Conflicting regulations on medicines and controlled drugs may expose pharmacists to criminal liability — the law must swiftly change

Contradictions in misuse of drugs regulations mean there are ways in which pharmacists dispensing controlled drugs could be seen to be breaking the law. Two decades after their last revision, these regulations are surely due a rethink.

There are inconsistences in the regulations surrounding controlled drugs.

Exactly which type of health professional can prescribe specific drugs is open to interpretation, but it is the pharmacist who dispenses these drugs who could be liable to criminal prosecution.

Laying out the law

Under the Misuse of Drugs Act 1971 (MDA) possession, production and supply, import or export of controlled drugs is totally prohibited — except under licence from the Home Secretary, or as allowed by regulations,[1 (ss. 3–5)] including the Misuse of Drugs Regulations 2001 (MDRs).[2]

While it is illegal to supply a controlled drug under s.4 of the MDA, a pharmacist may lawfully do so in accordance with provisions in reg.16 of the MDRs. Similarly, a patient is not guilty of the crime of possession of a controlled drug if it has been prescribed to them by an appropriate practitioner.[2 (reg. 10(2))]

Appropriate practitioners may write prescriptions for prescription-only medicines (POMs) by virtue reg. 214 of the Human Medicines Regulations 2012 (HMRs). Doctors, dentists, supplementary prescribers (SPs), nurse independent prescribers, and pharmacist independent prescribers are appropriate practitioners in relation to all POMs; while independent prescribers from healthcare professions (such as podiatrist independent prescribers) and “approved country health professionals” (that is, EU practitioners) are appropriate practitioners for certain POMs defined within the regulation.

A physiotherapist independent prescriber, for example, is an appropriate practitioner in relation to any POM, unless it contains a substance or product specified in Schedule 1, 2 or 3 to the MDRs other than dihydrocodeine; fentanyl; morphine; oxycodone; or temazepam.[3 (reg. 214(5B))] Schedule 1, 2 and 3 controlled drugs are designated by the HMRs as “products subject to special medical prescription.”[3 (reg. 213(3))]

Who can prescribe what?

Unfortunately, additional conditions for these “special medical prescriptions” are included not in the HMRs but in reg. 15 (‘Form of prescriptions’) of the MDRs. This regulation includes requirements that will be familiar to pharmacists, such as including the total quantity of the drug in both words and figures.

There are, of course, areas of overlap between medicines and drugs, but this fact is not well-served by provisions in the MDRs, which are unclear and even contradictory. For instance, controlled drugs included in reg. 214 of the HMRs are omitted from the MDRs, while other drugs are added; this creates a degree of ambiguity around who can prescribe what.[4] In the example of physiotherapist independent prescribers, the MDRs only permit physiotherapist IPs to prescribe the controlled drugs listed in reg. 214(5) of the HMRs for administration by a specified route (usually oral), plus two benzodiazepines that are not “products subject to special medical prescription.”

Independent prescribers including nurses and pharmacists, and physiotherapists and podiatrists are specifically authorised by regs. 6B and 6C the MDRs to prescribe controlled drugs; but, surprisingly, there is no equivalent provision for doctors and dentists, or radiographers and paramedics. While doctors and dentists are permitted by custom to prescribe controlled drugs, an interpretation of the law is that physiotherapists and podiatrists are not.[5-10]

This incongruity between relatively recent medicines regulations and ageing drugs legislation has been discussed at length;[4] however, there is also a significant degree of internal inconsistency within the MDRs themselves, which requires discussion and swift amendment.

Open to interpretation

Within the MDRs, the definition of a prescription states that it must be issued by a doctor, a nurse independent prescriber, a pharmacist independent prescriber, a supplementary prescriber or a dentist.[2 (reg. 2)] In unequivocally stating that only those groups can write prescriptions for controlled drugs, reg. 2 of the MDRs directly contradicts reg. 6C, which explicitly authorises both physiotherapist and podiatrist independent prescribers to prescribe medicines in this category.

One may interpret this in two ways. The first: a document written by a physiotherapist or podiatrist independent prescriber, which is otherwise fully compliant with all the requirements of reg.15 of the MDRs, would not authorise the supply of any Schedule 1, 2 or 3 controlled drugs, because “prescriptions” cannot be written by these practitioners. The authorisation in reg. 6C is therefore meaningless. Yet, current guidance from the Royal Pharmaceutical Society, the Chartered Society of Physiotherapy, and the Pharmaceutical Services

Negotiating Committee — among others — specifies these groups may prescribe the controlled drugs specified in reg. 6C of the MDRs.[10, 11 (p. 1706), 12-14]

In a second interpretation, one might determine that the definition of a prescription is invalid, in which case doctors and dentists cannot write prescriptions for controlled drugs because there is no equivalent to reg. 6C that authorises them to do so. Their authorisation to prescribe is implied by their inclusion in the definition of a prescription, which is now redundant.

At present, only nurse and pharmacist independent prescribers are authorised by each of the necessary elements, namely: regulation 214 of the HMRs; and regulations 2 and 6B of the MDRs to write prescriptions for Schedule 1, 2 and 3 controlled drugs. There would appear to be no workable solution to this that does not require a change to the definition of a prescription and/or explicit authorisation for doctors and dentists to prescribe controlled drugs as afforded to other groups by regs. 6B and 6C.

Internal inconsistencies of this kind exist throughout the MDRs. Regulation 6(2) states that any person who has in their possession a controlled drug that has been supplied against the prescription of a doctor or dentist, a registered nurse, a pharmacist independent prescriber, a physiotherapist independent prescriber, a chiropodist (not podiatrist, as specified in the HMRs) independent prescriber, or a supplementary prescriber, may supply that drug to any pharmacist for the purpose of destruction. This would appear to state that each of these groups may prescribe controlled drugs, which cannot be true as the law — however you choose to interpret it — is currently written.

Why this matters for pharmacists

Pharmacists wondering what this regulation means for them should know that poor drafting of this kind affects them — as the suppliers of controlled drugs — much more than it does those who write prescriptions for them.

The prescriber would not commit any offence in writing what they believed was a valid prescription, but both the pharmacist and the patient would commit the offences of supply and possession, respectively,[1 (ss. 4-5)] as no lawful order would exist that fulfils the requirements of regs. 8 to 10 of the MDRs.

At present, any pharmacist dispensing a controlled drug prescription issued by either a physiotherapist or podiatrist independent prescriber (or by a doctor or dentist, depending on which interpretation they prefer) would be doing so unlawfully within the letter of the MDRs.

Given the current guidance in this area, however, it seems unlikely that either a prosecution or fitness-to-practice proceedings would be the likely outcome of doing so. Nonetheless, this

leniency would be at the discretion of the Crown Prosecution Service or General Pharmaceutical Council.

Inconsistently drafted laws must change

Inconsistent and ambiguous drafting is not limited to just one area of the MDRs. As already stated, there are major inconsistencies between medicines regulations originating within the Department of Health and Social Care, and the drugs legislation arising from the Home Office, especially where these two areas of law overlap.

Elsewhere, regulations 8 and 9 of the MDRs deal with the production and supply of Schedule 2, 3, 4 and 5 controlled drugs. Rather than dealing with each of these prohibited acts for all schedules of controlled drugs within its own separate regulation, these have been organised in a way that deals with both acts simultaneously: once for drugs in Schedules 2 and 5; and again for Schedules 3 and 4. Although both deal with the same actions, there is little correlation between the two regulations. For example, persons authorised to supply Schedule 2 and 5 controlled drugs by paragraphs 2(d) and 2 (da) of reg. 8 are authorised to supply Schedule 3 and 4 controlled drugs by paragraph 3(b) of reg. 9. There appears to be no reason other than indifferent drafting to explain why these regulations should not correlate.

The Misuse of Drugs Regulations in the form that we currently recognise them first came into force some fourteen years after the Misuse of Drugs Act received its Royal Assent.[15] Another sixteen years passed before these regulations were revoked and re-enacted, with amendments, in December 2001.[2] As the twentieth anniversary of that date approaches, it is surely time to revisit these regulations with a view to ensuring that they are clear, unambiguous, and compatible with all other UK laws.

Cathal Thomas Gallagher, reader in healthcare ethics and law, Department of Clinical and Pharmaceutical Sciences, University of Hertfordshire.

The views and opinions expressed in this article are those of the author and do not necessarily reflect the official position of the University of Hertfordshire.

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