Regulatory Impact Statement

Classification of Tapentadol under the Misuse of Drugs Act 1975

Agency Disclosure Statement

This Regulatory Impact Statement has been prepared by the Ministry of Health.

Tapentadol is new chemical entity and not yet available in New Zealand; there is therefore no information on its misuse in New Zealand. The Expert Advisory Committee on Drugs (EACD) has based its evaluation of tapentadol's potential harm on an Assessment of Abuse Potential provided by the manufacturers.

The Ministry has only considered regulation under the Misuse of Drugs Act (1975) as non-regulatory options or the status quo would be inconsistent with the control of other similar substances.

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Status quo and problem definition

1. Tapentadol is a new opioid analgesic, which is marketed by the pharmaceutical company Grünenthal as Palexia® for the relief of acute and chronic pain. It is currently listed under the Medicines Act 1981 as a prescription-only medicine pending a decision whether or not to schedule it in the Misuse of Drugs Act 1975 (the Act). Tapentadol is not yet available in New Zealand and the manufacturers are awaiting Parliament's decision regarding scheduling under the Act before initiating the process of marketing Palexia® here.

2. The Expert Advisory Committee on Drugs (EACD) is a statutory committee established under the Act and responsible for advising the Minister of Health on drug classification matters. The EACD has assessed the potential risk of harm posed by tapentadol from an Assessment of Abuse Potential provided by Grünenthal. The EACD has advised that there is a high risk of harm associated with its misuse and has recommended classifying tapentadol in the same schedule of the Act as other similar opioids, such as oxycodone.

3. The current controls under the Medicines Act restrict the importation and supply of tapentadol but do not provide the same restrictions as the Misuse of Drugs Act which mandates prescription monitoring, secure storage and controls over advertising. All other opioid medications are scheduled in the Act.

4. It is likely that tapentadol will be included in Schedule 1 of the United Nations (UN) Single Convention on Narcotic Drugs. New Zealand is a signatory to the Single Convention and is obliged to place appropriate controls on substances listed in the Schedules. Control under the Act would be the most appropriate vehicle for meeting any future obligations in relation to tapentadol.

Evidence of harm

5. As a new substance, there is no information regarding the diversion and misuse of tapentadol. Grünenthal has conducted a number of clinical trials and reported that drug users like tapentadol as much as other opioids, concluding that tapentadol has a similar potential for diversion as opioids such as oxycodone.

6. Similar to other opioids, tapentadol has the potential to cause a number of harms, including nausea, confusion, respiratory depression which can lead to coma and death. These risks are increased when opioids are used in combination with other drugs, particularly with depressants such as alcohol. It is estimated that 43% of drug-related hospital admissions (excluding alcohol) during 2009 were for opioids; 80% of these were defined as "poisonings" and 20% were repeat admissions suggesting that some opioid users engage in repetitive harmful behaviour.[1] Opioid use is associated with dependence; withdrawal symptoms include anxiety, pain, tremor and sweating.[2] Animal tests conducted by Grünenthal found that tapentadol exhibits similar reward and reinforcement effects to those of morphine.

[1] Information provided by the National Drug Intelligence Bureau.
[2] http://www.prnewswire.com/news-releases/data-comparing-nucyntar-tapentadol-tablets-to-oxycodone-immediate-release-tablets-presented-at-2010-american-pain-society-annual-meeting-93060849.html

Objectives

7. The first objective of this legislative change is to minimise the potential for the misuse of tapentadol by placing robust controls around its importation, distribution and prescription. The second objective is to future-proof the controls around tapentadol to ensure that New Zealand meets any future international obligations under the UN Drug Conventions if tapentadol is added to the Single Convention.

Regulatory impact analysis

8. The Ministry of Health has only considered regulatory controls under the Act, in addition to the non-regulatory measures already in place. This reflects the level of harm posed by tapentadol, the scheduling of all similar medications and future scheduling by the UN.

Non-Regulatory Options

9. There are a range of non-regulatory measures in place to address drug misuse in New Zealand. These measures include: community action plans; health promotion; assessment, advice, and treatment services; education of health professionals; and guidelines and protocols for good prescribing practice. Such measures come under the overarching National Drug Policy 2007-2012, which is based on a harm minimisation framework. The Ministry of Health is responsible for monitoring the prescribing of controlled drugs and minimising their diversion from legitimate use. Government agencies will continue to support legislative action with a range of non-regulatory measures.

Classification under the Third Part of the Second Schedule (Class B3) of the Misuse of Drugs Act 1975

10. The EACD has advised that the harm potential of tapentadol is similar to other opioids and the likelihood of its diversion is also similar. It has recommended a classification to reflect the potential high risk of harm to individuals and society from tapentadol misuse and to ensure a consistent level of control for opioids.

11. The classification of drugs under the Act is based on the risk of harm a substance poses to individuals and society. Drugs that pose a high risk of harm are classified as Class B drugs. Class B is subdivided into three parts to determine the prescribing rights for medical practitioners and whether ministerial approval is required. Class B3 drugs can be prescribed by medical practitioners without the need for ministerial approval.

12. The scheduling of tapentadol as a Class B3 controlled drug under the Act would place controls on its importation, distribution, storage and prescription. Scheduling as a controlled drug would make it a criminal offence to import, produce, or manufacture tapentadol except pursuant to a licence provided for under the Act. It would also be an offence to supply or administer tapentadol except by persons designated by the Act. Travellers would be able to bring up to a month's supply of tapentadol into New Zealand provided they were in possession of a prescription.

13. The Misuse of Drugs Regulations 1977 (the Regulations) set out the restrictions under the Act for controlled drugs used for medicinal purposes. These include the need for an import licence for each consignment of a controlled drug to be brought into the country, a locked safe for storage and prescriptions to be written on a triplicate form provided by the Director-General of Health. In addition, medical practitioners can

prescribe no more than what is appropriate for one month's pain relief and must maintain a written record of all prescriptions.

14. Offences and penalties for Class B controlled drugs are set out in Sections 6 and 7 of the Act. These are:

- Imprisonment for a term not exceeding 14 years for the illegal importation or supply;
- Imprisonment for a term not exceeding 10 years for conspiring to import or supply;
- Imprisonment for a term not exceeding 3 months and/or to a fine not exceeding $500 for possession without a prescription.

15. Scheduling tapentadol as a Class B3 controlled drug under the Act would give effect to the advice of the EACD that the potential for the misuse of tapentadol is consistent with other strong opioids which are scheduled as Class B3 controlled drugs. It would also be consistent with overseas scheduling of tapentadol and meet international obligations under the UN Single Convention if tapentadol is included in Schedule 1.

Compliance and other costs

16. There are a number of compliance requirements associated with a Class B classification for manufacturers, importers and suppliers which are set out in the Regulations. It is likely that tapentadol will be prescribed as an alternative to other opioids and therefore insignificant additional costs to the user are anticipated.

17. Medical practitioners wishing to prescribe tapentadol would be subject to a number of restrictions under Sections 29-33 of the Regulations including the requirement to use a H572 triplicate form provided by the Director-General of Health. Pharmacies would be required to store tapentadol in a locked safe. Locked storage and triplicate forms are required for all similar opioid medications used in the community and so there are unlikely to be any additional costs for pharmacists and medical practitioners prescribing or dispensing tapentadol as opposed to another opioid. Medical practitioners are allowed under the Act to possess and prescribe controlled drugs without a licence.

18. Each consignment of tapentadol would require controlled drug labelling and an importation licence. The Ministry of Health has consulted with the New Zealand agents for the manufacturers of Palexia®. They have not provided any indication of the likely costs in terms of licences and labelling costs, however they have signalled their support for the classification of tapentadol under the Act. The Ministry of Health requires distributors of controlled drugs to purchase a licence to deal which costs $966 per annum. This does not represent an additional cost to the distributor as it already holds a licence for other controlled drugs. Each consignment of tapentadol imported into New Zealand requires an import licence which will cost the distributor $194.22 per licence.

19. There may be some costs to government agencies, such as Police and Customs in enforcing the provisions of the Act. Customs does not foresee a significant increase in costs and any workload increase could be met within baseline. Police had no comment on potential costs or increased workload but noted that the introduction of tapentadol to the New Zealand market added another opioid which could be diverted and misused.

20. Tapentadol offenders would enter the criminal justice system and potentially increase costs to the Justice sector. Justice is unable to quantify any potential increase to caseloads and ensuing costs as the extent of tapentadol misuse is unknown.

21. The Ministry of Health is responsible for monitoring and controlling access to controlled drugs used as medicines. No significant cost is anticipated.

Consultation

22. The Ministry has consulted with the other agencies of the Inter-Agency Committee on Drugs (Justice, Police and Customs) as well as Te Puni Kokiri, the Ministry of Economic Development, the Treasury, and the Ministry of Economic Development. New Zealand Hospital Pharmacists' Association, Pharmaceutical Society, Medical Council, Pharmacovigilance Centre, Medical Council, New Zealand Medical Association, and the New Zealand agents for Grünenthal have also been consulted. The Department of Prime Minister and Cabinet has been informed.

23. There has been no objection to the scheduling of tapentadol as a Class B3 controlled drug.

Conclusions and recommendations

24. The risk of harm to individuals and society from the misuse of tapentadol has been assessed by the EACD. The EACD has advised that tapentadol poses a high risk of harm similar to other opioids classified under the Act. The United Nations is currently assessing tapentadol for inclusion in Schedule 1 of the Single Convention.

25. In order to provide robust controls around tapentadol, a consistent scheduling of all similar substances and meet New Zealand's international obligations, a Class B scheduling in the Act is recommended. The proposed option is to classify tapentadol under Schedule 2, Part 3 (Class B3) of the Act. This is the least restrictive option commensurate with the potential harm posed by tapentadol.

Implementation and review

26. To ratify the proposed classification, Parliament must approve an Order in Council to classify tapentadol in the Act.

27. Enforcement of the classification would be carried out by Police and Customs and the management of legitimate access would be carried out by the Ministry of Health.

28. The effectiveness of drug classifications is not directly evaluated, instead proxy measures are used to assess the presence of a substance in New Zealand and thereby extrapolate the effectiveness of supply control efforts. (Eg, national surveys of drug use are used to measure the demand for a drug). Seizure statistics provide an indication of activity at the border and within the community but is only a proxy measure as seizures depend upon the priority given to a particular substance by Police and Customs and do not necessarily affect the availability of a substance. Price and availability are estimated through interviews with frequent drug users. Drug prices are used as another proxy measure on the assumption that increasing price indicates decreasing availability and therefore successful supply control activities.

29. These measures are used to monitor the diversion and misuse of opioids in New Zealand. Whilst some of these measures are generic and include all opioids, others will pick up any trends specifically relating to tapentadol.