

# **The Pharma Legal Handbook**

---

## **Cannabinoid Drugs, Medicinal Cannabis & Opioid Drugs**

# Cannabinoid Drugs, Medicinal Cannabis & Opioid Drugs

**This Pharma Legal Handbook answers essential questions about the legal and regulatory environment for Cannabinoid Drugs, Medicinal Cannabis & Opioid Drugs in 39 countries.**

**Prepared in association with leading local and international law firms and consultancies, it is a must-have for any company operating in/or looking to enter these niches in any of these countries.**

PharmaBoardroom is not responsible for any mistakes contained within this publication. For specific advice on any legal issue, please contact a qualified professional.

Copyright: All rights reserved. No part of this publication may be reproduced in any form or by any means, whether electronic, mechanical or otherwise including photocopying, recording or any information storage or retrieval system without prior written consent of PharmaBoardroom. While every attempt is made to ensure the accuracy of the information contained in this report, neither PharmaBoardroom nor the authors accept any liabilities for errors and omissions. Opinions expressed in this report are not necessarily those of the authors.

**\* THIS REPORT WAS ORIGINALLY PUBLISHED IN NOVEMBER 2019 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**

**\*\*LAST UPDATE: FEBRUARY 2022**

# CONTENTS

---

List of countries by alphabetical order:

## **ALGERIA**

Page 5

## **ARGENTINA**

Page 17

## **BRAZIL**

Page 27

## **BULGARIA**

Page 37

## **CANADA**

Page 49

## **CHILE**

Page 61

## **CHINA**

Page 71

## **COLOMBIA**

Page 79

## **CROATIA**

Page 89

## **CZECH REPUBLIC**

Page 97

## **DENMARK**

Page 109

## **ECUADOR**

Page 119

## **EGYPT**

Page 129

## **GERMANY**

Page 149

## **GREECE**

Page 161

## **INDIA**

Page 173

## **INDONESIA**

Page 183

## **JAPAN**

Page 193

## **LUXEMBOURG**

Page 201

## **MALAYSIA**

Page 211

## **MEXICO**

Page 221

## **NIGERIA**

Page 231

## **NORWAY**

Page 241

## **PANAMA**

Page 257

## **PERU**

Page 265

## **POLAND**

Page 273

## **PORTUGAL**

Page 283

## **ROMANIA**

Page 293

## **RUSSIA**

Page 303

## **SAUDI ARABIA**

Page 313

## **SINGAPORE**

Page 327

## **SLOVAKIA**

Page 335

## **SOUTH AFRICA**

Page 345

## **SPAIN**

Page 357

## **SWITZERLAND**

Page 367

## **THAILAND**

Page 383

## **UKRAINE**

Page 393

## **URUGUAY**

Page 409

## **VENEZUELA**

Page 423

List of partners in order of appearance:

<p>THE ALGERIAN SOCIETY FOR REGULATORY AFFAIRS &amp; PHARMACOECONOMICS - ALGERIA</p> 	<p>PRK PARTNERS - CZECH REPUBLIC &amp; SLOVAKIA</p> <p><b>P / R / K</b></p> <p>ATTORNEYS AT LAW</p>	<p>EMMANUELLE RAGOT - LUXEMBOURG</p>  <p>EMMANUELLE RAGOT</p>	<p>LIDINGS - RUSSIA</p>  <p>Leading the Way in Russian Law</p>
<p>MARVAL, O'FARRELL &amp; MAIRAL - ARGENTINA</p>  <p>MARVAL O'FARRELL MAIRAL</p>	<p>GORRISSSEN FEDERSPIEL - DENMARK</p>  <p>Gorrissen Federspiel</p>	<p>SKRINE - MALAYSIA</p> <p><b>SKRINE</b></p>	<p>STA - SAUDI ARABIA</p> 
<p>TRENCH ROSSI WATANABE - BRAZIL</p> 	<p>CORRAL ROSALES - ECUADOR</p>  <p>International standards, local vanguard</p>	<p>OLIVARES - MEXICO</p>  <p>OLIVARES<sup>®</sup></p>	<p>DREW &amp; NAPIER - SINGAPORE</p>  <p>DREW &amp; NAPIER</p>
<p>PHARMDICT / KINSTELLAR - BULGARIA</p>  <p>PharmDedict</p> <p><b>KINSTELLAR</b></p>	<p>YOUSRY SALEH - EGYPT</p>  <p>YOUSRY SALEH &amp; PARTNERS</p>	<p>OLANIWUN AJAYI LP - NIGERIA</p>  <p>OLANIWUN AJAYI</p>	<p>FAUS &amp; MOLINER ABOGADOS - SPAIN</p> <p><b>Faus &amp; Moliner</b> Abogados</p>
<p>FASKEN - CANADA &amp; SOUTH AFRICA</p> <p><b>FASKEN</b></p>	<p>HEUKING KÜHN LÜER WOJTEK - GERMANY</p>  <p>HEUKING KÜHN LÜER WOJTEK LAWYERS AND TAX ADVISORS</p>	<p>ALFARO, FERRER &amp; RAMÍREZ - PANAMA</p>  <p>ALFARO, FERRER &amp; RAMÍREZ Abogados / Attorneys at Law</p>	<p>WENGER PLATTNER - SWITZERLAND</p>  <p>WENGER PLATTNER ATTORNEYS AT LAW</p>
<p>CAREY - CHILE</p> 	<p>CALAVROS LAW FIRM - GREECE</p>  <p>CALAVROS LAW FIRM FILELIS • BABINIOTIS • KLOUKINAS</p>	<p>OSTERLING ABOGADOS - PERU</p>  <p>OSTERLING A B O G A D O S</p>	<p>TILLEKE &amp; GIBBINS - THAILAND</p> 
<p>FANGDA PARTNERS - CHINA</p> <p><b>FANGDA PARTNERS</b> 方達律師事務所</p>	<p>NISHITH DESAI ASSOCIATES - INDIA</p>  <p>Nishith Desai Associates LEGAL AND TAX COUNSELING WORLDWIDE</p>	<p>DLA PIPER - NORWAY, POLAND</p>  <p>DLA PIPER</p>	<p>SAYENKO KARENKO - UKRAINE</p>  <p>SAYENKO KHARENKO</p>
<p>CAVELIER ABOGADOS - COLOMBIA</p>  <p>CAVELIER A B O G A D O S</p>	<p>ABNR - INDONESIA</p>  <p>ABNR COUNSELLORS AT LAW</p>	<p>CUATRECASAS - PORTUGAL</p>  <p><b>CUATRECASAS</b></p>	<p>FERRERE - URUGUAY</p>  <p><b>FERRERE</b></p>
<p>DANIJEL PRIBANIĆ - CROATIA</p> <p><b>DANIJEL PRIBANIĆ</b> Odjelnik / Attorney-at-Law</p>	<p>NISHIMURA &amp; ASAHI - JAPAN</p>  <p><b>NISHIMURA &amp; ASAHI</b></p>	<p>MUŞAT &amp; ASOCIAȚII - ROMANIA</p>  <p>MUŞAT &amp; ASOCIAȚII Attorneys at Law</p>	<p>HOET PELAEZ CASTILLO &amp; DUQUE - VENEZUELA</p>  <p>HOET PELAEZ CASTILLO &amp; DUQUE</p>

# Algeria

A stylized graphic at the bottom of the page depicts a landscape. It features a dark teal, wavy shape representing hills or mountains, and a solid terracotta-colored shape below it representing the ground or a body of water. The overall design is minimalist and modern.

**This chapter about Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs in Algeria was published in association with:**



The Algerian Society for Regulatory Affairs & Pharmaco-economics is a non-profit organization, created on 26 October 2015 under the provisions of the Law No. 12-06 related to Associations. Its mission is to provide information and continuing education for all stakeholders in the Algerian pharmaceutical sector, and to promote research in the field of pharmaceutical regulations and HEOR.

A: 67 Rue Badji Abdelkader, Lot Amara 2, Cheraga, Algiers 16000, Algeria.

E: [contact@saarpe.org](mailto:contact@saarpe.org)

T: +213 5 55 53 51 79

F: +213 23 36 75 15

**\* THIS CHAPTER ABOUT ALGERIA WAS FIRST PUBLISHED IN DECEMBER 2019 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**

# THE AUTHOR

---

# Algeria



## YACINE SELLAM

---

**YACINE SELLAM, PHARMD, PHD  
PRESIDENT OF THE SAARPE.**

+10 years experience in the pharmaceutical sector in Algeria. Yacine acted as Regulatory evaluator of drugs registration dossiers, and as Permanent secretary of the Economic Inter-Ministerial Committee in charge of Pharmaceutical Products Pricing at the Ministry of Health. Yacine is senior consultant in regulatory affairs & market access, and an Advisory board member for several pharmaceutical companies (Novo Nordisk, Eli Lilly, Johnson & Johnson...). Yacine is also Associate professor and Scientific board member at Pharmacy School of Algiers. He has been a keynote speaker & panelist across various healthcare congresses, and is a contributor to the PharmaBoardroom website.

([yacine.sellam@gmail.com](mailto:yacine.sellam@gmail.com))

# CANNABINOID DRUGS, MEDICINAL CANNABIS AND OPIOID DRUGS

## CANNABINOID DRUGS

### 1. Are Cannabinoid Drugs authorized in your country?

Cannabinoid drugs, i.e. drug products as defined in Article 208 of Health Law No 18-11, dated of 2 July 2018, where the active substance is cannabinoids, can be authorised in Algeria in accordance with the Health Law No 18-11 provisions related to drugs.

### 2. What are the regulatory authorities with jurisdiction over Cannabinoid Drugs?

The National Agency for Pharmaceutical Products (“ANPP” – “Agence Nationale des Produits Pharmaceutiques”, a financially independent institution newly created under Article 223 of Health Law No 18-11, dated of 2 July 2018, and placed under the administrative authority of the Ministry of Health, Population and Hospital Reform (“MSPRH” – “Ministère de la Santé, de la Population et de la Réforme Hospitalière”) is the national regulatory authority with jurisdiction over cannabinoid drugs for human use in Algeria.

### 3. Is there a specific regulatory framework for the authorization pricing, and reimbursement of Cannabinoid Drugs?

As per provisions of Article 245 within the Health Law No 18-11, cannabinoid drugs are subject to a specific administrative, technical and security control that encompasses:

- The production, manufacture, packaging, processing, importing, exporting, offering, distribution, disposal, acquisition, holding of substances or drugs with narcotic and/or psychotropic properties;
- The use of plants or parts of plants with narcotic and/or psychotropic properties.

The overall regulatory framework for the authorization, pricing, and reimbursement remains the same as for the other drugs (see answer to [question 2 of Chapter 1: “Regulatory, pricing and Reimbursement Overview”](#), available in [The Pharma Legal Handbook Algeria](#)).

### 4. Which are the Cannabinoid Drugs that have received market approval to date?

According to the national database of drugs for human published in August 2019 by the Ministry of Health, there are not yet cannabinoid drugs authorized for marketing in Algeria.

### 5. Who can prescribe Cannabinoid Drugs?

Authorized cannabinoids drugs can be prescribed by any physician providing healthcare services, in both public and private sectors, and registered on

official list of the Doctors Order National Council, excepting those who are involved in drugs procurement and those under prescription ban (punished by Article 419 of the Health Law No 18-11).

---

**6. Is there a list of doctors authorized to prescribe Cannabinoid Drugs?**

No, cannabinoid drugs can be prescribed by any physician according to answer to [question 5](#).

---

**7. What approvals or notifications are required to prescribe Cannabinoid Drugs?**

No approvals or notifications are required. Authorized physicians can prescribe cannabinoid drugs to their patients in their own discretion, on regular prescription.

---

**8. Which organizations are authorized to sell/distribute Cannabinoid Drugs available?**

According to national regulations, all drugs (i.e. including cannabinoid drugs) are only dispensed to patients through hospital pharmacies or private community pharmacies (see answer to [question 14 of Chapter 1: “Regulatory, pricing and Reimbursement Overview”, available in The Pharma Legal Handbook Algeria](#)).

---

**9. Is there a list of retailers/distributors authorized to sell Cannabinoid Drugs?**

No, all hospital pharmacies (public/private) and private community pharmacies are authorized.

---

**10. Are there proposals for reform or significant change to the regulation of Cannabinoid Drugs?**

There is a new Decree underway that aims to lay down the procedures for specific administrative, technical and safety control of substances and drugs with psychotropic properties (i.e. including cannabinoid drugs) as introduced by Article 245 of Health Law No 18-11. The main objective of the ongoing reform is to insure traceability of these drugs from the reception of the raw materials until the dispensation at pharmacy level.

According to the draft of the aforementioned Decree, prescription of drugs with psychotropic properties will be limited to three (03) months, and must be written on a special prescription in three copies of different colors (white, yellow and pink):

- White and yellow color copies are given to the patient;
- The pink copy must be kept by the prescribing physician for a period of two years;
- The yellow copy is saved by the pharmacist after dispensing the drugs;
- The white copy is returned to the patient after dispensation or directly sent to the payer.

Every prescribing physician must record his prescriptions in a register opened for this purpose, marked and initialed by the Provential Health and Population Directorate (“DSPW” – “Direction de la Santé et de la Population de Wilaya”)

for those practicing in the private sector, and by the health structure director for those in the public sector. The register must be kept for five years.

The prescription of psychotropic drugs for hospital use with a restricted prescription must be made by a specialized physician at the exercise hospital. The maximum duration of prescription will be limited to one (01) month. The dispensing of these drugs is reserved for hospital pharmacies, and the list of these psychotropic drugs will be fixed through Ministerial Decree.

**11. When are they likely to come into force?**

The aforementioned Decree is expected to be published in the Official Gazette by Q1 2020.

## MEDICINAL CANNABIS

**12. Is Medicinal Cannabis authorized in the country?**

Medicinal cannabis can be authorised in Algeria in accordance with provisions of Decree No 07-228 dated 30 July 2007 and published in the Official Gazette, laying down the procedures for granting authorization to use narcotic and psychotropic substances for medical or scientific purposes.

According to Article 3, the authorization provided for by this Decree No 07-228 may be granted only if the use of the plants, substances and preparations is intended for medical or scientific purposes.

**13. What are the regulatory authorities with jurisdiction over Medicinal Cannabis?**

The Ministry of Health is the national regulatory authority with jurisdiction over medicinal cannabis.

**14. What is the regulatory framework for the authorization, pricing, and reimbursement of Medicinal Cannabis?**

The Decree No 07-228 dated 30 July 2007 and published in the Official Gazette, laying down the procedures for granting authorization to use narcotic and psychotropic substances for medical or scientific purposes, alongside with the Law No 04-18 dated of 25 December 2004 and published in the Official Gazette, on the prevention and repression of the illicit use and trafficking of narcotic and psychotropic substances, form together the regulatory framework for medicinal cannabis.

Plants, substances and preparations intended for “compassionate use” under the regimen of temporary authorization for use (“ATU” – “Autorisation Temporaire d’Utilisation”) are regulated under provisions of Article 233 within the Health Law No 18-11, when prescribed as part of the management of serious diseases in situations where there is no equivalent treatment in the national territory, and have proven their therapeutic benefit.