Regulatory Impact Statement

Executive summary

On 28 September 2009, as part of proposals to reduce the harms associated with methamphetamine, Cabinet agreed in principle to the reclassification of pseudoephedrine (PSE) and ephedrine (EPH) as Class B2 controlled drugs under the Misuse of Drugs Act 1975 (MoDA).

Cabinet has also invited the Associate Minister of Health to report back by 30 November 2009 on progressing the reclassification and with further advice from the Expert Advisory Committee on Drugs (EACD) about the amount, level and quantity at and over which PSE and EPH might be presumed to be for supply.

This Regulatory Impact Statement focuses on the costs and impact of the proposed reclassification of PSE and EPH as Class B2 controlled drugs. The Associate Minister of Health is proposing a Misuse of Drugs Amendment Bill to effect this change. Four other issues proposed for inclusion in the Bill are discussed briefly in this Regulatory Impact Statement. None of these issues are considered to require regulatory assessment.

Adequacy statement

The Ministry of Health has reviewed the Regulatory Impact Statement and adequacy criteria and considers that the statement is adequate according to these criteria.

Status quo

Pseudoephedrine (PSE) is available mainly as a decongestant and is contained in a number of cold and flu remedies on the New Zealand market. Ephedrine (EPH) is used to a much more limited extent and is not available from retail pharmacies. Both PSE and EPH are scheduled as controlled drugs in the Misuse of Drugs Act 1975 (MoDA), however there are differences in the way they are scheduled. PSE is currently available from pharmacies as an over-the-counter medication in slow-release and lower dose formulations and scheduled as a Class C3 controlled drug in the MoDA. All other forms of PSE are prescription only medicines available in higher dose formulations and scheduled as Class C5. EPH is available only with a prescription (Class C5) and is sometimes dispensed by hospital pharmacies for specific conditions. In addition, PSE and EPH are listed as precursor substances in Schedule 4 of the MoDA.

Most pharmacies currently have voluntary measures in place to reduce the likelihood of diversion of PSE while safeguarding staff from pressure to effect sales and from possible theft. Many pharmacies already keep PSE products behind the counter and limit sales. A number of pharmacies have ceased to stock PSE products altogether. Representatives from the pharmaceutical industry estimate that approximately 16 percent of cold and flu products on the market currently contain PSE, with the remainder of the market made up of phenylephrine based products.

Problem definition

In addition to their use in medications for the relief of cold and flu symptoms, PSE and EPH are precursor chemicals used in the manufacture of methamphetamine. PSE is the main active ingredient used in methamphetamine manufacture in New Zealand. New Zealand Police has reported that one in three clandestine methamphetamine laboratories detected contain traces of domestically sourced PSE. This does not suggest that 30% of methamphetamine in New Zealand is manufactured using domestic PSE, however Police considers that the levels diverted for illegal purposes is significant.

The Expert Advisory Committee on Drugs (EACD), a statutory committee established under the MoDA responsible for advising the Minister of Health on drug classification issues, has recommended that PSE and EPH be reclassified in Part 2 of Schedule 2 (Class B2) of the MoDA. In making this recommendation, the EACD was primarily concerned that PSE and EPH are being used as precursor chemicals in the manufacture of methamphetamine, a Class A controlled drug.

The Chief Science Adviser to the Prime Minister, Professor Sir Peter Gluckman has also expressed concern at the diversion of PSE and EPH for illegal purposes and provided separate advice to the Prime Minister recommending PSE and EPH be reclassified as Class B2 controlled drugs.

Both the EACD and Professor Gluckman considered the published clinical evidence on the quality, safety and efficacy of cold decongestants and recommended that PSE-based products are removed from over-the-counter sale as there are effective alternatives available and the risk of diversion of PSE-based products into the manufacture of methamphetamine outweighs the benefits of their over-the-counter availability.

While a significant amount of PSE currently available in over-the-counter medications is considered to be diverted for non-legitimate purposes, the majority of PSE used to manufacture methamphetamine is illegally imported. The source of this is believed to be almost exclusively extracted from “Contac NT”, a relatively high dose PSE-bearing product available in China. The New Zealand Customs Service is leading the enforcement response to illegal importation. This proposal may have the unintended consequence of increasing levels of illegally imported PSE, however Customs is concurrently increasing its capability to deal with methamphetamine and precursor trafficking at the border.

Objectives

The objective of the reclassification of PSE and EPH is to restrict the availability of these drugs in order to limit the amount being diverted from retail pharmacies to the manufacture of methamphetamine. The effect of reclassification is to make all PSE-bearing products prescription only medicines. Restricting access to PSE in this way, combined with targeted intensified border enforcement will make it harder for criminals to source the key active ingredients for manufacture.

The reclassification will impact on those wishing to continue to use PSE by requiring them to visit a general practitioner or specialist to obtain a prescription. Approximately 20 percent of cold and flu products currently on the New Zealand market contain PSE. In recent years the market has shifted to providing alternatives to PSE, such as phenylephrine, which are not able to be converted into methamphetamine. Products containing phenylephrine currently make up approximately 84% of the market. It is expected that the trend toward alternatives will escalate following reclassification of PSE and EPH.

Alternative Options

Regulatory options

There are no other regulatory options proposed at this time since Government has already decided this course of action. However, technical details on who may prescribe and dispense PSE and EPH are expected to be developed during the passage of the Misuse of Drugs Amendment Bill proposed by this Cabinet paper.

Non Regulatory Options

There are a range of non-regulatory measures in place to address illegal drug use in New Zealand by attempting to reduce demand. These measures include: community action plans; health promotion materials; assessment, advice, and treatment services; education of health professionals; and guidelines and protocols for good prescribing practice. Such measures all come under the overarching National Drug Policy 2007-2012, which is based on a harm minimisation framework. Government agencies will continue to support legislative action with a range of non-regulatory measures. However, these measures need to be supported by appropriate regulatory measures under the Misuse of Drugs Act 1975 to control supply.

Preferred Option

The option chosen by Ministers is to classify PSE and EPH in Part 2, Schedule 2 of the MoDA. This legislative change would give effect to the recommendations of the EACD and the Chief Science Adviser to the Prime Minister and the noting by Cabinet that the harms of ongoing availability of PSE now outweigh the benefits.

As with other Class B2 controlled drugs, Ministerial approval (delegated to Medsafe) would be required before a medical practitioner could prescribe PSE to an individual patient. A number of other regulatory requirements would also apply, such as the completion of prescriptions in triplicate, restrictions on dose, and recordkeeping and reporting requirements.

The effect of this amendment would mean that it would be an offence to import, export, produce, manufacture, supply, administer, offer to supply or administer, or otherwise deal PSE or EPH, except as pursuant to a licence or permitted by regulations, or provided by section 8 of the MoDA. Section 8 provides for lawful supply by medical practitioners, and designated prescribers.

The penalty for unlawful dealing of a Class B controlled drug is imprisonment for a term not exceeding 14 years.

It would also be an offence to procure, possess, or otherwise use PSE or EPH, except as pursuant to a licence or permitted by regulations, or provided by section 8 under the MoDA. Section 8 allows for administration when lawfully supplied by a medical practitioner and designated prescriber.
The penalty for unlawful possession or use of a Class B controlled drug is imprisonment for a term not exceeding 3 months or to a fine not exceeding $500, or to both.
New enforcement powers will be available to Police and Customs should PSE and EPH be made Class B2 controlled drugs. The Misuse of Drugs Amendment Act 1978 provides for powers under section 13 to search someone suspected of having a Class B drug secreted within their body, and also provides, under section 14, for warrants to intercept private communication.

Schedule 4 of the MoDA provides for search and seizure powers for precursor substances, however as PSE and EPH are already listed in Schedule 4 these powers would remain unchanged.

Other matters proposed for Misuse of Drugs Amendment Bill

Removal of provisions preventing hazardous substances from being restricted substances

This proposal is to remove the exclusion in the Misuse of Drugs Amendment Act 2005 that restricted substances can not also be hazardous substances. This is required as the current wording unintentionally prevents the scheduling of any substance as a restricted substance under that Act. This is a technical change only.

Controlled Drug Analogue provisions

This proposal is to broaden the analogue provisions of the MoDA. It is intended only to 'future proof' the legislation to capture a wider range of amphetamine type substances that are subject to abuse.

Prohibited Utensils provisions

This proposal seeks to tighten the existing restrictions on the importation and sale of drug utensils. It is already illegal to import or sell utensils and this proposal is to remove the ability to bring in incomplete or disassembled utensils over the border and to advertise or display utensils from retail outlets. This is really to close a 'loophole and there is no cost or significant impact associated with this proposal.

Thalidomide

This proposal is to remove thalidomide from Schedule 1 (Class A) of the MoDA. This is an historical anomaly and the EACD considers the Medicines Act already provides for appropriate controls around thalidomide.

Consultation

Key stakeholders

A targeted consultation was undertaken by way of meetings and written submissions on the proposal to reclassify PSE and EPH as Class B2 controlled drugs. Due to the limited timeframe, key stakeholders in the pharmaceutical industry, medical and pharmacy professions were approached on the understanding that further consultation is likely should legislation be progressed for the proposed reclassification.

The organisations consulted were: the Pharmaceutical Society of New Zealand; the Pharmacy Guild of New Zealand; the Royal New Zealand College of General Practitioners (RNZCGP); Johnson & Johnson (NZ) Ltd; and the New Zealand Self-Medication Industry (NZSMI).

Johnson & Johnson (JNJ) accepts the reclassification proposal and is willing to work with Government to achieve an effective transition. However, the company advised that this is an uncertain period as it is required to place forward orders now to meet the demand for PSE products in the 2010 cold and flu season, yet it is unknown when the reclassification will take effect. It also advised that its business model requires the company to replace the potential lost market with other product lines, including replacements for PSE. The Ministry indicated that it would be normal practice to prioritise any applications from current suppliers for alternative products to replace existing medications.

JNJ considers that a Class B2 regime is not likely to be viable in the long term. This is due to a number of factors including: the restrictions and requirements for approving, prescribing and administration; that most pharmacies do not have enough space in their safes for storage of PSE as is required of Class B2 drugs; and because PSE is not on the pharmaceutical schedule (i.e. not subsidised) and therefore it is up to pharmacist discretion to stock it and this will now be less likely. There may also be greater risk of burglary and 'ram raids' of pharmacies due to the increased street value of PSE, which would reduce their desire to stock product.

JNJ advised that the New Zealand PSE market is currently valued in excess of $7 million, of which JNJ is the major player, at 63 percent. The second largest player holds 18%. JNJ has nine over-the-counter (Class C3) product lines and no prescription-only (Class C5) PSE products in the market. Current stockholding of PSE containing products held in JNJ, wholesalers and retail pharmacy is estimated at $1.9 million (retail). Sales have already decreased due to market uncertain of legislative timing and lack of clarity in refund policies by manufacturers of the products. JNJ also noted that Taranaki pharmacists have recently decided they will cease stocking and selling PSE now in light of the upcoming changes.

JNJ forecasts that the majority of 'pipeline' stock will require writing off and the estimated cost for the company is $1.2 million (retail). A possible option would be to rework and export for Australian supply, but different requirements for that market mean this may be cost prohibitive. JNJ also advised that it does not have a complete phenylephrine range to convert cold and flu sufferers within its brands and that is now a competitive disadvantage as consumers will likely purchase a competitor product. The company estimates this will equate to around $5 million in lost sales (retail) and a further $11.5 million in lost sales and marketing spend to rebuild brand sales and equity over the 2011 to 2014 period.

JNJ estimates the total cost of the rescheduling of PSE to a Class B2 drug at $17.5 million over the next three to 4 years.

JNJ advised that allowing another season of PSE sales for the 2010 winter period would allow the company to manage inventory, communicate with the trade on a timely exit and allow it to work with Medsafe in ensuring a range of alternative cold and flu products available for sale in time for the 2011 season. In summary, JNJ proposes a complete exit of PSE containing products by October 2010 in consideration of Medsafe fast tracking its non PSE containing cold and flu products in time for 2011 launch. This would negate most of the identified costs and, in addition, allow both Government and industry to stand together to resolve New Zealand's unique "P" problem.

NZSMI represents a small number of companies that are involved in the PSE over-the-counter market. The Executive Director of NZSMI advised that his organisation's first concern is the lack of timely, accurate information on the reclassification proposal that would allow forward planning to take place. There is confusion on which medical practitioners will be able to prescribe PSE and whether it will be available from retail pharmacy or hospital pharmacies only and it is also uncertain how long it will be until reclassification comes into effect.

NZSMI advised the current market value of PSE containing products is $7 million. The organisation expects demand to reduce and therefore for stock to take longer to clear and expiry dates become a problem. NZSMI considers it difficult to envisage a business case for a company continuing to supply combination PSE products for cough/cold symptoms from a prescription base only. In addition, most dispensary safes are small and would not be able to hold a variety of product.

NZSMI considers companies currently marketing PSE products will be disadvantaged and it would require Medsafe to 'fast-track' phenylephrine product replacements on to the market. Costs will include inevitable stock write-offs, possible redundancies for category managers and reduced support for community initiatives as profitability declines. For some companies it will result in reducing their New Zealand office commitment or withdrawing from the market altogether. Benefits include the simplification of the supply chain to pharmacy by removing the extra security component cost from manufacturer to wholesaler to retail pharmacy. In addition, an overall reduction in PSE stock may reduce the number of break-ins and 'ram raids' on pharmacies.

NZSMI estimates there to be six to 9 months of product in the supply pipeline. The organisation advises that in order for industry to effectively manage transition to a new regime and its financial impact, it requests that changes in legislation do not come into effect until at least October 2010.

Representatives from the Pharmaceutical Society and the Pharmacy Guild described the impact of the removal of over-the-counter PSE as a source of professional annoyance to pharmacists as they will be frustrated they cannot continue to supply an effective product. The Pharmaceutical Society recently conducted a survey of 10 pharmacies that showed sales of between 150 and 200 packets of PSE products per month and this indicates to the Society that people will be, at least initially, lining up at GPs for prescriptions for PSE-based decongestants.

The Pharmacy Guild advised that if no PSE remained on the market many pharmacies will make significant losses as the most common alternative, phenylephrine, is also available from supermarkets (except 'combination' products containing codeine or antihistamines, which are pharmacy only medicines). The Guild predicted that larger, well-performing pharmacies will adapt better to the change but less well-performing businesses may struggle to cope. The Guild advised that recent data from mainly larger or chain pharmacies showed that 40 percent now do not stock PSE products. The Guild also suggested that most pharmacies would not have enough storage capacity in their safes to stock PSE products lines, should they be dispensed in similar packaging following reclassification.

The Pharmaceutical Society highlighted that the biggest issue for pharmacists is that the transition to Class B2 should be managed and communicated and that pharmacies ideally would need one to 2 months from enactment of a change until a new regime comes into effect. This is considered to be rather less than industry would need.

One representative from RNZCGP advised that he would be surprised if many people would pay a fee to visit a medical practitioner for a PSE prescription. He also considers that even if legislation allowed for GPs to prescribe, not many would do so as doctors are more likely to suggest alternative treatments to relieve symptoms, such as steam inhalation, perhaps menthol and eucalyptus therapies and suggest bed rest and keeping up with intake of liquids. However, a GP visit would provide opportunity for a diagnosis and treatment of other medical conditions.

Another representative from RNZCGP provided a submission following discussion with other GPs, workers at an alcohol and other drug (AOD) treatment clinic and hospital psychiatrists. He advised that none of the doctors spoken to had written a prescription for PSE or EPH for some time. They recognised that following reclassification some patients will request prescriptions, but most doctors are unlikely to agree as in general there are few indications that warrant use. There is also no psychiatric use for these drugs. The AOD staff advised that they would be happy to see these chemicals off the street and the less available, the better. The representative considers that a Class B classification will allow much tighter controls and while PSE products will still find their way on to the street close monitoring of prescribing patterns will restrict the level of diversion.

Government agencies

All Inter-Agency Committee on Drugs (IACD) member agencies as well as Women's Affairs and the Treasury were consulted on the paper considered by Cabinet on 28 September 2009 on the proposed classification of PSE and EPH. All IACD agencies, the Ministry for the Environment and the Treasury were also consulted for this Cabinet paper and Regulatory Impact Statement. All agencies consulted and any substantive comments received from these agencies have been noted in the Cabinet paper.