EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (ENGLAND AND WALES AND SCOTLAND) (AMENDMENT) (NO. 2) REGULATIONS 2023

2023 No. 1345

1. Introduction

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

2. Purpose of the instrument

2.1 This instrument amends the Misuse of Drugs Regulations 2001 (S.I. 2001/3998) ("the 2001 Regulations") to enable the prescribing of five specified controlled drugs by paramedic independent prescribers and six specified controlled drugs by therapeutic radiographer independent prescribers. These drugs are listed in paragraph 7.6 below.

2.2 The instrument also enables the supply of three codeine products, which are all Schedule 5 controlled drugs, by specified registered podiatrists. These are outlined in paragraph 7.7.

2.3 The instrument makes technical amendments in relation to podiatrist independent prescribers and physiotherapist independent prescribers. These are outlined in paragraph 7.11.

2.4 The instrument also makes amendments to specify that possession of ketamine by healthcare professionals acting under patient group directions is lawful. This is explained further in paragraph 7.12.

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 extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law) is England and Wales and Scotland.

4.2 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England and Wales and Scotland.

5. European Convention on Human Rights

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

6. Legislative Context

6.1 This instrument is made under sections 7, 10, 22 and 31 of the Misuse of Drugs Act 1971 ("the 1971 Act"). Section 31(3) of the 1971 Act provides that the Secretary of State may not make regulations under the 1971 Act except after consultation with the Advisory Council on the Misuse of Drugs ("ACMD"). The ACMD has been

consulted and approved the amendments listed in paragraph 2.1 to 2.4. The reports containing their advice are available on GOV.UK at the following links:

6.1.1 ACMD-Further-advice-therapeutic-radiographers.pdf (publishing.service.gov.uk) published on 19th January 2017 and ACMD advice on administration rights for therapeutic radiographer independent prescribers - GOV.UK (www.gov.uk) published on 22nd April 2020.

6.1.2 ACMD advice on independent prescribing by paramedics - GOV.UK (www.gov.uk) published on 18th October 2019.

6.1.3 ACMD advice on the interim podiatrists supply proposal from NHS England (accessible version) - GOV.UK (www.gov.uk) published on 14th June 2022.

6.2 Whilst the Home Office has legislative responsibility for the 2001 Regulations, the policy area is shared with the Department of Health and Social Care (DHSC) and this instrument has been drawn up in consultation with DHSC. DHSC has responsibility for the Human Medicines Regulations 2012 ("the 2012 Regulations"), which govern the use of medicines in healthcare.

7. Policy background

What is being done and why?

7.1 This instrument enables the prescribing of specified controlled drugs in Schedules 2 to 5 to the 2001 Regulations by paramedic independent prescribers and therapeutic radiographer independent prescribers. It also allows the supply of three codeine products by registered podiatrists and registered chiropodists against whose names are recorded in the relevant register annotations, signifying that they are qualified to use the medicine provided, to align with Schedule 17 of the 2012 Regulations. The instrument makes further amendments in relation to podiatrist independent prescribers and physiotherapist independent prescribers and specifies that possession of ketamine by healthcare professionals acting under patient group directions is lawful. These amendments follow recommendations from the ACMD, which is a statutory, independent advisory body established by the 1971 Act. The ACMD makes recommendations to Government on appropriate control of dangerous or otherwise harmful drugs, which includes advice on access for their legitimate use in healthcare, as provided for in the 2001 Regulations.

Paramedic Independent Prescribing and Therapeutic Radiographer Independent Prescribing

7.2 NHS England consulted on proposals to enable prescribing of five specified controlled drugs by paramedic independent prescribers between 26 February and 27 May 2015, which were then reviewed by the Commission on Human Medicines (CHM). Changes to the 2012 Regulations came into force on 1 April 2018 to implement this policy.

7.3 At the same time NHS England consulted on proposals to enable prescribing of six specified controlled drugs by radiographers in 2015, which were then reviewed by the CHM. Changes to the 2012 Regulations came into force on 1 April 2016 to implement this policy for therapeutic radiographer independent prescribers.

7.4 Amendments to the 2001 Regulations can only be made following consultation with the ACMD, in line with our statutory requirement as set out in Section 31(3) of the 1971 Act. The 2001 Regulations enable legitimate access to controlled drugs in

healthcare. Following advice from the ACMD, as outlined in paragraphs 6.1.1-6.1.3, the Home Office is now bringing forward this instrument to implement the ACMD recommendations, which will also ensure alignment with the 2012 regulations in respect of paramedic independent prescribers and therapeutic radiographer independent prescribers.

7.5 As the proposals related to controlled drugs, the ACMD provided advice on them. The ACMD recommended that both proposals were implemented through amendments to the 2001 Regulations. The ACMD concluded that such proposals, subject to clinical and professional competence, would not increase the risk of diversion. The Home Office accepts this view.

7.6 The instrument amends the 2001 Regulations to complement changes made to the 2012 Regulations and implement NHS England's proposals. The instrument authorises paramedic independent prescribers to prescribe and administer the following controlled drugs in Schedules 2 to 5 to the 2001 Regulations: morphine sulphate by oral administration or by injection; diazepam by oral administration or by injection; midazolam by oromucosal administration or by injection; lorazepam by injection; and codeine phosphate by oral administration. The instrument authorises therapeutic radiographer independent prescribers to prescribe and administer the following controlled drugs in Schedules 2 to 5 to the 2001 Regulations: tramadol by oral administration; lorazepam by oral administration; diazepam by oral administration; morphine by oral administration or by injection; oxycodone by oral administration; and codeine by oral administration. The instrument also makes several additional consequential amendments required to give effect to the intention of these proposals.

Registered Chiropodist and Registered Podiatrist Supply

7.7 The ACMD considered a proposal from NHS England to enable supply of co-codamol, co-dydramol and codeine phosphate by podiatrists. In 2022, the ACMD recommended that the Home Office amend the 2001 Regulations to complement the existing legislative framework in the 2012 Regulations to enable podiatrists to supply co-codamol, co-dydramol and codeine phosphate with necessary safeguards in place.

7.8 Previously, podiatrists have supplied these medicines under a "Group Authority" issued by the Home Office's Drugs and Firearms Licensing Unit. Currently, registered chiropodists and registered podiatrists (who meet the definition in the relevant paragraphs of Schedule 17 of the 2012 Regulations) supply these medicines under a written authority issued by the Secretary of State under regulation 8(4) of the 2001 Regulations. The instrument will replace the written authority, enabling the same practice to occur under the 2001 Regulations. The written authority will be revoked after this instrument comes into force.

7.9 The Royal College of Podiatry and NHS England report that there are no concerns with the supply of these medicines by podiatrists in their professional practice. The Government has further consulted the ACMD and it agreed that guidance issued on the applicable safeguards, including a restriction to a 3-day supply of these drugs by registered chiropodists or podiatrists, is sufficient rather than including it in the 2001 Regulations.

Technical amendments

7.10 The instrument amends the 2001 Regulations to ensure alignment with the 2012 Regulations in respect of podiatrist independent prescribers and physiotherapist independent prescribers; and for the possession of ketamine by healthcare professionals acting under patient group directions. These amendments ensure that previous ACMD advice is properly implemented.

7.11 The instrument will clarify that patient possession for administration, pursuant to a prescription by a podiatrist independent prescriber or physiotherapist independent prescriber is lawful. It will also amend the definition of "prescription" in the 2001 Regulations to include those issued by podiatrist independent prescriber or physiotherapist independent prescriber.

7.12 The instrument will specify that possession of ketamine by healthcare professionals, including paramedics, that supply or administer controlled drugs under patient group directions, is lawful, as intended.

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 2018 / implement any future relationship agreement with the European Union within the meaning provided by section 37 of the European Union (Future Relationship) Act 2020.

9. Consolidation

9.1 This instrument amends another instrument, the Misuse of Drugs Regulations 2001, which the Government intends to consolidate in the future.

10. Consultation outcome

10.1 NHS England conducted two public consultations in 2015, one on proposals to introduce independent prescribing by paramedics and the other for independent prescribing by radiographers. The vast majority of respondents gave approval for the changes being implemented. Summaries of the responses from each consultation were published by NHS England and were deemed sufficient to enable amendments to be made to the 2012 Regulations without the Government publishing a consultation response. No public consultation was conducted regarding the supply of codeine products by podiatrists as the issue predates the 2012 Regulations. However, prior to the introduction of the current written authority, the Royal College of Podiatrists was consulted and agreed that supply of the specified codeine products by registered podiatrists should be allowed.

10.2 The ACMD has been consulted as statutorily required and the Government accepted its recommendations, which are outlined in paragraphs 7.1-7.12. The Home Office has also consulted the DHSC and NHS England who supported the changes being implemented.

11. Guidance

11.1 The law changes and their consequences will be communicated to key stakeholders, including healthcare professionals, and the wider public by the Home Office and the

DHSC. The Home Office will issue a circular explaining the changes further and the DHSC will communicate them to the healthcare sector.

11.2 Guidance issued by NHS England and the professional bodies will be updated to reflect the law change. This will include guidance from the Royal College of Podiatrists on safeguards that apply to the supply of codeine products.

12. Impact

12.1 The impact on the public sector, specifically the NHS, is moderate and beneficial. Paramedic independent prescribers and therapeutic radiographer independent prescribers will be able to prescribe a range of controlled drugs where clinically appropriate, without the need to refer to other clinicians. This will reduce pressure on NHS staffing and deliver faster treatment for patients. There will be a small cost to the NHS associated with the time taken for additional training, although this is not considered significant as NHS staff are already highly trained. There are no anticipated social costs.

12.2 The impact on business is positive but small, reflecting a relatively small market share for the relevant healthcare. There is no significant impact on charities or voluntary bodies from this instrument.

12.3 A full impact assessment will be published alongside the explanatory memorandum on legislation.gov.uk the date the instrument is laid.

13. Regulating small business

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

13.2 No specific action is proposed to minimise regulatory burdens on small businesses. The basis for the final decision on what action to take is that no impact on small business is identified from the impact assessment besides the potential savings to be achieved from the proposals as a result of prescribing duties moving over to paramedic and therapeutic radiographer independent prescribers.

14. Monitoring & review

14.1 The Government will monitor the changes through the oversight of Controlled Drug Accountable Officers and the healthcare regulatory bodies in England, Wales and Scotland.

14.2 A statutory review clause is not included in the instrument.

15. Contact

15.1 Lauren Teer at the Home Office, Telephone: 07587299202 or email: lauren.teer@homeoffice.gov.uk can be contacted with any queries regarding the instrument.

15.2 Marcus Starling, Deputy Director for the Drug Misuse Unit at the Home Office can confirm that this explanatory memorandum meets the required standard.

15.3 The Minister for Crime, Policing and Fire, the Rt. Hon. Chris Philp MP, can confirm that this explanatory memorandum meets the required standard.