Midwives and Medicines
Second Edition
Foreword

This second edition of *Midwives and Medicines* brings the reader up to date with recent changes to the legislation pertinent to midwives exemptions and non-medical prescribing. This update is in parallel to the work on a national formulary of medicines for midwives which is being developed at Healthcare Improvement Scotland.

It details current medicines legislation relevant to midwives and the implications for practice and puts into context the use of Patient Group Directions, Patient Specific Directions, Midwives Exemptions and Midwives Supply Orders. The history of nurse/midwife prescribing, its chronology of legislation and its relevance and impact on midwifery practice is also outlined.

This report authored by Mary Vance (RM, BSc (Hons) Midwifery, PGCert T.L.T. MPhil Med Law) a LSA Midwifery Officer with expert knowledge in this field, seeks to inform, raise awareness and clarify understanding on the legislative opportunities and constraints pertinent across professional and service boundaries. It is therefore dedicated towards midwives, doctors, pharmacists, service managers, clinical educators, Accountable Officers and their teams and higher education colleagues.

We would also like to thank all the Supervisor of Midwives, pharmacists and Accountable Officers who have contributed to this report.

**Lucy Powls**  
Educational Projects Manager  
*(Midwifery & Reproductive Health)*  
NHS Education for Scotland

**Fiona Dagge-Bell**  
Clinical Development & Improvement Team Leader, Midwifery Advisor  
*(Women’s, Children’s & Specialist Services)*  
Healthcare Improvement Scotland
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Midwives at the point of registration may supply and/or administer, on their own initiative, any of the substances that are specified in medicines legislation under midwives exemptions, provided it is in the course of their professional midwifery practice. They may do so without the need for a prescription, a Patient-Specific Direction (PSD) from a medical practitioner or a Patient Group Direction (PGD) provided the requirements of any conditions attached to those exemptions are met. If a medicine is not included in the midwives exemptions then a prescription, a PSD or a PGD will be required.

Despite the legislation, there has been confusion around midwives rights and responsibilities in relation to the supply and administration of medicines both within the midwifery profession itself and within the multidisciplinary team. In particular, there is confusion around PGDs in relation to midwives exemptions provided within the Medicines Act 1968 and relevant statutory instruments.1 This confusion appears to be due to a lack of understanding of how exemption orders work in practice. Furthermore, it is apparent that there is a lack of understanding in respect of the difference between exemptions and prescribing and PGDs and prescribing.

The development of good governance, information, communication and education systems to provide midwives with the tools, knowledge and skills in this key area of clinical practice is integral to safety and public protection. The purpose of updating this paper is therefore to clarify current legislation and support midwives in their understanding of the legislative and governance framework of medicines. It seemed a good opportunity to refresh and update this document in parallel to the work on a national formulary of medicines for midwives which is being developed at Healthcare Improvement Scotland (formerly NHS Quality Improvement Scotland). The formulary will support midwives in exercising their role in the supply and administration of medicines to women. The web-based monographs in the formulary were developed by pharmacists overseen by a steering group and, together with other materials, will be accessible to all NHS boards.

However, it is out with the scope of this paper to provide guidance on safe systems for midwives to secure stock of the medicines that they can supply under exemptions and the subsequent safe systems required for the transport, storage, record of administration, integration of the information into patients records and disposal. It is the responsibility of the local health board to ensure safe systems are in place for these aspects.

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The two main Acts of Parliament, which control the administration and use of medicines, are the Medicines Act 1968 and the Misuse of Drugs Act 1971.

**The Medicines Act 1968**

The 1968 Act was introduced following the Thalidomide tragedy, which highlighted gaps in controls relating to the manufacture, marketing and supply of medicines. The 1968 Act requires the manufacture and wholesale of medicines to be in accordance with the appropriate market authorisation, unless specified exemption criteria are fulfilled. It also controls the retail sale, supply and administration of medicinal products. Medicinal products fall into one of three categories, general sale list, pharmacy medicines and prescription only medicines.

**General Sale List Medicines**

General sale list medicines (GSL) need neither a prescription nor the supervision of a pharmacist; they can be obtained from retail outlets. However all GSL medicines except those that have been designated as foods or cosmetics, must have market authorisation as products.

**Pharmacy Medicines**

A pharmacy medicine (P) means a medicinal product which is not a prescription only medicine and which is either (a) not a medicinal product on a GSL, or (b) a product referred to in Regulation 8 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980. Pharmacy medicines can only be sold from pharmacies, either by a pharmacist or by their staff under their supervision.

**Prescription Only Medicines**

Under section 58(2)(a) of the 1968 Act prescription only medicines (POMs) are those medicines which may only be sold or supplied in accordance with a prescription of an appropriate practitioner. (The main classes of POMs can be seen in appendix A). However the Prescription Only Medicines (Human Use Order) 1997, relaxes the requirements of section 58(2)(a) by providing that POMs may be sold or supplied in accordance with the written directions of a doctor or dentist notwithstanding that those directions do not amount to a prescription.

The only restriction on the administration of POMs relates to the administration of parenteral medicines which may only be

- self-administered
- administered by a doctor or subject to certain limitations, an independent nurse, midwife or allied health professional (NMAHP) prescriber or supplementary prescriber
- administered by a NMAHP acting in accordance with the patient-specific directions of a doctor or subject to certain limitations, an independent nurse/ midwife prescriber or supplementary prescriber
- administered by those listed in the legislation covering the use of PGDs in the NHS (see locally agreed and national documents).

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2The Medicines Act 1968
3see for instance S v Distillers Co (Biochemicals) Ltd [1970] 1 W.L.R. 114
4NOTE: a medicinal product made up in a pharmacy for sale from that pharmacy without a marketing authorisation is classified as a pharmacy medicine even though all its ingredients are in the Medicines (Pharmacy and General Sale - Exemption) Order 1980, SI 1980/1924
5The Medicines Act 1968
6The Prescription Only Medicines (Human Use) Order 1997 is a statutory instrument made under the Medicines Act 1968 which details the requirements and exemptions for the prescribing, supply and administration of prescription only medicines
The Misuse of Drugs Act 1971

The 1971 Act\(^7\) consolidated and simplified the legislation relating to dangerous or otherwise harmful drugs. It divides controlled drugs into Class A, B and C according to the perceived degree of harm. Class A drugs are those, which are considered the most harmful when misused e.g. morphine, diamorphine, heroin, cocaine, ecstasy and lysergic acid diethylamide (LSD). Class B drugs are considered less dangerous than Class A drugs but they can still be harmful; they include barbiturates, speed, cannabis, mephedrone and codeine. Class C drugs are considered less dangerous to the user than Class A and Class B drugs however they are still illegal; they include ketamine, gammahydroxybutrate (GHB), anabolic steroids and benzodiazepines.

Misuse of Drugs Regulations

The Misuse of Drugs Regulations 2001\(^8\) revokes and re-enacts, with amendments, the provisions of the Misuse of Drugs Regulations 1985\(^9\). They provide certain exemptions from the provisions of the Misuse of Drugs Act 1971 which, subject to these regulations, prohibit the production, importation, exportation, possession and supply of controlled drugs, which are specified in Schedule 2 to that Act.\(^{10}\)

Controlled drugs are divided into five schedules corresponding to their therapeutic usefulness and potential for misuse. The schedules also have the effect of specifying the controlled drugs to which certain provisions of the Regulations apply (appendices B - F). Nevertheless, as the majority of controlled drugs are also POMs, even if the prescribing or supply is not restricted by the Misuse of Drugs Legislation, the requirements of the 1968 Act\(^{11}\) still apply.

The persons who are specifically authorised to have controlled drugs in their possession are listed in the Misuse of Drugs Regulations 2001. Section 11 specifies the conditions under which midwives may possess and administer controlled drugs (appendix G). Midwives need to note that this means they cannot possess an opiate for a home birth without having obtained it via a Midwife’s Supply Order i.e. they cannot take an ampoule from a maternity unit drug cupboard for use at a home birth.

\(^7\)The Misuse of Drugs Act 1971  
\(^8\) The Misuse of Drugs Regulations 2001, SI 2001/ 3998 available online @ http://www.legislation.gov.uk/uksi/2001/3998 (accessed 06/02/2011)  
\(^9\) Misuse of Drugs Regulations 1985, SI 1985/2066  
\(^{10}\) Misuse of Drugs Act 1971 available online @ http://www.legislation.gov.uk/ukpga/1971/38 (accessed 06/02/2011)  
\(^{11}\) The Medicines Act 1968
Exemptions from the Controls on Sale, Supply and Administration of Medicines

There are certain exemptions from the restrictions that apply to general sales list medicines, pharmacy medicines and prescription-only medicines (the main classes of persons and the bodies exempted can be seen in appendix H). However, for the purposes of this paper the focus will be on exemption for midwives.

Exemption for Midwives


Exemptions are distinct from prescribing which requires the involvement of a pharmacist in the sale or supply of the medicine. Exemptions also differ from the arrangements for Patient Group Directions (PGDs) as the latter must comply with specific legal criteria, be signed by a doctor or dentist and a pharmacist and authorised by an appropriate body.

Exemption from Restrictions on Sale or Supply

Under the ‘sale or supply’ exemptions for midwives, a registered midwife, in the course of her professional practice, may supply but not offer for sale:

(a) all medicinal products on the general sales list and all pharmacy medicines\(^\text{13}\)

(b) POMs containing any of the substances (but no other prescription-only medicines) listed in schedule 5 Article 11(1)(a) part 1 - exemption from restrictions on sale or supply\(^\text{14}\) (appendix I).

For an example of how a midwife might utilise exemptions from restrictions on sale or supply see scenario 1.

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\(^{12}\) as amended by the Prescription only Medicines (Human Use) Amendment Order 2010


\(^{14}\) The Prescription Only Medicines (Human Use) Order 1997
Exemptions from Restriction on Administration

Registered midwives may also administer parenterally (not through oral route), in the course of their professional practice, POMs containing any of the substances listed in part III Article 11(2) - exemptions from restriction on administration (appendix I). However, it is important to note that midwives may not administer any other substance specified in column 1 of Schedule 1 of the Order15, even if the medicine contains a substance listed in part III Article 11(2). For examples of how a midwife might utilise exemptions from restriction on administration see scenarios 2 and 3.

Midwife’s Supply Order

As already explained a registered midwife may administer, on her own right so far as is necessary for the practice of her profession, POMs for parenteral administration containing any of the substances specified in column 1 of Schedule 1 of the Order16. However, the supply of controlled drugs17 may only be made to the midwife on the authority of a midwife’s supply order signed by the appropriate medical officer who is a doctor authorised in writing by the local supervising authority, or more commonly a supervisor of midwives. The order must specify the name and occupation of the midwife, the purpose for which the controlled drug is required and the total quantity to be obtained (appendix G). The pharmacist must retain the midwife’s supply order for two years.

A midwife is required to keep a record of supplies of diamorphine, morphine and pethidine received and administered in a book used solely for that purpose. She must not destroy surplus stock but should surrender it to the supplying pharmacy (appendix L). Please note this is not to be confused with discarding the quantity in ampoule not given. As diamorphine, morphine and pethidine are Schedule 2 Controlled Drugs, an appropriate entry is required in the CD register. Temazepam is a Schedule 3 Controlled Drug and therefore no entry is required in the CD register. A midwife’s records relating to administration of medicines should be regularly audited by her named supervisor of midwives and any concerns should be reported to the Accountable Officer for Controlled Drugs and the Local Supervisory Authority Midwifery Officer.

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15 The Prescription Only Medicines (Human Use) Order 1997
16 The Prescription Only Medicines (Human Use) Order 1997
17 specifically pethidine, morphine and diamorphine
Scenario 1: Midwives exemptions - the supply of medicines

Community midwife, Margaret Brown runs an antenatal clinic each Tuesday afternoon at the local health centre. This clinic is a midwife-only clinic and Margaret sees approx 10 – 15 women each session.

Although the women Margaret sees at the clinic are low risk, many of them present with a variety of pregnancy related conditions. On first reading, this may present as a problem for Margaret and the women under her care especially as there is no doctor present during the clinic. However, it is important to remember that under midwives exemptions, Margaret is able to supply treatments to women that fall into the categories of GSL and P medicines. For example, when women present with the following conditions Margaret can supply the substances suggested without the need for a prescription or a PGD.

<table>
<thead>
<tr>
<th>Condition</th>
<th>GSL/P</th>
</tr>
</thead>
<tbody>
<tr>
<td>iron deficiency anaemia</td>
<td>ferrous sulphate (P)</td>
</tr>
<tr>
<td>acid indigestion</td>
<td>ranitidine hydrochloride 75mg only (P)</td>
</tr>
<tr>
<td>constipation</td>
<td>lactulose (P)</td>
</tr>
<tr>
<td>haemorrhoids</td>
<td>Anusol Plus HC* ointment (GSL)</td>
</tr>
</tbody>
</table>
Scenario 2: Midwives exemptions – possession of controlled drugs

Jackie, a community midwife, is preparing for the home birth of Debra a 28-year-old gravida 2 + 0. Debra had a home birth with her last baby two years ago and required morphine for pain relief, she tells Jackie that she wants to manage without morphine this time round but would want it on hand just in case. Under midwives exemptions Jackie can possess and administer morphine to Debra without the need for a prescription (appendices A and I).

Jackie orders morphine for Debra’s birth via a ‘supply order’ (the supply order is held by the link/contact supervisor of midwives and signed by her supervisor of midwives), from her local hospital pharmacy (or designated community pharmacy / dispensing doctor in remote or rural areas). Jackie records the receipt of the morphine in her controlled drug register and drug record book, and stores it safely and securely until required (appendix K).

Having delivered Debra of a healthy baby boy, without the need for morphine, Jackie has two options

- Retain the morphine if there are further home births planned (agreement on this should be made locally with the supervisor of midwives). Jackie will remain responsible for its safe storage during this time.
- Return the morphine to the supplying pharmacy where it will be destroyed in the presence of an authorised medical officer. A record of the return is made against the relevant entry in her controlled drug register and drug record book (appendix K)
Scenario 3: midwives exemptions - the administration of medicines

Amanda, a 23-year-old primiparous woman is admitted to the labour ward at 41 weeks gestation. Amanda has been having contractions, four in 10 minutes for the last half hour and is requesting pain relief.

Sally, the midwife looking after Amanda, performs a vaginal examination (with consent) in order to make a judgement on appropriate pain relief to offer Amanda. Sally finds that Amanda’s cervix is 4cm dilated. Sally then discusses the pain relief options available to Amanda.

Under midwives exemptions, Sally can administer the following substances for pain relief (following local policy and procedures):
- Nitrous oxide and oxygen
- Diamorphine
- Morphine
- Pethidine hydrochloride

Sally then records the medicines given on the medicines kardex to ensure that others prescribing know what has been administered (appendix J). Sally should make it clear that she administered the medication under midwives exemptions rather than prescribing them. She should also record the medications in the partogram and where applicable, in a controlled drugs register.

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nitrous oxide and oxygen is covered by midwives exemptions from sales or supply as it is a pharmacy medicine (P)
Following the 1989 Crown Report\textsuperscript{19}, amendments were made to the Medicines Act 1968 in order to allow practitioners other than doctors, dentists and veterinary surgeons and practitioners to prescribe. These amendments, which were included in the Medicinal Products: Prescription by Nurses etc. Act 1992, were brought into force by the Medicinal Products: Prescription by Nurses etc. Act 1992 (Commencement No.2) Order 1996.\textsuperscript{20} (See Appendix M for full history of nurse/midwife prescribing).

Changes to regulations in Scotland in May 2006\textsuperscript{21} enabled nurses and midwives who train and qualify as ‘nurse independent prescribers’ to be able to prescribe any licensed medicine for any medical condition they are competent to treat, this includes a limited range of controlled drugs for specific medical conditions (appendix O).\textsuperscript{22}

### Aims of independent prescribing by nurses/midwives

Government policy extended prescribing responsibilities to non-medical professions to:

- Improve the quality of service to patients without compromising patient safety;
- Make it easier for patients to get the medicines they need;
- Increase patient choice in accessing medicines;
- Make better use of the skills of health professionals
- Contribute to the introduction of more flexible team working across the NHS.

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\textsuperscript{20}\textit{This Order brought into force on 1st July 1996 section 3 of the Medicinal Products: Prescription by Nurses etc. Act 1992 (extension of pharmaceutical services in Scotland). Section 3 is the last provision from that Act to be brought into force, sections 4 to 6 having come into force on Royal Assent and sections 1 and 2 having been commenced on 3rd October 1994 by SI 1994/2408}

\textsuperscript{21}\textit{The National Health Service (Pharmaceutical Services) (Scotland) Amendment (No. 2) Regulations 2006. SSI No. 245 : The National Health Service (Charges for Drugs and Appliances) (Scotland) Amendment (No. 2) Regulations 2006. SSI No. 246 : The National Health Service (General Medical Services) (Scotland) Amendment Regulations 2006. SSI No. 337}

\textsuperscript{22}\textit{Unlicensed medicines - changes to the indicative content of the independent and supplementary nurse prescribing programme - V300. NMC circular 03/2010 available online @ http://www.nmc-uk.org/Documents/Circulars/2010circulars/NMCircular03_2010.pdf}
Standards of proficiency for nurse and midwife prescribers

Under the legislation, prescribers must have sufficient knowledge and competence to:

- Assess a patient/client’s clinical condition
- Undertake a thorough history, including medical history and medication history, and diagnose where necessary, including over-the-counter medicines and complementary therapies
- Decide on management of presenting condition and whether or not to prescribe
- Identify appropriate products if medication is required
- Advise the patient/client on effects and risks
- Prescribe if the patient/client agrees
- Monitor response to medication and lifestyle advice.

The NMC has set out standards\(^{23}\) for the educational preparation for nurse/ midwife independent prescribing. The standards apply to both community practitioner nurse prescribers, nurse independent prescribers and supplementary and independent prescribers and underpin the principles of prescribing practice within the context of the scope of nursing and midwifery practice. The standards are grouped into the following domains:

- Clinical pharmacology, including the effects of co-morbidity
- Consultation, history-taking, diagnosis, decision-making and therapy, including referral
- Influences on, and psychology of, prescribing
- Prescribing in a team context and sharing information
- Evidence-based practice and clinical governance in relation to nurse/midwife prescribing
- Legal, policy and ethical aspects of prescribing
- Professional accountability and responsibility
- Prescribing in the public health context.

The NMC will only approve programmes in Approved Education Institutions that meet these standards.

The Controlled Drugs (Supervision of Management and Use) Regulations 2006 (Appendix N) contain measures relating to arrangements underpinning the safe management and use of controlled drugs in England and Scotland and the Scottish Government issued specific guidance on the management of Controlled Drugs (CD) in secondary care in February 2008 (CEL 7 (2008)).

All Health Boards, Hospices and Independent Hospitals (general and psychiatric) registered under the Regulation of Care (Scotland) Act now have a responsibility to assure that the quality of their CD management is an integral part of their clinical governance processes. New requirements for collaboration and information sharing between all health and social care providers, and relevant regulators and agencies have also been introduced.

Appointment of an Accountable Officer (AO)
The Regulations specify who may be appointed as an Accountable Officer (AO). The AO must be a “fit, proper and suitably experienced person” who does not routinely supply, administer or dispose of CDs as part of their duties. A designated body can nominate or appoint an AO who has an occasional, exceptional role in the use of CDs (for example, in emergencies). However, their use of CDs should be open to the scrutiny of another person to whom they are answerable. They should have credibility with all healthcare and social care professionals and sufficient seniority to be able to take action regardless of how a concern is raised.

Designated bodies must inform the Scottish Government Health Directorate (SGHD) in writing of their nomination or appointment as AO and of any subsequent changes. Arrangements have been made for hospices and independent hospitals to inform the Care Commission on an annual basis of the person they have appointed as the Accountable Officer.

Overview of responsibilities of Accountable Officers (AO)
Ensure the safe and effective use and management of CDs within their own organisation and by any body or person providing services to their organisation.

Establish and ensure appropriate arrangements to comply with Misuse of Drugs legislation.

Ensure adequate and up-to-date SOPs are in place in relation to the management and use of CDs.

AOs must have regard to best practice in relation to the management of CD and must:
- Ensure adequate destruction and disposal arrangements for CDs
- Ensure monitoring and auditing of the management and use of CDs
- Ensure relevant individuals receive appropriate training
- Assess and investigate concerns
- Maintain a record of concerns regarding relevant individuals
- Take appropriate action if there are well founded concerns;
- Establish arrangements for sharing information
The Regulations state that SOPs must cover the following:

- Who has access to CDs
- Where the CDs are stored
- Security in relation to storage and transportation of CDs as required by Misuse
- Disposal and destruction of CDs
- Who is to be alerted if complications arise
- Record keeping including
  - Maintaining relevant CD registers (CDR) under Misuse of Drugs
  - Maintaining a record of Schedule 2 CDs that have been returned by patients

The legislation also contains arrangements in relation to periodic inspections of premises used for the management and use of controlled drugs, where these issues would not be dealt with as part of other health and social care inspections, and other measures in relation to powers of entry.

AOs in special health boards must produce quarterly reports of their CD occurrences and provide them to the AO leading the Local Intelligence Network (LIN) of which their organisation is a member. The occurrence report must describe details of concerns the organisation has regarding the management of CDs or confirmation that there have not been any concerns.

**Standard operating procedures (SOPs)**

Regulations made under the Health Act 2006 require each healthcare organisation holding stocks of CDs to have SOPs for the use and management of CDs. The Regulations require AOs to ensure that their organisation, and those organisations providing services to the organisation, have adequate and up-to-date SOPs in relation to the use of CDs.

The Regulations state that SOPs must cover the following:

- Who has access to CDs
- Where the CDs are stored
- Security in relation to storage and transportation of CDs as required by Misuse
- Disposal and destruction of CDs
- Who is to be alerted if complications arise
- Record keeping including
  - Maintaining relevant CD registers (CDR) under Misuse of Drugs
  - Maintaining a record of Schedule 2 CDs that have been returned by patients

The legislation also contains arrangements in relation to periodic inspections of premises used for the management and use of controlled drugs, where these issues would not be dealt with as part of other health and social care inspections, and other measures in relation to powers of entry.
Scenario 4 – an example of when a prescription is required

As explained in scenario 1 Margaret (a community midwife) is able to supply medicines for the treatment of conditions such as constipation and iron deficiency anaemia because a registered midwife, in the course of her professional practice, may supply but not offer for sale all medicinal products on the general sales list and all pharmacy medicines\(^\text{24}\) and the medicines Margaret is supplying/administering fall under the category of GSL or P medicines and midwives.

However, if a woman presented at the antenatal clinic with a urinary tract infection Margaret would not be able to supply or administer antibiotics because as prescription-only medicines (POMs) they do not fall into the category of POMs that midwives are allowed to administer (appendices D and E). In this instance, Margaret would have to refer the woman to her GP for treatment.

Alternatively, if Margaret had undergone training as a NMAHP prescriber she would be able to prescribe a course of amoxicillin trihydrate.

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\(^{24}\) see the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 SI No 1923 and the Medicines (Pharmacy and General Sale - Exemption) Order 1980 SI No 1924
On the 4th May 2001, Lord Hunt announced that the Government intended to take steps to allow supplementary prescribing by nurses. Supplementary prescribing is a voluntary partnership between an independent prescriber and a supplementary prescriber, to implement an agreed patient-specific clinical management plan, with the patient’s agreement. Unlike independent nurse prescribing, there is no specific formulary or list of medicines for supplementary prescribing.

A supplementary prescriber is able to prescribe:
- all GSL medicines, P medicines, appliances and devices, foods and other borderline substances approved by the Advisory Committee on Borderline Substances.
- all POMs
- medicines for use outside of their licensed indications (i.e. 'off label' prescribing), 'black triangle' drugs, and drugs marked ‘less suitable for prescribing’ in the BNF
- unlicensed medicines (with effect from 7 April 2005)

as part of the agreed clinical management.

However, it is important to note that supplementary prescribing is not suited to emergency, urgent or acute prescribing situations because an agreed clinical management plan is required before prescribing can begin.

A change to legislation now allows Allied Health Professionals (AHPs) (physiotherapists, radiographers, and podiatrists) to become supplementary prescribers. The preparation for prescribing roles is regulated, approved and monitored by the professional body for each profession.

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25 a doctor or dentist
26 currently nurses, pharmacists, podiatrists, physiotherapists, diagnostic and therapeutic radiographers and optometrists
27 Supplementary prescribers are required to successfully complete a period of training and to have their name annotated to that effect on their professional register before they are eligible to practise as supplementary prescribers.
28 see http://www.nice.org.uk/page.aspx?o=114280&mode=normal
29 see guidance from Medicines and Healthcare products Regulatory Agency online at http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=154 (accessed 19/11/05)
A Patient Specific Direction (PSD) is the traditional written instruction, from a doctor, dentist, nurse, midwife or pharmacist independent prescriber, for medicines to be supplied or administered to a named patient. The majority of medicines are still supplied or administered using patient specific prescriptions or directions.

In primary care, this might be a simple instruction in the patient’s notes. Examples in secondary care include the directions for administration written in the Patient Medicines Administration Chart, sometimes called the Medicine Kardex. As a PSD is individually tailored to the needs of a single patient, it should be used in preference to a Patient Group Direction (PGD) wherever appropriate.

The PSD must identify the individual patient, whether on a clinic list such as a vaccine clinic or an eye clinic. In some settings PSDs have been developed for groups of patients and then individualised and signed by the prescriber when the patient is assessed.

Where a PSD template has been developed for local use, it is advisable to have this approved by the organisation to ensure accountability and communications issues are addressed. The template also needs to fit within the local clinical governance framework.

The healthcare professional administering the medication is accountable for their actions and should be aware of the professional standards for administration of medicines. Medication administration can be delegated under a PSD, provided the professional delegating is satisfied the person is competent to carry out the task. The delegating professional is responsible for all aspects of the administration.
In 1997 Dr Crown was appointed to review the prescribing supply and administration of medicines. The report, which was published in 1998, focussed the attention of doctors, nurses and pharmacists on the issues around the supply, prescribing and administration of medicines in general.

Recommendations were made that tighter regulations should apply to the use of group protocols. As a consequence, new regulations came into force in August 2000, which provide for Patient Group Directions (PGDs) to be drawn up to make provision for the sale or supply of a prescription-only medicine in hospitals and those services funded by the NHS but were provided by the private, voluntary or charitable sector, in accordance with the written direction of a doctor or dentist.

PGDs are intended to permit the supply and/or administration of POMs by authorised health professionals in circumstances that would otherwise require a prescription, or patient-specific written direction from an appropriate practitioner. They are useful for clearly defined conditions where there is a proven advantage for care, without compromising safety. However, a limitation of PGDs is that they may only be used for patients who are not individually identified before presentation for treatment.

To be lawful the PGD must cover the particulars set out in part 1 of schedule 7 of the Prescription Only Medicines (Human Use) Amendment Order 2000 (appendix P).

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31 A group protocol is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by doctors, pharmacists and other appropriate professionals, and approved by the employer, advised by the relevant professional advisory committees. It applies to groups of patients or other service users who may not be individually identified before presentation for treatment
32 Prescription Only Medicines (Human Use) Amendment Order Statutory Instrument 2000 No 1917
To assist in the development of PGDs NHS Education for Scotland has set up a web site. This website facilitates the development, implementation and audit of PGDs by healthcare professionals by providing information on the following:

- the use of PGDs
- the Legal framework for PGDs
- Patient Specific Directions (PSD)
- Where PGDs are not required
- To PGD or Not to PGD (Scottish version)
- PGD development
- Guidance on the development and review of PGDs
- PGD examples
- Implementation and audit of PGDs
- Links to Guidance and information on PGDs

It is important to note however that none of the midwives exemptions, contained in the medicines legislation, have been replaced by the legislation concerning PGDs and there is therefore no legal requirement to move existing locally agreed policies into PGDs. However, if there was a specific group of women requiring a POM on a regular basis and the POM is not on the midwives exemption list, a PGD may be the appropriate option (appendix Q and scenario 5).

33 http://www.nes.scot.nhs.uk/pgds
Scenario 5 – an example of where a PGD would be appropriate in midwifery practice

Hailey, community midwife working in a remote area, is reviewing Bethany who is 36 weeks pregnant and is feeling generally unwell. She is complaining of severe headaches, visual disturbances, nausea and vomiting and has epigastric pain. On examination, Hailey notes that Bethany is markedly oedematous and her blood pressure is 200/160mmHg. She establishes that Bethany is suffering from severe pre eclampsia and requires immediate treatment.

Under the Midwives rules and standards (NMC 2004), Hailey is required to execute emergency measures in the absence of a doctor however; Labetalol medications (POMs) are not covered under midwives exemptions.

The treatment would preferably be Labetalol 50mg IV over five minutes or if Hailey was unable to give IV drugs, Labetalol 200mg could be given orally. The midwife would normally need to call for the attendance of a GP to give Labetalol a delay that could cost the woman her life. On the other hand, the situation could be dealt with effectively by Hailey if a PGD had been set up to give Labetalol when dealing with severe pre eclampsia.

Student Midwives and the Administration of Medicines

For many years, it has been the custom and practice for student midwives to administer medicines on the midwives’ exemption list, including those for parental use, under the supervision of a registered midwife.

However, medicines legislation is clear that the exemptions relate only to registered midwives and that a registered midwife cannot delegate any aspect of those exemptions to a student. Nor can a registered midwife delegate such responsibilities under a PGD. A student could administer parenteral medicines under the directions of a prescriber; however, as there are currently few midwife prescribers and the majority of midwifery care is provided by midwives without referral to or attendance by a doctor or other prescriber, this causes an issue with student midwives gaining experience in the administration of parenteral medicines. While students can simulate parenteral administration, this is not wholly satisfactory. Therefore, the ability of midwifery students to gain the necessary skills for them to work unrestricted at the point of registration, is being hampered. This in turn impacts on the provision of safe and effective care of women and their families by newly qualified midwives.

On the 24 August 2010, the MHRA launched a consultation which proposed an amendment to medicines legislation to allow student midwives to administer those parenteral medicines on the midwives’ exemption list, subject to the requirement that the administration only takes place under the direct, personal supervision of a registered midwife. However, it is important to note that, the proposed amendment does not extend to the CDs on the exemption list, as the inclusion of controlled drugs would require consultation on additional amendments to the Misuse of Drugs Regulations 2001 and mirror amendments to the Northern Ireland’s Regulations. Nevertheless, the NMC take the view that student midwives can gain the necessary expertise by having access to the “non-controlled” parenteral medicines on the exemptions list.

On the 13th January 2011, at a meeting of the Commission on Human Medicines, the proposed amendments were discussed. Although it was acknowledged that a whole scale review of the Act is planned and that this issue would be part of that review; in the meantime, through the proposed amendments, student midwives could participate in the procedures relating to CDs and gain experience of administration by having access to the other parenteral medicines on the Midwives’ Exemption list. In this context, the Chairman thought it would be helpful if the NMC defined the term “parenteral” in guidance. Furthermore, it was recommended that the NMC should produce a formal statement clearly setting out the steps, timing and context of training both for students and mentors. At the time of writing this is still awaited.
Summary

As discussed above there are many options available to midwives in relation to the supply, administration and prescription of medicines.

For instance:

- Midwives have exemptions from the restrictions that apply to GSL medicines, P medicines and POMs (appendices D and E).
- Midwives are entitled to train to become independent NMAHP prescribers.
- Midwives as supplementary prescribers could enter into a voluntary partnership with an independent prescriber to implement an agreed patient-specific clinical management plan, with the patient’s agreement.
- PGDs can be set up to enable midwives to supply and/or administer POMs in circumstances that would otherwise require a prescription, or patient-specific written direction from an appropriate practitioner.

Nevertheless, midwives’ utilisation of these processes has been inhibited by a number of factors. Firstly, midwives’ exemptions have fallen into disuse in the community setting partly due to concerns over community midwives carrying POMs (more specifically controlled drugs). This has been compounded by the fact that community midwives have not been able to obtain supply orders in order to secure supplies of controlled drugs permitted under midwives’ exemptions. In the past midwives could purchase these items from the Regulating Body the United Kingdom Central Council for Nurses Midwives and Health Visitors (UKCC); the predecessor to the Nursing and Midwifery Council (NMC). However, the NMC has stated, ‘it is for the supervising authorities (LSAs) to determine their own systems for providing midwives with supply orders in their local area, as this is not the function of the Nursing and Midwifery Council.’ As discussed above a fit for purpose supply order will soon be available to enable midwives to obtain CDs for use at home deliveries.

Secondly, although some midwives have undertaken training as independent NMAHP prescribers they are not currently able to prescribe opiates for pain control in labour (appendix O).

Thirdly, supplementary prescribing is not suited to emergency, urgent or acute prescribing situations because an agreed clinical management plan is required before prescribing can begin. Supplementary prescribing would therefore be of limited use within midwifery practice.
Finally, it is not uncommon for PGDs to contain many if not all of the substances midwives can supply or administer under midwives exemptions, demonstrating a lack of knowledge and/or understanding of the operationalisation of exemption orders especially in relation to GSL and P medicines. In particular, there appears to be no mechanism for midwives to obtain supplies of said substances. It is anticipated that the development of a National Formulary especially for midwives that will include all medicines commonly used in midwifery practice, will specifically highlight those which are supplied or administered under midwives exemptions or PGDs. This will prevent extensive individual discussions in each NHS Board area in relation to midwives powers and will also provide national and professional consistency across Scotland.
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The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 SI No 1923

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The Misuse of Drugs Act 1971


The Misuse of Drugs Regulations 2001

The Prescription Only Medicines (Human Use) Order 1997

The Prescription Only Medicines (Human Use) Amendment Order 2000

The Prescription Only Medicines (Human Use) Amendment Order 2002

The Prescription Only Medicines (Human Use) Amendment Order 2004

The Prescription Only Medicines (Human Use) Amendment Order 2010

The main classes of prescription-only medicines

1. Medicinal products in respect of which a marketing authorisation has been granted, which in the marketing authorisation are classified as being prescription-only medicines;

2. Medicinal products in respect of which no marketing authorisation has been granted consisting of or containing a substance listed in column 1 of Schedule 1;

3. Medicinal products that are for parenteral administration;

4. Medicinal products that are Controlled Drugs unless a marketing authorisation has been granted in respect of that medicinal product in which the product is classified as being a pharmacy or general sale list medicine;

5. Cyanogenetic substances, other than preparations for external use;

6. Medicinal products that on administration emit radiation, or contain or generate any substance which emits radiation, in order that radiation may be used;

7. Medicinal products in respect of which marketing authorisation has been granted consisting of or containing alopixrin, aspirin or paracetamol in the form of non-effervescent tablets or capsule which in the marketing authorisation are classified as being pharmacy only or general sale list medicines.

8. Medicinal products in respect of which a marketing authorisation has been granted consisting of or containing pseudoephedrine salts or ephedrine base or salts in all pharmaceutical forms which in the marketing authorisation are classified as being pharmacy only medicines.

Appendix B - Schedule 1

Controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 19, 20, 23, 26 and 27

Have no recognised medicinal use and include cannabis, coca leaf, lysergic acid diethylamide (LSD) and mescaline.

Production, possession and supply of these drugs are limited to research or other special purposes.

Practitioners (‘practitioner’ is defined in s.37 MDA1971 as a doctor, dentist, veterinary practitioner or veterinary surgeon) and pharmacists may not lawfully possess Schedule 1 drugs except under license from the Home Office.

For a complete list of Schedule 1 drugs go to:

Appendix C - Schedule 2

Controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 19, 20, 21, 23, 26 and 27

Includes diamorphine (heroin), morphine, remifentanil and pethidine

Are subject to safe custody requirements and so must be stored in a locked receptacle, usually in an appropriate CD cabinet or approved safe, which can only be opened by the person in lawful possession of the CD or a person authorised by that person

A licence is required to import or export drugs in Schedule 2.

The drug may be administered to a patient by a doctor or dentist, or by any person acting in accordance with the directions of a doctor or dentist.

A register must be kept for Schedule 2 CDs and this register must comply with the relevant regulations.

The destruction of stock CDs in Schedule 2 must be carried out in the presence of a person authorised to do so (‘Authorised Witness’).

For a complete list of Schedule 2 drugs go to:

Appendix D - Schedule 3

Controlled drugs subject to the requirements of regulations 14, 15 (except Temazepam), 16, 18, 22, 23, 24, 26 and 27

Includes a small number of minor stimulant drugs and other drugs which are less likely to be misused than the drugs in Schedule 2.

Examples are the barbiturates (except secobarbital, now Schedule 2), buprenorphine, diethylpropion, mazindol, meprobamate, midazolam, pentazocine, phentermine, and temazepam.

Are exempt from safe custody requirements and can be stored on the open dispensary shelf except for temazepam, buprenorphine and diethylpropion, which must be stored in a locked CD receptacle which can only be opened by the person in lawful possession of the CD or a person authorised by them.

Are subject to the same special handwriting requirements as Schedule 2 CDs, except for temazepam and phenobarbital. Phenobarbital and temazepam can be dispensed in response to a computer-generated prescription but the prescriber’s signature must be added by hand.

There is no legal requirement to record transactions in a CD register.

The requirements relating to destruction do not apply unless the CDs are manufactured by the individual.

Invoices must be retained for a minimum of two years.

For a complete list of Schedule 3 drugs go to:

Appendix E - Schedule 4

Part I: Controlled drugs subject to the requirements of regulations 22, 23, 26 and 27

Part 2: Contains most of the anabolic and androgenic steroids such as testosterone, together with clenbuterol (adrenoceptor stimulant) and growth hormones (5 polypeptide hormones).

These drugs are exempt from safe custody requirements, with destruction requirements only applying to importers, exporters and manufacturers.

Specific CD prescription-writing requirements do not apply.

CD registers do not need to be kept, although records should be kept if such CDs are produced, or if a licensed person imports or exports such drugs.

There is no restriction on the possession when it is part of a medicinal product.

A Home Office licence is required for the importation and exportation of substances unless the substance is in the form of a medicinal product and is for self-administration by a person.

For a complete list of Schedule 4 drugs go to:

Controlled drugs which are exempt from the prohibition on importation, exportation and possession and subject to the requirements of regulations 24 and 26

This includes preparations of certain controlled drugs (e.g. codeine, pholcodine, morphine) which are exempt from full control when present in medicinal products of low strengths, as their risk of misuse is reduced.

There is no restriction on the import, export, possession, administration or destruction of these preparations and safe custody regulations do not apply.

A practitioner, pharmacist or a person holding an appropriate licence may manufacture or compound any CD in Schedule 5.

Therefore, exempt from virtually all CD requirements other than that invoices must be kept for a minimum of two years.

For a complete list of Schedule 5 drugs go to:

Appendix G

Extract from the Misuse of Drugs Regulations 2001

11 Exemptions for Midwives

(1) Notwithstanding the provisions of sections 4(1)(b) and 5(1) of the Act, a registered midwife who has, in accordance with the provisions of rules made under section 14(1)(b) of the Act of 1997, notified to the local supervising authority her intention to practise may, subject to the provisions of this regulation:

(a) so far as necessary to her professional practice, have in her possession;
(b) so far as necessary as aforesaid, administer; and
(c) surrender to the appropriate medical officer such stocks in her possession as are no longer required by her of any controlled drug which she may, under and in accordance with the provisions of the Medicines Act 1968 and of any instrument which is in force thereunder, lawfully administer.

(2) Nothing in paragraph (1) authorises a midwife to have in her possession any drug which has been obtained otherwise than on a midwife's supply order signed by the appropriate medical officer.

(3) In this regulation:

"the Act of 1997" means the Nurses, Midwives and Health Visitors Act 1997

“appropriate medical officer” means

(a) a doctor who is for the time being authorised in writing for the purposes of this regulation by the local supervising authority for the region or area in which the drug was, or is to be, obtained; or
(b) for the purposes of paragraph (2), a person appointed under and in accordance with section 15 of the Act of 1997 by that authority to exercise supervision over registered midwives within their area, who is for the time being authorised as aforesaid;

"local supervising authority” has the meaning it is given by section 15(1) of the Act of 1997;

“midwife's supply order” means an order in writing specifying the name and occupation of the midwife obtaining the drug, the purpose for which it is required and the total quantity to be obtained.
Appendix H

The main classes of persons and the bodies exempted from the controls on retail sale of medicines

- hospitals and health centres
- practitioners – a doctor or dentist to a patient of his, or to a person under whose care such a patient is
- midwives; sale or supply and administration
- chiropodists/podiatrists: sale or supply
- ophthalmic opticians/optometrists: sale or supply
- drug treatment services
- owners and masters of ships
- Factories Act (NI) 1965 requirements
- Royal National Lifeboat Institution
- British Red Cross Society and other bodies
- occupational health schemes
- first aid personnel on offshore installations
- ambulance paramedics: administration
### SCHEDULE 5

Article 11(1)(a)

PART I

EXEMPTION FROM RESTRICTIONS ON SALE OR SUPPLY

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persons exempted</td>
<td>Prescription only medicines to which the exemption applies</td>
<td>Conditions</td>
</tr>
<tr>
<td>4. Registered midwives.</td>
<td>4. Prescription only medicines containing any of the following substances&lt;br&gt; - Diclofenac&lt;br&gt; - Ergometrine maleate&lt;br&gt; - Hydrocortisone Acetate&lt;br&gt; - Lidocaine&lt;br&gt; - Lidocaine Hydrochloride&lt;br&gt; - Miconazole&lt;br&gt; - Nystatin&lt;br&gt; - Phytomenadione</td>
<td>4. The sale or supply shall be only in the course of their professional practice and in the case of Ergometrine maleate only when contained in a medicinal product which is not for parenteral administration.</td>
</tr>
</tbody>
</table>

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35 as amended by the Medicines for Human Use (Miscellaneous Amendments) Order 2010
### EXEMPTIONS FROM RESTRICTION ON ADMINISTRATION Column 1

<table>
<thead>
<tr>
<th>Persons exempted</th>
<th>Prescription only medicines to which the exemption applies</th>
<th>Conditions</th>
</tr>
</thead>
</table>
| 2. Registered midwives. | 2. Prescription only medicines for parenteral administration containing any of the following substances but no other substance specified in column 1 of Schedule 1 to this Order:  
Adrenaline  
Anti-D immunoglobulin  
Carboprost  
Cyclizine hydrochloride  
Diamorphine  
Ergometrine maleate  
Gelofusine  
Haemaccel  
Hartmann’s solution  
Hepatitis B vaccine  
Hepatitis immunoglobulin  
Lidocaine  
Lidocaine hydrochloride  
Morphine  
Naloxone hydrochloride  
Oxytocins, natural and synthetic  
Pethidine hydrochloride  
Phytomenadione  
Prochlorperazine  
Sodium chloride 0.9%. | 2. The administration shall only be in the course of their professional practice and in the case of Lignocaine and Lignocaine hydrochloride shall only be while attending on a woman in childbirth |

**Note:** Further changes to the list are proposed to take account of the following:

1. Oral ergometrine and Haemaccel are no longer commercially available.
2. Lidocaine and lidocaine hydrochloride for topical use are pharmacy drugs and do not, therefore need to be on the list.
3. Cyclizine hydrochloride is licensed for oral use only and cannot be used for IM or IV use. The reference to hydrochloride was an error.
### Nurse/midwife Administration by Symptomatic relief Policy or other Protocol

**Warning:** Check the As Required and Regular Prescription sections to ensure that the drug has not already been prescribed by a doctor.

<table>
<thead>
<tr>
<th>DATE</th>
<th>DRUG</th>
<th>DOSE</th>
<th>ROUTE</th>
<th>TIME (24HR)</th>
<th>NURSE (PRINT &amp; SIGN)</th>
<th>GIVEN BY</th>
<th>TIME GIVEN (24HR)</th>
</tr>
</thead>
</table>

**FOR PRESCRIBERS:**
1. Prescribe drugs generically using the Approved Name (except in circumstances where bioavailability differences between brands of the same name are so important as to warrant prescribing by brand name e.g. in the case of sustained release lithium or theophylline).
2. Time should be recorded in 24hr format e.g. 0000, 1200.
3. When drugs are discontinued, draw a diagonal line through the prescription box, initial and date the appropriate boxes and record reason.
4. If an existing prescription entry is to be modified, delete the existing prescription and re-write the new instructions as a new prescription entry.
5. The following metric unit abbreviations must be used -
   - Milligram = mg
   - Gram = g
   - Microgram = μg
   - Nanogram = ng
   - Millimoles = mmol
   - Millilitre = ml
   - Millimoles = mmol
   - Microgram / Nanogram / Units - Do not abbreviate, write in full
   - Fractions of a milligram should be written in micrograms. The use of decimal points should be avoided. If decimal points must be used, a zero must be written in front of the decimal point (e.g. 0.5ml NOT .5ml).
6. The route of administration can be abbreviated using the following -
   - ID = intradermal
   - ID = intradermal
   - IM = intramuscular
   - INH = inhaled
   - ID = intradermal
   - SC = subcutaneous
   - SC = subcutaneous
   - SL = sublingual
   - SL = sublingual
   - PR = per rectum
   - PR = per rectum
   - NG = nasogastric
   - NG = nasogastric
   - PEG = percutaneous endoscopic gastrosomy
   - PEG = percutaneous endoscopic gastrosomy
   - NJ = nasojejunostomy
   - NJ = nasojejunostomy
   - PEJ = percutaneous endoscopic nasojejunostomy
   - PEJ = percutaneous endoscopic nasojejunostomy
   - PV = per vagina
   - PV = per vagina
   - RIG = radiologically inserted gastrosomy
   - RIG = radiologically inserted gastrosomy
   - TOP = topical
   - TOP = topical
   - ETT = endotracheal
   - ETT = endotracheal
   - INHAL = inhaled
   - INHAL = inhaled
   - NEB = nebulised
   - NEB = nebulised
   - INHAL = inhaled
   - INHAL = inhaled
   - TOP = topical
   - TOP = topical
   - Please note - intrathecal must be written in full.

**FOR NURSES:**
1. The ‘Once only’, ‘Regular’ and ‘As required’ sections should be checked at each administration round to ensure that inadvertent omission or double dosing are avoided.
2. Insert initials in the relevant date column and time row each time a drug is administered.
3. Document the full reason in the patient’s notes.

**Notes for Users**
- Authorised Nurses/Midwives Only (Maximum number of doses as per protocol)
- Preprinted copies of the above are available from the Approved Name (except in circumstances where bioavailability differences between brands of the same name are so important as to warrant prescribing by brand name e.g. in the case of sustained release lithium or theophylline).

**Codes for Non-Administration of Drugs**

- Patient refused
- Drug not available
- Nil by mouth/fasting
- Patient unavailable
- Other - record in nursing notes
- Patient asleep
- Time varied on doctor’s instructions
- Dose withheld on doctor’s instructions
- Unable to swallow
- No intravenous access
- Nausea/vomiting
- Prescription clarification required
- Patient Self-Administration of Medicine

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**Example of a medicine Kardex**

[Image of a prescription form with columns for date, drug, dose, route, time, nurse, given by, and time given, along with codes for non-administration of drugs.]
13.2 Supply and Administration of Controlled Drugs

13.2.1 The Misuse of Drugs Regulations 2001 in conjunction with the provisions of the Medicines Act 1968 provide for the supply of pethidine, [pentazocine\(^{40}\)], morphine and diamorphine to midwives using a supply order signed by the Supervisor of Midwives, or other Appropriate Medical Officer.

13.2.1.1 The Supervisor of Midwives or other Appropriate Medical Officer should be satisfied that locally agreed procedure is being followed before signing the supply order (e.g. that the amount being requested is appropriate etc).

13.2.2 Supplies of pethidine, [pentazocine\(^{41}\)], morphine and diamorphine should be obtained from a hospital pharmacy, a dispensing general practitioner within the territory in which the midwife works, or a pharmacist in the community to whom he/she has been officially introduced.

13.2.2.1 It should be the duty of the pharmacist or the dispensing GP to ensure that medicines are only supplied on the instruction of an authorised person.

13.2.3 Once medicines are received by midwives working in the community or independent midwives, they become the responsibility of the midwife, and should be stored safely and securely.

13.2.3.1 Where it is necessary for midwives to keep medicines in their homes, the medicines should be placed in a secure, locked fixture. If necessary, this should be provided by the employing body.

13.2.4 Midwives should record full details of supply and administration of pethidine or other Schedule 2 drugs in their Controlled Drugs Register, which should be made available for inspection as required by the Supervisor of Midwives.

13.2.4.1 Administration of Controlled Drugs by midwives should be in accordance with locally agreed procedures.

13.2.4.2 A record of administration of the Controlled Drugs should also be kept in the patient’s records.


\(^{40}\) NOTE: pentazocine is no longer available under midwives exemptions

\(^{41}\) as above
13.3 Supply and Administration of other Medicines

13.3.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product.

13.3.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training.

13.3.3 A list of medicines (prescription-only and others) which may be supplied to, and used by midwives in accordance with Part III of the Medicines Act 1968 and listed in Schedule 5 Parts I and III of the Prescription Only Medicines (Human Use) Order 1997 should be decided by the Supervisor of Midwives in accordance with local policy. Any medicines to be supplied or administered by a midwife under a PGD should be taken into account in compiling the list.

13.3.3.1 Medicines are usually obtained from the hospital pharmacy. Where the local arrangement is that medicines are obtained from the hospital Maternity Unit stock, the midwife should complete the Unit records.

13.3.3.2 Where local arrangement (e.g. for a rural area) is that a Community Pharmacist supplies these medicines, the pharmacist should keep a record of supply.

13.3.3.3 Midwives should keep a record of supply, administration and disposal of all prescription-only medicines issued to them.

13.3.4 When in the custody of the midwife, the midwife is responsible for the safe and secure transport and storage of medicines.
13.4 Return/Disposal of Controlled Drugs

13.4.1 When a midwife is in possession of reusable stock that is no longer required this should be returned to the pharmacist from whom it was obtained, [or to an Appropriate Medical Officer43].

13.4.1.1 A record of the return should be made.

13.4.2 When a Schedule 2 Controlled Drug has been prepared/drawn up but is no longer required, and/or no longer usable, it should be destroyed by the midwife, in accordance with current regulations.

13.4.2.1 A record of the destruction should be made in the midwife's Controlled Drugs Register.

13.4.3 Controlled Drugs obtained by a woman by prescription from her doctor, for use in her home birth are her own property and are not the midwife's responsibility. Even when no longer required they should not be removed by the midwife, but the woman should be advised to return them to the community pharmacy for destruction.

13.5 Return/Disposal of other Medicines

13.5.1 Where a midwife is in possession of other medicines, which are no longer required, but are still usable, they should be returned to the supplying pharmacy.

13.5.1.1 A record of the return of prescription-only medicines should be made in the midwife's record.

13.5.2 When a midwife returns a prescription-only medicine to the supplying pharmacist a receipt should be obtained, and an entry made in the midwife's records.

13.6 Audit of Records

13.6.1 Supervisors of midwives should, as part of their duties, periodically audit and reconcile the records of Controlled Drugs and prescription-only medicines kept by each midwife. Any discrepancies should be investigated.


43 NOTE: under the Controlled Drugs (Supervision of Management and Use) Regulations 2006 accountable officers are now responsible for the disposal and destruction of controlled drugs;
13.7 Midwives Working in Hospitals and Birth Centres

13.7.1 Administration of Controlled Drugs and other medicines to patients by midwives working in hospitals should be in accordance with locally agreed procedures.

13.7.1.1 It may be locally decided that midwives within the hospital may follow the same practice as midwives working in the community, regarding administration of medicines. This is seen to pose no additional safety or security problems provided that full record keeping procedures are strictly followed, noting that each patient should have only one medicine record.

13.8 Risk Management

13.8.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

13.8.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced.
Appendix M

History of Nurse/Midwife Independent Prescribing

The 1992 Act added a new clause to the 1968 Act, which stated that:

'The appropriate ministers may by order specify descriptions or classes of medicinal products for the purpose of this section; and in relation to any description or class so specified, the order shall state which of the following, that is to say - a) doctors, b) dentists, c) veterinary surgeons and practitioners, d) registered nurses, midwives and health visitors who are of such description and comply with such conditions as may be specified in the order, are to be appropriate practitioners for the purposes of this section.'

Statutory Instrument 1994/2402 set out the necessary training and qualifications for nurses to prescribe; it stated that registrants who are able to prescribe must be

- a registered nurse who holds a current district nurse qualification and is a district nurse
- a registered midwife
- a registered health visitor

In addition, the authority to prescribe was limited to nurses who were employed by a district health authority or an NHS trust and who had completed the necessary educational preparation approved by the NMC (appendix M).

Changes in legislation in Scotland in 1996 resulted in a phased implementation to allow community nurses in Scotland with either a district nursing or health visiting recordable qualification to prescribe from this limited formulary.

Since 1999, prescribing has been integral to the education of all district nurses, health visitors/public health nurses and practice nurses and the NMC register is annotated to signify that they have successfully completed the assessment requirements of either the stand alone or integrated course.

Although the legislation clearly states that registered midwives are eligible to train as prescribers, the Nurse Prescribers’ Formulary for Community Practitioners, which lists the preparations which may be prescribed for a range of specific conditions, is more suited to the practice of district nurses and health visitors than midwives.

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$^{44}$ Section 58 d of the Medicines Act 1968

$^{45}$ The Medicines Act 1968

$^{46}$ The Medicinal Products; Prescription by Nurses, etc, Act 1992 (Commencement (No. 2) Order) 1996; and The National Health Service (Pharmaceutical Services) (Scotland), (General Medical Services) (Scotland), and (Charges for Drugs and Appliances) (Scotland) Amendment Regulations 1996.

$^{47}$ see British National Formulary online at http://www.bnf.org
Extended Nurse Prescribing

The conditions specified in the legislation for nurse prescribing excluded nurses working in non-community settings. It could be argued that this was discriminatory and undermined not only the UKCC Scope of Professional Practice\(^48\) but also the work undertaken by many clinical nurse specialists. This exclusion was reviewed by Dr Crown in 1999\(^49\), with the recommendation that nurse prescribing be extended to include nurses 'beyond currently authorised prescribers' and to allow prescribing by other healthcare professionals registered with a recognised regulatory body.

The report was accepted by the government in March 2000 and on 4 May 2001 Lord Hunt announced that nurse prescribing was to be extended meaning that it was not necessary for a nurse to hold a district nursing or health visiting qualification in order to be eligible to undertake the specific programme of preparation and prescribe from the Nurse Prescribers' Extended Formulary. This extended formulary gave extended nurse prescribers access to a wider range of medicines covering four broad areas of practice: minor ailments, minor injuries, health promotion and palliative care.

Lord Hunt stated that, "this is a crucial step forward in our efforts to give patients better and quicker access to the medicines they need. It will also make better use of nurses' skills and free up doctors' time allowing them to deal with more serious cases." In effect, what Lord Hunt was announcing was the extension of independent prescribing to nurses and midwives albeit under strict conditions.

In independent NMAHP prescribing the prescriber takes responsibility for the clinical assessment of the patient/client, establishing a diagnosis and the clinical management required, as well as the responsibility for prescribing, and the appropriateness of any prescribing.

Amendments to the Prescription Only Medicines (Human Use) Order\(^50\), NHS (Pharmaceutical Services) (Scotland) Regulations\(^51\), NHS (Charges for Drugs and Appliances) (Scotland) Regulations\(^52\), came into force on 1 April 2002. Under the provisions of the amended regulations, prescribers must be a 1st level registered nurse or registered midwife; and

(a) in each case the nurse's or midwife's name must be held on the NMC professional register with an annotation signifying that the nurse has successfully completed the specific programme of preparation for extended nurse prescribing approved by NHS Education for Scotland and is qualified to order medicines and medical devices from the Extended Formulary.

In 2005, the University of Southampton completed an evaluation of nurse prescribing for the Department of Health, England. It was clear from the evaluation's conclusion that nurses and some doctors felt that the format of the Nurse Prescribers' Extended Formulary was in some cases restricting benefit to patients and efficient NHS practice. Experience had also shown that updating the Extended Formulary was a long and resource intensive process, with proposed changes taking 1 - 1½ years to put into effect.

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\(^48\) United Kingdom Central Council for Nurses, Midwives and Health Visitors, 1992, Scope of Professional Practice, London: UKCC
\(^50\) The Prescription Only Medicines (Human Use) Amendment Order 2002
\(^51\) NHS (Pharmaceutical Services) (Scotland) Regulations 2002
\(^52\) NHS (Charges for Drugs and Appliances) (Scotland) Regulations 2001
At the same time, a joint consultation by the Department of Health England & Medicines and Healthcare products Regulatory Agency (MHRA) examined the options for the future of independent nurse prescribing. A similar consultation examined options for the introduction of independent prescribing by pharmacists. These proposals aimed to benefit patients by providing greater access to pharmacists’ knowledge and expertise, and a faster and more accessible service.

The responses to both consultations were considered by the Committee on Safety of Medicines who recommended to Ministers that suitably trained and qualified nurses and midwives should be able to prescribe any licensed medicine for any medical condition within their competence. These recommendations were agreed by Ministers and announced in a press release on 10 November 2005.
responsible and accountable for assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management including prescribing

can prescribe from a LIMITED Nurse Prescribers FORMULARY

EXTENDED FORMULARY for nurse prescribers - all general sale list and pharmacy medicines prescribable by GPs plus POMs, as above, in limited Nurse Prescribers Formulary. No controlled drugs

SUPPLEMENTARY NURSE PRESCRIBERS
• in voluntary partnership with doctor or dentist
• implement and agreed CLINICAL MANAGEMENT PLAN
• patient specific, agreed with patient

able to prescribe ANY LICENSED medicine for any medical condition within their competence plus a LIMITED list of controlled drugs
Appendix N

The Controlled Drugs (Supervision of Management and Use) Regulations 2006

Designated bodies
3 The following are prescribed as designated bodies for the purposes of section 17 of the 2006 Act:
(a) a Primary Care Trust;
(b) a Health Board;
(c) an NHS trust;
(d) an NHS foundation trust;
(e) an English or Scottish independent hospital; and
(f) the following Special Health Boards—
   (i) the Scottish Ambulance Service Board,
   (ii) the National Waiting Times Centre Board, and
   (iii) the State Hospitals Board for Scotland.

Persons who may be appointed as accountable officers
5 (1) An English independent hospital may only nominate or appoint a person as its accountable officer if:
   (a) the person is:
      (i) its registered manager, or
      (ii) one of its officers or employees who is answerable to its registered manager,
      (iii) and if the person is its registered manager, he must be answerable to the chief executive, chairman or managing director of the hospital; and
   (b) the person does not routinely supply, administer or dispose of controlled drugs as part of his duties.

   (2) Two or more English independent hospitals may jointly nominate or appoint one registered manager to be the accountable officer for both or all of the hospitals if the registered manager:
      (a) is registered as manager in relation to both or all of the hospitals; and
      (b) does not routinely supply, administer or dispose of controlled drugs as part of his duties.

   (3) A Scottish independent hospital may only nominate or appoint a person as its accountable officer if:
      (a) the person is:
         (i) its manager, or
         (ii) one of its officers or employees who is answerable to its manager,
         and if the person is its manager, he must be answerable to the chief executive, chairman or managing director of the hospital; and
(b) the person does not routinely supply, administer or dispose of controlled drugs as part of his duties.

(4) Two or more Scottish independent hospitals may jointly nominate or appoint one manager to be the accountable officer for both or all of the hospitals if the manager:
   (a) is the manager of both or all of the hospitals; and
   (b) does not routinely supply, administer or dispose of controlled drugs as part of his duties.

(5) Subject to paragraph (6), a designated body which is neither an English nor a Scottish independent hospital may only nominate or appoint a person as its accountable officer if:
   (a) the person is an officer or employee of the designated body, and:
       (i) a member of the board of directors, or the management or executive committee of the designated body,
       (ii) a member of the body (howsoever it may be called) that has responsibility for the management of the designated body, or
       (iii) is answerable to a person referred to in paragraph (i) or (ii); and
   (b) the person does not routinely supply, administer or dispose of controlled drugs as part of his duties.

(6) Two or more designated bodies which are neither English nor Scottish independent hospitals but which are of the same type may jointly nominate or appoint one person to be the accountable officer for both or all of the bodies, if:
   (a) the person satisfies paragraph (5)(a) in relation to one of the designated bodies;
   (b) each designated body is satisfied that the person can properly discharge his responsibilities in relation to it; and
   (c) the person does not routinely supply, administer or dispose of controlled drugs as part of his duties.

(7) In this regulation:
   “manager”, in relation to a Scottish independent hospital, means the person appointed as the manager of that hospital pursuant to regulation 17(1) of the Regulation of Care (Requirements as to Care Services) (Scotland) Regulations 2002 (appointment of manager); and
   “registered manager”, in relation to an English independent hospital, means the person who is registered under Part II of the 2000 Act as the manager of the hospital.
Nurse Independent Prescriber: Controlled Drugs

Nurse independent prescribers are able to prescribe the following list of Controlled Drugs, solely for the medical conditions indicated:

- diamorphine, morphine, diazepam, lorazepam, midazolam, or oxycodone for use in palliative care
- buprenorphine or fentanyl for transdermal use in palliative care;
- diazepam, lorazepam, midazolam for the treatment of tonic-clonic seizures
- diamorphine or morphine for pain relief in respect of suspected myocardial infarction, or for relief of acute or severe pain after trauma including in either case post-operative pain relief
- chlordiazepoxide hydrochloride or diazepam for treatment of initial or acute withdrawal symptoms, caused by the withdrawal of alcohol from persons habituated to it
- codeine phosphate, dihydrocodeine tartrate or co-phenotrope (no restrictions on medical conditions)
Appendix P

Extract from The Prescription Only Medicines (Human Use) Amendment Order 2000

Statutory Instrument 2000 No. 1917
SCHEDULE 7
Articles 12A to 12C
PART I
PARTICULARS TO BE INCLUDED IN A PATIENT GROUP DIRECTION

(a) the period during which the Direction shall have effect;

(b) the description or class of prescription only medicine to which the Direction relates;

(c) whether there are any restrictions on the quantity of medicine which may be supplied on any one occasion, and, if so, what restrictions;

(d) the clinical situations which prescription only medicines of that description or class may be used to treat;

(e) the clinical criteria under which a person shall be eligible for treatment;

(f) whether any class of person is excluded from treatment under the Direction and, if so, what class of person;

(g) whether there are circumstances in which further advice should be sought from a doctor or dentist and, if so, what circumstances;

(h) the pharmaceutical form or forms in which prescription only medicines of that description or class are to be administered;

(i) the strength, or maximum strength, at which prescription only medicines of that description or class are to be administered;

(j) the applicable dosage or maximum dosage;

(k) the route of administration;

(l) the frequency of administration;

(m) any minimum or maximum period of administration applicable to prescription only medicines of that description or class;

(n) whether there are any relevant warnings to note, and, if so, what warnings

(o) whether there is any follow up action to be taken in any circumstances, and, if so, what action and in what circumstances;

(p) arrangements for referral for medical advice;

(q) details of the records to be kept of the supply, or the administration, of medicines under the Direction.
To PGD or Not to PGD? - That is the question
A guide to choosing the best option for individual situations

You need to consider whether a Patient Group Direction (PGD) would be appropriate for an area of practice that involves the supply or administration of medicines.

Medicines Matters published by Department of Health is a useful reference source which describes the mechanisms available for the prescribing, supply and administration of medicines. This diagram takes the practitioner through a logical process that aims to assist decision-making. SCOTTISH VERSION ONLY

NOTE: The majority of clinical care should still be provided on an individual, patient-specific basis.

START

YES

Are the products involved all licensed medicines?

NO

A PGD is not needed for dressings and other medical devices - the PGD legislation applies only to licensed medicines. Consider protocol or treatment guidelines.

YES

Independent prescribing may be more appropriate.

NO

Are the medicines that these practitioners need to supply or administer listed in the exemptions? (See RPSGB “Medicines Ethics & Practice" guide for details)

YES

A PGD may not be required if the professional activity fits within the exemptions in the Medicines Act (1968) and associated statutory instruments.

NO

A PGD may need to be considered.

Are the practitioners involved accredited as non-medical prescribers with the NMC or RPSGB or other professional bodies, AND the medicines involved included in the relevant prescriber’s formulary?

YES

Are the medicines involved P (Pharmacy) or GSL (General Sales List) medicines?

NO

Are the medicines involved P (Pharmacy) or GSL (General Sales List) medicines?

YES

NO

Does the practitioner want to administer only, and does not need to supply the medicines for patient to take at home?

P medicines

P medicines can only be sold or supplied through registered pharmacies, so PGD may be required.

NO supply is required.

NO

GSL medicines

PGD not required. Could use local protocol/policy.

YES

A Protocol can be implemented to administer medicines that are P or GSL. This may also apply for medical gases, none of which are POM. POM may require PGD for administration.

Note: some organisations use PGOs in these circumstances although not a legal requirement.

SCOTTISH VERSION ONLY
Are the practitioners who will supply or administer medicines able to do so under a PGD. Check the MHRA website – links to PGDs in the private sector and PGDs in the NHS

NO → An alternative will need to be sought for practitioners who cannot work under PGDs

YES → Is the treatment provided by:
- Scottish Health Boards
- Dental Independent hospital, agency or Partnership
- Clinic registered with the Care Commission in Scotland
- Defence medical services (UK)

Community Health (and Care) GP or practice
- NHS commissioned service
- Prison healthcare service
- Police services

NO → PGDs cannot be used in other organisations e.g. Care homes, independent schools providing healthcare outside the NHS

YES → Does activity involve the administration of diamorphine by a nurse in a CCU or A & E for cardiac pain OR involve the supply of a Schedule 5 CD? Or Midazolam (Schedule 3)

PGD may be used

NO → This may be addressed most appropriately through supplementary prescribing. It does not fit the present definition for a PGD unless very clear criteria for dose adjustment can be defined within the PGD.

YES → Does activity involve the supply of a Schedule 4 part 1 CD?

If yes, is this drug in parental form for the treatment of addiction?

YES → PGDs cannot be used

NO → HDL (2001) 7) states that ‘supply or administration of medicines under PGD should be reserved for those limited situations where this offers an advantage of patient care (without compromising patient safety) and where it is consistent with appropriate professional relations and accountability’. Does the proposed activity need these principles? See Medicines Matters for further information

NO → An alternative method will need to be considered e.g. using individual prescriptions, PSD or local protocols see NPC PGD Guidance March 2004

YES → A PGD may be the most appropriate route to provide this clinical activity. Follow national guidance (Scotland only NHS HDL (2001) 7) and local CHICIP or organisational policy.