Background for the safer management of controlled drugs

The Shipman Inquiry was set up on 31 January 2001 and was chaired by Lady Justice Janet Smith DBE as an independent public inquiry into the issues arising from the case of Harold Shipman. The Inquiry's Fourth Report was published on 14 July 2004 and made a number of recommendations to strengthen the prescribing of controlled drugs and for monitoring their movement from prescriber to dispenser to patient. In December 2004 the Government's response, Safer Management of Controlled Drugs was published. The response accepted that the current systems can be strengthened provided that this doesn't hinder the use of controlled drugs to meet patients' needs.

New arrangements for private prescriptions came into effect from 1 April 2006 and were given statutory backing through amendments to the Misuse of Drugs Regulations, which were made on 12 June 2006 and came into force on 7 July 2006. The Medicines (Sale & Supply) (Miscellaneous Provisions) Amendment Regulations 2007 have also been amended to remove the requirement for dispensing contractors to retain dispensed private controlled drug prescriptions for two years.

Therefore from 1 September 2007, dispensing contractors should submit original private controlled drug prescriptions for Schedule 2 or 3 CDs to the NHS Business Services Authority (NHSBSA) using their private controlled drug account.

Changes to the Misuse of Drugs Regulations effective from 14 November 2005

The principal changes allowed:

- all details on prescriptions for controlled drugs except the signature to be computer generated
- computerisation of controlled drugs registers for drugs listed in Schedules 1 and 2.

Changes to the Misuse of Drugs Regulations effective from 7 November 2006

- Introduction of special forms (FP10PCD) for any private prescription of Schedule 2 and 3 controlled drugs dispensed by community pharmacists. Records of these

prescriptions will be held on a central database so that they can be monitored by local PCTs (now the responsibility of NHS England).
- Modified arrangements for the dispensing of NHS prescriptions for Schedule 2 and 3 controlled drugs, including a new requirement for patients or other people collecting medicines on their behalf to sign for them.
- Validity of any prescription for Schedule 2, 3 and 4 controlled drugs to be restricted to 28 days.
- Introduction of requirement that all healthcare providers holding stocks of controlled drugs should have and comply with the terms of an agreed Standard Operating Procedure (SOP).
- Strong recommendation that the maximum quantity is limited to 30 days for prescriptions of Schedule 2, 3 and 4 controlled drugs.
- Re-emphasis of professional guidance that doctors should prescribe controlled drugs for themselves or family members only in exceptional circumstances.

Changes to the Misuse of Drugs Regulations effective from 1 September 2007

- The requirement for dispensing contractors to retain dispensed private controlled drug prescriptions for Schedule 2 and 3 controlled drugs for two years rescinded allowing dispensing contractors to submit the original prescription to NHS Prescription Services.
- Accountable officers responsible for the monitoring and management of controlled drugs to have the authority to appoint authorised witnesses to observe the destruction of controlled drugs.
- Operating Department Practitioners to possess and supply any controlled drug in a hospital ward, theatre or any other department for the purposes of administration to a patient.

Changes to the Misuse of Drugs Regulations effective from January/February 2008

- The reclassification of midazolam from a Schedule 4 controlled drug to a Schedule 3 controlled drug. However, midazolam is exempt from the Schedule 3 safe custody requirements.
- New regulations covering requisitions used for the supply of Schedule 2 and 3 controlled drugs. Suppliers of controlled drugs (excluding wholesalers and hospitals) are required to provide information about the supply of controlled drugs in the absence of a prescription to NHS Prescription Services.
- Changes to the requirements covering the format of Controlled Drug Registers (CDRs). From February 2008 the regulations covering the format of CDRs were replaced with more flexible arrangements, but still require certain fields of information

to be recorded including the identity of a person collecting a Schedule 2 controlled drug.

Changes to the Misuse of Drugs Regulations effective from June 2014

- Tramadol added to Schedule 3. However, tramadol is exempt from the Schedule 3 safe custody requirements.
- Lisdexamfetamine added to Schedule 2; zopiclone and zaleplon added to Schedule 4.

Changes to the Misuse of Drugs Regulations effective from 01 June 2015

The Misuse of Drugs Regulations should be referred to for full details of all changes, but the principal changes are summarised below:

- The removal of the exemptions for temazepam, therefore any prescriptions for temazepam must now fully comply with the usual writing requirements for other Schedule 3 drugs.
- Limited prescribing of certain controlled drugs allowed for registered independent physiotherapists and independent podiatrist prescribers.
- The use of a standardised form for the requisition of Schedule 2 and 3 controlled drugs in the community was made mandatory.
- The emergency supply of phenobarbital was made permissible in the absence of a compliant prescription.
- Changes made to midwife supply orders to make them patient specific.
- Changes made to move ketamine from part 1 of Schedule 4 to Schedule 2, also exemptions provided for continued use by specified healthcare professionals under Patient Group Directions.

Changes to the Misuse of Drugs Regulations effective from July 2015

- The introduction of electronic prescribing of Schedule 2 and 3 controlled drugs. This instrument introduces the electronic prescribing of of Schedule 2 and 3 controlled drugs under the National Health Service Electronic Prescribing Service (EPS) structure with its incorporated layers of security, including the use of an Advancerd Electronic Signature. The authority granted applies to England, Wales and Scotland and restricts the electronic prescribing of these drugs to EPS only. Private prescribing of Schedule 2 and 3 drugs are also enabled under these provisions, but are also restricted to when such prescribing takes place under EPS. The provisions introducing electronic prescribing of Schedule 2 and 3 drugs are enabling and not mandatory. Prescribing of these drugs under 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.

The DH as lead department for this policy will progress the necessary structural changes required to implement this policy, including in respect of private prescribing of these dugs under EPS in England.