1 Doctor or drug dealer? International legal provisions for

2 the legitimate handling of drugs of abuse

3	Cathal T. Gallagher,* Sanaa K. Atik, Libin Isse, and Sanpreet K. Mann
4 5	Department of Clinical and Pharmaceutical Sciences, University of Hertfordshire, Hatfield, Herts., UK
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	*Corresponding author: Department of Pharmacy, University of Hertfordshire,
26	Hatfield, Herts, AL10 9AB, UK. Tel: +44 (0)1707 285 075; Fax: +44 (0)1707 284 506.

27 Email: <u>c.t.gallagher@herts.ac.uk</u>

1 Doctor or drug dealer? International legal provisions for

2 the legitimate handling of drugs of abuse

3 Abstract

4 In this paper, we compare how five jurisdictions (the USA; UK; Canada; New

- 5 Zealand; and Australia) balance the disparate objectives of preventing the misuse of
- 6 drugs and allowing their legal use for medical purposes. The statutory law
- 7 underpinning each country's method of categorising drugs depict distinctive outlooks
- 8 from the different jurisdictions, as each works towards these same goals. In
- 9 examining how each country's legislation deals with controlled substances, initial
- 10 consideration will be given to whether drugs are categorised once only, or twice:
- 11 once for dealing with their criminal misuse; and again for ensuring their safe
- 12 medicinal use.
- 13 In effectively dealing with criminal activities associated with drugs of abuse,
- 14 Australia's system of imposing penalties based on the quantity of a drug possessed,
- 15 rather than on its grouping with other drugs of a broadly similar type offers the most
- 16 flexibility. In terms of managing the legitimate use of such drugs, however, it is
- 17 perhaps the least flexible of the four jurisdictions operating parallel systems of
- 18 categorisation. The greatest level of flexibility is offered by Canada and the UK,
- 19 which have functionally very similar protocols in this respect.

20 Keywords

21 Comparative law; categorisation of drugs; international drug statutes

22

1 Introduction

2 National drug-control legislation has a two-fold remit, namely: to carry out provisions

3 of international drug control treaties; and to allow legal use of drugs for useful

4 (usually medical) purposes.

5 Such legislation represents action in line with treaty commitments under the three

6 major drug control treaties currently in force, namely: the Single Convention on

7 Narcotic Drugs (Single Convention, 1961), the Convention on Psychotropic

8 Substances (Psychotropic Convention, 1971), and the Convention against Illicit

9 Traffic in Narcotic Drugs and Psychotropic Substances (Traffic Convention, 1988).

10 The Single Convention on Narcotic Drugs of 1961 is an international treaty to prohibit

11 production and supply of named narcotic drugs except under licence for specific

12 purposes, such as research and medical treatment. As its scope was limited to drugs

13 with opium-like effects, coca and cannabis, the Single Convention did not ban the

14 many newly-discovered psychoactive drugs, such as amphetamines, barbiturates,

15 benzodiazepines, and psychedelics, and these were subsequently dealt with under

16 the Psychotropic Convention. The Traffic Convention provides additional legal

17 mechanisms for enforcing the Single Convention and the Psychotropic Convention.

Since the Single Convention is not self-executing, signatories must pass laws to carry out its provisions, and the United Nations Office on Drugs and Crime (UNODC) works with countries' legislatures to ensure timely implementation. As a result, most of the national drug statutes in the UNODC's legal library share a high degree of conformity with the Single Convention and its supplementary treaties. The Single Convention has been used as the basis for the standardisation of national drug-

24 control laws.

25 Parallel to meeting international treaty obligations, national laws must make

26 provision for the safe and secure use of drugs for the benefit of society. This is

27 generally achieved by the implementation of so-called *regimes of control*, which may

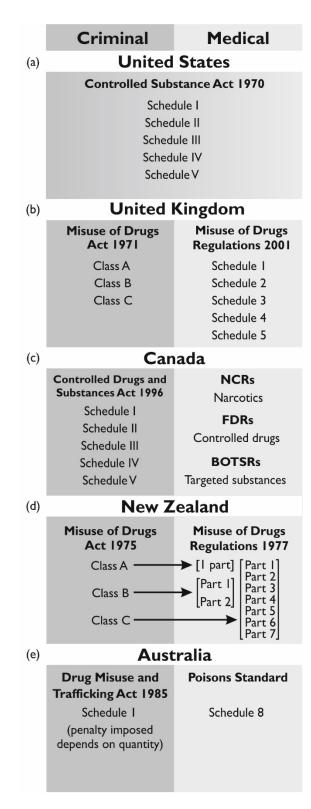
28 include provisions for safe custody, record-keeping, sale, supply, administration, and

29 destruction.

30 Here, we compare how five jurisdictions with roots in English common law – namely:

31 the USA; UK; Canada; New Zealand; and Australia – balance these opposing

1 objectives. The legal provisions underpinning each jurisdiction's method of 2 categorising drugs depict distinctive outlooks from the different authorities, as each 3 works towards these same goals. In examining how each country's legislation deals 4 with controlled substances, initial consideration will be given to whether drugs are 5 categorised once only, or twice: once for dealing with their criminal misuse; and 6 again for ensuring their safe medicinal use, as outlined in Figure 1. Where dual 7 categorisation is applied, a comparison of the subtly different systems and how their 8 two categories interplay will be made. We will discuss the relative merits of each of 9 the constituent legislative provisions from all five jurisdictions with a view to 10 assessing their relative strengths and weaknesses, and to assessing whether the 11 strongest and most flexible examples from each category could be combined for the 12 purpose of maximising medical benefit while minimising misuse.



- 1
- 2 Figure 1: Overview of the legal classification of drugs of misuse in (a) the United
- 3 States, (b) the United Kingdom, (c) Canada, (d) New Zealand, and (e) Australia.
- 4 Legislation prohibiting the possession, etc. of such drugs are listed in the left column
- 5 ("Criminal"), and regulations enabling their legitimate use in the right column
- 6 *("Medical").*

1 **USA**

2 Controlled substances

3 The Controlled Substance Act 1970 is the federal legislation controlling manufacture, 4 importation, possession, use, and distribution of controlled substances, including 5 hallucinogens, narcotics, depressants, and stimulants (Controlled Substances Act 6 1970; s. 801). The Act categorises drugs into five schedules based on their potential for abuse, any medical benefits they may provide, and their risk to health (Controlled 7 8 Substances Act 1970; s. 812). Schedule I substances, for example, have a high 9 potential for abuse, have no currently accepted medical use in treatment in the US, 10 and are considered unsafe for use, even under medical supervision (Controlled 11 Substances Act 1970; s. 812(b)(1)). This schedule includes diamorphine, LSD, 12 mescaline and peyote. To be valid, a controlled substance prescription must be 13 issued for a legitimate medical purpose by an individual practitioner acting in the 14 usual course of his professional practice (21 CFR; s. 1306.04(a), 2001). As such, 15 healthcare practitioners may not legitimately hold stocks of Schedule I drugs. At the 16 bottom end of the scale, Schedule V drugs, such as pregabalin, have a low potential 17 for abuse, a currently accepted medical use, but may lead to limited physical or 18 psychological dependence. Substances in Schedules II-IV contain drugs with 19 increasing medical benefits and reducing abuse potential between these two 20 extremes (Table 1). 21 The Controlled Substance Act was drafted to achieve uniformity between State laws 22 and those of the Federal government. It is a uniform Act sponsored by the Uniform 23 Law Commission (ULC) and intended to be enacted by each individual state with or

- 24 without changes (Guide to Uniform and Model Acts, 2018). It provides an interlocking
- trellis of Federal and State law to enable government at all levels to control more
- 26 effectively the drug abuse problem, and has been adopted by 44 States, including
- 27 California, which we will use as an exemplar in this discussion (Uniform Controlled
- 28 Substances Act 1973).
- In California's Uniform Controlled Substances Act 1973, controlled substances are
 those listed in s.11054-11058 (Uniform Controlled Substances Act 1973; s.11053).
- 31

- **Table 1:** Descriptors for abuse potential and medical benefit for controlled
- 2 substances as outlined in The Controlled Substances Act 1970, together with
- 3 examples from California's Uniform Controlled Substances Act 1973.

Schedule	Abuse potential	Medical use	(Addiction potential)	Examples
1	High	None	Unsafe, even under medical supervision	Diamorphine; dipipanone
2	High	Accepted (potentially with severe restrictions)	Severe psychological or physical dependence	Oxycodone; morphine; codeine
3	Less than Schedules 1 or 2	Accepted	Low or moderate physical dependence or severe psychological dependence	Ketamine; secobarbital
4	Less than Schedule 3	Accepted	None	Diazepam; modafinil
5	Less than Schedule 4	Accepted	Preparations containing limited quantities of certain narcotics	Not more than 200 milligrams of codeine per per 100 grams

1 **UK**

2 Controlled drugs

3 Classes

4 The Misuse of Drugs Act 1971 controls the export, import, production, supply and 5 possession of dangerous or otherwise harmful drugs (Misuse of Drugs Act 1971; ss. 6 3-7A). These substances are listed in Schedule 2 to the Act, and the term "controlled" 7 drug" means any substance or product so listed. The Schedule is divided into three 8 parts or classes largely on the basis of decreasing order of harmfulness: Part I 9 (Class A); Part II (Class B); and Part III (Class C). This division into three classes is 10 solely and specifically for the purpose of determining penalties for offences under the Act (Misuse of Drugs Act 1971; s. 25). 11

Although the Act functions primarily to prohibit any of the activities listed above, it is
 recognised that many controlled drugs have useful – often medical – functions, and

14 allowance is made in s. 10 of the Act for regulations to be made preventing the

- 15 misuse of controlled drugs in such circumstances.
- 16 Schedules

The Misuse of Drugs Regulations 2001 arrange controlled drugs into five schedules
defined by the regimes of control which must be applied to these drugs when used

defined by the regimes of control which must be applied to these drugs when used
 for lawful purposes (Misuse of Drugs Regulations 2001).¹ The five schedules are

20 numbered in descending order of control, with the most stringent controls applying to

- 21 drugs in Schedule 1.
- 22 Schedule 1 controlled drugs have no recognised medical use, and their production
- 23 and possession is limited to purposes of research or other special purposes. Very
- 24 few classes of person (e.g. police constables) have a general authority to possess
- these drugs in the course of their work, but others may only produce, supply or
- 26 possess the drugs within the authority of a licence issued by the Secretary of State
- 27 for the Home Department.(Misuse of Drugs Regulations 2001; reg. 7)

¹ In England, Scotland and Wales, controlled drugs are scheduled under the Misuse of Drugs Regulations 2001. In Northern Ireland, the same outcome is achieved under the Misuse of Drugs Regulations (Northern Ireland) 2002.

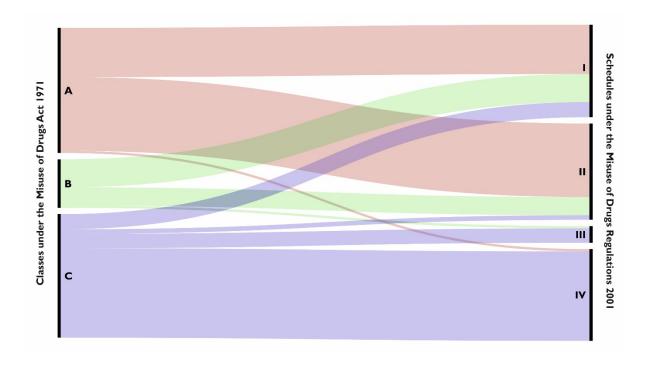
1 Schedule 2 includes opiates, amphetamines, and other drugs with a high potential 2 for misuse. A licence is needed to import or export drugs in this schedule, but they 3 may be manufactured or compounded by a practitioner, or a pharmacist when acting 4 in their capacity as such, or a person holding an appropriate licence. A pharmacist 5 may supply a Schedule 2 controlled drug to a patient only on the authority of a 6 prescription in the required form issued by an appropriate practitioner. (Misuse of 7 Drugs Regulations 2001; regs. 15 and 16) Special requirements as to custody and 8 destruction apply to these drugs, and the provisions relating to labelling of containers 9 and the keeping of records must also be observed (Misuse of Drugs Regulations

- 10 2001; regs. 18 and 19).
- 11 Most barbiturates and a number of minor stimulants are listed in Schedule 3, which
- 12 are not thought likely to be so harmful when misused as the drugs in Schedule 2.
- 13 The number of regulations that apply to each schedule are reduced as the schedule
- 14 number increases, as outlined in **Table 2**. For example, Schedule 2 drugs are
- 15 subject to record-keeping obligations under reg.19 of the regulations, which do not
- 16 apply to other Schedules; and drugs in Schedules 2 and 3 have specific
- 17 requirements as to the form of prescriptions (reg. 15), which are not applicable to
- 18 Schedule 4 or 5 drugs.
- 19 Schedule 4 is split into two parts: Part I contains the benzodiazepines, save a few
- 20 such as flunitrazepam and temazepam, which are in lower schedules for safety
- 21 reasons; Part II contains the anabolic and androgenic steroids. The major difference
- 22 between the two classes is that there is no restriction on the importation of Part II
- 23 drugs for self-administration (Misuse of Drugs Regulations 2001; reg. 4(2)).
- Schedule 5 specifies those preparations of certain Controlled Drugs for which there
 is only negligible risk of abuse, such as compound analgesics and opiate-based
 antitussives.
- 27 **Table 2:** UK Misuse of Drugs Regulations 2001 and the schedules of controlled
- 28 drugs to which they apply. Note that for Schedules 2 to 5, as the schedule increases,
- 29 the number of regulations applied to the drugs within it decrease.

Schedule	Regulations that apply
Schedule 1	14, 15, 16, 18, 19, 20, 23, 26, 27

Schedule 2	14, 15, 16, 18, 19, 20, 21, 23, 26, 27
Schedule 3	14, 15*, 16, 18, 22, 23, 24, 26, 27
Schedule 4, Part I	22, 23, 26, 27
Schedule 5	24, 26
	*except temazepam

2 The UK effectively maintains two separate lists of the same controlled drugs: one for 3 the purpose of preventing crime; and another for ensuring the safe and secure use of 4 such drugs for legitimate reasons, such as the treatment of injury (Figure 2). These 5 two lists are largely independent of one another: to move a drug from one class to 6 another, for example, requires the amendment of the 1971 Act, while changing its 7 schedule involves amending the 2001 Regulations. This level of independence 8 allows a drug's potential for abuse to be considered separately to its accepted 9 medical use when determining how it should be categorised. For example, 10 ethylphenidate, a stimulant with only moderate potential for misuse, but with no 11 recognised therapeutic use, is classified as Class B and Schedule 1, while 12 diamorphine, which has a significant history of abuse and an established medical 13 function can be categorised as Class A and Schedule 2. In contrast, diamorphine is 14 not a licensed medicine in the US, as its potential for abuse is deemed to far 15 outweigh its benefits through legitimate use, when both are considered together.



1

2 **Figure 2:** Alluvial diagram showing how the same 393 controlled drugs (or families

3 of structurally-related drugs) are categorised into three classes for the purpose of

4 fixing penalties, and five schedules for the purpose of maintaining regimes of control,

5 *in the United Kingdom.*

6 Canada

7 Controlled substances

- 8 The Controlled Drugs and Substances Act 1996 (CDSA) categorises all synthetic 9 and natural forms of controlled substances in terms of offenses and penalties 10 associated with their misuse. Controlled substances are defined as those named in 11 Schedules I-V of the Act (Controlled Drugs and Substances Act 1996; s.2.2) with 12 Schedule I substances attracting the most severe penalties, and Schedule V the 13 least severe. Substances are placed in their respective schedules based on whether 14 they have a currently accepted medical use in treatment in Canada, their relative 15 abuse potential, and their likelihood of causing dependence when abused.
- 16 The Governor-in-Council may define new regulations, to enforce the requirements of
- 17 the Act. This includes, but is not limited to, regulations regarding medical application
- 18 and distribution of controlled drugs (Controlled Drugs and Substances Act 1996; s.
- 19 **55(1)**). The Governor-in-Council may specify regulations affecting, for example, the
- 20 importation and exportation of controlled substances, their administration,

1 production, and packaging (Controlled Drugs and Substances Act 1996; s. 55(1)(a)).

2 Qualifications required by an individual performing certain activities with regard to

3 controlled substances may be specified by such regulations (Controlled Drugs and

4 Substances Act 1996; s. 55(1)(h)).

5 Narcotics and controlled drugs

6 Medicines containing controlled substances are scheduled according to the

- 7 regulatory framework within the CDSA. They are further categorised in terms of
- 8 regimes of control in accordance with several sets of regulations, namely: the
- 9 Narcotic Control Regulations (NCRs); the Food and Drug Regulations (FDRs); and

10 the Benzodiazepines and Other Targeted Substances Regulations (BOTSRs).

11 Narcotics

12 Narcotics are defined at those substances listed in the schedule to the NCRs, and

- 13 include: opiates; coca alkaloids; phenylpiperidines; moramides; morphinans; and
- 14 fentanyls. Any preparation intended for parenteral use; or containing only narcotic
- 15 substances (excluding excipients), or fewer than two non-narcotic medicinal
- 16 substances; or containing diamorphine, hydrocodone, methadone, oxycodone, or
- 17 pentazocine is defined as a narcotic drug. Narcotic preparations, also referred to as
- 18 verbal prescription narcotics, are those containing only one narcotic substance
- 19 together with two or more other medicinal ingredients at a recognised therapeutic
- 20 dose (Narcotic Control Regulations; reg. 2).
- 21 Controlled drugs
- 22 Controlled drugs are categorised in three parts, listed in the schedule to Part G of the
- 23 FDRs. The schedule is further subdivided into three parts. Part 1 includes
- 24 amphetamines; Part 2 lists barbiturates; and Part 3 contains the anabolic steroids.
- 25 Benzodiazepines and other targeted substances
- 26 Targeted substances are those listed in Schedule 1 of the BOTSRs. They are sub-
- 27 sorted in two classes. Class 1 Targeted Substances include most benzodiazepines,
- 28 meprobamate, zolpidem, and other depressants. There is currently only one Class 2
- 29 substance: the benzodiazepine, flunitrazepam. Schedule 2 of the regulations lists the
- 30 specified names (essentially, the international nonproprietary names) of the Targeted
- 31 Substances listed in Schedule 1.

1 New Zealand

2 Controlled drugs

3 A controlled drugs is any substance, preparation, mixture, or article specified or 4 described in Schedule 1, Schedule 2, or Schedule 3 of the Misuse of Drugs Act 1975 5 (Misuse of Drugs Act 1975; s. 2). Schedule 1 lists all Class A controlled drugs, Class 6 B controlled drugs are listed in Schedule 2, and Schedule 3 catalogues all controlled 7 drugs in Class C. Precursor substances are listed in Schedule 4. The classification of 8 a drug under the Act is based on the risk of harm the drug poses to individuals, or to 9 society, by its misuse (Misuse of Drugs Act 1975; s. 3A). Drugs that pose a very high 10 risk of harm are classified as Class A drugs; drugs posing a high risk of harm are 11 Class B; and those posing a moderate risk are in Class C. 12 Schedule 2 of the Act is further subcategorised into three parts; Schedule 3 is split 13 into seven parts. The different regimes of control needed to allow controlled drugs to 14 be put to their legitimate uses are contained in the Misuse of Drugs Regulations 15 1977, which were drafted with specific reference to these parts under s. 37 of the 16 Act. Schedule 1 and Part 1 of Schedule 2 are subject to regulations restricting import 17 and export (Misuse of Drugs Regulations 1977; reg. 7), supply (Misuse of Drugs 18 Regulations 1977; reg. 22), labelling (Misuse of Drugs Regulations 1977; reg. 25) 19 and custody (Misuse of Drugs Regulations 1977; reg. 28), as well as those which

20 apply to the much less-regulated Parts 6 and 7 of Schedule 3 (Misuse of Drugs

21 Regulations 1977; regs. 29, 31, 31A, and 35) with other parts subject to various

22 intermediate regimes (Table 3).

23 **Table 3:** New Zealand Misuse of Drugs Regulations and the categories of controlled

24 drugs, as described in the Misuse of Drugs Act 1975 to which they apply.

Class	Schedule	Regulations that apply
Class A	Schedule 1	3, 7, 22, 25, 28, 29, 31, 31A, 33, 35
Class B	Schedule 2, Part 1	3, 7, 22, 25, 28, 29, 31, 31A, 33, 35
	Schedule 2, Part 2	22, 25, 28, 29, 31, 31A, 33, 35
	Schedule 2, Part 3	25, 28, 29, 31, 31A, 33, 35

Class C	Schedule 3, Part 1	3, 7, 22, 25, 28, 29, 31, 31A, 35
	Schedule 3, Part 2	25, 28, 29, 31, 31A, 35
	Schedule 3, Part 3	25, 28, 29, 31, 31A, 35
	Schedule 3, Part 4	25, 28, 29, 31, 31A, 35
	Schedule 3, Part 5	25, 29, 31, 31A, 35
	Schedule 3, Part 6	29, 31, 31A, 35
	Schedule 3, Part 7	29, 31, 31A, 35

2 Australia

3 Prohibited drugs

In Australia, laws concerning the possession, supply and manufacture of illicit drugs
are largely the remit of States and Territories. As a consequence, illicit drugs are
defined slightly differently in each jurisdiction: however, there are federal controls
over imports and exports by virtue of international treaty obligations.

8 The Commonwealth *Narcotic Drugs Act* (1967) implements the Single Convention 9 (1966), and defines prohibited drugs by reference to it. Each of Australia's six states 10 and two mainland territories legislate separately to list the drugs and substances 11 prohibited in each jurisdiction, though there is near uniformity in their respective lists. 12 In New South Wales (NSW), Schedule 1 of the Drug Misuse and Trafficking Act 13 1985 lists all prohibited drugs for the purpose of defining offences (Drug Misuse and 14 Trafficking Act 1985). There is no explicit distinction between classes of drugs within 15 the schedule as exists in the UK: rather, the seriousness of the penalty imposed 16 depends on the weight or quantity of the drug seized, as set out in the schedule. For 17 example, a person found with less than 3g of cocaine would most likely be charged 18 with the summary offence of possession (Drug Misuse and Trafficking Act 1985; s. 19 10); and a person in possession of between 3g and 5g would be required to prove on 20 the balance of probabilities that he or she had the drug otherwise than for supply 21 (Drug Misuse and Trafficking Act 1985; ss. 30-31); while someone possessing 5g or more would automatically face the indictable charge of supply (Drug Misuse and 22 23 Trafficking Act 1985; s. 25). Unlike the other countries discussed here, which classify

- 1 drugs into three or five classes or schedules for the purpose of setting penalties,
- 2 Australia has a single schedule, which provides cut-off amounts for each drug with
- 3 regard to various offences, such as possession and trafficking (Table 4). It has, in
- 4 effect, 368 drug classes: one for each of the substances listed in Schedule 1 of the
- 5 Act.

6 Medicines

- 7 As with prohibited drugs, medicines are classified on a state-by-state basis against
- 8 federally-agreed standards. The Advisory Committee on Medicines Scheduling
- 9 (ACMS) established under paragraph 52B of the (Commonwealth) Therapeutic
- 10 Goods Act (1989) makes decisions at a federal level on the Standard for Uniform
- 11 Scheduling of Medicines and Poisons (SUSMP), or Poisons Standard (Standard for
- 12 Uniform Scheduling of Medicines and Poisons, 2019). ACMS decisions on the
- 13 SUSMP do not in themselves have the force of law: rather they are
- 14 recommendations for incorporation into state and territory legislation. The Poisons
- 15 Standard categorises all medicines and controlled drugs into ten schedules (Table
- 16 **5**). Schedule 8 lists controlled drugs.
- 17

Table 4: Extract from Schedule 1 of the New South Wales Drug Misuse and Trafficking Act 1985 giving cut-off amounts of selected common prohibited drugs for the purpose of determining offences under Part 2 of the Act. For example, a person who has not less than the traffickable quantity is deemed to have the prohibited drug in his or her possession for the purpose of supply.

Prohibited plant or drug	Small	Traffickable	Indictable	Commercial	Large commercial
Cannabis resin	5.0g	30.0g	90.0g	2.5kg	10.0kg
Cocaine	1.0g	3.0g	5.0g	0.25kg	1.0kg
Flunitrazepam	0.2g	0.6g	1g	0.1kg	0.5kg
Heroin	1.0g	3.0g	5.0g	0.25kg	1.0kg
Hydrocodone	1.0g	3.0g	5.0g	0.5kg	2.0kg
Methylamphetamine	1.0g	3.0g	5.0g	0.25kg	0.5kg
Morphine	1.0g	3.0g	5.0g	0.25kg	1.0kg
Oxycodone	2.5g	7.5g	12.5g	1.25kg	5.0kg

- **Table 5:** Schedules in the Standard for Uniform Scheduling of Medicines and
- 2 Poisons (Australia).

Schedule 1	Not currently in use
Schedule 2	Pharmacy Medicine
Schedule 3	Pharmacist Only Medicine
Schedule 4	Prescription Only Medicine
Schedule 5	Caution
Schedule 6	Poison
Schedule 7	Dangerous Poison
Schedule 8	Controlled Drug
Schedule 9	Prohibited Substance
Schedule 10	Substances of such danger to health as to warrant prohibition of sale, supply and use

4 Controlled drugs

5 Australia has no central body to regulate the handling of Schedule 8 drugs. Rather, 6 each state and territory self-regulates under the general principles established by the 7 federal Therapeutic Goods Administration (TGA) and has its own interpretation and 8 legislation regarding controlled drugs, resulting in varied requirements to ensure 9 legal compliance (Hua et al., 2015). Although each State and Territory is free to 10 interpret the SUSMP as it sees fit, the vast majority of medicines and poisons are 11 classified according to the SUSMP with a view to achieving uniform national 12 regulation.

- 1 In NSW, for example, the regulation of medicines, including controlled drugs, is set
- 2 out in the Poisons and Therapeutic Goods Act (1966) and the associated Poisons
- 3 and Therapeutic Goods Regulations (2008). It imposes limitations on the use of
- 4 controlled drugs by restricting their distribution, prescription and/or administration to
- 5 appropriately qualified and authorised persons.
- 6 In 2016, the NSW Government adopted Schedules 1 to 9 of the Poisons Standard as
- 7 a replacement for its own Poisons List (Poisons and Therapeutic Goods (Poisons
- 8 List) Proclamation 2016). Accordingly, all controlled drugs in NSW are as listed in
- 9 Schedule 8 of the SUSMP. Each state or territory enacts its own legislation defining
- 10 the requirements for storage and handling, prescriptions, labels and containers, etc.
- 11 Again, there is significant similitude between these various state laws.

12 **Discussion**

13 Four of the five jurisdictions examined here maintain two separate lists - one for 14 each of the primary remits of drug legislation – with only the US categorising drugs in 15 a single scheduling system for both use and misuse. Of the four, the UK, New 16 Zealand, and Canada classify drugs based on their potential for abuse for the 17 purposes of enforcement: the latter territory having five such hierarchical schedules, 18 while the others maintain three classes (Figure 2). These classes or schedules 19 generally include all drugs of the same functional type (e.g. opioids, amphetamines, 20 benzodiazepines), subject to specific exceptions. Only Australia's system of 21 classifying drugs is entirely independent of their mechanism of action; instead 22 specifying quantities at which increasingly serious charges may be levied for 23 possession of each individual drug. This recognises that different drugs from within 24 the same class may pose greatly differing levels of risk to public health through 25 misuse, effectively creating over 350 discrete classes of drugs for the purpose of 26 determining penalties, and statutory guidance as to which charges should be levelled 27 in court. Elsewhere, all drugs within the same class are subject to the same 28 penalties, and relevant circumstantial evidence including – for example – the quantity 29 of the drug, its presentation, or the accompanying possession of drug supply 30 paraphernalia or unexplained cash, play a significant role in what the relevant charge 31 will be.

1 In dealing with the legitimate use of controlled drugs, there is significantly more 2 variation between each country. While New Zealand's Misuse of Drugs Regulations 3 do categorise drugs on the basis of decreasing management requirements, the 4 categories are not independent of the three drug classes defined in their Misuse of 5 Drugs Act. Rather, classes are further subdivided into parts, which are subject to 6 decreasing regimes of control (Table 3). Thus, no Class C drug has more onerous 7 controls placed on its legitimate medical use than any drug in Class B, which itself is 8 subject to less control than Class A drugs.

9 In Australia, all Schedule 8 poisons (Controlled Drugs) from diamorphine to codeine 10 (as a single ingredient) are subject to the same regimes of control. This schedule -11 containing mostly opioids, together with ketamine and two benzodiazepines which 12 have been identified as particularly prone to misuse - maps well against Schedule 2 13 of the UK's Misuse of Drugs Regulations. However, other drugs – including most 14 benzodiazepines – which would be Schedules 3 or 4 CDs in the UK are classified as 15 Prescription Only Medicines (POMs) in Australia, and therefore subject to none of 16 the additional controls with respect to storage, record-keeping, etc. that such drug 17 warrant in former jurisdiction.

Australia's lack of any additional categories between POM and controlled drug greatly reduces the subtlety and granularity afforded by the UK's five schedules of controlled drugs. It essentially runs a binary system of controls for medicines, with products subject to either all additional controls or none. The UK, in contrast, utilises a series of gradually increasing restraints with regard to record-keeping, storage, possession and supply.

24 Canada's regimes of control, although generated through three separate sets of 25 regulations, are essentially very similar to those in force in the UK. The NCRs and 26 Parts 1 and 2 of the FDRs contain broadly the same range of drugs as Schedules 2 and 3 of the UK's MDRs, and those drugs listed in Part 3 of the FDRs and BOTSRs 27 28 map well against those in Schedule 4 of the MDRs. Compound preparations 29 containing low strengths or low doses of narcotics are treated as medicines, which 30 are scheduled under the NDS: under UK regulations, such preparations would be 31 Schedule 5 controlled drugs, which are subject to only very slightly stricter controls 32 than other medicines.

1 Where a single schedule is maintained for all controlled substances based on a 2 combination of factors from both categories – as in the US – there exists the 3 possibility that a drug with tangible medical benefits may be placed into an 4 unnecessarily low schedule based on a perceived potential for abuse. Diamorphine, 5 for example, is licensed for the treatment of chronic pain in the UK, Australia, New 6 Zealand, and Canada, but not in the US. The reputation of diamorphine (heroin) as a 7 drug anchored in "powerful discourses of crime, death and pleasure" has seen it 8 listed in Schedule 1 of the US's Controlled Substance Act 1970 despite its 9 recognition as a useful analgesic elsewhere in the world (Schepelern Johansen and 10 Schepelern Johansen, 2015).

11 Most benzodiazepines are Class C drugs in the UK, as they have relatively little 12 capacity for harm, and so attract more lenient punishments for offences such as 13 possession or supply. Many benzodiazepines, such as diazepam, are widely used in 14 medicine and are classified as Schedule 4 controlled drugs, which are subject to 15 regimes of control only slightly more stringent than for other prescription-only 16 medicines (POMs). In common with other benzodiazepines, flunitrazepam is a Class 17 C drug: however, its tendency to induce anterograde amnesia in sufficient doses led 18 to its misuse in drug-facilitated sexual assault (DFSA), resulting in it being moved to 19 Schedule 3 in 1998 (Misuse of Drugs (Amendment) Regulations 1998; reg. 2(4)). 20 Schedule 3 drugs are subject to more stringent regulations with regard to security 21 (Misuse of Drugs (Safe Custody) Regulations 1973). This resulted in an additional 22 barrier to the diversion of flunitrazepam from legitimate sources without the need to 23 increase the punishment for its possession.

24 Conclusion

The benefit of maintaining two separate lists categorising the same controlled drugs
is that it recognises the disparity between the two main requirements of drug
legislation, namely: preventing the misuse of dangerous drugs to the detriment of
society; and allowing dangerous drugs to be used for the benefit of society. Such a
system allows for considerable flexibility with regard to how controlled drugs can be
managed, and how failure to comply with management regimes is punished.
In dealing with criminal activities associated with controlled substances, Australia's

32 system of imposing penalties based on the quantity of a drug possessed, rather than

1 on its often-arbitrary grouping with other drugs of a broadly similar type offers the

- 2 most flexibility. In terms of managing the legitimate use of such drugs, however, it is
- 3 perhaps the least flexible of the four jurisdictions operating parallel systems of
- 4 categorisation. The greatest level of flexibility is offered by Canada and the UK,
- 5 which have functionally very similar protocols in this respect, although the latter
- 6 manages to achieve the same goals using a single set of regulations compared to
- 7 the former's three.

8 Acknowledgements

- 9 The authors are grateful to Philip L. Hudson, owner of Beechwood Wellness
- 10 Pharmacy and past-president of the Ontario College of Pharmacists, for his early
- 11 guidance on Canadian pharmacy law.

12 Funding

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

15 **References**

- Benzodiazepines and Other Targeted Substances Regulations. Statutory Orders and
 Regulations/2000-217. Ottawa: Government of Canada Publications; 2019.
- 18 Controlled Drugs and Substances Act 1996. Revised Statutues of Canada. Chapter
- 19 19. Ottawa: Government of Canada Publications.
- 20 Controlled Substances Act 1970. United States Code: Title 21; Chapter 13.
- 21 Washington DC: United States Government Publishing Office.
- 22 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.
- 23 Vienna: United Nations; 1988.
- 24 Convention on Psychotropic Substances. Vienna: United Nations; 1971.

1	Drug Enforcement Administration (Department of Justice). Code of Federal
2	Regulations: Title 21; Chapter 2. Washington DC: United States Government
3	Publishing Office.
4	Drug Misuse and Trafficking Act 1985. No. 226. Sydney: New South Wales
5	Government; 2019.
6	Food and Drugs Regulations. Consolidated Regulations of Canada. Chapter 870.
7	Ottawa: Government of Canada Publications; 2019.
8	Guide to Uniform and Model Acts 2018-19. Chicago: Uniform Law Commission;
9	2018.
10	Hua AC, Shen F and Ge X. (2015) State based legal requirement for Schedule 8
11	prescriptions: why so complicated? <i>Med J Aust</i> 203: 64-66.
12	Misuse of Drugs (Amendment) Regulations 1998/882. London: HMSO.
13	Misuse of Drugs Act 1971. Chapter 38. London: HMSO.
14	Misuse of Drugs Act 1975. No. 116. Wellington: Parliamentary Counsel Office.
15	Misuse of Drugs Regulations 1977/37. Wellington: Parliamentary Counsel Office.
16	Misuse of Drugs Regulations 2001/3998. London: HMSO.
17	(Misuse of Drugs (Safe Custody) Regulations 1973/798. London: HMSO.
18	Narcotic Control Regulations. Consolidated Regulations of Canada. Chapter 1061.
19	Ottawa: Government of Canada Publications; 2019.
20	Narcotic Drugs Act 1967. No. 53. Canberra: Office of Legislative Drafting and
21	Publishing; 2011.

- Poisons and Therapeutic Goods (Poisons List) Proclamation 2016/410. Sydney:
 New South Wales Government.
- Poisons and Therapeutic Goods Act 1966. No. 31. Sydney: New South Wales
 Government; 2019.
- 5 Poisons and Therapeutic Goods Regulation 2008/392. Sydney: New South Wales
 6 Government; 2019.
- Schepelern Johansen B and Schepelern Johansen K. (2015) Heroin: From Drug to
 Ambivalent Medicine. *Culture, Medicine, and Psychiatry* 39: 75-91.
- 9 Single Convention on Narcotic Drugs. Vienna: United Nations; 1966.
- Standard for Uniform Scheduling of Medicines and Poisons No. 23. Canberra: Office
 of Parliamentary Counsel; 2019.
- 12 Therapeutic Goods Act 1989. No. 21. Canberra: Therapeutic Good Administration;13 1990.
- 14 Uniform Controlled Substances Act 1973. Health and Safety Code. Division 10.
- 15 Sacramento: Office of Legislative Counsel.
- 16