

09 SEP 2016

No. 1 The Terrace
PO Box 5013
Wellington 6145
New Zealand
T +64 4 496 2000

Mr Shane Le Brun
Medical Cannabis Awareness New Zealand (MCANZ)
Email: Shane@mcawarenessnz.org

Ref: H201603281

Dear Mr Le Brun

Thank you for your email of 12 August 2016 requesting official information, as follows:

Can you please supply any assessment documents regarding the application for the Cannabis based product "Aceso Calm Spray" several months ago, and that were used to aid in the application process and inform the Associate Health Minister Peter Dunne.

Please also include any Lab reports etc.

The process followed when a prescriber makes an application to prescribe a non-pharmaceutical grade cannabis based product for medicinal use is:

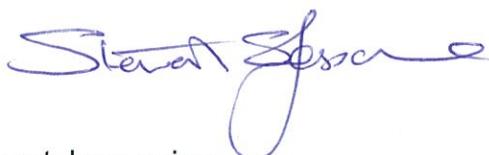
1. The prescriber completes the appropriate application form. The forms are available on the Ministry of Health (Ministry) website.
2. The information provided is assessed by Ministry officials against the "Guidelines for assessing applications for Ministerial approval to prescribe supply and administer" in accordance with regulation 22 of the Misuse of Drugs Regulations 1977. These guidelines are on the Ministry website.
3. Further information is requested from the prescriber if necessary.
4. Ministry officials may also source further information, for example, whether any laboratory analysis documentation provided has been obtained from a laboratory with an internationally accepted accreditation and a review of the evidence available to demonstrate that the requested product may be of benefit in the condition being treated.
5. The information is collated and provided to a senior Ministry physician for their assessment and recommendation.
6. A Health Report is prepared for the Associate Minister of Health, the Hon. Peter Dunne, with the Ministry's recommendation.
7. The Associate Minister of Health makes the final decision as to whether the application is approved. Ministerial approval to import the requested product is also requested.

Please find attached the following documents relating to the application to prescribe and import Aceso Calm Spray.

Document released	Information withheld and grounds for withholding
Laboratory analysis provided for the Aceso Calm product to which the application related.	
Library request for journal articles referred to in the application and any further research evidence.	Reference to the condition being treated and the details of the articles relating to this condition are redacted under section 9(2)(a) of the Official Information Act 1982 to protect the privacy of natural persons.
Email sequence beginning 7/3/16 and concluding 16/3/16 from the Ministry to the applicant requesting further information and discussing the application process and other cannabis-based products.	NHI of patient has been redacted under section 9(2)(a) of the Official Information Act 1982 to protect the privacy of natural persons. The name and contact details of the applicant have also be redacted under the same section of the Act because they could lead to identification of the patient.
Recommendation of senior Ministry physician Dr John Crawshaw on 15/3/16.	Reference to the condition being treated is redacted under section 9(2)(a) of the Official Information Act 1982 to protect the privacy of natural persons.
Health Report 20160455 to the Associate Minister of Health recommending that Ministerial approval be granted for the application to import and prescribe Aceso Calm Spray.	All information that may identify the patient has been redacted, including the names and other identifying information of all clinicians and any specific details of the patient's medical condition. These redactions have been made under section 9(2)(a) of the Official Information Act 1982 to protect the privacy of natural persons.

You have the right to ask the Ombudsman to review my decisions on this request.

Yours sincerely



Stewart Jessamine
Director
Protection Regulation and Assurance

Appendix 1.

"Access Candy" - product applied
for

TEQ ANALYTICAL LABS

TEST REPORT

Left Bank LLC

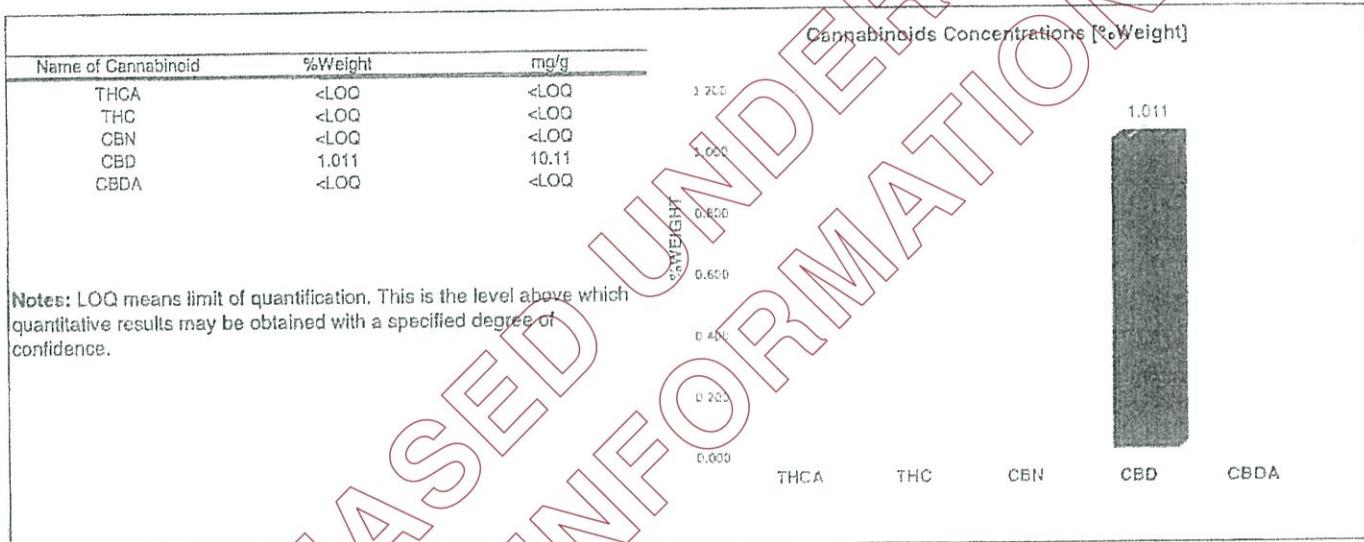
4990 Oakland Street,
Denver CO 80239

Work Order # 1601200001
Date Received 1/20/2016
Date Analyzed 1/21/2016
Date of Report 1/22/2016

Report No. 1601200001-1

Page 1 of 1

Sample ID (Client) CBD Sample (Non-Cannabis)
METRC ID: 1A400031268748A000023402
Sample Matrix Liquid Edible
Condition received Good
Test Performed Potency-S



Receipt of analytical services acknowledges the terms and conditions on the website www.teqanalyticallabs.com/terms. This report is not to be reproduced in whole or in part without obtaining prior written authorization. The results shown on this certificate of analysis apply only to the samples listed above. The information contained in this report is intended only for the individual or entity to whom it is addressed. Its contents are confidential and may contain privileged information. If you are not an intended recipient you must not use, disclose, disseminate, copy or print its contents.

Touraj Shokati, Ph.D., Laboratory Director

01-22-2016



Sent by: Sue Scott/MOH
24/02/2016 11:58 a.m.

To: Library/MOH@MOH,
cc:
bcc:

Subject: Request for information (urgent 2 days if possible)

Hi

Could you please access copies of the papers listed below and any other articles in peer reviewed journals on the use of cannabidiol (CBD) alone, or in combination with delta-9 THC, in the treatment of

Thanks

Sue

Sue Scott

Principal Advisor | Medicines Control
Provider Regulation | Clinical Leadership, Protection & Regulation
Ministry of Health

DDI: 04 816 3594
<http://www.moh.govt.nz>
mailto:Sue_Scott@moh.govt.nz





Sent by: Sue Scott/MOH
16/03/2016 11:21 a.m.

To:
cc: Michael Haynes,
bcc:
Subject: RE: Application for Aseco-Calm for patient

Hi

Your application is progressing and I would expect that you will have a response within the next week or so.

The possibility of obtaining Epidiolex for patients here either for compassionate use outside trials or as part of their trials was investigated by the MoH last year. The response was that product is not available.

However the NSW government has subsequently come to an agreement with the manufacturers GW for patients from NSW (not sure about wider Australia) to be included in Epidiolex trials.

There is information about this online.

Regards
Sue

Sue Scott

Principal Advisor | Medicines Control
Office of Chief Medical Officer | Protection, Regulation and Assurance
Ministry of Health

DDI: 04 816 3594
<http://www.moh.govt.nz>
mailto:Sue_Scott@moh.govt.nz

Morning Sue - Thanks for your mail...

16/03/2016 10:06:33 a.m.

From:
To: "Sue_Scott@moh.govt.nz" <Sue_Scott@moh.govt.nz>,
Date: 16/03/2016 10:06 a.m.
Subject: RE: Application for Aseco-Calm for patient

Morning Sue – Thanks for your mail – am I correct in believing that the only pharmaceutical grade of cannabidiol, epidiolex – is not yet available anywhere – except in phase 3 trials via gw pharmaceuticals? – would I have any higher likelihood of success in gaining access if the pharmaceutical company were prepared to let me have some of their pharmaceutical grade? – Many thanks for your time and opinion,

From: Sue_Scott@moh.govt.nz [mailto:Sue_Scott@moh.govt.nz]
Sent: Monday, 14 March 2016 12:31 p.m.
To:
Subject: RE: Application for Aseco-Calm for patient
Importance: High

Your letter has just arrived.

Regards

Sue

Sue Scott

Principal Advisor | Medicines Control
Office of Chief Medical Officer | Protection, Regulation and Assurance
Ministry of Health

DDI: 04 816 3594

<http://www.moh.govt.nz>

<mailto:Sue.Scott@moh.govt.nz>

----- Document: RE: Application for Aseco-Calm for patient
14/03/2016 12:29 pm -----

forwarded by Sue Scott on

Sent By: Sue Scott/MOH on 14/03/2016 11:34:38 a.m.

To:

Copy To:

Subject: RE: Application for Aseco-Calm for patient

Morning

I have not received any written reply - which was the reason I followed up with you. Did it come electronically or should I be expecting it by post? If coming by post, do you have a copy that you could scan?

Just briefly in relation to the inconsistency that you perceive, Sativex is a pharmaceutical grade product which is approved for distribution in NZ, albeit only for spasticity in MS. Aseco Calm is a non-pharmaceutical grade controlled drug product so the level of scrutiny of an application for medicinal purpose is higher. CBD is scheduled as a Class B1 controlled drug, the same as THC so the same requirements apply.

Regards

Sue

Sue Scott

Principal Advisor | Medicines Control
Office of Chief Medical Officer | Protection, Regulation and Assurance
Ministry of Health

DDI: 04 816 3594

<http://www.moh.govt.nz>

<mailto:Sue.Scott@moh.govt.nz>

From:
To: "Sue.Scott@moh.govt.nz" <Sue.Scott@moh.govt.nz>,
Date: 14/03/2016 09:17 a.m.
Subject: RE: Application for Aseco-Calm for patient

Morning Sue – Thanks for mail – my apologies I didn't confirm receipt – but I hope my written reply is with you – It does seem a little inconsistent to me that Sativex is permitted but cannabidiol alone wouldn't be – when thc is the worry – and cannabidiol alone has proven record in movement disorders – Interested to hear what the rational might be,

From: Sue Scott@moh.govt.nz [mailto:Sue Scott@moh.govt.nz]

Sent: Friday, 11 March 2016 9:10 a.m.

To:

Subject: Application for Aseco-Calm for patient

Dear

I just wish to confirm that you received the email below, to ensure that a breakdown in communication is not occurring in relation to your application.

I also left a message with your PA's phone on 7/3/16 but it is possible that you have had difficulties contacting me.

Regards

Sue

Sue Scott

Principal Advisor | Medicines Control
Office of Chief Medical Officer | Protection, Regulation and Assurance
Ministry of Health

DDI: 04 816 3594

<http://www.moh.govt.nz>

<mailto:Sue.Scott@moh.govt.nz>

----- Document: Application for Aseco-Calm for patient
11/03/2016 09:04 am -----

forwarded by Sue Scott on

Sent-By: Sue Scott/MOH on 7/03/2016 10:13:44 a.m.

To:

Copy To:

Subject: Application for Aseco-Calm for patient

Dear

I have discussed your application for Aseco-Calm for patient with Dr John Crawshaw, Director of Mental Health.

Preliminary review has determined that more information is needed in relation to criterion c in the list of criteria used to guide Ministerial approval for non-pharmaceutical grade medicinal cannabis.

Criterion states:

evidence that the risk/ benefit of the product has been adequately considered by qualified clinical specialists – that is, the risk of treatment with an unproven product is less than the risk of non-treatment and account has been taken of any evidence of potential benefit and

weighed against known adverse effects.

While you have provided some of this information in your application and a telephone conversation with me, it is not in a format that can be assessed for a recommendation to the Assoc. Minister of Health regarding the Aseco product.

Could you please collate all relevant information into a document that provides evidence for criterion c.

A link to the full criteria is given below.

<http://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/medicinal-cannabis>
is

Regards

Sue

Sue Scott

Principal Advisor | Medicines Control
Provider Regulation | Clinical Leadership, Protection & Regulation
Ministry of Health

DDI: 04 816 3594

<http://www.moh.govt.nz>

<mailto:Sue.Scott@moh.govt.nz>

*

Statement of confidentiality: This e-mail message and any accompanying attachments may contain information that is IN-CONFIDENCE and subject to legal privilege.

If you are not the intended recipient, do not read, use, disseminate, distribute or copy this message or attachments.

If you have received this message in error, please notify the sender immediately and delete this message.

*

This e-mail message has been scanned for Viruses and Content and cleared by the Ministry of Health's Content and Virus Filtering Gateway

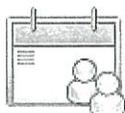
Notice of Legal Status and Confidential Information: This electronic mail message and any accompanying attachments may contain information that is privileged and CONFIDENTIAL. If you are not the intended recipient you are advised that any use, review, dissemination, distribution or reproduction of the information is strictly prohibited and may be unlawful. If you have received this document in error, please notify the sender immediately and destroy the message.

This email has been scrubbed for your protection by SMX. For more information visit smxemail.com

*

Statement of confidentiality: This e-mail message and any accompanying attachments may contain information that is IN-CONFIDENCE and subject to legal privilege.

If you are not the intended recipient, do not read, use, disseminate, distribute or copy this message or attachments.



Medicinal Cannabis Application Calendar Entry

Tue 15/03/2016 4:30 p.m. - 4:45
p.m.

Chair: John Crawshaw/MOH
Sent By: Janice Reeves/MOH
Location: Director's Office L3

Required: Sue Scott/MOH@MOH

Description

From: Sue Scott/MOH
To: Janice Reeves/MOH@MOH,
Date: 14/03/2016 01:48 p.m.
Subject: Discussion with John Re Medicinal Cannabis Application

Hi Janice

On 25 February I discussed an application that Medicines Control has received for medicinal cannabis for the treatment of John requested more information to be provided. That has now been received.

I know that John is acting DDG at the moment in addition to his other role, however, I need at least 15 minutes over the next few days to discuss the material with him and determine how he will make a recommendation to the Associate Minister of Health.

I cannot do 3-4pm today or 1-2pm tomorrow, but otherwise I am relatively free this week.

Thanks

Sue

Sue Scott
Principal Advisor | Medicines Control
Office of Chief Medical Officer | Protection, Regulation and Assurance
Ministry of Health

DDI: 04 816 3594
<http://www.moh.govt.nz>
mailto:Sue_Scott@moh.govt.nz

Discussed with Stewart Sessions. We believe think it not unreasonable in the circumstances to support trial for 3-6 months. Discussed with applicant how long a trial would be reasonable given rapid response to delivery but also sufficient time for cross-over

JLG
15/3/16

01 APR 2016

Database number: 20160455

Security classification: In-Confidence

File number: AD62-14-2016
Action required by: Routine

Ministerial Approval to Prescribe and Import a Non-pharmaceutical grade Cannabis Product Aseco Calm Spray

To: Hon Peter Dunne, Associate Minister of Health

Copy to: Hon Dr Jonathan Coleman, Minister of Health

Purpose

This report requests your decision as to whether Ministerial approval is granted for an application to import and prescribe Aseco Calm Spray for following an application from

Key points

- The Ministry of Health (the Ministry) received an application from [REDACTED] to prescribe and import Aseco Calm Spray for administration to [REDACTED] for Ministerial approval to [REDACTED] on 22 February 2016.
- Aseco Calm Spray contains cannabidiol, a Class B1 controlled drug and is a non-pharmaceutical grade product. Ministerial approval is required to import and prescribe Aseco Calm Spray.
- When Sativex was initiated four months ago, the patient rapidly demonstrated significant and sustained improvements in his symptoms of [REDACTED]
- The cost of Sativex is one factor in [REDACTED] making an application for an alternative non-pharmaceutical grade cannabis product.
- A second factor is that [REDACTED] reacts unfavourably to the tetrahydrocannabinol (THC) component of Sativex which limits the ability of the prescriber to increase the dose of the cannabidiol (CBD) component.
- [REDACTED] believes that the CBD component is principally responsible for the beneficial effects demonstrated and would like to trial increasing the CBD dose using a CBD-only product.
- No pharmaceutical grade CBD product is currently available either in New Zealand, or internationally (except in the Epidiolex trial).
- There appears to be no published scientific studies on the benefit of CBD alone in [REDACTED]
- [REDACTED] concedes that treatment of [REDACTED] is "uncharted territory" but considers that it will quickly be apparent if a CBD only product provides extra benefit for his patient.
- Dr John Crawshaw, Director of Mental Health, in consultation with Dr Stewart Jessamine, Acting Director of Public Health, has reviewed the information supplied and believe that it is not unreasonable in the circumstances to support a trial of Aseco Calm Spray for [REDACTED] for 3 to 6 months.
- Approval may set a precedent for further applications for non-pharmaceutical grade cannabis products from patients who cannot fund Sativex.

Contacts:	Michael Haynes, Manager Medicines Control, Protection, Regulation and Assurance	027 274 4851
	Sue Scott, Principal Advisor, Medicines Control , Protection, Regulation and Assurance	027 277 4839

Ministerial Approval to Prescribe and Import a Non-pharmaceutical grade Cannabis Product Aseco Calm Spray

Recommendations

The Ministry recommends that you:

- a) Agree to grant Ministerial approval to prescribe and administer Aseco Calm Spray for [redacted] for a trial period to be confirmed with the prescriber (between 3 and 6 months). Ministerial approval to allow import of Aseco Calm Spray is also granted.
- b) Note that this recommendation is due to the exceptional circumstances of this application and should not be viewed as setting a precedent.

Yes / No


Phil Knipe
Acting Director
Protection Regulation and Assurance


Minister's signature:

Date: 4.04.16

RELEASED
OFFICIAL INFORMATION ACT

Ministerial Approval to Prescribe and Import a Non-pharmaceutical grade cannabis product Aseso Calm Spray

The Application

1. The Ministry received an application on 22 February 2016 from [REDACTED] for Ministerial approval to prescribe and import Aseco Calm Spray for administration to [REDACTED]
2. Dr John Crawshaw, Director of Mental Health, Ministry of Health, made a preliminary assessment of the application against the Criteria for Access to Medicinal Cannabis Products that require Ministerial approval.
3. Further information was requested from [REDACTED] in relation to criteria c), that is: evidence that the risk/ benefit of the product has been adequately considered by qualified clinical specialists – that is, the risk of treatment with an unproven product is less than the risk of non-treatment and account has been taken of any evidence of potential benefit and weighed against known adverse effects.
4. Further information was received from [REDACTED] on 14 March 2016

The product requested

5. Aseco Calm Spray contains cannabidiol (CBD), a Class B1 controlled drug, and is a non-pharmaceutical grade product.
6. Direct Ministerial approval is required to import and prescribe Aseco Calm Spray as per the Criteria.
7. An analytical test report on the product has been provided by TEQ Analytical Laboratories. The laboratory's website documents that it is certified by the state of Colorado for potency (of five different cannabinoids) and residual solvent screening.
8. The test result states that the product contains 1.011% by weight of cannabidiol and the levels of THC and other cannabinoids that were analysed are less than the limit of quantification. That limit is not defined.

Patient history

9. The following information was provided by [REDACTED] initially for an application for the off-label use of Sativex oro-mucosal spray containing both CBD and tetrahydrocannabidiol (THC) on 20 August 2015.
- 10.
- 11.
12. [REDACTED] has over the years had adequate doses of various medications used for These medications have in some cases caused intolerable side effects and generally have had little benefit with regard to [REDACTED]

13. Sativex, at the time of the 10 February application, has been used reliably by for four months. had met with at least four times during this period and I had spoken with the patient's mother, GP and consultant neurologist
14. Trainee registrars videotaped pre-treatment and at regular intervals through his treatment and used both objective scales of and subjective rating scales. They are in the process of submitting a case report on the outcome.
15. reports that since starting Sativex, improvement in every aspect of life has been noted, not just by his family and his case worker, but also friends and people in shops.
16. has settled on a low dose of Sativex of two sprays twice daily. Higher doses were trialled, but it was found that these produced a sense of intoxication (with cognitive impairment and mild disinhibition) without other benefit and the patient has determinedly resisted any further increases. For this reason considers that he is an individual with a low potential for abuse.

Justification for the use of Aseco Calm Spray

17. One reason the applicant provides for making an application for a non-pharmaceutical grade of cannabis is the significant cost of Sativex of \$1300 per month (though it would last approximately two months at this low dosage). To date this has been borne solely by his family. Applications to WINZ, PHARMAC and the District Health Board for subsidy have been unsuccessful.
18. Aseco Calm Spray costs approximately \$70 per fortnight. In addition, a Licence to Import Controlled Drugs would have to be issued for each import costing \$194.22. A quantity sufficient for several months could be imported on one licence.
19. It is not known whether there would be any difficulties importing this product from the United States, however it is noted that a similar product Elixinol, with a much higher dosage of CBD, was previously able to be imported.
20. The second reason that wishes to trial Aseco Calm Spray is that he considers that the prescription of CBD alone would be preferable to the combination of CBD and THC (a known psychoactive compound) found in Sativex.
21. believes that it is the CBD in Sativex that is principally responsible for the effective effects already demonstrated.
22. If is permitted to access CBD alone it would be possible to increase the dose to potentially obtain greater effect without intoxication, and may enable effective treatment of
23. The scientific papers provided by all examine the use of THC alone or in combination with other cannabinoids in the treatment of CBD alone. No evidence has been provided of the benefit of
24. A Ministry of Health library search identified no published scientific studies on the benefit of CBD alone in
25. concedes that treatment of is "uncharted territory" but considers that it will quickly be apparent if a CBD-only product provides extra benefit for his patient.
26. would apply the same trial conditions used with Sativex with both subjective and objective rating scales.
27. refers to a letter titled which suggests that cannabidiol alone may retain the effects of cannabinoids whilst eliminating the psychoactive properties of THC, and could promise a new class of drugs useful in this debilitating condition. It should be noted that this is not a research paper.

Concordance with Criteria used to Guide Ministerial Approval for Non Pharmaceutical Grade products

28. On 8 September 2015 you agreed criteria to guide your assessment of applications for the use of non-pharmaceutical grade medicinal cannabis products.
29. You agreed that Ministerial approval for the use of a non-pharmaceutical grade medicinal cannabis product would not be delegated to Ministry officials at this stage.
30. This application has been assessed against the agreed criteria by Dr John Crawshaw, Director of Mental Health, in consultation with Dr Stewart Jessamine, Acting Director of Public Health.

Criterion for Ministerial approval	Information provided
Severe or life-threatening condition.	Condition severely debilitating but not life threatening.
Evidence that all reasonably applicable conventional treatments have been trialled and the symptoms are still poorly controlled.	There is evidence that standard treatments for [REDACTED] have been trialled. Sativex has been the most effective treatment used up to this point, but the cost is prohibitive and psychoactive or intoxication-like effects from the THC component limit dose increases that may improve residual motor tics and vocalisations.
Evidence that the risk/benefit of the product has been adequately considered by qualified clinical specialists – that is, the risk of treatment with an unproven product is less than the risk of no-treatment and account has been taken of any evidence of potential benefit and weighed against known adverse effects.	The patient does not like the psychoactive effects of THC and has resisted attempts to further increase the dose of Sativex. [REDACTED] considers that he may be able to increase the dose of the CBD-only product Aseco Calm Spray to obtain control of [REDACTED]. He accepts that he has little scientific data to support his theory. He also notes that benefits have been found in the treatment of Dravet's syndrome with CBD and states that Dravet's shares a number of similarities with [REDACTED]. [REDACTED] notes that the beneficial effects from Sativex appeared rapidly and have persisted for over four months so if Aseco Calm Spray is going to be effective, it will be evident after only a short trial.
Patient hospitalised when treatment is initiated.	No.
Patient or guardian has provided informed consent.	Written patient consent has been provided.
Application from a specialist appropriate to the medical condition being treated or the Chief Medical Officer of a District Health Board.	Yes.
Applicant or specialist prescriber has sought adequate peer review e.g., Hospital Ethics Committee approval, Drug or Therapeutics Committee review.	[REDACTED] states that he has the support of the Clinical Director of Mental Health Services, [REDACTED] and the Chief Medical Officer,
Provision of a Certificate of Analysis, preferably from an accredited laboratory, so that the concentration of the active ingredient(s) is known.	A Certificate of Analysis has been provided. The laboratory's website states that the company is state certified (Colorado) for potency for 5 different cannabinoids and residual solvent. Efforts are being made to determine if this certification is to an international laboratory accreditation standard.

31. Doctors Crawshaw and Jessamine believe that it is not unreasonable in the circumstances to support a trial of Aseco Calm for [redacted] for 3 to 6 months.
32. Dr Crawshaw suggests that the length of the trial can be determined by discussing with the applicant what would be a reasonable timeframe given the rapid response observed with Sativex and the time that would be needed for cross-over from Sativex to the Aseco Calm Spray.
33. If Ministerial approval is granted, [redacted] will be contacted to determine a reasonable timeframe.

Risks of Providing Ministerial Consent for this product

34. A risk may be that this approval sets a precedent for other Sativex users, who find Sativex beneficial but are struggling with the ongoing cost, to apply for a cheaper non-pharmaceutical grade product. Specialists may come under pressure to make applications to prescribe such products.
35. A specialist would still have to justify the prescribing of a non-pharmaceutical grade product that would likely have a different composition of cannabinoids than Sativex. The specialist would also have to agree to undertake the import of such a product and take responsibility for the administration of a non-consented, non-pharmaceutical grade product.

END.