Case Report

Drug Science

Drug Science, Policy and Law
Volume 8: 1–5


Article reuse guidelines:
sagepub.com/journals-permissions
DOI: 10.1177/20503245221112582
journals.sagepub.com/home/dsp
SAGE

The Misuse of Drugs Regulations 2001: A case study in poor legislative drafting

Cathal T Gallagher

Abstract

The Misuse of Drugs Regulations 2001 (MDRs) create exemptions to the offences of possession, production, supply, and administration of controlled drugs (CDs), which are necessary to allow healthcare professionals to treat patients without rendering themselves liable to prosecution for various offences under the Misuse of Drugs Act 1971.

As the scope of healthcare in the UK grows to include extended roles for an increasing number of professions, so must the law be amended to allow for these. The MDRs were poorly drafted in their original form, and this has been compounded by twenty years of equally poor amendments, leading to a degree of inaccuracy and ambiguity that is no longer acceptable. These regulations both lack internal consistency, and fail to align with the Human Medicines Regulations, such that neither healthcare professionals, their regulators, nor their representative bodies agree on either the spirit or letter of the law.

There are fewer than 30 active regulations in the MDRs, of which more than half contain ambiguities originating from poor drafting. While these could be clarified by a further series of amendments, the time is right to learn from previous mistakes and start over afresh.

Keywords

Misuse of Drugs Regulations, legislative drafting, controlled drugs, healthcare professionals

Introduction

The effect of ss. 3-5 of the Misuse of Drugs Act 1971 (MDA) is to impose a total prohibition on the possession, production and supply, import or export of controlled drugs (CDs). There are legitimate reasons why various classes of people may have cause to engage in a prohibited act: for example, a police officer may be required to take possession of drugs at a crime scene in the course of her duty, or a doctor may need to supply diamorphine (heroin) to a patient in severe pain. To facilitate such actions, exemptions are made by the Misuse of Drugs Regulations 2001 (MDRs). For example, regs. 6(6) and 6(7) of the MDRs permit a police constable (when acting in the course of his duty as such) to lawfully have any controlled drug in his possession.

Further complications are introduced where healthcare is involved. Many medicines are both CDs, as defined by s. 2 of the MDA, and medicinal products, as defined by reg. 2 of the Human Medicines Regulations 2012 (HMRs). To allow healthcare practitioners to lawfully prescribe such medicines, regs. 6B and 6C of the MDRs (authority to prescribe CDs) must align with reg. 214 of the HMRs (sale or supply of prescription only medicines). As these regulations, which originate from the Home Office and the Department of Health and Social Care (DHSC), respectively, are poorly aligned, there is understandable confusion among practitioners as to the extent of their prescribing rights under the law. The law as currently written can be interpreted in two ways: either non-medical prescribers are being prevented from prescribing the full range of medicines that the Human Medicines Regulations permit, or doctors and dentists are not legally permitted to prescribe CDs under any circumstances. As the latter would be unthinkable in practice, it must be concluded that non-medical prescribers are being curbed, reducing the number of roles they can undertake within the Health Service and limiting their clinical effectiveness (Gallagher, 2021c). In the fifteen years since nurses and pharmacists were empowered as the first non-medical prescribers, the MDRs have been amended

University of Hertfordshire. College Lane, UK

Corresponding author:
Cathal T Gallagher, Reader in Healthcare Ethics and Law, Department of Clinical, Pharmaceutical and Biological Sciences, University of Hertfordshire. College Lane, Hatfield, AL10 9AB, UK.
Email: c.t.gallagher@herts.ac.uk

to include three contradictory lists of practitioners who may write prescriptions for CDs (Gallagher, 2021b). The definition of a prescription in reg. 2 states that it can only be issued by a doctor, a nurse independent prescriber, a pharmacist independent prescriber, a supplementary prescriber or a dentist, before going on to state in reg. 6C that both physiotherapist and podiatrist independent prescribers may write prescriptions for CDs. Regulation 6(2), however, states that a patient may supply a CD prescribed by a third distinct group of practitioners to any pharmacist for the purpose of destruction. This group includes *all* nurses, not just nurse independent prescribers. Furthermore, pharmacists dispensing CDs prescribed under the regulations by certain classes of non-medical prescribers are doing so unlawfully as the MDRs are currently written (Gallagher, 2021a). Regulation 2 of the MDRs states that a prescription must be issued by a doctor, a nurse independent prescriber, a pharmacist independent prescriber, a supplementary prescriber or a dentist In unequivocally stating that only those groups can write prescriptions for CDs, reg. 2 of the MDRs directly contradicts reg. 6C, which explicitly authorises both physiotherapist and podiatrist independent prescribers to prescribe medicines in this category. This situation undermines the ability of the allied health professions to fully utilise their skills within the current legislative framework (Fitzpatrick and Borthwick, 2022). For example, podiatrists across the country with requisite qualifications were supplying compound analgesics to their patients without realising that approvals outlined in the Human Medicines Regulations had been omitted from the Misuse of Drugs Regulations.

As most healthcare professionals are not legal scholars, they rely on guidance provided by their professional regulatory bodies to determine how the law affects them in their daily practice. The ambiguous way in which the MDRs have been drafted has led to a situation in which this guidance is inconsistent across health professions that share common prescribing rights (The Society and College of Radiographers, 2018; Health and Care Professions Council, 2018; College of Paramedics, 2018; Health Education England, 2019; Pharmaceutical Services Negotiating Committee, 2020).

Administration, production, supply and possession

While the inconsistencies between drugs and medicines legislation have been thoroughly discussed in the literature, inconsistent and ambiguous drafting is not limited to one area of the MDRs. This is best illustrated by regs. 7–10, which deal with exemptions to the crimes of administration, production, supply and possession of CDs.

Within the MDRs, CDs are classified into five schedules to which decreasingly strict "regimes of control" apply (Langley, 2021). The most stringent controls apply to Schedule 1 drugs, which have no use in medicine. Administration, production, supply and possession of these drugs are made lawful only under the terms of a license issued by the Secretary of State. In contrast, drugs in Schedules 2 through 5 are typically exempted by regulations.

Administration

Regulation 7 authorises certain classes of people to administer drugs to others under specific circumstances. Each paragraph lists a class (or classes) of people and the subset of CDs in Schedules 2–5 they may administer. As originally drafted, reg. 7(1) authorised any person to administer any drug specified in Schedule 5 to another. Doctors and dentists were permitted to administer any drug in Schedule 2, 3, or 4 to a patient under reg. 7(2), while reg. 7(3) allowed any person to do likewise "in accordance with the directions of a doctor or dentist". This thoughtful initial drafting has allowed this regulation to be amended six times to accommodate additional healthcare professionals, including: extended formulary nurse prescribers (Misuse of Drugs (Amendment) (No. 3) Regulations, 2003); nurse and pharmacist independent prescribers (Misuse of Drugs (Amendment No.2) Regulations, 2012; Misuse of Drugs (Amendment) Regulations; 2006); and physiotherapist and chiropodist independent prescribers (Misuse of Drugs (Amendment) (No. 2) Regulations, 2015), as their clinical expertise has broadened. So, for example, in the most recent version of the regulations, regs. 7(8) and 7(9) mirror the format of regs. 7(2) and 7(3) in authorising physiotherapist and chiropodist independent prescribers, and people acting in accordance with their directions, to administer a specified subset of drugs listed in Schedules 2–4.

Possession

Just as reg. 7 deals only with administration, so reg. 10 deals only with exemptions to the crime of possession with respect to all schedules of CDs. By reference to classes of people and schedules of drugs specified in other regulations, it allows groups including members of the General Pharmaceutical Council's inspectorate to possess Schedule 2 drugs, and others including the person in charge of a care home to possess drugs in Schedule 3. Again, this regulation has undergone several simple amendments to authorise additional classes of people to possess CDs as their professional roles have developed.

Production and supply

Given that regs. 7 and 10 address a single prohibited act each, one might reason that regs. 8 and 9 – being sandwiched between the two – would adopt a similar approach in dealing with the remaining crimes of production and

supply: however, rather than addressing each of these prohibited acts for all schedules of CDs within its own separate regulation, these regulations have been organised in a way that deals with both acts simultaneously: once (in reg. 8) for drugs in Schedules 2 and 5; and again (in reg. 9) for Schedules 3 and 4.

> *7.* ***Administration*** *of drugs in* ***Schedules 2, 3, 4 and 5***
>
> …
>
> *8.* ***Production and supply*** *of drugs in* ***Schedules 2 and 5***
>
> …
>
> *9.* ***Production and supply*** *of drugs in* ***Schedules 3 and 4***
>
> …
>
> *10.* ***Possession*** *of drugs in* ***Schedules 2, 3 and 4*** *[author's emphasis]*

The original drafting of regs. 8 and 9 can be traced back to the Misuse of Drugs Regulations 1982, in which these consecutive regulations each had six paragraphs, of which the first five broadly correlated in respect of their general area of relevance. Regs. 8(1) and 9(1), for example, differed only by their references to drugs in Schedules 2 & 5, and 3 & 4, respectively, and remain essentially identical after several amendments.

As originally drafted, regs. 8(2) and 9(2) also match almost verbatim in terms of their content, but two classes of practitioner who may supply Schedule 2 and 5 drugs are added under 8(2)(d) and (e), causing an offset to be introduced (**Figure 1**). So, while 8(2)(a)-(c) map perfectly against 9(2)(a)-(c), regs. 8(2)(f)-(j) are reproduced in 9(2)(d)-(h). Furthermore, those classes of people added under 8(2)(d) and (e), namely persons in charge of hospitals and sisters in charge of wards, respectively, are addressed in 9(3)(b) and (c), not later in 9(2) as might reasonably be expected. The introduction of new classes of exempted persons in respect to production or supply required two separate regulations to be amended, causing more differences to be introduced. Moreover, the form of these amendments have further complicated the layout: when reg. 8(2)(da) was introduced to allow "the person in charge … of an organisation providing ambulance services" to supply Schedule 2 and 5 CDs, the equivalent paragraph was not added at 9(3)(ba), which would at least have be consistent with the numbering of the former amendment. Rather, reg. 9(3)(b) was amended to include such organisations in addition to two pre-existing groups. A analogous inconsistency was introduced when identical amendments were added in regs. 8(2)(ea) and 9(3)(d), respectively, by the Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations (SI 2007/2154).

Regs. 8(4) and 9(4) were and remain essentially identical, as do 8(5) and 9(5). Paragraphs 7 and 8 were added to both regulations to allow for non-medical prescribers and patient group directions, respectively (Misuse of Drugs (Amendment) (No. 3) Regulations, 2003). The addition by the same set of amendment regulations of essentially identical paras. 2A to reg. 8, and 3A to reg. 9, caused these regulations to further diverge. Finally, yet another unnecessary divergence was introduced when an identical definition of drug addiction was added first to reg. 9(8)(c), and subsequently to 8(9).

> *8(8) Notwithstanding the provisions of section 4(1)(b) of the Act–*
> *…*
> *(b) a registered nurse or a person specified in Schedule 8 may … supply … ketamine … except … for the purpose of treating a person who is addicted to a drug.*
> *…*
> *8(9) For the purposes of paragraph (8)(b) above, a person shall be regarded as being addicted to a drug if, and only if, he has as a result of repeated administration become so dependent upon the drug that he has an overpowering desire for the administration of it to be continued.*
> *…*
>
> *9(8) Notwithstanding the provisions of section 4(1)(b) of the Act, a registered nurse or a person specified in Schedule 8 … may supply … Midazolam … except …*
>
> *(b) … for the purpose of treating a person who is addicted to a drug;*
>
> *(c) for the purposes of paragraph (b) above, a person shall be regarded as being addicted to a drug if, and only if, he has as a result of repeated administration become so dependent upon the drug that he has an overpowering desire for the administration of it to be continued.*

Design by committee?

There is no reason other than poor draftsmanship why these consecutive regulations should not correlate. This takes two forms, namely: poor initial drafting and inconsistent amending.

Regulations 7 to 10 each have two variables, namely actors (A) and drugs (D). While regs. 7 and 10 were drafted such that D is subordinate to A, regs. 8 and 9 are organised with A subordinate to D. This creates an unnecessary link between regs. 8 and 9, requiring amendments to either regulation to be carefully coordinated with the other. This careful coordination is not in evidence. In the original version, before any amendments were even made, there was offset between analogous regulations, which grew more pronounced with every amendment.

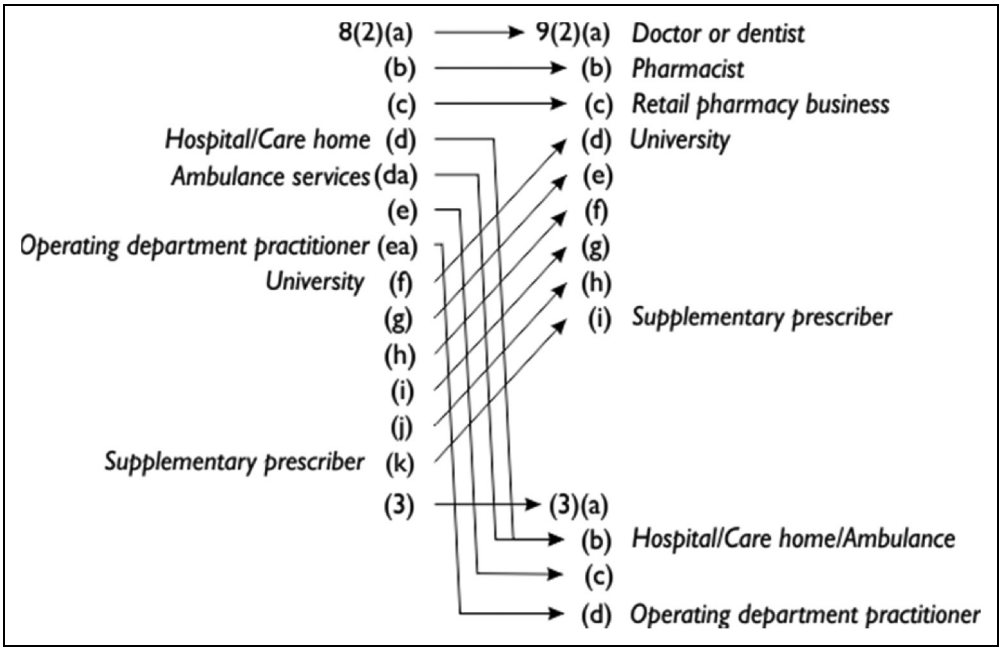

Figure 1. Current extent of the misalignment between the regulations permitting the same groups of clinicians and scientists to supply controlled drugs listed in Schedules 2 & 5 (reg. 8(2)) and Schedules 3 & 4 (regs. 9(2)-(3)) of the Misuse of Drugs Regulations 2001.

This has been further compounded by persistent inconsistencies in the location of corresponding amendments to regs. 8 and 9. While it might be possible to understand why the definition of a drug addict introduced at reg. 9(8)(c) in 2003 was reproduced in reg. 8(9) rather than in 8(8)(c) some twelve years later, the other two sets of amendments identified above were effected by consecutive paragraphs in the same amendment regulations (Misuse of Drugs (Amendment) (No. 3) Regulations, 2003, regs. 2(5) and 2(6); Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations, 2007, regs.4(5) and 4(6)). Although the identical wording of these amendments suggests a single hand, it defies logic that the same draftsperson would not amend interacting regulations in consecutive regulations in the same manner.

The need for consistency

Rather than having regs. 8 and 9 create exemptions for two separate unlawful acts each for a subset of drugs, it would make much more sense for each to deal with one single act for all drugs, as per regs. 7 and 10. This would alleviate the need for one to mirror the format of the other, as they each deal with unrelated acts. Decoupling regs. 8 and 9 in this way would require only one regulation to be exempted, rather than two. So, for example, the provisions of 8(1) (Production and supply of drugs in Schedules 2 and 5) and 9(1) (Production and supply of drugs in Schedules 3 and 4) that deal with production could be combined into a new regulation (called 8A here for simplicity). Within this regulation, each paragraph could refer to a different class of practitioner and to the subset of drugs which they are permitted to produce.

> *8A. Production of drugs in Schedules 2 to 5*
>
> *(1) Notwithstanding the provisions of section 4(1)(a) of the Act, any of the following persons, that is to say —*
>
> *(a) a practitioner;*
>
> *(b) a pharmacist;*
>
> *may, when acting in his capacity as such, may manufacture or compound any drug specified in Schedules 2 to 5;*
>
> …
>
> *(5) Notwithstanding the provisions of section 4(1)(a) of the Act, a person who is authorised by a written authority issued by the Secretary of State under and for the purposes of this sub-paragraph and for the time being in force may, at the premises specified in that authority and in compliance with any conditions so specified, produce any drug specified in Schedule 3 or 4.*

Equally, a single regulation dealing with supply of drugs in all schedules (9A) would allow for a major simplification of the MDRs.

9A. Supply of drugs in Schedules 2 to 5

(1) Notwithstanding the provisions of section 4(1)(a) of the Act, any of the following persons, that is to say —

(a) a practitioner;

(b) a pharmacist;

…

(m) a person who is authorised as a member of a group, under and in accordance with the terms of his group authority and in compliance with any conditions attached thereto;

may, when acting in his capacity as such, supply or offer to supply any drug specified in Schedule 2 to 5 to any person who may lawfully have that drug in his possession…

As with (proposed) reg. 8A, a new paragraph (9A(2), 9A(3)…) would apply to each relevant combination of Schedules 2–5 (e.g. 2, 3 and 4; 3 and 4, etc.) and list the classes of person for who an exemption exists.

Conclusion

Were the problems with the Misuse of Drugs Regulations limited to regs. 8 and 9, simply revoking these regulations and replacing them with new regulations in the style of 8A and 9A, above, might be a viable solution. If the current numbering was maintained, updating the internal cross-referencing would not be onerous. However, though serving as an excellent example of the unnecessary complexity of the current regulations, the poor standard of draftsmanship is not limited to these paragraphs alone. Significant ambiguities, inconsistencies, and errors in the wording of regs. 2, 3, 6, 6B, 6C, and 15, together with the potential consequences for healthcare practitioners, have already been identified (Gallagher, 2021a; Gallagher, 2021c; Gallagher, 2021b). Furthermore, regs. 20–24A each deal with an aspect of record-keeping. This could be regulated more efficiently and elegantly using a single consolidated regulation.

The first iteration of the Misuse of Drugs Regulations came into force some fourteen years after the Misuse of Drugs Act received its Royal Assent. Another sixteen years passed before these regulations were revoked and re-enacted, with only minor amendments, by Misuse of Drugs Regulations 2001. As the twentieth anniversary of their coming into force has now passed, it is surely time to revisit these regulations with a view to ensuring that they are clear, unambiguous, and compatible with both the UK's current misuse of drugs and medicines regimes. There are fewer than 30 active regulations in the MDRs, of which more than half contain ambiguities originating from poor drafting. While these could be clarified by a further series of amendments, a better solution would be to draft a new set of regulations based on the recommendations made here and elsewhere. Rather than working in isolation, it should behove the Home Office to engage with colleagues at the DHSC in this undertaking. To satisfactorily regulate at the intersection of "law and order" and healthcare, it is essential that the government departments with each of these portfolios have a substantial input into the drafting of new regulations. This is doubly important in this case, as it is the DHSC that oversees those who are most affected by the Misuse of Drugs Regulations, which were enacted in large part to exempt healthcare professionals from the crimes created by the Misuse of Drugs Act 1971.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

References

Fitzpatrick MTJ and Borthwick AM (2022) A decade of independent prescribing in the UK: A review of progress. *Journal of Foot and Ankle Research* 15: 35.

Gallagher CT (2021a) Conflicting regulations on medicines and controlled drugs may expose pharmacists to criminal liability. *The Pharmaceutical Journal* 306: E1.

Gallagher CT (2021b) Simplifying the legal management of controlled drugs as medicines in the UK. *International Journal of Pharmacy Practice* 29: 401–402.

Gallagher CT (2021c) UK non-medical CD prescribing law: Permissive or restrictive? *The Prescriber* 31: 15–19.

Independent Prescribing and Paramedics: FAQs (2019) Winchester: Health Education England.

Langley CA (2021) Controlled drugs. In: Reissner DH and Langley CA (eds) *Dale and Appelbe's Pharmacy and Medicines Law*, 12th ed. London: Pharmaceutical Press, pp.272.

Medicines entitlements of our registered professions (2018) London: Health and Care Professions Council.

Misuse of Drugs (Amendment) (No. 3) Regulations 2003/2429 (2003) London: HMSO.

Misuse of Drugs (Amendment) Regulations 2006/986 (2006) London: HMSO.

Misuse of Drugs (Amendment No.2) (England Wales and Scotland) Regulations 2012/973 (2012) London: HMSO.

Misuse of Drugs (Amendment) (No. 2) (England Wales and Scotland) Regulations 2015/891. London: HMSO; 2015.

Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007/2154 (2007) London: HMSO.

Practice Guidance for Paramedic Independent and Supplementary Prescribers (2018) Bridgwater: College of Paramedics.

Practice Guidance for Radiographer Independent and/or Supplementary Prescribers (2018) London: The Society and College of Radiographers.

Who can prescribe what? (2020) London: Pharmaceutical Services Negotiating Committee.