EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (AMENDMENT) (REVOCATION) (ENGLAND, WALES AND SCOTLAND) REGULATIONS 2022

2022 No. 559

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 This instrument revokes the Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2021 ("the 2021 Regulations"). The 2021 Regulations placed two controlled drugs, Gamma-Butyrolactone (GBL) and 1,4-Butanediol (1,4-BD), which have legitimate uses in industry, under stricter control, meaning that industrial users would require a controlled drugs licence. The impact assessment accompanying the 2021 Regulations assessed the impact on legitimate users but the impact was significantly underestimated.

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 Misuse of Drugs Act 1971 ("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 Misuse of Drugs Act 1971 (Amendment) Order 2022 ("the 2022 Order") which was laid before both Houses of Parliament on 15 December 2021 and came into force on 13 April 2022 moved Gamma-Hydroxybutyric Acid (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 recommended that it remain in Schedule 2 to the Misuse of Drugs Regulations 2001 ("the 2001 Regulations") and neither the 2021 Regulations nor this instrument 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 are 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) under which it is 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 The ACMD recommended that GBL and 1,4-BD should be placed in Schedule 1 to the 2001 Regulations and further recommended the removal of the exemption under regulation 4B of the 2001 Regulations, meaning that legitimate industrial users would require a controlled drugs licence. The Home Secretary accepted these recommendations, and they were implemented by the 2021 Regulations, which were laid on 15 December 2021 and are due to come into force on 15 June 2022. This instrument revokes the 2021 Regulations.

[1] The ACMD's report is available at the following link:
Assessment of the harms of gamma-hydroxybutyric acid, gamma-butyrolactone, and closely related compounds - GOV.UK (www.gov.uk)

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. The ACMD's report on GHB and related substances (GHBRS), "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."

7.2 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, and therefore recommended that GBL and 1,4-BD should be placed in Schedule 1 and the removal of the exemption under regulation 4B of the 2001 Regulations.

7.3 The Home Office considered the impact on legitimate industry in the impact assessment accompanying the 2021 Regulations, and while this was based on the available information from the sector at that time, the impact was significantly underestimated[2]. This is particularly due to the breadth and scale of the use of GBL and 1,4-BD in products where the GBL and 1,4-BD is in solution or blend, without having undergone chemical reaction, meaning that suppliers and end-users, not just manufacturers using neat GBL and 1,4-BD, would require licences. Given the impracticality and disproportionality of so many end users obtaining licences, these sectors are at risk of not being able to comply and potentially having to stop using or selling certain products, resulting in a significant negative impact on businesses. Therefore, the Government has decided to revoke the 2021 Regulations and to consult with industry on how best to deliver the ACMD's recommendation without causing disproportionate harm to business. The Government's initial view, subject to consultation, is that we will seek views on introducing a licensing requirement that captures neat GBL and 1,4-BD, but otherwise contains exemptions, including exemptions for end-products containing GBL and 1,4-BD in blend or solution, and end-products containing trace amounts of GBL and 1,4-BD as a by-product of reactive processes, from the need to acquire a licence. The revocation will mean that, as is the case now, no business will require a Home Office controlled drugs licence to lawfully import, export, produce, supply or possess these drugs from 15 June 2022.

[2] The Impact Assessment for the 2021 Regulations is available at the following link: The Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2021 - Impact Assessment (legislation.gov.uk)

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 instrument does not consolidate the 2001 Regulations; the Government will review whether to consolidate these in the future.

10. Consultation outcome

10.1 The Home Office has liaised with representatives of the chemical industry and associated businesses who make or supply products containing GBL and 1,4-BD in preparing this instrument.

11. Guidance

11.1 The effect of this instrument has been communicated to affected stakeholders through industry representative bodies and to prospective applicants for Home Office controlled drugs licences through the Home Office's Drugs and Firearms Licensing Unit. The effect of this instrument will be communicated to key stakeholders, including the police, through a Home Office Circular.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 A full Impact Assessment has not been prepared for this instrument because it maintains the existing regulatory position and no impact on business is foreseen.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses and maintains the existing regulatory position.

14. Monitoring & review

14.1 The effects of this instrument will not be monitored because it maintains the existing regulatory position.

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 Misuse of Drugs (Amendment) (Revocation) (England, Wales and Scotland) Regulations 2022 will not cause costs to business as they maintain the existing regulatory position. It would therefore 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.