

Reporting of Adverse Effects to Psychoactive Substances

This note is to seek the assistance of healthcare practitioners to report all the adverse effects they observe from the use of psychoactive products in patients they are treating. Reports should be sent to the Centre for Adverse Reactions Monitoring (CARM). The details on “How to Report” are set out below.

The Psychoactive Substances Act went live on 17 July 2013 with the creation of the Psychoactive Substances Regulatory Authority (PSRA). The scheme has been operational for about a month now and the Authority is completing the first task required by the Act by issuing interim licences to those manufacturers, products, retailers, and wholesalers on the New Zealand market that meet certain statutory criteria. Further information about the regulatory scheme can be found at <http://www.health.govt.nz/our-work/regulation-health-and-disability-system/psychoactive-substances>.

The Act requires that all psychoactive products on the market must pose no more than a low risk of harm to consumers. To make this judgement the PSRA has created a framework based on the classic

$$\text{“Risk = exposure x effect”}$$

approach to risk assessment. The framework scores reports of adverse effects submitted to the National Poisons Centre, the New Zealand Pharmacovigilance Centre (CARM), and a subset of data collected from hospital accident and emergency units, for severity and adjusts the scores by sales data which is used as a marker of user exposure.

As with all post-market safety monitoring systems, including medicines monitoring systems, the data sources available tend to underestimate the risk posed by a product. In order to ensure that products pose no more than a low risk of harm, the Authority has taken a precautionary approach by setting the risk score for acceptable products at a very low level.

The effect of this decision is that a single report of a severe adverse effect, such as an epileptic seizure, is sufficient to identify the product as posing more than a low risk of harm. Details of the risk framework and the products which have been assessed and approved are available on the Ministry of Health website.

The PSRA will continue to use and refine its risk assessment framework to monitor the safety of psychoactive products granted an interim licence. The PSRA review noted that remarkably few reports of adverse effects to psychoactive products have been reported by healthcare professionals. The Authority therefore encourages all healthcare professionals to report all moderate to severe adverse effects to psychoactive products to the Centre for Adverse Reactions Monitoring (New Zealand Pharmacovigilance Centre) at the University of Otago. In addition to the symptoms

observed, precise as possible information on the psychoactive products consumed would be appreciated.

The new regulatory scheme for psychoactive products empowers the PSRA to remove products from the market whenever significant safety issues emerge. Increasing healthcare practitioner reporting will increase the richness of the data available for regulatory decision-making. Ultimately this will improve the quality of the risk management framework and increase confidence that the PSRA can accurately identify and remove products posing increased levels of harm to consumers.

New Zealand is the first country in the world to introduce this kind of regulatory scheme and identifying and defining the market is only the first step in what will be a long and involved process. Further details of the regulatory requirements proposed for psychoactive products will be released in a consultation document later this year.

Methods for reporting adverse reactions to CARM

1. Use the **Yellow Card**
2. For those Medical Practices with the **BPAC tool** added to the Patient Management System, you can send details via this reporting tool
3. Visit the NZ Pharmacovigilance website www.otago.ac.nz/carm > Reporting
 - a) **PDF form** - you can print, complete and send by:
Fax to (03) 4797150 or

FreePost to Freepost 112002
NZPhvC
P O Box 913
Dunedin
 - b) **Word document** - you can download and complete and send
 - c) **On-line** - enter your report direct into our secure system
4. Email details carmnz@otago.ac.nz
5. Fax details to (03) 479-7150
6. Phone details to (03) 479-7247