

25 May 2022

s 9(2)(a)

By email: s 9(2)(a)  
Ref: H202205721

Dear s 9(2)(a)

### Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 27 April 2022 for information regarding medicinal cannabis. I will respond to each part of your request in turn.

*I respectfully request, under the Official Information Act 1982, publicly available information on medicinal cannabis pack numbers in total and broken down by product definition - via monthly tables if possible.*

*Please could you provide the data on medicines containing cannabidiol (CBD) and/or tetrahydrocannabinol (THC) supplied under Section 29 during the period January 2021-March 2022. Please provide the total number of packs for each month across all pack forms.*

The information provided in Document 1, broken down as requested in your subsequent requests and attached to this response relates to the number of packs supplied each month under the exemption provisions in section 29 of the Medicines Act 1981.

When considering these data, it is important to note:

- That the number of packs supplied cannot be used to determine the number of prescriptions or the number of patients.
- Reporting information is supplied retrospectively and therefore the number of packs reported as supplied in this response is accurate at the time of preparing the response but may change if additional reports are received.
- Sativex has consent for distribution as a medicine, and so supply of Sativex is not included in the figures supplied. Information on the supply of Sativex is not held by either the Ministry or Medsafe.

*Also, more specifically, please provide:*

*The number of packs of products defined as CBD only (<2% THC) that have been distributed to patients by month from January 2021 – March 2022.*

This information is provided in Document 1, Table 1. Please note that the information provided in this section relates to products that meet the definition of a CBD product in section 2A of the Misuse of Drugs Act 1975, where any other specified substances present must not be present in quantities greater than 2% of the amount of CBD in the product.

*The number of packs of products defined as containing CBD and THC in equal quantities (for example 10:10) that have been distributed to patients by month from January 2021 – March 2022.*

Document 1, Table 3 contains information on the number of packs of products containing both CBD and THC. Please note that this includes all products that contain a combination of both CBD and THC.

*The number of packs of products defined as THC only (<2% CBD) that have been distributed to patients by month from January 2021 – March 2022.*

Information on the number of packs of products containing only THC is provided in Document 1, Table 2 attached to this response.

*The number of packs of products defined as dried flower for tea that have been distributed to patients by month from January 2021 - March 2022.*

Information on products supplied as dried flowers for tea is included in the information supplied in Document 1. Information regarding the number of packs supplied, broken down as requested, is withheld under the following sections of the Act:

- Section 9(2)(b)(ii) of the Act as releasing this information would be likely to unreasonably prejudice the commercial position of the person who supplied or who is the subject of the information; and
- Section 9(2)(ba)(i) of the Act, to protect information which is subject to an obligation of confidence or which any person has been or could be compelled to provide under the authority of any enactment, where the making available of the information would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied.

I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

*Also, I request any information that confirms what recorded health conditions CBD and/or THC products been prescribed for since January 2021.*

This part of your request has been refused under section 18(g) of the Act as this information is not held by the Ministry of Health or Medsafe.

*Finally, I seek copies of all OIA responses by MOH to public, political, organisational, and business information requests pertaining to medicinal cannabis since 1 January 2022."*

The Ministry has identified 5 OIA responses in scope of your request. Please find these attached to this letter. Some information has been withheld under the following sections of the Act:

- Section 9(2)(a) to protect the privacy of natural persons; and
- Section 9(2)(ba)(i) to protect information that is subject to an obligation of confidence and making it available would likely prejudice the supply of similar information, or information from the same source; and
- Section 9(2)(b)(ii) where its release would likely unreasonably prejudice the commercial position of the person who supplied the information.

I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

I trust this information fulfils your request. Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: [info@ombudsman.parliament.nz](mailto:info@ombudsman.parliament.nz) or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: [www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests](http://www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests).

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Chris James', with a stylized flourish at the end.

Chris James  
**Group Manager**  
**Medsafe**

## Appendix 1: List of documents for release

#	Date	Title	Decision on release
1	2021 - 2022	Tables containing pack information	Released with some information withheld under the following sections of the Act: <ul style="list-style-type: none"> <li>• Section 9(2)(b)(ii) where its release would likely unreasonably prejudice the commercial position of the person who supplied the information; and</li> <li>• Section 9(2)(ba)(i) to protect information that is subject to an obligation of confidence and making it available would likely prejudice the supply of similar information, or information from the same source.</li> </ul>
2	14 February 2022	OIA H202200162	Released with some information withheld under section 9(2)(a) of the Act to protect the privacy of natural persons.
3	15 March 2022	OIA H202201678	Released with some information withheld under section 9(2)(a) of the Act to protect the privacy of natural persons.
4	15 March 2022	OIA H202201678 Binder	Released with some information withheld under the following sections of the Act: <ul style="list-style-type: none"> <li>• 9(2)(a); and</li> <li>• Section 9(2)(ba)(i), to protect information that is subject to an obligation of confidence and making it available would likely prejudice the supply of similar information, or information from the same source; and</li> <li>• Section 9(2)(b)(ii) where its release would likely unreasonably prejudice the commercial position of the person</li> </ul>



#	Date	Title	Decision on release
			who supplied the information.
5	17 March 2022	OIA H202201290	Released with some information withheld under section 9(2)(a) of the Act to protect the privacy of natural persons.
6	12 April 2022	OIA H202203023	
7	29 April 2022	OIA H202204931	

# Document 1

### Number of packs of products containing cannabidiol

2021

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of packs	1891	2445	2774	1972	2656	2403	2537	2036	2055	1468	2362	2446

2022

[illegible]

## Number of Packs of products containing tetrahydrocannabinol

2021

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of packs	26	181	68	158	-	280	189	268	460	297	334	350

**2022**

[illegible]

## 2021

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
No. of packs	136	213	132	550	548	668	665	768	632	569	726	1013

**2022**

[illegible]

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**From:** OIA Requests  
**Sent:** Monday, 14 February 2022 2:01 pm  
**To:** s 9 (2)(a)  
**Subject:** Your request for information, ref: H202200162

Tēnā koe s 9 (2)(a)

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 12 January 2022 for:

*“... a list of people with ministerial approval? Surely you must keep tabs on who has done this and who has not? If the list is confidential could I at least be given the number of approvals given? Is there a way I can request this using the freedom of information act?”*

I have interpreted your request to be for people at the Ministry with ministerial delegation. The Director-General of Health is the only person at the Ministry with ministerial delegation. The Director-General further delegates responsibilities within the Ministry where needed.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: [info@ombudsman.parliament.nz](mailto:info@ombudsman.parliament.nz) or by calling 0800 802 602.

Nāku noa, nā

**OIA Services**

Government Services

Office of the Director-General

Ministry of Health

E: [oiagr@health.govt.nz](mailto:oiagr@health.govt.nz)



15 March 2022

s 9(2)(a)

By email: s 9(2)(a)  
Ref: H202201678

Dear s

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 17 February 2022 for:

*"Emails and documents held by the Ministry of Health in regard to the unauthorised removal of cannabis product from the Helius Therapeutics Manufacturing site in East Tamaki in 2020."*

Information within scope of this request is itemised in Appendix 1 of this letter and copies of the documents are enclosed. The table in Appendix 1 outlines the grounds under which I have decided to withhold information. Where information is withheld, this is noted in the document itself. Where information is withheld under section 9 of the Act, I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

I trust this information fulfils your request. Under section 28(3) of the Act you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: [info@ombudsman.parliament.nz](mailto:info@ombudsman.parliament.nz) or by calling 0800 802 602.

Yours sincerely



Chris James  
**Licensing Authority**  
**Medicinal Cannabis Agency**

## Appendix One: Documents for release

Page no.	Date	Title	Decision on release
1	December 2020	Email chain: Notification from Bruce Wallace	Released with some information withheld under section 9(2)(a) of the Act to protect the privacy of natural persons.
7	31 January 2020	<i>Attached: Licence to Deal in Controlled Drugs</i>	Withheld in full under the following sections of the Act: <ul style="list-style-type: none"> <li>• 9(2)(a); and</li> <li>• 9(2)(b)(ii) where its release would likely unreasonably prejudice the commercial position of the person who supplied the information.</li> </ul>
8	14 August 2020	<i>Attached: Helius Medicinal Cannabis Licence</i>	Withheld in full under the following sections of the Act:
13	2 December 2020	<i>Attached: Helius deviation to investigate discrepancies identified in June 2020 stocktake</i>	<ul style="list-style-type: none"> <li>• 9(2)(a); and</li> <li>• 9(2)(b)(ii).</li> </ul>
22	8 December 2020	<i>Attached: Helius follow-up to MCA report (CAPA update)</i>	Released with some information withheld under section 9(2)(a).
24	December 2020	Email chain: Notification from Bruce Wallace with Investigation Report	
28	30 November 2020	<i>Attached: Independent Investigation Report</i>	Withheld in full under the following sections of the Act: <ul style="list-style-type: none"> <li>• 9(2)(a); and</li> <li>• 9(2)(ba)(i), to protect information that is subject to an obligation of confidence and making it available would likely prejudice the supply of similar information, or information from the same source.</li> </ul>
45	22 January 2021	Email: Helius CAPA update	Released with some information withheld under section 9(2)(a).
46	22 January 2021	<i>Attached: Helius CAPA update</i>	
47	4 February 2021	Helius memo signed 10 February 2021	Released with some information withheld under the following sections of the Act: <ul style="list-style-type: none"> <li>• 9(2)(a); and</li> </ul>

Page no.	Date	Title	Decision on release
			<ul style="list-style-type: none"> <li>9(2)(b)(ii).</li> </ul>
52	20 January 2021 – 10 February 2021	Email chain: Thank you	Released with some information withheld under section 9(2)(a).
56	10 February 2021	Email: Signed letter.pdf	
57	10 February 2021	<i>Attached: Letter to Helius</i>	
58	February 2021	Email chain: Response to Notification of removal of cannabis material	
63	February-March 2021	Email chain: Medicinal Cannabis Agency visit Tuesday 9 March	
67	9 March 2021	Email: Helius CAPA update	Released with some information withheld under the following sections of the Act: <ul style="list-style-type: none"> <li>9(2)(a); and</li> <li>9(2)(b)(ii).</li> </ul>
69	9 March 2021	<i>Attached: Helius CAPA update</i>	
70	16 March 2021	Email: Medicinal Cannabis Agency visit Tuesday 9 March	Released with some information withheld under section 9(2)(a).
71	Undated	Audit plan	Released with some information withheld under the following sections of the Act: <ul style="list-style-type: none"> <li>9(2)(a); and</li> <li>9(2)(b)(ii).</li> </ul>
74	April 2021	Email chain: Audit confirmation	Released with some information withheld under section 9(2)(a).
78	26 February 2021	<i>Attached: Employee handbook</i>	Withheld in full under section 9(2)(b)(ii).
108	21 January 2021	<i>Attached: Position description: Responsible Persons</i>	
109	21 January 2021	<i>Attached: Position description: Authorised Persons</i>	
110	27 April 2021	Helius Therapeutics Audit Report <i>Attachments mentioned in this document which are already included in the appendix are as follows:</i> <i>For CAPA update 8 Dec see p.39</i> <i>For CAPA update 22 Jan see p.42</i>	Released with some information withheld under the following sections of the Act: <ul style="list-style-type: none"> <li>9(2)(a); and</li> <li>9(2)(b)(ii); and</li> <li>9(2)(ba)(i).</li> </ul>

Page no.	Date	Title	Decision on release
		<i>For CAPA update 9 Mar see p.63</i> <i>For CAPA 5 see p.71</i> <i>For CAPA 8 see pp.101, 102</i> <i>For CAPA 4 see p.152</i>	
117	15 April 2021	<i>Attached: Meeting register</i>	Released with some information withheld under section 9(2)(a).
118		<i>Attached: CAPA A1</i>	Released with some information withheld under the following sections of the Act: <ul style="list-style-type: none"> <li>• 9(2)(a); and</li> <li>• 9(2)(b)(ii).</li> </ul>
120		<i>Attached: CAPA A2</i>	Released with some information withheld under the following sections of the Act: <ul style="list-style-type: none"> <li>• 9(2)(a); and</li> <li>• 9(2)(b)(ii).</li> </ul>
122		<i>Attached: CAPA A4</i>	Withheld in full under section 9(2)(b)(ii).
130	4 March 2021	<i>Attached: CAPA A6</i>	
132		<i>Attached: CAPA A7</i>	
134		<i>Attached: Helius Licence 2 March 2021</i>	
141		<i>Attached: CAPA 6</i>	Withheld in full under section 9(2)(ba)(i).
144		<i>Attached: CAPA 6 screenshot of camera movement</i>	
145		<i>Attached: CAPA 7</i>	
150		<i>Attached: CAPA 9</i>	Released with some information withheld under the following sections of the Act: <ul style="list-style-type: none"> <li>• 9(2)(b)(ii).</li> </ul>
152	April-May 2021	Email chain: CAPA 4 – Update Monthly Board Report	Released with some information withheld under the following sections of the Act: <ul style="list-style-type: none"> <li>• 9(2)(a); and</li> <li>• 9(2)(b)(ii); and</li> <li>• 9(2)(ba)(i).</li> </ul>
159		<i>Attached: Helius board meeting minutes</i>	Released with some information withheld as out of scope.
161		<i>Attached: CAPA A3 notes</i>	Released with some information withheld under the following sections of the Act:



Page no.	Date	Title	Decision on release
			<ul style="list-style-type: none"> <li>• 9(2)(a); and</li> <li>• 9(2)(b)(ii).</li> </ul>
163		<i>Attached: Camera view analytical lab</i>	Withheld in full under the section 9(2)(ba)(i).
164	26 May 2021	Email chain: Helius audit response letter	Released with some information withheld under section 9(2)(a).
166	26 May 2021	<i>Attached: Helius letter of response</i>	Released with some information withheld under the following sections of the Act: <ul style="list-style-type: none"> <li>• 9(2)(a); and</li> <li>• 9(2)(b)(ii).</li> </ul>
168	May-June 2021	Email chain: Helius audit response letter	

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT 1992



Sent by:

s 9(2)(a)

09/12/2020 11:30 am

To: Andrea.Eng@health.govt.nz

cc: s 9(2)(a)

bcc:

Subject: CONFIDENTIAL: Notification from Bruce Wallace

Morning Andrea

I wanted to reiterate on behalf of myself and the team at Helius that Bruce and I are open for any clarifications or questions either via video conference or in person if required.

We committed to working with the agency to identify root causes and put the appropriate systems and processes in place in the form of CAPAs. I am seeing this as a learning opportunity and a chance for Helius to be better going forward.

Carmen Doran  
Chief Operating Officer

**Helius Therapeutics**

18 Ron Driver Place, East Tamaki  
Auckland 2013, New Zealand

[www.helius.com](http://www.helius.com)

Mobile: s 9(2)(a)

IMPORTANT: The contents of this email and any attachments are confidential. It is strictly forbidden to share any part of this message with any third party, without a written consent of the sender. If you received this message by mistake, please reply to this message and follow with its deletion.

**From:** Andrea Eng <Andrea.Eng@health.govt.nz>  
**Sent:** Tuesday, 8 December 2020 5:40 pm  
**To:** Bruce Wallace s 9(2)(a)  
**Cc:** Carmen Doran s 9(2)(a)  
**Subject:** RE: CONFIDENTIAL: Notification from Bruce Wallace

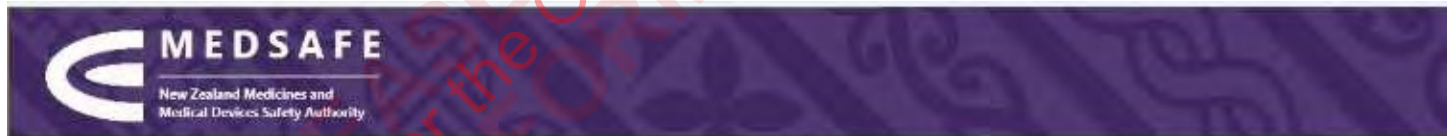
Thanks Bruce

We will review the additional information and respond to you shortly.

Kind Regards

Andrea

Andrea Eng | Manager | Regulatory Practice and Analysis | Medsafe | Ministry of Health | s  
s 9(2)(a) | s 9(2)(a)



**From:** Bruce Wallace s 9(2)(a)  
**Sent:** Tuesday, 8 December 2020 5:33 pm  
**To:** Andrea Eng <[Andrea.Eng@health.govt.nz](mailto:Andrea.Eng@health.govt.nz)>  
**Cc:** Carmen Doran s 9(2)(a)  
**Subject:** RE: CONFIDENTIAL: Notification from Bruce Wallace

Hi Andrea,

In our voluntary notification of unauthorised removal of cannabis-based materials, we committed to conducting a review of our systems and controls and to reporting back to the Medicinal Cannabis Agency on any additional corrective and preventative actions (CAPAs). The attached letter details the additional CAPAs and timelines for completion.

I am copying Helius' Interim Chief Executive Officer, Carmen Doran on this email. Carmen led the review of our security and cannabis handling systems to identify these CAPAs and is overseeing their implementation.

Please let us know if there are any questions or feedback from the agency.

Kind regards,

Bruce

**From:** Bruce Wallace

**Sent:** Friday, 4 December 2020 10:55 am

**To:** Andrea Eng <[Andrea.Eng@health.govt.nz](mailto:Andrea.Eng@health.govt.nz)>

**Subject:** RE: CONFIDENTIAL: Notification from Bruce Wallace

Dear Andrea,

Please see attached Helius Therapeutics voluntary notification of unauthorised removal of cannabis-based materials from the location of licenced activity. Supporting documents included with this notification are:

- Helius Licence to Deal in Controlled Drugs RI5040001-00 (in force at time removal occurred)
- Helius Medicinal Cannabis Licence 106423 for Cultivation and Possession for Manufacture Activities (currently valid)
- Helius deviation DV-IC200602\_Rev03 to investigate discrepancies identified in June 2020 stocktake (updated recently as described in covering non-conformance NC-18)

- Investigation Report from barrister s 9(2)(a)

As indicated in our notification letter, we have halted all handling of cannabis-based materials, except where necessary to keep plants alive, while we undertake an urgent review of our systems and controls. We will report back to the medicinal cannabis agency within one week on further proposed corrective and preventative actions.

We are committed to working closely with the agency to address this issue promptly and effectively; we welcome any questions, feedback or suggestions.

Kind regards,

Bruce Wallace

**From:** Andrea Eng <[Andrea.Eng@health.govt.nz](mailto:Andrea.Eng@health.govt.nz)>  
**Sent:** Thursday, 3 December 2020 11:45 pm  
**To:** Bruce Wallace s 9(2)(a)  
**Subject:** RE: CONFIDENTIAL: Notification from Bruce Wallace

Thanks Bruce.

Kind Regards

Andrea

**From:** Bruce Wallace s 9(2)(a)  
**Sent:** Thursday, 3 December 2020 5:18 pm  
**To:** Andrea Eng <[Andrea.Eng@health.govt.nz](mailto:Andrea.Eng@health.govt.nz)>  
**Subject:** CONFIDENTIAL: Notification from Bruce Wallace

Dear Andrea,

As discussed on our call yesterday, the Helius board of directors commissioned an independent investigation of the concerns raised about the potential removal of cannabis-based materials from the Helius location. We have received legal advice that we must redact personal information relating to certain employees from the report, in order to meet our obligations under the Privacy Act 2020. The work to redact the investigation report is ongoing, so we are unable to provide our written notification today. I will send it prior to 11:00 AM tomorrow (Friday, 04-Dec-2020).

If you have any questions or requests in the meantime, please let me know.

Kind regards,

Bruce

---

**Bruce Wallace**  
Chief Quality Officer



**Helius Therapeutics**  
18 Ron Driver Place, East Tamaki  
Auckland 2013, New Zealand  
[www.helius.com](http://www.helius.com)  
Mobile: s 9(2)(a)

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Released under the Official Information Act 1982





Director-General of Health  
c/o Medicinal Cannabis Agency  
Ministry of Health  
PO Box 5013  
Wellington 6140

Tuesday, 08 December 2020

Dear Sir,

**Re: Follow up to voluntary notification of unauthorised removal of a medicinal cannabis product**

In Helius' voluntary notification to the Director General of Health and the Medicinal Cannabis Agency, we committed to undertake an urgent review to ensure our processes are robust and to identify any additional changes needed to ensure control of cannabis-based materials. The purpose of this letter is to report back to the agency on the additional corrective and preventative actions (CAPAs) being implemented to Helius' security arrangements and systems for cannabis handling.

Previously Implemented CAPAs:

DV-IC200602 was raised on 16-Jun-2020 to investigate discrepancies in the quantities of the following cannabis-based materials:

- Post-Extraction Run Flower
- CO<sub>2</sub> Terpene Extract
- CO<sub>2</sub> Crude Oil Extract

The following (CAPAs) were implemented in response to this deviation:

ID	Action	Department	Due Date
A1	s 9(2)(b)(ii)	Production	Complete
A2		Production	Complete
A3		Production	Complete
A4		Extraction	Complete
A5		Quality	Complete
A6		Production	Complete
A7		Quality	Complete

For action A7, the relevant staff members received training on the following updated SOPs:

Number	Name
SOP-1-006	s 9(2)(b)(ii)
SOP-1-007	
SOP-2-008	
SOP-2-009	
SOP-10-001	





Additionally, all Responsible Persons and Helius Authorised Persons received specific training on their responsibilities under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019. Responsible and Helius Authorised persons then completed a training assessment to ensure their understanding of these obligations. The training assessment included a declaration that they would fulfil these responsibilities.

Additional CAPAs:

In light of the new information revealed in the Investigation Report issued to the Helius Board of Directors by s 9(2)(a) on 30-Nov-2020, all handling of cannabis-based materials was halted, except as necessary to keep plants alive. Access to secure storage locations was removed for all staff except the s 9(2)(a)

The Helius Operations and Quality teams conducted an urgent review of current controls and systems for security and handling of cannabis-base materials. Based on this review, the following additional CAPAs will be implemented:

CAPA	CAPA Description	Due Date
1	s 9(2)(b)(ii)	14-Dec-2020
2		Complete
3		05-Mar-2021
4		18-Dec-2020
5		26-Feb-2021
6		18-Dec-2020
7		18-Dec-2020
8		15-Jan-2021
9		15-Jan-2021
10		18-Dec-2020
11		18-Dec-2020
12		29-Jan-2021

\*During the review, the Helius team highlighted the critical role of company culture/values in maintaining control and compliance. This was based on lessons learned from overseas medicinal cannabis producers and security issues identified at those sites. Helius' current values were developed more than 2 years ago and reflect the pioneering start-up phase of the company. With time and staff changes, the focus of the business has changed to that of a GMP pharmaceutical manufacturer and the team agreed that the values should be updated to reflect that evolution.

Helius commits to update the agency monthly on the status of these CAPAs.

Yours Sincerely,

Bruce Wallace  
Chief Quality Officer  
Helius Therapeutics Limited

08-DEC-2020



Sent by:  
Andrea.Eng@health.govt.nz

To: s 9(2)(a)  
cc:  
bcc:

04/12/2020 11:54 am

Subject: CONFIDENTIAL: Notification from Bruce Wallace

Thanks Bruce

Acknowledging receipt of the report, and appreciate the notification. I will discuss with Chris James and respond to your letter early next week.

Kind Regards

Andrea

**From:** Bruce Wallace s 9(2)(a)  
**Sent:** Friday, 4 December 2020 11:05 am  
**To:** Andrea Eng <Andrea.Eng@health.govt.nz>  
**Subject:** RE: CONFIDENTIAL: Notification from Bruce Wallace

Hi Andrea,

As per my email below, Investigation Report from barrister s 9(2)(a) is attached.

Kind regards,

Bruce

**From:** Bruce Wallace

**Sent:** Friday, 4 December 2020 11:03 am

**To:** 'Andrea Eng' <[Andrea.Eng@health.govt.nz](mailto:Andrea.Eng@health.govt.nz)>

**Subject:** RE: CONFIDENTIAL: Notification from Bruce Wallace

Dear Andrea,

Please see attached Helius Therapeutics voluntary notification of unauthorised removal of cannabis-based materials from the location of licenced activity. Supporting documents included with this notification are:

- Helius Licence to Deal in Controlled Drugs RI5040001-00 (in force at time removal occurred)
- Helius Medicinal Cannabis Licence 106423 for Cultivation and Possession for Manufacture Activities (currently valid)
- Helius deviation DV-IC200602\_Rev03 to investigate discrepancies identified in June 2020 stocktake (updated recently as described in covering non-conformance NC-18)
- Investigation Report from barrister s 9(2)(a) (I will send this in a separate email as it is a very large file)

Is indicated in our notification letter, we have halted all handling of cannabis-based materials, except where necessary to keep plants alive, while we undertake an urgent review of our systems and controls. We will report back to the medicinal cannabis agency within one week on further proposed corrective and preventative actions.

We are committed to working closely with the agency to address this issue promptly and effectively; we welcome any questions, feedback or suggestions.

Kind regards,

Bruce Wallace

**From:** Andrea Eng <[Andrea.Eng@health.govt.nz](mailto:Andrea.Eng@health.govt.nz)>

**Sent:** Thursday, 3 December 2020 11:45 pm

**To:** Bruce Wallace s 9(2)(a)

**Subject:** RE: CONFIDENTIAL: Notification from Bruce Wallace

Thanks Bruce.

Kind Regards

Andrea

**From:** Bruce Wallace s 9(2)(a)

**Sent:** Thursday, 3 December 2020 5:18 pm

**To:** Andrea Eng <[Andrea.Eng@health.govt.nz](mailto:Andrea.Eng@health.govt.nz)>

**Subject:** CONFIDENTIAL: Notification from Bruce Wallace

Dear Andrea,

As discussed on our call yesterday, the Helius board of directors commissioned an independent investigation of the concerns raised about the potential removal of cannabis-based materials from the Helius location. We have received legal advice that we must redact personal information relating to certain employees from the report, in order to meet our obligations under the Privacy Act 2020. The work to redact the investigation report is ongoing, so we are unable to provide our written notification today. I will send it prior to 11:00 AM tomorrow (Friday, 04-Dec-2020).

If you have any questions or requests in the meantime, please let me know.

Kind regards,

Bruce

---

**Bruce Wallace**  
Chief Quality Officer



**Helius Therapeutics**

18 Ron Driver Place, East Tamaki

Auckland 2013, New Zealand

[www.helius.com](http://www.helius.com)

Mobile: +64 9(2)(a) [REDACTED]

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Sent by:  
s 9(2)(a)

22/01/2021 09:29 am

To: Andrea.Eng@health.govt.nz  
cc: s 9(2)(a)  
bcc:

Subject: Helius CAPA update from voluntary notification

Dear Andrea,

Please see the attached CAPA update in response to our voluntary notification of removal. If you have questions or need evidence for any of these CAPAs, please let me know.

Kind regards,

Bruce

Bruce Wallace  
Chief Quality Officer



**Helius Therapeutics**

18 Ron Driver Place, East Tamaki  
Auckland 2013, New Zealand

[www.helius.com](http://www.helius.com)

Mobile: s 9(2)(a)

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deletion.  - Helius CAPA update from MCA Notification\_22-Jan-21.pdf  - put-in-cabinet-data.json



Director-General of Health  
c/o Medicinal Cannabis Agency  
Ministry of Health  
PO Box 5013  
Wellington 6140

Friday, 22 January 2021

Dear Sir,

**Re: CAPA update from voluntary notification of unauthorised removal**

In Helius' follow up letter (dated 08-Dec-20) to our voluntary notification to the Director General of Health and the Medicinal Cannabis Agency, we committed to several additional corrective and preventative actions (CAPAs) to Helius' security arrangements and systems for cannabis handling. The purpose of this letter is to provide an update on the status of these CAPAs.

CAPA	CAPA Description	Due Date
1	s 9(2)(b)(ii)	Complete
2		Complete
3		05-Mar-2021
4		Complete
5		26-Feb-2021
6		Complete
7		Complete
8		Complete
9		Complete
10		Complete
11		Complete
12		29-Jan-2021

Helius will continue to update the Director General and Agency monthly on the status of these CAPAs.

Yours Sincerely,

Bruce Wallace  
Chief Quality Officer  
Helius Therapeutics Limited

# Memo

## Response to Helius Therapeutics Limited notification of unauthorised removal of cannabis-based material

<b>Date:</b>	4 February 2021
<b>To:</b>	Chris James, Group Manager Medsafe
<b>Copy to:</b>	Michael Haynes, Medicines Control, Medsafe Derek Fitzgerald, Compliance Management Branch, Medsafe Jane Hubbard, Deputy Chief Legal Advisor
<b>From:</b>	Andrea Eng, Manager Regulatory Practice and Analysis, Medsafe
<b>For your:</b>	Decision

### Purpose of memo

1. This memo seeks your agreement to respond to Helius Therapeutics Limited (Helius) regarding notification of unauthorised removal of cannabis-based material from their premises last year.
2. If you agree, please sign the attached letter as the licensing authority for the Medicinal Cannabis Agency (the Agency).

### Notification of unauthorised removal

3. On 2 December 2020 I was verbally advised by Helius's Chief Quality Officer (CQO) Bruce Wallace, of the potential removal of cannabis-based material from Helius's premises at 18 Ron Driver Place, East Tamaki, Auckland. On 3 December 2020 Mr Wallace advised that the Helius Board of Directors had commissioned an independent investigation into the matter in September 2020.
4. On 4 December 2020 I received the following documents from Helius by email:
  - a. Voluntary notification of unauthorised removal of cannabis-based material from Helius's premises. The letter also notified the Agency of s 9(2)(a) [REDACTED] from the medicinal cannabis licence issued under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (medicinal cannabis licence).
  - b. A copy of Helius's licence to deal in controlled drugs issued under the Misuse of Drugs Regulations 1977 (deal licence), which is being surrendered as it has been superseded by the issue of the medicinal cannabis licence.
  - c. A copy of Helius's current medicinal cannabis licence.



- d. A copy of the independent investigation report into claims that cannabis-based s 9(2)(b)(ii) were illegally taken off site by the company's s 9(2)(a) s 9(2)(a)
5. On 8 December 2020 I received a letter from Mr Wallace advising of additional corrective and preventative actions being implemented to Helius's security arrangements and systems for cannabis handling.
6. The documents above are available on file should you wish to review them.
7. Helius noted that at the time of manufacture of the s 9(2)(b) and when the stocktake identified the discrepancies, the company was operating under their deal licence. Under this licence there is no requirement to notify the Agency of unauthorised removal, loss, or activity in relation to medicinal cannabis product. Helius notes that therefore the notification is voluntary.

## Investigation into stocktake discrepancies

8. In May 2020 Helius manufactured two trial batches of medicinal cannabis products totalling approximately s 9(2)(b)(ii) for the purpose of research and development under their deal licence.
9. As part of the company-instigated monthly stocktake in June 2020, Helius became aware of discrepancies in the quantities of cannabis-based materials. An internal investigation was carried out and the discrepancies were "almost entirely reconciled" and attributed to minor losses during transfer of material, s 9(2)(b)(ii)  
[REDACTED]  
[REDACTED]
10. A review of security surveillance and records did not identify any unauthorised activity. However, as a result of the stocktake investigation, additional staff training and several changes were made to Helius's processes and procedures to address the issues identified above.

## Investigation into unauthorised removal of material

11. In mid-September 2020, concerns were brought to the attention of s 9(2)(a), including that s 9(2)(a) had taken s 9(2)(b)(ii) off-site. The Helius board of directors commissioned an independent investigation into the concerns.
12. The terms of reference for the independent investigation focused on the concerns brought to the attention of s 9(2)(a), specifically:
  - a. Whether s 9(2)(a) directed any employee to make a medicinal cannabis solution for s 9(2)(a); and
  - b. To investigate the circumstances relating to the potential removal of a controlled substance by s 9(2)(a) from the Helius premises.
13. Through interviews with witnesses, the investigator concluded that s 9(2)(a) did not direct any employees to make a medicinal cannabis solution for s 9(2)(a), and that the s 9(2)(b)(ii) were created for research and development purposes.

14. The investigator also concluded that s 9(2)(a) did remove a controlled substance from the premises and that the substances remained unused and were subsequently returned, accounted for and destroyed.

## Helius response to internal stocktake investigation and independent investigation

15. On 16 June 2020 Helius initiated an investigation into discrepancies in the quantities of cannabis-based material and identified and implemented seven corrective and preventative actions relating to their security arrangements and systems for cannabis handling (set out in their letter of 8 December 2020). These actions included updating their standard operating procedures in relation to recording, tracking inventory and handling procedures and implementing further training for staff on these procedures.
16. Responsible persons and Helius Authorised persons also received specific training on their obligations under the regulations and were assessed on their understanding.
17. In light of new information revealed in the independent investigation report, handling of cannabis-based material was halted except as necessary to keep plants alive, and access to secure storage locations was restricted to three key staff.
18. An urgent review of controls and systems for security and handling identified further corrective and preventative actions which are currently being implemented (set out in their letter of 8 December 2020). Helius undertook to update the Agency monthly on the status of these actions.
19. Helius submitted a formal request on 15 January 2021 for:
  - a. the removal of s 9(2)(a)
  - b. the removal of s 9(2)(a) for the activities covered by the medicinal cannabis licence.
  - c. The addition of s 9(2)(a) and s 9(2)(a) as responsible persons for the medicinal cannabis licence, subject to Ministry of Justice checks returning no result.
20. A review and update of company values and culture as a critical component of maintaining control and compliance is also currently under way.

## Agency response

21. The letter of 4 December 2020 from Bruce Wallace, CQO advising of unauthorised removal (of cannabis product), indicates that *"on 24 July 2020, Helius's internal investigation (into the stock discrepancies) was concluded ..... and it was confirmed that the small discrepancy was due to a combination of s 9(2)(b)(ii)*  
*" and that "there was no evidence of theft or unauthorised access in relation to cannabis-based materials".*
22. However, it appears that during the investigation into the stocktake discrepancies, unauthorised cannabis-based material was removed from the premises for a period of a

"few weeks", and subsequently recovered, accounted for and destroyed. The timing of this is unconfirmed.

23. It also appears that the unauthorised removal of cannabis material from the premises was not identified through the company's audit system or the investigation into stocktake discrepancies but through concerns raised by s 9(2)(a) [REDACTED]. The external investigation report into the unauthorised removal noted that *"the company's audit system worked well to detect the discrepancy"* and *"the investigation was professionally undertaken resulting in the s 9(2)(b)(ii) [REDACTED] being accounted for and subsequently destroyed"*. It is unclear as to whether the unauthorised removal would have been detected were it not for the concerns raised by s 9(2)(a) [REDACTED].
24. Helius were issued a medicinal cannabis licence to cultivate and to possess for manufacture on 14 August 2020. Under this licence, regulation 57 of the medicinal cannabis regulations requires the licence holder to report the removal or loss *"as soon as practicable, but within 3 days, to the Director General"*. If concerns were raised in mid-September 2020 regarding the unauthorised removal of cannabis material from Helius' premises, then Helius was required to notify the Agency within the three-day reporting period. However, the agency was not notified until after an independent investigation was carried out, approximately six weeks after concerns were raised.
25. We recommend that the Agency undertake a site visit to:
  - a. clarify the sequence of events relating to the unauthorised removal of cannabis material from the premises and what specific measures have been implemented to prevent a recurrence
  - b. audit and review Helius's updated standard operating procedures and changes being implemented to their security arrangements and systems for cannabis handling
  - c. follow up on whether the additional and corrective actions have been effective in addressing systemic issues relating to stock records.
26. If you agree to the above, please sign the attached letter for responding to Helius.

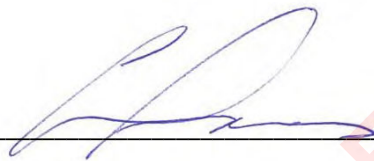
27.

## Recommendations

It is recommended that you:

1.	note	The actions being undertaken by Helius in response to the stock discrepancies and the notification of unauthorised removal of cannabis material	Yes/ <del>No</del>
2.	agree	That the Agency undertake a site visit and audit of Helius's premises to follow up on the issues outlined in paragraph 25(a)-(c) above	Yes/ <del>No</del>
3.	sign	The attached letter to send to Helius, that makes clear the Agency expectations of notification within three days of unauthorised removal, loss or activity relating to cannabis material, and advising of the site visit.	Yes/ <del>No</del>

Signature



Date: 10 February 2021

Chris James

**Licensing Authority**

**Medicinal Cannabis Agency**



Sent by:  
s 9(2)(a)

10/02/2021 12:57 pm

To: Andrea.Eng@health.govt.nz  
cc: s 9(2)(a)  
bcc:

Subject: Thank you

Hi Andrea,

I'm sure Chris has a lot on his plate but any idea when he might review/sign the response letter?

Thanks,

Bruce

**From:** Andrea Eng <Andrea.Eng@health.govt.nz>

**Sent:** Thursday, 28 January 2021 9:19 am

**To:** Bruce Wallace s 9(2)(a)

**Cc:** Carmen Doran s 9(2)(a)

**Subject:** RE: Thank you

Will send it to you both next week – currently going through peer review for Chris to sign out. I am meeting him on Monday

**From:** Bruce Wallace s 9(2)(a)

**Sent:** Thursday, 28 January 2021 9:12 am

**To:** Andrea Eng <[Andrea.Eng@health.govt.nz](mailto:Andrea.Eng@health.govt.nz)>

**Cc:** Carmen Doran s 9(2)(a)

**Subject:** RE: Thank you

Hi Andrea,

Do you think you will send the agency response letter to us this week? I'm asking because I will be out of the office next week and without internet coverage for much of the time. If you do happen to send it next week, can you please copy Carmen Doran?

Thanks,

Bruce

**From:** Andrea Eng <[Andrea.Eng@health.govt.nz](mailto:Andrea.Eng@health.govt.nz)>  
**Sent:** Wednesday, 20 January 2021 5:24 pm  
**To:** Bruce Wallace s 9(2)(a)  
**Subject:** RE: Thank you

Hi Bruce

I will aim for Friday

Kind Regards  
Andrea

**From:** Bruce Wallace s 9(2)(a)  
**Sent:** Wednesday 20 January 2021 12:18 pm  
**To:** Andrea Eng <[Andrea.Eng@health.govt.nz](mailto:Andrea.Eng@health.govt.nz)>  
**Cc:** Carmen Doran s 9(2)(a)  
**Subject:** Thank you

Hi Andrea,

Thank you for your call yesterday – that was very helpful.

During the call, you mentioned the agency will issue a letter to Helius in response to our voluntary notification. We would like any responses we give to queries from the press or others to be aligned with the information in agency's letter to us. Could you give us an idea of when we could expect to receive that?

Thanks again,

Bruce

---

**Bruce Wallace**  
Chief Quality Officer



**Helius Therapeutics**  
18 Ron Driver Place, East Tamaki  
Auckland 2013, New Zealand  
[www.helius.com](http://www.helius.com)  
Mobile: +s 9(2)(a) [REDACTED]

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OFFICIAL INFORMATION ACT 1982






Sent by:  
Andrea.Eng@health.govt.nz  
Z


To: s 9(2)(a)  
cc: Susan.Thomson@health.govt.nz  
bcc:

10/02/2021 06:00 pm

Subject: Signed Letter.pdf

Hi Bruce

Se attached letter my apologies for the time it has taken to respond to you.  - Signed Letter.pdf

 - put-in-cabinet-data.json

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OFFICIAL INFORMATION ACT 1982

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Bruce Wallace  
Chief Quality Officer  
Helius Therapeutics Limited

10 February 2021

By email s 9(2)(a)

Dear Bruce

**Re: Notification of unauthorised removal of medicinal cannabis product from the premises of Helius Therapeutics Limited**

Thank you for your letter notifying the Medicinal Cannabis Agency of the unauthorised removal of medicinal cannabis product from the premises of Helius Therapeutics Limited (Helius), and the subsequent correspondence outlining the investigations and corrective and preventative actions implemented or in progress.

We have reviewed the information provided and would like to take up the opportunity to meet to discuss and clarify the matters relating to the unauthorised removal of material. We would also like to arrange an audit of Helius's systems and processes to review the corrective and preventative actions and their effectiveness in preventing any further unauthorised removal of cannabis material.

We note that you became aware of the unauthorised removal of cannabis material from Helius's premises in September 2020 after the granting of your medicinal cannabis licence in August 2020; as such we would expect to have been notified of the unauthorised removal within three working days and prior to the commissioning of an independent investigation.

We also note the following (in relation to this matter):

- Helius will provide the Agency with monthly updates on the status of the identified corrective and preventative actions outlined in your letter of 8 December 2020; in particular whether they have been effective in identifying any further stock discrepancies
- we have received your notification of changes to s 9(2)(a) and will amend your medicinal cannabis licence accordingly (subject to Ministry of Justice checks returning no result for both)
- the surrender of Helius's licence to deal issued under the Misuse of Drugs Regulations 1977.

Please feel free to call us to arrange the meeting and audit mentioned above.

Yours sincerely



Chris James  
**Licensing Authority**  
**Medicinal Cannabis Agency**



Sent by:  
s 9(2)(a)

15/02/2021 12:40 pm

To: Andrea.Eng@health.govt.nz, s 9(2)(a)  
cc: Susan.Thomson@health.govt.nz  
bcc:

Subject: Response to Notification of removal of cannabis material

Thanks Andrea for your prompt response. We will tentatively hold this date and look forward to a confirmation next week all going well.

Looking forward to welcoming you and Susan onsite at Helius for this follow-up

Carmen Doran  
Chief Executive Officer



**Helius Therapeutics**

18 Ron Driver Place, East Tamaki  
Auckland 2013, New Zealand

[www.helius.com](http://www.helius.com)

Mobile: s 9(2)(a)

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**From:** Andrea Eng <Andrea.Eng@health.govt.nz>

**Sent:** Monday, 15 February 2021 12:31 pm

**To:** Bruce Wallace s 9(2)(a)

**Cc:** Susan Thomson <Susan.Thomson@health.govt.nz>; Carmen Doran

s 9(2)(a)

**Subject:** RE: Response to Notification of removal of cannabis material

Thanks Bruce – Tuesday 9 March probably works best for us. We will confirm next week once the Alert levels are confirmed going forward.

Kind Regards

Andrea

**From:** Bruce Wallace s 9(2)(a)

**Sent:** Monday, 15 February 2021 11:40 am

**To:** Andrea Eng <[Andrea.Eng@health.govt.nz](mailto:Andrea.Eng@health.govt.nz)>

**Cc:** Susan Thomson <[Susan.Thomson@health.govt.nz](mailto:Susan.Thomson@health.govt.nz)>; Carmen Doran <s 9(2)(a)>

**Subject:** RE: Response to Notification of removal of cannabis material

Dear Andrea,

Thank you for your email and letter.

We would like to tentatively propose March 9, 11 or 12 for an audit of Helius' security and cannabis-handling systems. Our process validation campaign was scheduled to commence this week but with Auckland going into COVID Level 3 lockdown, we are delaying that. Would it be possible to confirm the exact date once we have a clearer picture of the extent of the current lockdown?

Kind regards,

Bruce

---

**Bruce Wallace**  
Chief Quality Officer



**Helius Therapeutics**  
18 Ron Driver Place, East Tamaki  
Auckland 2013, New Zealand  
[www.helius.com](http://www.helius.com)  
Mobile: s 9(2)(a)

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**From:** Andrea Eng <[Andrea.Eng@health.govt.nz](mailto:Andrea.Eng@health.govt.nz)>  
**Sent:** Thursday, 11 February 2021 8:08 am  
**To:** Bruce Wallace s 9(2)(a)  
**Cc:** Susan Thomson <[Susan.Thomson@health.govt.nz](mailto:Susan.Thomson@health.govt.nz)>  
**Subject:** Response to Notification of removal of cannabis material

Hi Bruce

Attached is a letter in response to your notification of removal of cannabis material - my apologies for the time it has taken to respond.

Please contact me to arrange for the visit to Helius for the meeting and audit.

On 19 January 2021 we received an OIA request from a reporter at NBR regarding whether “the MoH has any record of cannabis being unlawfully/improperly removed from the Helius Therapeutics cannabis cultivation facility in East Tamakai”. We intend to respond in the affirmative with no further details other than that the matter is under investigation.



Kind Regards

Andrea

Andrea Eng | Manager | Regulatory Practice and Analysis | Medsafe | Ministry of Health | s 9(2)(a) | s 9(2)(a)



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Sent by:  
s 9(2)(a)

02/03/2021 09:16 am

To: Susan.Thomson@health.govt.nz  
cc: Andrea.Eng@health.govt.nz, s 9(2)(a)  
bcc:

Subject: Medicinal Cannabis Agency visit Tuesday 9 March

Good morning Susan,

Thank you for letting us know – we understand, and agree that minimising the health risk has to be the top priority. Having said that, it would be great to conclude the current investigation as it is still hanging over us. We understand TGA has conducted GMP audits via Zoom. I wonder if that could be a helpful alternative? We could give you a tour via iPad and all of our documents are electronic so you could view any procedures or records. Just an idea.

Kind regards,

Bruce

**From:** Susan Thomson <Susan.Thomson@health.govt.nz>

**Sent:** Tuesday, 2 March 2021 9:02 am

**To:** Bruce Wallace s 9(2)(a)

**Cc:** Andrea Eng <Andrea.Eng@health.govt.nz>

**Subject:** RE: Medicinal Cannabis Agency visit Tuesday 9 March

Good morning Bruce

Whilst our planned visit is outside the current Alert level 3 lockdown period, we have decided to cancel our travel. Andrea will contact you to make alternate arrangements to discuss the investigation and arrangements for an audit will be made once the alert level is back down to

one. Thank you

Regards

Susan Thomson

**From:** Bruce Wallace s 9(2)(a)  
**Sent:** Thursday, 25 February 2021 8:59 am  
**To:** Susan Thomson <[Susan.Thomson@health.govt.nz](mailto:Susan.Thomson@health.govt.nz)>  
**Subject:** RE: Medicinal Cannabis Agency visit Tuesday 9 March

Hi Susan,

Yes, we will certainly make sure we are all available for your audit – feel free to book your flights.

I would normally propose a loose agenda for an audit, subject to changes based on what you would like to look at, for example:

- Introductions and confirm audit scope – 10 min
- Site tour/questions – 50 min
- System/document/data review – most of day
- Closing meeting – 15 min

...but I was not sure if your email meant you would arrive between 9:00 - 11:00 AM or if the whole visit would be approximately between those times. Could you please confirm?

We look forward to hosting you and Andrea.

Kind regards,

Bruce

---

**Bruce Wallace**  
Chief Quality Officer



**Helius Therapeutics**  
18 Ron Driver Place, East Tamaki  
Auckland 2013, New Zealand  
[www.helius.com](http://www.helius.com)  
Mobile: s 9(2)(a)

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**From:** Susan Thomson <[Susan.Thomson@health.govt.nz](mailto:Susan.Thomson@health.govt.nz)>  
**Sent:** Wednesday, 24 February 2021 3:36 pm  
**To:** Bruce Wallace s 9(2)(a)  
**Subject:** Medicinal Cannabis Agency visit Tuesday 9 March

Good afternoon Bruce

Andrea and I would like to confirm our visit for Tuesday 9 March. We would like to meet with you 9.00 – 11.00 am (or thereabouts). If you are available for this time I will organise our flight.

Thank you

Susan Thomson | Senior Advisor | Ministry of Health |

**MEDICINAL  
CANNABIS  
AGENCY**

\*\*\*\*\*

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Sent by:  
s 9(2)(a)

09/03/2021 09:42 am

To: Andrea.Eng@health.govt.nz  
cc: s 9(2)(a)  
bcc:

Subject: Helius CAPA update from voluntary notification

Dear Andrea,

Please see the attached CAPA update in response to our voluntary notification of removal. If you have questions or need evidence for any of these CAPAs, please let me know.

Kind regards,

Bruce

Bruce Wallace  
Chief Quality Officer





**Helius Therapeutics**

18 Ron Driver Place, East Tamaki  
Auckland 2013, New Zealand

[www.helius.com](http://www.helius.com)

Mobile: s 9(2)(a)

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Director-General of Health  
c/o Medicinal Cannabis Agency  
Ministry of Health  
PO Box 5013  
Wellington 6140

Tuesday, 09 March 2021

Dear Sir,

**Re: CAPA update from voluntary notification of unauthorised removal**

In Helius' follow up letter (dated 08-Dec-20) to our voluntary notification to the Director General of Health and the Medicinal Cannabis Agency, we committed to several additional corrective and preventative actions (CAPAs) to Helius' security arrangements and systems for cannabis handling. The purpose of this letter is to provide an update on the status of these CAPAs.

CAPA	CAPA Description	Due Date
1	s 9(2)(b)(ii)	Complete
2		Complete
3		01-Jun-2021*
4		Complete
5		Complete
6		Complete
7		Complete
8		Complete
9		Complete
10		Complete
11		Complete
12	s 9(2)(b)(ii)	Complete

Helius will continue to update the Director General and Agency monthly on the status of these CAPAs.

Yours Sincerely,

Bruce Wallace  
Chief Quality Officer  
Helius Therapeutics Limited





Sent by:  
s 9(2)(a)

16/03/2021 05:32 pm

To: Andrea.Eng@health.govt.nz  
cc: s 9(2)(a) Susan.Thomson@health.govt.nz  
bcc:

Subject: Medicinal Cannabis Agency visit Tuesday 9 March

Hi Andrea,

Hope you are well. I wanted to reach out again now that Auckland is back to Level One to schedule the audit.

At Helius, we would love to close this matter and appreciate working together with the agency to confirm the learnings have been put in place.

Carmen Doran  
Chief Executive Officer



**Helius Therapeutics**

18 Ron Driver Place, East Tamaki  
Auckland 2013, New Zealand

[www.helius.com](http://www.helius.com)

Mobile s 9(2)(a)

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Helius Therapeutics Audit - Bruce Wallace: s 9(2)(a)

CAPA	CAPA Description	8 Dec update	Comment
	A1-7 implemented in response to deviation 16 June 2020	Implemented	
A1	s 9(2)(b)(ii)	Complete	
A2		Complete	
A3		Complete	View
A4		Complete	View
A5		Complete	View
A6		Complete	View
A7		Complete	What are these and view training records?

Confirm scope of CAPAs – cannabis-based materials – not plants??

CAPA	CAPA Description	8 Dec update due date	22 Jan update due date	9 Mar update due date	Comment
1	s 9(2)(a)	14 Dec 20	Complete	Complete	s 9(2)(a)
2	s 9(2)(b)(ii)	Complete	Complete	Complete	Review – given implemented above what is current status?

CAPA	CAPA Description	8 Dec update due date	22 Jan update due date	9 Mar update due date	Comment
	s 9(2)(b)(ii)				
3		5 Mar 21	5 Mar 21	1 Jun 21	CAPA extended to 1 Jun 21 s 9(2)(b)(ii)
4		18 Dec 20	Complete	Complete	View monthly board report – is this a standard agenda item or what?
5		26 Feb 21	26 Feb 21	Complete	Requested copy, received 7/4/21
6		18 Dec 20	Complete	Complete	What was outcome of this action? Where recorded?
7		18 Dec 20	Complete	Complete	What does this mean? Was it done/evidence?
8		15 Jan 21	Complete	Complete	Requested copy, received 7/4/21  Authorised & Responsible persons - Cannabis based materials – does this include plants?
9		15 Jan 21	Complete	Complete	What was the scope of this? Assessment of SOP and/or actual staff training Evidence?

CAPA	CAPA Description	8 Dec update due date	22 Jan update due date	9 Mar update due date	Comment
	s 9(2)(b)(ii)				
10		18 Dec 20	Complete	Complete	View approval process – SOP and any records
11		18 Dec 20	Complete	Complete	What is the outcome of this action?
12		29 Jan 21	29 Jan 21	Complete	How linked to 5? Records for staff





Sent by:

s 9(2)(a)

07/04/2021 05:46 pm

To: Susan.Thomson@health.govt.nz

cc: s 9(2)(a)

bcc:

Subject: Helius Therapeutics - Audit Confirmation?

Hi Susan,

Yes, you have received all of our CAPA updates. I have attached copies of the following documents to this email:

- POL-14 (Helius Employee Handbook). The sections on personal conduct, property and serious misconduct all address behavioural expectations. Additionally, we are going through a values review and update. The employee handbook will be updated once our new values are finalised.
- PD-4 (Position Description for Responsible Person)
- PD-5 (Position Description for Authorised Person)

Please let me know if you have any questions or requests for further documents. Otherwise, we will see you around 10:40AM next Thursday.

Kind regards,

Bruce

**From:** Susan Thomson <Susan.Thomson@health.govt.nz>

**Sent:** Wednesday, 7 April 2021 8:03 am

**To:** Bruce Wallace s 9(2)(a)

**Subject:** RE: Helius Therapeutics - Audit Confirmation?

Good morning Bruce

My flight arrives in Auckland at 9.50 am and I have hired a car so expect me around 10.40am. It is a bit hard to confirm exit time but I imagine it won't go beyond 1ish.

Based upon our files, we received three CAPA updates – 8 December 2020, 22 January 2021 and 9 March 2021 – can you confirm that we have received all to date.

Could you send me a copy of the:

- employee handbook, detailing expectations of behaviours
- job description for Responsible persons and Helius Authorised Persons to better define roles and responsibilities

At the audit I would like to review any documentation associated with CAPA 2, 4, 7, 9, 10, 11 & 12

It would be good to look at the new inventory tracking system and to know the outcome of CAPA 6.

Thank you

Susan Thomson

**From:** Bruce Wallace s 9(2)(a)

**Sent:** Tuesday, 6 April 2021 8:47 am

**To:** Susan Thomson <[Susan.Thomson@health.govt.nz](mailto:Susan.Thomson@health.govt.nz)>; Susan Thomson <[Susan.Thomson@health.govt.nz](mailto:Susan.Thomson@health.govt.nz)>

**Cc:** Carmen Doran s 9(2)(a)

**Subject:** Helius Therapeutics - Audit Confirmation?

Good morning Susan,

Would it be possible to confirm the times for your audit next Thursday, April 15? Our CEO, Carmen Doran, will attend the audit and needs to organise flights around it.

Many thanks,

Bruce

---

**Bruce Wallace**  
Chief Quality Officer



**Helius Therapeutics**  
18 Ron Driver Place, East Tamaki  
Auckland 2013, New Zealand  
[www.helius.com](http://www.helius.com)  
Mobile: s 9(2)(a)

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- POL-14 Version 1.0.pdf



- PD-4 Version 2.0.pdf



- PD-5 Version 2.0.pdf



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# MEDICINAL CANNABIS LICENCE

## Audit Report

### Helius Therapeutics Limited

## Background

Helius Therapeutics Limited (Helius) holds a medicinal cannabis licence with cultivation, possession for manufacture and supply activities.

In June 2020 Helius identified discrepancies in the quantities of cannabis-based materials. As listed in CAPA update 8 December 2020, the corrective and preventative actions CAPA A1 to A7 were implemented in response to the discrepancies.

In November 2020, following an allegation into the unauthorised removal of a medicinal cannabis product, Helius conducted an urgent review of controls and systems for security and handling of cannabis-based materials. CAPA update 8 December 2020 listed the additional CAPA (1 to 12) to be implemented and the time frame for completion:



CAPA update 8  
December 2020.pdf

Helius updated the Medicinal Cannabis Agency monthly on the completion status of the additional CAPAs as per CAPA update 22 January 2021 and CAPA update 9 March 2021:



CAPA update 22  
January 2021.pdf



CAPA update 9  
March 2021.pdf

## Purpose of the audit

To review the corrective and preventative actions and their effectiveness in preventing any further unauthorised removal of cannabis material.

The audit was undertaken at the Helius premises, 18 Ron Driver Place, East Tamaki, Auckland 2013 on 15 April 2021.

**Opening meeting 10.45am to 11.00am; participants:**

Bruce Wallace, Chief Quality Officer

s 9(2)(a)

s 9(2)(a)

s 9(2)(a)

s 9(2)(a)

Carmen Doran, Chief Executive Officer



Meeting  
Register.pdf

**Audit meeting, 11.00am to 1.15pm; participants:**

Bruce Wallace, Chief Quality Officer

s 9(2)(a)

Carme Doran, Chief Executive Officer

**Finding:**

Documented evidence was sighted confirming completion of:


- CAPAs A1 to A7 implemented in response to the deviation of 16 June 2020
- CAPAs 1 to 12 (with the exception of CAPA 3) implemented in response to the unauthorised removal of material November 2020.


I am satisfied with the scope of the review into the controls and systems for security, handling of cannabis-based materials, changes to the company's systems and processes, and staff training undertaken by the company. I am confident that these measures, combined with the ongoing work with staff on the employee handbook and company culture and values will prevent any further unauthorised removal of cannabis material.


Susan Thomson  
Senior Advisor  
Medicinal Cannabis Agency  
27 April 2021

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## Audit finding


CAPA	CAPA Description	MCA finding/comment
	A1 to A7 implemented in response to deviation 16 June 2020, all complete as per CAPA update 8 December 2020	
A1	s 9(2)(b)(ii)	Attachment 1 DV-IC200602 (2 pages)  CAPA A1.pdf
A2		Attachment 2 DV-IC200602 (2 pages)  CAPA A2.pdf
A3		Attachment 3 DV-IC200602 (8 pages)  CAPA A4.pdf
A4		
A5	s 9(2)(b)(ii)	
A6		
A7		Email from Bruce Wallace to staff, 19 June 2020 Notification on use of cannabis starting material (Preventative action for deviation DV-IC200602): Attachment 4 DIV-IC200602 (2 pages)

		 CAPA A7.pdf
--	--	--

		8 Dec Helius update	22 Jan Helius update	9 Mar Helius update	
CAPA	CAPA Description	due date	due date	due date	MCA finding/comment
1	s 9(2)(b)(ii)	14 Dec 20	Complete	Complete	<p>Amended licence issued by the Medicinal Cannabis Agency 2 March 2021</p> <p>  Helius licence 2 March 2021.pdf</p> <p>Cultivation and Possession for Manufacture activities:</p> <ul style="list-style-type: none"> <li>New responsible persons - s 9(2)(a) [REDACTED] s 9(2)(a) [REDACTED]</li> <li>Previous responsible persons - s 9(2)(a) [REDACTED] s 9(2)(a) [REDACTED]</li> </ul> <p>[Supply activity added to licence: Responsible persons - s 9(2)(a) [REDACTED] s 9(2)(a) [REDACTED]]</p>
2		Complete	Complete	Complete	s 9(2)(b)(ii) [REDACTED]

		8 Dec Helius update	22 Jan Helius update	9 Mar Helius update	
CAPA	CAPA Description	due date	due date	due date	MCA finding/comment
3	s 9(2)(b)(ii)	5 Mar 21	5 Mar 21	1 Jun 21	CAPA extended to 1 Jun 21 – Not reviewed
4		18 Dec 20	Complete	Complete	s 9(2)(b)(ii)
5		26 Feb 21	26 Feb 21	Complete	
6		18 Dec 20	Complete	Complete	



		8 Dec Helius update	22 Jan Helius update	9 Mar Helius update	
CAPA	CAPA Description	due date	due date	due date	MCA finding/comment
					 CAPA 6 Screenshot list of all camera mo s 9(2)(ba)(i)
7	s 9(2)(ba)(i)	18 Dec 20	Complete	Complete	s 9(2)(ba)(i)



		8 Dec Helius update	22 Jan Helius update	9 Mar Helius update	
CAPA	CAPA Description	due date	due date	due date	MCA finding/comment
8	s 9(2)(b)(ii)	15 Jan 21	Complete	Complete	s 9(2)(b)(ii)
9		15 Jan 21	Complete	Complete	
10		18 Dec 20	Complete	Complete	
11		18 Dec 20	Complete	Complete	
12		29 Jan 21	29 Jan 21	Complete	

End


133 Molesworth Street  
PO Box 5013  
Wellington 6140  
New Zealand  
T+64 4 496 2000

Organisation: Helius Therapeutics


Address: 18 Ron Driver Place

Topic: Medicinal Cannabis Licence Inspection

Auditor(s): Susan Thomson

Name	Position	Opening Meeting	Closing Meeting
		Time: 10:45 Date: 15-APR-21	Time: Date
		Signature	Signature
BRUCE WALLACE	CHIEF QUALITY OFFICER		

s 9(2)(a)

CARMEN DORAN	CHIEF EXECUTIVE OFFICER		

118A.1

Attachment 1 to DV-IC200602 (2 pages)

s 9(2)(a)

Date	Original Product	Original Strain	Original Inventory ID	Original Inventory Quantity	Original Inventory New Quantity	New Product	New Strain	New Inventory ID	New Inventory Quantity	Conversion Waste	User	Location
05/19/2020 04:20 PM	s 9(2)(b)(ii)											
05/19/2020 04:22 PM	s 9(2)(a)											
												Helios Therapeutics
												Helios Therapeutics

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Date	Original Product	Original Strain	Original Inventory ID	Original Inventory Quantity	Original Inventory New Quantity	New Product	New Strain	New Inventory ID	New Inventory Quantity	Consensus Name	Line	Location	Parent Metric ID	Connected Amount	Child Metric ID
06/19/2020 09:11 PM	s 9(2)(b)(ii)											9(2)(a)	testis thymuspectes		s 9(2)(b)(ii)

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Attachment 2 DV-IC200602 (2 pages)

s 9(2)(a)

Location	Product	Barcode	Old Qty	New Qty	Difference	Percent	Date	User	Reason
Helius Therapeutics (Lab Sample Store)	s 9(2)(b)(ii)						06/23/2020 01:34 PM	s 9(2)(a)	s 9(2)(b)(ii)
Helius Therapeutics (Lab Sample Store)							06/23/2020 01:35 PM		

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Location	Product	Barcode	Old Qty	New Qty	Difference	Percent	Date	User	Reason
Helius Therapeutics	s 9(2)(b)(ii)						06/18/2020 03:35 PM	s 9(2)	s 9(2)(b)(ii)
Helius Therapeutics							06/18/2020 03:36 PM	(a)	
Helius Therapeutics							06/18/2020 03:36 PM		
Helius Therapeutics							06/18/2020 03:37 PM		
Helius Therapeutics							06/18/2020 03:37 PM		
Helius Therapeutics							06/18/2020 03:37 PM		





Re: Evidence for Closure of Action 9 for CAPA-25

s 9(2)(b)(ii)



Handwritten signature of Bruce Wallace in black ink.

Bruce Wallace (Dec 14, 2020 12:21 GMT+13)

Bruce Wallace  
Chief Quality Officer

14-Dec-2020

Date

Handwritten signature of Carmen Doran in black ink.

Carmen Doran (Dec 14, 2020 12:17 GMT+13)

Carmen Doran  
Chief Operations Officer

14-Dec-2020

Date

# Evidence for closure of CAPA-25, Action 9

Final Audit Report

2020-12-13

Created:	2020-12-13
By:	Bruce Wallace (bruce.wallace@helius.co.nz)
Status:	Signed
Transaction ID:	CBJCHBCAABAA_ORMF2L9K62dd5zRRp1Myfl-D_FxS6wr

## "Evidence for closure of CAPA-25, Action 9" History

-  Document created by Bruce Wallace (bruce.wallace@helius.co.nz)  
2020-12-13 - 11:15:13 PM GMT- IP address: 121.99.170.79
-  Document emailed to Carmen Doran (carmen.doran@helius.co.nz) for signature  
2020-12-13 - 11:17:00 PM GMT
-  Email viewed by Carmen Doran (carmen.doran@helius.co.nz)  
2020-12-13 - 11:17:27 PM GMT- IP address: 125.238.201.63
-  Document e-signed by Carmen Doran (carmen.doran@helius.co.nz)  
Signature Date: 2020-12-13 - 11:17:48 PM GMT - Time Source: server- IP address: 125.238.201.63
-  Document emailed to Bruce Wallace (bruce.wallace@helius.co.nz) for signature  
2020-12-13 - 11:17:50 PM GMT
-  Email viewed by Bruce Wallace (bruce.wallace@helius.co.nz)  
2020-12-13 - 11:21:40 PM GMT- IP address: 121.99.170.79
-  Document e-signed by Bruce Wallace (bruce.wallace@helius.co.nz)  
Signature Date: 2020-12-13 - 11:21:49 PM GMT - Time Source: server- IP address: 121.99.170.79
-  Agreement completed.  
2020-12-13 - 11:21:49 PM GMT



Sent by:  
Susan.Thomson@health.govt.nz

13/05/2021 01:02 pm

To: s 9(2)(a)  
cc:  
bcc:

Subject: CAPA 4 - Update Monthly Board report

Afternoon Bruce, its good to hear of the progress with the GMP audit.

My audit report is finished; that and a letter to be sent to your CEO is with Andrea, prior to going to Chris James. But time is moving on so I will have to see where the letter is at. Subject to their review, nothing else is required at this point, thank you.

Regards

Susan Thomson

**From:** Bruce Wallace s 9(2)(a)  
**Sent:** Thursday, 13 May 2021 12:49 pm  
**To:** Susan Thomson <Susan.Thomson@health.govt.nz>  
**Subject:** RE: CAPA 4 - Update Monthly Board report

Hi Susan,

I hope all is well with you. We survived our GMP audit and while it was a very good, thorough challenge of our systems, the feedback seemed generally positive. We are just waiting for their audit report now.

Speaking of reports, I took at note that we could expect the approved report from your 15 April audit of Helius by the end of May. I wanted to check if you are on track for that or if you needed anything else from us.

Many thanks,

Bruce

**From:** Susan Thomson <[Susan.Thomson@health.govt.nz](mailto:Susan.Thomson@health.govt.nz)>  
**Sent:** Tuesday, 20 April 2021 8:26 am  
**To:** Bruce Wallace s 9(2)(a)  
**Subject:** RE: CAPA 4 - Update Monthly Board report

Thank you Bruce, that's all that I require. I will let you get organised for your GMP audit. After I left you, I remembered that your know s 9(2)(a) given your previous working relationship.

Kind Regards

Susan

**From:** Bruce Wallace s 9(2)(a)  
**Sent:** Monday, 19 April 2021 6:10 pm  
**To:** Susan Thomson <[Susan.Thomson@health.govt.nz](mailto:Susan.Thomson@health.govt.nz)>  
**Subject:** RE: CAPA 4 - Update Monthly Board report


Hi Susan,

Yes, no problem at all.

For CAPA A3, I have attached the CAPA list and the screenshot from our s 9(2)(b)(ii) showing the inventory adjustment. If you look to the right of the inventory adjustment, the reason for the adjustment is listed as the deviation number in our old system (DV-IC200602)

For CAPA 6, I have attached a screenshot below showing the list of all the camera movements or additions. I have highlighted the one for the analytical lab that we viewed during the audit. I've also attached the evidence (camera view) from that camera move.

s 9(2)(ba)(i)



If this is not what you need or if you'd like any other documents, please just ask.

Kind regards,

Bruce

**From:** Susan Thomson <[Susan.Thomson@health.govt.nz](mailto:Susan.Thomson@health.govt.nz)>

**Sent:** Monday, 19 April 2021 11:52 am

**To:** Bruce Wallace s 9(2)(a)

**Subject:** RE: CAPA 4 - Update Monthly Board report

Many thanks Bruce

Under CAPA A3 is it possible to have a screenshot sample referencing the deviation where an inventory weight in s 9(2)(b)(ii) has been adjusted to the current physical inventory weight?

Under CAPA 6 (security cameras) we viewed and discussed a document which listed the proposed actions and actual action -s 9(2)(ba)(i)

could I have a copy of the first page of this document

Thank you

**From:** Bruce Wallace s 9(2)(a)  
**Sent:** Friday, 16 April 2021 1:46 pm  
**To:** Susan Thomson <[Susan.Thomson@health.govt.nz](mailto:Susan.Thomson@health.govt.nz)>  
**Cc:** s 9(2)(a)  
**Subject:** RE: CAPA 4 - Update Monthly Board report

Hi Susan,

Thanks for making the trip up to conduct our audit. Here is a copy of the Quality Board Report for March that we looked at on screen. If you need any other information or documents for your report, do not hesitate to ask.

Kind regards,

Bruce



---

**Bruce Wallace**  
Chief Quality Officer



**Helius Therapeutics**  
18 Ron Driver Place, East Tamaki  
Auckland 2013, New Zealand  
[www.helius.com](http://www.helius.com)  
Mobile: s 9(2)(a)

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**From:** Susan Thomson <[Susan.Thomson@health.govt.nz](mailto:Susan.Thomson@health.govt.nz)>  
**Sent:** Friday, 16 April 2021 9:24 am  
**To:** s 9(2)(a)  
**Cc:** Bruce Wallace s 9(2)(a)  
**Subject:** CAPA 4 - Update Monthly Board report

Good morning s 9(2)(a)

Thank you very much for your time yesterday.

Looking over the documents, I don't seem to have a copy of the board meeting page re CAPA 4; I think there was difficulty printing the month we looked at which also discussed the MoH audit to take place.

Kind Regards

**Susan Thomson** | Senior Advisor | Ministry of Health |

**MEDICINAL  
CANNABIS  
AGENCY**

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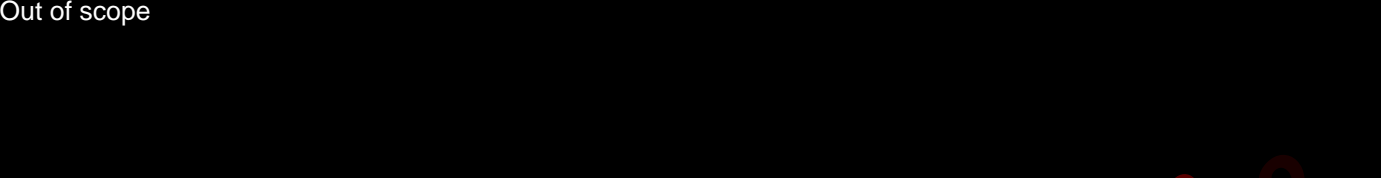
BOARD MEETING 18 March 2021

---

## Quality Overview

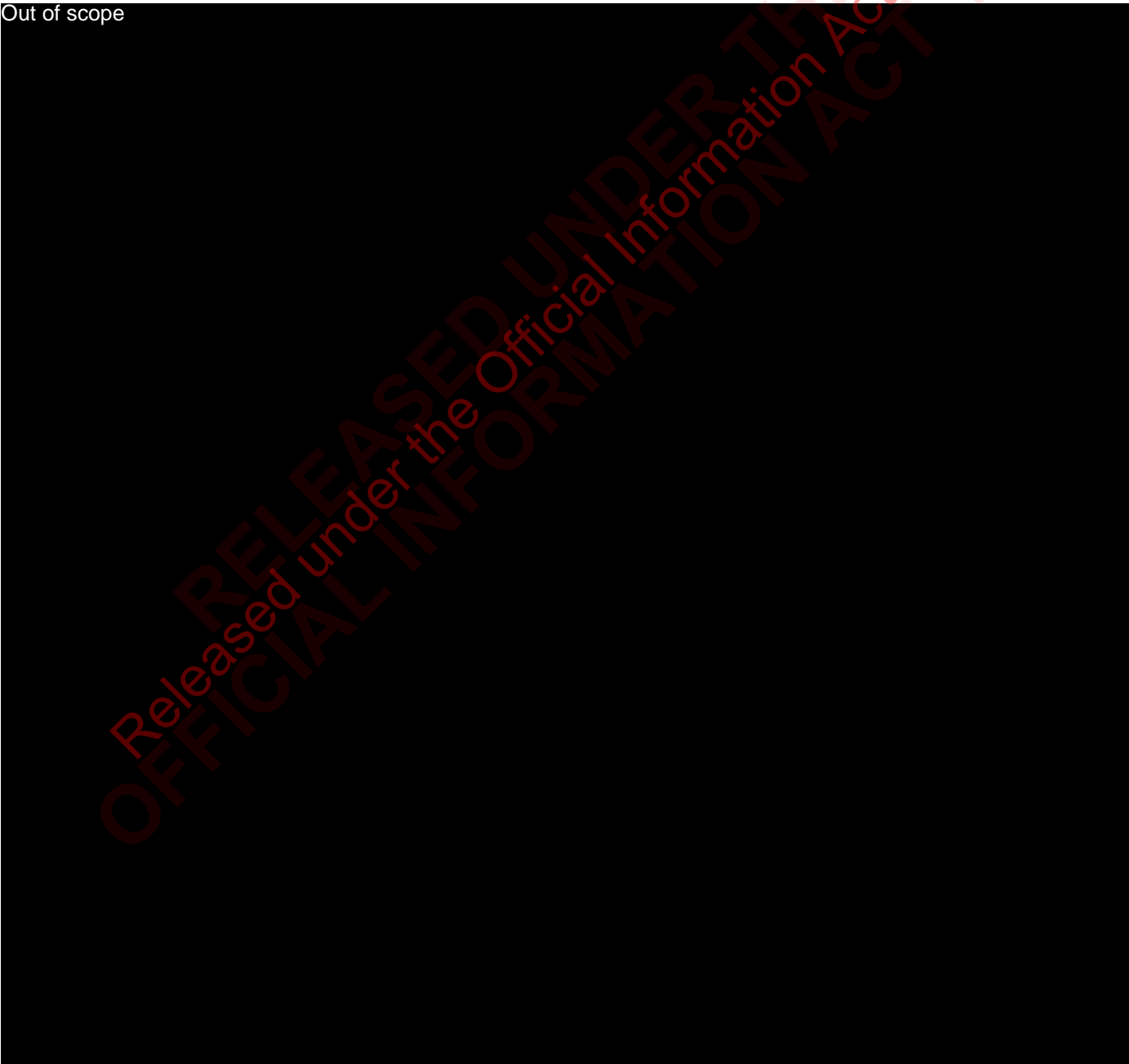
### Cannabis Handling Issues

Out of scope

A large black rectangular redaction box covering the content of the 'Cannabis Handling Issues' section.

The Medicinal Cannabis Agency (MCA) provided a letter in the first week of February, formally responding to our voluntary notification of removal of cannabis. The agency scheduled, then cancelled a meeting and audit for 09-Mar-2021. CQO discussed with the Manager of the MCA on 08-Mar-2021 and agreed they would hold a Zoom meeting with CQO and CEO in the coming weeks. The audit would be rescheduled in the next month.

Out of scope

A large black rectangular redaction box covering the majority of the lower half of the page. A diagonal watermark is visible across this area.



Out of scope

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SOP-4-012\_FORM1 REV 01

## Action / Effectiveness Check Completion

Originating Document Reference	DV-IC200602	Revision	01
Completion of	<input checked="" type="checkbox"/> Actions <input type="checkbox"/> Effectiveness Checks		

Action ID	Evidence Attached
DV-IC200602-A1	s 9(2)(b)(ii)
DV-IC200602-A2	
DV-IC200602-A3	
DV-IC200602-A4	
DV-IC200602-A5	
DV-IC200602-A6	
DV-IC200602-A7	

Comments: All actions completed.

Do the Effectiveness Checks indicate that the Action has been Successful?

☒ N/A☐ Yes☐ No, Next Steps:

All Actions / Effectiveness Checks associated with the Originating Document have been completed

Department

Approver

Signature / Date

Quality

s 9(2)(a)



s 9(2)(a)

Location	Product	Barcode	Old Qty	New Qty	Difference	Percent	Date	User	Reason
Helius Therapeutics (Lab Sample Store)	s 9(2)(b)(ii)						06/23/2020 01:34 PM	s 9(2)(a)	s 9(2)(b)(ii)
Helius Therapeutics (Lab Sample Store)							06/23/2020 01:35 PM		

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Sent by:  
s 9(2)(a)

26/05/2021 07:09 pm

To: Susan.Thomson@health.govt.nz  
cc: s 9(2)(a) Andrea.Eng@health.govt.nz  
bcc:

Subject: Helius Audit response letter

Thank you Susan and Andrea

Appreciate your feedback and support in this matter. Looking forward to seeing you next week.

Carmen Doran  
Chief Executive Officer



**Helius Therapeutics**

18 Ron Driver Place, East Tamaki  
Auckland 2013, New Zealand

[www.helius.com](http://www.helius.com)

Mobile: s 9(2)(a)

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**From:** Susan Thomson <Susan.Thomson@health.govt.nz>

**Sent:** Wednesday, 26 May 2021 2:32 pm

**To:** Carmen Doran s 9(2)(a)

**Cc:** Bruce Wallace s 9(2)(a) Andrea Eng <Andrea.Eng@health.govt.nz>

**Subject:** Helius Audit response letter

Good afternoon Carmen

Please find attached the Medicinal Cannabis Agency letter of response.

If you have any questions please contact Andrea, thank you.

Kind Regards

**Susan Thomson** | Senior Advisor | Ministry of Health |

**MEDICINAL  
CANNABIS  
AGENCY**

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26 May 2021

Carmen Doran  
Chief Executive Officer  
Helius Therapeutics Limited

By email: s 9(2)(a)

Dear Carmen Doran

Further to my letter of 10 February 2021, I understand that a meeting and audit relating to the unauthorised removal of medicinal cannabis product from the premises of Helius Therapeutics Limited has been completed.

I note that Helius Therapeutics Limited has provided two monthly updates, dated 22 January 2021 and 9 March 2021 on the status of the identified corrective and preventative actions (CAPAs). With the exception of CAPA 3, the transition from s 9(2)(b)(ii) for inventory tracking and status management, all CAPAs were completed as at the 9 March 2021 update.

On 25 March 2021, Andrea Eng, Manager, Medicinal Cannabis Agency (the Agency) and Susan Thomson, Senior Advisor met (through Zoom) with you and Bruce Wallace, Chief Quality Officer to discuss and clarify matters relating to the unauthorised removal of material from the premises. More detailed information on the detection and management of identified stock discrepancies and the unauthorised removal of cannabis material was provided. Confirmation on the nature and amount of the unauthorised removal was also provided after the meeting.

An on-site audit was undertaken by Susan Thomson at Helius Therapeutics Limited, 18 Ron Driver Place, East Tamaki on 15 April 2021. Attendees at the meeting were yourself, Bruce Wallace and s 9(2)(a). The purpose of the audit was to review the CAPAs and their effectiveness in preventing any further unauthorised removal of cannabis material.

Documented evidence was sighted by Susan confirming completion of:

- CAPAs A1 to A7 implemented in response to the deviation of 16 June 2020
- CAPAs 1 to 12 (with the exception of CAPA 3) implemented in response to the unauthorised removal of material November 2020.

The Agency is satisfied with the scope of the review into the controls and systems for security and handling of cannabis-based materials, changes to the company's systems and processes, and staff training undertaken. The Agency is confident that these measures, combined with the ongoing work with Helius's staff on the employee handbook and company culture and values will detect and mitigate the risk of unauthorised removal of cannabis material.

As the completion date for CAPA 3 is expected to be finalised 1 June 2021, no further monthly updates are required by the Agency, however please advise when CAPA 3 has been completed. The new inventory tracking system will be viewed at your next routine licence audit.

As such, I consider this matter now closed and would like to thank yourself and your staff for their time and cooperation in assisting Agency staff with this matter.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Chris James', is positioned above the printed name.

Chris James  
**Licensing Authority**  
**Medicinal Cannabis Agency**

RELEASED UNDER THE  
OFFICIAL INFORMATION ACT 1982

Released under the Official Information Act 1982





Sent by:  
Susan.Thomson@health.govt.nz

02/06/2021 08:06 am

To: s 9(2)(a)  
cc:  
bcc:

Subject: Helius Audit response letter

Thank you Bruce, your email is sufficient notification on completion of CAPA 3 and I appreciate your feedback

Regards

Susan

**From:** Bruce Wallace s 9(2)(a)

**Sent:** Tuesday, 1 June 2021 12:11 pm

**To:** Susan Thomson <Susan.Thomson@health.govt.nz>; Andrea Eng <Andrea.Eng@health.govt.nz>

**Cc:** Carmen Doran s 9(2)(a)

**Subject:** RE: Helius Audit response letter

Dear Susan and Andrea,

Thank you for the Medicinal Cannabis Agency letter of response. We are writing to notify you that the final CAPA associated with this investigation (CAPA-3) has been completed: all Helius inventory has been transferred from s 9(2)(b)(ii) and this system is now being used for inventory management. Please let us know if you need evidence of this action closure.

Finally, we would like to thank you for your constructive approach as we worked through this challenging matter.



Kind regards,

Bruce

---

**Bruce Wallace**  
Chief Quality Officer



**Helius Therapeutics**  
18 Ron Driver Place, East Tamaki  
Auckland 2013, New Zealand  
[www.helius.com](http://www.helius.com)  
Mobile: s 9(2)(a)

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**From:** Susan Thomson <[Susan.Thomson@health.govt.nz](mailto:Susan.Thomson@health.govt.nz)>  
**Sent:** Wednesday, 26 May 2021 2:32 pm  
**To:** Carmen Doran s 9(2)(a)  
**Cc:** Bruce Wallace s 9(2)(a); Andrea Eng <[Andrea.Eng@health.govt.nz](mailto:Andrea.Eng@health.govt.nz)>  
**Subject:** Helius Audit response letter

Good afternoon Carmen

Please find attached the Medicinal Cannabis Agency letter of response.

If you have any questions please contact Andrea, thank you.

Kind Regards

**Susan Thomson** | Senior Advisor | Ministry of Health |

**MEDICINAL  
CANNABIS  
AGENCY**

\*\*\*\*\*

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- put-in-cabinet-data.json

17 March 2022

By email: [REDACTED]  
Ref: H202201290

Tēnā koe [REDACTED]

### Response to your request for official information

Thank you for your requests under the Official Information Act 1982 (the Act). Your first request was received by the Ministry of Health (the Ministry) on 11 February 2022:

*May I please request all communications to/from the INCB to all departments, regulators, politicians in the lead up to, and post, the cannabis referendum.  
Separately, I would like to request all incb communications in regards to hemp; and cbd*

A second request for official information was received on 13 February 2022 for:

- 1. all minutes, documents aide memoirs and emails relating to, and involving, the INCB AND the issues of a) cannabis, hemp; b) the cannabis referendum, c) CBD, d) THC, e) medical cannabis since 2004*
- 2. All cabinet, ministerial, and dpmc documents and communications relating to same.*

A third request for official information was received on 15 February 2022 for:

- All government/parliamentary and departmental / ministerial records relating to the creation of MoDA that specifically relate to the reasons and rationales for:*
- 1. Prohibiting cannabis sativa (the horticultural plant) in its entirety as a controlled drug*
  - 2. Rather than simply controlling THC*
  - 3. Doing so in defiance of cannabis sativad explicit release from international control requirements in UNSCN 1961 "when grown for horticultural purposes"  
Eg. Opium poppies are not illegal under MoDA, but extracting opium is.  
So, in summary, please provide me with all documents and communications that may help to explain*
  - 4. Why was a blanket approach to controlling and prohibiting cannabis taken - when cannabis sativa is expressly excluded from control under UNSCN 1961, when "grown for horticultural purposes*

As you were advised on 22 February 2022, your requests have been consolidated under section 18(A)(2) of the Act as H202201290.

You were also advised that the Ministry decided to partially transfer the parts of your request for *Cabinet and ministerial [documents]* to the office of Hon Andrew Little, Minister of Health and to the Department of the Prime Minister and Cabinet (DPMC) for *dpmc documents and*

*communications relating to same*, pursuant to section 14(b)(ii) of the Act. You can expect a response to these parts of your request from and the Office of the Minister of Health, Hon Andrew Little and DPMC in due course.

On 22 February 2022, you refined the remainder of your request to:

*May I please*

- 2. request all records relating to Cannabis Sativa between the INCB and all departments, regulators, politicians from 2016 until today*
- 3. and all incb related communications in regards to hemp; and cbd, from 2004 until today.*

Industrial hemp is not required to be reported to the International Narcotics Control Board (INCB) and scoping has not identified any INCB related communications in regard to hemp. As such, this part of your request is refused under section 18(e) of Act as the information requested does not exist or despite reasonable efforts to locate it, cannot be found.

Unfortunately, the remainder of the information you have requested sits across many databases throughout the Ministry and identifying all documents within scope of your refined request would be a time-consuming process that would unreasonably interfere with the operations of the Ministry. Furthermore, the Ministry deems that individually reviewing each document likely to be within scope of your request would be a complex and lengthy process. Therefore, the remainder of your request is refused under section 18(f) of the Act as the information requested cannot be made available without substantial collation or research. I have considered whether charging or extending the time to compile the information would enable us to respond, however, I do not believe it is in the public interest to do so. The Ministry remains willing to engage with you on a revised scope for your request.

Under section 28(3) of the Act you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: [info@ombudsman.parliament.nz](mailto:info@ombudsman.parliament.nz) or by calling 0800 802 602.

Nāku noa, nā



Jan Torres  
**Acting Manager OIA Services**  
**Office of the Director-General**

12 April 2022

s 9(2)(a)

By email: s 9(2)(a)  
Ref: H202203023

Dear s 9(2)(a)

### Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 22 February 2022 for information regarding the Misuse of Drugs Act 1975 and the COVID-19 Response Act.

Please find a response to each part of your request below:

*I ask for the drafts of the both bills and all information associated with the creation of the bill  
expert advice at the time/s*

The drafts of bills are legally privileged documents and are therefore withheld in full under section 9(2)(h) of the Act, to maintain legal professional privilege.

*The source of the advice medical literature the assessments of conflicts of interest*

The Ministry did not identify any information in scope of this part of your request and is therefore refusing it under section 18(g)(i) of the Act as the information requested is not held by the Ministry.

*I also request the crowns economic reports about cannabis prohibition.*

As a result of the 2020 cannabis referendum, considerable information in scope of this part of your request was generated and is available online. There is also information on other government websites including the Police, Ministry of Social Development and Ministry of Justice as well as information generated by non-governmental research organisations. Therefore, the Ministry is refusing this part of your request under section 18(d) of the Act, as the information you have requested is publicly available. Please refer to the below links:

- [www.justice.govt.nz/assets/Documents/Publications/Market-structure-for-recreational-cannabis-PROACTIVE-FINAL.pdf](http://www.justice.govt.nz/assets/Documents/Publications/Market-structure-for-recreational-cannabis-PROACTIVE-FINAL.pdf)
- <https://ndhadeliver.natlib.govt.nz/webarchive/20201124190040/https://www.referendums.govt.nz/>
- [www.justice.govt.nz/assets/Documents/Publications/Cannabis-Referendum-2019-RIA-PR-MoJ.pdf](http://www.justice.govt.nz/assets/Documents/Publications/Cannabis-Referendum-2019-RIA-PR-MoJ.pdf)
- [www.justice.govt.nz/assets/Documents/Publications/Proactive-release-Cabinet-paper-2020-Cannabis-Referendum-7-May-2019.pdf](http://www.justice.govt.nz/assets/Documents/Publications/Proactive-release-Cabinet-paper-2020-Cannabis-Referendum-7-May-2019.pdf)
- [www.justice.govt.nz/assets/Documents/Publications/Cannabis-Legalisation-and-Control-Bill-Exposure-Draft-for-Referendum2.pdf](http://www.justice.govt.nz/assets/Documents/Publications/Cannabis-Legalisation-and-Control-Bill-Exposure-Draft-for-Referendum2.pdf)



- [www.justice.govt.nz/assets/Documents/Publications/2020-Cannabis-Referendum-Public-Release-27-April.pdf](http://www.justice.govt.nz/assets/Documents/Publications/2020-Cannabis-Referendum-Public-Release-27-April.pdf)
- [www.police.govt.nz/about-us/publication/proactive-release-ministerial-briefing-national-cannabis-recovery-operation](http://www.police.govt.nz/about-us/publication/proactive-release-ministerial-briefing-national-cannabis-recovery-operation)
- [www.police.govt.nz/sites/default/files/publications/police-illicit-drug-strategy-2009.pdf](http://www.police.govt.nz/sites/default/files/publications/police-illicit-drug-strategy-2009.pdf)
- [www.msd.govt.nz/about-msd-and-our-work/publications-resources/journals-and-magazines/social-policy-journal/spj18/cannabis-black-market18-pages31-43.html](http://www.msd.govt.nz/about-msd-and-our-work/publications-resources/journals-and-magazines/social-policy-journal/spj18/cannabis-black-market18-pages31-43.html)
- [www.drugfoundation.org.nz/assets/uploads/Cost-benefit-analysis-drug-law-reform.pdf](http://www.drugfoundation.org.nz/assets/uploads/Cost-benefit-analysis-drug-law-reform.pdf)
- [www.nzier.org.nz/publications/nzs-cannabis-referendum-2020-some-facts-and-recommendations-about-the-process-of-cannabis-legalisation-nzier-public-discussion-paper-20201](http://www.nzier.org.nz/publications/nzs-cannabis-referendum-2020-some-facts-and-recommendations-about-the-process-of-cannabis-legalisation-nzier-public-discussion-paper-20201)

*I also request any obligations NZ has to anything in regards to any controlled substances*

New Zealand has ratified three major United Nations drug control Conventions, which all place certain obligations on signatory countries. When the UN classifies a substance under one of the three Conventions, it requires signatory countries to include the substance in question under their domestic drug control regimes; however, each country still retains the discretion as to how it classifies the substance under its domestic legislation. The international drug control Conventions provide the legal basis for the international control of drugs of abuse are:

- the Single Convention on Narcotic Drugs, 1961 (as amended by the 1972 Protocol) ('the 1961 Convention')
- the Convention on Psychotropic Substances, 1971 ('the 1971 Convention')
- the Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 ('the 1988 Convention').

Generally, the underlying objective of the Conventions is to restrict the use (including the movement, trade, accumulation, or consumption) of controlled drugs and precursor substances to purely medical and scientific purposes. Each signatory State to a particular Convention is bound to implement appropriate legislation, introduce the necessary administrative and enforcement measures, and to cooperate not only with other States but also with the UN drug control organisations, including the Commission on Narcotic Drugs (CND) and the International Narcotics Control Board (INCB). In summary, the Conventions can be described as follows:

- The 1961 Convention limits the possession, use, trade, distribution, import, export, manufacture and production of drugs exclusively to medical and scientific purposes, with the aim of addressing drug trafficking through international cooperation to deter and discourage drug traffickers. It identifies the narcotic substances that are subject to international controls and the extent of those controls. As party to the 1961 Convention, New Zealand must ensure that it implements these controls domestically.
- The 1971 Convention contains provisions relating to the international trade in psychotropic substances. It is a response to the diversification and expansion regarding the spectrum of drugs and drug abuse and imposes controls over a number of synthetic drugs according to their abuse potential in comparison to their therapeutic value. Control measures agreed to by parties to the convention include import and export controls and record keeping, licensing systems, and the provision of annual statistics to the INCB. The convention identifies the psychotropic substances that are subject to controls and the extent of those controls. Amphetamines, barbiturates and tranquilizers are controlled under the 1971 Convention. New Zealand must comply with controls on the export, import, manufacture, sale, and use of such substances. New Zealand has been a party to the 1971 Convention since 1990.



- The 1988 Convention is primarily a law enforcement convention, concerned with the adoption of a wide range of measures to strengthen domestic laws and international co-operation to reduce the trafficking of illicit drugs. In Table I and Table II of its annex, the 1988 Convention lists substances used as precursors in the manufacture of controlled substances. This allows the Convention to require monitoring, criminal penalties and cooperation between signatories to prevent the diversion of precursor substances for the manufacture and trade of narcotic drugs or psychotropic substances on both a national and international scale.

*I would like a report on the effects of reducing / increasing diversity of new Zealand from prohibition*

While the Act allows New Zealanders to ask for information from Ministers and government agencies, there is no requirement for agencies to create new information, compile information they do not hold or provide or prove an opinion. The Act does not support requests where an opinion, comment, argument, or hypothetical statement is put to the Ministry for response, or the agency is asked to create information, couched as a request for information. This part of your request is therefore refused under section 18(g) of the Act on the grounds that the information sought is not held by the Ministry.

*I also request the source of scientific information that the government used to claim cannabis is harmful psychoactive thing and the jurisdiction in which the info was sourced if it wasn't asserted from our own Country \$\$\$*

The New Zealand classification of cannabis as a controlled drug follows scheduling under the UN Single Convention 1961.

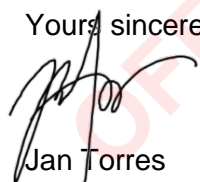
*Im also curious if the crown know that these monkeys were suffocating because of the flawed nature of the "experiment" brain cells dieing from lack of oxygen.*

The Ministry is not a research organisation and is unable to comment on research undertaken more than 40 years ago. This part of your request is therefore refused under section 18(g) of the Act on the grounds that the information sought is not held by the Ministry.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: [info@ombudsman.parliament.nz](mailto:info@ombudsman.parliament.nz) or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: [www.health.govt.nz/about-ministry/information-releases](http://www.health.govt.nz/about-ministry/information-releases).

Yours sincerely



Jan Torres  
**Acting Manager, OIA Services**  
**Office of the Director-General**

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**From:** OIA Requests  
**Sent:** Friday, 29 April 2022 4:42 pm  
**To:** s 9 (2)(a)  
**Subject:** Your request for information, ref: H202204931

Kia ora s 9 (2)(a)

Thank you for your request under the Official information Act 1982 (the Act) to the Ministry of Health (the Ministry), received on 2 April 2022 for:

*"Please could you provide under the OIA copies of all internal and external advice and any analysis provided to the Minister of Health, Cabinet and/or any decision maker at Ministry of Health about the NZ Bill of Rights, Human Rights and/ or Ti Tiriti implications of the medicinal cannabis regime including access and compliance costs.*

*Please also provide all consultation with any other Minister, the Human Rights Commissioner, Health and Disabilities Commissioners, Police, any NGO, and any NZ or International medicinal cannabis expert about any of these issues.*

*Please also advise what NZ sourced medicinal cannabis products are currently approved for sale in New Zealand, any specifications for these products, including CBD, THC and/or other cannabinoids and any information held about the price of these products."*

On 21 April 2022, you were contacted by the Ministry and advised that this part of your request, as it is currently worded, necessitates a search through a large volume of and were given the opportunity to refine your request. On the same date, you refined your request to:

*"The relevant period of time is information used to inform Cabinet advice that led to the Dec 2018 amendment of the Misuse of Drugs Act and/ or the Misuse of Drugs (Medicinal Cannabis) Regulations 2019."*

Unfortunately, providing a response to your refined request would still necessitate a search through a large volume of information that sits across many databases and inboxes within the Ministry. This would require an individual member of staff to go through hundreds of emails to identify any information within scope. Therefore, this part of your request is refused under section 18(f) of the Act as the information requested cannot be made available without substantial collation or research. I have considered whether charging or extending the time to compile the information that would enable the Ministry to respond, however, as each piece of correspondence would have to be individually reviewed.

Under section 28(3) of the Act you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: [info@ombudsman.parliament.nz](mailto:info@ombudsman.parliament.nz) or by calling 0800 802 602.

Ngā mihi

**OIA Services Team**



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