



STATUTORY INSTRUMENTS.

S.I. No. 557 of 2021



MISUSE OF DRUGS (PRESCRIPTION AND CONTROL OF SUPPLY OF
CANNABIS FOR MEDICAL USE) (AMENDMENT) REGULATIONS 2021

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MISUSE OF DRUGS (PRESCRIPTION AND CONTROL OF SUPPLY OF CANNABIS FOR MEDICAL USE) (AMENDMENT) REGULATIONS 2021

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:

1. These Regulations may be cited as the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) Regulations 2021.

2. The Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019 (S.I. No. 262 of 2019) are amended by substituting for Schedule 1 (as amended by Regulation 2 of the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) Regulations 2020 (S.I. No. 505 of 2020)) the following:

“SCHEDULE 1

*Regulation 2**Specified Controlled Drugs*

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	MGC Pharmaceuticals d.o.o., Kamniška ulica 29, 1000, Ljubljana,

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 29th October, 2021.

		contains cannabidiol (CBD) 10% w/v (100mg/ml)	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 Canada Ltd., 1100 Maughan Road, Nanaimo, BC, V9X 1J2, Canada
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

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3. The Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) Regulations 2020 are revoked.



GIVEN under my Official Seal,
27 October, 2021.

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 amend the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019 to replace Schedule 1 in order to list certain cannabis products or preparations for medical use as “specified controlled drugs”.

These Regulations may be cited as the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) Regulations 2021.

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