

Simplifying the legal management of controlled drugs as medicines in the UK

In the UK, the management of controlled drugs (CDs) is achieved through two major pieces of legislation. The Misuse of Drugs Act 1971 (MDA) controls the export, import, production, supply and possession of dangerous or otherwise harmful drugs.^{[1](ss. 3-7A)} These substances are categorised into three classes (A-C) for the purpose of determining penalties for offences under the Act.^{[1](s. 25)} While the Act is largely prohibitive in its terms, it is recognised that many CDs have useful medical functions, and section 10 allows for regulations to be made to facilitate these functions. In England, Scotland and Wales, the Misuse of Drugs Regulations 2001 (MDRs) arrange controlled drugs into five schedules (1-5) defined by the regimes of control that must be applied when used for lawful purposes.^[2]

The MDRs provide legal means for various healthcare professionals to engage in activities that would otherwise be prohibited under the MDA. For example, a pharmacist may lawfully supply a controlled drug in accordance with provisions in reg.16 of the MDRs. Failing to adhere to these conditions would make the supply unlawful under s.4 of the MDA, rendering the pharmacist a drug dealer in the eyes of the law.

The Misuse of Drugs Regulations in the form that we currently recognise them first came into force in 1985, some fourteen years after the Misuse of Drugs Act received its Royal Assent.^[3] Another sixteen years passed before these regulations were revoked and re-enacted, with amendments, by Misuse of Drugs Regulations 2001. In the following twenty years, the landscape of healthcare provision has undergone significant changes, many of which have necessitated major amendments to the MDRs. We have now reached a point at which there have been so many piecemeal alterations to the regulations, they are riddled with inconsistencies and no longer fit-for-purpose.

In the fourteen years since nurses and pharmacists were empowered as the first non-medical prescribers, the MDRs have been amended to include three contradictory lists of practitioners who may write prescriptions for CDs. 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.^[4] Furthermore, reg. 6(2) states that a patient may supply a CD prescribed by a third distinct group of practitioners – which includes all nurses, not just independent prescribers – to any pharmacist for the purpose of destruction. Internal inconsistencies of this kind exist throughout the MDRs: regs. 8 and 9. deal with the production and supply of Schedule 2 and 5, and 3 and 4 CDs respectively. These consecutive regulations were originally drafted almost verbatim one from the other: however, following no fewer than nineteen amendments, there is no longer any correlation between these two sets of provisions.

There are also major incompatibilities between the MDRs and other regulations with which they interact. Many CDs are also medicines, and are also subject to the provisions of the Human Medicines Regulations 2012 (HMRs).^[5] One might reasonably expect amendments made to the MDRs with regard to the authorisation of non-medical prescribers to align with those in the HMRs: however, the list of medicines included in reg. 6C the MDRs does not correlate with the list in reg. 214 of the HMRs,^[6] despite being entered into law almost two years later.^[7] Furthermore, one could interpret the law as currently written to mean that doctors and dentists cannot write prescriptions for CDs because there is no explicit authority them to do so in the MDRs, as exists for independent prescribers.^[8]

At the very least, it is surely time to revisit the MDRs with a view to ensuring that they are clear, unambiguous, and compatible with both the UK's current misuse of drugs and medicines regimes. Ideally, it would be embraced as an opportunity to rethink the way the UK regulates by maintaining two separate systems of classification of the same controlled drugs: one for criminal, and one for medical purposes.

In the USA, for example, the Controlled Substances Act 1970 categorises drugs five schedules based on a combination of their potential for abuse, any medical benefits they may provide, and their risk to health.^{[9](s. 812)} Schedule I substances have a high potential for abuse, have no currently accepted medical use in treatment and are considered unsafe for use even under medical supervision; while Schedule V drugs have a low potential for abuse, a currently accepted medical use, but may lead to limited physical or psychological dependence.

Australian laws concerning CDs fall under the remit of individual States and Territories. In New South Wales (NSW), drugs and medicines containing drugs are subject to separate legislative frameworks. Medicinal products containing CDs are treated as medicines, not as narcotics.^[10, 11] NSW's medicines legislation imposes limitations on the use of CDs in medicine by restricting their distribution, prescription and administration to appropriately qualified and authorised persons.

An alternative to maintaining two parallel systems of drugs management, whether from these or other jurisdictions,^[12] should – at the very least – be given careful consideration during any consultation on new regulations for the handling of drugs of misuse.

Twenty years on from the enactment of the MDRs, it is appropriate that we revisit these regulations with a view to drafting a new legislative framework that will remain fit-for-purpose for another twenty years.

1. Misuse of Drugs Act 1971. Chapter 38. London: HMSO; 2021.
2. Misuse of Drugs Regulations 2001/3998. London: HMSO; 2021.
3. Misuse of Drugs Regulations 1985/2066. London: HMSO; 2001.
4. Gallagher, C.T., *Conflicting regulations on medicines and controlled drugs may expose pharmacists to criminal liability*. The Pharmaceutical Journal, 2021. **306**: p. E1.
5. Human Medicines Regulations 2012/1916. London: HMSO; 2021.
6. Human Medicines (Amendment) Regulations 2013/1855. London: HMSO; 2013.
7. Misuse of Drugs (Amendment) (No. 2) (England Wales and Scotland) Regulations 2015/891. London: HMSO; 2015.
8. Gallagher, C.T., *UK non-medical CD prescribing law: permissive or restrictive?* Prescriber, 2021. **31**(12): p. 15-19.
9. Controlled Substances Act 1970. United States Code: Title 21; Chapter 13. Washington DC: United States Government Publishing Office.
10. Poisons and Therapeutic Goods Act 1966. No. 31. Sydney: New South Wales Government; 2021.

11. Poisons and Therapeutic Goods Regulation 2008/392. Sydney: New South Wales Government; 2021.
12. Gallagher, C.T., et al., *Doctor or drug dealer? International legal provisions for the legitimate handling of drugs of abuse*. *Drug Science, Policy and Law*, 2020. **6**: p. E3.