Psychoactive Substances Expert Advisory Committee

Annual Report for the year ended December 2014

December 2014

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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 first annual report, provides background information about our function, reviews the work of the Committee for the period 1 January to 31 December 2014 and describes what we see as our future role.

Richard Robson
Chair
Psychoactive Substances Expert Advisory Committee

Stewart Jessamine
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 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 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

Five meetings were held with the Authority over the past year. Below is a summary of the outcomes of our work, relating to the passage of psychoactive susbstances legislation.

During the interim period after the Act came into effect

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 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.

Due to the regulation of psychoactive products being a novel field internationally, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines formed the basis for the development of a risk assessment framework for psychoactive substances in New Zealand. It also formed the basis for what testing would need to be undertaken to show conclusively that psychoactive products currently available posed only a low risk of harm. The ICH Guidelines were developed through a process of scientific consensus involving technical experts from a number of countries.

The Committee's role in the interim period was to review and advise on the use of the risk assessment framework and to peer/quality review updates to the risk assessment framework to incorporate monthly data from the National Poisons Centre, the Centre for Adverse Reactions Monitoring and the Alcohol and Drug Helpline.

In terms of testing the safety profiles of pyschoative products for sale, to ensure that anything approved in the transitional period posed no more than a of low risk of harm, we advised that data of product interactions with other common stimulants, such as alcohol be included. Discussions about the risk of harm associated with psychoactive products also focused on the form in which they were presented; powders and liquids were deemed too high risk.

The collection and collation of adverse reaction reports underpinned the development of a workable system to identify psychoactive products that were deemed too high risk to continue being available on the market. The risk assessment framework classified the adverse reports as mild, moderate, or severe and allocates scores accordingly.

Products assessed as having a total risk score of greater than 2 were deemed to pose more than a low risk of harm to consumers and regulatory follow-up and/or action was required to manage this risk. Products with a score of 3 were monitored. Where adverse reaction reports were received for one 'umbrella product' (range of products included in a brand family) all products were included for assessment.

Manufacturers who were supplying psychoactive products with a borderline risk profile were also required to provide evidence that these products were low risk, and advise what they were doing in terms of monitoring and quality control to ensure a consistent low risk profile for their product.

Under this system eleven products were recalled in the interim period (Anarchy, Voodoo, Karma, Apocalypse, Outbreak, AK47, White Rhino, Blueberry, Crush, WTF, Lemon Grass). Continued monitoring of adverse reactions ensured only low risk products remained on the market.

When the Act was amended

The Psychoactive Substances Amendment Act 2014 (the Amendment Act) was passed under urgency, and took effect on 8 May 2014 due to public concern about the safety of untested products being sold, and strong public opposition to the use of animal testing for determination of psychoactive products which pose no more than a low risk of harm.

The Amendment Act ended the interim transitional period, leading to a recall of all products which were previously allowed on the market and placed a ban on animal testing.

The Amendment Act removed the ability of the Committee to have regard to the results of animal testing when considering whether a psychoactive product should be approved for use by individuals.

The Committee is required, under section 11(3) of the Act 2013, to have regard to the following when evaluating psychoactive products to assess whether they should be approved for use by individuals:

- the specific effects of the product, including pharmacological, psychoactive, and toxicological effects; and
- the risks, if any, to public health; and
- the potential use of the product to cause death; and
- the potential for the product to create physical or psychological dependence; and
- the likelihood of misuse of the product; and
- the potential appeal of the product to vulnerable populations; and
- any other matters that the Authority considers relevant.

The ‘avoidance of doubt’ provision in section 37(2) of the Act makes it clear that the Authority must refuse to approve a psychoactive product if it is unable to satisfy itself that the degree of harm that the product poses to individuals using the product is no more than a low risk of harm.

The Committee referred to the ICH Guidelines, which address the same elements that the Committee is required to consider for psychoactive substances. After considering the ICH guidance and cognisant also of the consensus views of international toxicology experts in relation to risk assessments of chemicals in food the Committee concluded that the tests required to address the following aspects of safety are currently only satisfactorily determined in animal models:

- Teratogenicity
- Toxicokinetics
- Immunotoxicity
- Carcinogenicity
- Addiction modelling.

The Committee’s position is, therefore, that until suitable and internationally recognised non-animal study alternatives exist for assessing these aspects of product safety, it would be unable to recommend approval of any psychoactive products.

The Committee’s future role

Regulations allowing for product approvals and licensing for import, research, manufacturing, sale of unapproved psychoactive substances and product approvals came into force on 3 November 2014. Because it is unlikely that any products will be approved in the immediate future, 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/