EXPLANATORY MEMORANDUM TO THE MISUSE OF DRUGS (AMENDMENT No.2) (ENGLAND, WALES AND SCOTLAND) REGULATIONS 2012

2012 No. 973

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 amends the Misuse of Drugs Regulations 2001 (the "2001 Regulations") to remove the restrictions on the prescribing of controlled drugs by nurse independent prescribers, and enable the prescribing of all controlled drugs listed in Schedules 2 to 5 to the 2001 Regulations by nurse and pharmacist independent prescribers.

2.2 The instrument also regularises the "mixing of medicines" that include controlled drugs, enables morphine and diamorphine to be supplied by nurses and pharmacists where administration of such drugs is required for the immediate, necessary treatment of sick or injured persons, and authorises the possession of controlled drugs by a person specified in Schedule 8 to the 2001 Regulations acting in accordance with a Patient Group Direction ("PGD").

2.3 The instrument also amends the current disapplication of the provisions specified in regulation 4(2) of the 2001 Regulations for drugs listed in Part II of Schedule 4 by requiring importation and exportation of such drugs to be carried out by the person who then administers them to himself, and further removes the term "medicinal product" from the 2001 Regulations (previously defined in regulation 2(1) of the 2001 Regulations).

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 This instrument is made under sections 7, 10, 22 and 31 of the Misuse of Drugs Act 1971 ("the Act"). Section 31(3) of the Act provides that the Secretary of State may not make regulations under the 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 2.3 above.

4.2 Whilst the Home Office has the legislative responsibilities for the 2001 Regulations, the policy area is shared with the Department of Health and this instrument has been drawn up in consultation with them.

5. Territorial Application and Extent

5.1 This instrument applies to England, Wales and Scotland. The Northern Ireland Department for Health, Social Service and Public Safety (DHSSPS) will make separate legislative arrangements.

6. European Convention on Human Rights

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

7. Policy Background

Nurse and Pharmacist Independent Prescribing

7.1 In 2005 the Department of Health, following recommendations from the then Committee on Safety of Medicines (CSM), consulted on proposals to expand independent prescribing by appropriately qualified nurses and introduce pharmacist independent prescribing. The CSM's recommendation in principle also included drugs controlled under the Act. Changes were made to medicines legislation as a result to implement this policy. In 2007 the Home Office consulted on proposals to implement the CSM's recommendation as it relates to controlled drugs. The vast majority of the responses were supportive of the proposal. Following the consultation, the ACMD advised that changes should be made to controlled drugs legislation to enable nurse and pharmacist independent prescribers to prescribe all controlled drugs listed in Schedules 2 to 5 of the 2001 Regulations. The CSM and the ACMD both concluded at the time that the proposal to enable nurse and pharmacist independent prescribers to prescribe an unrestricted range of controlled drugs, subject to clinical and professional competence would not increase the risk of diversion. The Home Office accepts this view.

7.2 The instrument amends the 2001 Regulations to complement changes made to the Prescription Only Medicines (Human Use) Order 1997 to implement the full policy intent of the CSM's recommendation. Nurse and pharmacist independent prescribers are now to be authorised to prescribe all controlled drugs listed in Schedules 2 to 5 within their competence, except cocaine, diamorphine and dipipanone for the treatment of addiction. Nurse and pharmacist independent prescribers are also authorised to supply, offer to supply or administer morphine and diamorphine under PGDs.

Mixing of Medicines

7.3 Current provisions under the 2001 Regulations authorise only doctors and pharmacists to "*manufacture or compound*" any controlled drug before it is administered. In 2008 the Medicines and Healthcare products Regulatory Agency ("MHRA") recognised that the legal position under both medicines legislation and the 2001 Regulations needed to be regularised. In the absence of specific provisions enabling other healthcare professionals or carers to compound or 'mix' medicines that also include controlled drugs, the MHRA, in consultation with the Home Office, issued a statement advising that it would not support enforcement action against those prescribing and administering mixtures of licensed medicines in clinical practice, unless it would be in the public interest to do so. The ACMD has considered the need for this change and is supportive of the proposal. The policy aim is to enable controlled drugs to be 'compounded' prior to administration to a patient as opposed to the "manufacture" of controlled drugs in general. In practice compounding relates to the 'mixing' of two or more drugs which include a controlled drug(s), for instance for palliative care.

7.4 The instrument will give authority to a doctor or a dentist to give written directions to others to 'compound' two or more drugs that include controlled drugs in clinical practice; allow nurse independent prescribers and supplementary prescribers when acting in accordance with a clinical management plan to 'compound' two or more drugs that include controlled drugs and, in addition to pharmacist independent prescribers, direct others acting in accordance with their written directions to 'compound' medicines that include controlled drugs prior to administration to a patient.

Clarifying amendment to Patient Group Directions (PGDs)

7.5 PGDs were first introduced in the 2001 Regulations in 2003. No corresponding change was made to the 2001 Regulations at the time to give authority to those acting under a PGD to possess the relevant controlled drugs such as ketamine and midazolam. This means that although specific healthcare professionals listed in Schedule 8 to the 2001 Regulations, including paramedics, are authorised to supply and/or administer drugs such as ketamine and midazolam, they currently have no specific authority under the 2001 Regulations to possess these drugs.

7.6 The clarifying amendment is being implemented by the Home Office to correct the current anomaly and provide paramedics, and the specific healthcare professionals listed under Schedule 8, with the requisite authority to possess the specific drugs – ketamine and midazolam – under a PGD.

Amendments relating to Schedule 4

7.7 At present the provisions specified in regulation 4(2) of the 2001 Regulations (the prohibition on importation and exportation of controlled drugs) are disapplied in relation to drugs listed in Part II of Schedule 4 to the 2001 Regulations in respect of the prohibition on importation and exportation when imported or exported "*by any person for administration to himself" and when contained in a medicinal product.*

7.8 The instrument will make clear that regulation 4(2) of the 2001 Regulations is limited to importation and exportation of drugs listed in Part II of Schedule 4 when carried out in person by the same person who then administers such drugs to himself. The instrument also removes the term "*medicinal product*" from the 2001 Regulations (including by omitting the definition of such term contained in regulation 2(1)) with the effect that the term "*medicinal product*" no longer applies to provisions under the 2001 Regulations in general.

- ***Consolidation***

7.9 The Government intends to consolidate the 2001 Regulations in 2012. Proposals to consolidate the 2001 Regulations have been the subject of a public consultation.

8. Consultation outcome

8.1 The Home Office conducted a public consultation in 2007 on proposals relating to independent prescribing. The vast majority of respondents gave approval for the changes being implemented. The ACMD has been consulted as statutorily required. The Home Office has also consulted the Department of Health and the MHRA who supported the changes being implemented.

9. Guidance

9.1 The law changes and their consequences will be communicated to healthcare professionals and the wider public by the Home Office and the Department of Health. The Home Office will issue a circular explaining the changes further. The Department of Health will issue guidance to healthcare sector using their usual communication channels.

10. Impact

10.1 Regulatory Impact Assessments are attached to this memorandum.

10.2 The regulatory impact assessment on independent prescribing identifies savings as a result of a proportion of prescribing duties moving over to nurse and pharmacist independent prescribers. Savings also accrue to the private and third sectors. However these cannot be separately quantified.

10.3 No impact is identified from the changes relating to compounding of controlled drugs, possession authorities under PGDs and changes relating to personal exemptions for Part II Schedule 4 drugs on businesses or the third sector.

11. Regulating small business

11.1 This legislation applies to small business. However, no impact on small business is identified from the Impact Assessment besides the savings to be achieved from the proposals as a result of prescribing duties moving over to nurse and pharmacist independent prescribers.

12. Monitoring & review

12.1 The Government will monitor the changes through the oversight of Accountable Officers and the healthcare regulatory bodies in England and the Devolved Administrations.

13. Contact

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