1 Keeping Up to Date with Legal and Professional Frameworks for Non-Medical Prescribing

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Introduction

The purpose of this chapter is to consider the relevance of keeping up to date with legal and professional frameworks that govern non-medical prescribing. This has implications for both non-medical prescribers and the organisations that employ them.

Professional responsibility refers to the liability to be called to account for actions (Dimond 2008). The duty of care as a non-medical prescriber implies a responsibility to demonstrate appropriate knowledge in relation to the prescribing of drugs and medicines. This includes knowledge of the legal framework that governs the licensing, supply and administration of drugs and medicines as applied to the non-medical prescribing role. This also includes standards for professional practice, which relates to continuing professional development (CPD) and, although not legally binding, constitute best practice within non-medical prescribing.

This chapter outlines the current legal and professional frameworks for non-medical prescribing. Explicit reference will be made to significant legal changes and professional recommendations for standards for non-medical prescribing. The chapter will also consider how the non-medical prescriber can keep up to date with these aspects once qualified and the role of the employer in this process.

In our experience of running non-medical prescribing courses and providing CPD updates for non-medical prescribers, keeping up with changes in the legal and professional frameworks that underpin non-medical prescribing can be a challenging issue. This is because there have been rapid changes within these frameworks within a relatively short space of time, especially between the years 2002 and 2006.

The law as it applies to medicines

The term *law* here includes Acts of Parliament and Statutory Instruments and applies to legislation of the European Community and legislation of the state. The main legislation in the United Kingdom is the Medicines Act 1968 and the Misuse of Drugs Act 1971.

This legislation regulates the supply, storage and administration of medicines, and the purpose is to protect the public from harm. The Medicines Act 1968 is a comprehensive statute and encompasses the Medicines and Healthcare products Regulatory Agency (MHRA) which is the governmental body that oversees the licensing and safety of medicines. Furthermore the Medicines Act 1968 categorises drugs for purposes of sale and supply to the public into three groups: Pharmacy-only Products (P), General Sales List (GSL) and Prescription-only Medicines (POM).

The qualified non-medical prescriber has a duty of care to keep up to date with how these regulations are amended and with ongoing safety profiles as applied to the formulary of drugs within their sphere of competence. Timely information can be accessed from the MHRA website http://www.mhra.gov.uk/index.htm.

The British National Formulary (BNF), is a joint publication of the British Medical Association (BMA) and the Royal Pharmaceutical Society of Great Britain (RPSGB). It is published biannually and aims to provide prescribers with thorough and up to date information on the legal and clinical use of medicines, which includes medicine regulations.

The Misuse of Drugs Act 1971 lists and classifies controlled drugs and creates criminal offences in relation to the manufacture, supply and possession of controlled drugs, gives the Secretary of State the power to make regulations and directions to prevent misuse of controlled drugs and powers of search, arrest and forfeiture.

In 2001, the statutory instrument Misuse of Drug Regulations 2001 classified controlled drugs into five schedules outlining the requirements, which govern the import, export, production, supply possession, prescribing and record keeping. The non-medical prescriber has a duty of care to keep up to date with these schedules as applied to the formulary of drugs within their sphere of competence. Timely information can be accessed as an appendix of the BNF.

The law as it applies to non-medical prescribing roles

Independent prescribing

The Prescription by Nurses Act 1992 was implemented following the recommendations of the first Crown Report (DH 1989). This enabled

health visitors and district nurses who had completed specific training to prescribe from a designated limited formulary of medicines. Approximately 29,000 community nurses in the United Kingdom hold this qualification. Since May 2006, this is referred to as *community practitioner nurse prescribing* and it is still possible to undertake the training as a component of the Nursing and Midwifery Council (NMC) Specialist Community Practitioner Award.

A second Crown Report (DH 1999) was commissioned in order to provide strategic and consistent direction for extending prescribing rights and responsibilities to other groups of health professionals. The report outlined the sphere of possibilities for non-medical prescribing and explored the implications for professional bodies, National Health Service (NHS) organisations, education providers and other stakeholders. Following consultation on the report, Section 63 of the Health and Social Care Act 2001 amended the Medicines Act 1968, and The NHS Act 1977 Regulations were amended (Dimond 2008) in order to allow the extension of nurse prescribing from the Extended Independent Nurse Prescribers' Formulary. This allowed nurses, midwives and health visitors who had completed specific nurse-independent extended prescribing training to prescribe a limited range of drugs licensed to explicit medical conditions categorised under four headings: minor illness, minor injuries, palliative care and health promotion.

Following a number of incremental changes to increase the range of drugs and medical conditions, the Extended Independent Nurse Prescribers' Formulary became defunct on 1 May 2006 owing to the implementation of the Independent Prescribing (IP) Regulations 2006. This enables nurses, midwives, health visitors and pharmacists who have completed specific IP training to prescribe any licensed medicine (including private prescriptions) for any medical condition that the practitioner is competent to treat. This also includes a limited range of borderline substances and off-label prescribing where it constitutes best practice. For nurses, midwives and health visitors this also includes a limited range of controlled drugs where appropriate.

In 2007, further amendments enabled optometrists to prescribe licensed medicine (including private prescriptions) for any medical condition that the practitioner is competent to treat.

In July 2009 the MHRA announced that further legal changes would take place by the end of 2009 to enable independent nurse prescribers to prescribe unlicensed medicines where this constitutes best practice to treat any condition.

Responsibility for accrediting training courses for IP for optometrists will rest with the General Optical Council (GOC). Optometrists who pass the final assessment will receive an endorsement on their GOC registration to denote the additional qualification.

If the legislative timetable proceeds as anticipated, it is likely that the first cohort of optometrists with the IP qualification will appear in 2009.

Supplementary prescribing

The Crown Report (1999) also recommended the implementation of dependent prescribing, which is now known as *supplementary prescribing*. The intention was to enable prescribing to specific health-care professionals for the management of long-term conditions. In 2003, further amendments were made to the Health and Social Care Act 2001 to enable supplementary prescribing by nurses and pharmacists who had completed specific supplementary prescribing training. Unlike IP there was no specific formulary, although unlicensed medicines and controlled drugs were initially restricted. The crucial aspect about supplementary prescribing is the specific legal requirement that there is an individual patient clinical management plan in place prior to supplementary prescribing. A medical or dental independent prescriber and the supplementary prescriber with the agreement of the patient must draw up the clinical management plan. The clinical management plan specifies the medical conditions, the range of medicines and the parameters for referral back to and review by the independent prescriber. The independent prescriber within this context is responsible for the initial assessment and diagnosis for the medical condition of the patient as outlined in the clinical management plan.

In 2005, Department of Health (DH) podiatrists, chiropodists, physiotherapists and radiographers became eligible to train and become supplementary prescribers (DH 2005). Restrictions in relation to controlled drugs and unlicensed medicines were lifted at the same time.

A consultation on IP of controlled drugs by nurse and pharmacist-independent prescribers (Consultation MLX 3338) to consider broadening the range of controlled drugs available to these groups of prescribers closed in July 2006. The outcome of this consultation is still awaited, although it is anticipated that the legislation will be laid before Parliament to lift the restrictions around the prescribing of controlled drugs for independent non-medical prescribers.

In July 2009 the Department of Health published a scoping report on a project that had focused on the evidence base to extend prescribing rights for groups of allied health professionals (DH 2009). The rationale for the project was to explore the impact on the quality of patient care of current prescribing arrangements for these professional groups. Based on the findings of a scoping exercise the following recommendations have been made to the chief professional officers within the Department of Health. There is a need to carry out a two-phase project to consider the following:

Phase 1
Further evidence to support the progression of

- physiotherapists and podiatrists to train as independent prescribers;
- dieticians to train as supplementary prescribers.

Phase 2
Further evidence to support the progression of

- radiographers to train as independent prescribers;
- speech and language therapists, orthoptists and occupational therapists to train as supplementary prescribers.

These are currently recommendations only so the timescale for any outcomes is as yet unknown.

The non-medical prescriber, however, has a duty of care to keep up to date with legal changes that apply to their own sphere of prescribing. Griffiths (2006) points out that before any practitioner prescribes or administers a drug he or she should ensure that they have the legal right to do so.

The National Prescribing Centre (NPC) issues daily current awareness bulletins http://www.npc.co.uk/ecab/ecab.htm, which non-medical prescribers and their employers can subscribe to in order to receive daily email alerts. The bulletins contain a wealth of information on health and social care and this includes updates on legal and safety aspects of medicines.

When prescribing medicines, the prescriber is judged against the standard of an experienced prescriber carrying out that role. McHale & Tingle (2007) have highlighted the unequivocal perspective that the DH (2006) has about this in that prescribers are accountable for every aspect of their decision making. This means that they should prescribe only those medicines that they know to be safe and effective and appropriate to the patient and the condition being treated.

It is also important to point out that laws that relate to consent, confidentiality and record keeping also apply to the non-medical prescribing role.

Professional standards as applied to non-medical prescribing

The NMC, Health Professions Council (HPC), The Royal Pharmaceutical Society for Great Britain (RPSGB) and DH work in partnership with the NHS strategic organisations and appropriate education providers in order to develop quality assurance arrangements for professional health-care education. This includes non-medical prescribing.

The Health Act 1999 determined the functions of the NMC, one of which is to determine the standards of education and training for

admission to practise and give guidance about standards of conduct and performance.

The NMC was formerly referred to as the *United Kingdom Central Council for Nursing, Midwifery and Health Visiting*. The NMC (formerly UKCC) set specific standards for future professional practice known as *PREP* (1999). These were revised in April 2002 following the establishment of the NMC.

The rules to establish the new NMC register in August 2004 required that the time frames for meeting practice and CPD standards should both be 3 years. The date for implementation of this rule was August 2006 and has categorised into two domains, CPD education standard and practice standard. The requirements for the CPD standard is for registrants to undertake at least 35 hours of learning in 3 years prior to renewal of registration, maintain a personal profile of this learning activity and comply with requests from the NMC to audit compliance with these requirements.

The practice standard requires registrants to complete 450 hours every 3 years within the clinical area for which they hold professional registration.

The NMC is required by the Nursing and Midwifery Order 2001 (The Order) 'to establish from time to time standards of education, training, conduct and performance for nurses and midwives and to ensure the maintenance of those standards' [Article 3 (2)]. The Order also states 'the Council may make rules requiring registrants to undertake such continuing professional development, as it shall specify in standards'.

The NMC published *Standards of Proficiency for Nurse and Midwife Prescribers* in May 2006. This was to coincide with the implementation of the Independent Prescribing Regulations 2006 and set standards for the education and practice for all nurses and midwives who were either training or had qualified as prescribers. This includes community practitioner prescribers and independent and supplementary nurse prescribers. Standard 15 clearly states to the prescriber 'it is your responsibility to remain up to date with knowledge and skills to enable you to prescribe competently and safely'.

The NMC committed itself to developing the standards for CPD for nurse prescribers (Box 1.1) further, and interim measures were announced in September 2008 (NMC 2008a).

Box 1.1 Standards for CPD for non-medical prescribers registered with the NMC

- It is the non-medical prescriber's own accountability to remain competent and up to date with the tasks that are required within their prescribing role.
- Appraisal of CPD needs for non-medical prescribers should be part of an annual performance review using a recognised tool.

- This will determine the level of input for CPD for prescribers.
- Principles for CPD should equally apply to all levels of prescribers, for example, community practitioner nurse prescribers and non-medical prescribers.
- Applies to all prescribers irrespective of the clinical setting, for example, primary care, secondary care or private practice.
- A portfolio should be maintained in order to record achievement of learning needs and ongoing reflection.
- Employers should ensure that where CPD needs are recognised, they are supported by the employee and the employer and met to the satisfaction of all parties.
- Registrants are responsible for their own CPD but employers have a responsibility to help the registrants meet them.
- Practice requirements:
  - Should undertake assessments and make regular prescribing decisions
  - Does not apply to the number of prescriptions written
  - Hours spent in prescribing/making prescribing decisions should be counted.

The overall recommendations are to maintain the standards of PREP in that no additional time is required for either education or practice for CPD for non-medical prescribers. This could be viewed as a controversial move because the outcome of the Shipman Enquiry recommended mandatory CPD for all prescribers. The NMC, however, states that the Standards are considered to be an interim measure until the implementation of revalidation for all health-care professionals (DH 2007).

The rationale for standards of CPD for non-medical prescribers is in part due to the fact that one of the main categories of cases, which are reviewed by the NMC 'Fitness to Practice' panel, are in relation to medicines management issues, which includes prescribing.

The HPC have not published specific standards for CPD for non-medical prescribers but provide clear guidelines for CPD for all registrants (2006), which would apply where this concerns a non-medical prescribing role (Box 1.2).

Box 1.2 Standards for CPD for practitioners registered with the HPC

Maintenance of a continuous, up to date and accurate record of CPD to demonstrate that CPD activities

- are a mixture of learning activities relevant to current or future practice;
- seek to ensure that their CPD benefits the service user;
- present a written profile containing evidence of their CPD upon request.

All registered pharmacists have a professional obligation to maintain a record of their CPD. From autumn 2008, this is a mandatory requirement, and comprehensive guidance, templates and competencies

have been drawn up to set standards and assist the practitioner with appropriate learning activities and frameworks for recording these. This includes additional competencies for independent and supplementary prescribing where this role is appropriate. The template is available at the website http://www.uptodate.org.uk/home/PlanRecord.shtml.

Personal responsibility

All prescribers are liable to be responsible for their actions and accountable for keeping their skills and knowledge up to date, which is required in order to fulfil their prescribing role. This also involves consideration of the development of the ongoing scope of practice.

Hobden (2007) has suggested that prescribers should consider the use of the following tools to support CPD: 360 Appraisal, critical incident analysis, reflection and objective data, which may be available within practice.

All qualified non-medical prescribers are required to be assessed within a competency framework during prescribing training (NMC 2006).

Competency frameworks have potential as a useful tool when qualified as a prescriber in order to self-assess competency and identify CPD needs and integrate all of the tools as outlined by Hobden. This also supports the development of the portfolio, which is required to demonstrate CPD for non-medical prescribers. Ideally, a portfolio would demonstrate how, where and why the prescriber has achieved the relevant competencies and identify unmet learning needs.

The NPC Competency frameworks (NPC 2000, 2001, 2003a, 2004a, 2004b, 2006, 2007) are ideal for this and can be accessed at the website http://www.npc.co.uk/prescribers/competency_frameworks.htm.

An evaluation of independent nurse prescribing carried out by Latter *et al*. (2007) indicated that post-qualification, a high majority of participants had been able to maintain a wide range of the NPC competencies within their prescribing roles.

The competency frameworks also give the prescriber an opportunity to consider how they would like to receive CPD in relation to personal context and learning style (Figure 1.1). An example of how this could be adapted is illustrated below by using a sample of competencies.

Medicines management

In addition to guidance for non-medical prescribers the NMC (2008b) have also set standards for medicines management that covers aspects such as administration and storage of medicines. Similarly, the RPSGB

	I have had experience of doing this and can produce clear evidence	**I have had experience of doing this but can produce no evidence to demonstrate this**	**I would like CPD on this topic in the following ways**
Demonstrates the ability to use the British National Formulary safely by selecting the most appropriate drug, dose and formulation.	Reflection on prescribing case histories. Objective data, e.g. PACT		E-cab bulletins
Demonstrates the ability to identify inappropriate use of medications, including misuse, under and over-use.	Critical incident review		
Demonstrates the ability to review and report prescribing errors and near misses within a clinical governance framework.		I would like to explore this more fully within the context of my organisational setting	Action learning. Prescribing update study day

Figure 1.1 Use of a competency framework as a tool for CPD. PACT, Prescribing Analysis and Cost.

(2005) have set standards for the safe and secure handling of medicines from a team approach. The non-medical prescriber would be expected to have knowledge of these standards, especially where they are prescribing medicines that will be administered by other health-care professionals.

The role and responsibilities of the employer

The professional bodies (NMC, HPC & RPSGB) are clear that the employer has a responsibility to support non-medical prescribers in meeting their CPD needs.

In relation to non-medical prescribers who are registered with the NMC, employers are responsible for ensuring that the standards for PREP are met. Ideally this will be integrated into the non-medical prescribing policy (Chapter 3), which the employer will have put in place on behalf of the health-care organisation. The employer also has a duty to support the NMC Standards for CPD for non-medical prescribers (2008).

Scotland, Wales and Northern Ireland have devolved parliaments and have also developed legislation for non-medical prescribing. NHS Education for Scotland (NES) has a history of developing resources to support prescribers and their employing organisations. Accordingly the NES (2003) has developed a CPD tool to support the individual non-medical prescriber and identify the responsibility of the employer (Box 1.3). (http://www.nes.scot.nhs.uk).

Box 1.3 Employer's responsibility for CPD for non-medical prescribers (NES 2003)

- Identification of resources for CPD
- Use interprofessional opportunities for CPD
- Identify methods for CPD
- Identify appropriate timing and frequency of CPD
- Implement support systems for prescribers
- Record keeping and audit
  - What CPD has been undertaken within the organisation?
  - Have identified where CPD needs been met?
  - How have they been evaluated by participants?
  - What quality assurance processes are in place?
  - What are the outcomes of non-medical prescribing within practice?

This is a useful tool for all employers of non-medical prescribers. The individual chapters of this book provide a range of approaches and resources for CPD.

The NPC (2008) has recently published a guide for all NHS managers about what they need to know in relation to prescribing, the drugs bill and medicines management (http://www.npc.co.uk/policy/publications/publications.htm?type=all). This is a very useful resource for employers in order to support the CPD of prescribers because it contains basic facts about medicines, especially the legal framework and how medicines are supplied to patients and who should have the legal right to prescribe.

Accountability of the prescriber to the employer

The contract of employment outlines the instructions of the employer and it is anticipated that the employee will follow these instructions with appropriate levels of care and skill. If there is evidence of negligence, then the employer has the right to exert disciplinary

powers. It is therefore important that the employment contract and job description of a non-medical prescriber outlines the boundaries of the prescribing role that the employer wishes the non-medical prescriber to hold. (Refer Section 1:2 of Appendix 1 for an exemplar job description, which includes non-medical prescribing.) Similarly, processes need to be in place to ensure that the non-medical prescriber can remain competent within that role and the employer has a duty to develop and uphold these.

In our experience of running non-medical prescribing courses and CPD updates, non-medical prescribers report that they are much clearer about their own professional boundaries once they have completed a prescribing course and have more confidence in negotiating the boundaries of their individual prescribing role with their employers and other health-care professionals within their multidisciplinary teams.

Test your knowledge about the law as it applies to non-medical prescribing

(See Section 1:3 of Appendix 1 for answers.)

Test your knowledge

1. **What does professional responsibility mean in relation to non-medical prescribing?**
2. **What is the main legislation within the United Kingdom that relates to medicines?**
3. **What does this legislation regulate?**
4. **Name three resources, which can support a non-medical prescriber in keeping up to date with this legislation.**
5. **When did the Nurse Prescribers' Independent Extended Formulary become defunct?**
6. **What standards did the NMC implement on the same date?**
7. **Which professional groups can legally train and qualify as supplementary prescribers?**
8. **Which professional groups can practice as independent prescribers?**
9. **Which organisation has developed competency frameworks in order to support the CPD and education of non-medical prescribers?**

Conclusion

It is an important aspect of professional responsibility for non-medical prescribers to keep up to date with the legal and professional frameworks that regulate and govern their prescribing role and the tasks that they are required to carry out in relation to this.

Professional bodies leave no doubt to registrants that this is a personal responsibility; however, managers and employers also have a responsibility to support and develop this and also keep up to date with the developments within these frameworks and how they apply to the health-care organisation.

This chapter has outlined the current legal and professional frameworks that relate to non-medical prescribing and has identified accessible resources to support and facilitate this process. These resources will support both the non-medical prescriber and his or her employer to promote the ongoing development of non-medical prescribing, which is safe and effective.

Key learning points

- The 1968 Medicines Act and the 1971 Misuse of Drugs Act regulate the supply, storage and administration of medicines.
- Subsequent amendments to these acts and The Prescription by Nurses Act, 1992 have broadened the scope of professional groups who have prescribing rights.
- Professional standards for CPD, education and practice for these professional groups are being developed accordingly and include the following:
  - Requirements for PREP
  - NMC *Standards of Proficiency for Nurse and Midwife Prescribers* (2006)
  - NMC *Standards for CPD for Nurse and Midwife Prescribers* (2008a)
  - Standards for CPD for practitioners registered with the HPC (2006)
  - Standards for CPD for pharmacists RPSGB (2008)
  - *Standards for Medicines Management* (NMC 2008b)
- Explicit within these standards is the individual responsibility for the non-medical prescriber to keep up to date. This can be underpinned by the following:
  - Competency frameworks
  - Reflection on practice, identification of unmet learning needs and preference for how these can be met
- Explicit within these standards is the responsibility of managers and employers:
  - Identification of CPD needs
  - Identification of appropriate resources to meet these needs
  - Access to appropriate educational resources

Key resources in Section Three

- List of web resources for keeping up to date with legal and professional issues
- Example job description, demonstrating the clear incorporation of non-medical prescribing as a key element of the role
- Answers to 'Test your knowledge' quiz.

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