

# Part 2

## PROPOSALS FOR REFORM



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# Chapter 8

## Our proposed approach to drug regulation

### SUMMARY

This chapter considers the factors that are relevant to the choice of regulatory model for the non-therapeutic use of drugs and suggests a possible approach to drug regulation for New Zealand. It considers also the approach that should be taken as an alternative to prohibition for new recreational psychoactive substances that are not covered by the international drug conventions and identifies the core features that this type of regulatory regime should have. It invites feedback on these issues and on whether regulation under the Hazardous Substances and New Organisms Act 1996 (HSNO) or under a separate regime designed specifically for new recreational psychoactive substances would be the better approach.

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**INTRODUCTION** 8.1 In chapter 7, we identified and assessed the possible models of regulation for the non-therapeutic use of drugs. In this chapter we consider the factors that are relevant to the choice of model and suggest a possible approach for New Zealand.

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**THE CHOICE OF REGULATORY MODEL** 8.2 There are a number of factors to consider when choosing the best regulatory model.

#### **Effectiveness**

8.3 In chapter 7, we suggested that the primary justification for regulating drugs is to minimise the harm drugs cause to persons other than the drug user and to society as a whole. It follows that the key question for our review is which regulatory approach will most effectively minimise drug-related harm.

- 8.4 The answer to this question is far from straightforward. MacCoun and Reuter suggest there are four steps involved in the assessment of alternative drug control regimes:<sup>630</sup>
- (i) identifying all the relevant consequences under the current control regime;
  - (ii) measuring the magnitude of those consequences;
  - (iii) quantifying their dollar value (to facilitate comparison with alternative approaches); and
  - (iv) quantifying the dollar value of changes in drug-related consequences brought about by a change to an alternative drug control regime.
- 8.5 However, there are significant gaps in the evidence, so that this kind of assessment may not be possible. We pointed out some of the challenges in measuring drug harms in chapter 2. These include a lack of robust evidence about the full range of drug-related harms, their uneven distribution, and their differential impact on groups such as users, families, employers and taxpayers. When considering the consequences of the existing regime it is also necessary to take into account the effects of the regime itself. For example, the consequences of the current regime include not only the benefits of any reduction in the consumption or abuse of drugs that flows from prohibition, but also the costs that directly flow from prohibition: the growth of black markets and associated crime; the marginalisation of drug users; and limitations on the ability to promote public health messages about illegal drugs. All of this makes it enormously difficult to identify the effects of, let alone quantify the cost of, the current regime.
- 8.6 Moreover, even if more robust evidence was available, there are significant elements of judgement involved. Many drug harms are intangible and cannot readily be quantified in monetary terms. What value is attached to these harms is inherently subjective. There are also subjective trade-offs to be made between the priority and weight to be given to the various harms suffered by different persons and groups.
- 8.7 So far as possible, drug policy should be evidence-based. But when it comes to determining the appropriate regulatory approach, it is important to recognise the significant limitations of the evidence and also the extent to which the choice of regulatory model necessarily involves making value judgements.
- 8.8 Even if all of the benefits and costs of the current regime could be quantified, there is no evidence about the effects of alternative regulatory approaches. While some commentators<sup>631</sup> have attempted to draw conclusions by extrapolating from the experience with substances like alcohol, tobacco and regulated activities such

630 Robert J MacCoun and Peter Reuter *Drug War Heresies: Learning from Other Vices, Times and Places* (Cambridge University Press, Cambridge, 2001).

631 See *ibid*, chs 7 and 8.

as gambling and prostitution, there are limits to this type of analysis because of their different social and historical contexts. Reuter and MacCoun describe the problem as follows:<sup>632</sup>

[T]he harms are highly variegated and that variety is part of the policy problem, since it prevents effective aggregation and thus straightforward comparison of different regimes. For many reasons, there are not even approximate numbers on most of the harms under the current regime, let alone for any hypothetical regime that is substantially different.

- 8.9 Finally, we note that the choice of regulatory regime needs to be made on a substance by substance basis. Though drug policy debates tend to focus on illegal drugs as a whole and question whether prohibition or regulation is the better approach, there are significant differences between drugs that need to be taken into account in determining the appropriate policy response. There are potentially a wide range of regulatory options that can be applied to different substances depending on the purpose for which they are used and the nature and magnitude of risks they pose.

### Convention drugs

- 8.10 We outlined in chapter 6 New Zealand's international obligations. The three United Nations drug conventions require states to prohibit dealings with the substances listed in the schedules to the conventions except for medical and scientific purposes. There are over 100 narcotic drugs and psychotropic substances listed in the conventions. These substances have historically been the most widely used psychoactive substances for medicinal, scientific and recreational purposes.
- 8.11 There is a significant debate internationally about the effectiveness of the prohibitory approach required by the drug conventions. It is argued that prohibition has not deterred drug use and itself causes very substantial harm. Whatever the merits of that debate, states that have ratified the conventions are bound under international law to comply with the obligations the conventions impose. The only alternative is for a state to denounce one or more of the conventions,<sup>633</sup> an action no state has ever taken.<sup>634</sup>
- 8.12 Compliance with the conventions is consistent with New Zealand's role as a member of the international community. A very high proportion of countries are signatories to the conventions and, despite the increasing disquiet over the effectiveness of prohibition, there still remains a high level of international

<sup>632</sup> Ibid, 101.

<sup>633</sup> See Single Convention on Narcotic Drugs 1961, as amended by the 1972 Protocol (the 1961 Convention), art 46. A State Party cannot denounce part of the Convention. Any denunciation must be of the whole Convention.

<sup>634</sup> However, it should be noted here that a few countries declared reservations when ratifying the 1961 Convention and do not consider themselves to be bound by those reserved provisions. Saudi Arabia, Bahrain, Andorra and Vietnam for example have declared upon ratification that they will not be bound by article 48, paragraph 2 (which provides for mandatory referral to the International Court of Justice of any dispute which cannot be resolved under paragraph 1 of that article).

consensus on the broad parameters of drug policy.<sup>635</sup> Moreover, it is not feasible for one party to the conventions to legislate in this area in isolation from others. To do so risks compromising the effectiveness of international efforts towards drug control. There are also likely to be significant adverse consequences for that state, as experience in the Netherlands illustrates. There, the policy of tolerating the sale of cannabis in coffee shops resulted in an influx of tourists taking advantage of the ready availability of cannabis, creating a significant public nuisance.<sup>636</sup> There is of course scope within the prohibitory framework of the conventions for different approaches to be taken to the possession and use of drugs. We discuss these and other options for minimising drug-related harm within the convention framework in chapters 6, 7 and 11.

## Non-convention drugs

- 8.13 There is not a similar international obligation to prohibit psychoactive substances that are not covered by the conventions. Regulatory approaches alternative to prohibition can therefore be considered for new synthetic drugs as they emerge and other organic substances not covered by the conventions. As we noted in chapters 4 and 5, various psychoactive substances, some in the form of party pills, have emerged over recent years. Benzylpiperazine (BZP), trifluoromethylphenylpiperazine (TFMPP) and more recently preparations containing 1,3 dimethylamylamine (DMAA) are all examples of psychoactive substances that have been incorporated into party pills and other products. It is also likely that new psychoactive substances will continue to be developed.
- 8.14 We suggest that a model of legalisation with regulatory restrictions should be the starting point for regulating drugs not covered by the conventions. Any such restrictions that are imposed should also normally be the minimum necessary to prevent or reduce that harm and obviously must not cause more harm than they alleviate. In a free and democratic society full prohibition should be a last resort option when lesser regulatory restrictions have proved ineffective.
- 8.15 As a general rule, the level or degree of regulation should increase with the level of risk, with restrictions imposed reflecting the purpose for which things are used and the nature of the risks they pose. This is the approach taken to the regulation of medicines, food, hazardous substances and a few recreational drugs (notably alcohol and tobacco).
- 8.16 In all these existing regulatory schemes the decision to prohibit goods, services or activities altogether is the last resort and is generally only justified if it can be shown to be the only effective way to prevent the harm. This occurs where the harm is so significant that there is virtually no way to safely undertake the activity or use the goods, or where the less restrictive alternative regulatory option is not an efficient model because the costs of regulating exceed the benefits of not prohibiting.

635 Over 95 % of United Nations members are parties to the 1961 Convention covering 99 % of the world's population; see International Narcotics Control Board *Report of the International Narcotics Control Board for 2008* (United Nations, New York, 2009) 3.

636 MacCoun and Reuter, above n 630, 247–248.

- 8.17 In our view there is no reason to take a different approach in relation to psychoactive substances that are used recreationally and are not covered by the conventions. The starting presumption in a free and democratic society should, where possible, be that use should be regulated rather than prohibited. Psychoactive substances should only be prohibited if that is shown to be the only efficient and effective way to prevent the harm associated with their use. If it is possible to effectively regulate their use, that option must be preferred.
- 8.18 There are some risks inherent in this approach. Arguably, if the supply and use of some psychoactive substances is legal, that might lead to an increase in the prevalence of their use as recreational drugs. For example, alcohol and tobacco are both legally available and are the first and second most widely used drugs in New Zealand. Before BZP was prohibited it was legally available and was reported to be the fourth most widely used drug in New Zealand (although it was not as widely used as cannabis, which is of course not legally available).
- 8.19 But it is important to recognise that an increase in prevalence of use across the population does not necessarily mean an increase in drug-related harm. Some prevalent drugs, like alcohol, are used by many people in moderation with limited adverse consequences. More serious drug-related harm tends to be experienced by the subset of people who use harmful drugs (including alcohol) regularly or excessively. Moreover, there could potentially be a reduction in drug-related harm if the differential application of regulatory controls encourages a shift away from more to less harmful drugs and to safer modes of administration. One study on the prevalence of BZP use, which was undertaken before BZP was reclassified as a Class C controlled drug in 2008, found that 44 % of respondents who used BZP had been mostly using illegal drugs but had substituted BZP for their illegal drug use.<sup>637</sup> Another study that surveyed users of BZP found that just under half who indicated they were otherwise likely to use BZP in the future would be more likely as a result of the ban on BZP to use ecstasy instead.<sup>638</sup> On that basis, arguably, the legal availability of BZP may have prevented at least some people from using other more harmful drugs.
- 8.20 Where regulation rather than prohibition of a drug will not have the effect of encouraging a shift from more to less harmful drugs, the option of prohibition would remain. Prohibition might be appropriate, for example, if a new psychoactive substance is found to be more harmful than a convention drug and might be more widely used because of its legal status. In other words, one of the factors that will need to be considered when determining how a new drug should be regulated is the impact this decision could have on the decisions people might make about substituting one drug for another.
- 8.21 If the approach we recommend is taken, it will be important that the regulatory regime that applies to new regulated psychoactive substances is carefully monitored and evaluated. This will allow for early intervention if the controls on a substance prove to be ineffective. It will also provide important information that could assist

637 C Wilkins and others *Legal Party Pill Use in New Zealand: Prevalence of Use, Availability, Health Harms and "Gateway Effects" of Benzylpiperazine (BZP) and Trifluoromethylphenylpiperazine (TFMPP)* (Centre for Social and Health Outcomes Research (SHORE) & Te Ropu Whariki, Massey University, 2006) 43.

638 James A Green "Partying on? Life After BZP-based Party Pills" (2008) 121 NZMJ 4.

in assessing the effectiveness of alternative regulatory approaches. In the longer term, information of this kind could usefully inform the international debate about the effectiveness of alternative drug control regimes.

Q1 Do you agree that the model for regulating drugs other than convention drugs should generally be regulation with restrictions, rather than prohibition, but with prohibition available as a last resort where regulation has proved ineffective?

## A NEW FRAMEWORK FOR REGULATION

- 8.22 We turn to consider what regulatory restrictions should be imposed as an alternative to prohibition for new recreational psychoactive substances that are not covered by the conventions. We identify the core features that this type of regulatory regime should have and then consider whether a separate regime or regulation under the Hazardous Substances and New Organisms Act 1996 (HSNO) would be the better approach. If a separate regime is considered the better approach, it should be included in the new legislative framework we are proposing in this paper to replace the Misuse of Drugs Act.

### Recap of the current position

- 8.23 As we outlined in chapter 5, an amendment to the Misuse of Drugs Act in 2005 introduced the restricted substances regime. This was intended to provide a regime for regulating new recreational psychoactive substances that were not harmful enough to justify prohibition.
- 8.24 Chapter 5 discussed a definitional problem with the restricted substances regime. “Hazardous substances”, “foods”, “medicines” and “controlled drugs” are all excluded from the restricted substances regime. However, the definition of “hazardous substances” currently includes substances that are toxic. By their nature recreational psychoactive substances temporarily change the physiological functioning of the brain and are therefore toxic and excluded from the restricted substances regime. If a psychoactive substantive is not a “food”, a “medicine”, or a “controlled drug”, it must be a “hazardous substance”. Since all of these are excluded from the restricted substances regime, there appear to be no substances that can come within the regime. We understand that an amendment to the Act is being considered by the Government to address this particular problem.
- 8.25 The current position therefore is that technically all new recreational psychoactive substances other than those classified as food or medicines fall under the regime in HSNO. The Ministry of Health is an enforcement agency under that Act. However, in practice the HSNO regime has never been used to deal with recreational psychoactive substances. As a result, party pills containing BZP appeared on the market without any regulatory controls.
- 8.26 The question arises whether new drugs should be dealt with by HSNO (which would require operational but not necessarily legislative change) or whether they are better regulated under a regime (like the current restricted substances regime) which is separate from HSNO and designed specifically for new recreational psychoactive substances.

- 8.27 In order to resolve that question, we need to determine what the core features of a regulatory regime for new recreational psychoactive substances should be.

### Approval of new substances

- 8.28 A key difference between the restricted substances regime and HSNO is that the restricted substances regime proceeds on the assumption that there are no legal restrictions on the manufacture, supply and use of new psychoactive substances before they are brought under the regime. These activities are all left unregulated until a substance is made a restricted substance. Section 32 of the Misuse of Drugs Amendment Act 2005 gives the Expert Advisory Committee on Drugs (EACD) the function of carrying out evaluations of substances to assess whether or not a recreational psychoactive substance should be restricted and, if so, the type of restrictions that are appropriate. However, in practice an evaluation is not normally undertaken by the EACD until a substance comes to its attention because it is perceived to be causing harm. In the case of BZP, this occurred only after products containing BZP had been on the market for some time. By that stage, there were already a number of manufacturers, importers and suppliers engaged in the distribution and promotion of these products.
- 8.29 In contrast, the hazardous substances regime automatically covers all substances that meet the definition of hazardous and requires that they be approved by the Environmental Risk Management Agency (ERMA) before being manufactured or imported.<sup>639</sup> This ensures that appropriate regulatory controls to promote the safe use of the substance can be imposed before the substance can be legally manufactured or imported. It also places on the manufacturer or importer the responsibility of showing that a substance can be managed with appropriate controls.
- 8.30 In our view, any regulatory regime for new recreational psychoactive substances should follow the approach in HSNO. New recreational psychoactive substances should require an approval before they can be manufactured, imported or distributed in New Zealand. We think that it is better for all new psychoactive substances, other than food and medicine, to automatically fall within a regulatory regime of this sort. This would ensure that the risks associated with the recreational use of a substance are assessed by a regulatory body, and appropriate controls are put in place, before it becomes available for sale.
- 8.31 We also suggest that, as part of the approval process, the importer or manufacturer of such a substance should be required to provide to the regulatory body all available information about the composition of the substance and its known health effects, in order to assist in the determination of what regulatory controls are appropriate.
- 8.32 If a substance is assessed and not approved, because it appears from the available evidence (such as, for example, the experience with it in other jurisdictions) that it has such significant adverse effects that these cannot be adequately managed with conditions, the regulatory body should refer the substance to the agency responsible for prohibited drugs so that the substance can be brought under the prohibited drugs regime.

<sup>639</sup> Where there is uncertainty as to whether a substance is hazardous or not an application can be made for a determination under section 26 of the Act. This process is discussed in chapter 5.

8.33 We think that other products that contain psychoactive substances but are primarily manufactured, imported and distributed for other purposes – such as solvents, butane, petrol and various other domestic and industrial products – should continue to be regulated under HSNO for their dominant use and not as recreational psychoactive substances. However, we suggest that when ERMA is assessing these substances and determining appropriate controls under that regime, greater consideration should be given to the potential for these products to be misused for their psychoactive effects. Where there is evidence that substances are being used in this way, the restrictions, particularly on retail sales, should reflect the harm such misuse may cause.

Q2 Do you agree that a psychoactive substance falling within the ambit of the proposed regime should require an approval from the regulatory body before it can be manufactured or imported?

Q3 Do you agree that all new psychoactive substances that are manufactured or imported for recreational use should be covered by the proposed new regulatory regime?

### Generic or specific regulatory controls

8.34 Under HSNO, the controls that apply to the manufacture, import and distribution of any hazardous substance normally depend upon the conditions attached by ERMA to the substance's approval. In other words controls are tailored to reflect the type of substance for which approval is sought. This is generally required because of the extensive and diverse range of substances that fall within the hazardous substances regime.

8.35 Regulations may be made under HSNO to prescribe generic default controls which then apply to all hazardous substances falling within a specific hazard classification (for example, explosives, flammable gases).<sup>640</sup> ERMA may also issue a common set of conditions (called a “group standard”) that applies instead of an individual approval to all substances that fall within the criteria set for that group.<sup>641</sup> The objective is to cover existing and new products that have similar profiles and uses and cause similar toxic effects. ERMA may issue, amend or revoke a group standard on its own initiative or on application by any person.<sup>642</sup> In practice, the conditions in group standards tend to be in broadly similar areas, including information requirements and restrictions relating to site and storage, transportation and disposal. Group standards are really designed for products that are at the lower end of the hazard spectrum. ERMA must be satisfied that issuing a group standard is a more efficient and effective way of managing the risks of all the hazardous substances in the identified group than the ordinary approval process.<sup>643</sup>

<sup>640</sup> Hazardous Substances and New Organisms Act 1996, ss 75 and 140.

<sup>641</sup> Hazardous Substances and New Organisms Act 1996, s 96A.

<sup>642</sup> Hazardous Substances and New Organisms Act 1996, s 96B(3).

<sup>643</sup> Hazardous Substances and New Organisms Act 1996, s 96C(1)(a)–(c).

8.36 In contrast, there are a number of regulatory controls in the restricted substances regime that are generic. We described these in chapter 5, although it is useful to briefly recap. The restricted substances regime prohibits:

- the sale or supply of a restricted substance to any person under the age of 18 years;<sup>644</sup>
- any person under the age of 18 years from selling any restricted substance;<sup>645</sup>
- any manufacturer, distributor, importer or retailer of a restricted substance from distributing or supplying it free of charge or from offering a range of incentives, such as promotional gifts, to encourage purchase;<sup>646</sup>
- the advertising of a restricted substance on television or radio or in a newspaper or other periodical such as a magazine, or in any other medium specified by regulation.<sup>647</sup>

8.37 There are also broad powers to make regulations relating to:<sup>648</sup>

- (i) the places at which restricted substances can be sold or supplied;
- (ii) additional advertising restrictions and requirements;
- (iii) labelling restrictions and requirements;
- (iv) packaging and storage restrictions and requirements;
- (v) health warning requirements;
- (vi) signage and display requirements;
- (vii) quantity, dosage, form and serving requirements;
- (viii) record-keeping requirements.

To date, one set of generic regulations that apply to all restricted substances has been made. The Misuse of Drugs (Restricted Substances) Regulations 2008 impose generic restrictions on the place of sale or supply, advertising, labelling, packaging, storage, and signage and display for all restricted substances.

8.38 Regulations can be made that generally apply to all restricted substances or to any particular type of restricted substances, or even one particular substance. There is scope, therefore, to tailor regulations so as to impose appropriate conditions, although it could become quite cumbersome and complex if there were separate sets of regulations for each different substance.

8.39 In addition, the Director-General of Health may issue codes of manufacturing practice.<sup>649</sup> Where a code is in place, only those substances that comply fully with the code may be manufactured or imported.

644 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.

645 Misuse of Drugs Amendment Act 2005, s 38.

646 Misuse of Drugs Amendment Act 2005, s 42.

647 Misuse of Drugs Amendment Act 2005, s 43.

648 Misuse of Drugs Amendment Act 2005, s 62.

649 Misuse of Drugs Amendment Act 2005, s 63.

## Minimum regulatory controls

- 8.40 There are significant differences between psychoactive substances which might require different controls. For example, it is difficult to see how a generic regulation relating to dosages could ever be made to work because different dosages will be appropriate for different substances.
- 8.41 However, we suggest also that there are some regulatory requirements that should apply to all recreational psychoactive substances, if they are approved. These generic conditions should be included in primary legislation.

## Age restrictions

- 8.42 Age restrictions should probably apply to the sale and supply of all recreational psychoactive substances.
- 8.43 As has been noted, legislation currently prohibits the sale or supply of a restricted substance to, or by, a person under 18. This restriction is consistent with current age restrictions on the sale of alcohol under the Sale of Liquor Act 1989 and tobacco under the Smoke-free Environments Act 1990. These all set a minimum age at which psychoactive substances can be purchased by young people or supplied to them. Age restrictions of this type are used across the world to limit the access young people have to legally available psychoactive substances. In the case of alcohol a legal purchase age is recognised internationally as being a highly effective and inexpensive supply control mechanism.<sup>650</sup> We suggest it might have a similar effect for other psychoactive substances.
- 8.44 Alcohol and other psychoactive drugs have the potential to affect neurological development in adolescents. Age restrictions might therefore be justified from a harm reduction perspective, because there is evidence that such substances do pose a greater risk of harm to young people. In chapter 2 we noted, for example, the increasing evidence of a causal relationship between cannabis use in early teens and some mental health disorders, and the greater impact of cannabis on the perceptions, short-term memory, attention, and motor skills of young people. In chapter 4 of the Law Commission's Issues Paper *Alcohol in Our Lives*, we also note that new research has found that young people experience more harm per standard drink than other drinkers.<sup>651</sup>
- 8.45 Whether the recreational psychoactive substances that would be regulated under the type of regime proposed here would affect young people and their development more adversely than others is difficult to assess. This is partly because we do not at present know what those substances are. Based on experience with other psychoactive substances, it is reasonable to assume that some might, while others might not. But even if new psychoactive substances that are developed in the future do not affect young people more adversely than other people, it can be assumed that they will have the potential to cause a range of physical and psychological harms,

650 See the discussion on this point in New Zealand Law Commission *Alcohol in Our Lives: an Issues Paper on the Reform of New Zealand's Liquor Laws* (NZLC IP 15, Wellington, 2009) 151.

651 See the discussion on this point and the harm alcohol causes youth in *ibid*, 47.

particularly if used repeatedly or excessively.<sup>652</sup> Again we think this is a reasonable assumption to make based on experience to date with the new synthetic drugs that have emerged over recent decades, including party pills.

- 8.46 Given the risk of harm, there is a strong argument for the state to take a paternalistic approach and to impose age restrictions aimed at preventing access to these potentially harmful substances until young people are sufficiently mature to assess the risks for themselves. As discussed in chapter 7, in the area of drug use, a paternalistic approach in respect of children and young people is necessary.
- 8.47 The difficulty comes with determining the appropriate age at which such restrictions are no longer justified. In the case of alcohol and tobacco this has been quite contentious. The legal purchase age for alcohol has been under discussion for a number of years. An important consideration in that debate has been concern over the extent to which a lower age limit may increase the level of access those younger than the set age will have in practice. While there may be some important differences between the risks of harm associated with alcohol and those associated with the types of psychoactive substances that may ultimately be regulated under the regime proposed here, there are similar considerations around a young person's maturity to make decisions on substance use, for example, in relation to likely addiction, impact on schooling and social development. There are also similar issues around the impact of age restrictions on the access of those younger than the set age. There is therefore good reason for applying the same age limit that applies to alcohol to new psychoactive substances.
- 8.48 Another argument for aligning the purchase age for psychoactive substances with the purchase age for alcohol is that it would avoid the possibility of young people shifting their use from alcohol to other psychoactive substances. Against that, evidence suggests that alcohol is at least as harmful as, if not more harmful than, many other psychoactive substances.<sup>653</sup>
- 8.49 On that basis we suggest that 18 should be the statutory minimum age for the supply of any psychoactive substance. This is consistent with the current approach to alcohol and tobacco. We note the Government intends to introduce new legislation regulating alcohol later this year. The legal purchase age for alcohol will be reconsidered in that context. If the age at which alcohol can be purchased is increased, consideration may need to be given to increasing the age at which new psychoactive substances can be purchased to align it with the age that applies to the purchase of alcohol. An intermediate option would be a statutory minimum age of 18, with the regulatory agency having power to increase the purchase age to 20 if that was appropriate having regard to the particular nature of the substance.

652 In one study undertaken on the use by young people of legally available party pills containing BZP, a range of negative emotional or psychological effects were identified as occurring during the "comedown" period. These included feeling depressed or down, tense and edgy, angry or annoyed, socially withdrawn, or anxious or paranoid. Other negative impacts relating to the "comedown" period included lack of sleep/ inability to sleep, loss of appetite, lethargy, headache, nausea, aching and tense body, impaired work or study performance (including absences) and dehydration. See Janie Sheridan and Rachael Butler *Legal Party Pills and their Use by Young People in New Zealand: A Qualitative Study Final Report of Findings* (University of Auckland, Auckland, 2007) vii.

653 See for example David Nutt and others "Development of a Rational Scale to Assess the Harm of Drugs of Potential Misuse" (2007) 369 *Lancet* 1047.

## *Advertising/promotional restrictions*

- 8.50 The restricted substances regime prohibits the advertising of restricted substances in the mainstream media. Restricted substances cannot be advertised on television or radio or in a newspaper or other periodical such as a magazine. Regulations can also be made specifying other media in which advertising is prohibited. There is also a prohibition on other promotions of restricted substances such as the distribution or supply of a restricted substance free of charge or the offering of incentives such as promotional gifts to encourage purchase. Regulations made under the Act provide that advertising for a restricted substance may appear only on premises where a restricted substance is sold or supplied. Such advertising must be confined to the inside of the premises and must not be easily visible or audible from outside the premises. However, the regulation expressly excludes advertising on the Internet from these restrictions.
- 8.51 Even broader advertising restrictions apply to the advertising of tobacco products in New Zealand. Section 22 of the Smoke-free Environments Act prohibits the publication of, or the making of arrangements to publish, any tobacco product advertisement. The term “tobacco product advertisement” is broadly defined in section 2 of the Act. It means “any words, whether written, printed or spoken including on film, video recording or other medium, broadcast or telecast and any pictorial representation or device used to encourage the use or notify the availability or promote the sale of any tobacco product or promote smoking behaviour” and includes:
- (a) any trade circular, any label and any advertisement in any trade journal; and
  - (b) any depiction in a film, video recording, telecast or other visual medium, of a tobacco product or tobacco product trade mark where in return for that depiction any money is paid or any valuable thing is given whether to the maker or producer of that film, video recording, telecast or visual medium or to any other person; and
  - (c) the use in any advertisement or promotion to the public of a tobacco product manufacturer’s name where that name or any part of that name is used or is included in a tobacco product trade mark.

This definition would appear to include advertising on the Internet.

- 8.52 In contrast, far less restriction is currently placed on the advertising and promotion of alcohol. The model here is one of industry self-regulation. Advertisements for alcohol that comply with the Code of Practice for Advertising Liquor can be run in all mainstream media. The Code requires that all advertising of alcohol must adhere to certain principles. There are also guidelines issued to help advertisers interpret and apply the principles in the Code. In 2009, a separate Alcohol Promotions Code was established to cover promotion. The alcohol industry in New Zealand spends millions of dollars annually on alcohol advertising through print, broadcast, news media and sponsorship.<sup>654</sup>

<sup>654</sup> See Report of the Steering Group for the Review of the Regulation of Alcohol Advertising (2007) 33 <http://www.ndp.govt.nz> (accessed 16 November 2009).

- 8.53 The Advertising Standards Authority (ASA) oversees the Code. Complaints can be made to the ASA about any advertisement in any media that any person considers breaches the Code. The ASA funds a separate self-regulatory body called the Advertising Standards Complaints Board that adjudicates on complaints received about advertisements that may breach a code of advertising practice. Where a complaint is upheld, advertisers are required to voluntarily withdraw the advertisement.
- 8.54 In addition, section 154A of the Sale of Liquor Act deals with some forms of promotion. It is an offence for a licensee or manager of licensed premises to do anything in the promotion of the business (or any event or activity held on the premises) that is intended or likely to encourage people on the licensed premises to consume alcohol excessively.
- 8.55 The different models for tobacco and alcohol represent the two ends of the spectrum of approaches that might be taken to regulating the advertising and promoting of other recreational psychoactive substances.
- 8.56 If new recreational psychoactive substances are to be legal and regulated rather than prohibited, it will be important to prevent the kind of commercialisation that surrounds alcohol and tobacco. Some commentators suggest that the harm associated with products such as alcohol and tobacco stem as much from the commercialisation of these products as from their mere availability. MacCoun and Reuter, for example, drew on evidence from gambling, tobacco, alcohol and Dutch cannabis coffee shops to argue that commercial promotion may matter as much as or more than the mere availability of a substance.<sup>655</sup>
- 8.57 The experience with alcohol advertising suggests that self-regulation is not an effective regulatory model. The submissions on the Commission's Issues Paper *Alcohol in Our Lives* strongly supported much more stringent regulation of alcohol advertising and promotion.<sup>656</sup> Moreover, although there are now extensive restrictions applying to the advertising and promotion of tobacco in New Zealand, historically that has not been the case. The earlier experience with tobacco is often used by commentators to illustrate the risks around commercialisation. One way of preventing commercialisation is by imposing and enforcing broad restrictions on advertising and promotion.
- 8.58 We therefore strongly favour the type of restrictions found in the Smoke-free Environments Act. The restrictions should include a prohibition on advertising on the Internet.
- 8.59 We acknowledge that restrictions on advertising raise issues of consistency with the right to freedom of expression in section 14 of the New Zealand Bill of Rights Act 1990. Section 14 protects the right to freedom of expression, including the freedom to seek, receive and impart opinions of any kind and in any form. The right to freedom of expression has been interpreted to extend to all forms of communication which attempt to express an idea or meaning, including commercial speech such as advertising.<sup>657</sup>

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655 MacCoun and Reuter, above n 630, 77.

656 New Zealand Law Commission, above n 650.

657 *Irwin Toy Ltd v Attorney-General (Quebec)* [1989] 1 SCR 927 (SCC).

- 8.60 However, courts in other jurisdictions have generally been willing to limit commercial expression more readily than other forms of speech. For example, in *Markt Intern and Beerman v Germany*,<sup>658</sup> the European Court of Human Rights held that member states have a wider margin of appreciation when it comes to imposing limitations on freedom of expression that impinge on commercial expression than they do with other forms like artistic or academic expression.
- 8.61 Nevertheless, in both the United States and Canada the courts have struck down blanket bans on advertising. In the United States, the Supreme Court struck down a blanket ban on advertising the price of prescription drugs.<sup>659</sup> In Canada, the Supreme Court held that a blanket advertising ban on cigarette advertising infringed the Canadian Charter of Rights and Freedoms because it did not limit the right to freedom of expression as little as reasonably possible in the circumstances. The Court accepted that a more targeted tobacco advertising ban could be justified.<sup>660</sup>
- 8.62 These cases concerned advertising products that were already legal. We consider that broad restrictions on the advertising of new recreational psychoactive substances similar to those in the Smoke-free Environments Act are at least arguably a justified limitation on the right in section 14 under the Bill of Rights Act for a number of reasons. These include that:
- (i) research suggests there is a need to prevent commercialisation of new recreational psychoactive substances to ensure they do not become as prevalent as alcohol and tobacco and to minimise the harm they might otherwise cause;
  - (ii) if advertising restrictions are not imposed, it may be necessary to prohibit the manufacture or import of these substances altogether which would entail a greater restriction on individual freedom (although not a right protected by the Bill of Rights Act);
  - (iii) as these are new products, those who choose to enter the market will do so knowing of the restrictions that are imposed;
  - (iv) it is consistent with the approach taken to the advertising of tobacco products.
- 8.63 In any event, any uncertainty over whether advertising restrictions of this nature might be considered inconsistent with the Bill of Rights Act would be less important if Parliament enacted the restrictions in primary legislation rather than leaving them to regulations which could be vulnerable to challenge.
- 8.64 We also favour a prohibition on the promotion of recreational psychoactive substances similar to that currently applying to restricted substances.

658 *Markt Intern and Beerman v Germany* (1989) 12 EHHR 61 (ECHR).

659 *Virginia State Board of Pharmacy v Virginia Citizens Consumer Council Inc* 425 US 748 (1976).

660 *RJR McDonald Ltd v Canada* [1995] 3 SCR 199.

*Places of sale restrictions*

- 8.65 As outlined earlier, the restricted substances regime provides for regulations to be made limiting places from which restricted substances can be sold or supplied. Regulations currently prohibit the sale or supply of restricted substances from:
- (i) places where alcohol is sold;
  - (ii) petrol stations;
  - (iii) non-fixed premises such as vehicles, tents and mobile street cars;
  - (iv) places where children gather (schools, recreational facilities and sports facilities).
- 8.66 By way of contrast, the Sale of Liquor Act requires premises at which alcohol is sold to be licensed.
- 8.67 We doubt that there would be a sufficient number of new recreational psychoactive substances to warrant the introduction of a full licensing system like that applying to alcohol. However, we suggest that the restrictions currently in the Misuse of Drugs (Restricted Substances) Regulations should be included in legislation setting minimum requirements applying to the sale of all recreational psychoactive substances.
- 8.68 It is desirable to keep the sale of alcohol and other psychoactive substances separate, since the combination of alcohol and some other psychoactive substances is more harmful than either substance individually. It would send the wrong message if they were able to be sold together. We note that the harms associated with all new psychoactive substances may not necessarily be increased by alcohol, but there is evidence that when some drugs (for example, BZP, ecstasy, fantasy) are combined with alcohol the toxicological effects are much harder to predict.
- 8.69 Similarly, driving while under the influence of alcohol or other drugs is inherently undesirable. For this reason, the Sale of Liquor Act prohibits the sale of alcohol at petrol stations.<sup>661</sup> The same principle should apply to other legally available psychoactive substances. Their sale should be separated from activities related to driving. We would also add pharmacies to the list of places prohibited from selling or supplying psychoactive substances. The substances we are concerned with here are not therapeutic products and there should be no room for misunderstanding about that. As well as these statutory restrictions, the regulatory body should have the power to impose additional restrictions on the place of sale, if appropriate, having regard to the nature of the substance.

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<sup>661</sup> Section 36(3)(a) of the Sale of Liquor Act prohibits an off-licence from being granted to sell alcohol from any service station or other premises in which the principal business is the sale of petrol or other automotive fuels.

### *Restrictions on who can supply recreational psychoactive substances*

- 8.70 The restricted substances regime imposes no restrictions on who can sell or supply restricted substances other than a restriction on sale or supply by persons under 18. However, the court can prohibit a person from selling or manufacturing a restricted substance if that person is convicted of an offence relating to a restricted substance within two years of being sentenced on another such offence. When imposing the sentence for the second (or subsequent) offence, the court may make an order to this effect.<sup>662</sup>
- 8.71 In our view, there need to be further protections. In a market where some recreational psychoactive substances are legal and others are not, it is important that the legal market is kept separate from the black market. On that basis, we suggest that there should be a prohibition on the manufacture and sale of legal substances by any person who has been convicted within the previous five years of a dealing offence under the Misuse of Drugs Act or a serious offence under the Crimes Act 1961 with a maximum penalty of seven years. We think the court should also have the power, when sentencing a person convicted of an offence related to a legally available psychoactive substance, to prohibit that person from manufacturing or selling substances under the regime. Unlike the restricted substances regime, do not think that two convictions should be needed to trigger this power, as there may be cases where there is such a blatant disregard for the regulatory requirements that immediate action is appropriate.

### *Other restrictions*

- 8.72 Two other restrictions, currently in the Misuse of Drugs (Restricted Substances) Regulations, would also be useful for inclusion as minimum requirements. These are a requirement for these substances to be stored in child-proof and tamper-proof containers and a requirement that the label contain the phone number and address of the National Poisons Centre. Both requirements are obviously useful safety precautions. They also make it abundantly clear to potential purchasers or users of these substances that they are potentially harmful and, as such, send a useful health message.

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662 Misuse of Drugs Amendment Act 2005, s 54.

- Q4 Do you agree that the following should be standard minimum requirements:
- (a) restrictions on the sale or supply of recreational psychoactive substances to persons under 18 (if so, should the age be changed in the event of a change to the purchase age for alcohol?);
  - (b) advertising restrictions along the lines of the restrictions on advertising tobacco products under the Smoke-free Environments Act;
  - (c) a prohibition on the promotion of these substances similar to that currently applying to restricted substances;
  - (d) a prohibition on the sale of these substances at:
    - (i) places where alcohol is sold;
    - (ii) petrol stations;
    - (iii) non-fixed premises such as vehicles, tents, and mobile street cars;
    - (iv) places where children gather;
    - (v) pharmacies;
  - (e) a prohibition on the manufacture, importation and sale of these substances by any person:
    - (i) under the age of 18 years; or
    - (ii) who has been convicted within the previous five years of a dealing offence under the Misuse of Drugs Act or an offence under the Crimes Act punishable by seven years imprisonment; or
    - (iii) who has been convicted of an offence under the regime applying to these substances and has been prohibited by the court from undertaking any of these activities;
  - (f) a requirement that these substances be stored in child-proof and tamper-proof containers; and
  - (g) a requirement that the labels should contain the contact details of the National Poisons Centre?

- Q5 Are there other matters that should become minimum standard requirements?

### Conditions of approval

- 8.73 We suggested earlier that, as well as the statutory minimum requirements, more tailored conditions are required. Therefore, legislation should also specify a range of matters where the regulatory body has power to impose additional tailored conditions as part of an approval to manufacture or import a recreational psychoactive substance. Additional conditions could relate to any or all of the following:
- (i) additional place of sale restrictions;
  - (ii) labelling restrictions and requirements;
  - (iii) packaging restrictions and requirements;

- (iv) health warning requirements;
  - (v) signage requirements;
  - (vi) quantity, dosage, form and serving requirements;
  - (vii) storage and display restrictions;
  - (viii) record-keeping requirements;
  - (ix) any other requirements considered necessary or desirable to minimise the harm that might occur as a result of use of the substance.
- 8.74 The legislation would require any person selling or supplying a psychoactive substance, as well as the manufacturer or importer, to comply with any specific conditions relating to these matters that have been specified in the manufacturing or importing approval for a substance.
- 8.75 Provisions are also needed to enable the regulatory body to amend the conditions of an approval or revoke it if it becomes evident that the risks associated with a particular substance are more or less significant than was assessed based on the information available at the time the approval was given. Appeal and review mechanisms will also be needed.
- 8.76 The legislation should also empower the regulatory body to issue codes of manufacturing practice. These would bind manufacturers and importers of different substances.

Q6 Do you agree that the regulating body should have power to impose additional conditions on an approval for a new recreational psychoactive substance? If so, should the conditions cover:

- (i) additional place of sale restrictions;
- (ii) labelling restrictions and requirements;
- (iii) packaging restrictions and requirements;
- (iv) health warning requirements;
- (v) signage requirements;
- (vi) quantity, dosage, form and serving requirements;
- (vii) storage and display restrictions;
- (viii) record-keeping requirements;
- (ix) any other requirements considered necessary or desirable to minimise harm that might occur as a result of use of these products?

Q7 Should the regulatory body have the power to issue manufacturing codes of practice?

### Powers to recall products

- 8.77 Under the restricted substances regime, the Minister has power to recall a restricted substance if the Minister considers the substance is:
- (a) unsound or unfit for human consumption;
  - (b) damaged, deteriorated or perished;
  - (c) contaminated with any poisonous, deleterious or injurious substance.

- 8.78 We consider a power of this kind is necessary and should rest with the regulatory body, rather than with the Minister. This would ensure that a recall can occur as soon as a problem becomes apparent.

Q8 Do you agree that there should be a power of recall? If so, in whom should that power vest?

### Offences

- 8.79 The regulatory requirements will need to be supported by offence provisions that apply to any person who manufactures, imports, exports, sells or supplies any new recreational psychoactive substance without an approval, or in breach of the minimum statutory conditions or any additional conditions that were imposed at the time of approval.
- 8.80 Offences under the restricted substances regime are punishable by fines not exceeding \$5000 in the case of an individual and \$10,000 in the case of a body corporate. In addition, as we have already noted, the court may prohibit a person from selling or manufacturing a restricted substance if that person is convicted of an offence relating to a restricted substance within two years of being sentenced on another such offence. In contrast, the penalties for contraventions of the HSNO regime attract penalties of up to three months imprisonment and fines of up to \$500,000.
- 8.81 If new recreational psychoactive substances remain within HSNO, that offence regime will apply. That regime covers a broad range of hazardous substances as well as new organisms, some of which can create significant environmental or public health risks. Very few of the types of offences that might be committed with new recreational psychoactive substances will involve this type of risk.
- 8.82 Alternatively, if there is a separate regime specifically for new recreational psychoactive substances, penalty levels might instead be set at levels that are comparable with those imposed for breaches of the equivalent regulatory controls on alcohol and tobacco. Comparable offences involving a breach of the restrictions on tobacco (including advertising and display restrictions) are punishable by fines of up to \$50,000. The level of fine varies depending on whether an offence is committed by an individual or a body corporate and whether the person is a manufacturer, distributor or retailer. There are some comparable offences under the Sale of Liquor Act attracting a maximum fine of \$40,000 and up to three months imprisonment.

Q9 Should penalty levels for offences be set at the levels currently provided for in HSNO or should they be set at similar levels to penalties in regimes regulating drugs like alcohol and tobacco?

### Enforcement powers

- 8.83 We discuss enforcement powers in chapter 14. In particular, we suggest that a power of entry and inspection for regulatory purposes is required. We note in passing here that currently under HSNO, where new psychoactive substances are

imported without an approval, they become prohibited imports under section 54 of the Customs and Excise Act 1996 so that section 209 of that Act applies.<sup>663</sup> Consequently section 122 of HSNO provides a power for customs officers to direct that hazardous substances imported in breach of HSNO remain on the ship or vessel by which they were brought to New Zealand or to require that they be removed from New Zealand at the importer's expense. In addition, prohibited imports are forfeited to the Crown<sup>664</sup> and can be seized.<sup>665</sup> These would seem useful provisions to include in any new regime for recreational psychoactive substances.

- 8.84 Finally, we note that whatever regime is to deal with new recreational psychoactive substances, it is essential that the requirements are actively enforced. One of the main reasons for the EACD recommendation to reclassify BZP as a Class C controlled drug was the “absence of a significant administration and enforcement capacity such as exists for pharmaceuticals and for legal drugs, tobacco and alcohol.”<sup>666</sup> In our view the administrative and enforcement capacity to regulate these substances should be made available. There is certainly reason to believe that appropriately regulating these substances may be more effective at minimising drug-related harm than prohibiting them altogether and there is the opportunity to test this in a closely monitored and controlled environment. The restricted substances regime in New Zealand has been the subject of significant international interest for this reason. It would be unfortunate if the failure to provide adequate resources for administration and enforcement means that this opportunity is wasted.

### HSNO or a separate regime

- 8.85 As we have already said, technically new recreational psychoactive substances that are not foods or medicines are hazardous substances and can be regulated by HSNO. The issue is whether they should be dealt with under that Act or under a new separate regime that replaces the restricted substances regime. If they remain within HSNO, any new psychoactive substance that is not approved because it has significant adverse effects that cannot be adequately managed by the imposition of conditions, would need to be referred by ERMA to the agency responsible for prohibited drugs so the substance could be brought under the prohibited drugs regime.

- 8.86 The advantages of regulating these substances under HSNO are:
- the mechanisms are already in place for approving the import and manufacture of hazardous substances and appeals against approval decisions;
  - there may be an insufficient number of new recreational psychoactive substances to justify the expense of a separate system;
  - it avoids the need for a separate definition of new recreational psychoactive substances and the attendant difficulties at the margins of determining which regime should regulate a particular substance;
  - with one agency assessing and approving all harmful substances, there may be more consistency over the level of hazard tolerated and less need for coordination between different agencies.

663 Under section 209 of the Customs and Excise Act 1996 it is an offence to import a prohibited import.

664 Customs and Excise Act 1996, s 225.

665 Customs and Excise Act 1996, s 226.

666 Meeting Minutes, Expert Advisory Committee on Drugs (29 November 2006).

- 8.87 However, there are also disadvantages with use of the HSNO system and advantages in having a separate regime. Firstly, we have suggested that there are some regulatory requirements that should form a set of statutory minimum controls applying to all recreational psychoactive substances. If the substances were to be regulated under HSNO, some changes would need to be made to that regime to place such minimum controls in statute.
- 8.88 Secondly, substances have not historically been regulated under the predecessor statutes to HSNO. As a result ERMA does not necessarily have the specific expertise required to deal with this particular type of substance. Moreover, the large number of substances that fall to be regulated under HSNO creates a risk that these new substances may not receive as much attention as they would under a separate regime. As we said earlier, if new recreational psychoactive substances are to be regulated rather than prohibited, it is important that there be careful monitoring and evaluation of the effectiveness of the regulatory regime. This is more likely to occur under a separate regime.
- 8.89 Thirdly, the criteria in HSNO are not entirely appropriate for psychoactive substances. When considering an application for an approval for a hazardous substance, 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.
- 8.90 If the positive effects of the substance outweigh the adverse effects, the application can be approved, but otherwise it must be declined. An application can also be declined if the applicant fails to provide sufficient information for the assessment.
- 8.91 The positive effects of a psychoactive substance that is for recreational use are much less tangible than for substances typically evaluated by ERMA. Without more specific guidance it may be difficult to weigh the intangible recreational benefits people may enjoy against a substance's more tangible adverse effects. The matters ERMA considers do not expressly include the likely consequences of any proposed regulatory model or the possible displacement effects that may result from the way other substances are regulated. This suggests that criteria tailored specifically for assessing psychoactive substances may be preferable.
- 8.92 On balance, therefore, we are inclined to the view that a new separate regime is preferable to regulation through HSNO.
- 8.93 For such a regime, tailored criteria would need to be devised for deciding whether a substance should be regulated and an approval issued. Relevant criteria seem to be:
- (i) the nature of the harm caused by the substance and any benefits associated with its use;
  - (ii) whether that harm can be effectively managed by the imposition of regulatory controls (including considering any research into the impact of different regulatory controls on minimising harm generally and also specifically (if available) for that substance);

- (iii) the likely consequences of any proposed regulatory controls or prohibiting the substance (including the cost of different regulatory options); and
  - (iv) any possible displacement effects that might occur because of the way other substances are regulated. (While this is an aspect of the previous criterion, it is important enough to be expressly included.)
- 8.94 In looking at issues of effectiveness under the second criterion, it would be important to consider the prevalence of use of a substance. If a substance is widely available and widely used, some types of regulatory restriction or prohibition might be less effective than they may be with a less prevalent substance.
- 8.95 Under the third criterion, the relevant consequences of all alternative drug control options for the substance would be assessed. This would involve identifying the consequences, measuring the magnitude of those consequences, and, to the extent it is possible, quantifying them to facilitate comparison with the consequences of other options for control (that is, prohibition).
- 8.96 The fourth criterion expressly requires consideration of the risk that full prohibition of a substance might encourage the use of more harmful substances. It also takes into account the possibility that the use of more harmful prohibited drugs may be discouraged by the availability of less harmful alternatives.
- 8.97 As we discussed at the beginning of this chapter, there are significant gaps in the available evidence concerning the effectiveness of different regulatory approaches. There are also important elements of subjective value judgement involved in weighing up the evidence and the tangible and intangible costs and benefits. While it is important to acknowledge these limitations, the regulatory authority should consider what evidence is available and base its judgements on the available evidence. This will require a common sense judgement about matters such as the experience of the substance in other jurisdictions and its similarity to other substances and their known effect.
- 8.98 If a separate regime for recreational psychoactive substances is established, there are good reasons for the regulatory and enforcement authority to be the same as that responsible for regulating prohibited drugs. If an approval to manufacture or import a substance is declined, the substance should normally be brought under the control regime that applies to prohibited drugs. This suggests that either the Minister or the Director-General of Health, rather than ERMA, should be the regulatory authority, and that the Ministry of Health should administer and enforce the regime.
- 8.99 We note that there are some possible disadvantages in giving either the Minister or the Director-General the function of issuing manufacturing and importation approvals for these substances. An approval from either the Minister or the Director-General may be seen as sanctioning such substances for use. It may therefore send quite the wrong message over their use. The counter-argument is that the purpose of the regulatory controls is to minimise the harm associated with recreational psychoactive substances and the involvement of the Minister or the Director-General in harm minimisation is appropriate, particularly if such decisions are informed by expert evidence and evaluation.

- 8.100 We think that decisions on whether approvals are issued or not should be made by the Minister of Health. The choice between the Minister and the Director-General concerns the appropriate level within the executive at which these types of decisions need to be made. The Legislation Advisory Committee Guidelines advise that the broader the policy element the more appropriate it may be for the matter to be settled by Ministers who are responsible to Parliament, and ultimately to the electorate. We suggest that the Minister of Health should probably therefore hold the decision-making power under the regime because of the important elements of subjective value judgement involved in decisions on approvals.
- 8.101 Whether the decision-maker is the Minister or the Director-General, it will be essential to have the involvement of a committee with appropriate expertise to review and evaluate the evidence and make recommendations to the decision-maker. The committee's expertise will be particularly important in identifying the nature of the harm that may be caused by any substance. We will discuss the functions of the committee in these areas in more detail in chapter 9.
- 8.102 We suggest also that there needs to be a clear link between decisions to approve or not approve a substance, and a subsequent decision to bring an unapproved substance within the prohibited drugs regime. It seems logical that, where an approval is declined because legalisation with restrictions is not appropriate, the Minister considers initiating steps to prohibit the substance. However, there may be some situations where this would not necessarily be appropriate. For example, an application might be declined because there is insufficient information on which to adequately assess the risks associated with the substance. In such circumstances it might be premature to make a decision on whether the substance should be prohibited.
- 8.103 There will also be situations where a new psychoactive substance, which has not been approved, comes to the attention of the Ministry of Health or another enforcement authority. Although such a substance would not be legally available in New Zealand, it would not be subject to the enforcement and sanction regime for prohibited drugs. We suggest that the regulatory body should be able to initiate an assessment of such a substance in advance of any application to manufacture or import it, and refer it to the expert committee for evaluation and advice.

Q10 Do you agree that new recreational psychoactive substances should be regulated by a separate regime designed specifically for new recreational psychoactive substances rather than HSNO?

Q11 Under the proposed separate regime, do you agree that the Minister of Health rather than the Director-General should issue approvals?

## Coordination between regulatory bodies

- 8.104 If recreational psychoactive substances are to be dealt with under a new separate regime as we have suggested, careful consideration needs to be given to how the substances that fall within the regime are defined. It will, for example, be necessary to specifically exclude the substances from HSNO to avoid the problem that has arisen with the restricted substances regime. In addition, the new regime should probably be restricted to those substances that are manufactured for the primary purpose of being administered, ingested, inhaled, or injected in order to induce a psychoactive response. This is the position under the restricted substances regime. Otherwise the regime would capture substances like paint, glue and other solvents which, though capable of being used recreationally, are primarily used for other purposes. In our view these substances are better dealt with under HSNO. Substances that are medicines and foods will similarly also need to be excluded.
- 8.105 In chapter 5, we noted that some difficulties have occurred at the margins over the coverage of the different regulatory regimes for foods, medicines, hazardous substances and restricted substances. One example we discussed is when psychoactive substances are incorporated into drinks or tablets that are marketed as stimulants and energy enhancers. Recently new “energy shots” have emerged in a liquid form containing high levels of caffeine. These products are consumed orally; they contain some psychoactive ingredients but also other ingredients and nutrients that are commonly used in food. We suggested in chapter 5 that there can be a degree of uncertainty over which regime applies to such products.
- 8.106 Issues over the application of the different regulatory regimes need to be addressed. One option would be a requirement for regular consultation between the relevant regulatory bodies. The aim would be to ensure that potentially harmful products do not fall between the cracks of the various regulatory regimes. It would also be possible to establish a panel comprising representatives of the various regulatory bodies that could make determinations about which regulatory regime applies where there is doubt. Any person intending to import or manufacture a substance which falls at the margins of the various regimes could then seek a determination from the panel about which regime applies. This would protect importers/manufacturers from possible prosecution for failing to obtain the appropriate approvals.

Q12 Is any formal mechanism required to ensure effective coordination between the various regulatory bodies responsible for foods, medicines, hazardous substances and new psychoactive substances?