

An overview of midwifery regulation

The Nursing and Midwifery Council

We are the independent regulator for nurses, midwives and nursing associates. We hold a register of around 700,000 nurses, midwives and nursing associates who can practise in the UK.

Better and safer care for people is at the heart of what we do, supporting the healthcare professionals on our register to deliver the highest standards of care.

We make sure nurses, midwives and nursing associates have the skills they need to care for people safely, with integrity, expertise, respect and compassion, from the moment they step into their first job.

Learning does not stop the day nurses, midwives and nursing associates qualify. To promote safety and public trust, we require professionals to demonstrate throughout their career that they are committed to learning and developing to keep their skills up to date and improve as practitioners.

We want to encourage openness and learning among healthcare professions to improve care and keep the public safe. On the occasions when something goes wrong and people are at risk, we can step in to investigate and take action, giving patients and families a voice as we do so.

This is an information document for midwives, women and families and any other interested parties. It describes our approach to the regulation of midwives but it is not a regulatory standard. It contains sections relating to each of the NMC's statutory functions: the education of midwives, registration and revalidation, standards and guidance, and fitness to practise. It should be read in conjunction with the Code and other standards and guidance.

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INTRODUCTION

Midwifery is a distinct profession, with its own standards of proficiency and part of the NMC register. Midwives are accountable as the lead professional and have a unique relationship with the women, newborn infants, partners and families they care for and support.

The care of women and their babies requires specific expertise. There are health conditions that manifest differently or uniquely through pregnancy and birth with the need for the midwife to work collaboratively with a range of healthcare professionals.

Midwives must provide care based on the best available evidence. They must keep their knowledge and skills up to date to make sure their care is responsive to emerging evidence and future developments.

Midwives work in partnership with women, respecting their human rights and involving them in decisions about their care. Midwives should optimise physiological processes, and support safe psychological, social and cultural situations, working to promote positive outcomes and to anticipate and prevent complications.

Protected title and protected function

Midwifery is regulated as a distinct profession. The title of 'midwife' is protected in law and there is a protected legal function associated with this title. It is an offence for someone to practise as a midwife while not registered, to falsely claim to have a midwifery qualification, or to use the title 'midwife' when not entitled to do so. Only those recorded on the NMC's register as holding a qualification in midwifery may therefore use the protected title of 'midwife'.

Only the following people may attend a woman in childbirth².

- A midwife.
- A registered medical practitioner.
- A student undergoing training with a view to becoming a midwife or a medical practitioner, as part of an approved course of practical instruction.

The exception to this is in a case of 'sudden or urgent necessity'.

Scope of practice

The term 'scope of practice' is frequently used in relation to professions such as midwifery, but UK health professionals tend not to be regulated with reference to a specified 'scope of practice'. A midwife's 'scope of practice' might be taken to mean 'the range of things that the midwife has the skills, knowledge and proficiency to do' and it should not be confused with 'protected function' which means 'something that only midwives can legally do' (see above).

The standards of proficiency and the Code are important factors in thinking about scope of practice. A midwife's scope of practice may change depending on the nature of their roles and the learning they have undertaken. The Code requires midwives not to practise outside of their skills, knowledge or competence. It is important that providers of maternity services are mindful of this professional duty when they deploy midwives.

The NMC's functions and objectives and its regulatory powers are set out in <u>legislation</u>. Midwives must uphold the Code in order to remain on the register and practise as a midwife in the UK. The Code requires midwives to uphold the relevant laws of the country in which they practise.



Education standards

The NMC sets <u>standards for programmes</u> leading to the award of midwifery qualifications.

The UK is a member state of the EU, so the standards comply with the minimum standards for the training of midwives set down in EU law.³

The NMC sets proficiency standards for registered midwives known as the <u>Standards of proficiency for midwives</u>. These set out the standards that midwives must meet when they qualify, and maintain relevant to their scope of practice. To stay on the register, midwives must keep their knowledge and skills up to date.

The lead midwife for education

The lead midwife for education is responsible for midwifery education in the relevant approved education institution (AEI) and is suitably qualified and experienced to lead and advise on matters relating to midwifery education.

The lead midwife for education and their designated midwife substitute must be midwives registered with the NMC.

We require an AEI to do the following:

- appoint a lead midwife for education who is responsible for midwifery education
- inform the NMC Council of the name of the lead midwife for education.

The requirements of the lead midwife for education are set out in Rule 6 (1)(a)(ii) and Rule 6 (3) of the Nursing and Midwifery Council (Education, Registration and Registration Appeals) Rules 2004 (S1 2004/1767).

The lead midwife for education will:

- be responsible for midwifery education in the AEI
- be accountable for signing the supporting declarations of health and character for applicants applying for admission to the register after completing a preregistration midwifery programme or for applicants applying for readmission to the register following a return to practice programme

1: Education

• be accountable for signing the supporting declarations of health and character for applicants who have successfully completed an adaption programme in the UK.

If the lead midwife for education (or their designated midwife substitute) can't be assured of a student's health and character they must not sign the supporting declaration. The student therefore, can't be recommended for admission to the midwives' part of the register.

In the case of a student who is already registered with the NMC, action should be taken in accordance with the NMC Guidance on health and character.

In conjunction with <u>Part 3: Standards for prescribing programmes</u> and <u>Return to practice standards</u> the lead midwife for education should work with the programme leader and the practice assessor to ensure adequate support for any midwives undertaking prescribing programmes and return to practice programmes.

AEIs in partnership with practice learning partners and/or work based earning partners have overall responsibility for the quality of their education programmes and AEIs may assign the responsibilities they determine appropriate to the lead midwife for education in order to enable them to carry out their role.

This may include but is not limited to, advising on academic standards and quality in midwifery education, contributing to the development, delivery, quality assurance and evaluation of their programmes and providing input at strategic and operational levels within the AEIs on matters relating to midwifery education.

Student midwives

Student midwives work towards achieving the NMC's standards of proficiency by the time they complete their education programmes. The AEI where the student midwife is studying is responsible for monitoring their achievement of proficiencies, offering support as required and deciding whether the student is making sufficient progress.

1: Education

AEIs are required to have policies in place to address issues such as conduct and health that may affect a student's fitness for practise as a midwife. AEIs will use the Code and this document as a reference point. The NMC checks that AEIs do this effectively through the quality assurance of midwifery programmes.

Student midwives, particularly on practice placements, may witness or become aware of something that gives them cause for concern. Where this is the case, they can raise that concern locally in the first instance to seek its resolution. Please read <u>Raising concerns</u>: <u>Guidance for nurses</u>, <u>midwives and nursing</u> associates.



2: Joining the register and maintaining registration

The midwifery part of the register and further entries in the register

Midwifery is recognised in the law as a distinct profession and has its own separate part of <u>the register</u>. The register holds a range of information, for example certain post-registration qualifications can be recorded. Not all of the information held on the register is publicly available.

Joining the register

There are a number of different ways for qualified midwives to join the NMC register. All must meet the NMC's statutory requirements of holding an approved qualification, being capable of safe and effective practice (including meeting the Council's requirements relating to health and character), holding an appropriate indemnity arrangement, having the necessary knowledge of English, and paying a registration fee.

<u>UK trainees</u> who have graduated from approved education programmes will be uploaded by their AEI onto the NMC's registration database. The AEI will also make a declaration in relation to the trainee's health and character. Once this has taken place the trainee will make an application to join the register.

Midwives trained outside the UK, in the EU or outside of the EU/EEA can apply for registration with the NMC.

Once registered, midwives must meet the NMC's <u>revalidation requirements</u> every three years to maintain their registration.

Midwives whose registration lapses will need to apply to <u>rejoin the register</u> if they wish to return to practice in the UK. They may need to complete a return to practice (RtP) programme or take a test of competence in order to demonstrate that they meet the requirements of registration at the point of re-entry.

2: Joining the register and maintaining registration

Revalidation

Revalidation is the process that all midwives in the UK need to undergo every three years to maintain their registration. Revalidation contributes to assurance that midwives on the register remain capable of safe and effective practice. The NMC sets the requirements for practice hours, continuing professional development, feedback and reflective learning, health and character declarations, and appropriate professional indemnity arrangements. Revalidation is not an assessment of a midwife's fitness to practise, nor is it an alternate route for the raising of concerns.

Every year midwives must pay an annual registration fee. A failure to pay could lead to a lapse in registration and prevent midwives from practising.

Indemnity insurance

In order to hold registration, midwives must declare that they have an <u>indemnity</u> <u>arrangement</u> appropriate for their role and the risks associated with their practice. The cover must be relevant to their scope of practice, so that it is sufficient if a claim is made against them.⁴

If a midwife works for the NHS or within Health and Social Care (HSC) in Northern Ireland, they may already have an appropriate indemnity arrangement. It is a midwife's responsibility to ensure that they have an appropriate indemnity arrangement in place.

The NHS/HSC insures its employees for work carried out on its behalf. If a midwife is employed in private healthcare (for example, at a private hospital or birthing centre) it is likely that their employer will have an appropriate indemnity arrangement for them. However, arrangements may vary between employers so midwives should always check to be sure.

If a midwife is self-employed, works as a consultant or through an agency, they will probably be required to have their own indemnity arrangement in place.

Professional bodies may offer professional indemnity insurance, or midwives can arrange their own cover directly through a commercial provider. It is important that midwives understand the terms of their insurance policy.



3: Standards and guidance

The NMC's expectations about how midwives will practise their profession are set out in its <u>standards</u>, including the Code. Fitness to practise investigations will consider whether a midwife has breached the Code or other standards.

The Code

The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates sets out the professional standards that midwives must uphold in order to remain registered, and therefore to be able to practise in the UK. It is central to the NMC's statutory duty to protect the public.

The Code is structured around four themes:

- prioritise people
- practise effectively
- preserve safety
- · promote professionalism and trust.

The Code also sits at the heart of the NMC's revalidation requirements.

The professional duty of candour

Midwives must be open and honest with women and their families in the event that something goes wrong with their care, or where that care causes (or has the potential to cause) harm or distress. Midwives must also be open and honest with their colleagues, employers and relevant organisations, and take part in reviews and investigations when requested. They should support and encourage nurses, other midwives and nursing associates to be open and honest, and must not attempt to prevent someone from raising concerns.

The NMC has jointly produced guidance with the General Medical Council on the professional duty of candour. This guidance supports the Code's requirement to preserve safety.

Raising and escalating concerns

The NMC has developed guidance for midwives on <u>raising and escalating concerns</u> about poor care and poor practice. It sets out broad principles that will help midwives to think through the issues and take appropriate action in the public interest.

It includes details about the laws that protect whistleblowers and also contains information on organisations that midwives can go to for further advice.

Record keeping

Record keeping is covered by the Code in paragraph 10.

Midwives should also be aware of and comply with the provisions in the law that cover the creation, handling, storage, retention and sharing of service users' personal information such as those set out in the relevant Data Protection legislation. Most midwives will need to meet the requirements of an employer or service provider. Midwives working outside such a structure may wish to take advice about their legal obligations.

Midwives should ensure that the records they complete and that are retained are of a high standard, so if they are needed at a later date they provide an account of the care provided to women and babies. Midwives employed by the NHS (or its equivalents across the UK) or in private practice will usually create, maintain and store records in accordance with their employer's or healthcare provider's formal policy. Midwives working outside of such a structure should ensure that they take appropriate advice and comply with their legal obligations.

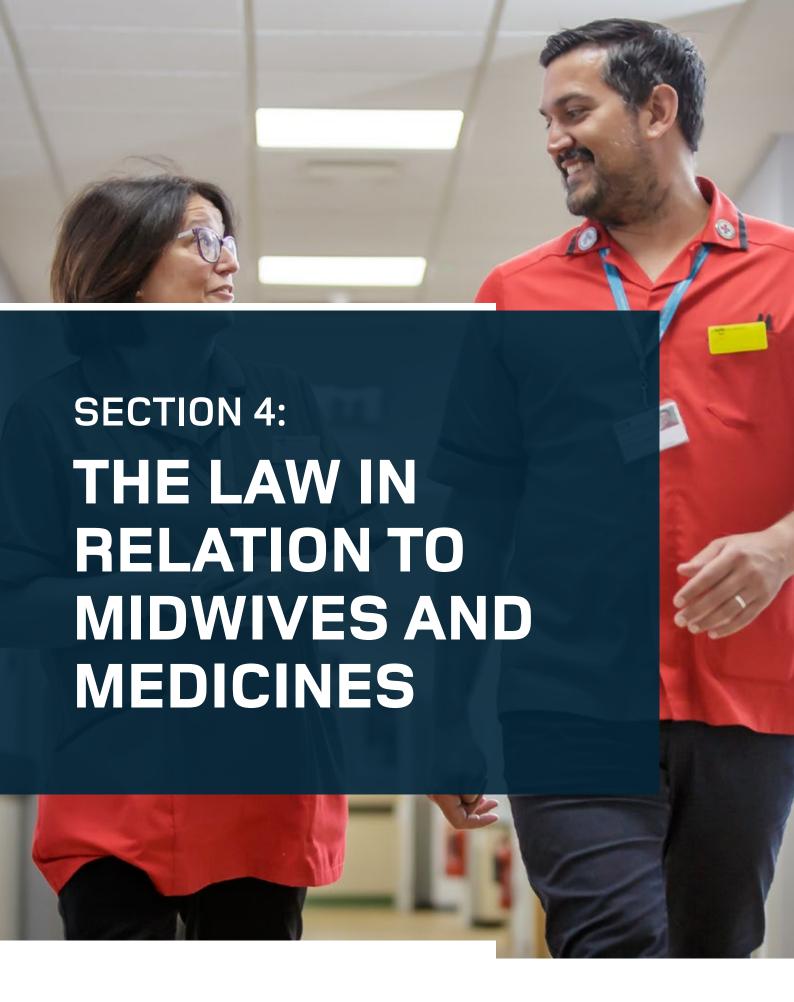
3: Standards and guidance

Guidance on using social media responsibly

The NMC has published <u>Guidance on using social media responsibly</u>. This supports the Code.

Conscientious objection by midwives

Paragraph 4.4 of the Code states that if midwives have a conscientious objection to a particular procedure they must tell colleagues, their manager and the person receiving care. They must also arrange for a suitably qualified colleague to take over responsibility for that person's care. The law on conscientious objection varies by country of practice, and it is the responsibility of midwives to ensure that they are aware of the law, in the country where they are practising. The NMC has published information about conscientious objection.



The <u>Human Medicines Regulations 2012</u>, amended in 2016, ("the Regulations") consolidated many of the pre-existing pieces of legislation related to the administration, sale and supply of medicinal products for human use.

The Regulations govern the ways that medicines can be lawfully sold and supplied in the UK. The Regulations set out the rules for prescription, supply and administration of medicines by midwives with reference to patient-specific directions (PSD), patient-group direction (PGD) and midwives exemptions.

Midwives can supply all general sale list medicines (GSL) and pharmacy medicines (P) in accordance with their scope of practice. Medicines not included in midwives' exemptions (this includes GSL, pharmacy (P) and specified POM medicines), require a prescription, a patient-specific direction (PSD) or patient-group direction (PGD).

Midwives can also supply and administer a limited list of prescription only medicines (POMS). Schedule 17 of the Human Medicines Regulations lists the midwives exemptions from restrictions on supply and administration of prescription only medicines. An up-to-date version of the relevant parts of schedule 17 is attached at Annexe A.

The Secretary of State for Health and Social Care can amend the list of medicines in the exemptions. They do so in the exercise of the powers conferred by section 2(2) and (5) of the European Communities Act 1972, having been designated for the purposes of section 2(2) of that Act in relation to medicinal products.

The relationship between the NMC and midwives exemptions

This information replaces the information contained within the Circular, "Changes to Midwives Exemptions" (07/2011). Please follow the link to the relevant section in the <u>Human Medicines Regulations</u> which describes the legislation for midwives and student midwives and the current list of exemption medicines. It is important that every midwife reviews this information regularly as the list can change and it is important that you keep this area of your knowledge and competence up to date.

At the point of entry onto the register all midwives will have been deemed

competent by the AEI to select, acquire and administer safely a range of permitted drugs consistent with the Human Medicines Regulations 2012, amended in 2016, applying knowledge and skills to the situation.

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.

We will continue to act in a consultative role and work closely with the DHSC, MHRA and others with regard to midwives exemptions.

Prescribing, supplying and administering medicines⁵

We do not provide guidance on the dosage of medicines, including those on the midwives exemptions list.

To provide this information would be outside our scope as a professional regulator. Please refer to relevant information e.g. the <u>British National Formulary</u> for information about medicines that you may administer.

Prescribing

Medicinal products fall into one of three categories, general sale list (GSL), pharmacy (P) medicines and prescription only medicines (POMs). Midwives can supply all GSL and P medicines in accordance with their scope of practice. Prescription only medicines (POMs)⁶ are those medicines which may only be sold or supplied by a midwife in accordance with a prescription from an appropriate prescribing practitioner (unless the medicine is included in the list of midwife exemptions).

Only midwives (including dual qualified nurses/midwives) who have completed the NMC-approved independent and supplementary prescribing qualification (V300)⁷, and have had that qualification recorded on the NMC's register, may prescribe medicines, within the limits of those qualifications.

Paragraph 18 of the Code requires all nurses and midwives who advise on, prescribe, supply, dispense or administer medicines to do so within the limits of their training and competence, the law, NMC guidance and other relevant

policies, guidance and regulations. More detail is available in <u>the Code</u> the <u>Royal Pharmaceutical Society A Competency Framework for all Prescribers</u> which we have adopted as our new standards of proficiency for nurse and midwife prescribers and our new Standards for <u>prescribing programmes</u>.

Supplying

In certain circumstances midwives can lawfully supply and administer specified prescription only medicines (POM) without a prescription.

Part 1 of Schedule 17 of the Human Medicines Regulations 2012, amended 2016 outline the provisions in relation to midwives' exemptions from restrictions on the sale and supply of prescription only medicines and midwife exemptions on the administration of prescription only medicines.

A midwife should also refer to their local trust or health board policies and guidance on medicines about their ability to supply and dispense medicines. This includes medications which are not prescription only medicines, for example, the giving of paracetamol and administration of nitrous oxide and oxygen using Entonox apparatus.

Administering

In certain circumstances midwives can lawfully administer pharmacy (P) and specified prescription only medicines (POM).

Schedule 17 of the Human Medicines Regulations 2012, amended 2016 outline the provisions in relation to midwives' exemptions from the restrictions on the administration of prescription-only medicines.

Student midwives

All midwives who support, supervise and assess student midwives should ensure that they are familiar with the law in relation to the supply of medicines, including the midwives' exemptions, in order to safely support and supervise student midwives who may administer medicines to women in their care.

In accordance with Part 3 of Schedule 17 of the Regulations student midwives can administer the drugs included within the midwives' exemptions (with the exception of controlled drugs) under the direct supervision of a midwife. Student midwives are not permitted to administer controlled drugs using midwives' exemptions, including Diamorphine, Morphine and Pethidine Hydrochloride. They may participate

in the checking and preparation of controlled drugs under the supervision of a midwife.8

Student midwives may administer prescribed drugs (including controlled drugs) parenterally if prescribed by a doctor or an appropriate practitioner according to their directions for administration. ¹⁰ This must be under the direct supervision of a midwife.

A registered nurse during their clinical placement on the shortened programme acts as a student midwife for the purposes of all drug administration.



5: Fitness to practise

Midwives¹¹ can be referred to the NMC if concerns arise about their fitness to practise and those concerns cannot be managed by their employer, or are so serious that there is a need to take immediate action. Referrals can be made by an employer, a colleague, a member of the public, or anyone else. Midwives have a duty to self-refer if they believe their own fitness to practise may be impaired.

The NMC has a statutory duty to consider each referral and where necessary take appropriate action. Allegations that a midwife's fitness to practise may be impaired include, for example, matters such as:

- Misconduct behaviour that falls short of what can be reasonably expected
 of a midwife which could put women, babies and families at risk or undermine
 the public trust in midwives. Such cases may relate to conduct in work, or
 outside of work.
- Lack of competence evidence of a lack of knowledge, skills or professional judgment that raises a question as to whether the midwife is capable of meeting the required standards for safe and effective practice.
- **Health** a question as to a midwife's ability to provide safe care arising from a serious, long-term, untreated or unacknowledged health condition that cannot be managed with the support of the employer.
- Convictions or cautions where a midwife has received a criminal conviction or caution that calls into question their fitness to practise or has the potential to undermine the public trust in the midwifery profession.
- Not having the necessary knowledge of English evidence that a midwife does not have the necessary knowledge of English to practise safely and effectively in the UK.
- **Determinations of other regulatory bodies** where a midwife has had a finding of impairment made against them by another regulator of a health and social care profession, within the UK or by a licensing body elsewhere.



Annexe A: List of midwives exemptions

This unofficial consolidated version of the legislation relates to midwives exemptions. This is accurate as of 7 January 2019. Please consult legislation. gov.uk to identify if any further amendments have been made.

Please note this list only refers to prescription only medicines. Midwives are able to supply all general sale list (GSL) and pharmacy (P) medicines in accordance with their scope of practice and subject to local policies.

<u>Schedule 17 of the Human Medicines Regulations</u>¹² details the exemptions for sale, supply or administration of prescription only medicines by certain persons.

Schedule 17, Part 1 makes the following provision in relation to midwives regarding the sale and supply of certain prescription only medicines:

Column 1 Persons exempted	Column 2 Prescription only medicine to which the exemptions apply	Column 3 Conditions
4. Registered midwives	4. Prescription only medicines containing any of the following substances— (a) Diclofenac; (b) Hydrocortisone Acetate; (c) Miconazole; (d) Nystatin; (e) Phytomenadione;	4. The sale or supply shall be only in the ourse of their professional practice.

Annexe A: List of midwives exemptions

Schedule 17, Part 2 lists the exemptions on supply of prescription only medicines. 13

Column 1 Persons exempted	Column 2 Prescription only medicine to which the exemptions apply	Column 3 Conditions
12. Registered midwives	12. Prescription only medicines for parenteral administration that contain- (a) Diamorphine (b) Morphine (c) Pethidine hydrochloride	12. The supply shall be only in the course of their professional practice.

Annexe A: List of midwives exemptions

Schedule 17, Part 3 lists the exemptions from the restriction on administration of prescription only medicines. The following exemptions are listed:

Column 1 Persons exempted	Column 2 Prescription only medicine to which the exemptions apply	Column 3 Conditions
2. Registered midwives and student midwives.	2. Prescription only medicines for parenteral administration containing any of the following substances but no other substance that is classified as a product available on prescription only- (a) Adrenaline (b) Anti-D immunoglobin (c) Carboprost (d) Cyclizine lactate (e) Diamorphine (f) Ergometrine maleate (g) Gelofusine (h) Hartmann's solution (i) Hepatitis B vaccine (j) Hepatitis immunoglobin (k) Lidocaine hydrochloride (l) Morphine (m) Naloxone hydrochloride (n) Oxcytocins, natural and synthetic (o) Pethidine hydrochloride (p) Phytomenadione (q) Prochloperazine (r) Sodium chloride 0.9%	2. The medicine shall- (a) in the case of Lidocaine and Lidocaine hydrochloride, be administered only while attending on a woman in childbirth, and (b) where administration is- (i) by a registered midwife, be administered in the course of their professional practice; (ii) by a student midwife- (aa) be administered under the direct supervision of a registered midwife; and (bb) not include Diamorphine, Morphine or Pethidine hydrochloride

End notes

- 1. Article 44 of the Nursing and Midwifery Order 2001.
- 2. Article 45 of the Nursing and Midwifery Order 2001.
- 3. Article 40 of EU Directive 2005/36/EC on the recognition of professional qualifications, as amended by Directive 2013/55/EU of the European Parliament and of the Council.
- 4. Article 12A of the Nursing and Midwifery Order 2001.
- 5. The NMC is currently reviewing its standards of proficiency for midwives. In the future this will reflect any new MSO arrangements.
- 6. Section 11 of the Misuse of Drugs Regulations 2001, subject to amendment.
- 7. V300: Independent and supplementary prescribing
- 8. Section 2.1 Standards for supervision and assessment, NMC 17 May 2018
- 9. Regulation 7 Misuse of Drugs Regulations 2001
- 10. Regulation 214 The Human Medicines Regulations 2012: (3) The following are appropriate practitioners in relation to any prescription only medicine—
 - (a) a doctor;
 - (b) a dentist;
 - (c) a supplementary prescriber;
 - (d) a nurse independent prescriber; and
 - (e) a pharmacist independent prescriber.
 - (4) A community practitioner nurse prescriber is an appropriate practitioner in relation to a prescription only medicine specified in Schedule 13.
 - "Nurse independent prescriber" and "community practitioner" include a midwife with an appropriate prescribing annotation. This list sets out who can prescribe the full range of prescription only medication and does not affect the midwives' exemptions.
- 11. Student midwives do not appear on the register and do not fall within the regulatory reach of the NMC's fitness to practise process. It is a function of approved education institutions (AEIs) to identify and address any concerns about the conduct or health of a student midwife.
- 12. SI 2016/186
- 13. This was amended by Regulation 16(3) of the Human Medicines (Amendment) Regulations 2016/186.