Importation and exportation of medicinal products and unauthorised or falsified (counterfeit) medical preparations

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1 Introduction

Medicinal products and medical devices are not ordinary consumer goods and their manufacture, distribution, control of supply and importation/exportation is highly regulated and closely controlled.

However, the availability of illegally prescribed, falsified (counterfeit) medicines on the internet and the illegal importation of medicines is growing and is a serious threat to public health and a significant risk to the economy. Falsified medicines may contain ingredients which are sub-standard or poor quality as they have not undergone the same rigorous quality and safety checks that apply to legitimate medicines.

The Health Products Regulatory Authority (HPRA) is the authority with responsibility for licensing medicines and testing them for safety, quality and efficacy in Ireland. Revenue, in partnership with the HPRA, work closely to identify and seize illicit medicinal products and devices and prosecute offenders.

The purpose and objective of this manual is to provide instructions to Revenue officers relating to the control, detention, seizure, investigation and prosecution of offences relating to the importation/exportation of medicinal products and medical preparations, which come within the control and the remit of the HPRA.

2 Control regime

The licensing and control of these products are a matter for the Department of Health and the HPRA. All legitimate importations and exportations are subject to normal customs controls such as report, entry and production of valid authorisations, where required. However, a person travelling and passing through a customs point may carry on their person or in their baggage a reasonable amount of such medicines for personal use without an authorisation, with the exception of persons travelling from the Schengen Area. Travellers from the Schengen area will be required to produce an Article 75 Certificate for prescribed narcotics/psychoactive substances containing active substances (controlled drugs) found in Schedule 2 and 3 of the Misuse of Drugs Regulations 2017 (S.I. 173/2017). The active substance is identified on the certificate. A separate certificate is required for each prescribed product. The Article 75 Certificate is for a maximum 30-day supply of the prescribed products for personal use. A copy of an Article 75 Certificate is attached at Appendix 1.

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[…]

This “personal use” exemption does not apply to products imported by other means, for example by post, by courier or in merchandise. All unauthorised imports of

medicines, except by travellers for personal use as specified above, should be dealt with in accordance with the procedures outlined in section 3 below.

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A schedule of products which are controlled by the HPRA can be found in Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2018 (see Appendix 3).

3 Enforcement

The HPRA has responsibility for the control of medical products in the State. Revenue's Customs Service, which is strategically placed at postal depots and at the sea, air and land borders, has responsibility for the implementation of import/export controls and is committed to support the HPRA in its work. A Memorandum of Understanding (Appendix 2) exists between Revenue and the HPRA to ensure effective enforcement, co-ordination and co-operation in deterring the international trafficking of such products.

The powers available to Revenue officers and the arrangements for dealing with detections are detailed below.

3.1 Revenue and HPRA powers available to officers

Revenue officers are empowered to deal with the detention, sampling and seizure of prohibited or restricted medical preparations and medicinal products imported from **third countries** under the Customs Act 2015 and to refer serious cases for prosecution under current standing instructions. All such products, subject to prohibition or restriction on importation are deemed to be prohibited on importation under Section 50 of the Customs Act 2015.

Additionally, an "Officer of Customs and Excise" is deemed to be an authorised officer under section 32B of the Irish Medicines Board Act 1995, as inserted by section 17 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006. An authorised officer is entitled to examine and detain any product for the purposes of enforcement of the HPRA controls whether such product has been imported from a third country or has been consigned to the State from Other Member States (OMS) within the EU.

3.2 Small consignments

Most medicinal products encountered by Revenue are of the nature of small quantities consigned to private individuals for their own personal use.

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3.6 Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019

S.I. No. 262 of 2019 amended by S.I. No. 505 of 2020 outlines the legal requirements and details of the Medical Cannabis Access Programme which enables the importation, prescribing and supply of cannabis-based products or preparations. The purpose of these regulations is to allow certain cannabis products or preparations for medical use to be prescribed and supplied under certain circumstances for the treatment of persons with certain medical conditions under the care of a medical consultant.

S.I. No. 282 of 2019 (The Misuse of Drugs (Amendment) Regulations 2019) amends S.I. No. 173 of 2017 (Misuse of Drugs Regulations 2017) to reschedule certain acceptable cannabis-based products for medical use under the Medical Cannabis Access Programme from Schedule 1 to Schedule 2.

S.I. No. 505 of 2020 lists certain cannabis products or preparations for medical use as "specified controlled drugs" by replacing Schedule 1 of the previous Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulation 2019.

S.I. No. 505 of 2020 lists four manufacturers approved to import accepted specified controlled drugs (cannabis-based products) into Ireland and S.I. No. 200 of 2023 amended this list which is reflected in the table below:

Name of Cannabis product or preparation and brand name	**Dosage form**	**Concentration of THC (percentage, weight/weight or weight/volume)**	**Name of manufacturer**
Aurora High CBD Oil Drops	Oral solution	Less than 3% w/v (< 30mg/ml) This product also contains cannabidiol (CBD) 60% w/v (600mg/ml)	Aurora Cannabis Enterprises Inc., 4439 Township Road 304, Cremona, Alberta, Canada, T0M 0R0
CannEpil ™	Oral solution	0.5% w/v (5mg/ml) This product also contains cannabidiol (CBD) 10% w/v (100mg/ml)	MGC Pharmaceuticals d.o.o., Kamniška ulica 29, 1000, Ljubljana, Slovenia
Tilray Oral Solution THC10:CBD10 (25ml)	Oral solution	1% w/v (10mg/ml) This product also contains cannabidiol (CBD) 1% w/v (10mg/ml)	Tilray Portugal Unipessoal Lda., Zona Industrial de Cantanhede, Lote 121, Cantanhede,

			3060-197, Portugal
Aurora Sedamen Softgels	Capsules	5mg/capsule This product also contains cannabidiol (CBD) less than 0.2mg/capsule	Aurora Cannabis Enterprises Inc. 4250 14th Avenue, Markham, Ontario, Canada, L3R 0J3
Oleo Bedrobinol	Dried flower	13.5% w/w (135mg/g) This product also contains cannabidiol (CBD) less than 1.0% w/w (less than 10mg/g)	Bureau voor Medicinale Cannabis Postbus 16114 2500 BC DEN HAAG The Netherlands
Oleo Bedrocan	Dried flower	22% w/w (220mg/g) This product also contains cannabidiol (CBD) less than 1.0% w/w (less than 10mg/g)	Bureau voor Medicinale Cannabis Postbus 16114 2500 BC DEN HAAG The Netherlands
Althea CBD12:THC10 (50ml)	Oil	1% w/v THC (10mg/ml) This product also contains 1.25% w/v (12.5mg/ml) cannabidiol (CBD)	Tasmanian Alkaloids pty Ltd T/A Extractas Bioscience, Westbury, Tasmania, Australia 7303
Oleo Genetics 10:10	Oil (oral solution)	1% w/v (10mg/ml) This product also contains cannabidiol (CBD) 1% w/v (10mg/ml)	ADREX Pharma GmbH Firmungstrabe 4 56068 Koblenz Germany
Oleo Genetics 25:1	Oil (oral solution)	2.5% w/v (25mg/ml) This product also contains cannabidiol (CBD) <0.1% w/v (<1mg/ml)	ADREX Pharma GmbH Firmungstrabe 4 56068 Koblenz Germany
Althea THC20:CBD1 (50ml)	Oil	2% w/v THC (20mg/ml) This product also contains <0.1% w/v (<0.1mg/ml) cannabidiol (CBD)	Tasmanian Alkaloids pty Ltd T/A Extractas Bioscience, Westbury, Tasmania, Australia 7303

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3.7 Exports

All exports of medicinal products to third countries are prohibited unless authorised by the HPRA under section 5 of S.I. No. 538 of 2007 (Medicinal Products (Control of Wholesale Distribution) Regulations 2007 to 2021). Officers are empowered to act under the Customs Act 2015 in respect of exports to third countries and as authorised officers under the HPRA legislation. The general procedures outlined in sections 3.1, 3.2, 3.3 above should be followed.

4 Samples/Product Identification/Custody

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5 Information/Intelligence sharing

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6 Investigations

The following material is either exempt from or not required to be published under the Freedom of Information Act 1997.

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7 Joint operations/Liaison network

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8 Role of An Garda Síochána

The following material is either exempt from or not required to be published under the Freedom of Information Act 1997.

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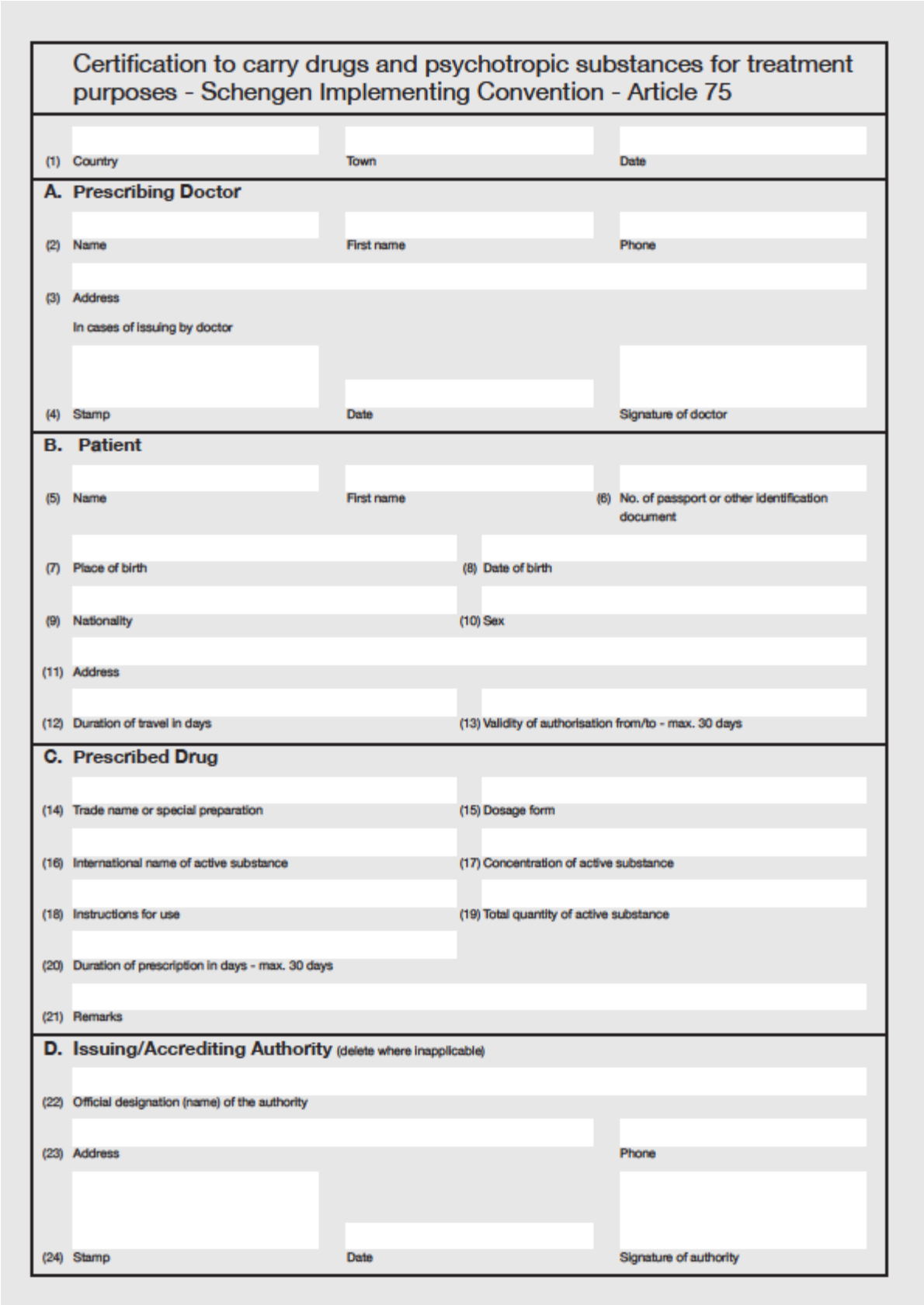
9 Related Instructions/Legislation

- EU Regulation 608/2013 – IPR
- EU Regulation 515/97 amended by EU Regulation 2015/1525
- Customs Act 2015
- Misuse of Drugs Act 1977 to 2017
- Misuse of Drugs Regulations 2017 (S.I. 173/2017)

- Intellectual Property Rights Manual
- Enforcement Procedures Manual
- Statutory Instruments on Medicinal Products (see Appendix 3)

Appendix 1 Article 75 Certificate



Certification to carry drugs and psychotropic substances for treatment purposes - Schengen Implementing Convention - Article 75

(1) Country | Town | Date

A. Prescribing Doctor

(2) Name | First name | Phone

(3) Address

In cases of issuing by doctor

(4) Stamp | Date | Signature of doctor

B. Patient

(5) Name | First name | (6) No. of passport or other identification document

(7) Place of birth | (8) Date of birth

(9) Nationality | (10) Sex

(11) Address

(12) Duration of travel in days | (13) Validity of authorisation from/to - max. 30 days

C. Prescribed Drug

(14) Trade name or special preparation | (15) Dosage form

(16) International name of active substance | (17) Concentration of active substance

(18) Instructions for use | (19) Total quantity of active substance

(20) Duration of prescription in days - max. 30 days

(21) Remarks

D. Issuing/Accrediting Authority (delete where inapplicable)

(22) Official designation (name) of the authority

(23) Address | Phone

(24) Stamp | Date | Signature of authority

Figure 1: Article 75 Certificate

Appendix 2 Memorandum of Understanding

MEMORANDUM OF UNDERSTANDING

BETWEEN

REVENUE COMMISSIONERS

AND

HEALTH PRODUCT REGULATORY AUTHORITY

WITH RESPECT TO

LAW ENFORCEMENT OF MEDICINAL PRODUCTS,
DRUG PRECURSORS,
MEDICAL DEVICES
AND
OTHER HEALTH PRODUCTS

MEMORANDUM OF UNDERSTANDING BETWEEN THE REVENUE COMMISSIONERS AND THE HEALTH PRODUCTS REGULATORY AUTHORITY WITH RESPECT TO LAW ENFORCEMENT OF MEDICINAL PRODUCTS, DRUG PRECURSORS, MEDICAL DEVICES AND OTHER HEALTH PRODUCTS

The Head of Revenue Investigations & Prosecutions Division of the Revenue Commissioners and the Chief Executive of the Health Products Regulatory Authority.

HAVING REGARD to the good working relationship already in place between Revenue's Customs Service and the Health Products Regulatory Authority.

HAVING REGARD also to improving and coordinating the work of both services in countering the illicit trafficking in and distribution of medicinal products, drug precursors, medical

devices, other health products, in particular counterfeit/ falsified and fraudulently diverted products.

NOTING the increasing international dimension to the trafficking of falsified/counterfeit medicinal products, drug precursors, medical devices, other health products.

NOTING the trafficking of such products is detrimental to the wellbeing of society and to public health.

HAVING REGARD to the strategic position of Revenue's Customs Service at the State's frontiers and in the control of goods moving into and out of the State.

RECOGNISING the need to avoid compromising the international exchange of intelligence.

RECOGNISING that Revenue's Customs Service and the Health Products Regulatory Authority both have an important contribution to make in combating the illegal importation and exportation of and control of medical products, drug precursors, medical devices, other health products, in particular falsified /counterfeit medicinal products, drug precursors, medical devices and other health products.

AWARE that Revenue's Customs Service and the Health Products Regulatory Authority enjoy somewhat similar enforcement powers for dealing with the unauthorised importation of medicinal products, drug precursors, medical devices and other health products and recognising that clear and agreed lines of demarcation between these authorities may lead to more coordinated enforcement action.

AFFIRMING that, in these circumstances, full cooperation at all levels between Revenue's Customs Service and the Health Products Regulatory Authority is vital to develop effective working relations so as to ensure optimum outcomes.

PURPOSE

The purpose of this Memorandum of Understanding is to establish a framework for cooperation that supports the common interest of Revenue's Customs Service and the Health Products Regulatory Authority.

GENERAL PRINCIPLES OF COOPERATION

Both parties agree that working relationships and practical cooperation between Revenue's Customs Service and the Health Products Regulatory Authority shall be based on the following principles:

1. This agreement is intended to promote mutual cooperation between Revenue's Customs Service and the Health Products Regulatory Authority and should be interpreted in that spirit.

2. Revenue's Customs Service and the Health Products Regulatory Authority agree that the sharing of information/intelligence at strategic and tactical levels will enhance the deployment of risk prioritised operation enforcement resources.

   Revenue's Customs Service has primary responsibility for the surveillance of the frontiers of the state (including controls at inland Approved Customs Premises and Approved Postal Depots). While the Revenue's Customs Service has primary responsibility for the prevention, detection, interception, detention, seizure and investigation of unauthorised and falsified/counterfeit medicinal products, drug precursors, medical devices and other health products intended to be smuggled or illegally imported into or illegally exported from the state, it is recognised that the Health Products Regulatory Authority has the primary responsibility for the enforcement of the relevant legislation governing the manufacture, authorisation and distribution of all medicinal products, medical devices and other health products in, into and from the State.

3. Revenue's Customs Service has primary responsibility for the apprehension and arrest of persons suspected of the smuggling or illegal importation and exportation of unauthorised and falsified/counterfeit medicinal products, drug precursors and medical devices at the frontiers of the State.

4. Where Revenue's officers detain or seize any smuggled or illegally imported unauthorised or falsified/counterfeit medicinal products, drug precursors or medical devices or other health products and/or detain/arrest a person or persons in connection with the smuggling or illegal importation/exportation of unauthorised or falsified/counterfeit medicinal products, drug precursors, medical devices or other health products, they shall promptly notify the Health Products Regulatory Authority through its Enforcement Section.

5. The Health Products Regulatory Authority via its Enforcement Officers will provide expert assistance to Revenue officers in the identification of suspect substances and products. The analysis of detained or seized substances and products will be carried out by arrangement with the Health Products Regulatory Authority. In the case of

suspected falsified/counterfeit goods, samples will be provided by arrangement of both parties to the Right Holders for analysis, test or examination.

The Health Products Regulatory Authority has primary responsibility for the enforcement of the legislation governing medicinal products, medical devices and other health products, including falsified products in inland areas within the State. This does not affect the Health Products Regulatory Authority's remit in international cooperation and investigation in relation to any enforcement issues of medicinal products, medical devices and other health products.

6. The Health Products Regulatory Authority and Revenue's Customs Service have a shared responsibility for gathering intelligence on the smuggling of medicinal products, drug precursors, medical devices and other health products.

7. The Health Products Regulatory Authority and Revenue's Customs Service shall engage in the full exchange of information and intelligence between them in regard to the smuggling of such products and, in this regard, each agency shall facilitate the other in exchanging information (including information obtained in the course of investigations. In this regard, both parties shall formalise the exchange of data between them.

8. The Health Products Regulatory Authority and Revenue's Customs Service agree to:

    a. Exchange contact details of designated Liaison Officers at national and local level;

    b. Establish and operate a Joint Task Force to deal with intelligence-driven operations and "controlled deliveries";

    c. Observe data protection legislation and in particular, comply with the Data Exchange Agreement between the Revenue Commissioners and the Health Products Regulatory Authority;

    d. Develop training and liaison exchange programmes for relevant personnel;

    e. Appoint relevant designated contacts to oversee the implementation of this memorandum of understanding and associated work programmes. These contacts will meet at least twice annually and also, if required, at short notice at the request of either authority.

9. Members of the Health Products Regulatory Authority and Revenue's Customs Service are placed under a special duty to support and cooperate fully with each other in connection with all aspects and matters that arise in an area for which one

authority has been given primary responsibility and in which the other authority may be expected to have a special interest.

The provisions in this Memorandum shall be reviewed after five years from the date of signature and shall be subject to formal review annually by the parties. Amendments may be made from time to time in the light of experience and by agreement of the signatories. Both parties are committed to resolving any issues arising under this memorandum through normal administrative channels.

Head of Revenue Investigations Division	Chief Executive
Revenue Commissioners	Health Products Regulatory Authority
Printed Name: Marie-Claire Maney	Printed Name: Lorraine Nolan
Date: 12th March 2019	Date: 12th March 2019

Appendix 3 Medicinal Products Statutory Instruments

Prescription and control of supply

Principal regulation

Medicinal Products (Prescription and Control of Supply) Regulations 2003 (SI 540/2003)

Please also refer to Associated Regulations - SI 540/2003

Manufacture

Principal regulation

Medicinal Products (Control of Manufacture) Regulations 2007 (SI 539/2007)

Please also refer to Associated Regulations

Placing on the market

Principal regulation

Medicinal Products (Control of Placing on the Market) Regulations 2007 (SI 540/2007)

Please also refer to Associated Regulations

Wholesale Distribution

Principal regulation

Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (SI 538/2007)

Please also refer to Associated Regulations

Misuse of Drugs Regulations

Principal regulation

Misuse of Drugs Regulations 2017 (173/2017)

Please also refer to Associated Regulations

Principal regulation

Misuse Of Drugs (Prescription And Control Of Supply Of Cannabis For Medical Use) Regulations 2019 (262/2019)

Associated Regulations Refer