusted to an external audit company which has never expressed any objection.

4.6 *Balance sheet area protocols and procedures*

All NOVARTIS activities that may have repercussions on the balance sheet are subject to an interconnected, specific process of verification and auditing conducted and monitored by an already proceduralised system.

The scope of the protocols and procedures intended to safeguard this delicate area is aimed not only at avoiding gaps in the application of principles, national and international, when drawing up the balance sheet but also at avoiding anomalous situations arising that may give rise to a significant risk in terms of the application of Statutory Decree 231/2001.

The directives of the specific sector, furthermore, are so designed as to ongoing and prompt verification of activities undertaken by the various company actors, also with a view to promptly identifying any situations considered anomalous.

The system is subject to an ongoing check undertaken both by company functions designed for the purpose but also by internal group audits by the auditors' committee, the audit company and the ODV.

Verification and a cohesive check on the accounting and financial information for the company is ensured, furthermore, by a detailed system of delegated powers and authorisations and expenditure, and by the management of the entire cycle by means of the SAP data processing system.

4.7 Farindustria certification system

The Company belongs to the Farindustria certification system by means of which the more sensitive stages of the business of scientific information are verified and the limits and requirements laid down by law and the Framindustria ethical code, subscribed by the company, are observed.

It should be noted that this particular type of controls gives rise each year to a report which, if positive, allows certification to be obtained. The checks are not formal or procedural in nature but, on the other hand, are of substantial extent and include an in-depth verification of all activities falling within the certification area.

The checks are carried out by a certifying body external to the company and possessing the necessary requisites.

Organisation, management and control model

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SPECIAL PART “A”

Offences in dealings with the public authorities

A.1 Public authorities and persons entrusted with public services

A.1.1 Public administration

For the purposes of the Decree, **Public Administration** means all persons, whether under private or public law, undertaking a “*public function*” or a “*public service*”.

It will be noted that:

- **the authoritative power** is the power that permits the Public Administration to achieve its own purposes by true and proper orders, compared with the private, which is in a position of making suggestions. This concerns activities in which the *so-called official powers* are expressed which include both powers of coercion (arrest, seizure, etc.) and accusations of breaches of the law (confirmation of infringements etc.), and powers of hierarchical seniority within the public offices;
- **the certifying power** is that which gives a person undertaking certifications the power to confirm a fact to prove it as against a falsehood.

A.1.2 Public function and public official

Art. 357 Criminal Code defines a “public official” as a person who “exercises a public legislative, judicial or administrative function”.

A public function is therefore an activity governed by the rules of public law relating to the functions of

- **legislation** (the State, the Regions, the Provinces with special status, etc.).
- **administration** (members of the state and territorial administrations, the forces of order, members of supra-national administrations – e.g. the EU -, members of the Authorities, of the anti-trust bodies, the Chambers of Commerce, members of the

Building Commissions, inspectors of public works, surveyors under the Italian Naval Register, etc.) and

- **the Judiciary** (judges, court officials, auxiliary services for the Administration of Justice such as receivers or liquidators in bankruptcy, etc.).

Examples of public officials generally may be

- employees of a University if they have certifying and/or authoritative powers;
- notaries;
- members of the Financial Police;
- members of the armed services of the Carabinieri (Gendarmerie);
- members of the State Police;
- members of the body of City police;
- administrators of public economic bodies;
- sworn guards;
- etc.

A.1.3 Public service and persons entrusted with a public service

Art. 358 Criminal Code defines a “person entrusted with a public service” as one who “provides a public service by any title”.

Public service means

- the activities of producing goods and services of general interest and subject to supervision by a Public Administration and
- activities undertaken to guarantee the rights of a person to life, health, freedom, providence and social assistance, instruction, freedom of communication, etc. within a system of concessions and/or agreements (e.g. Hospital Services, ASL, I.N.P.S., I.N.A.I.L., members of the Municipal Councils, Banks, Post Offices, Customs Offices, the Railways, the Motorways, Municipal Undertakings, Airlines, Navigation Companies, classification/certification bodies, RINA, SACE, etc.).

The public service is an activity governed by the same forms of public function but characterised by the absence of the powers typical of the latter (authoritative and certifying powers) and excluding the discharge of ordinary duties of orderliness and the providing of purely material works.

The idea of Public Administration as taken for the purpose of identifying areas of risk is that drawn from Art. 357 and 358 of the Criminal Code, on the basis of which all

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persons who – whether or not bound to the Public Administration by a contract of employment, discharge duties governed by public law and official documents are public officials and entrusted with the public service. On the basis of this idea, the following may be noted by way of example:

1. *persons who discharge a public legislative/administrative function, such as, for example*

- members of parliament and members of the Government;
- regional and provincial councillors;
- members of the European Parliament and of the Council of Europe,
- persons who discharge accessory duties (concerned with the safekeeping of parliamentary acts and documents, the preparation of shorthand reports, administrative services, technical service, etc.)

2. *persons discharging a judicial public function such as e.g.*

- magistrates (ordinary magistracy before the lower courts, court of appeal, supreme court of cassation, high court of waters, TAR, Council of State, the Constitutional Court, military tribunals, lay judges at the assize courts, justices of the peace, honorary deputy police commissioners and associates, members of official arbitration boards and parliamentary commissions of inquiry, judges before the European Court of Justice, and the various international courts, etc.
- persons who undertake associated functions (officials and agents of the judicial police, the financial police and carabinieri (Gendarmerie), clerks of the court, secretaries, judicial custodians, court officials, court messengers, receivers in bankruptcy, persons entitled to issue certificates at the office of clerks to the courts, surveyors and consultants assisting the Public Prosecutor, liquidation commissioners in bankruptcy proceedings, liquidators in voluntary composition, extraordinary commissioners undertaking extraordinary administration of major undertakings in difficulties, etc.);

3. *persons discharging an administrative public duty, such as, e.g.*

- the employees of the State, international and foreign organisations and territorial bodies (e.g. officers and employees of the State, the European Union, supra-national health organisations, foreign states and territorial bodies, including the Regions, the Provinces and Local Authorities; persons who discharge accessory duties in connection with the financial institutions of the State, such as members of a municipal technical office, members of a building committee, the head of the administrative office for public amnesties, local authority messengers, employees of offices concerned with the occupation of public land, local authority correspondents associated with labour exchanges, employees of statutory

undertakings and municipal undertakings; persons concerned with the collection of taxes, staff of the ministries and superintendents' offices, etc.). In particular, this applies to relations with university tutors, university assistants assisting academics with research or teaching activities; primary hospital staff and paramedics; members of the ASI and AO call for tenders commission; the NAS; sanitary inspectors; sanitary officials; doctors and pharmacists.

- Employees of other national and international public bodies (e.g. officers and staff of the Chamber of Commerce, the Bank of Italy, the Supervisory authorities and public provident institutions, ISTAT, the UN, FAO, etc.)
- Private persons discharging public duties or public services (e.g. notaries, private individuals operating under a concession scheme or whose activities are otherwise governed by rules of public law and official acts, etc.).

It will be noted in this respect that persons who discharge similar duties to those described above in connection with local authority organisations, other member states of the European Union, foreign states or international public organisations are regarded as equivalent to public authorities.

A.2 The types of crime connected with the public authorities (arts. 24 and 25 of the Decree)

Within the scope of the present Special Part "A", a brief description is provided below of offences committed under arts. 24 and 25 of the Decree, with a reference back to the General Part for a definition and examples concerning aspects of Public Administration, public functions, public officials, public service and persons entrusted with a public service.

Fraudulent conversion to the detriment of the State, another public body or the European Communities (art. 316 a Criminal Code)

This type of crime applies in cases where after funding or contributions have been received from the State or from another public body or from the European Communities, the sums obtained are not used for the purposes for which they were intended (action, in fact, comprising misuse, even partly, of sums obtained without evidence that the schedule activity has been undertaken).

Having regard to the fact that the point of committing the crime coincides with the executive phase, the crime itself may also apply with reference to funding already obtained which have not now been devoted to the purposes for which they were provided.

Improper receipt of payments to the detriment of the State, another public body or the European Communities (Art. 316 b Criminal Code)

This kind of crime occurs in cases where – through the use or submission of declarations or forged documents or by withholding necessary information – contributions, funding, assisted loans or other payments of the same kind are obtained, without entitlement, granted or issued by the State, by other public bodies or by the European Communities.

In this case, unlike that referred to in the preceding item (art. 316 a), the purpose for which the payments is used is irrelevant since the crime is committed at the point when the funding is obtained. Furthermore, it should be noted that this type of crime is residual in relation to the circumstances of the fraudulent act to the detriment of the same persons, to the effect that punishment in this respect will apply only in cases where it is not imposed as a result of the fraudulent acts concerned.

Finally, it should be noted that this kind of crime is residual in relation to the circumstances of fraud to the detriment of the State, in terms of

Extortion (Art. 317 Criminal Code)

This type of crime occurs in the case where a public official or a person providing a public service forces another to obtain for himself or for others moneys or other benefits to which he is not entitled, by abusing his own position.

Corruption through an official deed or contrary to public duty (Arts. 318-319 Criminal Code)

These types of crime arise in the case where a public official or a person providing a public service for himself or for others receives moneys or other advantages to undertake action contrary to his own office, or to undertake, omit or delay action by his own office (providing an advantage in favour of the perpetrator).

It will be noted that the crime of corruption is necessarily one of complicity, where both the corruptor and the person corrupted are punished (cf. Art. 321 Criminal Code).

Corruption, i.e. in the strict sense, is that through the committing of an act contrary to the duties of an office (e.g. acceptance of money to guarantee adjudication in a competition) may be committed by a public officer and by a person holding public office, while corruption in the extended sense is that concerning an act to be taken (e.g. speeding up a practice, avoiding which falls within his competence) may be committed by a public officer and by a person entrusted with a public service possessing the status of a public employee. Corruption may be so called active (a director or an employee corrupt a public officer or a person providing a public service to obtain an advantage for the company) or corruption may be passive) the representative of a company receives money or other benefits to undertake action required under or contrary to public duties), in cases where the action taken in complicity may be regarded as a public function or a public service.

A crime of this kind differs from extortion insofar as there is agreement between the corruptor and the person corrupted aimed at achieving a mutual advantage, while

under extortion, the private person is merely passive participant, who is affected by the conduct of the public officer or the person providing a public service.

Instigation to corruption (Art. 322 Criminal Code)

This type of crime arises in a case where, faced with conduct aimed at corruption, the public officer or a person providing a public service refuses the offer unlawfully made to him (*even in this case, where improper instigation to corruption is concerned, the person providing the public service must at the same time also have the status of a public employee, which is not necessary in the case of instigation to corruption in the strict sense*).

Corruption in legal documents (Art. 319 b)

This type of crime may arise in cases where the organisation is concerned in legal proceedings and, with a view to obtaining an advantage in such proceedings, corrupts a public official (not only a magistrate but also a clerk of the court or other officer) through its representative.

Fraud to the detriment of the State, another public body or the European Union (Art. 640 (2) 1. Criminal Code)

This kind of crime arises in a case where, to achieve undue profit, tricks or subterfuges are adopted to induce error or cause damage to the State (or another Public Authority or the European Union).

This crime may occur for example if, when submitting a document or data for participation in call for tenders, the Public Administration is provided with untrue information supported by forged documents in order to obtain an award in the competition.

Aggravated fraud to obtain public funds (Art. 640 a Criminal Code)

This type of crime arises in cases where the fraud is committed to obtain undue public benefits.

These circumstances may arise in a case where tricks or subterfuges are adopted, e.g. by providing untrue data or submitting false documents, in order to obtain public finance.

Data fraud to the detriment of the State and other public bodies (Art. 640 b Criminal Code)

This type of crime arises in cases where an undue benefit is obtained, causing damage to the State or to another public body, by altering the operation of a data processing or remote data system or manipulating the data contained in it.

The crime may be committed e.g. if the data process system is infringed once funding has been obtained in order to introduce a sum with regard to funding in excess of that legitimately obtained.

A.3 Areas of activity at risk (“sensitive activities”)

The crimes referred to above presuppose the setting up of relations with the Public Administration (taken in the broad sense) and the pursuit of activities entailing a public function or a public service.

Having regard to the multiplicity of relations that NOVARTIS is maintaining with the Public Administrations and with persons discharging a public function or public service, a series of activities are identified, on completion of a process of self-assessment, that are particularly at risk of the crimes referred to in Decree 231 being committed as specifically indicated in Annex A.

Any inclusion of the said areas of activity at risk or “sensitive activities” may be arranged by the Administrative Body at NOVARTIS following consultation with the Supervisory Body or on request by the latter, mandated to update and assess the adequacy of the Model and to introduce appropriate operating provisions.

A.4 Addressees of the special part

The present Special Part refers to conduct pursued by directors, managers and staff (hereinafter called the “Company Representatives”) at NOVARTIS in a area of activity at risk and by external Workers and Partners as already defined in the General Part (hereinafter all called “Addressees”).

This Special Part is aimed at all Addressees as described above adopting rules of conduct conforming to its requirements in order to prevent the crimes referred to in the Decree from being committed.

A.5 General principles of conduct and implementation of conduct prescribed for areas of activity at risk

The present Special Part provides for an **express obligation** on addressees to

1. observe and respect all the laws and regulations governing company activities, with special reference to those comprising contacts and relations with the Public Administration and activities relating to the discharge of a public function or a public service;
2. to introduce and maintain any kind of relations with the Public Administration on the basis of criteria of maximum courtesy, transparency and legality;
- 3/4 to introduce and maintain any kind of relationship with third parties in all activities concerning the discharge of a public function or a public service on the basis of criteria of correctness, transparency and legality that guarantee the proper progress of the function or service and impartiality in pursuing it;
5. to be aware of the reference legislation and company procedures relating to the specific activities or function undertaken by them;
6. to inform the company of any irregularities with regard to the provisions of this model or any doubts or uncertainties in interpreting and applying its provisions.

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This Special Part consequently provides for an **express ban** on addressees to pursue

1. conduct likely to amount to a crime in the above terms (Arts. 24 and 25 of the Decree);
2. conduct which, although not in itself such as to amount to a crime falling within those in question, may nonetheless become one;
3. any kind of situation of conflict of interests in dealing with a Public Administration in connection with the provisions of the said circumstances of a crime;
4. any kind of behaviour which while not possessing the aspects of a crime may nonetheless prejudice the integrity and ethical values that have always distinguished the company.

Within the scope of the above conduct, **the following is prohibited in particular:**

- a) making cash donations to public officers;
- b) distributing gratuities or gifts beyond the provisions of the specific procedures and the rules for the industry or such as may give the impression that giving them may be intended to obtain favourable treatment in the conduct of any kind of company business. In particular, any form of gift to Italian or foreign public officers or to members of their family that may influence their discretion or independence of judgement or result in any kind of advantage for the company is prohibited. As provided by the company's Code of Ethics and the Code of Conduct, gratuities given will always be in the nature of low-value gifts. All gifts offered – except for those of minimal value – must be suitably recorded to permit the Supervisory Body to audit them as well;
- c) offering other advantages and benefits of any kind (promises of employment, etc.) in favour of representatives of the Public Administration that may result in the consequences referred to in the previous paragraphs;
- d) offering benefits to Partners without proper justification in the context of the relations formed with the Partners concerned;
- e) granting remuneration to external Workers without proper justification having regard to the type of work they are doing and current practice in the area concerned;
- f) receiving or soliciting contributions in cash, gratuities, gifts or advantages of any other kind in connection with the discharge of public functions or a public service; any person receiving gratuities or advantages of any other kind not included in the permitted examples is required to advise their direct superior and the Supervisory Body directly, who will assess the appropriateness and take steps to advise the person making such contributions of NOVARTIS policy in this connection;
- g) submitting untrue declarations to national or Community public organisations in order to obtain public payments, contributions or scheduled funding and to

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allocate sums received from public and national or Community organisations in the way of payments, contributions or funding for purposes other than those for which they were requested and intended.

For the purpose of pursuing the conduct referred to above:

1. relations with the Public Administration for the said areas of activity at risk and those instituted with third parties in connection with the discharge of a public function or a public service must be managed in uniform fashion, proceeding with the identification of an established person responsible for each operation or set of operations undertaken within the areas of business at risk, as in any event laid down by the existing procedures and company policies;
2. the tasks entrusted to external Workers and consultants must be drawn up in writing, with an indication of the agreed payment, and will be put forward and verified according to the existing procedure for authorising expenses. Furthermore, any service provided must be properly recorded and filed;
3. any agreements for associating with Partners must be set out in writing and referred to all the conditions of the agreement concerned, with special reference to the financial terms agreed for joint participation in the procedure, and must contain explicit references to the company's ethical policy and to the Organisational Model 231;
4. no type of payment may be made in cash or in kind but must be granted by the company procedure concerning bank and postal giro payments;
5. declarations made to national or Community public organisations in order to obtain payments, contributions or funding must contain absolutely truthful information and, where they are obtained, they must be adequately traceable and accounted for at all times, as provided by the rules;
6. any person who discharges a duty of auditing and supervision on work connected with the discharge of such activities (managing the payment of invoices, funding obtained from the State and community organisations, etc.) must pay particular attention to the persons concerned meeting the requirements, with immediate reference to the direct superior and to the Supervisory Body when any irregularity arises.

A.6 Fundamental principles of the decision-taking process in areas of activities at risk (appointment of internal officer responsible for individual risky operations).

Any operation with a potential risk falling within the categories referred to in the above paragraphs must be uniformly administered and proper evidence shown of them. For this purpose, an internal person will be appointed (the “**Internal representative**” or “**Owner**”) to be responsible for each individual operation or set of operations as provided by the existing procedures and company policies.

The Internal Representative:

- will in general be the person to refer to and responsible for the operation at risk;
- is responsible, in particular, for managing relations with the Public Administration within the scope of the procedure to be undertaken;
- is responsible, in the case of activities undertaken in connection with a public service, for relations with third parties for the particular procedure to be undertaken;
- will refer to the Supervisory Body on progress with the activities at risk and will refer to it should queries arise, also of an interpretational nature, with reference to the aims of prevention under this Model.

A detailed plan of responsibilities according to the criteria set out above appears in Annex "E".

A.7 Tasks of the Supervisory Body

The **supervisory tasks** of the OdV with regard to observing and the efficiency of the model are governed by the rules of the Supervisory Body, in particular those concerning offences against the Public Administration, amongst which the following may be mentioned by way of example:

- gathering together and harmonising all existing internal procedures and company policies set up to safeguard areas at risk as indicated in the above points and auditing and monitoring their application;
- monitoring the effectiveness of internal procedures and the system of delegation and representation to prevent crimes against the Public Administration;
- examination of any specific indicators from the auditing bodies and any kind of employee, and introducing the confirmations considered necessary and desirable in response to indicators received;
- implementation of the internal data processing system to assist with distribution of the rules contained in the Model and eliminating any doubts in interpretation that addressees may have.

The Supervisory Body will report on the results of its surveillance and control activities as provided in the OdV rules. In cases where investigations made by the Supervisory Body should provide pointers to a breach of the principles and protocols contained in this Special Part of the Model, or the committing of a crime or an attempt to commit a crime, the Supervisory Body will without delay refer the matter to the Managing Director for him to refer in turn to the Board of Directors and the Audit Committee or to the appropriate Bodies and Authorities to take necessary or appropriate steps.

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SPECIAL PART “B”

Company crimes

B.1 Types of company crimes (Art. 25 b of the Decree)

With regard to the present Special Part “B”, the following is a brief description of the crimes covered by it, as set out in Art. 25 b of the Decree, which can be grouped into the following types.

1 – Forgery in communications, prospectuses and reports

False company communications (Art. 2621 and 2622 Civil Code)

If directors, the general managers, the auditors and liquidators issue material facts with the intention of deceiving shareholders or the public and of obtaining an undue benefit for themselves or for others, in the balance sheet, in the reports or in the other company communications required by law and directed at shareholders or the public, that do not comply with the truth, even if the subject of estimation or omit information the communication of which is imposed by law concerning the economic, asset or financial situation of the company or of the group of which it forms part, in such a way as to lead the addressees into error as to the said situation, will be punished by imprisonment of up to one year and six months.

Punishment will also extend to cases where information concerns goods held or administered by the company on third party account.

Punishment will not apply if the falsity or omissions do not appreciably affect representation of the economic, asset or financial situation of the company or the group to which it belongs. It will further not apply if the falsity or omissions result in an alteration of the economic result for the year, before tax, not exceeding 5% or a variation in net assets not exceeding 1%.

In any event, the fact will not be punishable if as a result of estimations made it does not, taken in itself, differ from the correct figure by more than 10%.

If when the above circumstances occur the persons concerned cause financial damage to shareholders or creditors they will be punished on a complaint by the person affected with imprisonment of six months to three years.

The same will apply on request if the facts include another crime, of more aggravated form prejudicing the assets of various persons amongst the shareholders and creditors, but not if committed to the prejudice of the State, other public bodies or the European Communities.

Punishability for the facts referred to in the first and third paragraphs extends also to a case where the information concerns property held or administered by the company on third party account.

The crime referred to in Art. 2621 Civil Code (false company communications) as amended by Art. 1 of the legislative decree of 11 April 2002 No. 61, differs from that under Art. 2622 of the same Code (false company communications to the detriment of shareholders and creditors), since in the former case, false communications aimed at shareholders or the public are punished while under the latter, those causing a reduction in the assets affecting shareholders or creditors.

It follows that while Art. 2621 of the Civil Code provides for a crime of risk (to protect the regular nature of balance sheets and other company communications, as they affect the general public), Art. 2622 introduces a crime of damage into the system, to protect the interest of shareholders and creditors.

Reports

The term “report” is used in civil law as applied to joint-stock companies to indicate the particular reports with information from appropriate persons, in written form and necessary in the situations laid down by law.

In particular, provision is made for a directors’ report (Art. 2428 Civil Code) and one by the Auditors (Art. 2429 of the Civil Code) to accompany the ordinary balance sheet for the year; the half-yearly report by the directors on the progress of the business of companies with shares listed on the exchange (Art. 2428 (III) Civil Code); the report by the directors required for the procedure laid down for the distribution of advances against dividends (Art. 2433a (V), Civil Code); the directors’ report intended to back up a proposal for a capital increase excluding or limiting option rights (Art. 2441 (VI) Civil Code); the director’s report and comments by the auditors’ committee on the situation of the assets on a reduction in capital following losses (Art. 2446 Civil Code); the auditors’ report on the final balance sheet on winding up (Art. 2453 (II) Civil Code); and the directors’ report on a merger or splitting proposal (Art. 2501 c., Civil Code and 2504 h of the Code).

The above list is not complete in itself but shows to what extent use of the term “reports” must be restrictive: in essence, it is intended to indicate only “typical relations” (i.e. the written relations concerning the company’s business expressly laid down by law).

The balance sheet

The “balance sheets” category certainly includes the balance sheet for the year or ordinary balance sheet (Arts. 2423 et seq. Civil Code) “taken as an instrument for

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information on the assets, finances and economic situation of a company as a going concern, namely a company characterised by ongoing operations”.

These must generally be taken to include the consolidated balance sheet (or the accounting document intended to provide a picture of economic and financial situation of the group jointly considered) and which could possibly be a source of falsehood as stated by Art. 2621 (1) Civil Code, and all balance sheets of an extraordinary nature, amongst which must be counted the accounting prospectuses that serve to indicate the company’s asset situation on occasions other than the ending of the normal financial year or in connection with particular legal or administrative procedures. The accounting prospectus required (under Art. 2433a (V) Civil Code) for the purpose of distributing an interim dividend is, for example, an extraordinary balance sheet; the final balance sheet on winding up referred to in Arts. 2311 and 2453 of the Code shows the asset situation drawn up observing the rules for the annual balance sheet (Art. 2501 b (I) Civil Code), which must accompany a proposal to merge (Art. 2501 (b)) or to split (Art. 2504 (h) Civil Code) the company; and the balance sheet that must be filed together with an application in the company’s bankruptcy (Art. 14 Bankruptcy Act).

The other company communications

It will be noted that, as a general principle, in order to identify what should be regarded as a company communication, account must be taken of the following three requirements: the first, concerning the subject matter of the instrument: “officialness”; the second, determined from its association with the subject matter “appropriateness to the company’s objects”; and the third, with regard to its addressees: “advice for the public”.

As to the first of these, the textbook writers and well-established precedent agree in regarding the official nature of the communication as an essential requirement (relevant in criminal law) whenever it is issued by persons qualified to do so in the discharge and by virtue of specific duties vested in them within a company already established or to be established.

The official nature requirement does not therefore apply to so-called confidential or private information, which if false would not meet the requirements for the crime under consideration but, within the combination of circumstances, be a reason for criminal liability in respect of fraud or speculation by the company.

The second requirement, namely appropriateness of the communication to the company’s objects, concerns the substance of the declaration and requires the company attribute to be applicable to communications that have “generic relevance to the existence and business of the company” and a declaration by the appropriate bodies of the company intended to provide information on the stock exchange in the country or abroad or whereby an announcement is made that powers of attorney have been granted to a particular person cannot be considered “generic to the business”.

The third requirement is intended to attribute criminal significance only to official information and that concerning the company’s objects that it potentially intended for a number of addressees, in other words the nature of the direction of advertising

would be “external relevance” which arises whenever the communication is intended for an indeterminate number of persons or for the shareholders, company creditors and third parties (potential shareholders or creditors), protected not individually but as “open category”.

With regard to the form, even if it could be questioned in theoretical terms, it should be noted that even purely verbal form may amount to communication of false information that must be borne in mind.

Examples include false declarations made by directors or by auditors to the shareholders meeting or to bondholders, or to the organisers of a subscribers’ meeting.

Neither communications that individual members of the governing bodies (the Board of Directors and Audit Committee) issue for the governing bodies concerned nor those made by directors to the internal audit body are therefore “company-aligned” strictly speaking.

Falsehood in the accounts and company’s books

In general terms, it must be said that also any alterations in the company’s books that may be regarded as “provided as a means of information for shareholders and possible third parties”, may be regarded as the offences of forgery within the meaning of the above crimes.

Other communications by the company

It will be noted that, as a general principle, in order to identify what should be regarded as a company communication, account must be taken of the following three requirements: the first, concerning the subject matter of the instrument: “officialness”; the second, determined from its association with the subject matter “appropriateness to the company’s objects”; and the third, with regard to its addressees: “advice for the public”.

As to the first of these, the textbook writers and well-established precedent agree in regarding the official nature of the communication as an essential requirement (relevant in criminal law) whenever it is issued by persons qualified to do so in the discharge and by virtue of specific duties vested in them within a company already established or to be established.

The official nature requirement does not therefore apply to so-called confidential or private information, which if false would not meet the requirements for the crime under consideration but, within the combination of circumstances, be a reason for criminal liability in respect of fraud or speculation by the company.

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country or abroad or whereby an announcement is made that powers of attorney have been granted to a particular person cannot be considered “generic to the business”.

The third requirement is intended to attribute criminal significance only to official information and that concerning the company’s objects that it potentially intended for a number of addressees, in other words the nature of the direction of advertising would be “external relevance” which arises whenever the communication is intended for an indeterminate number of persons or for the shareholders, company creditors and third parties (potential shareholders or creditors), protected not individually but as “open category”.

With regard to the form, even if it could be questioned in theoretical terms, it should be noted that even purely verbal form may amount to communication of false information that must be borne in mind.

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Falsehood in the accounts and company’s books

In general terms, it must be said that also any alterations in the company’s books that may be regarded as “provided as a means of information for shareholders and possible third parties”, may be regarded as the offences of forgery within the meaning of the above crimes.

False entries in a prospectus (Art. 2623 Civil Code)

Any person who in prospectuses required in order to attract investment or to be admitted for listing on regulated markets or in documents to be published in connection with public offerings for purchase or exchange **issues false information or conceals data** or notices in order to **lead the addressees into error** and with the intention to deceive them is guilty of the above criminal conduct.

The basis of incrimination repeats the model for false communications by the company, aimed at criminal acts in the event of the falsehoods not causing damage to the assets of the addressees of the prospectus (paragraph 9) and criminal acts whereby such damage occurs (paragraph 2).

It should be noted that

- there must be awareness of the falsehood and the intention to deceive the addressees of the prospectus (generic fraud);
- the conduct must be such as to deceive the addressees of the prospectus;

- the conduct must be aimed at obtaining an undue profit for oneself or for others (specific fraud).

The crime is regarded as a complicit one that may be committed by “anyone” who initiates the impugned conduct.

Falsity in relations or communications by the audit company (art. 2624 Civil Code)

The crime consists of **false assertions** or concealment of information **by those responsible for auditing**, with regard to the economic, asset or financial situation of the company, in order to obtain an undue profit for themselves or for others. The sanction is heavier if the conduct has caused damage to the assets of the addressees of the communications.

Active persons are those responsible within the audit company (actual crime) but members of the administrative and auditing bodies at NOVARTIS and their staff may be involved by way of complicity in the crime.

2 – Protection under criminal law for the share capital

Undue return of contributions (Art. 2626 Civil Code)

Typical conduct comprises the **return of contributions to shareholders** or freeing of the latter of the obligation to pay them, in a hidden or simulated way, **except in cases of legitimate reduction of the share capital**.

Persons committing the crime are the directors (own offence). However, the possibility of shareholders¹³ participating remains, having instigated the act or persuaded or assisted the directors.

Illegal distribution of profits or reserves (Art. 2627 Civil Code)

The criminal conduct with this offence, by nature a misdemeanour, consists in the **distribution of profits** or payments on account against profits **not effectively earned** or intended by law for the reserve, **or the distribution of reserves**, even if not consisting of profits, that may not be distributed by law.

The offence is nullified if the profits or the reserves are reconstituted before the time limit laid down for approval of the balance sheet.

Persons committing the crime are the directors (own offence).

Unlawful operations on shares in the company or in the controlling company (Art. 2628 Civil Code)

This offence is committed by the **acquisition or subscription of shares in the controlling company which harms the integrity of the share capital** and reserves that cannot be distributed by law.

¹³ According to the general rules referred to in Arts. 110 et seq. Criminal Code.

The crime is extinguished if the capital or reserves are reconstituted within the time limit laid down for approval of the balance sheet for the year in respect of which the action was taken.

The offence may be committed by the directors of NOVARTIS in respect of shares of the controlling company.

In the event of unlawful operations being undertaken on shares of the controlling company, the persons committing the offence are the directors of the subsidiary, but the controlling company's directors may be held liable only in the event of bankruptcy. Shareholders may also be liable in this respect.

Operations to the prejudice of creditors (Art. 2629 Civil Code)

The circumstances arise when the **share capital is reduced** in breach of the provisions of the law protecting creditors, or of a merger with another company or a split, **which damages creditors**. The offence is extinguished if the damage is made good to creditors prior to the law case.

Persons committing the crime are, in this case also, the directors.

Fictitious capital formation (art. 2632 Civil Code)

The offence is based on the following conduct:

- a. fictitious formation of or increase in the share capital by **allocating shares in a sum lower than their nominal value**;
- b. **reciprocal subscription of shares**;
- c. **substantial overvaluing of contributions of goods in kind**, credits, or assets of the company in the event of a transformation.

Persons committing the crime are the directors and contributing shareholders.

On the other hand, failure of control and possible auditing by the directors and auditors of the valuation of the contributions in kind (in terms of Art. 2343 (3) Civil Code) contained in the valuation report prepared by the expert appointed by the Court is not a criminal offence.

Undue distribution of the company's property by the liquidators (Art. 2633 Civil Code)

The crime is committed on the **distribution of the Company's property amongst shareholders prior to payment of the company's creditors** or the transfer to a provision of the necessary sums for this purpose, thereby damaging creditors. It will be noted that making good the loss to creditors prior to a law suit extinguishes the offence.

Persons committing the crime are exclusively the directors.

3. *Safeguarding under criminal law of the proper functioning of the company*

Prevention of an audit (Art. 2625 Civil Code)

The conduct comprises **preventing or obstructing the discharge of control or auditing activities** legally vested in the shareholders, the other governing bodies or the audit companies, by concealing documents or other appropriate records.

The offence may be committed by directors.

Unlawful influence over the meeting (Art. 2636 Civil Code)

Typical conduct is where **a majority at the meeting is obtained by simulated documents or by fraud** (constructive crime) **for the purpose of obtaining undue profit** (specific fraud) for oneself or for others.

The offence takes for the form of a common crime, and may therefore be committed by any person, even if unconnected with the Company.

4. *Protection under criminal law against fraud*

Speculation (Art. 2637 Civil Code)

The circumstances arise where false information is distributed or simulated or other **devices specifically intended to cause an appreciable change in the price of financial instruments** or to have a significant effect on public trust in the stability of assets of banks or banking groups are pursued.

This offence, too, is a common crime, which may be committed by any person.

5. *Protection under criminal law for the surveillance functions*

Obstructing the discharge of functions by the public surveillance authorities (Art. 2638 Civil Code)

The provision identifies two types of offence distinguished by conduct and the time they are committed:

- the first takes place through setting out in **communications** to the supervisory authorities set up by law and in order to obstruct its operations, of **material facts not corresponding to the truth**, or otherwise subject to assessment, concerning the economic, asset or financial position of those being supervised, or by concealing by fraudulent means wholly or partly, of facts that should have been communicated regarding the situation concerned;
- the second lies in the simple obstructing of the discharge of duties of surveillance, knowingly undertaken, in any form, also by failing to communicate with the supervisory authorities as required (paragraph 2);

It will be noted that

- the first of these cases is based on unlawful conduct for the specific purpose of obstructing the supervisory function (specific fraud);

- the second case consists of an offence of committal (preventing the exercise of supervisory functions) in universal form, i.e. achieved through any form of conduct, including failure to act, the subjective element of which consists of generic fraud.

The persons likely to commit either offence are directors, general managers, auditors and liquidators.

B.2 Areas of activity at risk

In relation to each of these types of offence as described above, specific areas may be identified at risk in the abstract. NOVARTIS for the most part is engaged in activities falling within potential areas at risk on the basis of specific procedures.

The areas of activity considered **most specifically at risk** in relation to company crime are felt to be the following:

1. drafting of the balance sheet, the directors' report, the internal balance sheet and other company communications;
2. the auditing activities undertaken by the Audit Committee and the audit company.

The Administrative Body within NOVARTIS may where applicable identify specific areas of risk and inform the Supervisory Body. Under this Special Part of the model, the following are therefore noted, in addition to other specific principles of conduct and implementation concerning the areas referred to above:

- the principles of conduct that NOVARTIS seeks to place at the basis of the Company's action in connection with all behaviour that may amount to company crime as laid down and sanctioned by the Decree;
- additional preventive and control measures in accordance with the particulars contained in the Guidelines issued by Confindustria regarding all activities at risk in the abstract.

Finally, the verification tasks of the Supervisory Body must be defined and the activities of distributing the Model and training in the legal principles regarding the committing of the offences described.

B.3 Addressees of the Special Part

Addressees of the Special Part "B" are the persons who are from time to time associated with incriminating circumstances (**directors, general managers, auditors, shareholders, liquidators**, etc.), i.e. "senior persons" at NOVARTIS and **staff subject to supervision and control** by the senior persons in the areas of activity at risk, hereinafter called the "Addressees".

With regard to the directors, the general managers, the auditors and liquidators, the law places persons who occupy these functions "de facto" are formally on the same footing as the former. In accordance with Art. 2639 Civil Code, in fact, any person who is required to

discharge the same duties, under a different name and any person who continuously and demonstrably possesses the typical powers associated with the status or job is liable for the company crimes laid down in the Civil Code.

The purpose of this Special Part is to ensure that, to prevent the offences referred to in the Decree from being committed,

- all addressees as indicated above are fully aware of the importance of the impugned conduct;
- and therefore adopt codes of conduct in line with what it lays down.

B.4 General principles of conduct

The present Special Part imposes an **express prohibition**

1. introducing, cooperating with or giving cause for the implementation of conduct likely to amount to the circumstances of the offence referred to above (Art. 25 b of the Decree;
2. initiating, cooperating with or giving cause of the implementation of conduct which, may not in itself be such as to amount to the circumstances of a crime falling within those in question, may potentially become such.

This Special Part consequently lays down an **express obligations** on the Addressees to

1. adopt correct, transparent and cooperative conduct in observing the requirements of the law and the company's internal procedures in all activities undertaking in drawing up the balance sheet and other company communications, in order to provide shareholders and third parties with true and correct information on the Company's economic, asset and financial position;
2. to adopt correct conduct in observing the requirements of the law and the company's internal procedures in order to ensure that investors' assets are protected, paying particular attention and ensuring accuracy in the acquisition, processing and presentation of data and information concerning the financial products and their issuers;
3. strictly to observe all the rules laid down by law to protect the integrity and effectiveness of the share capital and to act in all cases with respect for the company's internal procedures based on these rules, in order not to harm the security of creditors and third parties generally;
4. to ensure the proper functioning of the company and its governing bodies, ensuring and facilitating every form of internal control over the company management as required by law and the unbiased, correct implementation of the general meeting's desires;
5. to observe the rules safeguarding correct calculation of the price of financial instruments of the parent company, strictly avoiding any kind of behaviour likely to cause an appreciable change in relation to the specific situation in the market;

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6. to undertake the communications required by law and the regulations to the supervisory authority in good time, correctly and in good faith, without setting up any obstacle to the discharge of the supervisory functions undertaken by the latter.

With regard to the above conduct, the following are in particular **prohibited**:

- with reference to **Item 1** above:
 - 1.a. to put forward or pass on false or incomplete data or data not corresponding to the real facts regarding the Company's economic, asset and financial position, for processing or for inclusion in balance sheets, reports and prospectuses and other company communications;
 - 1.b. failing to communicate the data and information required by law concerning the Company's economic, asset and financial situation;

- with reference to **item 2** above:
 - 2.a. To alter data and information intended for inclusion in the prospectus;
 - 2.b. to present data and information used in such a way as to provide a distorted picture of considered opinion concerning the asset, economic and financial situation of the issuer (parent company) and on the trend of its business, and on the financial products and related rights;
 - 2.c. to reduce the comprehensibility of the prospectus by increasing the mass of data, information and descriptive parts contained in this prospectus out of proportion compared with what is required for the effective purpose of informing the investor

- with reference to **item 3** above:
 - 3.a. to return contributions to shareholders or free them from the obligation to pay them, except in cases of legitimate reduction in the share capital, in any form not specifically included amongst those described below;
 - 3.b. to distribute profits or payments on account against profits not effectively earned, or those earmarked by law for reserves;
 - 3.c. to acquire or subscribe shares in the Company or the controlling company except in the cases laid down by law;
 - 3.d. to reduce the share capital or undertake mergers or splitting in breach of the provisions of the law protecting creditors.
 - 3.e. to proceed with the formation or fictitious increase of share capital, allocating shares at a value of less than the nominal when setting up the company or increasing the share capital;
 - 3.f. diverting the company's property, on its liquidation, from being passed on to creditors, distributing it amongst shareholders prior to payment of creditors or the setting aside the necessary sums to cover it;

- with reference to **item 4** above:
 - 4a to engage in conduct that materially obstructs the discharge of the work of controlling or auditing the company's business by the Audit Committee or the audit company by concealing documents or using fraudulent means;
 - 4.b. to arrange for or influence the passing of resolutions at a general meeting through simulated or fraudulent actions aimed at altering the regular process of establishing the meeting's desires;

- with reference to **item 5** above:
 - 5.a to publish or pass on false information or engage in simulated operations or other conduct of a fraudulent or deceitful nature in connection with listed or unlisted financial instruments and likely substantially to alter their price (price sensitivity);
 - 5.b. to publish or pass on false information or engaging in simulated operations or other conduct of a fraudulent or deceitful nature likely to spread distrust amongst the public towards banks or banking groups, affecting their image of stability and liquidity;

- with reference to **item 6** above:
 - 6.a to fail to provide all the periodical information, with the required quality and speed, laid down by law and the regulations for the industry to the Supervisory Authorities concerned with the company's business, and the submission of data and documents as required law and/or specifically requested by the Authorities concerned;
 - 6.b. in the said communications and submissions, to set out facts that do not comply with the truth or to conceal relevant facts in relation to the economic, asset and financial conditions of the Company;
 - 6.c. to engage in any kind of conduct that may obstruct the exercise of the supervisory functions, also in the course of inspections by the Public Surveillance Authorities (deliberate opposition, unfounded refusals or also obstructive conduct or failure of cooperation, such as a delay in communications or in the provision of documents).

B.5 Principles for implementing the prescribed conduct

The principles and basis for pursuing the conduct referred to above in connection with the various types of company crime are described below by way of example.

B.5.1 Balance sheets and other company communications

The annual balance sheet and the directors' report will be drawn up by means of the specific company procedures existing in this connection, which

- clearly indicate the data and notices that each department must provide through its senior staff for the prescribed communications, the criteria for processing the data to be supplied, and the time limits for submitting data by the individual sections concerned with the relevant duties;
- provide for the submission of data and information to the department concerned (administration, finance and control) by means of the data processing system, which will permit the individual inputs to be traced and the persons entering data into the system to be identified;

B.5.2 Information prospectuses

The drafting or participation in the drafting of information prospectuses must be undertaken on the basis of procedures laid down on the following principles:

- verification, where possible, of the accuracy of the data and information;
- where verification in this way is not possible, due to the data to be used in the prospectus coming from outside sources, acquisition of a certificate of accuracy from the persons who have provided the information;
- appointment of a person to be responsible for each operation of editing or participation in editing of the information prospectus;
- monitoring of the professionalism of the persons in charge of the said operations, also with regard to the work of assessing the contributions by other persons concerned in drafting the prospectus.

B.5.3 Protection of share capital

All operations on the Company's share capital and those in setting up the company, acquiring and disposing of participating interest, mergers and splittings will be undertaken observing the **Company's procedures and policies** laid down in this respect, which

- provide for an opinion necessarily to be obtained from the CFO and submission to the Administrative Body or to the Board of Directors for approval;
- govern operational decision-making responsibility for the individual operations and the mechanisms for coordination with the central departments at NOVARTIS.

B.5.4 Regular operation of the Company

In order to prevent the offence of obstructing auditing of the company's business by the company's governing bodies and the audit company from being obstructive, the following internal rules and procedures will apply to ensure the principles of conduct laid down in paragraph 4 (4) above.

1. submission to the Audit Committee, sufficiently in advance, of all documents concerning points placed on the agenda for meetings of the General Meeting or Board of Directors or on which the law requires an opinion to be given;
2. providing the Committee with all documentation concerning the operations of the Company that the Committee may require for its periodical audits;
3. introduction/formal application of internal rules and procedures concerning observance of the company's rules and discipline in the method of executing audits by the Audit Committee and the audit company;
4. distributions of principles of conduct as provided by this Model in connection with the company's entire organisation, so that directors, the management and all staff can offer the auditing bodies and the audit company maximum cooperation and accuracy;
5. setting up of a programme for periodic training and information for directors, management and staff on offences and unlawful administrative acts in company matters;
6. arranging of periodic meetings of the Audit Committee with the Supervisory Body to ensure that discipline is maintained in connection with the company rules and consistent conduct is adopted by Directors, management and staff.

B.5.5. Speculation

In order prevent the crime of speculation being committed and to take appropriate steps to protect investors, the following **safeguards** are provided:

1. adoption/formal introduction of internal procedures aimed at preventing breach of the principles of conduct laid down in this Model by ensuring participation of two or more persons in the discharge of activities at risk, the relevant monitoring and control procedures, and the appointment of a person responsible for the operation;
2. information and periodic training programme for directors, management and staff in connection with speculation;
3. holding of periodic meetings between the Audit Committee and the Supervisory Body to ensure that discipline is observed with regard to the company's rules;
4. authorisation procedures for any printed communications and distribution of analyses and studies concerned with the parent company's financial instruments.

B.5.6 Activities subject to supervision

With reference to the company's activities subject to supervision by public authorities in accordance with specific rules for the industry and in order to prevent the committing of the crimes of false communication to the authorities and obstruction of the supervisory functions, the activities subject to supervision will be undertaken on the basis of company procedures already in existence and subsequent procedures that may be necessary, laying down rules for the allocation of specific responsibilities in connection with

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1. the periodic notification of the authorities as provided by the laws and regulations;
2. the transmission to the latter of the documents indicated in the laws and regulations;
3. the transmission of data and documents specifically required by the supervisory authorities;
4. the conduct to be adopted during inspections.

The **principles** underlying these procedures are:

1. the need to ensure proper quality and speed in communication to the supervisory authorities;
2. the taking of all action of an organisational and accounting nature required to obtain data and information for the correct preparation of reports and their prompt despatch to the supervisory authorities on the basis and at the times laid down in the current rules applying;
3. ensuring that the said activities and decision-making procedures underlying them are supported by a reliable data system and efficient internal controls, to guarantee the reliability of information provided to the supervisory authorities;
4. proper drawing up of the procedures concerned and subsequent documentation for implementing the requirements made in them, with particular reference to the data processing activity;
5. in the course of inspections, the departments and sections of the business inspected will offer the maximum cooperation in the discharge of audits and in particular will provide the documents which those concerned consider it necessary to have, quickly and fully.

A Communications Officer will be appointed for each operation of communication with the public supervisory authorities, transfer of the documents concerned and inspections carried out by the authorities' staff, or for a self-contained, temporary series of such operations, from submission to inspection, who will ensure due execution of the individual requirements in the procedure and relative recording of activities undertaken.

These records must be placed at the disposal of the Supervisory Body for the periodic inspections to be made by the latter.

The person responsible for each function whose activity is subject to supervision will also submit an annual report on relations with the supervisory authority concerned, to be sent to the Supervisory Body at the latter's request, together with specific reports on particular, relevant communications or inspections by the authorities.

B.6 Tasks of the Supervisory Body

The **supervisory tasks** of the OdV concerning the observance and effectiveness of the model are governed by the Supervisory Body Rules, these being examples in connection with company crime in particular:

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- a. with reference to the balance sheet and other company communications, in the light of the fact that the NOVARTIS balance sheet is certified by an audit company, the tasks of the Supervisory Body are limited to the following
- Monitoring the effectiveness of the internal company procedures and policies to prevent crimes of false social communication;
 - examination of any specific reports issued by the control bodies or by any employee, and arranging of checks considered necessary or desirable in consequence of information received;
 - surveillance of the effective maintaining by the audit company of the necessary independence to ensure a proper audit of documents submitted by NOVARTIS;
- b. with reference to other activities at risk:
- periodic verifications of observance of internal company procedures and policies'
 - in particular, periodic audits on the conducting of communications with the supervisory authority and the outcome of any inspections made by the latter's employees;
 - monitoring the effectiveness thereof in preventing the committing of crimes;
 - examination of any specific messages obtained from the control bodies or any member of staff and arranging of the checks considered necessary or desirable as a result of reports received.

The Supervisory Body will report periodically to the Board of Directors on the results of its surveillance and control activities in connection with company offences.

Consequently, should points arise from the inspections made by the Supervisory Body indicating that the principles and protocols contained in this Special Part of the Model have been infringed, that crimes have been committed, or that crimes have been attempted, the Administrative Body or the Supervisory Body will refer the matter to the full Board and to the Audit Committee, who must call a meeting of shareholders to make necessary and due provision.

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SPECIAL PART “C”

The crimes of culpable homicide and serious or very serious injury committed in breach of the accident prevention laws and those protecting health and safety at work

C.1 Culpable homicide and serious and very serious injuries committed in breach of the accident prevention regulations and those safeguarding health and safety at work

Art. 25 f of the Decree entered into effect on 25 August 2007. As from that date, the offences referred to for the application of the Statutory Decree 231/01 also mentions the crimes referred to in article 589 Criminal Code (culpable homicide) and 590 (3) of the Code (serious or very serious culpable injury) committed in breach of the accident prevention rules and those safeguarding health and safety at work.

An extension of the organisation's liability to the above offences as well requires a necessary adjustment to the Model. This adjustment will have to take account of the fact that the area affected is already fully regulated and monitored by the company. All activities already deployed must therefore be recorded and harmonised with the provisions of the Decree. This updating will therefore be focused on the effectiveness of the process of risk assessment and subsequent stages in verifying the effective implementation of these provisions.

The model may be supplemented by means of

- acquisition of the “Risk Assessment Document” drawn up for the purposes of Statutory Decree 626/94;
- definition of the guidelines and formal approach to the risk assessment process, which includes the activity of verifying updates in connection with accident prevention and health and safety at work;
- definition of the guidelines and formal approach to the process of monitoring effective implementation of the system of safeguards described in the Risk Assessment Document, which also sets out the appropriate corrective and preventive action should non-conforming situations arise;
- acquisition of the documentation issued to obtain OHSAS (Occupational Health & Safety Assessment Series) certification 18001.

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OHSAS 18001 is an organisational instrument that allows the safety of workers to be constructively managed, focusing on the following requirements:

- identification of risks, risk assessment and methods of control;
- definition of tasks and responsibilities;
- training and familiarisation of personnel;
- controlled documentation management;
- preparation of suitable measures to identify, prevent and check possible incidents;
- monitoring of system performance for safety and health;
- re-examination of direction;
- ongoing improvement