DECREE-LAW 8/2019, OF 15 JANUARY (REGULATIONS OF LAW 33/2018, OF 18 JULY) MINISTERIAL ORDER 44-A/2019

USE OF CANNABIS-BASED MEDICINAL PRODUCTS, PREPARATIONS AND SUBSTANCES FOR MEDICINAL PURPOSES

I) Framework

Decree-law 8/2019, of 15 January and Ministerial Order 44-A/2019, of 31 January, entered into force of 1 February to regulate Law 33/2018, of 18 July, which set forth the legal framework for the use de cannabis-based medicinal products, preparations and substances for medicinal purposes, in particular their prescription and dispensation in a pharmacy – the *Law on the Medical Uses of Cannabis*.

In addition, Decree-Law 8/2019 introduced the fourth amendment to Ruling Decree 61/94, of 12 October, which sets forth the rules for control of the illegal market of narcotics and psychotropic substances, adapting the existing regime to the provisions of the *Law on the Medical Uses of Cannabis*.

In turn, Ministerial Order 44-A/2019 set the pricing of Cannabis-based preparations and substances for medicinal purposes.

II) Purpose

The above legislation governs cannabis-based medicinal products, preparations and sub-stances, def ned as follows:

a. *"Cannabis-based medicines"* – medicinal product exclusively containing as active sub-stances (i) one or more cannabis-derived substances; (ii) one or more cannabis-derived preparations; (iii) one or more cannabis-derived substances in combination with one or more cannabis-derived preparations;

b. *"Cannabis-derived Preparations"* – preparations obtained by subjecting cannabis-derived substances to treatments like extraction, distillation, expression, fractionation, purification, concentration or fermentation, such as comminuted or powdered cannabis-derived substances, tinctures, extracts, essential oils, expressed juices and processed exudates;
c. *"Cannabis-based substances"* – whole, fragmented or cut cannabis plants, or parts thereof, and exudates that have not been subjected to a specific treatment, or other substances defined by the cannabis plant part used and the botanical name, including the species, variety and author.

III) Authorisations

The cultivation, manufacture, wholesale, import, export and transit of cannabis-based medicinal products, preparations or substances for medicinal purposes are subject to authorisation from INFARMED (Medicines Agency), to be renewed on a regular basis, and the harvesting, manufacturing and distribution of the same must follow a good practice system and comply with safety rules.

The law excludes the granting of authorisations for own use.

The marketing of cannabis-based medicinal products, preparations and substances is also subject to specific authorisations to be granted by INFARMED – *Market Authorisation, for medicinal products, and Authorisation for Placement on the Market*, for preparations and substances.

The Market Authorisation for cannabis-based medicinal products follows the general regime for this type of authorisations, by virtue of Decree-Law 8/2009. In contrast, the Authorisation for Placement on the Market is specifically regulated by this statute, in particular the procedure and requirements for granting and renewing the same. It is worth noting the 90-day period for the decision to be made by INFARMED and the five-year validity period for the authorization, as well as the obligation of the applicant to notify the price placed on the preparation.

IV) Fees

The following are subject to payment of fees to *INFARMED*: a) *Application for Authorisation for Placement on the Market* – 1800€; b) Application for renewal of *Authorisation for Placement on the Market* – 1000€; and, c) Application for change of *Authorisation for Placement on the Market* - 500€. The processing of applications depends upon the payment of the corresponding fee.

V) Additional Obligations – Prescription and Dispensation

Prescription is limited to the medicinal products, preparations and substances that have been authorised by INFARMED and are listed on its website, and only in cases where it has been established that conventional treatments have not achieved the desired results or have had significant side effects.

INFARMED is responsible for drawing up and publishing on its website the list of therapeutic indications considered appropriate for purposes of prescription, which shall be reviewed on a regular basis, in line with scientific and technical advances.

The cannabis-based medicinal products, preparations and substances prescribed for medicinal purposes are dispensed exclusively in pharmacies, on prescription and with verification of the identity of the purchaser.

VI) Pricing

Ministerial Order 44-A/2019 creates a price-fixing mechanism based on a proposal being submitted to INFARMED by the holder of the Authorisation for Placement on the Market, which will be rejected should the price be disproportionate in comparison with the price on the international market. In this case, the holder of the Authorisation for Placement on the Market must propose a new price, which will be deemed tacitly accepted in the absence of a reply from INFARMED.

Once the price is accepted, the holder of the Authorisation for Placement on the Market must notify INFARMED of the date of actual placement on the market and any temporary or permanent cessation in placing on the market.

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