Psychoactive Substances Expert Advisory Committee

Annual Report for the year ended December 2016

December 2016

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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 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 third annual report, provides background information about our function and comment about the work of the Committee for the period 1 January to 31 December 2016 and for next year.

Richard Robson
Chair
Psychoactive Substances Expert Advisory Committee

Chris James
Group Manager, Medsafe
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 harm as designated through a pre-market approval regime. The psychoactive substances, and their final products, are only able to be imported, manufactured, distributed and sold by people and businesses licensed by the Authority.

A restriction on using trials that involve animal testing to support a product approval application was introduced when the Act was amended in May 2014. Section 12 of the Act states that the Committee is 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.

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 that 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 and role

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.

Due to the animal testing restrictions, it is unlikely that any products will be approved in the immediate future. As such, the Committee's function in this area will differ to that set out in the Act. We see our main role moving forward as building comprehensive 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 to ensure that any approved psychoactive products are of 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 manner 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://psychoactives.health.govt.nz/

The year in review

PSEAC did not convene this year due to the lack of applications for psychoactive products. Nor did the committee undertake any activity relating to framework design or evaluation of new scientific techniques that may preclude the need for animal testing for product approval.

The term of PSEAC membership expires in December 2016. Several of the members have indicated their interest in reappointment for a second (and final) term. Confirmation of

reappointment of existing members and any new members is subject to approval by the Authority in consultation with the Minister.

Next year

PSEAC will meet next year to consider a submission on alternatives to animal testing received from Psychoactive Research Limited, entitled *An approach to NPS safety assessments without animal testing,* written by David Nutt, Imperial College London.