Here we are interested only in the legal consequences of breaking the rules concerning pharmaceutical products. This regulation belongs to the legislation on consumer protection, which includes preventive measures and offers judicial protection through actions to establish civil, criminal or administrative responsibility. We will not consider the drug manufacturer’s responsibility, which is similar to that of the manufacturer of any other goods.34 We will examine the regulations concerning the production and sale of pharmaceuticals, and the relevant administrative, criminal and civil rules.

There are many legal provisions in Spain concerning the production, control and sale of drugs and medicines. We may mention the statute concerning the production and sale of vaccines of 10 October 1919, the statute of 8 February 1924, the Basic Law of National Health of 25 November 1944, many ministerial orders of 1942 and 1943 about medical and dietetic foods, orders concerning the register of pharmaceutical products, and the order of 10 May 1973 concerning the pharmaceutical industry. We will also mention the regulation of pharmaceutical professional practice, the order of 18 April 1860 governing the sale of drugs and medicinal plants, and the statute of 10 August 1963 concerning pharmaceutical laboratories and the registration, distribution and advertising of drugs; this statute governs the commercial cycle of pharmaceutics beginning at the laboratory, passing through the drugs register and ending at the pharmacist’s store.

The 1860 order, which is partially still in force, establishes some basic principles about the responsibility of pharmacists and pharmacologists; article 9 of this order declares that the pharmacist must have his store in his house, he must control any laboratory operation, he must attend the store and sell the drugs himself, and he must keep the key of the cupboard where poisons and dangerous products are stored.

Article 15, concerning civil and criminal responsibility is also very important; it states that the pharmacist is responsible for the quality of the drugs and their condition, not only of those drugs or compounds produced by him, but also of the drugs commercially produced, which must be analysed and, if necessary, purified, for he will be responsible for the harm caused by any drug sold at his store.

According to article 19, the pharmacist cannot sell any drug without a physician’s prescription except for those drugs in domestic and common use. Article 20 declares that even with a prescription the pharmacist may not sell a dangerous drug or huge quantities of a normal drug without previously consulting the physician who signed the prescription.

When the 1860 order was approved, an official book called the Spanish Pharmacopoeia was published periodically, containing rules and ideas concerning the pro-

duction and elaboration of drugs and medicines. An order of 3 March 1953 declared this book obligatory for any pharmaceutical product.

The decree of 10 August 1963 governing pharmaceutical laboratories, registration, distribution and publicity is very interesting with respect to drug control. It declares that pharmaceutical products can only be produced at officially authorized laboratories, and those products must be registered at the General Department of Health. Pharmacists may also elaborate medicines and prescriptions and sell them at their own stores.

Article 7-4 of the said decree says that laboratory owners will be responsible for the acts committed in their laboratories. The same article says that the laboratory owner and the pharmacist can be declared responsible for the same act, and according to the circumstances they will be declared conjointly or in solidum responsible. Any drug manufacturing firm that gives a share of the profits or any other financial interest to doctors will be declared illegal (article 10-3). The control department of the laboratory must have adequate instruments to perform the necessary physical, chemical and biological tests. All pharmaceutical tests or analyses that require special instruments or techniques can be made at the General Department of Health laboratories. The personnel and staff working at pharmaceutical laboratories will be medically surveyed and will not be allowed to work there if they have any contagious illness or skin disease.

All pharmaceutical products must be officially entered in the register of the General Department of Health. A non-registered drug will be regarded as clandestine and illegal. The registration of a pharmaceutical product can be refused for technical, medical or legal reasons. The registration is valid for 5 years; after that it must be renewed. The registration of a foreign medicine can be authorized by the General Department of Health. Drug prices are fixed by the General Department of Health and by the Ministry of Health.

Honest publicization of pharmaceutical products is authorized, but physicians, practitioners, health personnel and pharmacists may not be representatives or commission agents of firms or companies that produce drugs and medicines.

A 1963 statute governs the administrative penalties in the case of infringement of these rules. This statute regards as grave offences: the modification of the conditions of production, storage and control of pharmaceutical products without informing the health authorities; the alteration of the form and content of these products; alteration of the price without consultation with the General Department of Health; failure to indicate on the packet that a prescription is required.

Very grave offences are: the production or sale of non-authorized pharmaceutical products and the failure to indicate stupefacent drugs. The administrative penalties include temporary or permanent suspension from professional activity and the refusal to authorize the laboratory. The penalties are imposed by the General Department of Health and by the Ministry of Health: their decisions can be appealed against before an administrative court.

Apart from administrative responsibility, the owner of the laboratory can also be held civilly responsible according to articles 1902 and 1903 of the civil code. In this case, the concept of fault or negligence is not only that defined by article 1104-2 of

35 For further information see Santos Briz, J., op. cit. "La Responsabilidad Civil", pages 421 ff. The Supreme Court of Spain, mostly its First Hall, declares joint responsibility when the evidence is not sufficient to establish individual responsibility.