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Medicines management for nurses: exploring legal governance

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Abstract

There are multiple acts of law and case law that govern UK prescribing practice. This article looks at three aspects in particular: the classification and prescribing of controlled drugs, including the meaning of medicine classes and schedules and which healthcare professionals the law permits to prescribe; the prescribing of unlicensed medicines, including the difference between unlicensed and off-license medicines; and negligence in prescribing practice. The acts of law that are relevant to each topic are outlined and examples of significant case law or other legal rulings are provided to demonstrate how the law is relevant to nurses' clinical practice.

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Prescribing is a safety-critical activity in terms of the high volume of errors made and the potentially serious consequences, which can be life-changing or even fatal (Guthrie et al 2011, Guthrie 2016). Prescribing is also one of – if not the most – commonly applied interventions in healthcare (Elliot et al 2018, Cope et al 2020, NHS Confederation 2021). Clinical governance, knowledge and experience are essential factors in safe prescribing and legal governance provides boundaries that are designed to protect patients. The law provides both restrictions and permissions, which govern the clinical practice of prescribers.

This article discusses legal governance in three aspects of prescribing practice in the UK – the classification and prescribing of controlled drugs; the use of unlicensed medicines; and negligence in prescribing, with examples provided for each topic. Also in this article, legal governance is defined as a direct legal ruling in aspects of prescribing practice, either through an act of law or through case law. An act of law, otherwise known as an act of parliament, is a bill that has been approved in the UK House of Commons and House of Lords to create or amend a law (UK Parliament 2023). Case law follows a judge's ruling in a legal case that creates a precedent and therefore sets a legal standard (University of Exeter 2023).

Controlled drugs

Controlled drug classification

There are two acts of law that govern the production, possession, and supply of controlled drugs, the Misuse of Drugs Act 1971, and the Misuse of Drugs Regulations 2001 (and subsequent amendments).

The Misuse of Drugs Act 1971 prohibits the unlawful production, possession, and supply of illegal or controlled drugs, and details the custodial penalties for possession and supply and/or maximum fines. The Act prohibits certain activities in relation to controlled drugs such as their manufacture, supply and possession. The penalties for offences are graded according to the 'harmfulness attributable to a drug when it is misused' and are defined by three classes, A to C (Table 1).

Table 1. Examples of controlled drugs and their classification*

Controlled drug class	Example drugs	Comment
A	» Cocaine » Fentanyl » Methadone hydrochloride » Morphine	Class A drugs are considered to be the most harmful
B	» Oral amfetamine » Cannabis » Codeine phosphate » Dihydrocodeine tartrate » Ketamine » Phenobarbital	Class B drugs are considered less harmful than class A, but may be reclassified as class A if they are injectable
C	» Buprenorphine » Lorazepam » Khat » Nitrazepam » Testosterone » Zopiclone	Class C drugs are considered to be the least harmful of all controlled drugs

* Table 1 shows a small selection of controlled drugs as examples; the full list of controlled drugs is extensive and classification is detailed by the Home Office (2022)

Controlled drug scheduling

The Misuse of Drugs Regulations 2001 (and subsequent amendments) defines who is authorised to supply and possess controlled drugs in a professional capacity. According to the 2001 regulations, controlled drugs are divided into five schedules, each specifying the requirements governing such activities as import, export, production, supply, possession, prescribing and record keeping.

A controlled drug's schedule is determined by its level of medically therapeutic value and the potential for misuse and addiction, and therefore the potential level of harm to society. For example, schedule 1 controlled drugs are those deemed to have no therapeutic value. The 2001 regulations specify which drug schedules can be prescribed by which professions. For example, nurse prescribers are able to prescribe from schedules 2-5.

A drug's formulation is also a significant factor in its scheduling. For example, codeine phosphate appears in schedule 2 and schedule 5. Schedule 5 drugs have a wide therapeutic value and much less potential for addiction. This means that codeine is available over the counter as a low dose oral formulation at schedule 5. However, the injectable formulation of codeine, which has a narrower medical use and higher potential for addiction, is classified under schedule 2.

Table 2 provides examples of controlled drugs and the schedule they have been assigned to.

Table 2. Examples of controlled drugs and the schedule they have been assigned to*

Controlled drug schedule	Example drugs	Comment
1	» Oral amfetamine » Cannabis » Khat	» Drugs considered to have no therapeutic value » No legal justification for manufacture, possession or supply

2	» Cocaine » Codeine phosphate » Dihydrocodeine tartrate » Fentanyl » Ketamine » Methadone hydrochloride » Morphine	» Schedule 2 drugs can be prescribed » Possession is unlawful by anyone who has not been issued with a prescription
3	» Buprenorphine » Phenobarbital	» Schedule 3 drugs can be prescribed » Possession is unlawful by anyone who has not been issued with a prescription » The differences between schedule 2 and schedule 3 drugs are in their storage and the record-keeping required. Schedule 2 drugs have to be recorded in a controlled drug register and must be kept in locked storage. Schedule 3 drugs do not have to be recorded in a register, and do not have to be in locked storage with four exceptions: temazepam, buprenorphine.
4	» Nitrazepam » Testosterone » Zopiclone	» There are two parts to schedule 4: – Part 1 controls most benzodiazepines. Possession is unlawful by anyone who has not been issued a prescription – In part 2, drugs can be possessed providing they are for personal use
5	» Codeine » Dihydrocodeine » Morphine	» Schedule 5 drugs can be bought over the counter without a prescription, but only in certain formulations and at certain doses

* Table 2 shows a small selection of controlled drugs as examples; the full list of controlled drugs is extensive and scheduling is detailed by the Home Office (2022)

Prescribing controlled drugs

Independent and supplementary prescribers

There are two types of non-medical prescribers – independent and supplementary. Nurses and midwives and other healthcare professionals including pharmacists, physiotherapists, podiatrists, radiographers and optometrists may train as independent or supplementary prescribers (Society of Radiographers 2020, Health and Care Professions Council 2021).

An independent prescriber can prescribe any medicine for any condition within their clinical competence. Conversely, a supplementary prescriber may prescribe any medicine within their clinical competence provided it has been included in a patient-specific clinical management plan. This plan is an agreement between the independent prescriber, the supplementary prescriber and the patient, and defines the scope of prescribing for an individual patient. It is important to note that the independent prescriber who signs and oversees the clinical management plan is required under the Prescription Only Medicine (Human Use) Amendment Order 2003 to be a doctor or dentist.

The types of controlled drugs practitioners will be able to prescribe is set by their clinical scope of practice. For example, physiotherapists have a limited formulary of controlled drugs they can prescribe under independent prescriber status, with the specific drugs being identified in the relevant legislation (UK Statutory Instruments 2015).

In 2006, independent nurse and pharmacist prescribers in the UK were first permitted to prescribe controlled drugs under new legislation (The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006), but only from part of schedule 3. Six years later, further legislation permitted independent nurse and pharmacist prescribers to prescribe most controlled drugs from schedules 2-5 with an important exception – the legislation forbade the prescription of cocaine, diamorphine hydrochloride or dipipanone hydrochloride for individuals who are addicted to those drugs (UK Statutory Instruments 2012). To be able to prescribe or administer these drugs, the nurse or pharmacist prescriber has to hold a specific license from the Secretary of State (National Institute for Health and Care Excellence (NICE) 2023a).

In terms of supplementary prescribers, the Department of Health (2023) states that supplementary prescribers can prescribe controlled drugs (from schedules 2-5), but only according to a patient-specific clinical management plan.

Unlicensed and off-license medicines

A medicine prescribed off-license (also called off-label) is one that has a license for a particular condition but can be prescribed to treat another condition if there is no suitable alternative. In the case of prescribing off-license, the medicine's form does not change, nor is it mixed with any other medicine.

Conversely, an unlicensed medicine is one that is administered to the patient in a form, mixture or combination that is different from the manufactured original; or a medicine that is so new it is administered only during clinical trials and before it has been issued with a license. The mixing of one medicine with another creates a medicine that has not been manufactured, and therefore does not carry a license. Mixing medicines includes combining two or more drugs in a solution for injection, infusion or nebuliser, or crushing and mixing two oral tablets or capsule contents – these are then considered to be new medicines (Medicines and Healthcare products Regulatory Agency 2008). Mixing medicines can also involve taking multiple oral medicines at the same time, some of which should not be taken together. For example, neither the antibiotics erythromycin nor clarithromycin should be taken while a patient is also taking the statin atorvastatin (either orally or intravenously; drug interactions have to be considered regardless of the route of administration) – this is because the antibiotics inhibit the CYP3A enzyme, resulting in increased availability of the statin and effectively increasing its dose (Abu Mellal et al 2019, NICE 2023b). However, taking different medicines at the same time does not constitute unlicensed prescribing or mixing of medicines unless they are crushed and combined before administration. Putting a single medicine in a solution that simply acts as a vehicle for that medicine does not constitute mixing and means that the medicine will still be licensed. For example, putting amoxicillin in sodium chloride 0.9% for intravenous infusion is not unlicensed, because amoxicillin is the active drug and sodium chloride is a vehicle solution (Joint Formulary Committee 2023).

The Medicines (Exemptions and Miscellaneous Amendments) Order 2009 ensured it was legal for nurse and pharmacist independent prescribers to prescribe off-license and unlicensed medicines. Later, the Human Medicines Regulations 2012 stated that nurse and pharmacist supplementary prescribers can legally prescribe unlicensed medicines. Supplementary prescribers can also prescribe off-license and unlicensed medicines if these are included in a clinical management plan for an individual patient.

When prescribing unlicensed medicines, it is necessary for the prescriber to consider clinical need and why an unlicensed medicine or formulation is the best choice given a patient's particular circumstance. The prescriber's clinical and pharmaceutical knowledge should lead them to consider the risks versus benefit of the medicine or formulation and its possible side effects (as with any prescription), as well as altered absorption and how changing a medicine's formulation may also change its bioavailability (for example, removing the contents of a capsule might mean that they are digested and absorbed too soon with increased or decreased bioavailability). This includes understanding how mixed medicines interact with each other.

The following two examples demonstrate where care is required by nurses when mixing medicines:

» Example 1 – in palliative care anti-emesis, the corticosteroid dexamethasone is reported to be compatible with the antihistamine cyclizine when mixed in a syringe driver, although possibly incompatible at higher doses (NICE 2021a). However, cyclizine and the prokinetic metoclopramide hydrochloride are not compatible and should not be mixed because cyclizine is an antimuscarinic and blocks the action of metoclopramide (NICE 2021b).

» Example 2 – in the case of patients with respiratory conditions such as asthma, it is now understood that salbutamol and the antimuscarinic medicine ipratropium bromide are compatible when mixed in a nebuliser (Chen et al 2020). This is due to the medicines' compatible pH levels and aerosol characteristics when mixed, which otherwise could affect the absorption of the medicines (Chen et al 2020). However, it is recommended that any mixing of these two medicines only involves preservative-free formulations, because preservatives can affect the stability of the medicines (NHS Specialist Pharmacy Service 2022a).

For the nurse prescriber, clinical guidelines, pharmacological knowledge and good communication with pharmacists are all essential when navigating which drugs can be mixed. In addition, understanding how different medicines interact with each other is essential for nurses when weighing up the risks and benefits of mixing medicines.

Polypharmacy

Polypharmacy is a separate topic to unlicensed and off-license prescribing and should also not be confused with mixing medicines. Polypharmacy is referred to as either appropriate or problematic. Appropriate polypharmacy involves multiple medicines being prescribed to treat an individual's complex or multiple conditions, whereas problematic polypharmacy is where an individual is taking multiple medicines that are not clinically required. For nurses, medication reviews and communication with the patient are important factors in identifying which types of medicines are being taken (NHS Specialist Pharmacy Service 2022b).

Negligence in prescribing

The issue of negligence, where a practitioner does not fulfil the required standard of care and as a result the patient sustains injury – be it temporary, life-changing or fatal – is a concern for all prescribers. To prove there was negligence, there are three conditions that have to be fulfilled (Buckley 2023):

» That there was a duty of care.

» That the duty of care was breached.

» That the injury sustained was directly and demonstrably the result of the given breach of duty of care.

Establishing if a practitioner has a duty of care to a patient is perhaps the simplest step because if a patient presents to a healthcare professional, whether by referral, self-presentation or admission to a service, then the healthcare professional has a duty of care to that patient. Ascertaining whether that duty of care has been breached includes considering if the required standard of care has been met or not (Miola 2015).

These three conditions also relate back to informed consent. In terms of prescribing practice, informed consent and paying attention to any particular risks to that patient due to co-morbidities, interactions or contraindications with concurrent medicines are of particular importance. For example, if the patient agreed to take the prescribed medicines but was not made aware of the possible side-effects or risks and subsequently suffered as a result, this could be considered negligent behaviour on the part of the prescriber because the standards of informed consent would not have been met.

In the case of Wilsher v Essex Area Health Authority [1988], a junior doctor was initially found to be negligent for prescribing excessive oxygen for a premature baby who sustained blindness due to retrolental fibroplasia (a proliferative vascular retinopathy), which could have been predicted given the excess oxygen that was prescribed. The ruling considered that the doctor was negligent, giving rise to the principle that ignorance is no defence when the error is a result of missing information that is well known and readily available. However, the ruling of negligence was overruled on appeal because the baby had other medical complications and it could not be verified that the doctor's administration of excess oxygen was the sole cause of the blindness. This case demonstrated that proving that a breach in the standard of care was the direct cause of an injury is not always straightforward.

Another case showed that a failure in critical support skills could result in a devastating delay in providing a patient with the necessary medicines. In the case of FB v Princess Alexandra Hospital NHS Trust [2017], incomplete history taking and clinical examination by a junior doctor meant that the patient (FB) was not prescribed the necessary antibiotics in a timely manner and then suffered irreversible brain damage. The initial ruling was that the doctor's inexperience meant that they could not have been negligent. This was overruled on appeal because it was decided that the doctor's lack of experience did not mitigate incomplete history taking and clinical examination, which should have been in their skillset. In this case, the final ruling was that the doctor was negligent.

The following examples show that poor prescribing and negligent practice can have severe consequences for patients:

» Drug interactions – for the nurse, checking interactions is a critical part of prescribing procedure. Failure to do so can result in serious side effects and harm to the patient. Drug-to-drug interactions should be considered, for example taking statins concurrently with antibiotics such as erythromycin as mentioned above. Drug-to-disease interactions are also a consideration. For example, beta-blockers are appropriate for treating arrythmia, but as a class of drug they are contraindicated for people with asthma because they can cause bronchospasm and can be potentially fatal.

» Selecting the appropriate class of controlled drug as well as the correct drug for the patient's condition is safety-critical and relies on the knowledge and thoroughness of the prescriber. For example, using opioids to treat a patient's migraine can have poor outcomes, resulting in potential adverse physiological events and aggravation of nausea and vomiting (Tepper 2012).

» Another example of negligent practice is inaccurate dose calculation. For example, when switching a patient's prescription from one opioid to another, it must be remembered that the doses needed for therapeutic effect are not the same. For example, 100mg of pethidine hydrochloride for a patient's pain would be a reasonable therapeutic dose, but 100mg of diamorphine could be toxic and potentially fatal.

Conclusion

The prescribing of controlled drugs is dependent on the profession of the prescriber, and different limitations are placed on each profession. There are multiple factors to consider when deciding if an unlicensed medicine should be prescribed or not. Negligence in terms of prescribing practice can have catastrophic results through errors, poor clinical practice, and poor professional judgment. It is important for nurses to remember that legal governance provides clear boundaries that enable prescribing practice. However, legal

governance is only part of the framework for optimal clinical practice and nurses should also consider their professional and clinical standards, experience and knowledge when taking prescribing decisions.

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