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AOP ORPHAN PHARMACEUTICALS ITALY S.R.L.

MODEL 231


ENGLISH VERSION¹

¹ This document is a summary of the Control Model (hereafter Model 231) that the Board of Directors of AOP Orphan Pharmaceuticals Italy S.r.l. approved on 16th June 2023 to comply with the Italian Legislative Decree no. 231/2001.

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1. OBJECTIVES OF THE CONTROL MODEL 231


AOP Orphan Pharmaceuticals Italy S.r.l. intends to adopt the Control Model 231 for the prevention of the crimes and offenses defined by Italian Legislative Decree 231/2001 in order to favor conditions of fairness and transparency in running its business activities.

Through the adoption of the Control Model 231, the Company also intends to pursue the following objectives:

- to reduce the probability that the organization may be sanctioned in case of the commission of a crimes included in the Legislative Decree n. 231. It is important to highlight that in case AOP Orphan Pharmaceuticals Italy S.r.l. does not adopt a Control Model 231 the sanction is automatically. The sanctions that the Italian judiciary authority may apply to organization include: a monetary penalty of 1,5 million Euro (at maximum); a ban (prohibition) to have a deal with the Public Administration for 2 years, the suspension of licenses and concessions, the exclusion from or cancellation of public finance, funding or subsidies;
- to determine in all those who work on behalf of the AOP Orphan Pharmaceuticals Italy S.r.l. the awareness of being able to cause risks for the organization in case they violate the provisions of Model 231 to commit the offenses mentioned in the following Section 3. As said above, the violation of the provisions of Model 231 can lead to sanctions against the company in addition to the sanctions that can be imposed against those who violate Model 231.
- to strengthen of the company’s internal control system, through the introduction of formal procedures to mitigate compliance risks in critical business process and the setting up of a control body (called “Organismo di Vigilanza 231”) as defined in next Section 4. These control measures can integrate those defined at Group level (by AOP Orphan Pharmaceuticals GmbH parent company) and concur to the prevention of the commission of crimes.

2. STRUCTURE OF THE CONTROL MODEL 231

For the definition of the Control Model 231 the CEO has appointed a project team made by external consultants who have run several interviews with AOP Orphan Pharmaceuticals Italy S.r.l.’s personnel. To develop the content of the Control Model 231, the project team has based on:

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1. the provisions of the Italian 231 law;
2. the Guidelines setting up by the Italian associations of company working in pharmaceutical industry (Assobiomedica and Farindustria) which regulates several aspects of the industry's relationship with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs);
3. the indications coming from the jurisprudence.

The Control Model 231 is structured as follows:

- 1) A general part, which includes the description of the Legislative Decree 231; the nature of the offenses and crimes; the general control measures for the entire company such as the setting up of the control body, its functions and activities; and the disciplinary code reported in Section 7;
- 2) A section called “Specific Part” referring to the individual categories of potential offense, which includes:
 - the identification of AOP Orphan Pharmaceuticals Italy S.r.l.’s business areas that present an exposure to a risk of crimes;
 - the identification of the general and specific rules of conduct that employee must apply to avoid the commission of crimes;
- 3) A document called “management protocols” which includes the description of control measure for those areas (e.g. procurement) which are crossed to individual categories of potential offences;
- 4) The Group Code of Conduct AOP Orphan Pharmaceuticals Italy S.r.l.;
- 5) The framework of information flows, containing the description of information that the CEO and other personnel have to send to the control body 231;
- 6) the risk matrix 231, an excel document that formalize the results of interviews running during the project and provide evidence to identify processes having a 231 risk;
- 7) the offences table 231, an excel document which contains a detailed description of the crimes (almost 160) included in the Legislative Decree 231) .

3. TYPE OF OFFENCE


According to the Legislative Decree 231/2001 the types of offenses which are relevant to configure the liability of the organization are the following macro categories:

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- offences committed against Public Administration (comprised HCPs), which includes corruption, embezzlement and others;
- corruption in running business activity with private customers and suppliers;
- false financial statements and other accounting crimes;
- tax crimes;
- receipt, laundering and use of money, goods or profits from illegal activities, as well as self-laundering;
- health and safety crimes;
- the protection of copyright and other related property rights;
- computer crime and illegal data processing;
- offences connected with association crime;
- forging money, public credit notes, revenue stamps and instruments or identity marks;
- industry and trade-related offences;
- offences connected to terrorism or the subversion of democracy;
- illicit intermediation and labor exploitation;
- abuse of insider information (insider trading) and “market manipulation”;
- offences connected to inducing individuals into not making statements or into making false statements to judicial authorities;
- environmental offences;
- employment of third-country citizens with irregular residential and labour status;
- crimes of Fraud in sporting competitions, abusive gaming or betting and games of chance performed using gaming machines prohibited;
- smuggling crimes;
- crimes relating to payment instruments other than cash;
- crimes against cultural heritage.

4. CODE OF ETHICS

The Code of Conduct is an official document of the group AOP Orphan Pharmaceuticals Italy S.r.l., containing the principles for an ethical conduct that must be respected in the relationship with the stakeholders.

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A copy of the Code of Conduct (and a summary of the Control Model 231) will be published on the Internet web site.

The Code of Conduct is an integral part of the Control Model 231.

All company subjects are required to comply with the conduct prescribed by the Code of Conduct.

5. CONTROL BODY 231

All organizations which adopt a Control Model 231 must appoint a Control Body having the task to check that the rules and provisions of this model has respected in the running of business activity and it should carry out other additional assignments listed below.


The Legislative Decree 231 requires that this Body should be independent and with adequate competencies. Regarding its composition (in terms of number) it can be made up of one person or (generally) three members. In small organization is generally made up of one person which is external to the organization (to preserve its independence from the CEO and other managers).

The Legislative Decree 231 also requires that the Control Body 231 has a financial autonomy to carry out its activities effectively. This means that this body can ask to the Board of Director a specific budget that can be used to hire consultants in order to perform activities required specialized skills.

The Administrative Body, at the same time as the appointment, establishes the term in office of the Control Body 231, which generally cannot be longer than three years.

The main assignments of the Control Body are defined as follows:

- supervision of the effectiveness of Model 231, that is, on the observance of the requirements by the recipients;
- monitoring of the implementation and updating of Model 231;
- verification of the adequacy of Model 231, that is, the effectiveness in preventing illegal behavior;
- analysis of the maintenance, over time, of the soundness and functionality requirements of Model 231 and promotion of the necessary updating;
- approval and implementation of the annual program of supervisory activities within the structures and functions of the Company;

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- care and analysis of the information flows defined in the Control Model 231.

6. INFORMATION FLOWS FROM THE CONTROL BODY TOWARDS THE BOARD

The Control Body reports on the implementation of Model 231, the emergence of any critical aspects and communicates the outcome of the activities carried out in the exercise of the assigned tasks.

The Control Body reports to the Board the activities carried out according to the timing specifically provided for in the Control Model 231 and in its operating regulations.

The following reporting lines are planned:

- **annually.** A specific annual report is prepared relating to the activity carried out with reporting of the outcome of the tasks performed;
- **immediate,** towards the Board, where facts of particular materiality or significance are ascertained.


7. DISCIPLINARY SYSTEM

The disciplinary system, that is to say the set of sanctions envisaged for the violation of the rules of the Control Models and of the Code of Ethics, is a mandatory component for guaranteeing the effectiveness and implementation of the Model itself.

The Legislative Decree 231 of 2001 expressly provides for the need to create a disciplinary system suitable for sanctioning non-compliance with the measures indicated in the Control Model.

Disciplinary sanctions are applied regardless of the outcome of any criminal proceedings instituted, due to the fact that it also constitutes a violation of the measures of the Control Model and the Code of Ethics.

AOP Orphan Pharmaceuticals Italy S.R.L. provides for a system that grades the extent and type of the applicable sanctions, in relation to the different degree of danger that the conduct of the subjects may present with respect to the commission of the crimes.

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Therefore, the disciplinary system sanctions, first of all, all infringements of the Model, from the most serious to the lightest, by means of a gradual system of the sanction and, secondly, it respects the principle of proportionality between the detected failure and the sanction imposed.

Recidivism constitutes an aggravating circumstance and involves the application of a more serious penalty.

Furthermore, the sanctioning system is subject to constant verification and evaluation by the Control Body 231.