EXPLANATORY MEMORANDUM TO

The Misuse of Drugs (Amendment No.2) Regulations (Northern Ireland) 2018

2018 No.173

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 powers conferred by sections 7, 10, 22 and 31 of the Misuse of Drugs Act 1971 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 this instrument is to amend the Misuse of Drugs Regulations (Northern Ireland) 2002 ("the 2002 Regulations") to provide greater access to cannabis-based products for medicinal use in humans.

3. Background

3.1. The Misue of Drugs Act 1971 controls drugs that are "dangerous or otherwise harmful" either to individuals or to society when they are misused. It lists all drugs subject to control in Schedule 2 to the Act in three categories; Classes A, B and C, according to their perceived degree of harm and applies maximum penalties to offences committed under the Act. Access to controlled drugs for legitimate medicinal purpose is permitted, but subject to regulation, through the Misuse of Drugs Regulations (Northern Ireland) 2002 ("the 2002 Regulations"). The 2002 Regulations establish a regime of control around prescribing, supplying or administering, safe custody, dispensing, record keeping, destruction and disposal. The single purpose of these restrictions is to prevent the diversion and misuse of controlled drugs for patient and public protection.

3.2. Cannabis, cannabis resin, cannabinol and cannabinol derivatives (not being dronabinol or its stereoisomers) are Class B drugs currently listed in Schedule 1 to the 2002 Regulations. This instrument places a defined category of these controlled drugs (cannabis-based products for medicinal use in humans) in Schedule 2 to the 2002 Regulations, with the effect that these products now become available for medicinal use and for use in clinical trials without the need for a Departmental licence. This instrument also, by new Regulation 16A, imposes additional controls on the order and supply of these products for the purpose of administration (whether to humans or others).

3.3. In line with the ACMD recommendations to ensure that access is limited to cannabis-based medicinal products only, this instrument introduces a definition based on form and purpose, as well as composition. There is a three-limb requirement to the definition of 'cannabis-based product for

medicinal use in humans' which is defined as a preparation or other product, other than those which have already been granted a marketing authorisation in the UK, which:

3.4. a) is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being Dronabinol or its stereoisomers);

3.5. b) is produced for medicinal use in humans and;

3.6. c) is a medicinal product or a substance or preparation for use as an ingredient of, or in the production of a medicinal product.

3.7. Only products satisfying all three-limbs of this requirement are being rescheduled to Schedule 2 to the 2002 Regulations. The requirement for the product to be both produced for medicinal use in humans and to be either a medicinal product or an ingredient in a medicinal product ensures that only products regulated as medicines and produced specifically for medicinal purposes are placed in Schedule 2. Any cannabis-based substance falling outside of this definition will remain a Schedule 1 drug to the 2002 Regulations.

3.8. Due to the harms associated with smoking, the ACMD recommended that any prescription of cannabis-based products for medicinal use did not include smoking as a route of administration. There was also a concern that permitting smoking of cannabis-based products for medicinal use would make it harder for enforcement of the existing ban on recreational use of cannabis, a ban which will not change, leading to wider societal harm. This instrument therefore continues to prohibit smoking of cannabis, by restricting the administration of cannabis-based products for medicinal use in humans by smoking.

4. Consultation

4.1. A full public consultation was not considered necessary in this case due to the need to ensure access to these products was made available at the earliest opportunity in line with the expert advice from the ACMD and the UK's Chief Medical Advisor, and to ensure a consistent regulatory regime and patient access to cannabis medicines throughout the UK. A range of stakeholders with statutory responsibilities in relation to controlled drugs were presented with the proposals at the Northern Ireland Controlled Drug Local Intelligence Network and were welcoming of the proposals.The rescheduling of cannabis-based products for medicinal use means that these products will be regulated under the controlled drugs and medicines regulatory regime. A review of the legislative change and the policy will be undertaken in two years.

5. Equality Impact

5.1. The amendments may have a positive impact on members of all Section 75 groups who have a clinical need and where a specialist prescriber deems it appropriate to prescribe a cannabis-based medicine.

6. Regulatory Impact

6.1. Overall the impact of the proposed changes is assessed as beneficial to both healthcare professionals, patients and carers. The proposals allow

healthcare professionals more flexibility in healthcare settings with the effect that suitable patients are be able to access cannabis-based treatments in a more timely and efficient manner under a framework that prevents the diversion and misuse of drugs considered to be dangerous when misused.

7. Financial Implications

7.1. There are no anticipated financial implications to the Department of Health although there may be implications for the wider Health Service.

8. Section 24 of the Northern Ireland Act 1998

8.1. The Department is satisfied that this legislation is compliant with section 24 of the Northern Ireland Act 1998

9. EU Implications

9.1. There are no anticipated EU implications.

10. Parity or Replicatory Measure

10.1. These regulations replicate amendments to the Misuse of Drugs Regulations 2001- which apply to England, Wales and Scotland.

11. Additional Information

11.1. Not applicable