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THE START OF A NEW INDUSTRY: UPDATES AND OPPORTUNITIES IN SOUTH AMERICA'S PROMINENT MARKETS

WITH

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Viviane Sedola
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Alfredo Pascual: Welcome to this webinar, which will be dictated in Spanish. But first, a few words in English to let those of you who don't speak Spanish know about this. Thank you for being here, this webinar will be in Spanish only, and the recording will be in Spanish also, but we will have an English transcript available. Switching back to Spanish, I'm very happy to be able to do this webinar with three amazing Latin-American speakers from Uruguay, Brazil, and Colombia.

First, I must clarify that I am recording this video after the webinar because, unfortunately, we could not record the first part. Due to technical issues, only the second part of the webinar was recorded, so now I'm doing a small introduction of who the panelists were. Then we can continue recording what we did manage to get.

So, with me today is **Martín Rodríguez**, who is the Executive Director of IRCCA, the Institute of Regulation and Control of Cannabis in Uruguay, also known as the government cannabis agency. Thank you very much for being here to talk about Uruguay.

We also have **Viviane Sedola**, who is the CEO of Doctor Cannabis in Brazil, and an expert in everything that has to do with what is happening with the cannabis industry in that country. Thank you very much for being here with us today.

Finally, **Julián Wilches** is the Director of Regulatory Affairs and co-founder of Clever Leaves, an international cannabis company that mainly operates in Colombia. He will speak mostly about cannabis in that country.

This recording ended to start broadcasting the webinar. Lastly, I wanted to let you know that we have just created a LinkedIn group for all those interested in continuing this conversation. It's called "*Marijuana Business Daily en Español*." Feel free to comment there, ask more questions, and you may even find some of the panelists there to contact them directly. We had over 100 questions, which obviously couldn't be answered in one hour.

But hey, it is great that there is so much interest in this fascinating industry in Latin America. We look forward to continuing the conversation in Spanish. Without further ado, I leave you with what we managed to record from the webinar. Thank you.

Martín Rodríguez: Products with CBD as an active ingredient, within the logic of unregistered products or passive use, depending on what the different countries call it, but one company has already managed to export dry cannabis flowers for medical use to Australia, Israel, and Portugal.

In this second case, I am always referring to flowers with a high concentration of THC. These are the first steps of foreign trade activity with Uruguay as the country of origin, which I think is a good omen. From a regulatory standpoint, it is very challenging because, as Julián said, the regulatory landscape, the international regulatory landscape, is very diverse.

I think that companies spend a lot of energy trying to understand how these channels work, what the regulatory chains of authorization are, and the logistics associated with the different possible types of commercial activities. If entrepreneurs start focusing on learning the particularities of each regulation and the requirements for the different markets and start developing and systematically improving their performance, there may be better opportunities out there.

Uruguay is a small country, with a society of less than three and a half million inhabitants, so both local and foreign entrepreneurs who come to Uruguay to develop their projects with cannabis usually have an eye on foreign trade developments. These are a challenge, clearly.

The same challenge is present in the local market, as it is small. Some products with CBD as the active ingredient are already sold for medical purposes in the pharmaceutical network and with a doctor's prescription or a normal prescription.

Some cosmetic products that include the same active ingredient have been developed. There is a company working on the development of medicines with CBD for veterinary use. We also know of licensed companies that are already working on these types of products or companies that are requesting a license. These include very interesting and diverse value-added products. We will surely be seeing their placement in the international market and, hopefully, at the local market soon.

Alfredo Pascual: Sure. There is a very good question that applies to what you were saying, Martín, and that the others can also answer because it applies to all countries. How do you see the development in terms of the sector's legitimacy vis-à-vis banks? I think that this has been an issue in Uruguay and Colombia; Viviane can tell us if in Brazil also.

Do you want to go over what happened in Uruguay with the banking issue? And what is the situation like today?

Martín Rodríguez: Yes. Basically, what has happened is that companies have found difficulties in accessing financial services from the very beginning. That directly translates into operational problems for the company; even receiving international investments is hard. A financial system channel has been demanded, of at least visible efforts for building it.

For example, in Uruguay, a group of pharmacies had to withdraw from the system of selling cannabis for non-medicinal use because the banks had issued an ultimatum to them directly. They couldn't continue their activity with those banks unless they withdrew from the sale of cannabis.

We feel this is a huge problem and a paradox, too, because this restriction is mainly the consequence of the extra-territorial influence of the federal regulations of the United States based on the necessary connection existing between the banks working in Uruguay with their correspondents in that country.

This, on the one hand, limits the possibilities of action of the national administrations. In the case of Uruguay, different delegations of our National Government were reminded of a meeting between the president of the Central Bank, the entity that regulated our financial system at that time, and the president of the Office of National Drug Control Policy in the United States. He also went to Canada to figure out how companies there were accessing financial services.

The truth is that it was difficult to transfer the different initiatives carried out there, among other things, because much of the activity in the United States took place through state-level financial institutions. In Canada, it was an agreement between Canadian banks and their correspondents in the United States. The connection between the two markets and the weight of the Canadian financial system in the United States is also very relevant.

We were trying to find other solutions, but they were not always easy to apply to our reality. In summary, it is still a problem. The discussions in the US Congress are of interest to all the jurisdictions outside the United States working with these issues.

It is to be expected that as this situation normalizes and the stigma attached to this activity is removed, other alternatives may also emerge. However, today it is undoubtedly a problem to attend to.

Alfredo Pascual: Julián, is it like this in Colombia? Anything to add about the issue with banks? Also, Julián, I have a rather specific question that came up several times. Do you think Colombia will allow flower exports anytime soon?

Julián Wilches: The situation with the banks is basically the same as in Uruguay, but I would like to add that it also happens with the airlines. It happens with the logistics operators, the suppliers, and the other countries that don't trust supplies from Colombia.

The question usually is, is there good regulation? The answer is yes. Can the level of quality required by other countries be achieved? Yes. Is there a good supply chain? Yes. This is basically about building trust.

The way to solve the issue with the banks and the others I have mentioned is to go to them, introduce yourself, and always handle things honestly and build trust. It is a relationship that needs one to go step by step for it to start working. We are opening a new industry, and that requires us to do these things. It is like getting to know your neighbor; you go over and introduce yourself. Then, you start sharing things over time. Then you become friends and end up having BBQ's or whatever. You become great friends.

Long-term relationships have to be the way to go about when getting banks on your side and opening new channels because, if you try to solve something in the short term but do damage in the long term, you end up with solutions that do not help the industry.

Regarding the dry flowers, Alfredo, I would say two things. First, medicinal cannabis cannot be sold as the solution to all problems, neither financial nor health, but there is enough evidence to confirm that it works for some pathologies. It has a very positive economic effect, but it is not possible to speak of these astronomical figures that one sometimes sees in some studies.

The same happens with the dry flowers. I believe that if Colombia had the opportunity to export dry flowers, it would be a great challenge. The markets are going to require certifications of good agricultural practices and manufacturing practices, and accessing these types of certifications is very complicated. In other words, that would require a lot of work, a lot of discipline, a lot of investment, highly-qualified teams, training, and documentation.

I believe there is an alternative, but we must be careful not to assume that this is the way to do, for example, crop substitution. These crops require technical treatment, with good infrastructure. Do not fall into that trap or that false promise that this is the solution to all problems.

Some are in favor of allowing the export of dried flowers from Colombia; some resist that idea. In any case, the market is advancing in favor of standardized derivatives with stability testing, which is easier to control and more scientific. Those are the two positions.

I believe that it is something that even the government has considered. I cannot speak on behalf of the government. Still, I believe that question has come up, especially in the context of reactivating the economy once the COVID crisis is over. Still, there are many different views on the subject.

Alfredo Pascual: Vivi, switching back to Brazil and in the context of COVID, someone asks if you think that this could lead to protectionist measures that, for example, allow cultivation, something that is still not regulated in Brazil. Do you think that in the short term we could see some positive measures? Not that they enable cultivation specifically but give any indication that it might be possible in the future.

Also, there are a couple of questions, Viviane, that talk about the role of NGOs in Brazil. If you could please expand on this, what role have they played in regulation so far, or what role are they currently playing?

There is also another question about Brazil. Do you think it will become an oligopoly of large corporations, considering the very high-quality requirements, or is there also room for small companies in the market?

Viviane Sedola: I'll need help to remember them all, but the first question--

Alfredo Pascual: I'll help you remember them.

Viviane Sedola: [laughs] I don't think COVID is going to promote any protectionist measures. In fact, the issue that is being treated in a special committee of Congress is precisely cultivation. I think the congress people who are part of the committee are very inclined to make that move. In fact, they went to Colombia at the end of last year to see what was done well there in terms of regulations.

I think it is great that we already have other very close examples, such as Uruguay and Colombia. I would like to say that what I love about the regulation of Uruguay, the work of IRCCA, is harm reduction, which is very important, and it is totally ignored here in Brazil. They think of public health as a whole.

I believe that we are going in that direction. I do not think that it will come out through ANVISA, because the regulations for cultivation come from the legislature, and it will not come out anytime soon, nor will it be rushed by COVID. I do not believe that will happen. Your second question, the last one if I remember was about:

Alfredo Pascual: Two questions that are connected. A couple of questions mention the role of NGOs in Brazil. What role have they been playing in the regulation of the industry? Perhaps it is worth mentioning. Another question is about the very high-quality requirements necessary to register products in Brazil. In fact, only one single company has achieved this under the new ANVISA rules. Do you think that this can become a monopoly or oligopoly, or is there also a chance for small businesses to thrive?

Viviane Sedola: NGOs were fundamental in this process. As I said, they acted as mothers in 2014. That happened throughout the world, but in Brazil, they organized themselves as associations, that is, NGOs. Today, they are fighting for self-cultivation. So, I would say that they did not have a role or at least were not contemplated in the regulation process. They are not interested in that issue.

On the contrary, they are very unhappy with the current situation and say that we are probably going to have a monopoly. That is what they say about the associations. They continue to fight for theirs; they continue to press for more exceptional authorizations for self-cultivation, and they are growing.

The legislature has a lot of pressure to create rules for cultivation. Self-cultivation too, but I'm not so sure that it will happen soon. Hopefully, it will. I don't think that this creates a problem for the market. Uruguay and Colombia are good examples of self-cultivation. I think it has been regulated in Colombia since 1996 if I am not mistaken. I don't think that it will cause problems for the industry.

Regarding the possible existence of an oligopoly, I think that what ANVISA has created is not out of this world for a pharmaceutical company. If any pharmaceutical company wants to enter the cannabis market, it is very simple because licenses, production processes, and quality controls are all things that they are very used to working with.

However, the cannabis market in the world was stronger in another area: food. As it was the case in the United States, for example, and entering that market was not that easy. What happened was that in Brazil, there was a pharmaceutical company that had already been tempted by the subject; it was already doing clinical trials.

Speaking about Congress again, when I was there in December, the CEO of the company that now has its product registered and already announced that they were doing clinical trials was there. They've spent the last two or three years doing clinical trials, which is the normal procedure regarding pharmaceuticals.

I think that is why they are more advanced. Still, there are other companies around the world which I have spoken with during the last few months that are ready, that already have stability studies for Brazil, for the IVB zone, and also have clinical trials in the making. They are ready for what ANVISA asks for.

When one considers public health, the level of control ANVISA asks for is not that high. Of course, ANVISA has been recognized worldwide as a very strict health agency, but it is still possible to enter the market. I don't think we are going to have an oligopoly. I think that very soon, maybe even this year, we will have about two or three more products available in drug stores.

Alfredo Pascual: You also will continue to have a policy for imports called "compassionate use," right?

Viviane Sedola: Yes, we still have that policy, and I believe we will still do so in the future. ANVISA has renovated the policy last January; they tried to make the whole process of authorization and importing easier for the patients. This will still be a possibility.

I believe that the market alone will deal with this issue. Once we have a product in the drugstores with a price that is accessible to the population, importing a less controlled and more expensive product will not make sense. They will just have to get authorization from ANVISA instead of also having to pay for the product's shipping. I think that issue will resolve itself.

Alfredo Pascual: Martín, there are many questions related to industrial hemp and CBD in Uruguay, and about possible reforms in this regard.

Could you make a brief summary of how the situation is today for licensed companies to grow, using the terms that the law uses to define it in Uruguay, non-psychoactive cannabis? What courses of action do these companies have today, and what is expected to change in the future?

Martín Rodríguez: It is clearly an issue of regulations evolving and being updated. We always argue that there must be a constant adaptation of regulation policies. This is a point that I put on the list of topics to attend to.

The current situation is that companies that have registered products as pharmaceutical to supply the local medicinal market are working with imported raw material of foreign origin. That makes us all look at what the next link is, what the next step in that link of integration between agricultural and industrial activities in the country is.

About 35 companies currently have authorizations issued by the Ministry of Livestock, Agriculture, and Fisheries to grow cannabis within the line of industrial hemp, non-psychoactive cannabis. We shared the limit of 1% maximum of THC in the flower with what Julián recently explained about the Colombian regulation.

Different varieties of non-psychoactive cannabis have been registered with the National Seed Institute. Types with this limit of THC can be grown under the authorization from the Ministry of Livestock, Agriculture, and Fisheries.

What is taking place now is a discussion with the Ministry of Health, Presidency, and the Ministry of Livestock. A scheme can be defined so that the flowers generated within the cultivation of non-psychoactive plants can have medicinal uses.

Today, very few companies have applied for a medicinal cannabis license. We must evaluate the conditions so that the companies that currently work with authorizations from the Ministry of Livestock and Agriculture can find a medicinal use for these flowers.

Very soon, maybe next week, there will be advancements in this area because the scenario being built benefits new companies wanting to start their activities growing non-psychoactive cannabis flowers or its derivatives for medicinal purposes and recreational use.

Also, companies currently working with authorizations issued by the Ministry of Livestock want to switch to producing non-psychoactive flowers for medicinal purposes.

It is a very good question, and we can now guarantee that a great effort is being made to get the authorities to define guidelines, a predictable and clear agreement for the different companies.

Alfredo Pascual: Thank you, Martin. Julián, going back to Colombia and seeing we only have a few minutes left, there are some questions about the integration of farmers and communities in Colombia, which I think was one of the objectives of the law and surely is one of the things that the government is still trying to achieve, right?

Julián Wilches: Yes. I'll explain it better for those of you who are watching at home. The regulations in Colombia say that for companies that have a license to manufacture derivatives, or laboratories, 10% of the raw materials they use must come from a small or medium grower, who at the same time require a license.

I think that it has not been working as well as it should because those small and medium growers have not been able to access the cultivation quotas as this applies only to psychoactive cannabis, which has more than 1% THC. So, I think it is not working very well.

However, I also believe, Alfredo, that we cannot lose sight of the fact that many other positive impacts can be generated and have a broader impact. Let's go back to the example of the farm. There are 400 employees on the farm. Formal rural employment with a gender focus, 70% women. Imagine how that modifies the social environment in a municipality of 7,000 inhabitants. I am talking about the example of Clever Leaves, but it also happens with other companies.

Formal rural employment, while in Colombia, informality in employment is almost 90%. It's having formal rural employment focused on gender and the territory. Only 2% of the people who work on the farm is not from the three or four neighboring municipalities.

Formal work generates a better environment, suppliers, and service providers. People can access banking services, loans; women invest the household resources much better than men. There is an improvement in housing, education, health.

To me, all of this generates much more impact than having a small or medium grower. Still, we must do it. It is in the regulation, and we must find the mechanisms to make it start working.

I think that we are all committed to this cause, the government and the companies, and we must do it, but we cannot lose sight of everything else that happens and the effects that have a positive impact on the community.

Alfredo Pascual: Vivi, we have a few minutes left, would you like to make some closing comments on how you think the situation in Brazil will evolve in the coming months? A review of things to come. What we can expect from Congress moving forward, perhaps more registered products, more "compassionate use" imports.

Viviane Sedola: Yes, sure. We had a lot of improvements due to telemedicine becoming available recently; it was not regulated in Brazil. With this, we were able to continue to care for patients and reach out to those who live in regions farther away from large centers and capitals. Brazil is a continental country. More people were able to access treatment. This has been a very important development.

It seems that COVID has allowed things to go faster. It took just over 40 days for ANVISA to issue the first health authorization for a product. I myself believed that before 2021 we would not have a product. We already have one, and we have like three others waiting for authorization. A lot can happen. We must see if these other three or four products are, in fact, ready. By the end of 2020, we can expect to have fewer imports than before. You never know.

Alfredo Pascual: Meanwhile, the process of importing has become easier compared to what it was before. Today, the patient, as you say, can do telemedicine from home and apply online with ANVISA, right?

Viviane Sedola: Yes, from their homes.

Alfredo Pascual: Quite an efficient process.

Viviane Sedola: Yes. They receive the product at home. They don't have to go out at all. It's very simple.

Alfredo Pascual: The only problem is the cost. It's still too high and many people can't access these products.

Viviane Sedola: Sure. Though imported products are a little bit cheaper right now because of the pandemic, there are discounts. Access to imported products in Brazil has never been cheaper and faster than nowadays.

Alfredo Pascual: Martín, one or two minutes of closing remarks?

Martín Rodríguez: I think that this was a nice exchange, a nice example of diversity, and some common problems faced by all the countries working with this agro-industrial chain becoming increasingly complex.

I believe that in the next few weeks and months in Uruguay, we'll have a lot of interesting activities and new things to come.

I would highlight that, for example, with cannabis for recreational use, which is aimed only at Uruguayans or foreigners who have residence in the country, we are looking forward to the development of that market and the incorporation of new companies that have obtained their license to supply the market. There is a strong commitment to substitute an illegal market, and the first indicators in this regard are positive and, therefore, a good omen.

I think we should wait to see the first steps of vertical integration where the complexity of this industrial chain being installed in Uruguay is better expressed.

I would also like to highlight that the increase in licenses for medicinal purposes will surely happen. There is currently a significant number, but from what we were talking about earlier, that number is very likely to increase soon.

Finally, I would like to point out that we have two laws that were approved by our parliament, which are now in the hands of the executive power for their regulation. One is linked to the development and specific scientific research on cannabis, which will be partially public-funded, and the other is strongly oriented towards greater accessibility to medicinal cannabis products. I think there is a very interesting development horizon there.

Also, with small and medium growers, there is a process of incorporation, which is no minor thing, that will be associated with the regulation of that law approved in December last year.

Alfredo Pascual: Thank you Martín. Julián, 30 seconds. Anything else you want to add?

Julián Wilches: So many things Alfredo, [laughs] but maybe I would invite-- I imagine that a large part of the audience is Latin American. I believe that this COVID scenario recalls the need for us to work together more, form greater alliances. The industry is maturing and specializing in different links of the chain.

Building networks between different countries and between different companies, I think, is one of the solutions to overcome this crisis and finally give patients in our countries what they want and conquer those markets like Europe, America, Australia, et cetera.

Alfredo Pascual: Thank you, Julián. Thanks to all of you, especially Viviane, who is speaking Spanish instead of Portuguese, and that is no small feat. I think her Spanish is even better than ours.

Alfredo Pascual: Above all, thanks to the entire audience that joined. There were a million questions to ask and to answer. For that purpose, we have also just created a LinkedIn group that we call *Marijuana Business Daily* en Español. The idea is that in this group, we can exchange questions and opinions about the cannabis industry in Latin America.

I think Lidia just put up the link in the chat; you can find it there. If not, you can find it when we send the link with the video of the recording of this webinar. So, in one way or another, we will continue with the conversation, and we will surely have more experiences like these in the future.

Thank you all. I'll give you a moment to say goodbye.

Martín Rodríguez: Thank you very much. It's been a pleasure talking to you all.

Julián Wilches: Thank you Martín, Viviane and Alfredo, thank you very much, and thanks to MJBiz for the invitation. Thank you to all who tuned in. I send my love to you all.

Viviane Sedola: Yes, it is a very big opportunity to speak in Spanish about Latin America. If anyone happens to do business with cannabis in Brazil, we can help. It's been a pleasure being here with all of you. Thank you very much, and thank you, Alfredo.

Alfredo Pascual: Great, everyone. We'll see those of you who are interested in continuing this conversation on LinkedIn, if not, till the next webinar.

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