EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (AMENDMENT No.3) REGULATIONS 2006

2006 No. 2178

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

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 This instrument amends the Misuse of Drugs Regulations 2001 to :

- Exclude veterinary prescriptions from the requirements that all non-NHS Schedule 1, 2 and 3 controlled drugs prescriptions must be issued on a standard form which includes the prescriber's unique identification number, and that all such prescriptions must be submitted to the relevant NHS agency
- Remove the requirement from the 2001 Regulations that all non-NHS Schedule 1-3 controlled drugs prescriptions shall be preserved for 2 years, thereby allowing for the originals of these prescriptions to be sent to the relevant NHS agency., with the exception of Schedule 1-3– veterinary prescriptions which must be retained on the premises for 2 years.

2.2 This instrument also amends the implementation date from 1 January 2007 to 1 January 2008 of two provisions of the Misuse of Drugs (Amendment No. 2) Regulations 2006 (S.I. 2006/1450), which were laid before Parliament on 9 June 2006. The provisions whose implementation date is being delayed are those amending the Misuse of Drugs Regulations 2001 ("the 2001 Regulations") requiring certain entries to be made in the Controlled Drugs Register ("CDR") on the supply of a controlled drug within Schedule 2 to the 2001 Regulations.

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

3.1 Because these Regulations amend provisions in the Misuse of Drugs (Amendment No. 2) Regulations 2006 ("the 2006 Regulations") before those provisions come into force, and is made in consequence of defects in the 2006 Regulations, this order is being issued free of charge to all known recipients of the earlier Regulations.

4. Legislative Background

4.1 These instrument is made under sections 7, 10, and 31 of the Misuse of Drugs Act 1971 ("the Act"). The Act received Royal Assent on 27 May 1971. Section 31(3) of the Act provides that the Secretary of State may only make

regulations under the Act after consultation with the Advisory Council on the Misuse of Drugs (ACMD). The ACMD has been consulted.

4.2 The 2006 Regulations made a number of changes to the 2001 Regulations. These were a first tranche of changes that the Government undertook to make in Safer Management of Controlled Drugs (2005), its Response to the Fourth Report of The Shipman Inquiry.

4.3 The 2006 Regulations established new arrangements for the supply of Schedule 1, 2 and 3 controlled drugs outside the NHS - i.e. on a private basis - requiring such prescriptions to be issued on a standard form, which includes the prescriber's unique identification number, and which must be submitted to the relevant NHS agency after the drug has been supplied. This instrument specifically excludes veterinary prescriptions from these arrangements.

4.4 The 2001 Regulations require all Schedule 1-3 non-NHS controlled drug prescriptions to be retained on the premises from which the drug was supplied and for all non-NHS controlled drug prescriptions to be preserved for 2 years. This instrument removes these requirements in respect of non-NHS prescriptions not issued by veterinary surgeons or veterinary practitioners containing controlled drugs in Schedules 1-3. (Such prescriptions, or copies, must be sent to the relevant NHS agency in accordance with Regulation 23(4) of the 2001 Regulations).

4.5 Regulations 7 and 10 of the 2006 Regulations introduced new recording requirements in the CDR in respect of requesting the identity of a person collecting Schedule 2 drugs on prescription, and new columns in the form of the CDR itself supporting those requirements. These changes were due to come into force on the 1 January 2007 and are now to come into force on 1 January 2008.

4.6 Whilst the Home Office has the legislative responsibilities for the Misuse of Drugs Act 1971 and its associated legislation, the policy area is shared with the Department of Health and this instrument has been drawn up in consultation with them.

5. Extent

5.1 These Regulations apply to England, Wales and Scotland.

6. European Convention on Human Rights

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

7. Policy background

7.1 The 2006 Regulations extended to private prescriptions the monitoring arrangements that were already in place for prescriptions for human use of Schedule 2 and 3 controlled drugs issued under the National Health Service. All private prescriptions for Schedule 1, 2 and 3 controlled drugs that are presented for dispensing in the community are now required to be written on a

standard form provided by a Primary Care Trust (or equivalent body) which must include the prescriber's unique identification number and be submitted to the relevant NHS agency after the drug has been dispensed. It is the policy intention that these new arrangements extend to prescriptions for human use only and NOT to prescriptions issued by veterinary surgeons or veterinary practitioners for the purposes of animal treatment. This instrument specifically excludes veterinary prescriptions from these requirements.

7.2 The requirement to submit all non-NHS, non-veterinary Schedule 1, 2 and 3 controlled drug prescriptions to the relevant NHS agency removes the need for such prescriptions to be retained on the premises (as required by Regulation 16(2) the 2001 Regulations) for a period of 2 years (as required by Regulation 23(3) of the 2001 Regulations). This instrument therefore removes these requirements in respect of such prescriptions (but retains the requirement for all veterinary prescriptions and all non-NHS Schedule 4 and 5 prescriptions to be retained for 2 years to ensure that they are available for inspection for that period. Schedule 1-3 controlled drug veterinary prescriptions must be retained for this time on the premises from which they are supplied.)

7.3 The 2006 Regulations also amended the 2001 Regulations, inter alia, to establish regulatory arrangements around the requirements for proof of identity of a patient, patient's representative or healthcare professional collecting a Schedule 2 controlled drug on prescription. The overall purpose of these amendments is to improve the system under which controlled drugs are dispensed in the community, in particular to provide a deterrent to wrongful collection and a valuable tool in the audit trail.

7.4 The requirements placed upon a person asked to supply a Schedule 2 controlled drug under Regulation 16(6) of the 2001 Regulations as amended by the 2006 Regulations came into force on 7 July 2006. Supporting recording requirements and new columns in the form of the CDR were to come into force on 1 January 2007.

7.5 However, notwithstanding consultation over the 2006 Regulations, it is only since those Regulations were laid that the need for a comprehensive review of the prescribed form of the CDR as set out in Schedule 6 to the 2001 Regulations, which is beyond the recommendations of The Shipman Inquiry, has been brought to the Government's attention.

7.6 The new recording requirements in the CDR relating to proof of identity of a person collecting Schedule 2 drugs on prescription and new columns in the form of the CDR are therefore to be delayed until 1 January 2008 when the new format of the CDR will come into force, following the CDR review and further regulation change. Pharmacy organisations will need time to develop and distribute CDRs in line with the new format of CDRs (which will include the new columns relating to proof of identity). Bringing all the changes to the recording requirements and the format of the CDR into force at the same time (1 January 2008) will be more convenient and create greater clarity for the pharmacy sector which will then only have to develop one new form of the CDR rather than two in quick succession.

7.7 In the interim, it is a matter of good practice to record the information obtained as a result of compliance with regulation 16(6) of the 2001 Regulations as amended by the 2006 Regulations.

8. Impact

8.1 A final Regulatory Impact Assessment was prepared by Department of Health alongside the Government's Response to the Fourth Report of The Shipman Inquiry and is available on the Department of Health website at www.dh.gov.uk. This Statutory Instrument therefore does not require a further RIA.

9. Contact

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