

**Senate Community Affairs Committee**

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

**Budget Estimates 2014 - 2015, 2/3 June 2014**

**Ref No:** SQ14-000508

**OUTCOME:** 2 – Access to Pharmaceutical Services

**Topic:** Generic Oxycodone

**Type of Question:** Written Question on Notice

**Senator:** Di Natale, Richard

**Question:**

- a) What work has the Department or Agency done on the issue of non-abusable/controlled release oxycodone, and the impending availability of the generic form of the drug with its high potential for abuse back in the Australian market?
- b) Will the Minister and/or the TGA be taking any steps to delay the availability of abusable oxycodone?

**Answer:**

- a) The Department of Health remains committed to pursuing opportunities to raise awareness of the abuse deterrent formulation of oxycodone so that the quality use of medicines can be optimised for at risk patients. Some of this responsibility will also lie with State and Territory governments who are responsible for regulating the prescribing and dispensing of controlled medicines in their jurisdictions as well as industry and health professionals who are active partners in promoting the responsible use of medicines.

Various mechanisms currently exist to support the appropriate prescribing and dispensing of pharmaceuticals, including opiates and benzodiazepines. Key amongst these is the focus on the quality use of medicines under the *National Medicines Policy* (NMP), the National Pharmaceutical Drug Misuse Framework for Action: 2012-2015 (the Framework), the National Drug Strategy: 2010-2015 (the Strategy) and the Electronic Recording and Reporting of Controlled Drugs Initiative (ERRCD).

**National Drug Strategy**

The Government's approach to dealing with illicit drugs and to diversion of licit drugs follows the overarching framework set out by the Strategy. The collaboration between health and law enforcement has been one of the major strengths of Australia's response to drug misuse, including pharmaceuticals, since the inception of the first National Drug Strategy in 1985.

**National Pharmaceutical Drug Misuse Framework for Action: 2012-2015**

The Framework provides a clear blueprint for responding to pharmaceutical misuse. It was endorsed by the Australian Health Ministers' Advisory Council in March 2013; the Standing Council on Police and Emergency Management in July 2013; and the Standing Council on Health in December 2013.

Whilst the Framework notes the importance of implementing and promoting tamper-resistant technologies, there is no imperative or direction to restrict the market or remove access to drugs that are not tamper-resistant, but which play an important therapeutic role. The Framework notes a need to ensure continued medical access to clinically necessary opiates and to maximise their appropriate use, while minimising opportunities for misuse.

### **NPS MedicineWise**

Supporting and encouraging the quality use of medicines is a key objective under the Government's National Medicines Policy. In support of this objective, the Department has engaged NPS to undertake a number of changes in communication and education following the availability in Australia of the addition of an abuse-deterrent formulation of sustained-release oxycodone:

- NPS has updated the consumer medicines information leaflet on its website and pharmacists manning the NPS Medicines Line have been briefed and are responding to consumer enquiries about the change.
- The June NPS Direct publication for GPs and pharmacists includes an article on this topic. It raises awareness but also balances the information by addressing the available evidence for the new formulation on reducing opioid abuse and misuse, and precautions in counselling patients on swallowing the reformulated, bulkier tablets. It is already available online and will be distributed in hard copy in June.
- Updating the pain management for health professionals campaign with a strong emphasis on misuse of opioids for release in 2015.

In addition to these activities, the Department is seeking to engage the NPS to assist in a multi-targeted approach to assist health professionals and drug and alcohol workers to identify, monitor and use evidence-based best practice to manage patients that have developed a dependence on prescription medicines, including opioids. As part of this strategy, the Department has reinforced the importance of raising awareness about the availability of abuse deterrent formulations and the option for prescribers to specify no generic substitution for OxyContin® prescriptions when they intend to prescribe the originator brand to deter inhaled and injectable misuse.

### **Electronic Recording and Reporting of Controlled Drugs**

The ERRCD initiative, which was publicly announced in February 2012 as part of the Fifth Community Pharmacy Agreement, is designed to give "real time" patient utilisation data and alerts about over use of all controlled drugs, not just oxycodone. However, with respect to this particular issue, its use by states and territories would provide prescribers, dispensers and jurisdictions with ready notification when tamper-resistant prescriptions are appropriate.

The ERRCD system was developed and implemented on behalf of the Commonwealth by the Department in cooperation with the Pharmacy Guild of Australia and is ready for use. All states with the exception of the NT and Victoria are currently testing the ERRCD systems to determine how they will incorporate it into their current systems and migrate the relevant data. The ACT and NSW are in the final stages of testing and NSW has advised they are close to moving from testing to implementation. ERRCD is based on the Tasmanian system for reporting and recording the use of controlled drugs, and Tasmania is in the process of migrating from their state-based system to the ERRCD.

- b) In Australia a product can only be removed from the Australian Register of Therapeutic Goods (ARTG) if, through normal use or use as indicated in the product information and as reviewed during the registration of the medicine, the benefit risk ratio changes – in other words, if risks start to counterweigh or exceed the benefits.

Further, there are patients who cannot utilise the tamper-resistant formulation. For example, patients with swallowing difficulties because of conditions like throat cancer or late stage multiple sclerosis; patients with mechanical bowel obstruction or patients who are at risk of intestinal obstruction because of conditions like bowel cancer or excessive bowel inflammation and swelling due to Crohn's disease; and patients who have difficulty understanding or following instructions because of confusion or dementia. It is appropriate that treatment options remain available to health professionals and patients in these circumstances.