

**HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS**

Prevention of corruption and protection of whistleblowers

Impact on the activity of the pharmaceutical industry

At the end of 2021, two laws were published to regulate the general framework for the prevention of corruption in the activity of companies: (i) Decree-Law 109-E/2021 of 9 December, which establishes the general rules for the prevention of corruption (“RGPC”) and (ii) Law 93/2021 of 20 December, which creates rules to protect whistleblowers (“RJPDJ”).

This legal framework is applicable to companies with their registered office in Portugal and to branches in Portugal of companies with their registered office abroad, which employ 50 or more employees.

For the purposes of applying the RGPC, “corruption and related offences” are understood to mean the offences of corruption, undue receipt and offer of advantage, embezzlement, unlawful economic participation in a transaction, extortion, abuse of power, misappropriation, influence peddling, laundering or fraud in obtaining or diverting a subsidy, grant or credit as provided for in the Criminal Code.

In turn, the RJPDJ is intended to encourage the reporting of (i) breaches of European Union rules or national rules that transpose or implement these rules, (ii) acts or omissions contrary to and detrimental to the financial interests of the European Union and European and national rules to prevent and combat fraud, (iii) acts or omissions contrary to the rules of the internal market and the free movement of goods, persons, services and capital, including competition and state aid rules as well as rules on corporate taxation (iv) acts considered to constitute violent crime, especially violent and highly organised crime, as well as crimes committed in the context of organised and economic-financial crime, and (v) acts or omissions contrary to the European Union rules applicable to works contracts, supply contracts and service contracts by contracting authorities or contracting entities in the fields of defence and security, or contrary to the aims of those rules.

This legal framework is applicable to companies with their registered office in Portugal and to branches in Portugal of companies with their registered office abroad, which employ 50 or more employees.

The RGPC entered into force on 8 June 2022. In the case of medium-sized companies (companies employing up to 250 people whose annual turnover does not exceed €50 million or whose annual balance sheet total does not exceed €43 million) the implementation of the measures imposed by the new legislation must take place by 8 June 2023.

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1. OBLIGATIONS OF COMPANIES

Under the new legislation, companies must implement the following measures:

- A plan to prevent risks of corruption and related offences;
- A code of conduct;
- Creation of an extraordinary training plan;
- A whistleblowing channel;
- Appointment of a compliance officer;

2. PENALTIES

Both approved laws establish a system of administrative offences associated with non-compliance with the obligations defined in them.

In the case of the RGPC, non-compliance with the obligations set out in it is punishable by a fine ranging from €1000.00 to €44,891.81.

Non-compliance with the requirements of the RJPDI constitutes an administrative offence, punishable with a fine of between € 1000.00 and € 250,000.

3. IMPACT ON THE ACTIVITY OF THE PHARMACEUTICAL INDUSTRY

Considering the extensive regulatory framework applicable to companies in the pharmaceutical industry, many already have internal regulations aimed at preventing the occurrence of situations that may potentially correspond to illegal acts covered by the legal framework now in force.

Transparency in the relationships within the pharmaceutical industry has been one of the most regulated aspects of the sector and this contributes to minimising the occurrence of situations that may correspond to illegal acts of corruption.

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Nevertheless, where internal instruments on transparency and the prevention of corruption already exist, it is important to ensure that these instruments are adapted to the requirements of the new legal framework.

The Codes of Conduct and Ethics of the pharmaceutical industry business associations (for example, at national level, the Codes of APIFARMA, APORMED, or at international level, those of the EFPIA or MedTech) already contain extensive regulations on the transparency of the pharmaceutical industry's relationships. These regulations are in line with the national and European system of penalties in these matters and many of the pharmaceutical industry companies' internal transparency instruments are based on these codes. However, the RGPC requires companies to go further in the range of measures they have to put into place. It requires them to implement the preventive measures defined in the RGPC in accordance with the requirements set out there.

One should also bear in mind that the national penalty arrangements applicable to the pharmaceutical industry are primarily of the nature of administrative offences, even though certain offences with criminal relevance are subject to penalties at this level. Bearing this in mind, there is a need to review the internal instruments of companies to ensure not only the mention of criminal offences of corruption and related offences as provided for in the Criminal Code in those instruments, as required by the RGPC, but also the inclusion of the remaining measures and requirements specifically defined by the RGPC.

A further important point regarding the impact of the RGPC on public tenders is the need to submit a plan for the prevention of corruption and related offences by the contractor in cases where the value of the contract to be entered into makes it subject to prior supervision by the Court of Auditors, unless it is a natural person or a micro, small or medium-sized enterprise, certified as such under the terms of the law. ■