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By Email

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24 January 2017

Dear Sirs

LEGAL OPINION – PROPOSED ACTIVITIES OF AUSCANN GROUP HOLDINGS LIMITED

We act for AusCann Group Holdings Ltd (ACN 601 953 860) (**AusCann**) on a reverse takeover which involves a 100% acquisition of AusCann shares by a public listed company, TW Holding Limited (ACN 008 095 207) (**TWH**) (**Acquisition**).

Upon completion of the Acquisition, TWH will make an application for the re-admission and quotation of TWH's securities on the ASX and change its name to "AusCann Group Holdings Limited" (**Merged Group**).

AusCann has requested our opinion as to:

(a) the Merged Group's legal right to operate its business and, accordingly, the ability to expend its funds in accordance with its disclosed use of funds; and

(b) whether there are any legal impediments to it carrying out certain activities which the Merge Group intends to carry out in Australia (**Proposed Activities**),

following completion of the Acquisition and re-admission of TWH to the official list of the ASX and having regard to the applicable legislation in Australia.

1. MATERIALS CONSIDERED

In order to provide this opinion, we have considered:

(a) TWH's Notice of Meeting provided to us on 30 September 2016 and TWH's prospectus dated 21 October 2016 and the replacement prospectus dated 21 November 2016 respectively (**TWH Documents**); and

(b) the relevant legislation, being the:

(i) *Narcotic Drugs Act 1967* (Cth) (**ND Act**);

(ii) *Misuse of Drugs Act 1981* (WA) (**MDA**);

(iii) *Criminal Code Act 1995* (Cth) (**Criminal Code**);

(iv) *Therapeutic Goods Act 1989* (Cth) (**TG Act**);

(v) *Therapeutic Goods Regulations 1990* (Cth) (**TG Regulations**);

(vi) *Customs Act 1901* (Cth) (**Customs Act**);

(vii) *Customs (Prohibited Imports) Regulations 1956* (Cth) (**CPI Regulations**);

(viii) *Poisons Act 1964* (WA) (**PO Act**);

(ix) *Poisons Regulations 1965* (WA) (**PO Regulations**); and

(x) *Standard for the Uniform Scheduling of Medicines and Poisons* (**Poisons Standard**).

2. PROPOSED ACTIVITIES

According to the TWH Documents, the Proposed Activities of the Merged Group will include:

(a) horticultural research and development;

(b) a joint venture with Chilean cannabis producer Fundación Daya (**DayaCann JV**);

(c) analytical testing and clinical trials to provide quality evidence of the efficacy of medicinal cannabis products and delivery mechanisms on targeted medical conditions with the initial focus of the clinical trials on treatment resistant childhood epilepsy and chronic pain using medicinal cannabis products from AusCann's Canadian partner, Canopy Growth Corporation (**Clinical Trials**); and

(d) applying for licences to grow and manufacture cannabis products for research and medicinal purposes under the ND Act (**Applications**).

With regard to horticultural research and development, we are instructed that the horticultural research and development activities will focus on the construction and use of greenhouse facilities at Murdoch University to model optimum growing conditions for cannabis plants. However, no cannabis material will be used in this modelling activity; accordingly, none of the legislation specified in paragraph 1(b) is applicable to that Proposed Activity.

With regard to the DayaCann JV, separate Australian and Chilean legal opinions will be provided in respect of that Proposed Activity.

With regard to the Applications, it is axiomatic that applying for a licence under the ND Act will not offend any of the provisions of the legislation specified in paragraph 1(b).

Accordingly, this legal opinion is limited to:

(a) a summary of the general Australian legislative framework surrounding the cultivation, production, manufacture, import, export, distribution, trade, possession, use and supply of cannabis and cannabis derived products (see paragraph 3.1 below); and

(b) a consideration of the application of the Australian legislative framework to the Clinical Trials.

3. THE REGULATORY FRAMEWORK

3.1 General legislative framework

The cultivation, production, manufacture, import, export, distribution, trade, possession, use and supply of cannabis and cannabis derived products are regulated by a number of Commonwealth laws. These laws include the:

(a) Criminal Code, which makes it illegal to traffic, import, export, manufacture, cultivate or possess cannabis in any form;

(b) ND Act, which addresses the production, cultivation and manufacture of narcotic substances (including cannabis). On 29 February 2016, the *Narcotic Drugs Amendment Act 2016* (**Amendment Act**) was given Royal Assent. The Amendment Act amended the ND Act to establish a licensing scheme for the cultivation, production and manufacture of cannabis and cannabis products for

medical and scientific purposes. All provisions of the ND Act came into force, including relevant regulations and subsidiary legislation, on 30 October 2016;

(c) Customs Act, which addresses the import and export of narcotic substances, including a regime under the CPI Regulations that allows for the importation of cannabis for medical and scientific purposes;

(d) TG Act, which is administered by the Therapeutics Goods Administration (**TGA**) and provides a national system regulating the import, export, manufacture and supply of medicines in Australia; and

(e) Quarantine Act 1908, which regulates quarantine activities in Australia.

In addition, the following laws also apply to activities to the extent they are undertaken in Western Australia:

(a) the MDA, which provides penalties for possessing, using, making or selling cannabis and the sale and possession of drug paraphernalia; and

(b) the PO Act and PO Regulations, which gives effect to the Poisons Standard and details the licences and permits required to sell or purchase scheduled substances.

3.2 Application of the legislative framework to AusCann's Proposed Activities

Clinical trials using "unapproved therapeutic goods" in Australia, being goods which have not been entered into the Australian Register of Therapeutic Goods (**ARTG**), are required to make use of the Clinical Trial Notification or Clinical Trial Exemption schemes. The Poisons Standard is Australia's national classification system, listing medicines and poisons into ten schedules according to the level of regulatory control over availability of the substance. Part 6-3 of the TG Act provides the basis for this system of access controls over goods containing scheduled substances. However, State legislation, being the PO Act and PO Regulation, gives effect to the Poisons Standard and details the licences and permits required to sell or purchase scheduled substances.

The TG Act works in tandem with the PO Act and the PO Regulations. Medical researchers would be required to comply with both legal regimes.

Under regulation 5 of the CPI Regulations, importing cannabinoids, which is listed in Schedule 4 of the CPI Regulations as a "drug", is prohibited unless the importer holds a licence to import drugs and has permission from the Secretary of the Department of Health (or other authorised person) to import that particular drug.

The ND Act is not relevant for the purposes of conducting the Clinical Trials as, under the ND Act, a person may only apply for permits and licences for the following purposes:

(a) cultivation, production or supply of cannabis for research purposes;

(b) cultivation, production or supply of cannabis for medicinal purposes; or

(c) drug manufacturing purposes.[1]

Further, the explanatory memorandum to the Amendment Act makes it clear that there are mechanisms in place to enable access to medicinal cannabis products for clinical trials through the TG Act.[2]

Accordingly, AusCann will need to obtain the requisite approvals under the TG Act, PO Act and CPI Regulations to undertake the Clinical Trials. Please refer to Section 4 below for further information on those required approvals.

We understand that the ASX has questioned whether the MDA, the Criminal Code and the Customs Act applies to AusCann's Proposed Activities. In our opinion, AusCann's Clinical Trials will not contravene the MDA, the Criminal Code or the Customs Act for the following reasons:

(a) if AusCann conducts its Clinical Trials pursuant to a permit granted under the PO Act, it will not commit an offence under the MDA;

[1] Sections 8E, 8P, 9D, 9N, 11G, 12, ND Act.
[2] Explanatory Memorandum, Narcotic Drugs Amendment Bill 2016 (Cth).

(b) if AusCann obtains approvals under the PO Act, TG Act and the CPI Regulations so that it may lawfully import medicinal cannabis products for its Clinical Trials, it will not commit an offence under the Criminal Code; and

(c) with the passage of the *Law and Justice Legislation Amendment (Serious Drug Offences and Other Measures Act 2005* (Cth), the relevant sections of the Customs Act relating to serious drug import and export offences were transferred to Part 9.1 of the Criminal Code.

4. APPROVALS AND LICENCES REQUIRED TO UNDERTAKE CLINICAL TRIALS

4.1 Use of Medicinal Cannabis Products

Unless there is an applicable exemption, it is an offence to import, export, manufacture or supply any therapeutic goods for use in humans, if those therapeutic goods are not registered on the ARTG.[3] However, through specified mechanisms, the TG Act allows limited access to "unapproved therapeutic goods."

As medicinal cannabis products are not registered on the ARTG, to undertake the Clinical Trials, the Merged Group will require either:

(a) an exemption from the requirements of the TG Act, through the Clinical Trial Notification Scheme (**CTN Acknowledgement**);[4] or

(b) approval to use "unapproved therapeutic goods," through the Clinical Trial Exemption Scheme (**CTX Approval**),[5]

on the ground that the medicinal cannabis products will be used solely for experimental purposes in humans.

The process for obtaining a CTN Acknowledgement is as follows:

(a) all material relating to the proposed trial must be submitted to the Human Research Ethics Committee (**HREC**). The HREC is responsible for assessing the scientific merit of the trial, the safety and efficacy of the substance and the ethical acceptability of the trial; and

(b) with regard to the HREC's advice, the institution or organisation at which the trial will be conducted then decides whether or not to give the final approval for the trial.

The process for obtaining CTX Approval is as follows:

(a) an application to conduct the trial is submitted directly to the TGA for evaluation and comment; and

(b) a delegate of the TGA decides whether or not to object to the proposed guidelines for use of the substance (i.e. whether to grant CTX Approval). Any comments made by the TGA Delegate are forwarded onto the HREC(s) at sites at which the trial will be conducted.

We are instructed that AusCann currently anticipates making an application for a CTN Acknowledgement for the proposed Clinical Trials. However by doing so, AusCann is not precluded from subsequently seeking CTX Approval should it so determine or require. However on the basis of this intended approach and for the purposes of this letter, we have assumed AusCann will seek and obtain CTN Acknowledgement.

We understand that the medicinal cannabis products being utilised include products currently prescribed to Canadian patients under the Health Canada access regime. Consequently, the safety aspects of the products have already addressed. Additionally AusCann's Clinical Trials will be conducted in partnership with renowned research organisations under the leadership of respected principal investigators. Even though these products may currently be used by patients international, the Clinical Trials will undertake will produce objective scientific efficacy data for Australian clinicians. AusCann is of the view that the Clinical Trials are scientifically and ethically sound.

[3] Sections 19B, 19D TG Act.
[4] Sections 18(1), 31A(1) TG Act; regulations 12, Item 3 of Schedule 5A TG Regulations.
[5] Sections 19(1)(b), 31B(1), 31B(2) TG Act; regulations 12AA-12AD TG Regulations.

4.2 Possession of Medicinal Cannabis Products

Importing medicinal cannabis products for use in clinical trials in accordance with the TG Act is now classified as a Schedule 8 substance.[6] The effect of this classification is that pursuant to section 25 of the PO Act, the Merged Group will require a research poisons permit to undertake the Clinical Trials (**Poisons Permit**).

In the absence of a Poisons Permit, regulation 42(1)(g) of the PO Regulations confirms that procurement and possession of this Schedule 8 substance by the Merged Group would be unauthorised.

An application for a Poisons Permit, in the approved form, must be lodged with the Department of Health, Medicines and Poisons Regulation Branch.

An applicant for a Poisons Permit must be a fit and proper person, which is satisfied where the applicant has either:

(a) a tertiary qualification relevant to the substances listed on the application; or

(b) 5 years experience in the manufacture, handling or selling of the substances.

Further, as the Merged Group's research purpose is human research in clinical trials, evidence that the research, for which the medicinal cannabis products will be used, has been approved by an appropriate ethics committee is required. Therefore CTN Acknowledgement is likely to be a pre-requisite for the grant of the Poisons Permit.

We are instructed that AusCann will partner in the Clinical Trials with research organisations that either currently hold a Poisons Permit or are eligible to do so.

4.3 Importing Medicinal Cannabis Products

Under regulation 5 of the CPI Regulations, importing a "drug" listed in Schedule 4 of the CPI Regulations is prohibited unless the importer:

(a) holds a licence to import drugs (**Drug Licence**); and

(b) has permission from the Secretary of the Department of Health (or other authorised person) to import that particular drug (**Secretary Permission**).

As "cannabinoids" is a drug listed in Schedule 4 of the CPI Regulations, the Merged Group will require both a Drug Licence and Secretary Permission to import medicinal cannabis products for use in the Clinical Trials.

Secretary Permission is only issued to importers who hold a Drug Licence and therefore, obtaining a Drug Licence is a pre-requisite to obtaining Secretary Permission. An application for a Drug Licence must be in writing and lodged with the Drug Control Section of the TGA.[7]

A Drug Licence application will be granted provided the applicant:

(a) establishes that the drug (medicinal cannabis products) is required for medical or scientific purposes (and will be used for these lawful purposes);

(b) lodges copies of all required State or Territory licences together with the application; and

(c) is deemed to be a fit and proper person to hold a Drug Licence (including any agents and employees).[8]

Therefore the following are likely to be pre-requisites for the grant of a Drug Licence:

(a) CTN Acknowledgment, to establish that the medicinal cannabis products are required for a medical or scientific purpose (i.e. use in the Clinical Trials); and

(b) a Poisons Permit, as this is a State licence required to undertake the Clinical Trials and a copy of which must be lodged with the Drug Licence application.

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[6] Medicinal cannabis products was previously classified as a Schedule 9 substance. However, on 31 August 2016, the TGA announced that the scheduling of cannabis and tetrahydrocannabinols in the Poisons Standard would be amended under subsections 42ZCZS and 42ZCZX of the TG Regulations. The effect of the amendments are that from 1 November 2016, medicinal cannabis products will be included in Schedule 8 of the Poisons Standard. The TGA announcement can be found at this link: https://www.tga.gov.au/final-decision-scheduling-cannabis-and-tetrahydrocannabinols-frequently-asked-questions

[7] The TGA is a division of the Department of Health, authorised to act on the Secretary of the Department of Health's behalf.

[8] Applicants are required to submit National Police Certificates together with the application.

We understand that AusCann anticipates obtaining CTN Acknowledgement for the reasons set out above and is partnering with research organisations that either currently hold a Poisons Permit or are eligible to do so.

5. LEGAL OPINION

In our opinion, the approvals or permits the Merged Group must obtain in order to carry out the Clinical Trials are as follows:

(a) regulatory approval under the TG Act, consisting, in this context, of a CTN Acknowledgement;

(b) a Poisons Permit under the PO Act; and

(c) a Drug Licence and Secretary Permission under the CPI Regulations to import the medicinal cannabis products.

Subject to the grant of the above approvals and permits, in our opinion the Clinical Trials can be lawfully conducted and there is no legal impediment to AusCann carrying out its proposed operations in Australia.

In our view, there is no reason for AusCann to believe that it would not obtain these approvals, licences and permits. We understand AusCann anticipates satisfying each of these conditions for the reasons set out above and upon doing so there will be no further legal or regulatory requirements to undertaking the Clinical Trials.

Yours faithfully

Allion Partners Pty Limited