International Journal of Drug Policy 26 (2015) 1273–1278

Contents lists available at ScienceDirect

International Journal of Drug Policy

journal homepage: www.elsevier.com/locate/drugpo

Policy Analysis

The challenge of a ban on animal testing for the development of a regulated legal market for new psychoactive substances (NPS) ('legal highs') in New Zealand: Issues and options for resolution

Marta Rychert *, Chris Wilkins

SHORE & Whariki Research Centre, Massey University, PO Box 6137, Wellesley Street, Auckland, New Zealand

ARTICLE INFO

Article history:
Received 24 March 2015
Accepted 5 August 2015

Keywords:
New psychoactive substances (NPS)
Legal highs
Regulated market
Animal testing ban
Policy impasse

ABSTRACT

Background: In mid-July 2013, New Zealand passed the Psychoactive Substances Act (PSA), which allowed 'low risk' psychoactive products ('legal highs') to be approved for legal sale. In early May 2014, following public protest, the Psychoactive Substances Amendment Act (PSAA) was passed banning animal testing of psychoactive products, potentially making the new regime unworkable.
Aim: To investigate strategies to overcome the impasse created by the animal testing ban.
Methods: Solutions to the impasse were investigated using 'scenario' and 'stakeholder' analysis. Legislation, parliamentary debates, and regulatory statements related to the PSA and animal testing were reviewed. Strategies to resolve the impasse were discussed with stakeholders including the Psychoactive Substances Regulatory Authority (PSRA) officials, health officials, a legal high industry lawyer, and a leading legal highs manufacturer. This process generated six possible scenarios and five decision-making criteria of key importance to major stakeholders. Scenarios were then evaluated based on feedback from the industry and regulators.
Results: The six scenarios were: (1) pragmatic modification of the animal testing ban; (2) waiting until new non-animal test models are internationally accepted; (3) use of non-validated replacement test methods; (4) judicial challenge of the animal testing ban; (5) 'creative compliance' by only presenting human clinical trial results; and (6) philosophical re-conceptualisation of the 'benefits' from psychoactive products. Options 1 and 5 appear to be the most attractive overall solutions. However, both rely on a new political consensus and astute framing of the issues by political communicators. Political decision makers may be happy to accept Scenario 2 which would impose significant delays.
Conclusions: A 'failed' pharmaceutical product with psychoactive effects may have the test data required to be approved under Scenarios 1 and 5. Ultimately, the pleasurable benefits from psychoactive products may need to be included in the debate.

Introduction

The enactment of the *Psychoactive Substances Act* (PSA) in New Zealand in July 2013 established the world's first regulated legal market for new psychoactive substances (NPS; 'legal highs'; New Zealand Parliament, 2013a; Wilkins, 2014a). This novel approach to the proliferation of NPS has received considerable international attention as a possible solution to ongoing problems with NPS that could be adopted by other countries (Brandt, King, & Evans-Brown, 2014; European Monitoring Centre for Drugs and Drug Addiction, 2014; Hughes & Griffiths, 2014; Meacher, 2013; New Psychoactive Substances Review Expert Panel, 2014; Newberry, Wodak, Sellman, & Robinson, 2014; Seddon, 2014). Under the new regime, sponsors can gain approval to legally manufacture and sell psychoactive products if they demonstrate through clinical trials that products are 'low risk' (New Zealand Parliament, 2013a; Wilkins, 2014a). Approved products would then be sold subject to a range of retail restrictions and other regulations (New Zealand Parliament, 2013a).

Since the passage of the PSA, implementation of the law has proven to be challenging and controversial (see Fig. 1). An interim regime was established which allowed a limited number of products available on the market prior to passage of the PSA to continue to be sold subject to new retail restrictions (i.e. R18, no sales from convenience stores, limited advertsing) until detailed regulations were finalised (Wilkins, 2014b). However, following

* Corresponding author. Tel.: +64 93666136.
E-mail address: m.rychert@massey.ac.nz (M. Rychert).

http://dx.doi.org/10.1016/j.drugpo.2015.08.006
0955-3959/

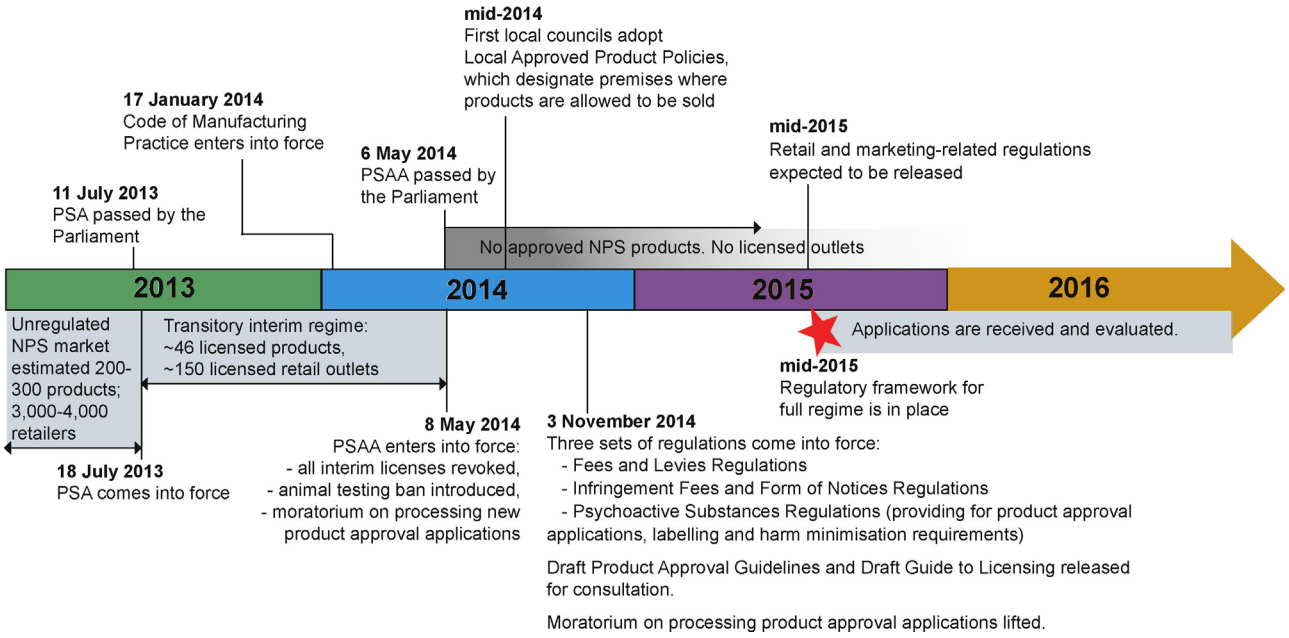

Fig. 1. Progress in the implementation of the PSA.

ongoing reports of adverse effects from interim licensed products, this transitory regime was brought to an abrupt end by the urgent passage of the *Psychoactive Substances Amendment Act* (PSAA) (New Zealand Parliament, 2014a) on May 6, 2014 (New Zealand Parliament, 2014b).

While the ending of the interim regime was widely viewed as a setback, a potentially more fatal impact of the PSAA was the decision to prohibit the use of animal tests (including tests conducted overseas (New Zealand Parliament, 2014b; OPSRA, 2014)) to assess the risk of psychoactive products. This followed numerous public protests against the harming of animals for the purpose of testing recreational psychoactive products with no therapeutic effects (MOH, 2014; New Zealand Anti-Vivisection Society, 2014). While work on regulations to implement the full PSA regime has continued, the Psychoactive Substances Regulatory Authority (PSRA) has gone so far as to state that 'it is unlikely that a product can be shown to pose no more than a low risk of harm without the use of animal testing'; suggesting the PSA is now unworkable (OPSRA, 2014).

The aim of this article is to investigate strategies to overcome the impasse created by the banning of animal testing for the purpose of pre-market approval of psychoactive products. We identify and critically evaluate six scenarios for the regime based on five criteria of key importance to major stakeholders, i.e. political decision makers and the legal highs industry. The issue of what role animal testing should play in determining the safety of legal recreational drugs with no therapeutic benefit will be of interest to other countries considering legal markets for NPS, or indeed for other drug types, such as cannabis products.

Political background: evolution of the animal testing provisions under the new regime

The PSA was passed with an overwhelming majority by the New Zealand Parliament on July 11, 2013 (117 ayes to 1 noes) with the one vote against due to the possibility of animal testing (New Zealand Parliament, 2013b). The original provisions of the PSA allowed testing of legal high products on animals, but only if there was no suitable alternative. In combination with the Animal Welfare Act 1999 (New Zealand Parliament, 1999), the PSA provided a framework for animal testing under the new regime (MOH, 2014). The PSA did not contain a limitation on the animal species allowed to be used for product testing. This led to widespread concerns about the possibility of testing NPS products on companion animals, such as 'beagle dogs', and this concern was manifested in public marches and petitions throughout 2013 and into 2014 (MOH, 2014; New Zealand Anti-Vivisection Society, 2014; New Zealand Parliament, 2014b).

Meanwhile, a political solution was discussed by which animal testing of products would be limited to rodents (MOH, 2014). The Psychoactive Substances Expert Advisory Committee (PSEAC) subsequently advised Cabinet that animal testing should be extended to include lagomorphs (e.g. rabbits) as "international guidelines require use of one rodent and one non-rodent species for assessment of reproductive toxicity and embryotoxicity" (Dunne, 2014; MOH, 2014). However, in May 2014, the Prime Minister announced a complete ban on the use of animal testing for the new regime, and this change was included in the May amendment legislation. This decision may have been influenced by the strength of public opinion on the issue and the impending general election in September of that year (Wodak, 2014).

In subsequent regulatory work on the full PSA regime, the Psychoactive Substances Regulatory Authority (PSRA), the body established by the PSA to oversee the new regime, closely aligned the testing regime for psychoactive products to internationally accepted testing standards for medicines. The International Conference on Harmonisation (ICH) Standards (ICH, no date) was designated as the minimum requirement for the approval of NPS products, and the US Food and Drug Administration "Guidance for Industry: Assessment of Abuse Potential of Drugs" (Food and Drug Administration, 2010) as the guide for investigations into the abuse potential of products (OPSRA, 2014). The Psychoactive Substances Expert Advisory Committee (PSEAC) advised that both these international standards require animal studies for assessing the following aspects of drug safety: "toxicokinetics, teratogenicity, carcinogenicity, reproductive toxicity and addiction potential" (OPSRA, 2014). The absence of validated non-animal models to test for these drug characteristics poses a fundamental issue in