

EXPLANATORY MEMORANDUM

The Misuse of Drugs (Amendment No. 2) Regulations 2006

2006 No. ****

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

2. Description

2.1 This instrument amends the Misuse of Drugs Regulations 2001 (“the 2001 Regulations”) in order to implement key elements of the action programme published in *Safer Management of Controlled Drugs* (December 2004) – the Government’s Response to the Fourth Report of The Shipman Inquiry, an independent public inquiry into the issues arising from the case of Harold Fredrick Shipman.

2.2 The intention of this instrument is to set out regulation that will strengthen the system for managing controlled drugs in order to minimise the risk to patient safety of the inappropriate use of controlled drugs. However, controlled drugs are used for a wide variety of clinical reasons and the changes made by this instrument take account of the need to balance this objective with the need to ensure that patients can access the medicines they need and that the legitimate use of controlled drugs by healthcare professionals is not compromised.

2.3 This instrument contains amendments :

- To set the maximum validity period of a prescription form for Schedule 2,3 and 4 controlled drugs to 28 days
- To allow occupational therapists, orthotists and prosthetists to supply or administer controlled drugs in Schedule 4 and 5 (except anabolic steroids) under Patient Group Directions
- To require any person who makes a supply of Schedule 2 and 3 controlled drugs for human use outside the NHS - ie on a private basis - to use a standard form which includes the prescriber’s unique identification number, which must be submitted to the relevant National Health Service Agency.
- To require a person who is asked to supply a Schedule 2 controlled drug on prescription to ascertain, and record in the Controlled Drugs Register, whether the person collecting is the patient, the patient’s representative or a healthcare professional acting in their professional capacity on behalf of the patient
- To require a person supplying a Schedule 2 controlled drug to obtain and record in the Controlled Drugs Register the name and address of a healthcare professional who is collecting it, request proof of identity and record whether proof of identity was provided
- To require a person supplying a Schedule 2 controlled drug to record whether proof of identity was requested of a patient or patient representative and whether proof of identity was provided

- To allow additional entries to be made in the Controlled Drugs Register beyond that required to be entered by the 2001 Regulations eg. a running balance of stock
- To allow a pharmacist to correct a limited number of errors on a prescription for a Schedule 2 or 3 controlled drug (except temazepam) which would otherwise not be dispensable under Regulation 16 of the 2001 Regulations.

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

3.1 None

4. Legislative Background

4.1 This instrument is made under sections 7,10,22 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 not make regulations under the Act except after consultation with the Advisory Council on the Misuse of Drugs (ACMD). ACMD has been consulted and approved the amendments to the 2001 Regulations. The changes were subject to a three month public consultation.

4.2 *Safer Management of Controlled Drugs* sets out a series of changes to be made to the 2001 Regulations. The amendments made by this instrument are the first tranche of those changes, with further amendments to the 2001 Regulations to follow. These changes set out in this instrument which relate to the Controlled Drugs Register will not come into force until 1 January 2007.

4.3 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 the negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy Background

7.1 *Safer Management of Controlled Drugs*, developed through widespread consultation with key stakeholders, set out a substantial programme of work to improve and strengthen the management arrangements for controlled drugs. These amendments to the 2001 Regulations are an important part of implementing that programme. In formulating the policy that underpins the new requirements, full consideration has been given to the fundamental need to ensure that patients’ access to the controlled drugs they need is not unnecessarily compromised by the parallel objective of strengthening the systems by which controlled drugs are managed and the risk to patient safety minimised. This issue has been particularly reflected in the consideration given to which Schedules

of controlled drugs the additional requirements should apply and the requirements around proof of identity on collection of Schedule 2 controlled drugs.

Maximum validity period of a prescription form for Schedule 2, 3 and 4 controlled drugs set at 28 days

7.2 The 2001 Regulations are amended to restrict the maximum validity period of a prescription form for a Schedule 2, 3 and 4 controlled drugs to 28 days. Schedule 2 and 3 prescriptions previously had to be dispensed no later than 13 weeks (91 days) from the date specified on the prescription and Schedule 4 controlled drugs prescriptions were not subject to a maximum validity period. The amendment will reduce the likelihood of these controlled drugs being dispensed beyond their clinical need and stored or diverted inappropriately.

Non-Medical prescribing, Supply and Administration

7.3 The 2001 Regulations are amended to allow occupational therapists, orthotists and prosthetists to supply or administer controlled drugs in Schedule 4 and 5 (except anabolic steroids) under Patient Group Directions (PGDs). Under existing 2001 Regulations, PGDs can already be used for these controlled drugs by a range of healthcare professionals. The inclusion of the additional groups of healthcare professionals will provide easier and greater access to medicines needed by patients but within the framework of the PGD mechanism.

7.4 Chiropodist/podiatrist, physiotherapist, radiographer and optometrist supplementary prescribers are able to prescribe controlled drugs, in partnership with a doctor and according to a patient's Clinical Management Plan. This was included in the public consultation and has been agreed by ACMD. No further amendment to the 2001 Regulations is needed to bring this into effect.

Private prescribing

7.5 The 2001 Regulations are amended to extend the arrangements that are already in place for prescriptions for human use of Schedule 2 and 3 controlled drugs issued under the National Health Service to private prescriptions. All private prescriptions for human use of Schedule 2 and 3 controlled drugs that are presented for dispensing in the community (not in a hospital) are now required to be written on a standard prescription 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 National Health Service Agency.

7.6 The purpose of these amendments is to facilitate the monitoring and analysis of the private prescribing of controlled drugs and will enable any apparent discrepancies and/or diversions to be identified and investigated at a local level. It will also help to establish an audit trail of the movement of controlled drugs in the community.

Identification requirements on collection of Schedule 2 controlled drugs

7.7 The 2001 Regulations are amended 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.

7.8 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. Whilst this is a matter for regulation, in order to maximise compliance, appropriate discretions have been given to the person who is asked to supply the controlled drugs - to be exercised in their professional judgement - to ensure that a patient's legitimate access to their medication is not unnecessarily withheld.

7.9 The person asked to supply a Schedule 2 controlled drug is required to ascertain the capacity in which the person collecting the drug is acting – whether patient, patient's representative or healthcare professional acting on behalf of the patient.

7.10 Where the patient or patient's representative collects the drug, the person supplying the controlled drug may ask for proof of identity and may supply the drug in the absence of such identity. These discretions are provided to reflect concerns that patient confidentiality could be compromised by making the request a requirement and may thereby deter patient's representatives from collecting. It also reflects concerns that some patients may not have proof of their identity. The circumstances in which this discretion should be exercised will be fully supported in guidance.

7.11 Where a healthcare professional collects the drug on behalf of the patient, the person supplying the controlled drug must obtain the healthcare professional's name and address and must ask for evidence of identity but may supply the drug in the absence of such identity. This discretion to supply in the absence of proof of identity has been given to ensure that a supply can be made if the healthcare professional does not have such identity immediately available. The intention is that the discretion should only be applied in emergency situations and Guidance will support this.

Record Keeping and the Controlled Drug Register

7.12 The 2001 Regulations are amended to enhance the record keeping requirements of the Controlled Drugs Register (CDR) for Schedule 2 controlled drugs. The purpose of these amendments is to improve the audit trail, and in particular aid any investigation where the controlled drug has been diverted. These amendments will come into force on 1 January 2007, thereby allowing those that are required to maintain a CDR the opportunity to prepare and/or adapt their current paper or electronic CDRs.

7.13 The amendments also make clear that the 2001 Regulations set out the minimum requirements of the CDR and do not prevent the inclusion of additional but related information. The inclusion of a running balance of stock will therefore be permitted, although at this time it will not be a mandated requirement. The type of additional information that can be included in the CDR will be the subject of Guidance.

7.14 The new recording requirements are :

- the capacity in which a person collecting the controlled drug is acting. If that person is a healthcare professional, their name and address must be recorded;
- whether proof of identity was requested of the patient or their representative;
- whether proof of identity was provided.

Technical Errors on the prescription

7.15 The 2001 Regulations are amended to allow a pharmacist to correct those prescriptions that are subject to the requirements of Regulation 15 - a Schedule 2 or 3 controlled drug (except temazepam) - if the prescription contains minor typographical errors or spelling mistakes, or does not include both the words and figures of the total quantity of the controlled drugs (or preparation or the number of dosage units) as required by the 2001 Regulations.

7.16 This amendment reflects concerns that the strict requirement that a pharmacist is not permitted to dispense a controlled drug prescription unless there is full compliance with every technical requirement of the 2001 Regulations was compromising patient care. As a safeguard to these changes, the pharmacist must satisfy two pre-conditions before amending the prescription and supplying the controlled drug. He must be satisfied on reasonable grounds, having exercised due diligence that the prescription is genuine and that he is supplying the drug in accordance with the intention of the prescriber. Any correction must be marked so as to be attributable to the pharmacist to ensure it is readily identifiable, for the purpose of audit. Guidance will support the amendment.

7.17 The scope of this amendment does not require any similar changes to the medicines legislation

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.

8.2 The impact on the public sector is expected to be beneficial in terms of reducing time costs for frontline NHS staff and improving the quality of patient care, providing better protection of patients through improved safeguards and reducing the opportunities for diversion of controlled drugs through better auditing procedures.

9. Contact

9.1 Angela Scrutton at the Home Office Tel: 020 7035 0458 ; e-mail: Angela.Scrutton@homeoffice.gsi.gov.uk or Chris Edwards at the Home Office on 020 7035 0464 or Chris.Edwards@homeoffice.gsi.gov.uk can answer any queries regarding this instrument.