MINISTRY OF HEALTH
MANATŪ HAUORA

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19 JUL 2016

[redacted]

Ref: H201602267

Dear [redacted]

Response to your request for official information

Thank you for your request of 1 June 2016 under the Official Information Act 1982 (the Act) for 'copies of all information including any internal or external advice, reports, assessment of benefits and risks and decision papers, including who recommended and who approved these medicines and any other related information that led to the scheduling of 313 Cannabidiol and 1830 Tetrahydrocannabinol as prescription medicines under schedule 1 of the Medicines Regulations 1984.'

Some of the information requested was previously explained in the response to the request for official information (refer H201602355) sent to you on 29 June 2016.

Your request of 1 June 2016 to Minister Dunne has been transferred to the Ministry of Health (the Ministry) under section 14(b)(ii) of the Act as notified to you in an email from the Minister's Office on 23 June 2016. Your request to the Minister stated 'Please could you provide copies of all information you personally have including any internal or external advice, reports, assessment of benefits and risks and decision papers, including who recommended and who approved these substances as medicines and any other related information that led to the scheduling of 313 Cannabidiol (CBD) and 1830 Tetrahydrocannabinol (THC) as prescription medicines under schedule 1 of the Medicines Regulations 1984.

Please include information about what if any specific THC and/or CBD products were considered as part of this approval

Please could you also advise what if any additional information you personally require before you will approve the use of these products as prescription medicines under Reg 22 of the Misuse of Drugs Regs bearing in mind that they are already scheduled for use as medicines, and why these products are treated differently from other scheduled medicines.

Pleas could you answer this question base don the information you personally have access to, as I have already OIA's your Ministry - and my particular interest is in understanding your personal views and decision making, and not your Ministry's views'

The first part of your request has been answered in the current response. The second part of your request has been answered by previous OIA responses.

Assessment of Sativex
Medsafe received a medicine application for Sativex (containing cannabidiol and tetrahydrocannabinol) in January 2008. After the initial assessment, the application was referred to the Medicines Assessment Advisory Committee (MAAC) as the applicant had not satisfactorily addressed issues and concerns raised during the assessment. The MAAC is an independent technical advisory committee that considers applications for the Minister's consent or provisional consent to the distribution of a new medicine referred to it under section 22(2) of the Medicines Act 1981.

The MAAC reviewed an application for Sativex at its 85th, 86th, 89th and 90th meetings. Excerpts of the relevant meeting minutes have been provided.

At the 90th meeting, the MAAC recommended that the Minister's delegate grant consent to GW Pharma for the distribution of Sativex. The Minister's delegate accepted the recommendation and granted consent by publication in the New Zealand Gazette https://gazette.govt.nz/notice/id/2010-go8368. As noted in the meeting minutes, a number of papers were presented for the MAAC's consideration. Some of those papers are covered by your request.

I am releasing the papers identified in table 1.

Table 1

Item description
a. Excerpt of MAAC 85th meeting minutes – 18 March 2008
b. Excerpt of MAAC 86th meeting minutes – 29 & 30 July 2008
c. Excerpt of MAAC 89th meeting minutes – 17 March 2010
d. Excerpt of MAAC 90th meeting minutes – 30 June 2010
e. Referral memo to the Deputy Director-General – 1 December 2009
f. Referral letter to the company – 7 December 2009
g. Medsafe internal memo from the evaluator – 27 October 2009
h. Quality Review – 19 November 2009
i. MAAC Report – 29 July 2008 [redacted]
j. MAAC Report on Preclinical and Clinical Data [redacted]
k. MAAC Report on Preclinical and Clinical Data [redacted]
l. MAAC Report on Preclinical and Clinical Data [redacted]
m. MAAC Report on Preclinical and Clinical Data [redacted]
n. MAAC Report on Preclinical and Clinical Data [redacted]
o. MAAC Report on Preclinical and Clinical Data [redacted]
p. Medsafe internal memo summarising the European Union decentralised procedure – 31 May 2010

I am releasing the key points in the Medical Advisor's report that relate to the safety and efficacy of Sativex in the document entitled Quality Review 19 November 2009 (item *h*).

I am withholding the documents specified in table 2 because these documents are not covered by your request. These documents relate to administration of a deferment of the application pending a regulatory decision by the United Kingdom medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA).

Table 2

Item description
q. Medical Advisor's Report – October 2009.
r. Request for withdrawal from MAAC agenda – 5 March 2010.
s. Application deferred to the next meeting – 8 March 2010.
t. Minutes of the teleconference held on 15 April 2010.
u. Email following the teleconference – 11 May 2010.
v. United Kingdom email correspondence – 5 May 2010.

Medicines and Healthcare products Regulatory Agency
I am withholding the MHRA reports that were provided to the MAAC under Section 6(b)(i) of the Act. The Decentralised Procedure Reference Member State assessment reports are provided confidentially to the applicant and concerned member states of the European Union. The MHRA does not release these reports to the public. It is inappropriate for the New Zealand Government to release information that is considered confidential by a UK Government Agency (the MHRA). Releasing the information may result in the MHRA and other medicine regulators refusing to entrust Medsafe with information about the safety and efficacy of medicines.

A copy of the information that the MHRA considers appropriate for public release is available at
http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con084961.pdf.

Medsafe Evaluation Report
I have decided that a copy of the Medsafe evaluation report dated 27 May 2008 will not be released.

Evaluation reports contain information about how the product is manufactured, by whom, the specifications the product is expected to meet, the packaging, the composition and an assessment of the safety, efficacy and quality data provided by the applicant.

I am refusing to release information about the manufacturers, the quantity of the active ingredient, the qualitative formulation, the packaging, the storage conditions, the indications and the New Zealand sponsor under section 18(d) of the Act because this information is publicly available at
http://www.medsafe.govt.nz/regulatory/DbSearch.asp.

I am withholding information that would disclose a trade secret such as the quantities of the excipients, product specifications, in house test method development, and method of manufacture under section 9(2)(b)(i) of the Act.

I am withholding the remainder of the report under section 9(2)(ba) to protect commercially sensitive information which is subject to an obligation of confidence which GW Pharma is compelled to supply to gain consent under the Medicines Act. Making this information available would mean that Medsafe would have difficulty obtaining

similar information from other pharmaceutical companies and it is in the public interest that the medicine regulator is fully informed about medicines supplied in New Zealand.

The conclusion of the evaluation report has been released as part of the document entitled Quality Review 19 November 2009 (item *h*).

Other Documents
I have withheld the articles from Scrip News provided to the MAAC under section 18(d) of the Act because they are publicly available at https://scrip.pharmamedtechbi.com/.

I have withheld the New Drugs Online Report dated 6 April 2010 under section 18(d) of the Act because the report is publicly available at http://www.ukmi.nhs.uk/applications/NDO/.

I have also withheld the GW Pharma regulatory update, dated 6 April 2010, under section 18(d) of the Act as this is a copy of the company media statements released in March 2010 and publicly available at http://www.gwpharm.com/news_2010.aspx.

Update to Schedule 1 of the Medicines Regulations 1984
In 2011, the Medicines Regulations 1984 were amended to update technical matters, reduce barriers to innovation, reduce unnecessary costs and address health and safety risks. At the same time, the Regulations were also amended to include all controlled drugs contained in prescription medicines, including CBD and THC.

Classifications for new medicines and changes to the classification of existing medicines are given immediate effect through a time-limited notice in the New Zealand Gazette and Schedule 1 is updated periodically to include recent additions and changes.

Consented medicines containing controlled drugs that are not listed in the Medicines Regulations, are not subject to a number of controls specified in the Medicines Act for scheduled substances, such as the labelling requirements. For this reason, all controlled drugs used in pharmacy only, restricted or prescription medicines were added to the Medicines Regulations as part of the 2011 amendment. This means they are controlled by both the Medicines Act and the Misuse of Drugs Act 1975 (MoDA). According to section 109(4) of the Medicines Act, in the event of any inconsistency between the Medicines Act and MoDA, the provisions of MoDA shall prevail.

I am releasing the papers identified in table 3. Some information in these papers is being withheld due to being out of the scope of your request.

Table 3

Item description
w. Health Report: Approval to Implement Changes to Medicines Regulations – 15 September 2010
x. Health Report: Approval to Submit Medicines Regulations Changes to Cabinet Legislation Committee – 30 June 2011
y. Email regarding controlled drugs to go in Schedule 1 with two attachments – 20 September 2010

z. Email regarding the reasoning behind scheduling controlled drugs as medicines – 12 September 2014

The initial Health Report proposing amendments to the Medicines Regulations has been withheld as it does not mention the update to Schedule 1 and is therefore out of the scope of your request.

The documents accompanying item *x* entitled 'Medicines (Standing Order) Amendment Regulations 2011' and 'Medicines Amendment Regulations 2011' are being withheld. The Standing Order is being withheld as it is out of the scope of your request and the Medicines Amendment Regulations 2011 are being withheld under section 18(d) of the Act due to being in the public domain. The link to the Medicines Amendment Regulations 2011 was provided in the response to your previous request for official information (refer H201602355).

I trust the information provided fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review my decision in response to this request.

Yours sincerely

Chris James
Acting Group Manager
Medsafe
Protection, Regulation and Assurance