From the Chief Medical Officer
Dr Michael McBride

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Castle Buildings
Stormont Estate
BELFAST
BT4 3SQ

Tel: 028 9052 0563
Email: Michael.McBride@health-ni.gov.uk

HSS(MD)46/2020

Our Ref: HSS(MD)46/2020
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FOR ACTION
Chief Executives, Public Health Agency/Health and Social Care Board/HSC Trusts/ NIAS
GP Medical Advisers, Health & Social Care Board
All General Practitioners and GP Locums (for onward distribution to practice staff)
OOHs Medical Managers (for onward distribution to staff)

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

RE-SCHEDULING OF EPIDIOLEX (CANNABIS BASED MEDICINE) AND INSERTION OF A NEW DEFINITION UNDER THE MISUSE OF DRUGS REGULATIONS (NI) 2002

Purpose

1. The purpose of this letter is to advise you of a forthcoming amendment to the Misuse of Drugs Regulations (NI) 2002

2. Following Advisory Council on the Misuse of Drugs (ACMD) recommendations Epidiolex, a cannabis-based medicine, will be rescheduled from Schedule 2 of the Regulations to Schedule 5 under a specified definition.

Background

3. Epidiolex is currently a Schedule 2 drug and received a marketing authorisation in September 2019 for the adjunctive therapy of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome, in conjunction with clobazam, for patients from 2 years of age and older. It should be initiated and supervised by physicians with experience in the treatment of epilepsy.

4. NICE Technology Appraisal guidance (TA614 and TA615) for cannabidiol use in these syndromes was also published in December 2019 and endorsed by the Department of Health in January 2020. Links to this Technical Appraisal guidance can be found at: https://www.health-ni.gov.uk/articles/nice-endorsed-technology-appraisals-20192020.

5. The ACMD has recommended that Epidiolex be moved from Schedule 2 to Schedule 5 of the 2002 Regulations under a specified definition (see below),

based on the assessment that, due to the low levels of Δ9-tetrahydrocannabinol (Δ9-THC) within Epidiolex the abuse potential and risks of dependency and illicit diversion are low.

6. The recommended definition for Epidiolex within Schedule 5 of the 2002 Regulations is as follows:

A liquid formulation—

(a) containing cannabidiol obtained by extraction and purification from cannabis;

(b) where the concentration of—

(i) delta-9-tetrahydrocannabinol is not more than 0.1 milligram per millilitre; and
(ii) cannabidiol is 95-105 milligrams per millilitre;

(c) which is presented in a bottle, as an oral solution for oral administration; and

(d) which was approved for marketing by the European Commission on 19th September 2019.

7. The rescheduling of Epidiolex from Schedule 2 of the Regulations to Schedule 5 means that it will become exempt from most of the requirements of controlled drugs such as register, prescription and safe custody requirements.

8. I would be grateful if you could cascade this information to relevant clinical teams within your organisation. We expect the legislative change will come into operation on 24 June 2020.

Yours sincerely

DR MICHAEL McBRIDE
Chief Medical Officer

CC Cathy Harrison, Chief Pharmaceutical Officer

Circulation List

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Trade Union Side

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