Legal provisions for non-medical prescribing of controlled drugs in the UK: permissive or restrictive?

Cathal T Gallagher, reader in healthcare ethics and law

School of Life and Medical Sciences, University of Hertfordshire, College Lane, Hatfield, UK

Correspondence to:

Cathal Gallagher
School of Life and Medical Sciences
University of Hertfordshire
College Lane
Hatfield
AL10 9AB

Email: c.t.gallagher@herts.ac.uk

Phone: +44 (0)1707 285 075

Word count: 2,271 words

References: 26

Conflicts of Interest

The author declares no conflicts of interest.

Key messages

- Prescribing controlled drugs is not expressly prohibited by the Misuse of Drugs Act 1971: however, the Home Office is inconsistent in how it deals with different healthcare professions with the same prescribing rights imparted by the Human Medicines Regulations 2012 (HMRs).
- Due to the inconsistent drafting of amendments to the Misuse of Drugs Regulations 2001, and the subsequent interpretation of these by regulators and professional bodies alike, current guidance prohibits four classes of independent prescribers from prescribing to their full extent.
- Therapeutic radiographer and paramedic independent prescribers may arguably prescribe any CDs specified in reg.214 of the HMRs without any need for the Misuse of Drugs Regulations 2001 (MDRs) to be amended.
- Furthermore, physiotherapist and podiatrist independent prescribers may arguably prescribe any CDs specified in reg.214 of the HMRs regardless of their intended route of administration.
- Regulations 6B and 6C of the MDRs serve no legal function and should be removed.

Legal provisions for non-medical prescribing of controlled drugs in the UK: permissive or restrictive?

Standfirst

Current guidance on non-medical prescribing of controlled drugs is a misinterpretation of the law as written.

Legal facilitation of independent prescribing

Nursing and pharmacy were the first professions permitted to engage in independent non-medical prescribing following an amendment to reg.2 of the Prescription Only Medicines (Human Use) Order 1997 (POM Order) in May 2006.[1] Optometrists were added to this list of prescribers or "appropriate practitioners" in June 2008.[2] Continuation of the list was transferred to reg.214 of the Human Medicines Regulations 2012 (HMRs), which repealed much of the POM Order, in August 2012. Since that time, other professions have gained independent prescribing rights under the HMRs. These include: podiatrists and physiotherapists in August 2013;[3] therapeutic radiographers in April 2016;[4] and paramedics in April 2018.[5] Regulation 214 of the HMRs stipulates medicines – specifically, those containing certain controlled drugs (CDs) – that each group of appropriate practitioners are permitted to prescribe.

Doctors, dentists, supplementary prescribers (i.e. non-medical prescribers working under the terms of a clinical management plan co-signed by a doctor or dentist), nurse independent prescribers, and pharmacist independent prescribers are appropriate practitioners in relation to any prescription only medicine (POM), including all CDs.[6 (reg.214(3))] Optometrist independent prescribers cannot prescribe any "products subject to special medical prescription",[6 (reg.214(5))] which is the collective term for Schedule 1, 2 or 3 CDs.[6 (reg.213(3))] The more recently added independent prescribers (IPs) – podiatrist, physiotherapist, therapeutic radiographer, and paramedic – are prohibited by the HMRs from prescribing all such CDs, subject to profession-specific exemptions. It is worth emphasising at this point that the HMRs do not adopt a permissive stance in this regard: rather, they restrict the prescribing of all Schedule 1, 2 or 3 CDs, then exempt some CDs from that restriction.

The current interpretation of the law is that, in order for IPs to prescribe controlled drugs, they must be authorised by *both* the HMRs, which authorise practitioners to prescribe, and the Misuse of Drugs Regulations 2001 (MDRs), which permit the supply of CDs by certain classes of healthcare professionals. This in neatly summarised in *Dale and Appelbe's Pharmacy and Medicines Law*, which is held to be "pharmacy's 'bible' on questions of law":[7]

> "The [Human Medicines Regulations 2012] were amended in 2016 to permit therapeutic radiographer independent prescribers to prescribe certain [CDs], but … corresponding changes ha[ve] not yet been made to the Misuse of Drugs Regulations [2001] and so, in effect, such prescribing is not currently permitted."[8 (p.224)]

Similarly, following the most recent amendment to the HMRs in 2018, which identified paramedic independent prescribers as appropriate practitioners with regard to certain CDs, no corresponding amendment was made to the MDRs.[5] This has been interpreted by Health Education England (HEE) as meaning that "[s]ubject to changes to the Misuse of Drugs Act, paramedic independent prescribers may be permitted to prescribe certain controlled drugs to be administered via specified routes."[9]

The assertion that authorisation to prescribe CDs must come from the MDRs is reiterated by the professional bodies for both paramedics and radiographers, which each state that "[f]urther changes to home office regulations will be required for therapeutic radiographers to independently prescribe controlled drugs."[10, 11]

The Health and Care Professions Council (HCPC), which is the statutory regulator for many of the professions who may engage in non-medical prescribing, similarly states that "[i]ndependent prescribers cannot prescribe controlled drugs unless extra laws have been passed which allow their profession to do so."[12]

The status of therapeutic radiographer and paramedic IPs with regard to CD prescribing is listed on the Pharmaceutical Services Negotiating Committee (PSNC) website as "currently awaiting approval."[13]

This, it will be argued, is a misinterpretation of the law resulting from an initial, unnecessary amendment of the MDRs. This led to a cascade of subsequent amendments, which stopped abruptly in 2015 leaving only confusion in their wake.

Misuse of drugs legislation

The Misuse of Drugs Act 1971 (MDA) imposes a total prohibition on the possession, production and supply, import or export of CDs, except under licence from the Home Secretary, or as allowed by regulations,[14 (ss.3-5)] such as the Misuse of Drugs Regulations 2001.[15] For example, it is illegal to possess a CD under s.5 of the MDA: however, a police officer (acting in her capacity as such) may legally possess CDs by virtue on an exemption in reg.10 of the MDRs. This is so that a constable taking possession of drugs in the course of her duty is not by this action committing a crime herself. Similarly, a patient in possession of CDs supplied on prescription may legally supply those drugs to a pharmacist for the purpose of destruction.[15 (reg. 6(2))] In this way dangerous drugs that are subject to misuse can be safely and responsibly disposed of to the general benefit of society.

While the MDA does prohibit the possession, production, supply, import and export of CDs, it does not prohibit the act of prescribing CDs. For this reason, no regulation allowing CDs to be prescribed under specific circumstances or by specific classes of people is required.

Nurse and pharmacist independent prescribers

As stated above: doctors, dentists, and supplementary prescribers are defined by the HMRs as appropriate practitioners (prescribers) in relation to *any* prescription only medicine, which include those POMs containing CDs listed in Schedules 1, 2 and 3 of the MDRs.[6 (reg. 214(3)(a-c))] Practitioners are exempted by regulations made under s.7(3) of the MDA from the unlawful acts of production,[15 (regs.8(1) & 9(1))] and supply.[15 (regs.8(2) & 9(2))] It is not, however, unlawful under the Act to prescribe CDs, so no regulation allowing them to be prescribed under specific circumstances or by specific classes of people is required.

Nurse independent prescribers and pharmacist independent prescribers are also appropriate practitioners in relation to any POM (including CDs).[6 (reg. 214(3)(d-e))] For some reason, a corresponding regulation (6B) *was* entered into the MDRs giving "authority" for these groups to prescribe CDs,[15 (reg.6B(1))] though – to reiterate – no equivalent regulation exists for doctors, dentists or SPs.

Regulation 6B of the MDRs was added in error or – at the very least – unnecessarily, as nurse and pharmacists IPs already have the same status with regard to CD prescribing as doctors, dentists and SPs, none of which have a corresponding entry in the MDRs. The alternative to this is that neither doctors, dentists, nor supplementary prescribers can prescribe any Schedules 1, 2 or 3 controlled drugs.

Physiotherapist and podiatrist independent prescribers

Subsequently, reg.6C was added to the MDRs because, if it was necessary to make an amendment for nurses and pharmacists, then it must also be necessary for physiotherapists and podiatrists. This did not happen until June 2015, some two years after physiotherapist and podiatrist IPs were added to the list of appropriate practitioners in reg.214 of the HMRs.[16] During that two-year period, guidance stated that these IPs could not prescribe any CDs pending changes to the MDRs.[17, 18] Though these changes are now in place, it is easy to demonstrate that they have made absolutely no difference to the law. This is best illustrated by reference to **Table 1**, which compares those regulations in each of the HMRs and MDRs in relation to physiotherapist IPs.

Table 1: *Side-by-side comparison of reg.214(5B) of the Human Medicines Regulations 2012/1916 with reg.6C of the Misuse of Drugs Regulations 2001/3998. Italic and bold highlights are the author's.*

Human Medicines Regulations 2012; reg.214(5B)	**Misuse of Drugs Regulations 2001; reg.6C(1)**
A physiotherapist independent prescriber is an appropriate practitioner in relation to any prescription only medicine *unless* that medicinal product contains a product subject to special medical prescription *other than*:	A registered physiotherapist independent prescriber *may* prescribe any of the following controlled drugs for the treatment of organic disease or injury provided that the controlled drug is prescribed to be administered by the specified method:
—	diazepam **(by oral administration)**;
dihydrocodeine;	dihydrocodeine **(by oral administration)**;
fentanyl;	fentanyl **(by transdermal administration)**;
—	lorazepam **(by oral administration)**;
morphine;	morphine **(by oral administration or by injection)**;
oxycodone; or	oxycodone **(by oral administration)**; or
temazepam.	temazepam **(by oral administration)**.

As can be seen, reg.214(5B) of the HMRs permits a physiotherapist independent prescriber to prescribe any POM unless it contains a Schedule 1, 2 or 3 CD other than dihydrocodeine, fentanyl, morphine, oxycodone, or temazepam. As emphasised above, it achieves this by *restricting* the prescribing of Schedule 1, 2 or 3 CDs, then *exempting* five CDs from that restriction.

Regulation 6C(1) of the MDRs permits a physiotherapist independent prescriber to prescribe seven CDs, provided they are to be administered by a specified method. Note that reg. 6C(1) is permissive in its terms: it allows the prescribing of seven specific CDs, but does not restrict the prescribing of any others permitted by reg.214(5B) of the HMRs.

Of those seven drugs in reg.6C, two (diazepam and lorazepam) are in Schedule 4 and therefore not subject to any restriction under reg.214(5B) of the HMRs. The remaining five are subsets of the five drugs listed in reg.214(5B).

By direct comparison to the situation for doctors and dentists, it should be clear that it was already permissible for physiotherapist IPs to prescribe morphine – whether for oral administration or by any other route – prior to the insertion of reg.6C(1) to the MDRs, and – given the permissive terms of that regulation – it remained so afterwards. That is to say: reg.6C of the Misuse of Drugs Regulations 2001 has no legal function whatsoever.

Furthermore, prescriptions written by physiotherapists and podiatrists under the authority of reg.6C fail to meet the definition of a prescription in reg.2, which may only be issued by a doctor, dentist, SP, nurse IP, or pharmacist IP. The various legal exemptions from the crimes of possession and supply afforded to patients and pharmacists, respectively, by the existence of a prescription do not apply if it was written by a physiotherapist or podiatrist IP.

Therapeutic radiographer and paramedic independent prescribers

No amendment to reg.6C has been ever made to accommodate therapeutic radiographers or paramedics, though these professions became independent prescribers in 2016 and 2018, respectively.

The current situation from a legal perspective

Having asserted that regs. 6B and 6C of the MDRs are legally unnecessary, the question now becomes, “What CDs can be prescribed by independent prescribers?” Having dismissed the superfluous regulations from the MDRs, it is a simple matter of referring to reg.214 of the HMRs for this information, which is summarised in **Table 2**.

Table 2: *Summary of Schedule 1, 2 and 3 CDs that may be prescribed by appropriate practitioners, as defined in reg.214 of the Human Medicines Regulations 2001.*

Appropriate practitioner	**Permitted CDs**
Doctor	all CDs
Dentist	all CDs
Supplementary prescriber	all CDs
Nurse independent prescriber	all CDs
Pharmacist independent prescriber	all CDs
Optometrist independent prescriber	no Schedule 1, 2 or 3
Podiatrist independent prescriber	dihydrocodeine temazepam
Physiotherapist independent prescriber	dihydrocodeine fentanyl morphine oxycodone temazepam
Therapeutic radiographer independent prescriber	codeine fentanyl midazolam morphine oxycodone temazepam tramadol
Paramedic independent prescriber	codeine fentanyl midazolam

	morphine
EEA health professional	no Schedule 1, 2 or 3

Clinical consequences

Increasingly, there are opportunities for independent prescribers to work across a variety of healthcare settings, away from their clinical roles. The NHS Long Term Plan advocates the transition of suitably-qualified paramedics into primary care,[19(para.4.26)]) and the new 5-year framework for general practice contracts outlines funding support for both "first contact community paramedics" and "first contact physiotherapists" to be employed within primary care settings from 2021.[20(para.1.17)]

A recent systematic review of the contribution of paramedics in primary care suggests that this may be an appealing career move to many paramedics wishing to further develop their professional practice, and that paramedics are among the group of allied health professionals who are attractive to GP surgeries based on this funding.[21] Paramedics working in primary care settings have been shown to decrease GP workload by assessing and treating urgent, non-complex patients:[22 23] however, if patients must subsequently see a GP in order to have certain medicines prescribed, paramedic independent prescribers may seem like a less attractive hire than either nurses or pharmacists.[24] In such cases, patients may fail to see the purpose of an assessment undertaken by a paramedic.[25]

Addendum: supply to addicts

The only necessary amendment made in reg.6B of the MDRs is that prohibiting – using restrictive language – nurse and pharmacist IPs from prescribing cocaine, heroin or dipipanone for the treatment of addiction:[15 (regs.6B(2-3))] however, this could have been more straightforwardly achieved by instead amending reg. 3 of the Misuse of Drugs (Supply to Addicts) Regulations 1997, which places the same prohibition on doctors.[26]

Conclusions

The law as written can be interpreted in two ways: either independent prescribers, including physiotherapists, podiatrists, radiographers and paramedics 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. There is no third option. As the latter option 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.

The Home Office must draft amendment regulations:

1. removing regs.6B and 6C and associated minor amendments from the Misuse of Drugs Regulations 2001;
2. amending the definition of a prescription in reg.2; and
3. modifying reg.3 of the Misuse of Drugs (Supply to Addicts) Regulations 1997, to include nurse and pharmacist independent prescribers.

The HCPC, professional bodies representing the various categories of independent prescribers, providers of approved independent prescriber training, and the PSNC should amend their respective guidance to clarify that non-medical prescribers may legally prescribe any controlled drug identified in the relevant paragraph of reg.214 of the Human Medicines Regulations 2012.

Bibliography

1. Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006/915. London: HMSO 2006.
2. Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2008/1161. London: HMSO 2008.
3. Human Medicines (Amendment) Regulations 2013/1855. London: HMSO 2013.
4. Human Medicines (Amendment) Regulations 2016/186. London: HMSO 2016.
5. Human Medicines (Amendment) Regulations 2018/199. London: HMSO 2018.
6. Human Medicines Regulations 2012/1916. London: HMSO 2012.
7. A fitting legacy. *The Pharmaceutical Journal* 2013;291:339.

8. Pitchford K. Controlled Drugs. In: Wingfield J, Pitchford K, eds. Dale and Appelbes's Pharmacy and Medicines Law. 11th ed. London: Pharmaceutical Press 2017.
9. Independent Prescribing and Paramedics: FAQs. Winchester: Health Education England 2019.
10. Practice Guidance for Radiographer Independent and/or Supplementary Prescribers. London: The Society and College of Radiographers 2018.
11. Practice Guidance for Paramedic Independent and Supplementary Prescribers. Bridgwater: College of Paramedics 2018.
12. Medicines entitlements of our registered professions. London: Health & Care Professions Council 2018.
13. Who can prescribe what? London: Pharmaceutical Services Negotiating Committee 2020.
14. Misuse of Drugs Act 1971. Chapter 38. London: HMSO 1971.
15. Misuse of Drugs Regulations 2001/3998. London: HMSO 2001.
16. Misuse of Drugs (Amendment) (No. 2) (England Wales and Scotland) Regulations 2015/891. London: HMSO 2015.
17. Practice Guidance for Physiotherapist Supplementary and/or Independent Prescribers. 2nd ed. London: Chartered Society of Physiotherapy 2013.
18. Physiotherapists and podiatrists join ranks of independent prescribers. *The Pharmaceutical Journal* 2013;291:174.
19. The NHS Long Term Plan. London: NHS England 2019.
20. Investment and evolution: a five-year framework for GP contract reform to implement The NHS Long Term Plan. London: NHS England 2019.
21. Eaton G, Wong G, Williams V, et al. Contribution of paramedics in primary and urgent care: a systematic review. *British Journal of General Practice* 2020;70(695):e421-e26.
22. Eaton G. Taking healthcare to the community: the evolving role of paramedics. *Journal of Paramedic Practice* 2017;9(5):190-91.
23. Spence D. Bad Medicine: Good medicine — the GP paramedic. *British Journal of General Practice* 2017;67(660):314-14.
24. Mason S, Coleman P, O'Keeffe C, et al. The evolution of the emergency care practitioner role in England: experiences and impact. *Emergency Medicine Journal* 2006;23(6):435-39.

25. Halter M, Marlow T, Mohammed D, et al. A patient survey of out-of-hours care provided by Emergency Care Practitioners. *BMC emergency medicine* 2007;7:4. doi: 10.1186/1471-227x-7-4 [published Online First: 2007/06/19]
26. Misuse of Drugs (Supply to Addicts) Regulations 1997/1001. London: HMSO 1997.