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## SPAIN

This country profile has been prepared in view of sharing information and assessing the current state of implementation of the MEDICRIME Convention under domestic legislation. It does not necessarily reflect official positions of the country covered<sup>1</sup> or of the Council of Europe.

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### **1. General overview**

By Organic Law 1/2015 of 30 March the Spanish Penal Code has been amended in depth<sup>2</sup>. As the Kingdom of Spain had previously signed and ratified the MEDICRIME Convention the Spanish legislator has modified also the provisions of the Penal Code related with medicament counterfeiting to comply with Convention requirements (Arts. 361 to 365 of the Penal Code).

As general assessment can be said that lawmaker has been extremely faithful to the text of the Convention. This fact and also strict entailment to the rule of law, required under Spanish law, has resulted in excessive casuistry, which was to be avoided as far as possible. Another flaw is

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<sup>2</sup> On the former regulation of adulterated medicaments see Mendoza Calderón, S., *Responsabilidad penal por medicamentos defectuosos*, 247 ff.

that legislative technique has included various offenses appearing jointly drafted instead of keeping them separated to prevent confusion when applying thereof.

## 2. Criminal conducts

Here we present a brief description of the offenses under the Spanish Criminal Code which are taken from the MEDICRIME Convention:

1. **Actions of traffic without autorisation or the documents of conformity** (Art 361):  
Which manufactures, imports, exports, supply, mediates, sells, offers or places on the market, or stored for these purposes, medicines, including human and veterinary use, and investigational medicinal products, lacking the necessary authorisation required by law, or medical devices that do not have the documents required under the provisions of a general nature.
2. **Trafficking of damaged medical products** (Art 361 *in fine*): When medicines were damaged, expired or failed to comply with the technical requirements for their composition, stability and efficiency, and thereby generates a risk to life or health of persons.
3. **Illegal manufacture of medical products** (Art 362.1): which develops or produces,
  - a) a medicine, including human and veterinary use, and investigational medicinal products; or an active substance or an excipient of such medicine;
  - b) a medical device, as well as accessories, components or materials which are essential to its integrity;so that this deceptively: its identity, including, where appropriate, packaging and labeling, expiry date, name or composition of any of its components, or, where appropriate, the dosage thereof; its source, including the manufacturer, country of manufacture, country of origin and the holder of the marketing authorization or compliance documents; data relating to compliance with legal requirements or requirements, licensing, compliance documents or authorisations; or its historical background, including the records and documents relating to distribution channels used, provided they were intended for public consumption or use by another, and create a risk to the life or health of people.

4. **Adulteration of medicines and other related substances** (Art 362.2): who alters, or to manufacture or produce it at a later time, quantity, dosage, expiration or genuine composition, as authorized or declared, of any of the medicines, excipients, medical devices, accessories, components or materials referred to in the previous section, in a way that reduces their safety, efficacy or quality, creating a risk to the life or health of people.
5. **Knowingly trafficking of counterfeit or adulterated products** (Art 362 bis Parag 1): which knowingly counterfeiting or alteration, imports, exports, announces or advertises, offers, displays, sells, provides, expends, dispatchs, packaging, supply, including brokering, traffic, distributes or places in the market, either of drugs, active substances, excipients, medical devices, accessories, components or materials which the previous article refers to, and thereby generate a risk to life or health of people.
6. **Acquiring or having in deposit** (Art 362 Parag 2): who acquires or has in deposit in order to be allocated to public consumption, to the use by third parties or any other use that may affect public health.
7. **Falsification of documents** (Art 362 Ter): Who draws in a document any false or deceitful content related to any of the medicines, active substances, excipients, medical devices, accessories, components or materials referred to in paragraph 1 of Article 362, including its packaging, labeling and instructions for use to commit or facilitate the commission of an offense of Article 362.
8. **Aggravating circumstances** (Art 362 Quater): The higher degree penalties than those listed in Articles 361, 362, 362 bis and 362 ter, when the crime has been perpetrated by attending any of the following conditions be imposed:
  - 8.1 That the perpetrator is authority, public official, physician, clinician, teacher, educator, physical or athletic trainer, and acts in the exercise of his or her employment, profession or occupation.
  - 8.2 That medicines, active substances, excipients, medical devices, accessories, components or materials referred to in Article 362:
    - a) have been offered through media on a large scale; or
    - b) had been offered or provided to minors, persons with disabilities need special protection, or particularly vulnerable in relation to the product supplied people.

8.3 That the perpetrator belonged to a criminal organization or group aimed towards the commission of such crimes.

8.4 That the facts were made in establishments open to the public by the managers or employees thereof.

9. **Criminal responsibility of legal persons** (Article 366): When in accordance with the provisions of Article 31bis a legal person is responsible for the crimes covered in the previous articles it will be imposed a fine of one to three years, or two to five times the value of substances and products referred to in previous Articles, or the benefit that is obtained or could obtain, applying whichever is higher.

10. **Doping** (Article 362 Quinquies). Doping is not part of the offences pursued by the MEDICRIME Convention, but in the Spanish Penal Code is included together with crimes related to counterfeit medicines as described above.

### 3. Penal sanctions and other measures

- **Natural persons:** Penalties established for natural persons include fine, prohibition on exercising the profession or trade up three years and imprisonment up to four years, depending of the seriousness of the offence. Exceptionally the former penalties maybe higher in a further step (which implies imprisonment up to six years) when offences of Articles 361, 362, 362 bis or 362 ter have been perpetrated under some aggravating circumstances (Art 362 Quater).
- **Legal Persons.** For legal persons the penalty will consist of a fine. Judges and courts may also impose penalties laid down in subparagraphs b. to g. of Paragraph 7 of Article 33: dissolution of the legal person (definite loss of its legal personality), suspension of its activities up to five years, closing its stores up to five years, temporary or permanent ban on its activities related to the crime committed, ineligibility for subsidies and public sector support, to contract with the public sector and to enjoy tax benefits and incentives from Social Assistance, judicial intervention to safeguard the rights of workers or creditors. (Art 366).

- **Confiscation.** In offenses under the preceding articles of this chapter shall be subject to confiscation of substances and products referred to in Articles 359 and following, as well as goods, means, instruments and profits subject to the provisions of Articles 127 to 128 (Art 362 Sexies).

#### **4. Reservations to the Convention**

No reservation to the Convention has been presented by Spain. Notwithstanding in the instrument of its ratification a Declaration has been introduced.