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Gómez-Acebo & Pombo

Cannabis for Medicinal Purposes Act

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Act 33/2018 of 18 July ("Cannabis for Medicinal Purposes Act") laid down the legal framework for the use of medicinal products, preparations and substances based on the cannabis plant for medicinal purposes. In this normative framework, the principles and objectives related to (i) prescription, (ii) dispensation in pharmacy, (iii) possession and transportation, (iv) scientific investigation, (v) information to professionals, regulation and supervision of activities related to the use of the cannabis plant for medicinal purposes.

The aforementioned Act was subsequently regulated by Decree-Law no. 8/2019 of 15 January, which has come into force on 1 February 2019. This Decree-Law defines and delimits for the aforementioned medicines, preparations and substances the following activities:

— Cultivation;

— Production, extraction and manufacturing;

— Wholesale trade;

— Import and export;

— Transit;

— Acquisition;

— Sale and delivery of medicines;

— Placing on the market.

The current legal framework distinguishes cannabis-based medicinal products that, being medicinal products for human use, are subject to the appropriate legal regime (namely Decree-Law no. 176/2006 of 30 August and Decree-Law no. 282/95 of 26 October), from preparations and substances based on the cannabis plant. Specific rules relating to the use of preparations and substances based on the cannabis plant are implemented, in particular as regards their placing on the market, prescription and dispensation, without prejudice to the application of the legal regime for narcotic and/or psychotropic substances (in particular Decree-Law no. 15/93 of 22 January - Legislation to combat drugs).

Also noteworthy is the system of good practices that cultivation, manufacturing and distribution activities must comply with, namely:

(a) Good agricultural and harvesting practices - Guideline on Good Agricultural and Collection Practice (GACP), published by the European Medicines Agency;

(b) Good manufacturing practices for active substances intended for medicinal products for human use, approved by Commission Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use;

c) Good practices in the manufacture of medicines, provided for in Decree-Law no. 176/2006 of 30 August, which lays down the legal regime for medicinal products for human use with appropriate adaptations;

(d) Good practices for the distribution of active substances and medicinal products within the framework of the European Union.

Finally, the specific rules applicable to the Military Laboratory of Chemical and Pharmaceutical Products should also be highlighted. According to said rules, this laboratory may contribute to the production of medicinal products, preparations and substances based on the cannabis plant for medicinal purposes without having to apply for the authorisations under Decree-Law 8/2019 nor having to pay the fees under Regulatory Decree No. 61/94 of 12 October.