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Memorandum

Para / To : Harry Karelis
Executive Director
AusCann Group Holdings Ltd.

De / From : Carey y Cía.

Ref. : Medicinal cannabis regulation - Chile

Fecha / Date : November 24, 2016

Dear Harry:

In connection to your queries, please find herein our report of the Chilean legal framework on medicinal cannabis. This report, as required, focuses in the Chilean regulation in force for medicinal cannabis and every related activity, namely: (i) cultivation of medicinal cannabis; (ii) processing and manufacturing of pharmaceutical products containing medicinal cannabis (whether dried flowers or extracted oils); (iii) execution of clinical trials for products containing medicinal cannabis; and (iv) export of pharmaceutical products containing medicinal cannabis (hereinafter the "Activities"). We also have included brief responses to each of your queries in the executive summary and a more extensive explanation regarding the applicable regulation in the following sections.

I. EXECUTIVE SUMMARY.

1. Are the Activities to be undertaken by Fundación Daya (Daya) and AusCann pursuant to the joint venture, able to be legally conducted under law in Chile?

All the Activities to be undertaken under the joint venture can be conducted in Chile, provided the legal requisites described below are met.

2. What laws and regulations govern the conduct of the Activities and are there any restrictions or limitations imposed by those laws?

The laws and regulations governing all the Activities are identified in the Legal Framework section (chapter II). The restrictions and limitations included in each of them are explained individually for each Activity.

3. What permits are required in order to conduct the Activities and what are the requirements to obtaining those permits?

For the cultivation of medicinal cannabis an authorization granted by the Agricultural and Livestock National Service (hereinafter "SAG") is needed. For every other Activity the authorizations needed must be requested and granted by the Public Health Institute (hereinafter "ISP"). The process to obtain each authorization and the relevant timeframe and costs are explained in each section below.

4. Are there any other legal impediments to carry out the Activities? (quantity for sale, possession and export, purchase and advertise)

The quantity of products for sale, possession and export of pharmaceutical products containing cannabis is limited by the number of units informed to the ISP in the months of October and November of each year by the manufacturer and/or exporter. Regarding the restriction to purchase the products, considering that they are controlled drugs, they can only be bought with the relevant retained medical prescription. Finally, concerning advertisement, the promotion of these products is subject to general rules. All the above is explained in the relevant sections below.

II. LEGAL FRAMEWORK.

The regulation in force for the Activities and medicinal cannabis in general in Chile is contained in the following regulatory bodies:

(i) Law No. 20,000 of 2005 –which replaces Law No. 19,336 which penalizes the illicit traffic of narcotics and psychotropics– (hereinafter "Law No. 20.000").

(ii) Supreme Decree No. 867 of 2008 issued by the Ministry of Internal Affairs –which contains the regulations of Law. No. 20,000– (hereinafter "S.D. No. 867/08").

(iii) Supreme Decree No. 03 of 2010 –which contains the general regulation for pharmaceutical products in Chile– (hereinafter "S.D. No. 03/2010").

(iv) Supreme Decree No. 404 of 1983 –which contains the regulations for narcotics– (hereinafter "S.D. No. 404/83").

(v) Supreme Decree No. 84 of 2015 –which modifies S.D. No. 404 and Supreme Decree No. 405, both of 1983– (hereinafter "S.D. No. 84/2015").

(vi) Supreme Decree No. 85 of 2016 –which modifies S.D. No. 03/2010 (hereinafter "S.D. No. 85/2016").

III. CULTIVATION OF MEDICINAL CANNABIS IN CHILE.

Firstly, the cultivation of cannabis in Chile is, in principle, prohibited. Indeed, article 8 of Law No. 20.000 states that:

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"The person who, without the necessary authorization, sows, plants, grows or harvests vegetal species of the cannabis gender or other with which narcotic or psychotropic drugs can be produced, will be punished with (…), unless he/she justifies that they are destined for personal use or exclusive and soon consumption".

As it can be observed, although the general rule regarding cultivation of cannabis is that such activity is prohibited, this activity can be executed as long the person or entity which sows, plants or grows vegetal species of cannabis, has the relevant authorization granted by the relevant authority, which, under article 9 of Law No. 20.000 is the SAG[1]. Please be aware that such authorization is not a general permission for cultivating and growing cannabis, but a very limited and restricted permit both in location, purpose and time.

The procedure under which such authorization can be obtained is regulated in articles 6 et seq. of S.D. No. 867/08[2].

Additionally, in connection to the requisites for farming, article 10 of S.D. No. 867/08 states that:

(i) Once the approval has been granted, the authorized person or entity should give notice to the SAG informing the exact date of sowing, cultivation and harvesting;
(ii) Once the product has been reaped, the authorized person or entity shall request to SAG the permission to transport the product;
(iii) The authorized person or entity should also keep the cultivation field duly locked with a system that impedes access to anyone who is not in charge of the cultivation; and
(iv) Once the product is separated, within the production process, the authorized person or entity must destroy the plants, stubbles, seeds and other surplus generated in the farming process.

Finally, the time to obtain such authorization, as informed by SAG, is of approximately 2 months and the costs of approximately US$10 (administrative fee).

Please be informed that, on November 11, 2016, SAG issued resolution No. 2104/2016 by means of which has granted to Fundación Daya an authorization to sow, plant, cultivate

[1] Indeed, article 9 of Law No. 20.000 states: *"The authorization referred in article 8 will be given by the Agricultural and Livestock National Service".*

[2] In this regard article 6 states that the application must be submitted before the SAG's office of the place where the cultivation will take place. On the other hand, article 7 states that the request shall be submitted at least four months before the beginning of the cultivation and shall include the following information: (i) identification of the applicant; (ii) information concerning the field where the cultivation will be performed; (iii) exact location of the field and the area where the cannabis will be planted; (iv) date of sowing season;(v) gender, variety and kind of cultivation; (vi) quantity of reproductive material to be used and the provider of it; (vii) exact harvesting date; and (viii) destiny of the harvested product. Additionally, article 9 lists the documents in connection to the field that shall be submitted with the application, together with information regarding the applicant. Finally, the regulation also requires a sworn statement regarding the destiny of the harvested product and the way under which the plants, stubbles, seeds and other surplus will be destroyed. Once the application has been received by the SAG, the same will be sent to the Regional Quartermaster (regional governor) for approval. Once approved, the SAG will be entitled to decide on whether granting the final authorization or not.

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and harvest specific species of cannabis in the city of Colbún, under the conditions stated in the same resolution.

IV. PROCESSING AND MANUFACTURING PHARMACEUTICAL PRODUCTS CONTAINING MEDICINAL CANNABIS EXTRACTS.

In connection to this matter article 5 of S.D. No. 404/83 states that:

*"The import, export, transit, extraction, production, manufacturing, fractioning, preparation, distribution, transport, transfer under any title, expending, possession of acetorphine, cannabis, resin of cannabis, extracts and tincture of cannabis [*among others*] is forbidden in the national territory. Notwithstanding the aforementioned, in qualified cases for purposes of scientific research, the utilization of such substances may be authorized by the Public Health Institute, under the conditions determined in the relevant resolution.*

Nonetheless, the Public Health Institute may authorize and control the use of cannabis, resin of cannabis, extracts and tinctures of cannabis for the manufacture of pharmaceutical products for human use".

In this regard, as it happens with the cultivation of cannabis, the production and manufacture of products containing cannabis is generally prohibited, unless expressly authorized by the ISP, pursuant to article 5 above quoted. Such authorization may be given for the production of

Once authorized for pharmaceutical use, the production and sale of products containing cannabis are subject to the procedure set in articles 16 et seq. of S.D. No. 404/83, which include several rules in such regard, namely:

(i) The manufacture of the products can only be performed by entities duly authorized for the production of pharmaceutical products. Before November 1st, of every year, the entity shall notify the ISP regarding the quantity of products that will be produced the next year.
(ii) The manufacturing entities shall acquire the products needed and used in the process only when the ISP has approved such acquisition.
(iii) The ISP must be notified on the date that the production starts and when it ends, plus any suspension of production that may occur.
(iv) The manufacturing entity shall also keep updated records concerning production and keep them available for any request of the ISP.
(v) There are specific rules and requirements in connection with the packaging and labeling of narcotic products.
(vi) The production and distribution of samples are forbidden.

Finally, the time to obtain such authorization, as informed by the ISP, is of approximately 3 months and the costs should be of approximately USD$ 100 (administrative fee).

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V. CLINICAL TRIALS FOR PRODUCTS CONTAINING MEDICINAL CANNABIS EXTRACTS (OR DRIED FLOWERS).

Pursuant to the wording of article 5 of S.D. No. 404, which expressly authorizes the utilization of cannabis for scientific research purposes, clinical trials with cannabis can be performed in Chile, as long all the requirements have been fulfilled by the interested party and the same is authorized by the ISP[3].

Please be informed that clinical trials are governed by several legal bodies, including the Sanitary Code, Law No. 20,120 –regarding scientific investigation in the human being–and Supreme Decree No. 114 –which contains the regulations of Law No. 20,120–, but, none of them include any specific regulation concerning medicinal cannabis.

Therefore, any clinical trial regarding cannabis for medicinal use should be subject to general rules for clinical investigation in Chile. In this sense, all the relevant authorizations for the execution of the study shall be requested before the ISP and the respective Ethic-Scientific Committees. Once such authorizations have been obtained the clinical trial can begin.

Finally, the time to obtain such authorizations, as informed by the ISP, is of approximately 6 months and the cost of approximately US$1,000.

VI. SANITARY REGISTRATION, COMMERCIALIZATION AND PROMOTION OF PHARMACEUTICAL PRODUCTS CONTAINING MEDICINAL CANNABIS.

According to article 20 of S.D. No. 03/2010, only registered products can be imported and distributed in Chile. Consequently, the only way under which any pharmaceutical product can be commercialized in our country is by having the relevant sanitary registration granted by the ISP.

Please have in mind that the sanitary registration of phytopharmaceuticals containing cannabis was not allowed until the issuance of S.D. No. 85/2016. Indeed, before such new regulation S.D. No.03/2010 stated that a phytopharmaceutical product could not contain any kind of narcotic or psychotropic substance. However, with S.D. No. 85/2016 such prohibition was deleted and, therefore, today the registration of phytopharmaceutical products containing cannabis is permitted.

As general background, please be informed that the sanitary registration is the process under which a pharmaceutical product is evaluated, resulting in a registration under sequential numbering on a special list held by the ISP prior to its distribution and use. On the other hand, regarding the registration itself, any new product (which should be the case

[3] Additional to this specific provision, S.D. 03/2010, in its article 21 letter c) permits the use of non registered drugs for clinical research as long as its use is authorized by the ISP.

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of any product containing cannabis as its active ingredient) shall be filed under the ordinary procedure, which rules are included in S.D. No.03/2010[4].

Once the registration has been granted, the holder of the sanitary registration will be able to commercialize the product in the Chilean market, subject to general requirements and regulations for pharmaceutical products, specifically for narcotics.

Hence, rules regarding the quantity of controlled products that can be sold, possessed or exported are applicable, as well the limitations regarding advertisement and promotion, namely, that any product which contains cannabis can only be sold under medical prescription (indeed, under article 23 of S.D. 404/1984 pharmaceutical products including cannabis are subject to retained medical prescription with quantity control) and, therefore, any kind of advertisement for the general public is forbidden. Indeed, such products can only be promoted under the process called "information to professionals", which entails that any kind of information of the product can be solely given to health care professionals authorized to prescribe and dispense pharmaceutical products.

Finally, the time to obtain such authorization, as informed by the ISP, is of approximately 8 months and the cost in governmental fees is of approximately US$1,900 (administrative fee).

VII. EXPORT OF PRODUCTS CONTAINING MEDICINAL CANNABIS.

As informed above, article 5 of S.D. No. 404/83 expressly forbids, in general, the export of products containing cannabis. However, paragraph two of the same article states that the ISP can authorize and control the utilization of cannabis for pharmaceutical products, which may include the export of such products.

The aforementioned possibility has been confirmed by the same ISP. Indeed, on February 16, 2016, the ISP, answering a query made by CannaGrow SpA, the authority has stated that the exportation of pharmaceutical products containing cannabis is allowed, as long the ISP has granted the relevant authorization, since products containing cannabis are controlled drugs.

[4] Ordinary Procedure: Under this procedure all the technical and scientific data shall be submitted by the applicant. In this regard, along with the registration request, the applicant shall provide the following information:

- The Ordinary Procedure form of request;
- Legal background information (the specific documents will vary if the products will be manufactured in Chile (e.g. sanitary authorization of the manufacturing plant) or abroad (e.g. CPP and PoA);
- Complete formula;
- Specifications and methodology (with its validations) of the drug substance and finished product.
- Manufacturing procedure (workflow) and its validations.
- Clinic-Pharmacologic Monographs;
- Brochure including information to professionals (equivalent to SmPC);
- Patients information leaflet; and
- Artwork and mock-up.

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In this sense, products containing cannabis can be exported provided the requisites included in article articles 8 et seq. of S.D. No. 404/83, regarding the importation and export of narcotics are met, which includes the following:

(i) The products can only be exported by authorized entities (laboratories, pharmaceutical wholesalers, drugstores, hospitals or institutions dedicated to medical and scientific research), with the relevant authorization of the ISP;
(ii) In the month of October of each year, such entities shall notify the ISP on the estimate number of products to be exported the next year;
(iii) All the information included in article 11 –including, among other, the name of the exporter/importer, country of destiny, name of the product, quantity of units to be exported, etc.– shall be submitted in order to get the authorization;
(iv) The certificate that authorizes the exportation expires in a term of four months after its issuance, and the export can be executed within a maximum period of 6 months since the same date.

Additionally, the maximum quantity to be exported is not stated by the regulation and the same will depend on how many units are requested to and accepted by the ISP.

Finally, the time to obtain such authorization, as informed by the ISP, is of approximately 3 months and the cost of approximately US$100 (administrative fee).

VIII. CURRENT SCENARIO FOR MEDICINAL CANNABIS IN CHILE.

Notwithstanding the regulation above explained and the regulatory possibilities for medicinal cannabis available, in connection to the current scenario for medicinal cannabis, we can inform as follows:

- In the last three years, only two entities have been authorized by SAG for the cultivation and harvest of medicinal cannabis, namely, Fundación Daya (three different times, in 2014, 2015 and 2016) and Forestal Agrofuturo Limitada (in 2015).

- The authorizations granted by SAG to Fundación Daya in 2016 is for the cultivation of cannabis in Colbún (a town located approximately 250 Km south east of Santiago, Chile)[5].

- Regarding the authorization that Knop Laboratories should obtain to manufacture products containing cannabis, the ISP unofficially informed us that no authorization has been given in such regard for clinical research.

- On the other hand, the ISP has informed that no clinical trial regarding medicinal cannabis has been requested, neither by Fundación Daya nor by Knop Laboratories[6].

[5] Such resolution is available in the following link:
http://ceropapel.sag.gob.cl/documentos/documento.php?idDocumento=33889921

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However, pursuant to unofficial information provided by the ISP´s personnel, the clinical trial protocol prepared by Knop Laboratories is currently under evaluation of the relevant Ethic-Scientific Committee. A favorable outcome will allow requesting permission before the ISP to carry out the clinical trial.

- Finally, the first sanitary registration for a pharmaceutical product containing cannabis was granted by the ISP on October 06, 2016. The name of the product is **SATIVEX SOLUCIÓN PARA NEBULIZACIÓN BUCAL (Extractos de Cannabis sativa L.)** – Registration No. N-577/16– and its holder is Laboratorio Biopas S.A. All the information publicly available concerning the product is included in the following link: http://registrosanitario.ispch.gob.cl/Ficha.aspx?RegistroISP=N-577/16.

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[6] The ISP has a public database and search engine for public consultation of currently authorized clinical trials with pharmaceutical products in Chile. There is no information on any clinical trial concerning a cannabis based product.

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