**PSYCHOACTIVE SUBSTANCES**

**APPEALS COMMITTEE**

**PSA 2013/003**

**IN THE MATTER OF** An appeal against the Psychoactive Substances Regulatory Authority’s decision

**BETWEEN** **AJ SHIPLEY/SNITCHELL HOLDINGS LIMITED**

Appellants

**AND PSYCHOACTIVE SUBSTANCES REGULATORY AUTHORITY**

Respondent

**DECISION OF THE APPEALS COMMITTEE**

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Appellant: in person

Respondent: Anita Miller, Claro, PO Box 11-455, WELLINGTON 6142

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**Introduction**

1. On 12 October 2013, the appellant filed a notice of appeal against the decision of the respondent, the Psychoactive Substances Regulatory Authority, refusing to grant an interim product approval for a psychoactive product called “G13” (“the Product”). The appellant operates a shop from which psychoactive products were sold. The Product was one that the appellant made and sold from his retail outlet.
2. The respondent’s decision to decline interim approval was made under Subpart 2 of the Psychoactive Substances Act 2013 (“the Act”), in conjunction with Schedule 1 of that Act which provides transitional provisions.
3. The Act came into force on 18 July 2013 and is intended to regulate the availability of psychoactive substances in New Zealand in order to protect the health of, and minimise harm to, individuals[[1]](#footnote-2) who use psychoactive products.[[2]](#footnote-3) It is apparent that the Act was created to regulate a pre-existing market engaged in the importation, distribution, and sale of psychoactive substances and products.
4. The Act establishes the Psychoactive Substances Regulatory Authority which is taxed with determining whether, among other things, particular psychoactive products should be approved for sale to the public.
5. In relation to psychoactive products, the relevant principle is that products approved for use by individuals should pose “no more than a low risk of harm” to individuals consuming the product[[3]](#footnote-4).
6. The Act also provides for the creation of regulations that will provide guidance on how psychoactive substances, psychoactive products, retail licences, and other approvals under the Act will be considered (ss 99-101). The Regulations are not in force at the present time.
7. As a result, Schedule 1 to the Act was introduced to provide transitional provisions that has enabled people in this market to apply for interim licences pending the Regulations coming into force.
8. An interim product approval is deemed to be cancelled within 28 days of the Regulations coming into force unless the holder makes a “full application” under the Act for a licence to carry out the activity to which the interim licence relates. In that case the interim licence will continue until the date on which the full application is determined (cl 9).
9. The full license application will then be determined by reference to the Regulations.
10. The Product was the subject of an interim psychoactive product approval application by the appellant which was declined by the respondent on the grounds that the product posed a degree of harm to individuals that was more than a low risk of harm.[[4]](#footnote-5)

**The Appeal**

1. The appellant, who was not represented by counsel, provided a detailed notice of appeal setting out nine grounds in support of the appeal. In essence, the appellant contended that the respondent had an insufficient evidential foundation to conclude that the Product posed more than a low risk of harm to individuals.
2. The respondent in this and other interim product approval applications has relied on information derived from a number of sources, including a register kept by the New Zealand National Poisons Centre. The respondent has developed a scoring system based on the number and type of reports made to that Centre from which the respondent has determined a level of risk posed by a particular product to individuals.
3. In the case of the Product, the respondent had identified two adverse reports in the register from which it determined a risk score for the Product. From that the respondent determined that the degree of harm posed to individuals by the Product was higher than the “low risk of harm” threshold prescribed in s37(b).
4. We do not traverse the detail of the respondent’s risk scoring methodology in this decision because ultimately it has been unnecessary for us to do so. Accordingly we have reached no view, generally, on that methodology and the utility of that methodology in light of the statutory test.
5. In a telephone conference convened on 22 January 2014, the appellant indicated that there was information available to him which would be relevant to the appeal. We gave leave for the appellant to file this additional material, with leave also being granted to the respondent to file additional information in response, if required.
6. As a consequence of the exercise of exchanging additional material, it became apparent to the respondent that the two adverse reports it had relied on to determine the risk score for the product related to the same adverse event. We were advised by the respondent that this could affect the risk score applied to the Product.
7. As a consequence the appellant and respondent filed a joint memorandum dated 19 March 2014. The parties requested that instead of determining the appeal under s45 of the Act, the Appeals Committee should instead make an order under s46(1) referring the decision back to the respondent for reconsideration. This would then enable the respondent to reconsider the application for interim approval of the Product on the basis its present understanding of the National Poisons Centre data.
8. In light of this the parties agreed that the hearing that was scheduled to occur on 1 April 2014 could be commuted to a telephone conference.
9. At that telephone conference, the appellant again represented himself with the respondent being represented by Ms Miller.
10. We record that we confirmed with the appellant that he consented to the appeal being dealt with by the matter being referred back to the respondent for reconsideration. The appellant expressed dissatisfaction with the delay that had arisen as a consequence of this, and also voiced opposition to the use by the respondent of the National Poisons Centre data. The appellant did, however, confirm that this was the remedy sought, consistent with the joint memorandum of 19 March 2014.
11. The Committee indicated to the appellant that although the delay was frustrating his application and subsequent appeal, had been addressed as soon as reasonably possible.
12. With respect to the appellant’s submission that, generally, the National Poisons Centre data was not reliable, we indicated that if we granted the appeal on the basis that it was sought, then the Committee would not be considering that issue further.
13. We also indicated to the appellant that if the appeal was dealt with in the manner sought by both the appellant and the respondent, then this would bring the appellant’s appeal to an end. If the appellant was dissatisfied by any future decision of the respondent, it would then have to file a fresh appeal.
14. The appellant indicated that he understood this.
15. On 1 April 2014 we indicated the Committee’s result decision, namely that the matter would be referred back to the respondent for reconsideration. As this is consistent with the remedy eventually sought by both parties, we note our reasons, only briefly, below.

**Decision**

1. Appeals against the decision of the respondent are heard by the Appeals Committee pursuant to subpart 3 of the Act. Section 45(6) outlines the remedies the Appeals Committee may grant by way of confirming, reversing, or modifying the decision appealed against, or making any other decision that the Regulatory Authority could have made.
2. In addition, s46 permits the Committee to refer the appeal back to the Regulatory Authority for reconsideration and in doing so, the Appeal Committee may give a direction that the Regulatory Authority reconsider any specific matter.
3. We have considered the points on appeal raised by the appellant, and the concession made by the respondent that in making the decision, it relied on two adverse reports in the National Poisons Centre data which it now appears were a single event.
4. Because the respondent’s risk assessment scoring system is predicated both on the number and nature of adverse reports, we conclude, as the respondent responsibly accepted, that treating a single adverse event as two could materially affect the risk assessment. This may also make a difference to whether the Product posed a degree of harm to individuals that was more than a low risk of harm (s37).
5. For these reasons we agree that this matter should be referred back to the respondent under s46(1) of the Act. The decision of the respondent to decline interim approval of the Product was predicated on an erroneous understanding of the National Poisons Centre data. Now that this has been appreciated by the respondent it follows that the respondent should be permitted to reconsider the application. Given that the respondent has developed the risk scoring methodology, in the circumstances of this case it is appropriate that the respondent be given the opportunity to make the assessment afresh.
6. In referring the matter back to the respondent for reconsideration, we direct that the respondent reconsider the risk assessment of the Product in light of what is now understood about the National Poisons Centre data pertaining to the Product.
7. In making this decision, we express no view, one way or the other, as to the Product’s risk in light of what it may score on the revised assessment. We express no view on whether the product should be approved, or disapproved, under s37 of the Act. We explained this to the appellant during the telephone conference on 1 April 2014.
8. Therefore we direct that the matter be referred back to the respondent for reconsideration of the decision in light of what is now understood about the National Poisons Centre data relating to the Product.
9. This brings this appeal to an end.

Dated: 20 May 2014

**FLETCHER PILDITCH**

Chairman

Psychoactive Substances Appeals Committee

1. s3 [↑](#footnote-ref-2)
2. A “psychoactive product” is a finished product containing a “psychoactive substance” ready for retail sale; s8. [↑](#footnote-ref-3)
3. s4(a) [↑](#footnote-ref-4)
4. s37 [↑](#footnote-ref-5)