Psychoactive Substances Expert Advisory Committee

Annual Report for the year ended December 2015

December 2015

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Introduction

The Psychoactive Substances Expert Advisory Committee (the Committee) is an expert panel established to advise the Psychoactive Substances Regulatory Authority on technical matters relating to the Psychoactive Substances Act 2013.

Under section 11(11) of the the Psychoactive Substances Act 2013, the Committee is required to provide the Minister of Health with a written annual report of its operations.

The Committee was appointed in December 2013. This, our second annual report, provides background information about our function, reviews the work of the Committee for the period 1 January to 31 December 2015 and describes what we see as our future role.

Richard Robson
Chair
Psychoactive Substances Expert Advisory Committee

Chris James
Group Manager
Clinical Leadership, Protection & Regulation
Acting as the Psychoactive Substances Regulatory Authority under delegation of the Director-General of Health

Background

The Psychoactive Substances Act 2013

In 2013, the New Zealand Government introduced the Psychoactive Substances Act 2013 (the Act) to regulate the availability of psychoactive substances in New Zealand to protect the health of, and minimise harm to, individuals who use psychoactive substances.

The Psychoactive Substances Regulatory Authority (the Authority) was set up to ensure all products distributed in New Zealand that contain psychoactive substances pose no more than a low risk of harms to the user as designated through a pre-market approval regime. The psychoactive substances, and their final products, will only be able to be imported, manufactured, distributed and sold by people and businesses licensed by the Authority.

The Act came into effect on the 18 July 2013. The interim period was the transitional period between the introduction of the Act and amendment to the Act (the Amendment Act) in May 2014. The interim period allowed for the continued sale of psychoactive products which had been on the market for three months prior to the introduction of the Act.

The Amendment Act required all products that had been available for retail during the interim period to be made unavailable for purchase until such a time that they were shown to pose no more than a low risk of harm to the user. The Amendment Act also added section 12 of the Act which states that the Committee not to have regard to results of trials involving animals –

(1) In performing the function set out in section 11(2)(a), the advisory committee must not have regard to the results of a trial that involves the use of an animal.
(2) However, the advisory committee may have regard to the results of a trial undertaken overseas that involves the use of an animal if the advisory committee considers that the trial shows that the psychoactive product would pose more than a low risk of harm to individuals using the product.

Due to the testing required for a product to be determined no more than a low risk of harm to the user, current technologies that exist for determining these effects mean that it is most likely that no products will gain approval for sale for at least the next five years.

The Psychoactive Substances Expert Advisory Committee

The Committee is an expert panel established to advise the Authority on technical matters relating to the Act. Committee members have a commitment to work for the public of New Zealand and to take account of government policy on psychoactive products. Members are accountable to the Authority.

Committee members must collectively have expertise in the following areas:

- Pharmacology
- Toxicology
- Neurosciences
- Medicines

- Any other area the Authority considers relevant.

The Committee may comprise up to six members, including one person to be nominated as the Chair. Committee members are appointed on terms and conditions the Authority sees fit following consultation with the Minister of Health. The current Committee members are:

Associate Professor Peter Larsen
Department of Surgery and Anaesthesia, University of Otago, Wellington.

Dr Shanika Perera
Auckland Medical Officer of Health, Auckland District Heath Board.

Associate Professor Richard Robson (Chair)
Executive Director, Christchurch Clinical Studies Trust Ltd.

Professor Susan Schenk
School of Psychology, Deputy Dean (Research), Faculties of Science and Engineering, Victoria University of Wellington.

Dr Malcolm Tingle
Associate Professor, Pharmacology, Auckland University.

The Committee's function

The functions of the advisory Committee are set out in section 11(2) of the Act and are as follows:

- to evaluate, with regard to the results of trials, psychoactive products to assess whether they should be approved for use by individuals
- to advise the Authority about whether a psychoactive product should or should not be approved for use by individuals
- increase public awareness of the advisory committee's work in relation to psychoactive substances, for example, by the timely release of papers, reports, and recommendations.

The year in review

The ongoing work of the Committee has been to inform policies and frameworks to be implemented under the Act. Position statements on the definition of a psychoactive substance and the legal status of herbal smoking products have been discussed with the Authority and have informed frameworks implemented this year.

One meeting was held with the Authority over the past year. The meeting's main focus was to discuss two position statements that had been drafted by the Authority. The first position statement aimed to determine the definition of a psychoactive substance under the Act. The second position statement set out to define how low level psychoactive substance herbal smoking products should be regulated.

Definition of a psychoactive substance

A position statement on the definition of a psychoactive substance was presented to the Committee for discussion. The Committee suggested that it be made clear that this definition was intended as an operational interpretation of the legislative definition. As well as providing an operational definition of a psychoactive substance, the position statement aims to outline the roles and responsibilities amongst different agencies with which the Act interfaces.

This position statement is still in draft form. However, the discussions around the position statement formed the basis of a report at ministerial level to develop a policy for regulating substances and ingredients that sit at the interface of foods, herbal remedies, dietary supplements, herbal smoking products, and psychoactive substances.

Herbal smoking products

A discussion around the position statement on herbal smoking products concluded that, provided they meet the operational definition of a psychoactive substance, herbal smoking products would be regulated under the Act regardless of how low level the psychoactive effect elicited by the product is.

Subsequently the Authority made the decision that herbal products that elicited a low level psychoactive effect did not meet the operational definition of a psychoactive substance and therefore should not be regulated under the Act. The justification for this included that, although some herbal smoking products are believed to produce low level psychoactive effects, they have been available both internationally and in New Zealand for decades with no evidence of adverse reactions. The position statement has since been finalised reflecting this view.

There have been a number of reported cases where herbal smoking products have been adulterated by synthetic cannabinoids. Due to these incidences it has been agreed, at ministerial level, to implement a testing regime for herbal smoking products. The position statement on herbal smoking products has informed the development of a framework around testing of these products to ensure that they haven't been adulterated by synthetic cannabinoids and provide confidence that psychoactive products, which aren't approved products, are not commercially available in New Zealand.

The herbal smoking products testing regime has been in place since September 2015. The regime has already resulted in the successful identification, and subsequent confiscation, of herbal smoking products, which had been adulterated by synthetic cannabinoids, that had been for sale in a chain of retail outlets in New Zealand.

The Committee's future role

The amendment to the Regulations that allows for retail sale and wholesale of approved psychoactive products is due to be enacted in early 2016. To date, there have been no major breakthroughs in scientific techniques to be used in place of animal testing for proof of low risk of harm in humans. Due to this, we still believe that it is unlikely that any products will be

approved in the near future, therefore the Committee's function in this area will continue to differ to that set out in the Act.

We will continue to have input into a variety of frameworks to be implemented under the Act, including frameworks for adverse reaction monitoring and defining what a low risk of harm would be for a psychoactive product to gain approval. As well as this, any new scientific techniques that may preclude the need for animal testing for product approval will be sought and evaluated on their individual merits. We will continue to work with the Authority in this capacity, and as needed, to ensure that any approved psychoactive products that become available for retail in New Zealand pose no more that a low risk of harm before they appear on the market.

The Committee strives to conduct its activities openly and transparently. An aspect of our role is to publish information in a timely and relevant mannner to keep the public informed and aware of our work in the psychoactive substances area. Accordingly, this report will be made available on the Authority's website at: http://psycvhoactives.health.govt.nz/