



STATUTORY INSTRUMENTS.

**S.I. No. 5 of 2023**



MISUSE OF DRUGS (PRESCRIPTION AND CONTROL OF SUPPLY OF  
CANNABIS FOR MEDICAL USE) (AMENDMENT) REGULATIONS 2023

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## MISUSE OF DRUGS (PRESCRIPTION AND CONTROL OF SUPPLY OF CANNABIS FOR MEDICAL USE) (AMENDMENT) REGULATIONS 2023

I, Stephen Donnelly, Minister for Health, in exercise of the powers conferred on me by sections 4 and 5 (as amended by section 3 of the Misuse of Drugs (Amendment) Act 2016 (No. 9 of 2016)) of the Misuse of Drugs Act 1977 (No. 12 of 1977), hereby make the following regulations:

*Citation*

1. These Regulations may be cited as the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) Regulations 2023.

*Definitions*

2. In these Regulations-

“Principal Regulations” means the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019 (S.I. No. 262 of 2019) as amended by the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) Regulations 2021 (S.I. No. 557 of 2021) and Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) Regulations 2022 (S.I. No. 237 of 2022).

*Amending the Principal Regulations*

3. The Principal Regulations are amended by substituting for Schedule 1 the following;

## “SCHEDULE 1

*Regulation 2**Specified Controlled Drugs*

<b>Name of Cannabis product or preparation and brand name</b>	<b>Dosage form</b>	<b>Concentration of THC (percentage, weight/weight or weight/volume)</b>	<b>Name of manufacturer</b>
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)	MGC Pharmaceuticals d.o.o., Kamniška ulica 29, 1000,

*Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 24th January, 2023.*

		This product also contains cannabidiol (CBD) 10% w/v (100mg/ml)	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



GIVEN under my Official Seal,  
19 January, 2023.

STEPHEN DONNELLY,  
Minister for Health.

## EXPLANATORY NOTE

*(This note is not part of the Instrument and does not purport to be a legal interpretation.)*

The purpose of these Regulations is to update and replace the current Schedule 1, in the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019 (as amended) (“the Principal Regulations”), in order to include additional cannabis products or preparations for medical use as “specified controlled drugs”.

The purpose of the Principal Regulations is to allow additional 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.

These Regulations may be cited as the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) Regulations 2023.

BAILE ÁTHA CLIATH  
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