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REGULATIONS AND OPPORTUNITIES IN KEY LATIN AMERICAN MARKETS: URUGUAY

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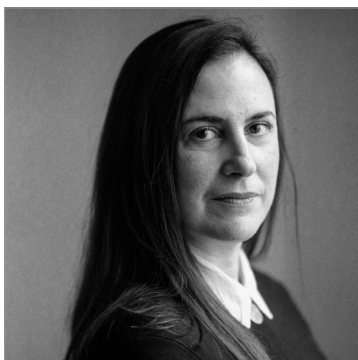
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Alfredo Pascual: Hello everyone. Welcome. My name is Alfredo Pascual, I am international analyst for Marijuana Business Daily. This is the first in a series of four webinars that we are doing this week.

They will be in Spanish not because we do not know how to speak English, but because it is a conscious decision that we made to do them in Spanish because I think it is important that the industry in Latin America begins to talk about these issues at a regional level and not always talk directed toward North American investors.

For this reason, I think it is important that this discussion takes place at the regional level. Although we are going to focus on four countries, the idea is to do so with a regional focus.

Today the webinar is about Uruguay, but before starting, a reminder that this is going to be recorded and the four webinars then are going to be transcribed, and the transcripts translated into English.

So, in case anyone is still listening and not understanding anything because this is going to be a Spanish just letting you know that we will transcribe and and send it next week.

For those who are understanding everything in Spanish, before starting, clarify that you can ask questions whenever you want through the application itself and with that we begin.

I am very happy for this panel from Uruguay to have three excellent panelists that I am going to introduce in alphabetical order. First we have Lucía Patrón, she is a lawyer and I recently read a very good report from Lucía, analyzing the current legal situation in Uruguay. Also the possibility of making regulatory changes that facilitate exports, which is one of the most important issues, more at the moment in Uruguay, at this time and with that it is a pleasure to have you here. Lucia, do you hear me?

Lucia Patron: Hello. Thank you very much, Alfredo for the presentation.

Alfredo: Thank you for being here, Lucia. Then we have Mariela Ibarra. She is an agronomist and was an external advisor to the IRCCA, the Uruguayan Cannabis Agency, from practically the beginning until the end of 2019, with which, obviously, she saw many applications for licenses and is knows about how these processes work, so also a honor to have you here, Mariela.

Mariela Ibarra: Thank you Alfredo. Welcome everybody.

Alfredo: Thank you. Also Mercedes Ponce de León, an entrepreneur who has been in the cannabis industry in Uruguay since the early days, organizing a conference every year, but also today she is part of the chamber of companies of the industry that is also very relevant to give visibility to this chamber that is being organized in Uruguay, to represent the interests of companies. Mercedes.

Mercedes Ponce de León: Good morning everyone. Thank you very much Alfredo for the invitation. It is an honor to be here representing the emerging Uruguayan cannabis industry in this webinar.

Alfredo: Thank you, Mercedes. Also, the idea was not to have, as usually happens in webinars or in industry panels, the CEO of production company A, the CEO of production company B and the same of company C, but try to have different angles that they can contribute another analysis to the subject.

Starting with Uruguay, in particular, I am not going to start this by listing the types of licenses that exist, nor telling the audience that Uruguay was the first country in the world to fully legalize the different uses of cannabis, including recreational, that surely all those who are here today know. I'll do a very general review and then go on to talk a little about the different types of licenses more specifically.

Say that, although there is much to explain how the issue has evolved in Uruguay, because there is no implementation of the cannabis law in the world that has been perfect from the start.

I think there are many things to highlight and precisely in terms of the adult use part, it is noteworthy that, as Diego Olivera mentioned recently, from the National Drug Board, that three years after the sales of cannabis for recreational use began or adult, four tons were sold for about US \$ 5 million and that was money that did not go to the black market.

On top of that, no indicator went off an alarm saying that something dire was happening and that we must go back to prohibition. I think that is already a success in itself. It is not only about marijuana for adult use in Uruguay, but also the medicinal part and also the industrial one. Regarding the medicinal, we have, first of all, the part of the Uruguayan domestic market, which we are going to talk a little about in terms of the products that are available to patients today in Uruguay.

I think that this is one of the things that can be improved because of the few products that are available and because there is still no access to products with a high content of THC for medicinal use.

Also, we are going to talk at the end, but not as a minor topic, but also as an important topic of this panel, about exports, which took a long time for Uruguay to start exporting. The first significant exports started in the second half of last year and the first hemp exports actually started just a few weeks ago.

With which, we are going to try to analyze a little why it happened in this way and finish with what are the perspectives regarding how exports will continue in Uruguay.

With that, starting a little first with a review of the licensing issue, perhaps Lucía, Mariela or Mercedes, whoever wants to start, can give us a perspective on what the licensing situation is in Uruguay. Above all, from your perspective, what types of advice could you give to entrepreneurs who are currently considering applying for different types of licenses in Uruguay?

Lucía: From the legal side, to summarize a little bit, we could categorize licenses into production licenses, which are for cultivation, storage and commercialization, scientific research and industrialization licenses, which also allow commercialization. In turn, within cultivation, we can subdivide them depending on their purposes, if the production is for medicinal, industrial or recreational purposes. The process to obtain it is not the same in each case.

Depending on the type of license and its purposes, the competent body and in turn the requirements and the opportunity. To take an example, the license for the production of cannabis for medicinal purposes, regardless of the THC content, is filed with the IRCCA and requires authorization from the Ministry of Public Health.

The applicant can appear at any time to request the license.

Not so in the case of the cannabis production license for recreational purposes, it can only be presented when there is an open tender. I don't know if anyone wants to--

Alfredo: I have a question, Lucia. If we compare the number of licenses for the cultivation of cannabis for medicinal purposes, with those for the cultivation of hemp, there is a big difference, that there are many more for hemp. What do you think are reasons that explain this difference in number?

Lucía: The licenses for the cultivation of hemp, the authorization is given by the Ministry of Livestock and the procedures are not the same. The requirements for growing hemp are lower than the requirements for growing cannabis for medicinal purposes. That is given by the industry, it is not the same to produce cannabis for the production of human products that requires other types of security and controls, than cannabis, for example, hemp for industrial purposes.

Alfredo: It should be clarified that it does not allow the industrialization of the flower only by having the license of non-psychoactive cannabis or hemp. It's only until the harvest, right?

Lucia: There it is. The product can be conditioned, but when we go to the industrialization stage, we need a different license, which is specifically for that process.

Alfredo: That is something interesting about Uruguay, although there are licenses for the cultivation of psychoactive and non-psychoactive cannabis. If it is about industrialization, it could be said that it is a category of industrialization licenses and there it will always depend on the IRCCA and also on the Ministry of Health, right?

Lucia: Yes, correct. Because the place where the industrialization is going to take place has to be authorized by the Ministry of Public Health and the company as well.

Alfredo: Mariela, Mercedes, do you want to comment a little on the licensing issue?

Mariela: Yes, expand the information on Lucía a bit.

Alfredo: Sure.

Mariela: In the case of the licenses for medicinal purposes granted by the IRCCA, on the one hand, we have the cultivation licenses and on the other hand we have an industrialization license, they are two different licenses, in addition to the research and development licenses that also enter through the IRCCA window.

You were asking what would be the reason that most of the licenses or permits that we call permits are not strictly licenses granted by the Ministry of Livestock, they are simpler, if we can call them that. Simply by the type of material that is handled and by the conditions that are described in the specific decree that exists for hemp.

In the case of livestock, what it covers is the production of non-psychoactive cannabis, which in the case of Uruguay, to clarify the information a bit. Non-psychoactive cannabis is one that has less than 1% THC to the dried flower.

In the case of livestock permits, the varieties that are grown must be varieties that are already registered in the national cultivar registers of the National Seed Institute. The data and controls that fall on these permits, based on the basis that we are working with non-psychoactive material, are minor and for a purpose that is not that of human pharmaceuticals, they are less than those required by products for medicinal purposes that they go by orbit of the IRCCA.

Notwithstanding that, when livestock projects have some flower production for non-medicinal purposes and could eventually enter a chain of industrialization for non-medicinal purposes.

In addition to that, in what we call post-harvest handling, when we want or need a batch to have pharmaceutical quality, the post-harvest has to be carried out in an environment or with criteria set by the Ministry of Public Health that requires that post-harvest be authorized of the Ministry of Public Health and the corresponding certifications to guarantee the quality of the batches that leave there and eventually enter the pharmaceutical quality batch circuit.

Alfredo: Questions about it. Maybe they can clarify as well. Could it also be that in the case of non-psychoactive cannabis licenses or commonly called hemp, the applicant is not required to already have a buyer of that product, but when it comes to psychoactive cannabis, a plan is required that presents to what is the production going to allocate?

Mariela: Actually, in both cases it must be mentioned, it is not a commitment because it is clear that once licenses are granted, there must be letters of intent.

Alfredo: In all cases, including hemp?

Mariela: In both cases.

Alfredo: Perfect.

Mariela: Eventually, that may change on the fly, as long as they enter both livestock or IRCCA, in both cases the information must be endorsed or expanded. The licenses that are granted are not stagnant once they are granted, they are flexible, the information can be expanded, new information can be entered, the licenses can be expanded, it enters a process as dynamic.

At least, at this stage, we are in the initial processes of shaping it, of making applications and permits more flexible. In both cases it is necessary to state which will be the final buyer or the destination of the raw material, but also in both cases it is possible to modify.

Alfredo: Mercedes, what interests are you noticing regarding the licensing issue, if the interest is mostly in one type of license, another or everything?

Mercedes: I think that as the colleagues mentioned, due to the fact that the permits from the Ministry of Livestock were a little more lax or more flexible, the industry has found the greatest development in these areas. We have 42 licenses for the production of non-psychoactive cannabis, while we have only nine for industrialization. In fact, they have been delivered between 2008, 2009 and one now at the beginning of 2020, all within what was the past period.

For those who do not know have an idea, in March of this year, Uruguay changed its government. So far this new government has not issued new licenses, although it is saying that it wants to promote this sector. The industry has found in the cultivation licenses, of non-psychoactive, of hemp, it has found the space where it can develop further.

The licenses for psychoactive cultivation of cannabis with more than 1% THC, which are also nine, it is important to emphasize that there are five of them that are under the orbit of state control, with these tenders mentioned by Lucia for the sale of cannabis from adult use, within what is recreational in pharmacies.

Those that are for psychoactive cannabis, let's say, the other four, are for medicinal purposes, and those have also been delivered since 2018 to this part, in recent years. So, the industry is developing more on that side, but we hope in the future, obviously, to have greater potential for the development of the industry in all areas.

Alfredo: What is the degree of development of those licenses in the sense of how operational are the companies? Because many times it happens that there is a license, but then it ends up being a piece of paper for a long time and they don't end up doing more activities. At a general level, obviously, without talking in particular of any company, what kind of development do you see so far in all these licensees?

Mariela: It is important to emphasize that the cannabis industry in general has some restrictions, that companies end up struggling in some ways, with the issue of bankarization, with the issue of the different frames and approaches for the different processes of how they are going intertwining some licenses with others and the permits of each other.

Non-psychoactive cultivation licenses, the vast majority of companies are operating and are able to develop their projects. Those that are industrialized, some yes, others not so much. There are some bureaucratic problems, within what is the legal framework, the regulatory issue, to be able to develop and commercialize, especially abroad, this type of products.

There are some proposals to change specific regulations that we can develop now in the conversation, on some decrees, such as Decree 46 of 2015 on medicinal cannabis and even the decree on industrial hemp as well, in order to facilitate and promote the development of the sector in this regard .

Today, to give you an idea, there are hemp cultivation companies that have production ready, approximately 120 tons ready for export, and it would not be possible to facilitate that export due to a bureaucratic issue.

Now at this moment, we are at a key moment, precisely because there was a meeting in the presidency, where the chamber of companies that I represent from the private sector, other companies as well, the Ministry of Public Health, the Ministry of Livestock was , Presidency and all the authorities of the IRCCA and the National Drug Board.

To precisely commit to generating changes in the regulatory framework that allow promoting the development of exports and the development of the sector in general.

So we are at a really important moment for those flexibilizations of the regulatory framework, to allow the commercialization of those 120 tons, on which many companies depend to be able to really continue their operations and obviously boost themselves to what is the crop of the 2020 season.

We are at a key moment. Even the upcoming Italian harvest could lose interest in ours, which is ready to export. Actually, we are at a very important moment for the development of the sector.

Alfredo: Before continuing with exports, to close the issue of licenses, Mariela and Lucía, could you, if you want to comment on something about the registry of seeds or genetic varieties, how does it work at a general level?

Mariela, perhaps, if you want to give some particular advice from your experience working so many years at the IRCCA about what are the most common errors, perhaps, that the regulator sees when an application for a license arrives and what advice would you give to try to avoid those mistakes?

Lucía: The first question, how are varieties registered in Uruguay? The varieties in Uruguay of– In Uruguay we have for any plant species the regulatory body, the agencies, the National Seed Institute, it has to meet the requirements established by the National Seed Institute, INASE. The varieties have two possible registrations, in the case of hemp varieties with less than 1% THC, they can be registered in the commercial registry of plant varieties.

We call that here, the National Registry of Cultivars. Property can also be registered. We can request the ownership of a plant variety also in the INASE through the Property Registry of Cultivars. Here in Uruguay, as well as most of the countries, we have the breeder's right as the main way of applying for the property of plant varieties, not patents. In Uruguay patents are not granted for plant varieties, contrary to what happens, for example, in the United States.

It would be a procedure in which, in the varieties, both foreign and national, they have to request the corresponding records in the INASE. Once these varieties are registered, the corresponding livestock production licenses can be requested.

In the case of the licenses of the varieties, excuse me, they are high in THC, the property of the varieties can be registered, but the commercial registration of varieties high in THC is not yet open, that is a challenge, that is a must, which still has pending to regulate the IRCCA.

I understand that they have worked for a couple of years, in 2018 and 2019, there are many proposals, I hope that a specific regulation will be established soon for the commercialization of varieties with THC.

Alfredo: Rather, for Lucía, a couple of questions are coming in regarding the issue of foreign investment and whether there are restrictions on foreign investment. Perhaps you can use the opportunity, first to confirm that in principle there are no restrictions, but also to explain a little how SENACLAFT works in Uruguay, the issue of money laundering, which is something quite particular to Uruguay.

Lucía: It is important to note that licenses can be applied by both natural and legal persons, national or foreign. There is no particular requirement, nor a limitation to foreign companies. Even in Uruguay, if a company wants to set up and establish a Uruguayan company for the application of licenses, its shareholders are not limited, they can be from abroad or national, the same with their directors.

Regarding SENACLAFT, when it is applied to licenses, certain information must also be provided regarding the origin of the funds that are going to be used for the project and the final beneficiaries of that investment must be identified.

All this documentation is based on our regulations on money laundering and terrorist financing, and the control is carried out by SENACLAFT, which is the anti-money laundering secretariat.

This is a very important step, because a negative report from the anti-money laundering secretariat could truncate the license. The preparation of all these documents is very important, depending on the corporate structure you have or the level of investment, it can be an important paperwork, because also when the documents come from abroad they require certain formalities for their presentation in Uruguay, either apostille, translations, etc.

To give you an example, in terms of money laundering to prove the origin of the funds, what is required would be financial statements, for example, sworn statements of the legitimate origin of the activity, depending a little on each case it is armed, we work with customers to assemble the package.

Mariela: Able to complement a little what Lucía says, Alfredo. An important feature that also does a bit to what you asked us today, that licenses were not just papers. Here in Uruguay, when you present a license, both in livestock farming and in the IRCCA, you already have to have defined the model, the business plan, the amount of the investment and where that investment comes from.

Licenses are not given prior to obtaining an investment, which was always a discussion. They are granted once the is clearly defined, what are we going to do? How? Where? When? And the instructions or instructions for presenting the licenses are clearly defined and publicly accessible, the entire system is very transparent.

For example, the IRCCA website clearly establishes the protocols that must be presented, the procedures and instructions to present each of the different types of licenses that we have, that includes the origin of the funds and all that information that is It is presented as a separate folder, it is the one that is processed through SENACLAFT.

What are the main tips that I would give to someone who is thinking of applying for a license? To prepare the proposals as required by each competent body. That the instructions guide you and alert you to what the main requirements are.

What the regulator fundamentally evaluates is that all the information is consistent, from the number of plants that we are going to plant, the estimated production that will come out of that number of plants, if it has THC, if it does not have THC, the destination, where it will be, geographical coordinates, what production modalities will they have. Everything has to have a logic and what is the traceability of the seed to the final product. We are going to give the regulator tools so that it can carry out its inspection activities once the licenses have been granted.

Lucía: As Mariela said, coherence is very important when presenting the project, both the technical part and the business plan have to fit very well. It is very important to work together, both the technical part and the financial part and all the documentation that is presented to SENACLAFT.

On that side, what we always recommend is to try to make the applicant's corporate structure simple, not too complex, because the analysis will be easier to show, the documentation that is presented will be simpler and it will give less room for doubt or consultation of the Secretariat.

Obviously, if we are talking about large companies that are listed on a reputable public stock exchange, there would be no drawback, that is also easy to prove and just proving that would not require as much paperwork as perhaps a company that is not listed on the stock exchange, but has its capital atomized into many shareholders or a complex structure.

Alfredo: We are going to move on to another topic to put licenses aside a bit. There are several questions about something that is common in this industry: wanting to export. Uruguayans want to export, but there are also many listeners from other countries who want to export to Uruguay, with which we can go on to talk about the Uruguayan domestic market.

What are patients having access to today, under medical prescription in Uruguay? Products available in the country? Also the import route, a kind of compassionate use, as they are called, of unregistered products, which is very common in the region. From the point of view of a company from another country in the region that wants to send a product, for example, CBD or even with THC to Uruguay, what are the possibilities? Perhaps someone first to review the current situation and then the possibilities of exporting to Uruguay.

Mercedes: I can do a review, at least, with the current situation. Today we have pharmaceutical grade products available for sale at the pharmacy by prescription. We have a 2% and 5% CBD oil, which is an Epifratán and then we have a cream and a post-solar gel, which are more cosmetic products.

These oils, these extracts of medicinal cannabis, can today also be exported through compassionate use from Uruguay to other countries. Uruguay is already exporting this product to countries such as Argentina, Brazil, Paraguay, Chile, and it was even doing it to Peru, but today they are already working on the real export, not so much for compassionate use, but for sale in pharmacies in Peru of this same product.

To import to Uruguay through compassionate use, what you were referring to, Alfredo, the process changed over the years. Before, the compassionate use process was used with the authorization of the Ministry of Public Health and today, cannabinoids enter through an entry of cannabinoids not registered in the country.

This is how they were, under the authorization of a doctor and obviously with the endorsement of the Ministry of Public Health, there were patients in Uruguay who were entering cannabidiol for treatments here, either for epilepsy or for other ailments.

The reality is that this is changing and in the last month, the Ministry of Public Health informed patients that it will no longer allow the entry of cannabidiol, because it is registered and for sale in a pharmacy in Uruguay. It would no longer be within this non-registration qualification. That generates a change here, which has not yet been manifested, they who last month could import under this mechanism of the entry of unregistered cannabinoids and by this month they would no longer be able to do so.

That changes the rules of the game a bit for Uruguayan patients, there were many who still imported it and causes them to have to turn to drugs sold in pharmacies, which can raise the costs of treatments.

An encouraging news is that this same company, RAMM Pharma, would have available at the end of the month, authorized for sale in the pharmacy in Uruguay, a new product that would have CBD at 10%. I would call it Xalex and it is a product that will lower the costs of treatments here and also be able to export it later as compassionate use, or as pharmaceutical quality for other countries.

These products, it is interesting, because in Uruguay it is very important, they are products derived from the plant directly. CBD is extracted from the plant with pharmaceutical quality and would allow the first exports of medicines to Uruguay. This is something very interesting.

Alfredo: Mercedes, if a patient needs a medicinal product with THC, how does he do it?

Mercedes: In Uruguay today, there are no medicinal products with THC available for sale in the pharmacy. This is one of the complex issues in our regulation, partly for different reasons. In principle, the past government, no matter how much it gave licenses for psychoactive crops for medicinal use, in the domestic market CBD was always talked about or always promoted as a medicine.

THC productions really, today, have only been exported, let's say, they are not being consumed internally.

Mariela: Alfredo, maybe I can add there-

Alfredo: Go ahead.

Mariela: - that, according to national regulations, to the extent that there is a national product, as is the case of these mentioned by Mercedes, such as Epifractán and then some more will appear, containing CBD, it would nullify the possibility of importing unregistered products from abroad, as are most of the others.

It does not, of course, nullify the possibility of registering a foreign product as a medicinal, pharmaceutical product. That hasn't happened, we don't have a registered foreign product, but it could happen. In the case of drugs with THC and CBD, a formula that is not registered here yet. Eventually, the rule would allow that if a doctor considers that it is necessary for a patient to consume a product that has a certain percentage of THC included in its formulation, it could be imported for compassionate use, as long as there are no national products that contain it. That is a bit of the criterion.

The conditions are given, there is nothing that prevents the registration of medicinal products with THC, it is to give hope that yes, that in the next few times, as there are national products, that will happen.

Lucia: Exactly. As Mariela says, once a registered product with such a composition exists in our market, the compassionate use route could not be used, which would be an exception.

For patients who require products that are not in our country, because as you already know, cannabis as a medicine is prescribed specifically for each patient, it is a specific composition, depending on their tolerance, their ailments. In many cases, compassionate use will have to continue to be required, and this is done by means of a prescription and an endorsement by the Ministry of Public Health, in order to carry out that import, only for that patient.

Alfredo: Yes, go ahead Mariela.

Mariela: Last thing, let's put aside, too, the interest or growing interest in veterinary drugs, veterinary medicine, especially for children and animals. In this case, the medication records must be made at the Ministry of Livestock, at the General Directorate of Livestock Services. It would be basically the same procedure.

Alfredo: There is a question precisely about this that I imagine applies to both veterinary and human use products. Someone asks if clinical studies are already necessary to verify safety, efficacy, or only stability studies to be able to register them.

Mariela: Sorry, the vets?

Alfredo: Both.

Mariela: It's that products for human use have different requirements than products for veterinary use. Specifically, the optimum would be to have clinical studies, but I believe that this is the way to go with the Ministry of Public Health to have ad hoc requirements, or those specially designed for this type of product. In the case of veterinary products, the consultation corresponds to the Ministry of Livestock.

Alfredo: Lucia, did you want to add something?

Lucía: In the case of products for human use, whose registration is with the Minister of Public Health. Today there is no specific channel for cannabis products, so those products made with cannabis enter through it through the lane of the rest of the products, be it pharmaceutical or vegetable specialties. As Mariela said, the ideal would be for a specific pathway to exist, since they are beginning to be studied and there are no clinical studies as advanced as perhaps for other types of substances.

The Ministry of Public Health does require certain tests and a certain level of clinical studies for the registration of its products.

Alfredo: Before moving on to exports, we cannot put it aside, the last thing regarding the local market and I see that there are also a couple of questions in this regard. It is a cosmetic issue, we already said that there are a couple of registered products, but also the use of cannabis in food. There is something in Uruguay, but very little, right?

Mercedes: Yes, as of today the only, let's say, product of the food sector, would be a yerba mate, which has CBD, exactly, there you are taking one. It is a classic product in Uruguay, because yerba mate is widely consumed in Uruguay and the truth is that it is the only registered product so far. Hopefully in the future, really, more can be registered, because for an animal protein exporting country, actually having high-quality vegetable protein sources could become a very interesting niche for the agro-industrial development of our country.

Alfredo: The Ministry of Public Health depends again, right?

Mercedes: Things that have to do with human consumption, yes, and livestock of course, too.

Lucia: The good news is that in January of this year the hemp seed protein was added to our food product, to our Bromatological Regulations, so we hope that foods with this protein will begin to be seen.

Alfredo: You will clarify just in case-

Mariela: We have both available, grain or seed oil and the protein derived from that oil, that pressing, but it is grain.

Alfredo: Today the CBD products, those are all under medical prescription, they are not like food, right?

Let's move on to the topic of exports, otherwise the webinar is going to end and we don't talk about it and it is the topic of the moment in Uruguay. Uruguay is news with this too, internationally.

Doing a little review, the first significant exports began last year, about the end of last year, especially when in October, Fotmer, a company that grows psychoactive cannabis in Uruguay, made a very large shipment to Portugal. To date, being the last known shipment in May, Fotmer has already exported almost 3,000 kilos, mostly to Portugal and is the only company that so far has managed to export cannabis with a high THC content.

As for what has to do with hemp flower, the first shipments of samples will have been made before, but the first significant ones began a couple of weeks ago and at least until last Friday, only two companies were those that managed to make shipments only to Switzerland for about 500, 600 kilos.

Obviously this generates a lot of enthusiasm, that doors have been opened for Uruguay and there is also a lot of talk with the Government about facilitating these exports. I'm leaving you two questions and see how you want to answer them.

The first is, why was it not continued or why is it apparently no high-THC cannabis being exported at this time since May?

The second is, why did the hemp ones just start now?

Mercedes: I take the floor.

From the Chamber of Medicinal Cannabis Companies, in fact it is one of the issues that we are working on precisely, in these meetings that I mentioned that we have had with the presidency, to promote the development of this sector. There are different characteristics from the regulatory point of view, which have allowed this type of thing and have also blocked, let's say, this type of issue.

On the one hand, the exports that were made, as you said, of medicinal cannabis by this Fotmer company to Portugal, were like a relaxation by the Ministry of Public Health at that time for that company and today what is happening is that The regulations are being applied as is and therefore these exports today would not be able to be made so simple.

There is a very specific issue here, which has to do with Decree 46 of 2015. Even in article 46 of this same decree, something important to emphasize, that the regulation, this decree preceded the practice of exporting. It is a decree that was first regulated and later, when there was no export market. Now, given the characteristics of the international market, what is happening is that this decree would be blocking the activity.

The Government undertook to make modifications to this decree and also to the industrial hemp decree, to make it more flexible and allow the exports of these products.

That has to do with the issue of the medical use of Fotmer, then Lucia can say more about the specific regulatory issue.

Basically Decree 46 says that the Ministry of Public Health requires the efficacy of these products to export them for medicinal purposes and the country of destination where they go does not request it, why would the Ministry of Public Health be asking for the efficacy of a product when the destination country is not requesting it? This efficacy today is very difficult to prove for medicinal cannabis products, therefore our own ministry would be blocking the possibility of export.

This is the key point, this modification will allow companies not to have to prove that efficacy and that they can export, which will depend on the acceptance of the regulations of the destination countries where the export of this medicine goes.

Regarding the issue of hemp flowers, in recent times, something very important, the Swiss market was released for non-medical purposes. This occurred because in May and June of this year there were agreements between the Ministry of Livestock, the Ministry of Public Health and the Presidency. It was also the confirmation of the local Swiss regulations, by the Uruguayan ambassador to Switzerland, who played a very important role, Alejandro Garofali, in this matter. This allowed the opening of the market for non-medical flowers to Switzerland.

This company, the company that made the largest export now, which has appeared in all the media that plan, exported flowers of two varieties, they also requested authorizations, for more varieties, but for now they have exported two and are exporting approximately two tons per week, would be the plan.

As of today, Monday, let's say, they have already sent more than three and a half tons, and this Thursday another three and a half tons would be completed. By the end of this week we would have more than seven tons of flowers for non-medical use exported to Switzerland, which makes it one of the obviously largest exports, at least for the world and obviously for our country. This company has also authorized 14 tons of flowers and 20 tons of biomass, we hope that in the coming months these numbers will increase and that all these shipments will be completed, let's say.

Something to emphasize, in terms of the industry for Uruguay. Production costs in Uruguay are lower than those of other countries and there are also few countries in the world that allow the export of flowers. Uruguay really has an advantage in this regard compared to other countries, for example Colombia, which does not allow the export of flowers, but only extracts. In addition, these flexibilities or these changes in the decrees will speed up the processes.

For companies that are already working in Uruguay, a very important opportunity really opens up.

Lucia: Complementing what Mercedes said a bit, why now? As she rightly said, markets have opened in which the State was working. One of them is Switzerland, they are also working on the opening with the United States.

On the other hand, with regard to the export of cannabis for specific medicinal purposes, what happens is that a restrictive interpretation of our regulations is being applied, Decree 46, which is a regulatory decree referring to medical and scientific cannabis, has a prohibition on foreign trade, which refers only to cannabis for medicinal purposes within the categories of plant specialty and pharmaceutical specialty.

These categories are categories within the Ministry of Public Health, which in turn have their requirements for registration. What happens is that without prejudice to international regulations, which Uruguay has ratified, in this case it would be the Single Narcotics Convention in 1961, which establishes certain requirements for foreign trade. Uruguay adds other internal requirements by categorizing medical cannabis into these two categories, so to speak.

What we have also been seeing is that lately, the latest regulation regarding medical cannabis, which was published now in January, was promulgated in December and published in January, which declares access to quality medical cannabis in Uruguay of public interest. , expands these categories of medicinal cannabis products, incorporating others. It could be interpreted that indirectly the State is allowing, because otherwise this new norm would not make sense, that medical cannabis can be registered in those others and therefore that it can be commercialized.

Unfortunately, this law has not yet been regulated and as of today it does not specifically provide articles regarding foreign trade. What we do hope is that with this commitment of the Government to improve regulation on today's market and on scientific advances, work will be done for coherence and to make the requirements more flexible, either through the regulation of this new law on access to cannabis. medicinal, or by direct modification of Decree 46.

There are several paths, but it is very important that this has been recognized and that work is being done to improve processes and the market. It is not less than it has been said that they want to boost the medical cannabis market at the meat level. I don't know if everyone knows, but in our country there are more cows than people. So if we put that into perspective, I think it's a very good thing to look out for.

Alfredo: Simplifying then, the objective is that medicinal cannabis products can be exported, from the flower, or manufactured products, that do not necessarily have to be registered in Uruguay or that a registration is allowed in new categories that do not exist today and that make more flexible that record, right?

Lucia: Exactly.

Alfredo: As long as that does not come out, the option seems to be limited to the export of non-medicinal cannabis, but to comply with international drug control conventions, these cannot be psychoactive and that is why the export of hemp is happening now. to Switzerland.

Mariela, do you want to add something?

Mariela: No, I am confirming everything you are saying [laughs].

Alfredo: Let's see, time issue. Obviously none can speak on behalf of the Government, but what do they estimate? Weeks? Months? End of the year? Someday?

Mariela: I estimate that in weeks we will have all the four or five months of suspension, of the authorizations of the IRRCA, they will be resolved in the next few weeks. The board of directors has already been appointed since last week-

Alfredo: With that Mariela, sorry to interrupt you, what you mean is that new licenses are being granted, for example, and other types of permits that have been stopped in recent months.

Mariela: Of course, all that are pending, because what happened with the change of government, that the board of directors is appointed by the representatives of the competent authorities. Until last week we did not have a new board of directors, the whole effect of the pandemic and the prioritization of other activities led to a lot of delay in the appointment of the board.

As it is the board of directors of the IRRCA, which grants the licenses, many licenses for research and development, cultivation, psychoactive, not psychoactive are pending.

Now shortly we will have a large number of licenses granted. Also, as a side effect of this signal that we have managed to see the circle close from licensing, growing, harvesting to commercialization, there is now obviously much more interest in investors. It is clearer where you can go, what doors are opening.

There are many expectations. Initially, it was not known what the new government's position might be on medical cannabis or recreational cannabis. It's already pretty clear that they are pushing it.

On the other hand, it is expected in the coming months, already prior to the spring-summer sowing, that there will be a large number of new licenses requested. So, both the IRRCA and the Ministry of Livestock already expect that they will have many more license applications to process in the next three months.

Mercedes: Speaking a bit about this, about the new authorities you mentioned, Alfredo. In Uruguay we are really at an important moment, as Mariela said, we are looking forward to the development of the sector. Beyond the regulatory changes to promote the development of those companies that already exist, as we mentioned, we have 120 tons ready to export.

The government committed itself to the companies, to really facilitate these paths and allow the sustainability of the sector itself. Actually the statements of the deputy secretaries of the presidency or the president of IRRCA have been to promote the development of the medical cannabis and hemp industry, strong.

As Lucia said, compare it with the meat industry, which is one of the most important industries in our country. Even government economic advisers have mentioned it as the agricultural industry par excellence of this century.

The state agency Uruguay XXI, has analyzed the entire sector and has mentioned it as that it could become the first agro-export item in our country. All this indicates that we really are facing the most important window for the development of our industry.

It is also interesting to mention that these new IRCCA authorities, who have now run for office and now the board has been appointed, that they will begin to be able to sign these new licenses, has among the representatives– The IRCCA is composed, for those who do not They know, by representatives of ministries, the Ministry of Health, the Ministry of Livestock, the Ministry of Development, but also the Presidency and the National Secretariat of Drugs.

Participants from the Ministry of Health and Livestock have as alternates two undersecretaries from these ministries. This really makes it very clear, it is a very clear message from the authorities, to really commit to the development of this type of sector, for example, never has the IRCCA directive had so much power at the hierarchical level. Having two undersecretaries on the board indicates that the authorities are really going to be above the development of the sector, unlike what it was, for example, at other times, where there was not so much political will for this.

So from an industry point of view, we are pleasantly surprised by these new authorities and we really hope that this will help and promote our development.

Alfredo: We are running out of time. A few last words of a few seconds, Lucia and Mariela?

Mariela: That not everything is rosy, that we see an interesting future, we see that we are in the right place, in Uruguay, but obviously there are a lot of challenges ahead from a technical point of view, technologies applied to cultivation, extraction, industry, records, scientific information, not to mention the banking system.

That not all the game is played in Uruguay, as you started by saying, we are a country that looks outside, we are agro-exporters, our internal market is quite small. Investments come when you can export. Everything does not depend on us, it does depend on how it evolves in the destination countries, the requirements, the opportunities and the possibilities for development at a global level. We are directly impacted by how it is playing in other countries as well.

Alfredo: I think that is a good point Mariela. What is being said today from Uruguay, that this is going to be like meat, reminds me a lot of Colombia six, nine months ago, where the industry said cannabis exports were going to be like petroleum. This is how all Latin American countries are, thinking that exports will be huge.

Undoubtedly there is a very large export potential, I do not want to minimize this possibility, but I also believe that you have to be a little careful with the communication that is made, because I already have friends, acquaintances saying to me, “I have a little field, I want to plant marijuana and export it as medicinal to Germany. “ Good luck with that, it’s not that easy.

In years of development of this industry in Latin America, only one company in the entire continent has just achieved GMP certification, of good manufacturing practices, by an agency of the European Union, which is necessary to export medicinal cannabis value added products to Europe.

With which, without a doubt, it seems great to me that the Uruguayan government wants to promote this industry and facilitate exports from the Uruguayan side, no doubt, but no matter how much the president of Uruguay says, “Export what you want, where you want”, it depends on the destination country as well. Complying with the requirements of the country of destination, I would say that it is an even more important step than making it easier and easier to work from the Uruguayan side.

I think you have to take into account, not only what can I plant, what license can I have and then see where I sell it, but rather start from what I want to sell and then go back to see where I grow it and how .

Lucia, a few last words.

Lucia: For my part, I totally agree with all of you. There is much to do and on the regulatory side, we are confident that we have a broad framework that allows us to develop many activities, like any new industry, there is new regulation that will have to be strengthened. We hope that it can be up to the task and accompany the development of the industry as the law has to do in all areas.

Alfredo: I really appreciate all three of you for having participated in this webinar. My colleagues are going to kill me, I have to close down because they won't let me go on for more than an hour, but the subject goes a long way. On the web page where the hearing was registered you can find the names of the panelists.

I hope that this exchange has also been interesting for you, on the most Uruguayan issue among us and not always that they are binary in which Uruguay is compared with other countries and others, but rather speaking within Uruguay. Thank you very much and until next time.

Mercedes: Thank you very much.

Lucia: Thank you very much.

Mariela: See you later, thank you.

Alfredo: Bye.

**This transcript is a translation from the Spanish language and could be subject to some involuntary interpretation errors. Any discrepancies or differences in the translation are not binding and have no legal effect for compliance or enforcement purposes.*

