

EXPLANATORY MEMORANDUM TO
THE MISUSE OF DRUGS (AMENDMENT) (No. 2) (ENGLAND, WALES AND
SCOTLAND) REGULATIONS 2015

2015 No. 891

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

The purpose of this instrument is to amend the Misuse of Drugs Regulations 2001 (the “2001 Regulations”) in order to:

- include new definitions of “prisons” and “organisation providing ambulance services”, include specific provisions relating to prisons in the 2001 Regulations and provide Ambulance Trusts with a similar authority to that currently applicable to hospitals and care homes to possess and supply Schedule 2 to 5 controlled drugs;
- amend the definition of a health prescription to include National Health Service (NHS) prescriptions issued by independent and supplementary prescribers;
- regularise the emergency supply of phenobarbital in the absence of a compliant prescription;
- introduce limited independent prescribing authorities for registered physiotherapist independent prescribers and registered chiropodist independent prescribers;
- provide authority for NHS Ambulance Trusts to possess and supply controlled drugs directly to their employees for use in the immediate treatment of sick or injured persons;
- extend the authority to supply or offer to supply controlled drugs to senior registered nurses in charge of prison healthcare departments and midwife ward managers and include them in provisions relating to requisitions and record-keeping;
- change midwife supply orders from a system through which stocks of controlled drugs can be obtained by making them patient specific;
- make the use of a specific form for the requisitioning of Schedule 2 and 3 controlled drugs mandatory;
- include paramedics and operating department practitioners in the list of healthcare professionals requiring a requisition in order to obtain stocks of Schedule 2 and 3 controlled drugs;
- exempt hospices and prisons from the requirement to present requisitions when obtaining stocks of controlled drugs;
- remove the exemptions applicable to prescriptions for temazepam;
- make it a requirement for veterinary practitioners to include their Royal College of Veterinary Surgeon number on prescriptions for Schedule 2 and 3 controlled drugs;
- introduce the use of electronic prescription forms under the NHS Electronic Prescribing Service (EPS) in relation to Schedule 2 and 3 controlled drugs; and
- move ketamine from Part 1 of Schedule 4 to the 2001 Regulations to Schedule 2 and provide exemptions for continued use by specified healthcare professionals under Patient Group Directions;

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 1971 Act”). Section 31(3) of the 1971 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”).

4.2 The 1971 Act controls drugs that are “*dangerous or otherwise harmful*” either to individuals or to society when they are misused. It lists all drugs subject to control in Schedule 2 to the Act in three categories; Classes **A**, **B** and **C**, according to their perceived degree of harm and applies maximum penalties to offences committed under the Act. Access to controlled drugs for legitimate medicinal purpose is permitted, but subject to regulation, through the Misuse of Drugs Regulations 2001 (“the 2001 Regulations”). The Regulations establish a regime of control around prescribing, supplying or administering, safe custody, dispensing, record keeping, destruction and disposal. The single purpose of these restrictions is to prevent the diversion and misuse of controlled drugs for patient and public protection.

4.3 Whilst the Home Office has legislative responsibilities for the 2001 Regulations, the policy area is shared with the Department of Health (DH) and this instrument has been drawn up in consultation with them. The ACMD has also been consulted and approved the amendments to the 2001 Regulations.

5. Territorial Extent and Application

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

- What is being done and why

Amendments to the definition of “health prescriptions”

7.1 Health prescriptions are defined under the 2001 Regulations as “*prescriptions issued by a doctor or a dentist under the National Health Service....*” Other healthcare professionals such as nurses and pharmacists are currently able to prescribe controlled drugs under the NHS as independent or supplementary prescribers. These activities automatically become “private prescribing” under the current definition.

7.2 The instrument amends the definition of “health prescription” to include prescriptions issued by supplementary and independent prescribers under the NHS because, without this amendment, prescribing by other healthcare professionals under the NHS fall outside the

definition of a health prescription. All prescriptions issued under the NHS now qualify as “health prescriptions” under the 2001 Regulations.

“Organisation providing ambulance services– definition and authority to possess and supply controlled drugs to employees

7.3 The instrument inserts a new definition of an “organisation providing ambulance services” in regulation 2 to clarify the specific organisations that derive authority to possess and supply from changes being made to the 2001 Regulations.

7.4 Ambulance Trusts do not currently have authority under the 2001 Regulations to possess or supply controlled drugs to their employees (as is the case for hospitals). The introduction of a new definition of an “organisation providing ambulance services” is necessary as a result of new authorities being granted to such Trusts to put them on a similar footing with hospitals.

7.5 The authority currently provided to hospitals and care homes, under Regulations 8, 9 and 10 of the 2001 Regulations to possess and supply controlled drugs to healthcare professionals allows for a robust system to monitor controlled drug use within hospitals and care homes. In the absence of a similar authority for Ambulance Trusts, trusts currently use various arrangements under the current regulatory framework to enable paramedics to access the controlled drugs they are permitted to supply or administer under the 2001 Regulations and the Group Authorities issued under the 2001 Regulations. This includes arrangements where a trust sets up a contract with a community pharmacy which enables paramedics to requisition their stocks via the general contract directly from the pharmacy.

7.6 This instrument authorises “organisations providing ambulances services” (as defined) to possess, and supply controlled drugs in Schedule 2 to 5 to employees of the Trust. The authority granted does not extend to private ambulance services who will continue to need a licence for controlled drugs possessed and supplied by the Service.

7.7 The changes being implemented will provide Ambulance Trusts with a similar authority to that currently applicable to hospitals and care homes. This would enable Trusts to order, stock and supply drugs to paramedics and other healthcare professionals employed by the Trust. This system will be more robust, provide a good audit trail for controlled drugs used within this sector and will reduce the risk of diversion currently associated with ongoing practices.

Midwife Supply Orders – made patient specific

7.8 The Midwives Supply Order (MSO) was devised in 1985 to ensure that midwives had legal and monitored access to opiate drugs for home birth, using existing exemptions to administer the drug without prescription. Regulation 11 of the Misuse of Drugs Regulations 2001 provided a midwife with the authority to possess “*any controlled drug which she may, under and in accordance with the provisions of the Medicines Act 1968 ... lawfully administer*” provided the controlled drugs have been obtained via a MSO, signed by an “*appropriate medical officer*” i.e. a doctor or head of midwives.

7.9 MSOs are being made patient specific, rather than a means of obtaining stocks of controlled drugs. This will place MSOs on a similar footing to prescriptions i.e. when dispensed, the controlled drugs become the patient’s property and therefore their responsibility rather than the responsibility of the midwife; thereby removing the risks

associated with midwives carrying controlled drug stocks. The other arrangements for obtaining an MSO remain the same. Midwives continue to have authority to possess any unused controlled drugs and to supply them to a person who may lawfully have possession such as a pharmacist, for destruction.

Paramedics and Operating Department Practitioners – Regulation 14 requirements

7.10 The 2001 Regulations currently list a number of professionals who need to present a compliant requisition (specified information relating to the person obtaining controlled drugs and the purposes for which the drugs are being obtained) in order to obtain controlled drugs. The provisions under the 2001 Regulations enable the capturing of data on requisition activity by individual healthcare professionals in the community. Paramedics are currently permitted to possess and administer or supply specific controlled drugs under a Group Authority issued by the Home Office or under a Patient Group Direction set up under the 2001 Regulations. Some paramedics work within both the NHS and in a private capacity where they acquire the controlled drugs they are able to possess and supply or administer through community pharmacies. Paramedics are currently not required to present a compliant requisition in order to obtain these drugs, although this is encouraged as best practice. The change being implemented will put paramedics on a similar footing to other healthcare professionals, ensuring that their requisition activity can be monitored in line with the overarching aims of The Fourth Report of the Shipman Inquiry on requisitions.

7.11 Operating Department Practitioners (ODPs) also have authority under the 2001 Regulations to possess and supply controlled drugs when acting in that capacity in the hospital environment. However, ODPs do not currently have explicit authority under the regulations to requisition controlled drugs. The proposed amendments will bring ODPs in line with the other healthcare professionals currently listed under Regulation 14 of the 2001 Regulations, enabling ODPs to requisition the controlled drugs they need when acting in that capacity and within a hospital setting. This will enable the capturing and monitoring of individual requisition activity by ODPs within the hospital setting when required.

Senior Registered Nurses in charge of prison healthcare centres and Midwife Ward Managers – authorities to possess and supply in ward and health centre settings

7.12 The instrument inserts a new definition of a prison in Regulation 2 to include Her Majesty's prisons, young offenders' institutions and remand centres.

7.13 Prisons are generally covered by Crown immunity and until now have not been mentioned in the 2001 Regulations. However, in recent years healthcare in prisons is being provided through purely public services, the private sector or a combination of both. As a result, although the 2001 Regulations apply to this sector, prisons are not specifically mentioned in the 2001 Regulations. Amendments granting authorities to specific professionals within the prison sector (paragraphs 7.14 to 7.17) form part of the review exercise. This instrument also exempts prisons from the requisition requirements under the 2001 Regulations (see paragraphs 7.20 to 7.22 below). It is therefore necessary to include a definition of a prison in the 2001 Regulations to provide clarity on the institutions covered by the term 'prison' and the provisions that apply to professionals within the sector.

7.14 Most prisons do not have an on-site pharmacy or a pharmacist on the premises for a significant amount of time. Where there is an on-site pharmacy the pharmacist, having the legal authority to obtain and possess controlled drugs, takes responsibility for controlled drugs management in the pharmacy and for the management around the prison. Where there

is no on-site pharmacy, a doctor will be the person legally responsible for signing requisitions etc. Medical services are usually provided with one or more doctors providing sessions in the prison. As a result, there is usually a lack of a dedicated person who can take personal responsibility for controlled drugs in an effective manner. This makes governance arrangements in prisons without a pharmacy less than ideal.

7.15 The head of healthcare in a prison is usually a senior registered nurse. Where the head of healthcare is not a registered healthcare professional, they will not be able to assume any responsibility for the management of controlled drugs. This instrument extends the authorities to possess and supply controlled drugs to senior registered nurses in charge of prison health departments with no on-site pharmacy, in order to provide better governance for the management of controlled drugs in this sector. This extension does not negate the need for private companies operating in this sector to obtain a licence to possess and supply controlled drugs. Private healthcare providers in the prison sector will still require a Home Office licence for the possession and supply of controlled drugs to their employees.

7.16 Regulations 8(2)(e) and 9(3)(c) of the 2001 Regulations currently provide authority to senior registered nurses in charge of a ward, when acting in that capacity, to supply or offer to supply controlled drugs to patients in the case of a drug supplied to them by a person responsible for dispensing and supply of medicines in a hospital. Under regulation 10, senior registered nurses in charge of wards have authority to possess the relevant controlled drugs.

7.17 Some maternity wards are managed by registered midwives who do not hold registration as nurses as they may have undertaken direct entry training as midwives and have not trained as nurses or have terminated their nursing registration as a result of becoming midwives. This means that under current provisions, the authority for these registered healthcare professionals to possess and supply or offer to supply controlled drugs in the maternity ward setting is absent. The authorities being granted will correct the current anomaly and ensure registered midwife ward managers have the same authority and responsibility in relation to controlled drugs supplied to them for patients in a maternity ward as applies to senior registered nurses in charge of a ward.

Inclusion of Royal College of Veterinary Surgeon number on Schedule 2 and 3 Prescriptions

7.18 One of the key recommendations of The Shipman Inquiry was for private prescriptions for Schedule 2 and 3 controlled drugs in the community to include the prescriber's identification number issued by the then Primary Care Trust. This recommendation was implemented for human healthcare by Regulation 15(1)(ab) of the 2001 Regulations which came into force on 1 January 2007. Veterinary prescriptions are private prescriptions. However, under previous provisions veterinary practitioners were not required to include a unique identification code when prescribing Schedule 2 and 3 controlled drugs to enable activity in this sector to be monitored if required.

7.19 This instrument requires veterinary prescriptions for all Schedule 2 and 3 controlled drugs to include the unique Royal College of Veterinary Surgeons registration number. This change brings the veterinary sector in line with the human healthcare sector, improving the ability to collate data on individual prescribing activity for the veterinary sector for monitoring when required.

Hospices and Prisons – exemption from Regulation 14 requisition requirement

7.20 Designated bodies, such as hospices and prisons are currently required under the 2001 Regulations to present a Regulation 14 compliant requisition when ordering controlled drugs. Most hospices and prisons have contracts to receive their controlled drug supplies from a community pharmacy or from hospital pharmacies and have historically used duplicate books for their requisitions of controlled drugs. The requirement to present a requisition is not only a cumbersome process for these settings, but also is potentially less robust than the previous audited systems, as forms replace the duplicate books previously used by one with loose sheets of paper. The use of stock controlled drugs is a routine part of the service of designated bodies and so the number of these forms that needs to be managed is seen as an added risk factor.

7.21 Current methods of data capturing using these forms makes it difficult for any individual practitioner requisition data, within these environments, to be analysed as a result of the significant volume of hospice and prison controlled drug activity. The high volume of controlled drug activity therefore masks the true nature of requisition activity of individual practitioners in a given area.

7.22 The changes being implemented will ensure that requisition data provided to the NHS Business Services Agency and the subsequent analysis are more robust and reflect the original policy intent of capturing requisition activity by individual practitioners. In the absence of the requirement to present requisitions when obtaining controlled drugs, monitoring of requisition activity within these sectors will fall to Accountable Officers through their oversight of controlled drugs and therefore requisition activity, and the use of Standard Operating Procedures to deal with issues such as retention of duplicate copies, following implementation of these proposals. As part of their registration requirements, Accountable Officers also have a duty to retain records of requisition activity within their areas for longer periods than currently required under the 2001 Regulations. This will ensure an effective auditing and monitoring regime exists for these sectors when this exemption comes into force.

Introduction of mandatory requisition forms for Schedule 2 and 3 drugs

7.23 This instrument makes it mandatory to use a specific form for the requisitioning of all Schedule 2 and 3 controlled drugs in line with the Shipman recommendation to ensure that the purchase of all stocks of Schedule 2 and 3 controlled drugs by healthcare professionals within the community is capable of being monitored.

7.24 The Shipman Inquiry recommended in its Fourth Report that the purchase of all stocks of controlled drugs should follow a procedure that is capable of being monitored. The recommendation further highlighted the need for a standardised requisition form, similar to the one used for prescriptions, when individual healthcare professionals requisition controlled drugs, and for the form to be sent to the NHS Business Agency so that purchases of controlled drugs by individual healthcare professionals can be monitored.

7.25 The then Government agreed to the recommendation in its response to the Fourth Report, subject to further work on feasibility and cost. In 2006 the DH issued a recommended standard form with guidance to be used when healthcare professionals requisition controlled drugs. This requisition form is compliant with the data requirements under the 2001 Regulations. In its 2009 Annual report, the Care Quality Commission (CQC) recommended that DH should revisit the requisition regulations and guidance to ensure that they capture and

identify the purchase of controlled drugs by all individual doctors and healthcare professionals in line with the original policy intent. Data from the NHS Prescription Pricing Department indicate that about half of all requisition forms received in England are not on the DH recommended form.

Physiotherapists and Chiropodists – independent prescribing authorities

7.26 Physiotherapists and chiropodists are currently able to prescribe controlled drugs as supplementary prescribers (supervised by a medical prescriber such as a doctor), and can also supply medicines under exemptions in medicines legislation. The existing supply and administration mechanisms and supplementary prescribing are unable to realise their full potential to deliver safe, effective and timely care to patients in all modern healthcare contexts and settings due to the inherent limitations of each of the available mechanisms.

7.27 This instrument provides for limited independent prescribing authorities to physiotherapists and chiropodists under these changes to improve safety and health outcomes for patients through improved access to medicines and more timely treatment. Physiotherapists are being given authority to prescribe temazepam (oral), lorazepam (oral), diazepam (oral), dihydrocodeine (oral), morphine (oral and injectable), fentanyl (transdermal) and oxycodone (oral). Chiropodists are authorised to prescribe temazepam (oral), lorazepam (oral), diazepam (oral), and dihydrocodeine (oral). Both professions are authorised to administer the specific drugs they are authorised to prescribe, but are not authorised to possess, stock or supply these drugs.

Emergency supply of medicines containing phenobarbital or phenobarbital sodium

7.28 The 2001 Regulations do not contain provisions enabling the emergency supply of Schedules 2 and 3 controlled drugs, although the Human Medicines 2012 (HMR 2012) enable the supply of medicines containing phenobarbital or phenobarbital sodium, in the absence of a prescription, for the emergency treatment of epilepsy. This free standing provision in the HMR 2012 is considered to be at odds with the spirit of the 2001 regulations as it relates to the supply of the more potent Schedules 2 and 3 drugs.

7.29 The instrument therefore amends the 2001 Regulations to complement the HMR 2012 provisions and regularise the emergency supply of medicines containing phenobarbital or phenobarbital sodium for the emergency treatment of epilepsy in accordance with Regulations 224 and 225 of the HMR 2012.

Rescheduling of ketamine and Patient Group Directions

7.30 Following a review commissioned by the Home Secretary the ACMD reviewed its previous advice on ketamine and recommended that it should be reclassified to Class B and rescheduled to Schedule 2, subject to a public consultation to assess the impact on health and veterinary professionals. The advice to reclassify was accepted and ketamine was reclassified to Class B on 10 June 2014. The recommendation to reschedule was accepted in principle and a twelve week public consultation to assess impact was undertaken by the Home Office. The majority of respondents supported the ACMD's recommendation. The general view was that the veterinary sector already treats ketamine as a Schedule 2 drug in accordance with guidance issued by the Veterinary Medicines Directorate. In addition most hospitals also treat ketamine as a Schedule 2 drug.

7.31 In light of the ACMD's recommendation and the outcome of the public consultation, this instrument moves ketamine from Schedule 4 to the 2001 Regulations to Schedule 2, but with consequential changes to regulation 8 of the 2001 Regulations to ensure it continues to remain available for use under Patient Group Directions (PGDs) for the immediate treatment of sick and injured persons.

Introduction of electronic prescribing of Schedules 2 and 3 controlled drugs

7.32 Following the introduction of electronic prescribing of Schedule 4 and 5 drugs under the NHS Electronic Prescribing Service (EPS) for England, the DH put forward proposals to expand the use of EPS to drugs in Schedules 2 and 3. In 2014, following approval by health Ministers, these proposals were put forward for public consultation and the result shared with the ACMD for their consideration and advice. The ACMD subsequently recommended that EPS should be extended to Schedule 2 and 3 drugs as the system has been proven not to increase the risk of diversion or misuse and extending EPS to Schedule 2 and 3 drugs will enhance the audit trail for these drugs.

7.33 In recommending the extension of EPS to include Schedule 2 and 3 drugs, the ACMD considered that electronic prescribing should take place under the established NHS EPS structure with its incorporated layers of security, including the use of an Advanced Electronic Signature. The electronic prescribing of Schedule 2 and 3 drugs is also to be extended to private prescriptions, but only when private prescribing takes place under the NHS EPS in England. The provisions also apply to Wales and Scotland who do not currently have a system similar to that used in England but may consider implementing a similar system in the future. The EPS provisions are enabling and not mandatory. EPS will run alongside paper prescribing to provide flexibility and ensure prescribers are able to prescribe in settings where access to an electronic system is limited, such as in the community.

7.34 As lead department for controlled drug legislation, the Home Office is implementing changes to the legislation to enable the electronic prescribing of Schedule 2 and 3 drugs. The DH as lead department for this policy will progress the necessary structural changes required to implement this policy.

Removal of temazepam prescribing exemptions

7.35 The instrument amends the 2001 Regulations to remove the current exemptions applicable to prescriptions for temazepam with the effect that all the requirements applicable to Schedule 3 drugs, when prescribed, now also apply to temazepam. With the extension of EPS to Schedule 2 and 4 drugs (paragraphs 7.32 to 7.34 above) any impact from the removal of this exemption is further minimised.

7.36 Temazepam is an intermediate-acting psychoactive drug of the benzodiazepine class. Like many other drugs in the benzodiazepine family, it is also widely misused. In 1996 temazepam was rescheduled from Schedule 4 to Schedule 3 to the 2001 Regulations. At the time temazepam was rescheduled, the requirements applicable to prescriptions for Schedule 3 drugs under Regulation 15 had to be hand written. In order to limit the impact on prescribers from rescheduling, all prescriptions for temazepam were exempted from these requirements. However, private prescriptions for temazepam are still required to be written on a prescription form issued by the relevant NHS England's local lead Controlled Drugs Accountable Officer, Scottish Health Board lead Controlled Drugs Accountable Officer or Local Health Boards in Wales for the purposes of private prescribing, and submitted for auditing.

7.37 Subsequent changes in 2003 to the requirements under Regulation 15 mean that with the exception of a wet signature, all other information on a prescription for temazepam can now be computer generated. In light of the shift to computer generated prescriptions and the low number of prescriptions issued for temazepam annually, the Home Office explored, through a public consultation, whether the exemption applicable to temazepam prescription is still relevant. Respondents to the consultation shared the Home Office view that the current exemptions are no longer warranted. The ACMD subsequently recommended that the existing exemptions should be removed to bring temazepam in line with all other Schedule 3 drugs to ensure consistency.

- Consolidation

7.38 The Government intends to consolidate the 2001 Regulations at the earliest suitable opportunity. 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 2011 on proposals to consolidate and review specific provisions under the 2001 Regulations. The vast majority of respondents gave approval for the changes being implemented. The Home Office also consulted the public on the rescheduling of ketamine and the removal of temazepam prescribing exemptions. The vast majority of respondents supported both proposals. The DH also consulted on proposals to introduce limited prescribing authorities for Chiropodists and Physiotherapists and the introduction of electronic prescribing of Schedule 2 and 3 drugs. Both proposals were fully supported by the vast majority of respondents. The ACMD has been consulted on these changes as required by the 1971 Act. The Home Office has also consulted the DH and the Medicines and Healthcare products Regulatory Agency who support the changes being implemented. The summary of consultation responses for the above changes will be published alongside the statutory instrument at www.gov.uk.

9. Guidance

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

10. Impact

10.1 Regulatory Impact Assessments of the legislative changes are attached to this memorandum.

10.2 Overall the impact of the proposed changes is assessed as beneficial both to healthcare professionals and patients. The proposals provide enabling authorities to healthcare professionals enabling more flexibility in healthcare settings with the effect that patients are able to access treatment in a more timely and efficient manner under a framework that prevents the diversion and misuse of drugs considered to be dangerous when misused.

11. Regulating small business

11.1 This legislation applies to small business. However, only negligible impact on small business is identified from the Impact Assessments.

12. Monitoring & review

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

13. Contact

13.1 Des Niimoi at the Home Office, tel: 020 7035 3533 or e-mail: Desmond.Niimoi@homeoffice.gsi.gov.uk, can answer any queries regarding the instrument.