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AMENDMENTS TO THE REGULATION ON THE EXERCISE OF PHARMACEUTICAL ACTIVITIES

The new Regulation on the Exercise of Pharmaceutical Activity, (hereinafter "the Regulation"), was recently approved by Decree No. 16/2023, of 25 April, repealing Decree No. 21/99, of 4 May, in order to adjust it to the current stage of socio-economic development and the pharmaceutical market, in line with the changes brought about by the Medicines Law, Law No. 12/2017, of 8 September, the following changes being of note:

- The National Medicines Regulatory Authority (Autoridade Nacional Reguladora de Medicamentos, Instituto Público-ANARME, IP) has been appointed as the body responsible for establishing the mechanisms for implementing the provisions of the Regulation.

- The principle of exclusivity of the pharmaceutical activity is established, with such activity being allowed only to professionals who (i) hold a certificate of literary qualification in the area of pharmacy and (ii) are registered as pharmacists, without prejudice to the possibility of being assisted by pharmacy technicians.

- As regards the general duties of pharmacy professionals, (i) they will be bound to the duty of collaboration, being obliged to inform the competent authorities whenever they are aware of the existence of medicines or medicinal substances that do not meet the required conditions of purity and effectiveness; and (ii) as regards the duty of professional secrecy, this duty will continue after the cessation of the professional activity and pharmacy professionals must behave in such a way as to prevent third parties from obtaining information on the clinical condition of patients.

- Pharmaceutical establishments are classified as (i) manufacturing establishments; (ii) wholesale establishments; (iii) transporters; (iv) retail establishments (pharmacies and drugstores); (v) general trade establishments; and (vi) providers of pharmaceutical services to the public.

- The Regulation also sets out specific rules for each type of pharmaceutical establishment as regards the licensing and operation process.

- The Regulation also introduces, among others, (i) local content provisions with respect to the acquisition of pharmaceutical products for marketing; (ii) general conditions for the conduct of clinical trials by research institutions, (iii) a more extensive regime of incompatibilities and

illegal exercise of medicine, and (iv) the provision for offences punishable with a fine for disobedience to the provisions of the Regulation.

Thaís Gomes
Junior Consultant
Practice Area: Comercial