**PSYCHOACTIVE SUBSTANCES**

**APPEALS COMMITTEE**

**PSA 2013/003**

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

**BETWEEN** **LIGHT YEARS AHEAD LIMITED**

Appellant

**AND PSYCHOACTIVE SUBSTANCES REGULATORY AUTHORITY**

Respondent

**DECISION OF APPEALS COMMITTEE**

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**Introduction**

1. The appellant is a company that applied for interim approvals of a variety of psychoactive products under the Psychoactive Substances Act 2013 (“the Act”). The applications related to a variety of psychoactive substances which included three products called “Kronic Skunk”, “Kronic Pineapple Express” and “Kronic Tropical Explosion” (“the Kronic products”).
2. By letter dated 26 September 2013, the Psychoactive Substances Regulatory Authority (“the Authority”) declined to grant interim approval for the Kronic products to be sold.
3. By way of email dated 8 October 2013 the appellant appealed this decision to the appeals committee.
4. In essence there were two grounds of appeal:
5. That the Authority failed in its obligation to comply with s39(1) of the Act by not giving appellant an opportunity to respond to evidence the Authority relied on in making its decision to decline interim product approval; and
6. The evidential basis on which the Authority relied in making its decision was substantially flawed leading, to a decision that was both unreasonable and wrong in law.
7. Because the first ground of appeal related to a failure by the Authority to consider submissions and evidence the appellant could have provided we gave leave to the appellant to file additional evidence. This was subject to being satisfied, as a matter of law, that this Committee could receive fresh evidence on an appeal which is to be by way of rehearing.[[1]](#footnote-1) Equally we gave leave to the Authority to file fresh evidence by way of a response.
8. Once the Authority had filed a record of its decision, and received the fresh evidence on which both parties relied, we sought views from the parties as to whether an oral hearing was required. Both parties confirmed that an oral hearing was sought and accordingly the matter was set down for hearing in Wellington on 31 April 2014. At that hearing Mr Dunne and Mr Russell appeared for the appellant, and Ms Miller appeared for the Authority. Counsel for both parties filed submissions in advance of the hearing which were of significant assistance to us.
9. At the conclusion of the hearing, we gave an indication of the result, on the basis that our reasons would follow. We determined to grant the appeal but rather than approve the product on an interim basis, we instead indicated that we would direct that the matter be referred back to the Authority for reconsideration under s46 of the Act.
10. We record our reasons in this decision for that outcome but we must also record that legislative events that occurred while we prepared our reasons have overtaken this appeal rendering our decision nugatory.
11. Some weeks after this and other appeals were heard, the Associate Minister of Health communicated to media that the Government intended to pass law amending the principle Act in a number of ways. Included in those amendments was an intention to effectively ban the manufacture, distribution, and sale of psychoactive substances and products on an interim basis, which had been permitted by Schedule 1 of the principle Act until that point.
12. This legislation was passed under urgency on 6 May 2014, and came into effect at midnight on 7 May 2014.
13. Critical to the present appeal the Psychoactive Substances Amendment Act 2014 revokes every interim approval granted in respect of a psychoactive product under clause 4 of Schedule 1 of the principle Act.[[2]](#footnote-2)
14. Further, the Authority is required before the close of day after the date of commencement to recall every psychoactive product under s88 of the principle Act.[[3]](#footnote-3) Every interim licence to sell by retail or wholesale is also revoked in the same manner[[4]](#footnote-4). For the avoidance of doubt, regardless of the outcome of any appeal under Subpart 3 of Part 2, interim licences to sell by retail or wholesale or interim approvals may not be granted.
15. Accordingly, we now have no power to exercise any of the remedies available to us under s45 of the Act on an interim basis. While the power under s46, which we proposed to exercise in the present case, directing that the Authority reconsider an application, may theoretically still exist, s14 of the Amendment Act binds the Authority and so they may not grant an interim approval after the commencement of the amending legislation.
16. In the circumstances we do not consider that we are able to grant the relief we had earlier indicated to the appellant because to do so would be a vacuous exercise. We therefore decline the appeal because no other course is sensibly open to us.
17. However, out of deference to the careful and thorough manner in which both the appellant and the Authority advanced their cases in the appeal, and because the Act may nevertheless be utilised in the future for the regulation of psychoactive substances and products, we provide the reasons for our earlier indications. For the avoidance of any doubt this does not amount to us granting relief in any way for the reasons we have already outlined.

**Background**

1. It is important to canvass both the legislative and factual background to this appeal.
2. The Act came into force on 18 July 2013. The purpose as set out in s3 was to regulate the availability of psychoactive substances in New Zealand “to protect the health of, and minimise harm to, individuals who use psychoactive substances”.
3. The term “psychoactive substance” is defined broadly in s9 as “a substance, mixture, preparation, article, device or thing that is capable of inducing a psychoactive effect (by any means) in an individual who uses the psychoactive substance”.
4. In turn, a “psychoactive effect” means an effect of the substance on an individual’s mind.
5. A “psychoactive product” is a finished product packaged and ready for retail sale that either is a psychoactive substance or contains one or more psychoactive substances.
6. The Act was introduced to bring regulation to a pre-existing industry that manufactured, distributed, and sold a variety of substances that were commonly known as “legal highs”. The notion that they were “legal” is something of a misnomer. Many of the substances were not classified as controlled drugs under the Schedule to the Misuse of Drugs Act 1975, but nor were the substances that were intended for consumption by people in New Zealand, regulated in any way. The substances appeared to occupy a space between prohibition and explicit regulation and therefore there were no controls as to the manner in which the substances were composed, packaged, marketed, sold, and eventually consumed. This was of concern to the public and Parliament responded with the Act.
7. The substantive architecture of the Act established the Regulatory Authority which is taxed with the responsibility of determining whether psychoactive substances and psychoactive products could be imported, manufactured, distributed or sold in New Zealand and who should hold licences that would permit them to conduct these activities.
8. At the core of the Regulatory Authority’s function was the need to reflect the principles set out in Schedule 4 which in essence governed the manner in which psychoactive substances and products should be assessed.
9. Psychoactive products should pose no more than a low risk of harm to individuals who use it and those products that manifest no more than a low risk of harm should be approved. Conversely a psychoactive product that poses more than a low risk of harm to individuals should be prohibited.
10. A psychoactive substance or product that has not been approved, should be prohibited on a precautionary basis until it has been assessed. Assessments should be made on the basis of advice of an expert advisory committee and evidence including the results of preclinical and clinical trials.
11. Subpart 3, in addition to establishing the Regulatory Authority, also established the Psychoactive Substances Expert Advisory Committee.
12. Part 2 of the Act prescribes the regime by which people could apply for licences to import, manufacture, research, or sell psychoactive substances and products by retail or by wholesale. The provisions in Part 2 are the key mechanics of the Act by which applicants can seek approval for products and licences to sell those products. It is in this Part, Subpart 3, that this Appeal Committee is established.
13. Part 3 of the Act imposes a variety of controls on approved products including age restrictions and restrictions on where approved products could be sold. There are requirements concerning marketing of the products, in addition to offence provisions for when the Act is breached. The Subpart also provides a mechanism by which territorial authorities can establish policies about the location of stores selling approved psychoactive products within its territorial boundaries.
14. In Subpart 6 of Part 3, the Act provides for regulations to be created covering many aspects the trade in psychoactive substances and products. Included in the regulation making powers, is the ability to make regulations determining those substances that should or should not be psychoactive substances that are approved for the purpose of the Act. This in turn references back to the core architecture establishing the Regulatory Authority, the Expert Advisory Committee and the need for evidence of low risk of harm before psychoactive substances and productscould be approved.
15. We have been informed by counsel for the Regulatory Authority that the Ministry of Health responsible for administering this Act has expended considerable time to the exercise of preparing Regulations which will support the function of the Act and achieve its purposes. The preparation of those regulations is necessarily complicated and involved due to complex issues concerning the nature of the product and the need to provide reliable frameworks in which the products can be assessed. Although it had been hoped that the regulations would come into force by now, that has not occurred.
16. The gap between the Act coming into force and the creation of Regulations, was anticipated by Parliament which ultimately resolved that this essentially non-regulated market need regulation immediately.
17. Although psychoactive substances and psychoactive products cannot be assessed in the manner the legislation intends without the Regulations, Parliament nevertheless sought to bring the manufacture, distribution and sale of psychoactive substances and products within a regulatory environment in the interim.
18. As a consequence, Schedule 1 to the Act created an interim regime by which people could apply for interim approvals for products and correspondingly could apply for interim licences to sell those products pending the creation of the Regulations.
19. Under Schedule 1, Subpart 3 of the Act was utilised by applicants to apply for interim approvals of psychoactive products and interim licences. Those applications had to be made within 28 days of the Act coming into force. The schedule only applied to psychoactive substances or products that were lawfully being imported, manufactured, researched, or sold throughout the period of three months immediately before the commencement of the Act.
20. Because the Regulations will introduce permanent mechanisms and standards for assessing psychoactive substances, all interim approvals or interim licences extended only to the point when the Regulations came into force. At that point the licence was deemed to be cancelled unless the licence holder made a “full application” to carry on the activity to which the interim licence related. This application would then be assessed in terms of the Act and Regulations rather than on an interim basis.
21. This is significant. Interim approvals have been assessed on what data is available, which is limited. “Full Applications” will no doubt need to be advanced on the basis of pre-clinical and clinical trials.
22. We have been informed that there was a deluge of applications by persons previously engaged in the unregulated market for psychoactive substances and products to achieve interim approval for products and interim licences to continue to sell those products. The Regulatory Authority had to manage many applications based on what information was available to it about the psychoactive products and the applicants who intended to sell them.
23. We understand that approximately 42 psychoactive substances/products were approved and many have not been approved (some of which have been the subject of appeals to this Committee). Equally a number of interim retail licences were issued and again, some declined, (again some being the subject of appeals to this Committee).
24. It is therefore in this interim regime that the present appeal was brought and was considered by us.
25. As noted above, the Psychoactive Substances Amendment Act 2014 must now alter the approach that we take.
26. It is therefore important to record that although we previously indicated an intention of granting the appeal in part, nothing that we say in this decision can derogate or contradict Parliament’s clear intent to ban these products in the interim.
27. However we consider it important that we do provide reasons, notwithstanding the most recent developments of this legislation, because eventually the appellant may wish to make a full application. Our reasons may assist both the appellant but also the Regulatory Authority in any future application under the Regulations made by it.

**Issues**

1. The points raised on appeal pertains to the manner in which the Authority undertook the decision making process concerning the Kronic products and the evidence that the Authority had relied on in reaching its conclusion.
2. As to the first ground, it is necessary to briefly set out the chronology and the complaint advanced by the appellant. This was helpfully summarised in the submissions of the appellant at paragraphs 14 to 25 in addition to a full chronology at Appendix 1.

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| 14 August 2013 | Application for interim approval of Kronic products. |
| 11 September 2013 | The Authority notified a proposed adverse decision under s39 of the Act suggesting that the products posed more than a low risk of harm. In accordance with s39(1)(a), the Authority informed the appellant of the grounds for the proposed refusal citing five adverse reports that had been documented in relation to Kronic products by the National Poisons Centre (“NPC”). |
| 19 September 2013 | The appellant responded through is solicitors indicating that the adverse reports to the NPC prior to mid-April 2013 had to be disregarded because the Kronic products which were subject to the application contained a different psychoactive substance from that to which the earlier reports related. As a consequence only one of the NPC reports related to the product that was subject to the application and therefore the risk assessment was below the threshold at which product approval would be declined. The appellant’s correspondence also questioned the reliability of the NPC data. |
| 25 September 2013 | After a further exchange of emails, the Authority wrote to the appellant formally declining the application for interim approval on the grounds that the Authority had identified two further adverse reports on the NPC database in the month of August 2013 which post-dated the appellant’s change to its psychoactive product formulation. Its assessment of these two additional reports elevated the risk score to a point where it exceeded the threshold established by the Authority, indicating the Kronic products posed more than a low risk of harm to individuals who used it. |

1. It was common ground that these two additional NPC reports had not been referred to the appellant for comment prior to the Authority making its decision.
2. The grounds of appeal therefore focused on the failure by the Authority to afford the appellant an opportunity to comment on the new information on which the Authority relied, and then the quality of that data in terms of the Authority making its substantive decision.

**Approach**

1. As we noted above, because the first ground of appeal pertained to what the appellant asserted was both a breach of s39(1) and also generally a natural justice obligation, we granted leave to the appellant to file fresh evidence relating to those two reports for which the opportunity of comment was not afforded during the Authority’s decision making process. The respondent also filed fresh evidence in response.
2. Leave was granted on a preliminary basis because we were conscious that s45(5) of the Act directs that an appeal to us is by way of rehearing. Ordinarily an appellate body would consider the evidence that was presented in the lower Tribunal, but an appeal by way of rehearing is not a hearing de novo. We would not ordinarily expect to receive evidence that was not before the lower Tribunal. We identified this issue to the parties in pre-trial conferences. The parties were content to deal with this preliminary point at the substantive appeal.
3. We were assisted by the submissions in this regard, the appellant citing numerous authorities supporting the proposition that fresh evidence can be adduced if:
4. The evidence could not have been obtained with reasonable diligence for presentation to the original decision maker;
5. Would have influenced the result had it been available; and
6. Appears credible.
7. The principles are helpfully summarised in *Power NZ Limited v Mercury Energy Limited* [[5]](#footnote-5)whichwas cited to us.
8. The fresh evidence filed by the appellant was comprised of a statement of Matthew Wielenga who is a director of the appellant who undertook to try and identify from its sales data who may have contacted the NPC in relation to the two adverse reports relied on by the Authority. Based on information about its customers to whom Kronic products had been sold in the period following the formulation change, Mr Wielenga, by email, contacted customers that could be identified, inviting them to comment on their use of Kronic products and whether they contacted the NPC.
9. Of 18 separate purchases of the Kronic brands during August 2013, the appellant was able to contact nine customers who provided declarations that they did not suffer adverse effects from using the products or contact the NPC.
10. This, the appellant submitted was germane to a consideration of the NPC data and called into question its reliability, while acknowledging that the appellant had not been able to identify and therefore obtain declarations from every customer who used the product over that period.
11. Ms Miller for the Authority responsibly acknowledged that the two adverse reports on which the Authority eventually relied in making its decision had not been provided to the appellant during the decision making process. For this reason the Appeals Committee was likely to regard the evidence as material, and evidence which the appellant could not have provided at the time the Authority’s decision was made. That concession is of course correct because the appellant did not know of the adverse reports relied on. Therefore it was impossible for them to respond with the evidence that they have now adduced.
12. That concession necessarily flows to the first substantive ground of appeal which we address below, but for present purposes, we have little hesitation granting leave for the fresh evidence to be received and considered by us for the purposes of the appeal.
13. In terms of how we were to approach our decision, it was common ground that the Supreme Court’s dicta in *Austin Nicholls & Co Inc v Stitching Lodestar* [[6]](#footnote-6) applied to us and we adopt that approach in this appeal. We must come to our conclusion on the assessment of the evidence and merits generally and no particular weight must be placed on the manner in which the Authority approached its task. Of course in circumstances where the Authority has not complied with s39(1), and we have permitted the admission of fresh evidence, our judgment on that additional evidence is unique to us in any event.

**Submissions**

1. We do not traverse the submissions in detail on the first ground because the Authority recognised that both s39(1) and generally the requirements of natural justice, placed an onus on it to provide the additional evidence on which it relied to the appellant so that the appellant was placed in the position of being able to react to it.
2. Section 39(1) clearly states that the Authority must give the appellant “written notice that clearly informs the applicant of the grounds for the proposed refusal; and a reasonable opportunity to make written submissions”.
3. Once the Authority intended to rely on additional evidence that had not been referred to the appellant, the s39(1) obligation arose again and should have been complied with to ensure the procedural fairness mandated by the Act was met.
4. Correspondingly, having identified that procedural omission, the appellant ultimately agreed that this was remedied by us receiving the fresh evidence which would have been provided to the Authority. Therefore the omission to extend the s39(1) procedure to the additional NPC reports would not, of itself, justify us granting an approval unless we were satisfied that substantively the approval should have been granted in light of all of the evidence before us.
5. Therefore it was the second ground on which the substantive merits of the appeal had to be assessed; having admitted the fresh evidence in recognition of the procedural error committed by the Authority.
6. Before leaving this first ground we note our conclusions are not directed at criticising the Authority. To the contrary, the Authority has undertaken an onerous task with new legislation with commendable diligence. We hope our observations concerning the first ground of the appeal will provide some guidance on how s39 will be met in future cases.
7. We now turn to the second ground of appeal.
8. The appellant’s submission was essentially that the two NPC reports relied on by the Authority were unreliable. That contention was said to be supported by the appellant’s fresh evidence, being and the customer survey conducted by Mr Wielenga. It was submitted that the fact that this survey disclosed no adverse effects indicated that the NPC reports could not have been about the Kronic products subject to the application.
9. The Authority provided a substantial body of information outlining how it endeavoured to undertake its tasks under the Act with respect to the interim approval of psychoactive substances and products based on what information was known. As counsel for the appellant emphasised, the Authority was faced with a “data-poor” environment in which to make its decisions. The substantive regime established under the Act which will require products to undergo pre-clinical and clinical testing. But no such information was available at the time the interim regime, imposed by Schedule 1 to the Act, came into force.
10. Therefore the Authority looked for other evidence on which it could make an assessment as to the level of risk posed by a psychoactive substance or product.
11. In additional evidence filed by the Authority, Dr Stewart Sinclair Jessamine, a registered medical practitioner employed as a medical advisor and Dr Donald James Hannah, the manager of the Authority outlined these issues. They detailed the development of the risk scoring system the Authority adopted to test products.
12. The risk scoring system derived from a paper published by a Freiburg (German) Poison Centre by Hermanns-Clausen which was adopted and adapted by the Authority in the interim regime.
13. The rationale and the method was published by the Authority via the Ministry of Health’s website. This process was amplified by Dr Jessamine who explained that the Freiburg approach assessed scores based on the nature and severity of adverse effects. The system classified adverse effects into minor, moderate, or severe categories.
14. This approach was amended for New Zealand to include information associated with chronic use, withdrawal of a psychoactive product, sales data (where available) as a surrogate for consumer exposure in order to assess the prevalence of adverse effects in New Zealand.
15. In essence the Authority’s risk scoring system was designed to identify both the nature and number of adverse effects based on data available to it, which would produce a score from 0 to the low 20’s in the New Zealand context.
16. This risk scoring system was applied prior to the Authority making decisions on interim product approvals.
17. The Authority then determined, on the score produced from the risk assessment, where a “low risk of harm” as prescribed by the Act would fall.
18. It was determined that a risk score of 1 would result in a product being approved, a risk score of 2 could prompt further inquiry into the nature of the adverse reports to determine whether the risk was low, and a risk score of 3 or above would result in a product application being disapproved.
19. We understand that a score could be composed in different ways. For example a single severe adverse report could be sufficient to justify declining an application, but two minor adverse reports could result in a score below the threshold.
20. The assessment was therefore quantitative, and qualitative.
21. Ultimately the assessment relied on what information was available. Without preclinical and clinical trials anticipated by the principal Act, the information available in New Zealand comprised data from the NPC, case reports to the Centre for Adverse Reactions Monitoring at the New Zealand Pharmaco Vigilance Centre and any case reports from a subset of emergency departments and reports published in the *New Zealand Medical Journal*.
22. It should be noted that we were advised that there was no consistent reporting of psychoactive product effects from hospital emergency departments. Some were collating data at the time we heard this appeal, some were not.
23. In the present case the only reports that led to the Authority’s decision were those collected by the NPC in the August period.
24. One of the issues in the appeal was a lack of information to us about the manner in which the NPC collected its data. In the case of the Kronic products the NPC 0800 number was on the packaging. Inferentially people called using this number and presumably described symptoms so that the NPC could provide direction to assist the caller.
25. In the record of decision, the two entries, both dated August 13 contain these comments:

CALLER HAS BEEN SMOKING THIS AND HAS NOW DEVELOPED DIARROHEA AND FEELING HOT AND COLD. THIS HAS BEEN CONTINUING FOR TWO DAYS NOW. WANTING TO LET MANUFACTURER KNOW AS WELL.

SMOKED THIS YESTERDAY AND GOT HEART PALPITATIONS. WHY IS THIS LEGAL?

1. In its submissions the appellant emphasised that, in principle, it took no issue with the methodology of the risk scoring system and did not seek to challenge that methodology in the appeal. Further, the appellant accepted that in principle the Authority was entitled to rely on NPC data in making its decisions.
2. The appellant’s argument was grounded in a criticism of the quality of the two specific NPC reports of which numerous submissions were made.
3. The general proposition advanced was that for a decision maker to make a decision, a decision must be based on some probative evidence: *Re Erebus Royal Commission.*[[7]](#footnote-7) Of course as a general proposition that is correct.
4. In relation to the two adverse reports, it was asserted that they were unsubstantiated and lacked probative value. The entries merely referred to “Kronic” and did not differentiate which particular Kronic product was the subject of the complaint, nor had any enquiry been made regarding the property identity of the product.
5. It was submitted that the identity of the callers was not known and there was no way of establishing their identity to make further enquiry as to their claims. There was reasonable possibility that the “Kronic” to which the callers referred could have been from earlier batches which contained a different active ingredient. It was suggested that in these circumstances the evidence lacked all probative value and should not have formed the basis of a risk scoring assessment.
6. It was submitted that the risk scoring assessment should have excluded this, and presumably any other unreliable evidence and only relied on evidence which carried with it some assurance of reliability.
7. While the appellant accepted that the Authority could take a precautionary approach to approving products on an interim basis, this did not extend to the Authority relying on evidence that carried with it no weight in terms of an ultimate conclusion.
8. In response to the substantive issue, the respondent reiterated the data poor environment in which the Authority was bound to operate. In these circumstances it had to draw on what little data was available and for this reason the NPC reports were germane. The NPC is New Zealand’s only poison and hazardous chemical information centre which answers around 300 telephone enquiries each year and on its face has some system to differentiate between different brands of psychoactive products.
9. In this regard Ms Miller took us to various entries unrelated to the Kronic brands to demonstrate how the NPC could refine its data to be product specific.
10. It was submitted that the onus rested on the appellant to demonstrate the NPC reports were flawed or wrong and mere submission was in sufficient to discharge this burden.
11. It was further submitted that if the Authority could not rely on this information, in the interim regime, its function would be impossible.

**Discussion**

1. There is merit in the submissions advanced by both parties. The NPC spreadsheet contains minimal information, (although that is no criticism of the NPC which we infer records information that is communicated to it by callers calling the 0800 number). The decision of the Authority came down to two adverse reports referencing “Kronic” without more specificity as to which particular brand was consumed and when the product had been purchased.
2. However it cannot be said that the NPC data is irrelevant generally (and the appellant did not submit that), and this information on its face pertains to the product for which interim approval was sought (albeit generically).

1. From this point of view the information was relevant and needed to be taken into account by the Authority. On the other hand the fact that the Authority is operating in a data poor environment does not elevate the weight that should be attached to this information if that information carries little probative value.
2. Ultimately we do not consider that it is possible for us to properly assess the accuracy and reliability of this information in order to determine whether, on our independent assessment, the Kronic products for which interim approval was sought carry a low risk of harm to individuals.
3. We do not know how the NPC create their spreadsheet, the training that its staff have, nor do we have access to recordings of the calls from which these records were made.
4. Although generally, Ms Miller for the Authority submitted that the information was reliable, she could not provide further information underlying the processes employed by the NPC to ensure accuracy of its data. She did however indicate that this information was available to the Authority.
5. Therefore in assessing the appellant’s claims about the two adverse reports we are not presently in the best position to make that assessment independently.
6. It is for these reasons, principally, that we determined to grant the appeal but we were not prepared to reverse the Authority’s decision declining interim approval, and substitute our own decision. Rather we proposed to direct the matter back to the Authority under s46 of the Act so that the Authority could exchange further information with the appellant pertaining to the NPC data, and in particular information about how the NPC centre gathers its data which could either support or refute the reliability of the information relied on.
7. In making that decision, we express no view whether, on the face of the NPC adverse reports, the decision of the Authority was correct or otherwise. Our decision stems from the absence of information available to us concerning NPC processes.
8. However before concluding our decision, we also make these observations as it would have been relevant to the direction we would have made in referring the decision back to the Regulatory Authority.
9. The appellant appeared to premise the appeal on the basis that if the Authority was unable to demonstrate that the product in question posed more than a low risk of harm to individuals, then the Authority was bound to grant the approval.
10. This submission focused on s37 which mandated the Authority to approve a psychoactive product as an approved product if it was satisfied that the degree of harm that the product poses to individuals using the product is no more than a low harm of harm. In the absence of information indicating it posed more than a low risk of harm, it necessarily followed that the product posed a risk that was low, the appellant submitted, and therefore approval had to follow.
11. We do not necessarily agree with that analysis. Section 4 of the Act, containing the principles that govern the exercise of all decision making powers confirms that:

(c) A psychoactive product that poses no more than a low risk of harm to individuals who use the product should be approved;

(d) A psychoactive product that poses more than a low risk of harm to individuals who use the product should be prohibited.

1. This tends to indicate that the decision maker, the Authority, must reach some certainty as to either of the two propositions reflected in these paragraphs. To accord with the principles, the Authority must be satisfied that a product either poses no more than a low risk of harm, or poses more than a low risk of harm.
2. However, in the interim regime and the data poor environment described by the Authority, it is quite conceivable that the Authority could be left with uncertainty as to either of those propositions. If the approval of a psychoactive product, such as the Kronic products, falls to a consideration of a handful of words entered in the NPC database, the Authority could find itself between paragraph (c) and (d) of s4.
3. The question then was what the Authority was to do if, in a data poor environment, it was unable to reach a point where it could be confident either way. The Act did not explicitly address this middle ground which, in the interim regime had become manifestly problematic.
4. While ultimately the appellant’s contention that the two NPC reports carry no probative value might be correct, that may not inevitably lead to a conclusion that the s37/s4 tests are satisfied. When we consider the particular circumstances of the Kronic applications this issue is all the more apparent.
5. The appellant reformulated the Kronic products in April 2014 because, we understand, it anticipated that its earlier formulations were unlikely to meet the criteria for approval. Therefore on the most generous assessment available to the appellant it satisfied the criteria of Schedule 1; namely that the products had been sold for three months prior to the Act coming into force, this being a prerequisite for applications for interim approval under the interim regime. But that meant that the product had only been exposed to the population for a period of a few months.
6. In this regard we record that the Regulatory Authority’s own methodology required it to consider sales data, which would include sales volume. A corollary of the way in which this appeal occurred was that the sales volume data and customer survey provided to us was not available to the Regulatory Authority at the time it made its initial decision.
7. Even with minimal information concerning adverse effects the question is whether this period of exposure would be sufficient to establish that the product posed no more than a low risk of harm.
8. In our view, the absence of data indicating adverse effects equates to the absence of any evidence about the risk of the product, low or otherwise. Prima facie the absence of evidence proves nothing.
9. If it could be demonstrated that a psychoactive product had been sold and used many times, and by a wide variety of consumers, and that none suffered adverse effects then possibly the combination of these facts could point to a low risk of harm. But the mere fact that a product which may have only been used 10, 20, possibly 50 times did not produce adverse effects would not necessarily lead to a conclusion that the product was low risk.
10. Possibly this is why Parliament has recognised the invidious position in which the Authority found itself considering product applications with little or no evidence. The Psychoactive Substances Amendment Act 2014 introduced ss(2) to s37, which states that if the Regulatory Authority is in doubt about whether the product poses no more than a low risk of harm, it must disapprove the product.
11. For these reasons also, had we referred the matter back to the Regulatory Authority, in addition to addressing the reliability of the NPC data, we would have also directed that the Regulatory Authority specifically consider the sales data provided to us as evidence in this appeal.

**Result**

1. For the reasons outlined above, we would have granted the appeal and directed the matter back to the Regulatory Authority for reconsideration. This decision would have provided the Authority with our reasons for doing so and we would have directed the Authority to consider the matters raised above.
2. We would have also indicated that s39(1) would have required the Authority to disclose to the appellant the information gathered about the NPC processes and provided the appellant with a reasonable opportunity to make submissions on these discrete points.
3. We would have reiterated that in redirecting the matter back to the Authority, we expressed no view, one way or the other, on whether ultimately the product should have been approved.
4. However for the reasons outlined in the introduction to this decision we decline the appeal.

Dated 26 May 2014

Fletcher Pilditch

Chair

1. s45(5). [↑](#footnote-ref-1)
2. s11. [↑](#footnote-ref-2)
3. s11. [↑](#footnote-ref-3)
4. s13. [↑](#footnote-ref-4)
5. (1996) 1 NZLR 106 at [112]. [↑](#footnote-ref-5)
6. [2008] 2 NZLR 141 at [16]. [↑](#footnote-ref-6)
7. [1983] NZLR 662 [↑](#footnote-ref-7)