

Chapter 5

Current approach to drug regulation

SUMMARY

This chapter identifies and discusses the different regulatory schemes under which psychoactive substances are currently regulated and explores how these apply. It concludes that psychoactive substances that may be harmful are all currently regulated as controlled drugs, other psychoactive medicines, hazardous substances, or food and cannot consequently be included in the restricted substances legislative scheme established by the Misuse of Drugs Amendment Act 2005. It also concludes that the role the Medicines Act 1981 plays in regulating controlled drugs is not transparent and it is difficult to determine the true extent of the authorisations that provide for the therapeutic use of controlled drugs. There are difficulties also in determining whether a substance is a medicine, a food, or a hazardous substance.

INTRODUCTION 5.1 Most drugs other than alcohol and tobacco are controlled and regulated under the Misuse of Drugs Act 1975. However, the Medicines Act 1981, the Hazardous Substances and New Organisms Act 1996, and to a lesser extent the Food Act 1981 also currently play a role in regulating the production, distribution and use of different groups of psychoactive substances that fall within the scope of the Commission's review. In this chapter we examine the regulation of:

- controlled drugs;
- other psychoactive medicines;
- hazardous substances;
- restricted substances; and
- psychoactive substances that have been incorporated into food.

Our main objective is to identify the regulatory issues and problems that arise at the interface between the Misuse of Drugs Act and these other legislative schemes, rather than to provide a detailed exploration of all of the relevant Acts. We do, however, examine the regulatory controls that apply to controlled drugs in some detail since these are central to our review.

CONTROLLED DRUGS

- 5.2 The most important group of psychoactive substances for our review are those that are currently regulated as controlled drugs.
- 5.3 A controlled drug is defined in the Misuse of Drugs Act as a substance, preparation, mixture, or article identified or described in Schedules 1, 2, or 3 of the Act. A controlled drug analogue is also a controlled drug under the definition.²⁷³ An analogue of a controlled drug is any substance that has a structure substantially similar to that of a controlled drug but is not itself specified or described as a controlled drug in Schedules 1, 2, or Parts 1 to 6 of Schedule 3. Any analogue of a controlled drug that is a pharmacy-only medicine, a restricted medicine or a prescription medicine under the Medicines Act is excluded from the definition of controlled drug analogue.²⁷⁴
- 5.4 Controlled drugs are regarded as the most harmful psychoactive substances and are therefore the most strictly controlled. Sections 6 and 7 of the Act prohibit all dealing in, or use of, a controlled drug that is not expressly authorised by the Act, by regulations made under it, or by a licence.

Authorisations

- 5.5 The Act provides for two types of authorisation: licences and statutory exemptions. The purposes for which licences may be granted are not defined in the statute and most of the detail of the licensing regime is left to the regulations. However, in practice there are three broad purposes for which licences are available: industrial use, research and therapeutic purposes. Of these, licensing for therapeutic purposes is by far the largest category. Most of the statutory exemptions relate to the use of controlled substances for therapeutic purposes.

Licences for industrial use and cultivation for industrial use

- 5.6 Licences are occasionally granted for the manufacture, import, export, supply or cultivation of a controlled drug for use in some industrial or production process. For example, licences authorise the cultivation and processing of industrial hemp (that is, cannabis plant with a very low THC content).²⁷⁵ Another example is licences relating to the Class B controlled drug gamma-hydroxybutyrate (GHB) commonly known as fantasy. Substances from which GHB can be derived are also Class B controlled drugs and are occasionally used in food production.

²⁷³ See section 2 of the Misuse of Drugs Act 1975 for the definition.

²⁷⁴ For the purposes of the definition of controlled drug analogue a pharmacy-only medicine, prescription medicine, and restricted medicine all have the same meaning as in the Medicines Act 1981. We discuss these classifications of medicines later in paragraphs 5.65–5.67 of this chapter.

²⁷⁵ It must generally be below 0.35 % and not above 0.5 %. The fruit and seeds of plants that qualify as industrial hemp are included in the definition. See Misuse of Drugs (Industrial Hemp) Regulations 2006, reg 4.

- 5.7 However, the use of controlled drugs in industrial processes is fairly rare and few licences are issued for this purpose. Currently there are approximately 10 licences that allow the cultivation and processing of industrial hemp and 10 licences for use in other industrial processes.

Licences for research

- 5.8 Licences are also granted authorising the importation, supply, possession and use of controlled drugs in research and drug studies.²⁷⁶ Cultivation licences can also be granted for the purposes of research. Again, this is a very small category of authorisation; there are currently approximately 21 research licences.

Authorisations for therapeutic purposes

- 5.9 Licences and statutory exemptions that authorise the manufacture, import or export, supply, possession and administration of controlled drugs for therapeutic purposes fall into three different categories:
- **licences** that authorise the manufacture, import, export, and supply of controlled drugs for use as medicines or for use in the manufacture or production of medicines;
 - **statutory exemptions** that authorise specified classes of institutions and people to produce, supply and use all controlled drugs that are approved as medicines under the Medicines Act; and
 - **statutory exemptions** that authorise medical practitioners, certain other authorised health practitioners, and suppliers to procure, sell, supply and administer controlled drugs that are unapproved medicines for the purposes of treating specific patients.
- 5.10 We describe the three categories of authorisations and the restrictions that apply to them in more detail below.

Application of Medicines Act

- 5.11 Before doing so, however, it is necessary to explain in general terms the relationship between the Misuse of Drugs Act and the Medicines Act. The therapeutic use of controlled drugs is regulated by both Acts. The definition of “medicine” in the Medicines Act is broad and includes any substance that is manufactured, imported, sold, or supplied wholly or principally for administration to a human being for a therapeutic purpose.²⁷⁷ It follows that controlled drugs that fall within this definition (because they are principally manufactured, sold or supplied for one of these purposes) are also medicines.²⁷⁸

276 A licence granted for research is the only type of licence that can authorise the consumption, injection or smoking of a controlled drug. See Misuse of Drugs Act 1975, s 14(3).

277 The term therapeutic purpose is also defined broadly and covers the treatment, prevention, and diagnosis of disease, induction of anaesthesia, or any other intervention in the normal operation of a physiological function in the body.

278 There is some uncertainty as to whether a number of controlled drugs, which are not normally used therapeutically, are medicines when they are occasionally used to treat people. These issues are considered later in paragraph 5.60.

- 5.12 Section 109 of the Medicines Act governs the relationship between the two Acts. It provides that when a controlled drug is also a medicine the requirements in the Medicines Act (other than those that require a person to hold a licence) apply in addition to those imposed under the Misuse of Drugs Act, unless they are inconsistent with it. In the event of any inconsistency, the Misuse of Drugs Act prevails. An important caveat on this is that the statutory exemptions in the Misuse of Drugs Act do not authorise any person to deal with, possess, or use a controlled drug that is also a medicine in a way that contravenes the provisions of the Medicines Act.
- 5.13 Where a person is authorised by a licence under the Misuse of Drugs Act to manufacture, pack, or sell a controlled drug that is a medicine he or she is deemed to be licensed under the Medicines Act to undertake that activity. In other words there is no need to also have a licence under the Medicines Act.

Licensing for therapeutic purposes

- 5.14 Licences are granted for two purposes:
- to import, export, manufacture, and supply controlled drugs for use as medicines; and
 - to manufacture any medicine that contains a controlled drug.²⁷⁹
- 5.15 An exemption in the Misuse of Drugs Act authorises the import, export and supply of Class C drugs contained in Schedule 3, Part 6 (Class C6 drugs) without a licence issued under the Act. Class C6 drugs contain small amounts of controlled drugs like codeine that have been compounded in a way that means that either the controlled drug cannot be readily recovered, or if it can the yield is not at a level that would constitute a risk to health.²⁸⁰ However, a licence is still required under the Medicines Act to pack and label or supply by wholesale such a drug because it is a medicine and the licensing requirements in the Medicines Act therefore apply.²⁸¹ It should also be noted that the exemption for Class C6 drugs does not cover manufacturing, so a licence under the Misuse of Drugs Act is required to manufacture a Class C6 drug.

279 Section 109 of the Medicines Act 1981 covers situations where controlled drugs are used as ingredients in the manufacture of medicines, but only partially. Where the resulting medicine is not a controlled drug but is another medicine, a licence authorising its manufacture must also be obtained under the Medicines Act. This second licence is not to authorise the use of the controlled drug, but is required to authorise the manufacture of the other medicine. Under the Medicines Act anyone manufacturing a medicine is required to be licensed unless he or she is covered by one of the exemptions that apply to health care professionals.

280 For example, in the case of codeine, the Act specifies not more than 100 milligrams of the controlled drug can be incorporated into each dosage. There is some concern that this level is actually too high. The exemption for Class C6 drugs may need to be looked at.

281 Class C6 controlled drugs are classified as pharmacy only medicines under the medicines regime.

Licensing practice under the Misuse of Drugs Act

- 5.16 Regulations under the Misuse of Drugs Act provide for three types of licences:
- **Dealers' licences** allow the holder to deal in controlled drugs.²⁸² They are required by pharmaceutical manufacturers, wholesalers and distributors. There are currently approximately 170 dealers' licences in New Zealand. Only four of these licences authorise the manufacture or use of controlled drugs in manufacturing. The rest cover the supply chain.
 - **Import and export licences**, as the name suggests, authorise the holder to import or export controlled drugs.²⁸³ Under section 14 conditions may be attached to any licence to export drugs to ensure that the laws of the country receiving the export are not contravened.²⁸⁴ Import and export licences are issued per consignment. A person must, however, have a lawful authority to possess the controlled drugs before they will be granted an import or export licence. This means that they either need to hold another type of licence (for example, a dealer's licence) that entitles them to possess the drugs, or be a health practitioner authorised by a statutory exemption.
 - **Cultivation licences** allow the holder to cultivate and process prohibited plants for the purposes of extracting controlled drugs for use as medicines. A cultivation licence could, for example, be granted to authorise the cultivation of opium poppies (*Papaver somniferum*) for the purposes of manufacturing morphine or the cultivation of cannabis for the purposes of making a THC-based medicine like Sativex®. In practice no cultivation licences have ever been granted for the purposes of cultivating cannabis, although recently cultivation licences have been granted for trials involving the cultivation of non-morphine *Papaver somniferum* poppies.
- 5.17 Applications for licences are made to the Director-General of Health and licensing is closely controlled by the Ministry of Health. Regulations require the careful vetting of the suitability of applicants and also require premises at which controlled drugs are used or stored to be secure and closely controlled. Licence holders must comply with all conditions that are imposed by the Act and the regulations and also with any other specific conditions that are imposed on their licence. All licences that are issued are for a specified time period and expire. Dealers' licences are issued for one year, so applications must be made annually to have them renewed. Licences are personal and cannot be assigned to another person.
- 5.18 The Director-General does not have the power to revoke a licence but the Minister of Health can revoke a licence at any time by notice in the *Gazette* if:
- the licensee is convicted of an offence against the Misuse of Drugs Act or Misuse of Drugs Regulations 1977;
 - the Minister is satisfied that the licensee has breached or not complied with any of the conditions pertaining to the licence; or

282 Misuse of Drugs Regulations 1977, reg 4. "Dealing" as defined in the regulations covers manufacturing, use in manufacturing and also the supply of controlled drugs to those legally authorised to receive them.

283 Misuse of Drugs Regulations 1977, reg 7.

284 Misuse of Drugs Act 1975, s 14(5).

- the Minister is satisfied that the licence was granted in error or because of any misrepresentation or fraud, or was granted without the Minister's permission in circumstances where permission was required.

5.19 We note the grounds on which a licence can be revoked are limited and do not, for example, include convictions for serious offences under the Crimes Act 1961 or the Medicines Act. It also seems odd that a licence can be granted by the Director-General but revoked only by the Minister. If the involvement of the Minister is intended to signal the seriousness of the decision, it would seem more logical to apply the requirement to the issuing of licences rather than their revocation, but why the Minister is involved at all is open to question.

Restrictions imposed on granting licences

5.20 There are some general restrictions that apply to licensing under the Misuse of Drugs Act. Some of these are in the Misuse of Drugs Act and some are imposed by regulations made under it.

5.21 The statutory restrictions are:

- Ministerial approval is required for the grant of a licence to a person who has been convicted of an offence against the Act (or its predecessors) or has had an earlier licence revoked.²⁸⁵
- Licences cannot authorise the consumption, injection or smoking of any controlled drug other than for research purposes.²⁸⁶
- Licences cannot be issued that would permit the import or export of opium for smoking.²⁸⁷ (This special provision relating to opium appears to be a historical anachronism.)

5.22 The regulatory restrictions are:

- The written approval of the Minister of Health is needed before the Director-General can grant a licence authorising the manufacture, use in manufacture, supply, import or export of any of the following controlled drugs:
 - any Class A drug other than cocaine or its isomers, esters, ethers or salts;
 - any Class B drug in Part 1 of Schedule 2 (Class B1 drug) except morphine or opium, or their isomers, esters, ethers or salts; and
 - any Class C drug in Part 1 of Schedule 3 (Class C1 drug).²⁸⁸
- Licences cannot authorise the cultivation of any plant of the species *Lophophora williamsii* or *Lophophora lewinii* for the purposes of producing mescaline or the plants *Psilocybe mexicana* or *Psilocybe cubensis* for the purposes of producing psilocine or psilocybine.²⁸⁹

5.23 We note that the restrictions imposed by the regulations are significant. They would, for example, preclude licences for the import or supply of cannabis for medicinal use without the approval of the Minister of Health. In our view, restrictions as fundamental as these should be in primary legislation rather than in regulations.

285 Misuse of Drugs Act 1975, s 14(4).

286 Misuse of Drugs Act 1975, s 14(3).

287 Misuse of Drugs Act 1975, s 14(2).

288 Misuse of Drugs Regulations 1977, reg 22.

289 Misuse of Drugs Regulations 1977, reg 8(2).

Statutory exemptions

- 5.24 Section 8 of the Misuse of Drugs Act contains a number of statutory exemptions that allow certain types of institutions and certain classes of people to undertake various authorised activities with controlled drugs. Further specific authorisations in the form of permissions are contained in regulations made under the Misuse of Drugs Act. These provisions give the impression that any person who falls within the terms of one of these exemptions is permitted to deal with or use controlled drugs in the ways authorised by the exemption, but that is not the case.
- 5.25 As we have already noted, the Medicines Act also applies to controlled drugs that are also medicines. The exemptions in section 8 of the Misuse of Drugs Act must therefore be read together with the requirements of the Medicines Act. It is necessary, therefore, to briefly explain the scheme of the Medicines Act before considering the section 8 exemptions.
- 5.26 Section 20 of the Medicines Act requires, with some exceptions, that medicines be assessed and approved or provisionally approved by the Minister before they can be sold or distributed as a medicine in New Zealand.²⁹⁰ The underlying policy behind the section is to ensure that medicines or therapeutic drugs cannot be released on the New Zealand market until the Minister is satisfied that there are no unacceptable risks.²⁹¹
- 5.27 However, it is essential to provide for some use of medicines before they have been approved. Sometimes a medicine will not have been approved for use or for a particular use in New Zealand but will still be the most effective treatment for a patient with a particular condition. Many medicines in this category will have already been assessed as effective and safe for use in other countries, although where medicines are being used under an exemption allowing for clinical trials of new medicines, there will often be no overseas approval.²⁹²
- 5.28 There are also a number of specialist hospital medicines, including some psychoactive medicines used as anaesthetics, which never get approved in New Zealand because the market for such medicines is too small to justify the costs associated with obtaining an approval. Other medicines have been approved but the approval has effectively lapsed after changes have been made to the medicine, and a new approval has not been obtained. To facilitate some closely controlled use of such medicines, the basic prohibition on dealing with unapproved medicines is subject to exemptions that permit use of unapproved medicines (either new or changed medicines) in limited circumstances.
- 5.29 Though it is by no means apparent on the face of the Misuse of Drugs Act, the section 8 exemptions operate differently depending upon whether the medicine is an approved medicine or an unapproved medicine. This lack

290 All medicines that became medicines for the first time when the Act was commenced, all older medicines that were not generally available in New Zealand before the Act came into force, and all older medicines that were not issued an approval under earlier legislation must be approved for use as medicines under the Act. A medicine that has been unavailable for a period of five years, even if it was generally available when the Act came into force will also need an approval under section 20.

291 *The Ministry of Health v Pacific Pharmaceuticals Limited* (8 December 2000) HC AK A165/00, para 26.

292 Exemptions covering clinical trials of new medicines are provided for in section 30 of the Medicines Act 1981. We do not discuss these further.

of transparency is unsatisfactory. The difficulty is compounded by the fact that the exemptions in the Misuse of Drugs Act and the exemptions in the Medicines Act are in different terms which sometimes makes it difficult to determine the precise scope of the exemptions.

Section 8 – exemptions and approved medicines

5.30 The main statutory exemptions that apply to controlled drugs that are approved as medicines are:

- Medical practitioners may, in the course of their professional practice or employment, prescribe, produce, manufacture, supply, or administer controlled drugs for treating conditions other than drug dependence.²⁹³
- Dentists or veterinarians may, in the course of their professional practice or employment, prescribe, produce, manufacture, supply, or administer controlled drugs.²⁹⁴
- Midwives may prescribe, supply, or administer the controlled drug *pethidine* and any other controlled drugs specified in regulation but may not do so for treating drug dependence.²⁹⁵
- Other groups of health professionals (termed “designated prescribers”) may, if expressly authorised by regulation, prescribe, supply or administer any controlled drugs specified in regulation but may not do so to treat drug dependence.²⁹⁶
- Medical practitioners specified by name in a *Gazette* notice issued by the Minister may prescribe, administer or supply controlled drugs for the purposes of treating a person for drug dependence. Medical practitioners working in hospitals and clinics that have been specified by the Minister in a *Gazette* notice may also prescribe, administer or supply controlled drugs as a treatment for drug dependence.²⁹⁷
- Other classes of health professionals authorised by standing orders may supply the specific controlled drugs in certain circumstances that are set out in the standing order.²⁹⁸ Standing orders are written instructions issued by medical practitioners, dentists, midwives and veterinarians.²⁹⁹ A commonly used standing order allows ambulance crews to carry and administer morphine and certain other controlled drugs for pain relief.
- Pharmacists and employees under their supervision may produce, manufacture or supply any controlled drug required to fill a lawfully issued prescription for that drug, and pharmacists employed in hospitals are also authorised to produce, manufacture or supply any controlled drug that is needed within the hospital.³⁰⁰

293 See Misuse of Drugs Act 1975, s 8(2)(a).

294 Ibid.

295 Misuse of Drugs Act 1975, s 8(2)(aa) and (2A)(a). To date no regulations have been made authorising midwives to prescribe any additional drugs.

296 Misuse of Drugs Act 1975, s 8(2A)(a). To date only one group of designated prescribers, designated prescriber nurses, have been authorised to prescribe up to three days supply of certain controlled drugs listed in Schedule 1A to the Misuse of Drugs Regulations 1977.

297 Misuse of Drugs Act 1975, s 24(2).

298 Misuse of Drugs Act 1975, s8(2A)(b).

299 Section 2 of the Misuse of Drugs Act 1975 provides that “standing order” has the same meaning as it has in section 2(1) of the Medicines Act 1981.

300 Misuse of Drugs Act 1975, s 8(2)(b) and (ba).

- Any pharmacy or other licensed medicines retailer may sell or supply any Class C6 controlled drug without a prescription.
 - Patients may procure and self-administer any controlled drugs that have been lawfully supplied or prescribed for them³⁰¹ and those responsible for the care of patients may administer controlled drugs to them in accordance with the directions given by the prescribing professional.³⁰² A similar exemption allows controlled drugs to be administered to an animal when they have been prescribed by a vet.³⁰³
 - Any person may, when leaving or entering New Zealand, possess up to one month's supply of any controlled drug that has been lawfully supplied or prescribed for them. Carers may also possess drugs on these terms to administer to someone under their care or control.³⁰⁴
 - Any person may procure and administer any C6 controlled drug.
 - District Health Boards and other certified hospitals and other institutions and any manager or licensee of a certified hospital or institution that has the care of patients for whom controlled drugs are lawfully prescribed or supplied may possess those drugs for the purposes of treatment of those patients.³⁰⁵
- 5.31 The scope of this last exemption for District Health Boards and other institutions is uncertain. It is not clear whether the exemption allows these institutions to hold general supplies of controlled drugs for the purposes of treating patients (as practicality may dictate) or whether they can only hold drugs that have been specifically prescribed for particular patients. There is also uncertainty as to what types of care providers fall within the definition of "other institutions". Does it include certified rest homes, for example? This is unsatisfactory. It is important that the exemptions are clear, since an offence under sections 6 or 7 will be committed if the scope of an exemption is exceeded.

Permissions in the Misuse of Drugs Regulations

- 5.32 Regulations create a number of other exemptions which are described in the regulations as permissions.
- 5.33 The main permissions in the regulations are:
- Any person may sell by retail or wholesale any Class C drug in Part 3 of Schedule 3 (Class C3 drug) (other than one containing pseudoephedrine).³⁰⁶
 - Pharmacies may sell Class C3 controlled drugs that contain pseudoephedrine by retail as "pharmacy-only medicines".³⁰⁷
 - Any person may procure and administer a Class C3 drug (including one that contains pseudoephedrine).³⁰⁸

301 Misuse of Drugs Act 1975, s 8(2)(c).

302 Misuse of Drugs Act 1975, s 8(2)(d) and (da).

303 Misuse of Drugs Act 1975, s 8(2)(e).

304 Misuse of Drugs Act 1975, s 8(2)(l).

305 Misuse of Drugs Act 1975, s 8(2)(f).

306 Misuse of Drugs Regulations 1977, reg 20.

307 Misuse of Drugs Regulations 1977, reg 20. This will soon change because the Government has adopted a policy change that will see legislation reclassifying pseudoephedrine as a Class B drug. Once legislation implementing that decision is in place pseudoephedrine will only be available on prescription.

308 Misuse of Drugs Regulations 1977, reg 20.

- Hospital and care institution managers in approved hospitals and institutions that have been specifically approved by the Director-General for the purpose may possess supplies of any Class C drug in Part 2 of Schedule 3 (Class C2 drug).³⁰⁹
- A controlled drug can be supplied in an emergency without a prescription, provided that this complies with other regulations governing emergencies.³¹⁰
- The master of a ship within New Zealand's territorial limits may possess, import, export, and administer any controlled drug legally allowed to be carried on that ship for the treatment of sick or injured people.³¹¹
- A person in charge of an aircraft within New Zealand's territorial limits may possess, import, export, and in an emergency administer any controlled drug legally allowed to be carried on the aircraft for the treatment of sick or injured people.³¹²
- Approved first-aid kits may contain controlled drugs for use in the event of emergency and any person having control of an approved first-aid kit may possess and administer to any person any controlled drug included in the approved first-aid kit. A controlled drug may also be supplied to a person who has control of an approved first-aid kit without a prescription.³¹³

5.34 We note that some of the permissions listed above authorise activities with controlled drugs that are otherwise prohibited under the Act. This appears to have been contemplated by the regulation-making power which authorise regulations.³¹⁴

[P]ermitting the import, export, possession, production, manufacture, procuring, supply, administration or use of any controlled drugs, and the cultivation of prohibited plants, otherwise than pursuant to a licence...

5.35 However, the breadth of this regulation-making power goes beyond that stipulated as appropriate by the Legislation Advisory Committee Guidelines. Generally regulations are subservient to the authorising statute on the basis that the Executive should not be able to override decisions made by Parliament. The inclusion of significant matters of policy in regulations is also inconsistent with contemporary standards of legislative practice as set down in the Legislation Advisory Committee Guidelines, which require that such matters are in primary legislation.

Exemptions in the Medicines Act

5.36 The Medicines Act also has exemptions for facilitating the use of medicines. These apply to controlled drugs that are approved medicines and must be read along with the section 8 exemptions. These are:

- Any medical practitioner, dentist, registered midwife, or designated prescriber may manufacture, pack and label, procure, sell, supply or administer any controlled drug that is a medicine for the purposes of generally treating their patients.³¹⁵

309 Misuse of Drugs Regulations 1977, reg 15.

310 Misuse of Drugs Regulations 1977, reg 34.

311 Misuse of Drugs Regulations 1977, reg 17.

312 Misuse of Drugs Regulations 1977, reg 18.

313 Misuse of Drugs Regulations 1977, reg 19.

314 Misuse of Drugs Act 1975, s 37(d).

315 Medicines Act 1981, ss 25 and 27. The exemption also allows them to do these things at the request of another authorised prescriber: see Misuse of Drugs Act 1975, s 25(1)(d), (e) and (f).

- Any pharmacist may manufacture, and pack and label a controlled drug or supply a controlled drug that is a medicine under a prescription.³¹⁶

The Medicines Act and regulations made under it impose various conditions on these exemptions.

- 5.37 In so far as they apply to controlled drugs, these exemptions duplicate some of those in the Misuse of Drugs Act. The existence of two exemptions authorising similar activities, but on the different conditions stipulated in the different sets of regulations, is problematic. Section 109 of the Medicines Act requires a prescriber or pharmacist to comply with all the conditions that apply to both groups of exemptions. But what this means in practice may be difficult to determine in some situations. The current situation is confused and lacks transparency. The law would be simpler and more straightforward if the exemptions that applied to controlled drugs were in one Act and were subject to one consolidated set of conditions. It would probably be sensible for these to be in the Medicines Act and regulations since that Act covers all medicines including controlled drugs.

Exemptions for unapproved medicines

- 5.38 Section 25 of the Medicines Act provides a limited exemption for medical practitioners from the requirement under that Act that a medicine be approved by the Minister before it is sold or distributed in New Zealand. This exemption is considerably narrower than the exemptions in section 8 of the Misuse of Drugs Act and therefore imposes some additional restrictions on controlled drugs that are unapproved medicines.
- 5.39 The main additional restrictions are:³¹⁷
- Medical practitioners cannot produce, manufacture, or pack and label these medicines.
 - Only medical practitioners, dentists, registered midwives³¹⁸ and designated prescribers can procure, supply or administer them.
 - They may only be procured and supplied for particular and identifiable patients and not more generally.
- 5.40 Section 29 of the Medicines Act provides a related exemption for suppliers. Before a supplier can supply an unapproved medicine (either a new or changed medicine) a medical practitioner must request it for the treatment of a particular patient. This means that other groups or authorised prescribers can only obtain an unapproved medicine from the medical practitioner responsible for the care of the patient and not directly from a supplier.
- 5.41 An authorised supplier who provides a medicine to a medical practitioner under section 29 is required to provide the Director-General with a written report every month on any sales or supply in accordance with the exemption. The report must

³¹⁶ Medicines Act 1981, s 26.

³¹⁷ Medicines Act 1981, s 25(2).

³¹⁸ The restrictions in the Misuse of Drugs Act also apply. Registered midwives can therefore only supply pethidine or drugs specified in regulations. Similar restrictions apply to other designated providers.

name the medical practitioner, the medicine in question and the patient. It must also identify the date and place of sale. If the supplier fails to do so, the Minister may prohibit that person from supplying unapproved medicines.

Restrictions on distribution of changed medicines

- 5.42 If material changes are made to an approved medicine, the Medicines Act prescribes a notification process and certain restrictions apply to the subsequent use of that drug.³¹⁹ This process therefore applies to controlled drugs that have been approved medicines before changes were made to them.
- 5.43 Firstly, the importer or manufacturer responsible for the changed medicine must give written notification to the Director-General of Health of the changes made and their potential impact on the safety and efficacy of the drug.³²⁰ During a period of at least 90 days following the notification it is an offence for any person to sell or supply the controlled drug, except under the exemptions that apply to unapproved medicines or with the written permission of the Director-General. The earlier approval remains in force, but the changed product cannot be sold until it is approved or the 90 days has elapsed.³²¹
- 5.44 If the Director-General determines during the 90 day assessment period that the change is of such a character or degree that the controlled drug requires a fresh approval, the importer is notified and the drug is treated as an unapproved medicine until the approval is obtained. If a new approval is not required, the drug can again be used under the broader section 8 exemptions.

Restrictions apply to all exemptions

- 5.45 Sections 22, 23 and 25 of the Misuse of Drugs Act and regulation 22 of the Misuse of Drugs Regulations contain some general restrictions that apply across all of the statutory authorisations and impose some further limitations on the classes of people and the authorised activities that they may undertake with controlled drugs.

Section 22 – prohibition notices

- 5.46 Under section 22 of the Misuse of Drugs Act or section 37 of the Medicines Act, the Minister may issue a prohibition notice prohibiting the importation, manufacture, production, procurement, possession, supply, administration or other use of any controlled drug.³²² Prohibition notices override authorisations in a licence and statutory exemptions that would otherwise permit the prohibited activity with the prohibited drug.

319 Medicines Act 1981, s 24.

320 Alternatively, the importer of the medicine or the New Zealand manufacturer responsible for the medicine may form the view that the medicine is so changed it is actually a new and different medicine and apply for an approval for this new medicine, which could not be distributed until the approval had been obtained.

321 See Medicines Act 1981, s 24(3).

322 Note that section 22 of the Misuse of Drugs Act also covers prohibition notices that prohibit the importation or supply of pipes or other utensils, other than needles and syringes.

Section 23 – prohibition on specified prescribers

- 5.47 Under section 23 of the Misuse of Drugs Act, the Minister may, by notice in the *Gazette*, prohibit any specific prescriber from prescribing controlled drugs or may prohibit any other specified person (such as a pharmacist) from exercising any of the rights conferred by an exemption in section 8.
- 5.48 There are some issues over the application of section 23:
- It is very broad. For example, it allows the Minister to prohibit any person from exercising the rights conferred by section 8.³²³ Section 8 permits patients to take controlled drugs that are prescribed for them. The power in section 23 could therefore be used, at least in theory, to prohibit a patient taking a medicine that has been lawfully prescribed.
 - The Minister cannot exercise the power in relation to a prescriber or a pharmacist except on the recommendation of their governing registration authority. The Minister is circumscribed and it is unclear what objective the Minister's involvement serves.
 - Similar powers are included as sections 48 and 48A of the Medicines Act. This appears to involve unnecessary duplication. There probably should be one set of provisions, probably in the Medicines Act, providing for the therapeutic use of controlled drugs and imposing restrictions on that.

Section 25 – restrictions on supply to a particular person

- 5.49 Under section 25, a Medical Officer of Health can impose restrictions on the supply of any controlled drug to a “restricted person” if he or she is satisfied that the person is a drug seeker who has been obtaining controlled drugs over a prolonged period and is likely to continue to do so. The notice is issued to relevant health professionals and prohibits any further supply of controlled drugs to the restricted person. Alternatively, the notice may allow for some continued supply of controlled drugs by specified prescribers or from specified sources. For example, it may allow a restricted person to obtain a particular controlled drug like methadone only from a specified clinic.
- 5.50 After a notice has been issued, it is an offence for any person who has been made aware of it to supply or prescribe any controlled drug to the restricted person in contravention of the notice.
- 5.51 The restricted person also commits an offence if he or she attempts to procure a prescription or a supply of the drug in contravention of the notice. Any person who is aggrieved by the issue of a notice or by the refusal of the Medical Officer of Health to revoke, vary or modify any condition in it, may appeal to the Minister, whose decision is final.

Regulation 22 – restriction on the supply of certain controlled drugs

- 5.52 Regulation 22 of the Misuse of Drugs Regulations provides that certain controlled drugs may not be prescribed, supplied or administered except to the extent and in the circumstances approved by the Minister. These are:

³²³ Misuse of Drugs Act 1975, s 23(1)(c).

- any Class A controlled drug other than cocaine;
- any Class B1 drug or Class B drug in Part 2 of Schedule 2 (Class B2 drug) other than morphine or opium; or
- any Class C1 drug.

In practice this means for example that any cannabis based medicine such as Sativex® cannot be prescribed or supplied or used by patients without Ministerial approval because it is a Class B1 drug. It also means that some drugs that are widely used for therapeutic purposes, like Methylphenidate (Ritalin®) and dexamphetamine, need these approvals, while other substances like cocaine, which is now only rarely used therapeutically, and opium, which has no therapeutic use, are not.

- 5.53 In any event restrictions such as these should be in the Act rather than in regulations because they place significant restraints on the use of certain controlled drugs that have not been agreed to by Parliament.

Classification system for controlled drugs

- 5.54 As we have already noted, controlled drugs are classified under the Misuse of Drugs Act as Class A, B or C drugs and listed in Schedules 1, 2 or 3 respectively. Classification of a drug as “A, B or C” is primarily for the purpose of determining the maximum penalty that applies to an offence under sections 6 and 7 of the Act.
- 5.55 Class B and C drugs are divided into sub-classifications. Class B drugs in Schedule 2 are divided into the sub-classifications B1, B2 and B3 and listed in Parts 1 to 3 of that Schedule. Class C drugs in Schedule 3 are divided into seven sub-categories and are listed in Parts 1 to 7 of that Schedule.³²⁴
- 5.56 The only statutory reference to these sub-classifications is in section 18(2) and (3) of the Act which extends warrantless search powers to drugs listed in Schedule 1, Part 1 of Schedule 2 and Part 1 of Schedule 3.
- 5.57 The main purpose of the sub-classifications appears to be to regulate matters such as prescribing, storage and record-keeping by persons authorised to deal in controlled drugs, these matters being dealt with in regulations. For example, Class C6 drugs can lawfully be sold over the counter without prescription. Suppliers of Class C2 drugs can be held by approved managers or hospitals. Drugs listed in Part 5 of Class C (Class C5 drugs) are exempted from certain custody requirements. None of this is apparent on the face of the statute and the significance of the various sub-classifications is difficult to determine without a very close and careful reading of the regulations. In other words, the law is simply not accessible.
- 5.58 Moreover, there are significant risks in using a classification system for both law enforcement and regulatory purposes. The fact that particular categories of drugs might need a particular subset of regulatory controls does not necessarily mean that the same law enforcement powers should be available to detect misuse of those drugs. The considerations that apply to the application of law enforcement

³²⁴ Parts 1 to 3 of Schedule 2 and Parts 1 to 6 of Schedule 3 were included in the Act when it was passed, while Part 7 of Schedule 3 was added by section 10 of the Misuse of Drugs Amendment Act (No 2) 1987.

powers are quite different from those that apply to matters such as prescribing, storage and record-keeping. In our view, the law requires clarification to make it accessible and the regulatory controls on drugs and the law enforcement powers that apply to them dealt with separately.

OTHER PSYCHOACTIVE MEDICINES

- 5.59 Another group of psychoactive substances are psychoactive medicines that are not controlled drugs. As we have already discussed, the Medicines Act controls the manufacture, distribution, and supply of all medicines.

Problems determining whether some substances are medicines

- 5.60 Some interpretative difficulties may arise in applying the definition of medicines in the Medicines Act. The definition of medicine depends on whether a substance is imported, manufactured, sold or supplied wholly or principally for administering for a therapeutic purpose. The difficulty is that it may not always be clear what the principal purpose of dealing with a substance is and whether a purpose can be said to be therapeutic. We discuss this issue further in relation to herbal remedies.

Authorisations

- 5.61 Medicines, including those that are psychoactive, can only be manufactured, supplied, possessed and used on the conditions provided for in the Act. There are three categories of authorisation in the Act:
- **licences** that authorise the manufacture, sale by wholesale, packaging and labelling of medicines, or authorise the operating of a pharmacy;
 - **statutory exemptions** that authorise specific classes of people to produce, supply and use medicines that have been approved for use as medicines under the Act; and
 - **statutory exemptions** that authorise medical practitioners, certain other authorised health practitioners and suppliers to produce, supply and administer unapproved medicines for the purposes of treating specific patients.

Each of these categories is considered separately.

Licensing for therapeutic purposes

- 5.62 As we have already noted, anyone manufacturing any medicine or packing or labelling any medicine, or supplying any medicine by wholesale, or operating a pharmacy must be licensed unless they are covered by one of the statutory exemptions. A few licences are also issued under the Act to retailers in remote locations where there are no pharmacies. These authorise the retail sale of classes of medicine that can normally only be sold by a pharmacy.³²⁵

³²⁵ Pharmacy-only medicines can be sold pursuant to a licence to sell medicines by retail which can be issued to a retail outlet in an area where there is no pharmacy in a 10 km radius: Medicines Act 1981, ss 18(1)(c)(ii) and 51(2). The effect of such a licence is to allow the sale of pharmacy-only medicines, but not restricted or prescription medicines.

- 5.63 The Director-General of Health is the licensing authority under the Medicines Act and assesses the suitability of applicants and the adequacy of premises. Licences specify the classes of medicine and the activities that can be undertaken under the licence. Licence holders must comply with any terms that are imposed on their licences by the Act, or regulations, or by the licensing authority.

Exemptions for medicines approved under section 20

- 5.64 We have already discussed the requirement in section 20 of the Medicines Act that medicines be approved before they are sold or distributed in New Zealand. This requirement applies to all medicines, including psychoactive medicines that are not controlled drugs.

Classification system for medicines

- 5.65 Before a medicine is approved for distribution and supply under section 20 it is assessed and if appropriate classified under the classification system established by the Medicines Act. Medicines may be classified as prescription-only, restricted, or pharmacy-only.
- 5.66 The Act establishes a ministerial advisory committee, the Medicines Classification Committee, to assess the degree of risk any approved medicine may pose and recommend whether restrictions should be applied to the retail sale, supply and administration of the medicine. The Committee makes recommendations to the Minister of Health, who in turn recommends classifications for each medicine. These are normally assigned by regulation made by Order in Council. The Medicines Regulations 1984 contain a list of classified medicines in Schedule 1. Prescription medicines are listed in Part 1 of the Schedule; restricted medicines in Part 2; and pharmacy-only medicines in Part 3. Under section 109 of the Act the Minister may also, by notice in the *Gazette*, declare any medicine to be a prescription medicine, restricted medicine or pharmacy-only medicine. When issued, a section 109 notice overrides any inconsistent classification contained in regulations. Notices remain in force for up to six months and provide an interim mechanism for quickly changing classifications.³²⁶
- 5.67 We note here that many approved medicines are not classified. This is because they are assessed as posing little risk of harm if misused. These medicines are called general sale medicines³²⁷ and fewer restrictions are imposed by the Act on the retail sale or supply of these medicines.³²⁸ Small quantities of paracetamol and aspirin and various cough mixtures, for example, all fall within this group. However, psychoactive medicines are all classified medicines.

326 Medicines Act 1981, s 106.

327 Section 99 of the Medicines Act 1981 defines general sale medicines to mean medicines that may be lawfully sold in New Zealand, other than prescription medicines, restricted medicines, and pharmacy-only medicines. Under that section the Director-General of Health is required to publish a list of such medicines.

328 There is also a prohibition on selling these from vending machines and on auctioning medicines.

Exemptions for classified medicines

- 5.68 The classification of a medicine determines the extent to which the sale, supply, or use of the medicine is restricted under the Act. Exemptions under the Act authorise specific classes of people to undertake specific activities with specific classes of classified medicines.³²⁹ Unless one of the exemptions applies, it is an offence under the Act for a person to sell, supply or distribute a classified medicine in contravention of these restrictions. The most serious offence is committed where the breach involves a prescription medicine.³³⁰
- 5.69 The main statutory authorisations can be summarised as follows:
- Medical practitioners and other authorised prescribers may manufacture, pack and label, procure, sell, supply or administer any classified medicine for the purposes of treating patients.³³¹
 - A veterinarian may manufacture, sell, supply, or administer a classified medicine for the treatment of an animal under veterinary care.³³²
 - A registered optometrist may pack and label, sell or supply a classified medicine used in conjunction with contact lenses.³³³
 - A pharmacist may manufacture, pack, label and supply any medicine, including a classified medicine, although prescription medicines may only be sold by retail or supplied by a pharmacist pursuant to a prescription issued by a medical or dental practitioner, midwife, veterinary surgeon, or a designated prescriber.³³⁴ A restricted medicine may also only be sold by retail by a pharmacist, who must personally oversee the sale. Although a prescription is not required, regulations require the pharmacist to keep a record of sales of restricted medicines.³³⁵
 - Pharmacies and also licensed retail outlets in remote areas may sell pharmacy-only medicines by retail.³³⁶
 - Patients may take, and others may administer, prescription medicines in compliance with the directions of an authorised prescriber or in accordance with any standing order.³³⁷
 - People may procure and administer restricted and pharmacy-only medicines without a prescription.

329 As has already been discussed, some of these activities can be undertaken under a licence.

330 See section 18(5) of the Medicines Act 1981 which provides a maximum penalty of six months imprisonment and a \$40,000 fine for selling, supplying or distributing a prescription medicine in contravention of section 18(1). The maximum penalty for selling, supplying or distributing a restricted or pharmacy-only medicine is three months imprisonment and a fine of \$500: see Medicines Act 1981, s 78.

331 Other authorised prescribers are dentists, registered midwives and designated prescribers.

332 Medicines Act 1981, s 27(a).

333 Medicines Act 1981, s 27(b). This is in addition to their rights as designated prescribers under the first bullet point of the list.

334 See Medicines Act 1981, s 18(1)(a)(i), (2) and (2A). In addition, section 18(1)(a)(ii) allows for the supply of prescription medicines pursuant to a standing order.

335 See Medicines Act 1981, s 18(1)(b).

336 Pharmacy-only medicines can also be sold pursuant to a licence to sell medicines by retail which can be issued to a retail outlet in an area where there is no pharmacy in a 10 km radius: See Medicines Act 1981, s 18(1)(c)(ii) and s 51(2). The effect of such a licence is to allow the sale of pharmacy-only medicines, but not restricted or prescription medicines.

337 A standing order is similar to a prescription, in the sense that it is written by an authorised prescriber, but it is a general permission which authorises the administration of any specified medicines to any specified group of people by any specified health professional in certain circumstances.

- 5.70 Psychoactive medicines (assuming they are not controlled drugs) are almost always classified as prescription medicines, although on occasion mildly psychoactive medicines have been classified as restricted medicines and pharmacy-only medicines.³³⁸ Consequently very few psychoactive medicines can be purchased over the counter from a pharmacy without a prescription. When they can be purchased without a prescription, the sale must be personally overseen by a pharmacist who determines whether it is appropriate to sell the medicine. The more stringent controls outlined above will therefore normally apply to the supply of psychoactive medicines.

Exemptions for new or unapproved medicines

- 5.71 We have already outlined the limited exemptions that authorise some closely controlled use of unapproved medicines. There are two further exemptions which apply to psychoactive medicines but not controlled drugs. These are exemptions for herbal remedies and exemptions for natural therapists.

Exemptions for herbal remedies

- 5.72 Section 28 contains two exemptions that apply to herbal remedies. These may, at least in theory, cover unapproved medicines that have psychoactive effects. Firstly, any person may, without a licence, manufacture, pack and label, or supply in the course of their business any herbal remedy provided it is for administration to a particular person who has requested treatment from the herbal practitioner. Secondly, section 28 also authorises the manufacture, packing, labelling, sale and supply of any herbal remedy without a licence if the remedy is identified simply by reference to the plant from which it is made and the process to which the plant was subjected during production. For this exemption to apply no other name may be given to the product and there must not be any labelling or accompanying written material recommending the use of the remedy. If therapeutic claims are made for the herbal material or it is packaged and presented under some brand name, the exemption does not apply.
- 5.73 A “herbal remedy” is defined in the Act as a medicine consisting of any substance produced by subjecting a plant to drying, crushing, or any other similar process, or a mixture of two or more such substances. The only other ingredients that can be included are water, ethyl alcohol or any other inert substance. The Act prohibits any herbal remedy from containing any prescription medicine, restricted medicine or pharmacy-only medicine.
- 5.74 The exemption may possibly allow psychoactive herbs to be dried, packaged and sold. Whether it does turns on whether the herb is principally a therapeutic substance. For example, the herb *salvia divinorum* (diviner’s sage) has purportedly been used historically both for its psychoactive properties and as a herbal treatment for various conditions.³³⁹ Might *salvia divinorum* consequently be packaged and

338 Some sedating antihistamines (chlorpheniramine, diphenhydramine and promethazine), dextromethorphan and atropinic agents could be regarded as mildly psychoactive and some of these are restricted medicines and pharmacy-only medicines.

339 The Mazates Indians used the herb remedially at sub-visionary doses to treat a variety of conditions including arthritis, headache, and eliminatory complaints. See D J Siebert “Localization of Salvinorin A and Related Compounds in Glandular Trichomes of the Psychoactive Sage, *Salvia Divinorum*” (2004) 93 *Annals of Botany* 763, 763.

sold under this exemption as a herbal remedy? This illustrates the problematic nature of the definition of “medicine”, which depends on whether a substance is manufactured or sold wholly or principally for therapeutic purposes.

Exemption for natural therapists

5.75 Section 32 also contains an exemption for natural therapists. Any natural therapist, or indeed any person, may manufacture, pack, label, or supply by retail any medicine providing it is not, or does not contain, a prescription medicine, a restricted medicine, or a pharmacy-only medicine and is supplied for administration to a particular person who has requested the therapist to use his or her judgement and determine the appropriate treatment for the person requesting the remedy. The purpose of the exemption is to allow natural therapists like homeopaths, naturopaths, herbal practitioners and others to prepare remedies. However, on its face the exemption is broader than this, and authorises without restriction the manufacture, packing, labelling or supply of an unapproved medicine provided it does not contain one of the categories of medicine described above. At least in theory, psychoactive medicines that have not been approved and classified fall within this exemption and can therefore be supplied under it. We wonder whether the exemption is intended to be so broad, given the strict controls that are in place elsewhere in the Act to restrict the use of such substances by medical practitioners.

HAZARDOUS SUBSTANCES

5.76 The Hazardous Substances and New Organisms Act 1996 (HSNO) also applies to many psychoactive substances. The Act provides that no hazardous substance may be imported or manufactured otherwise than in accordance with an approval under the Act.³⁴⁰ If a substance is not hazardous, it is not regulated by the Act and no approval is needed. Although the Act does not directly regulate sales of hazardous substances, indirectly it regulates sales because only hazardous substances that have been imported or manufactured in accordance with an approval can be distributed and sold in New Zealand.

5.77 A “hazardous substance” is a substance that has one or more of the properties listed in the definition in section 2 of the Act. The listed property relevant to drugs or psychoactive substances is “toxicity including chronic toxicity”. A substance is “toxic” if it is “capable of causing ill health in, or injury to, human beings”.³⁴¹

5.78 The Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001, authorised and made under the Act, provide that a substance is not a hazardous substance unless it meets the minimum degree of hazard for at least one of the intrinsic properties. Schedule 4 of the Hazardous Substances (Minimum Degrees of Hazard) Regulations prescribes the minimum degree of hazard for toxic substances. The relevant part of Schedule 4 requires as a minimum degree that:

- (s) data for the substance indicates, in the opinion of an expert, evidence of a significant adverse biological effect or a significant toxic effect other than an effect referred to in any of paragraphs (a) to (r) on the function or morphology of an organ or on the biochemistry or haematology of an organism or human being as a result of exposure to the substance and in the case of a significant adverse biological effect the change is relevant to health.

³⁴⁰ Hazardous Substances and New Organisms Act 1996, s 25(1).

³⁴¹ “Toxic” is defined in section 2 of Hazardous Substances and New Organisms Act 1996.

Psychoactive substances meet the minimum degree of hazard

5.79 Most, if not all, psychoactive substances are likely to meet the minimum degree of hazard specified above, since they will have a significant adverse biological effect on health, at least if used to excess. People ingest psychoactive substances because they impact on physiology in a way that induces a change. To be pleasurable, a substance must cause physiological changes and these will almost invariably be sufficient to meet the threshold of toxicity.³⁴² However, some psychoactive substances are not hazardous substances because they are medicines or food and these have been expressly excluded from the scope of HSNO.

Medicines are not hazardous substances

5.80 Regulation 5 of the Hazardous Substances (Minimum Degrees of Hazard) Regulations provides that a “medicine” is not a hazardous substance unless it is:

- a new medicine that is an ingredient for use in another medicine, rather than a ready to consume medicine; or
- a new medicine for which an application for registration as a veterinary medicine under the Agricultural Compounds and Veterinary Medicines Act 1997 has been made.³⁴³

5.81 The definition of “medicine” in HSNO is the same as that in the Medicines Act except in one respect. The HSNO definition does not include a gas contained at a pressure greater than 170kPa in a container larger than 100ml, at any time between its containment and its being administered to a patient for a therapeutic purpose. Anaesthetic gases like nitrous oxide are therefore hazardous substances while they are contained and stored but cease to be hazardous substances at the point at which they are administered to a patient. At that point they come within the definition of “medicine” as the term is used in HSNO and are not hazardous substances. In contrast the definition of “medicine” in the Medicines Act does include these substances.

5.82 The vast majority of medicines, including most psychoactive medicines and controlled drugs that are medicines, will fall squarely within the exclusion for medicines and are not hazardous substances. All psychoactive medicines and controlled drugs that are approved medicines are regulated under the Medicines Act and the Misuse of Drugs Act and not under HSNO. However, as we discussed earlier there can be difficulties in determining whether a particular psychoactive substance falls within the definition of medicine in the Medicines Act. As a result it may also be difficult to determine whether these substances are excluded from HSNO. This creates the potential for some substances to slip between the cracks.

342 If a psychoactive substance was so mild it did not trigger the threshold then there would be little point in regulating its use.

343 Also any medicine that might have been regulated under the transitional provisions in Parts 13, 14, or 15 of the Hazardous Substances and New Organisms Act 1996 is not excluded from the definition of hazardous substance. These transitional provisions have now expired.

When the Medicines Act and HSNO both apply

- 5.83 There are some psychoactive substances that are covered by both the Medicines Act and HSNO. This is because they are medicines as defined in the Medicines Act but, because they fall within the exceptions for certain new medicines or take the form of a pressurised gas in storage, they are also hazardous substances. Nitrous oxide and anaesthetic gases are examples.
- 5.84 Sections 5A and 110 of the Medicines Act deal with the relationship between the Medicines Act and HSNO when a substance falls within both regulatory schemes. Section 5A says that the requirements of the Medicines Act are additional to the requirements of HSNO for any medicine that is or contains a hazardous substance or new organism. Section 110 provides that in the event of any inconsistency between the provisions of HSNO and the Medicines Act, or regulations made under them, the Medicines Act and regulations made under it will prevail. None of the provisions in the Medicines Act otherwise affect or derogate from HSNO.
- 5.85 We take this to mean that the regulatory regimes are cumulative. For example, a new medicine that is an ingredient for use in another medicine can only be imported in circumstances that comply with the Medicines Act and if an approval under HSNO has been obtained. The conditions in that approval also need to be complied with.

Psychoactive substances that are technically “food” are excluded from the definition of hazardous substance

- 5.86 Regulation 6 of the Hazardous Substances (Minimum Degrees of Hazard) Regulations provides that a “food” is not hazardous for the purposes of the Act. “Food” has the same meaning as in the Food Act 1981 except that it does not include a food additive if that additive has not been mixed with or added to any other food or drink.³⁴⁴ This means that a food additive, such as the propellant nitrous oxide, is a hazardous substance until it is mixed into food, for example, when it is included as a propellant in an aerosol container with cream.
- 5.87 In contrast, the definition of “food” in the Food Act includes unmixed food additives. As a consequence, this small group of substances, “unmixed food additives”, are regulated as both “hazardous substances” under HSNO and as “food” under the Food Act. Included in that group is at least one psychoactive substance, nitrous oxide.

Controls imposed by HSNO

- 5.88 The Act places responsibility for determining whether something is a hazardous substance on those who intend to manufacture or import the substance. It is an offence to manufacture or import an unapproved hazardous substance. Where there is an approval in place, a manufacturer or importer must comply with any conditions imposed by the approval. Where there is uncertainty as to whether

344 Also any food that might have been regulated under the transitional provisions in Parts 13, 14, or 15 of the Act is not excluded from the definition of hazardous substance. These transitional provisions have now expired.

a substance is a hazardous substance, an application may be made under section 26 to have the Environmental Risk Management Agency (ERMA) determine whether the substance is a “hazardous substance”. Any person may make an application under section 26. This includes government departments or officials.

- 5.89 Under section 26 of the Act, ERMA has the power by notice in the *Gazette* on application by any person to determine whether or not any substance is a “hazardous substance”. Before doing so ERMA must take into account:
- any information held by the Authority;
 - any information held by a department listed in Schedule 1 of the State Sector Act 1988 and any Crown entity;
 - any information provided by the applicant.

It is relevant to note that ERMA has access to a significant volume of international research material about a range of substances which may help to inform a section 26 determination.

Precautionary approach

- 5.90 Also relevant is section 7 of the Act which requires a “precautionary” approach when ERMA determines whether a substance is hazardous. It provides:

All persons exercising functions, powers and duties under this Act, including but not limited to functions, powers and duties under sections 28A, 29, 32, 45 and 48 shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

- 5.91 The HSNO process is available for assessing and imposing controls on psychoactive substances that are used recreationally as drugs although it has only recently begun to be used.³⁴⁵ If a substance, including a psychoactive one, is assessed as hazardous it cannot be manufactured or imported until an approval is obtained.

Approvals for “hazardous substances”

- 5.92 Approvals are issued by ERMA in accordance with the processes laid out in Part 5 of the Act. Section 29 of the Act gives ERMA the power to approve or decline applications for approval. ERMA must take into account:
- any controls that may be imposed on the substance;
 - all effects of the substance during the lifecycle of that substance;
 - the likely effect of the substance being unavailable.

If the positive effects of the substance outweigh the adverse effects the application can be approved, but if the adverse effects outweigh the positive effects it can be declined. An application can also be declined if the applicant fails to provide sufficient information for the assessment.

³⁴⁵ We understand that the Ministry of Health has asked ERMA to undertake an assessment of *salvia divinorum*.

Conditions imposed on approvals

- 5.93 Where an approval is given under Part 5 there are a broad range of controls that may be imposed. These include controls relating to retail sales and supply, labelling, storage and use of the hazardous substance. Section 77A of the Act enables the Authority to apply controls that it “thinks fit”. When determining what controls to impose, ERMA considers the predominant use of the substance. Currently ERMA sets exposure levels and other controls for toxic substances based on the intended and predominant use.
- 5.94 The legislation allows appropriate conditions to be imposed when there is evidence that a hazardous substance is being misused. For example, when setting conditions for methylated spirits ERMA took into account evidence that it was being drunk. The controls that have been imposed reflect this. Controls on solvents are currently set to ensure safe exposure when used correctly. They do not currently address the hazard such substances pose when deliberately inhaled for their psychoactive effects, although there is nothing to prevent ERMA from doing so.

RESTRICTED
SUBSTANCES

- 5.95 The Misuse of Drugs Amendment Act 2005 established a regime for regulating psychoactive substances that are not so harmful that they should be scheduled as controlled drugs and prohibited under the Misuse of Drugs Act. Restricted substances are substances that are assessed as posing a less than moderate risk of harm. They continue to be legally available under the regime but subject to regulatory controls.
- 5.96 Restricted substances are listed in Schedule 4 to the Amendment Act. However, there are presently no restricted substances. The regime was briefly used to regulate BZP. However, BZP was subsequently reclassified as a Class C controlled drug.³⁴⁶ The schedule has since remained empty.

The definition of “restricted substance” and “substance”

- 5.97 Only substances that fall within the definition of “substance” in section 31 of the Amendment Act may be added to Schedule 4 and regulated as “restricted substances”. A “restricted substance” is defined as any “substance” specified or described in Schedule 4 that is not a preparation, concentration, form or use exempted from being a restricted substance by regulations. The term “substance” is defined as:
- (a) any mixture, preparation, or article that is manufactured for the primary purpose of being administered, ingested, inhaled, or injected to induce a psychoactive response; but
 - (b) does not include any –
 - (i) agricultural compound or veterinary medicine (as defined in section 2(1) of the Agricultural Compounds and Veterinary Medicines Act 1997);
 - (ii) controlled drug, controlled drug analogue, or precursor substance (as defined in section 2(1) of the principal Act):

³⁴⁶ When the Misuse of Drugs Amendment Act 2005 was first enacted BZP was listed as the first restricted substance under the regime. However it was subsequently removed from the schedule of restricted substances in 2008 when it was classified as a Class C controlled drug by the Misuse of Drugs (Classification of BZP) Amendment Act 2008.

- (iii) dietary supplement (as defined in regulation 2(1) of the Dietary Supplements Regulations 1985):
 - (iv) food (as defined in section 2 of the Food Act 1981):
 - (v) hazardous substance (as defined in section 2(1) of the Hazardous Substances and New Organisms Act 1996):
 - (vi) herbal remedy (as defined in section 2(1) of the Medicines Act), medicine (as defined in section 3 of that Act), or related product (as defined in section 94 of that Act):
 - (vii) liquor (as defined in section 2 of the Sale of Liquor Act 1989): or
 - (viii) tobacco product or herbal smoking product (as defined in section 2(1) of the Smoke-free Environments Act 1990).
- 5.98 Any substance that falls within one of the exclusions listed in subsection (b) cannot be a restricted substance if it is primarily intended to induce a psychoactive response. The exclusions were inserted in the Bill when it was reported back by the Select Committee. The policy objective was to ensure that psychoactive substances that had other legal uses but might also be used recreationally for their psychoactive effects were not scheduled as restricted substances. The Committee considered that existing legislation, rather than the new regime, should be used to regulate such substances.³⁴⁷ The Committee wished to avoid unnecessary overlap between the restricted substances regime and other regulatory schemes.
- 5.99 The exclusions achieve this objective. Any substance that falls within the definition of one of the excluded substances cannot also be scheduled as a restricted substance. The difficulty is that **all** harmful psychoactive substances fall into one or other of the exclusions. There are therefore no substances that can come within the regime. The problem stems largely from the broad and inclusive way “hazardous substance” is defined in section 2(1) of HSNO which captures all harmful substances that are not medicines or food. If any psychoactive substances exist that do not meet the minimum degree of hazard, they would be relatively harmless so that there would be no reason to regulate them as restricted substances. If the restricted substances regime is retained, this problem needs to be fixed.
- 5.100 The problem could be fixed by making regulations under HSNO specifically excluding psychoactive substances that are “manufactured for the primary purpose of being administered, ingested, inhaled or injected to induce a psychoactive response”³⁴⁸ from the definition of hazardous substance under that Act. However, that would leave such substances unregulated until they were brought under the restricted substances regime.³⁴⁹ Alternatively, the problem could be fixed by making regulations under HSNO excluding only specific named substances at the same

347 (9 June 2005) 626 NZPD 21232.

348 This is the first part of the definition of substance in section 31 of the Misuse of Drugs Amendment Act 2005.

349 Regulation making powers under HSNO allow regulations to be made excluding substances from the definition of hazardous substance. We have noted already that the Hazardous Substances (Minimum Degrees of Hazard) Regulations expressly exclude food and medicines, so similarly certain psychoactive substances could also be excluded by regulation. Excluding all substances that are not food or medicines but have been manufactured for the primary purpose of being administered, ingested, inhaled or injected to induce a psychoactive response would be possible but this would leave these potentially harmful substances unregulated until they are brought within the restricted substances regime.

time as an Order in Council is made bringing those substances within the restricted substances scheme. While this alternative avoids substances falling between the two regimes, it does introduce additional complexity into the legislation. A better alternative may therefore be an amendment to the Misuse of Drugs Amendment Act 2005.

Controls that apply to restricted substances

5.101 When substances are scheduled as restricted substances they can be manufactured, imported, distributed, sold and used as recreational drugs provided the provisions of the Misuse of Drugs Amendment Act 2005 and regulations made under it are complied with. The Amendment Act prohibits the sale or supply of a restricted substance to any person under the age of 18 years.³⁵⁰ It also prohibits any person under the age of 18 years from selling any restricted substance.³⁵¹ Manufacturers, distributors, importers, and retailers of restricted substances may not distribute or supply restricted substances free of charge or as promotional gifts to encourage purchase and use.³⁵² Finally, the Act also prohibits the advertising of a restricted substance in the media.³⁵³

5.102 The Misuse of Drugs (Restricted Substances) Regulations 2008 prohibit:³⁵⁴

- restricted substances from being sold from premises that sell or supply alcohol to the public or from premises that sell petrol;
- restricted substances from being sold from places where children or minors gather such as schools or sports centres or from non-fixed premises such as tents or vehicles;
- the advertising of restricted substances except within the premises from which they are sold or supplied (although the restriction does not apply to advertising on the Internet).

Regulations also prescribe labelling, packaging, storage and display requirements. Labels on restricted substances must, for example, contain the statement that: “It is illegal to sell or supply a restricted substance to any person under the age of 18”. This statement must also be displayed in all premises selling or supplying restricted substances. Packaging must be tamper-proof and child-proof and restricted substances must be stored or displayed in a manner that does not allow public access.

5.103 The Misuse of Drugs Amendment Act 2005 provides also for manufacturing codes of practice to be issued by the Director-General of Health.³⁵⁵ Where a code is in place, only restricted substances that comply fully with the applicable parts of the code can be manufactured or imported into New Zealand.³⁵⁶ There are currently no licensing requirements that apply to the manufacture, importation,

350 The Misuse of Drugs Amendment Act 2005, ss 36 and 39: section 39(1)(b) also prohibits supply to any other person with the intention that it be supplied to a person under 18 years.

351 The Misuse of Drugs Amendment Act 2005, s 38.

352 The Misuse of Drugs Amendment Act 2005, s 42.

353 The Misuse of Drugs Amendment Act 2005, s 43.

354 The regulations came into force on 6 November 2008.

355 Section 63 of the Misuse of Drugs Amendment Act 2005 contains the process for issuing a code.

356 The Misuse of Drugs Amendment Act 2005, ss 49 and 50.

distribution or wholesale supply of restricted substances. There are currently no manufacturing codes of practice, so no specific restrictions apply to the manufacture or importation of restricted substances.

PSYCHOACTIVE SUBSTANCES IN FOOD

- 5.104 The Food Act and regulations and standards made under it play a more peripheral role than the other regimes we have considered in regulating psychoactive substances. The Food Act is relevant only because of recent developments that have seen psychoactive substances, including BZP before it became a restricted substance, sold in the guise of energy drinks and dietary supplements. We consequently need to briefly consider the way food is regulated.

Controls imposed by the Food Act

- 5.105 The Food Act regulates the manufacturing, preparation and packaging for sale, and the sale of food. The regulatory scheme established by the Food Act regulates substances that are used in the preparation of food for sale and also determines which substances may be incorporated into food or drink that is produced, marketed and sold. All manufacturers, importers, producers, suppliers and sellers of food have a responsibility to ensure that their products are safe and comply with the legal requirements imposed by the Food Act and by food standards and regulations made under it.
- 5.106 Under section 11C the Minister of Food Safety has the power to issue food standards setting minimum requirements for the quality and safety of food for sale. Food standards set requirements or standards for food that is manufactured or prepared for sale or sold in New Zealand or imported into New Zealand. Standards set under the Act cover all aspects of food production.
- 5.107 Section 9 of the Act imposes a general prohibition on selling food that does not meet any standard that has been set for food of that kind. It also imposes a complete prohibition on preparing or packing for sale or selling any food that is unsound or unfit for human consumption or any food that has been contaminated or contains anything that is injurious to health or harmful or offensive.³⁵⁷ No one may prepare or pack for sale or sell food in any packaging material or using any appliance that would render the food injurious to health or otherwise taint the food.

Definition of food and application of the Food Act

- 5.108 “Food” is defined as anything that is used or represented for use as food or drink for human beings. It includes any ingredient or nutrient or other constituent of any food or drink, whether that ingredient is consumed as a food in itself, mixed with other ingredients or used in the preparation of food or drink.
- 5.109 The definition is imprecise and somewhat circular. While it is relatively clear in most cases whether a substance is or is not a food, there are grey areas. One of these surrounds psychoactive substances incorporated into drinks or tablets that are marketed as stimulants and energy enhancers. These products

³⁵⁷ Food Act 1981, s 9(4).

are consumed orally; they contain some psychoactive ingredients but also other ingredients and nutrients that are commonly used in food. Do they fall within the broad definition of “food” in the Act?

- 5.110 It seems reasonably clear that energy drinks containing high levels of caffeine and sometimes other stimulants are food and are regulated under the Food Act. A food standard (standard 2.6.4), Formulated Caffeinated Beverages, covers such products.³⁵⁸ However, the position is not so clear when psychoactive substances are incorporated as an ingredient in a tablet form and marketed as energy or party pills. There is less certainty over whether or not the Food Act applies to these types of products. This has resulted in potentially harmful psychoactive substances falling between regimes.
- 5.111 In 2005, BZP was used as an ingredient in pills labelled and sold as “dietary supplements”. Dietary supplements are a group of foods that are regulated under the Dietary Supplements Regulations 1985. These pills were later withdrawn on the basis that they were not a permitted additive under the Dietary Supplements Regulations. This illustrates that there may be some uncertainty at the margins as to whether particular substances are foods, medicines or hazardous substances.
- 5.112 In the case of BZP, this became a moot point once the Misuse of Drugs Amendment Act 2005 came into force. However, the broader definitional issues at the interface between medicines, food and HSNO still may require attention. There is still a degree of uncertainty over which regime applies to some types of products containing psychoactive substances. We stress that the regulation schemes relating to food, medicines and hazardous substances appear to contain adequate controls for regulating these types of products and they must fall within one or the other. The uncertainty over which scheme applies to which products should be addressed because in practice it seems to result in neither regime being applied to some substances.

PROBLEMS WITH THE CONTROLLED DRUGS REGIME AND ITS INTERFACE WITH OTHER REGIMES

- 5.113 Psychoactive substances are all currently regulated as controlled drugs, other psychoactive medicines, hazardous substances, or as food.³⁵⁹ There are a number of problems with the interface between these various regulatory regimes. In summary:
- The regulation-making powers in the Misuse of Drugs Act are very broad. They permit regulations that override the statute and deal with significant matters of policy. While we acknowledge that there is a need for flexibility in this area to deal with new and changing circumstances, in our view too much is left to regulation.
 - The relationship between the Misuse of Drugs Act and the Medicines Act lacks transparency. There is also considerable overlap and duplication between the two regimes. This makes the law inaccessible. It would be improved if the exemptions that applied to controlled drugs were in one Act, probably the Medicines Act (with appropriate cross references), and subject to one consolidated set of conditions.

358 An interesting case arose in April 2005 when a “herbal” energy drink called Ammo that contained BZP was voluntarily recalled after the Food Standards Agency determined that the product breached the Food Code.

359 As has been noted already the regulatory schemes covering alcohol and tobacco have been excluded from our review.

- The powers of the Minister to override statutory authorisations to deal in controlled drugs are too broad. While there may be a need for powers to override licences and exemptions to deal with emergency situations, it is certainly not appropriate for the Minister to have powers that are so wide that they can override the prescriptions of medical practitioners.
- There is some inconsistency between the roles of the Minister of Health and the Director-General of Health. It does not make sense for the Director-General to have power to issue licences and the Minister to have the power to revoke them. In practice most of the powers of the Minister under the Act are delegated to the Director-General and it is questionable whether the Minister rather than the Director-General should continue to have the authorisation to make revocation decisions.
- The sub-classification system in the Misuse of Drugs Act is obscure. Moreover, it seems inappropriate because it serves both law enforcement and regulatory purposes which are not necessarily consistent with each other.
- There are difficulties at the margins in the definitions of “medicine” and “food”. This has the potential for some substances to slip between the cracks of the various regulatory regimes. While the overall regulatory framework relies on HSNO to catch potentially harmful substances that are not food or medicine, if it is unclear what a substance is, it may go unregulated.
- The restricted substances regime can have no content unless regulations are made under HSNO excluding psychoactive substances that might be brought within the restricted substances scheme from the definition of hazardous substance. Though intended as a regime for recreational psychoactive substances that pose relatively little harm, these substances are already controlled either as medicines, food or hazardous substances.