EXPLANATORY MEMORANDUM TO

The Misuse of Drugs (Amendment No. 2) Regulations (Northern Ireland) 2020

SR 2020 No. 104

1. Introduction

1.1. This Explanatory Memorandum has been prepared by the Department of Health to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2. The Statutory Rule is made under sections 7, 10, 22 and 31 of the Misuse of Drugs Act 1971 (the 1971 Act) as adapted by sections 7(9), 31(4) and 38 of that Act and now vested in it and after consultation with the Advisory Council on the Misuse of Drugs in accordance with section 31(3) of that Act and is subject to the negative resolution procedure.

2. Purpose

2.1. The purpose of the Statutory Rule is to move Epidyolex, a cannabis-based medicine, from Schedule 2 to Schedule 5 to the Misuse of Drugs Regulations (Northern Ireland) 2002 (the 2002 Regulations) under a specified definition.

2.2. The Regulations are subject to negative resolution before the Northern Ireland Assembly.

3. Background

3.1. The Misuse of Drugs Regulations 2002 (the 2002 Regulations) provide access to controlled drugs for legitimate medicinal or exceptionally for industrial purposes. Drugs which are controlled under the 1971 Act are listed in one of five Schedules to the 2002 Regulations, based on an assessment of their medicinal or therapeutic usefulness, the need for legitimate access and their potential harm when misused. The Schedule into which a drug is placed primarily dictates the extent to which it is lawful to import, export, produce, possess, supply and administer. It imposes requirements around prescribing, record keeping, labelling, destruction, disposal and safe custody. Schedule 1 controlled drugs are subject to the greatest restrictions and Schedule 5 to the lowest.

3.2. By provisions made under the 1971 Act the Department of Health may by Order designate a drug as one to which section 7(4) of the 1971 Act applies. Once designated under the The Misuse of Drugs (Designation) Order (Northern Ireland) 2001 (the 2001 Order), drugs can only be made available for use in research or other special purpose under a licence issued by the Department and cannot be used medically.

3.3. From 1 November 2018, cannabis-based products for medicinal use (CBPMs) were placed in Schedule 2 to the 2002 Regulations and removed from Part 1 of the 2001 Order meaning that CBPMs may be prescribed for medicinal use in Northern Ireland.

3.4. The ACMD has recommended that Epidyolex be moved from Schedule 2 to Schedule 5 of the 2002 Regulations under a specified definition (see below). This decision was based on the assessment that the risk of illicit possession or diversion of Epidyolex is small due to its low controlled drug (delta-9-tetrahydrocannabinol) content.

3.5. The recommended definition for Epidyolex 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.

3.6. This Statutory Rule removes Epidyolex from the definition of a CBPM in the 2002 Regulations. However, Epidyolex remains in the definition of a CBPM in the 2001 Order and so can continue to be freely prescribed.

4. Consultation

4.1. The ACMD recommendation requires an amendment to the 2002 Regulations. The Home Office consulted with the ACMD, the Department of Health and Social Care, the Medicines and Healthcare products Regulatory Agency and the manufacturers of Epidyolex extensively on the proposed scheduling and definition for Epidyolex. Relevant clinical and regulatory bodies and key stakeholders affected by the Scheduling decision were also consulted. As Epidyolex is already available for use in health care and the effect of the change will mean enhanced availability and fewer restrictions, a full public consultation is not considered appropriate in this case.

5. Equality Impact

5.1. The Department of Health has concluded that the proposed amendments will not have a significant impact on equality of opportunity for any group referred to in section 75 of the Northern Ireland Act 1998 and a full Equality Impact Assessment has not been considered necessary.

6. Regulatory Impact

6.1. It is not anticipated that there will be any adverse impact on business, charities, social economy or voluntary bodies. Prescribing and supply of Epidyolex will face fewer restrictions due to the move from Schedule 2 to Schedule 5 to the 2002 Regulations.

7. Financial Implications

7.1. None anticipated.

8. Section 24 of the Northern Ireland Act 1998

8.1. These Regulations do not breach section 24 of the Northern Ireland Act 1998, as they are not incompatible with any of the Convention rights or community law, and they do not discriminate against a person on the grounds of religious belief or political opinion.

9. EU Implications

9.1. There are no anticipated EU implications as a result of these amendments.

10. Parity or Replicatory Measure

10.1. The provisions included in the Statutory Rule seek to replicate amendments to the Misuse of Drugs Regulations 2001 which are being taken forward by the Home Office and will ensure that the legislative arrangements in Northern Ireland will be in line with GB.

11. Additional Information

11.1. Not applicable