EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (AMENDMENT) (ENGLAND, WALES AND SCOTLAND) REGULATIONS 2021

2021 No. 1427

1. Introduction

1.1 This explanatory memorandum has been prepared by the Home Office and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 Following an assessment of their harms, the Advisory Council on the Misuse of Drugs ("ACMD") has recommended that three drugs, Gamma-Hydroxybutyric Acid (GHB), Gamma-Butyrolactone (GBL) and 1,4-Butanediol (1,4-BD), be moved from Class C to Class B under the Misuse of Drugs Act 1971 ("the 1971 Act") and that GBL and 1,4-BD be placed in Schedule 1 to the Misuse of Drugs Regulations 2001 ("the 2001 Regulations") and further recommended the removal of an exemption from the 2001 Regulations that made certain activities in relation to GBL and 1,4-BD lawful, meaning that legitimate industrial users will require a controlled drugs licence. Collectively, these three drugs are referred to below as "GHB and related substances" ("GHBRS"). This instrument places GBL and 1,4-BD in Schedule 1 to the 2001 Regulations.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England, Wales and Scotland.

4.2 The territorial application of this instrument is England, Wales and Scotland.

5. European Convention on Human Rights

5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation no statement is required.

6. Legislative Context

6.1 The 1971 Act controls drugs that are "dangerous or otherwise harmful". Schedule 2 to the 1971 Act specifies these drugs and groups them in three categories – Part 1 lists drugs known as Class A drugs, Part 2 lists Class B drugs and Part 3 lists Class C drugs. The three-tier system of classification (A, B and C) provides a framework within which criminal penalties are set with reference to the harm that a drug has, or is capable of having when misused, and the type of illegal activity undertaken with regards to that drug.

6.2 The draft Misuse of Drugs Act 1971 (Amendment) Order 2022 ("the draft 2022 Order") which was laid before both Houses of Parliament on 15th December 2021

proposes to move GHB (referred to for the purposes of the 2022 Order as 4-Hydroxy-n-butyric acid), GBL and 1,4-BD from Class C to Class B under the 1971 Act following a recommendation made by the ACMD in its report, "Assessment of the harms of gamma-hydroxybutyric acid, gamma-butyrolactone, and closely related compounds", published on 20th November 2020[1].

6.3 Section 7(3) of the 1971 Act requires the Secretary of State to make regulations to allow drugs controlled under the 1971 Act to be used for medicinal purposes. This applies to GHB, which has medicinal uses. The ACMD has recommended that it remain in Schedule 2 to the 2001 Regulations and this instrument does not therefore affect the scheduling of GHB. Section 7(3) does not apply to any drug which is "designated" by order under section 7(4) Controlled drugs are designated where the Secretary of State is of the opinion that it is in the public interest for the production, supply and possession of that drug to be either wholly unlawful or unlawful except for research or other special purposes under licence. Designated drugs are listed in Schedule 1 to The Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015 ("the 2015 Order"). GBL and 1,4-BD are designated under the 2015 Order.

6.4 The 2001 Regulations provide access to controlled drugs for legitimate medicinal purposes (and exceptionally for industrial purposes) under the 1971 Act. Drugs are ordinarily placed into one of five Schedules to the 2001 Regulations. The Schedule into which a drug is placed is based on an assessment of its medicinal or therapeutic usefulness, the need for legitimate access as well as its potential for harm when used. The Schedule primarily dictates the circumstances under which it is lawful to import, export, produce, possess, supply and administer the drug. It may impose requirements in relation to prescribing, record keeping, labelling, destruction, disposal and safe custody. Schedule 1 drugs are considered to have no known medicinal use in the UK and are subject to the greatest restrictions, requiring a Home Office licence.

6.5 Designated drugs are ordinarily placed in Schedule 1. However, following previous ACMD advice in 2008 that GBL and 1,4-BD be controlled under the 1971 Act, they were designated in 2009 by the Misuse of Drugs (Designation) (Amendment) (England, Wales and Scotland) Order 2009 (S.I. 2009/3135), but not placed in a schedule. Due to their legitimate industrial use, they were instead subject to a bespoke provision in regulation 4B of the 2001 Regulations, inserted by the Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2009 (S.I. 2009/3136) that it was lawful to import, export, produce, supply or possess them in circumstances where they were not intended to be used for the purposes of human ingestion (other than as a flavouring in food).

6.6 Following the ACMD's report, this instrument will implement another of the recommendations of the ACMD by placing GBL and 1,4-BD in Schedule 1 to the 2001 Regulations, as they have no known legitimate medicinal use in the UK, and removing the exemption under Regulation 4B. This will mean that industrial users will need to apply for, and obtain, a controlled drugs licence from the Home Office to import, export, produce, supply or possess these drugs.

[1] The ACMD's report is available at the following link: https://www.gov.uk/government/publications/assessment-of-the-harms-of-gamma-hydroxybutyric-acid-gamma-butyrolactone-and-closely-related-compounds

7. Policy background

What is being done and why?

7.1 The ACMD is a statutory, independent advisory body under the 1971 Act. The ACMD makes recommendations to the government on the control of dangerous or otherwise harmful drugs, including the classification and scheduling under the 1971 Act and the 2001 Regulations. The ACMD also consider any substances which are, or appear to be, misused and which are capable, or appear to be capable, of having harmful effects.

7.2 The ACMD's report, "Assessment of the harms of gamma-hydroxybutyric acid, gamma-butyrolactone, and closely related compounds", said (paragraph 9.4): "In the UK in recent years, GHBRS have been used to facilitate serious crimes, including murder, rape, sexual assault and robbery. Some of these crimes occur in a chemsex context, however this is not exclusively the case." The report describes a number of criminal cases, which, it says "demonstrate the extreme harm that can be inflicted on others by predators using GHBRS". The ACMD found that in terms of the use of GHBRS to facilitate crime: "..there is strong new evidence of significant criminal harm from GHBRS, including murder, drug-facilitated sexual assault and robbery."

7.3 The ACMD also found that GHBRS use is associated with a wide range of health harms, including "a marked increase in deaths between 2008 and 2018, and that "there is a strong base of new evidence about the mental health harms caused by GHBRS since the Advisory Council on the Misuse of Drugs last considered their harms." The ACMD concluded: "There is increasing evidence of physical, mental and social health harms related to GHBRS. Of particular note are the new harms identified since the ACMD last considered GHBRS - severe harm from crimes facilitated by GHBRS and mental health harms associated with GHBRS use."

7.4 In respect of the status of GBL and 1,4-BD the ACMD concluded "There is a need to disrupt the unrestricted sale from suppliers of GBL and 1,4-BD on the open-web purporting to be 'cleaning materials' when clearly destined for the illicit market. While a licensing regime would 'catch out' illegitimate suppliers, large-scale legitimate chemical suppliers would most likely be able to adapt to the imposition of a licensing regime for GBL and 1,4-BD."

7.5 The ACMD made eight recommendations in its report. These include that GHBRS be moved from Class C to Class B. The draft 2022 Order was laid before both Houses of Parliament on 15th December 2021 to implement this recommendation. This instrument, the Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2021, implements the recommendation that GBL and 1,4-BD be placed in Schedule 1 and that their legitimate industrial uses are made subject to a Home Office controlled drugs licensing regime. This instrument therefore abolishes the previous status of GBL and 1,4-BD, under which it is lawful to import, export, produce, supply or possess them in circumstances where it is not intended to be used for the purposes of human ingestion (other than as a flavouring in food).

7.6 This instrument will come into force six months after it is laid, June 15 2022, to enable businesses to prepare for the introduction of the requirement to hold a Home Office licence, including to apply for and, subject to an assessment of their application, be granted a domestic controlled drugs licence in advance of the instrument coming into force.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

9.1 This Statutory Instrument does not consolidate the 2001 Regulations; the Government will review whether to consolidate these in the future.

10. Consultation outcome

10.1 The ACMD has recommended the control of GHBRS as Class B drugs under the 1971 Act, that GBL and 1,4-BD be listed in Schedule 1 of the 2001 Regulations, and the removal of the exemption under 4B. The Home Office has liaised with representatives of the chemical industry in preparing the Impact Assessment.

11. Guidance

11.1 The effect of the reclassification of GHBRS under the 1971 Act and the inclusion of GBL and 1,4-BD in Schedule 1 to the 2001 Regulations will be communicated to key stakeholders and the wider public before each comes into force. The Home Office will continue to engage with representatives of the chemical industry to communicate the changes, and will issue a Circular with legislative guidance primarily for the police and the courts. The Government will continue to update its messaging on the harms of these substances, including through its FRANK information and advisory service online.

12. Impact

12.1 The impact on business, charities or voluntary bodies is expected to be felt, economically, primarily by legitimate industrial users who will be required to obtain a licence from the Home Office to possess, import, export or supply GBL and 1,4-BD. Following discussions with the chemicals industry, the Impact Assessment estimates that there will be around 65 companies affected with a net compliance cost of £0.65m over a ten-year period. This estimated cost includes set-up costs of the police and Border Force officers who will need to become aware of the reclassification and rescheduling of GHBRS.

12.2 The Impact Assessment describes (but does not seek to quantify) the beneficial impacts of these policies. This includes but is not limited to the impact of drug-deaths avoided, and crime and justice system costs avoided. The benefits are likely to be derived primarily from individuals who, as a result, do not become victims of drug-facilitated crime.

12.3 The impact on the public sector is expected to be primarily of a benefit to the taxpayer from reduced spend on support services associated with these crimes.

12.4 A full Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

14. Monitoring & review

14.1 Government will continue to monitor the control measures through the regulatory framework governing controlled drugs, this will include national data collection and surveys on crime and drug misuse.

14.2 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015 Kit Malthouse MP, the Minister for Crime and Policing, has made the following statement:

"The costs to business of The Misuse Of Drugs (Amendment) (England, Wales and Scotland) Regulations 2021 is expected to be around £0.65m over a 10-year period. The impacts and effectiveness of the instrument will be monitored in the ordinary course of business, and so it would be disproportionate to include a formal review clause."

15. Contact

15.1 Paul Nicol at the Home Office, Telephone: 07717 591 537, or email: paul.nicol@homeoffice.gov.uk can be contacted with any queries regarding the instrument.

15.2 Marcus Starling, Deputy Director for Drug Misuse and Firearms Unit, at the Home Office, can confirm that this Explanatory Memorandum meets the required standard.

15.3 Kit Malthouse MP, Minister for Crime and Policing, can confirm that this Explanatory Memorandum meets the required standard.