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# REGULATIONS AND OPPORTUNITIES IN KEY LATIN AMERICAN MARKETS: COLOMBIA

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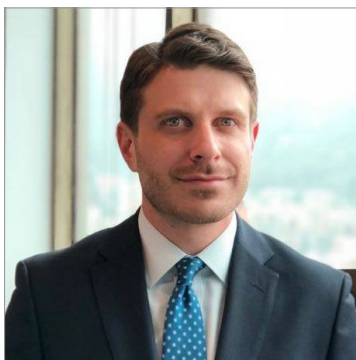
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## MODERATED BY

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## REGULATIONS AND OPPORTUNITIES IN KEY LATIN AMERICAN MARKETS: COLOMBIA\*

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**Alfredo Pascual:** Hello. My name is Alfredo Pascual, I am international analyst for Marijuana Business Daily. I welcome you to this second webinar on Latin America that we are doing this week. Yesterday we had a very good panel on Uruguay, today Colombia, tomorrow we will continue with Brazil and finally, on Thursday we will finish with Peru.

As you obviously realize, we are doing these webinars in Spanish, because it is important that the industry in Latin America begins to speak more in depth about how to develop the Latin American markets and not that the conversation is always directed toward the North American investor.

To do this, for example, we created a LinkedIn group called Marijuana Business Daily in Spanish, where we could exchange industry topics. Starting with Colombia, it is a great pleasure to have the three panelists that we have here. In alphabetical order I start with Ana Serrato, she is the Pharma Manager of Clever Leaves in Latin America and obviously she is going to give us her insights as an expert.

More than anything about the issues that have to do with the different products that can be registered, commercialized in Colombia and the region and commercial opportunities. So Ana, welcome.

**Ana Serrato:** Thank you Alfredo. Nice to join you today. We hope to share with everyone the experiences and knowledge acquired during this time.

**Alfredo:** Thank you Ana. We also have other regulatory experts, Camilo de Guzmán. He works for Natuera. Camilo, it will also be a pleasure to have your insights and also at the end of the session we want to talk a little about the changes that may come at the regulatory level in Colombia and how they can impact the industry.

**Camilo de Guzmán:** Hello Alfredo. Greetings to Ana and César. A pleasure to share with you in this panel and a special greeting to all the audience.

**Alfredo:** Thank you Camilo. Also, we have César Gutiérrez, CEO of Bastion Capital Advisors. Let's start with Caesar, now I'm going to say why. Caesar, are you around?

**César Gutiérrez:** Yes. Alfredo, thank you for the invitation. Hello Ana, Camilo and all the people who accompany us. What a pleasure to be here.

**Alfredo:** Thank you César. And everyone, please, those who want to ask questions, can do so at any time using the Zoom option of Q&A, no need to wait until the end.

Now I am going to say what this session is not going to be. It will not be about what has already been talked about a thousand times, which is to explain that in Colombia one can apply to obtain the license, A, B, C in the modality of X, Y, Z. We are going to start talking about a topic, which is an issue at the moment for, I would say, the vast majority of companies that are active in Colombia in some way or another and that is, how to get financing.

There are several positive news from Colombia, but also others that, suddenly, give rise to concern for many entrepreneurs. For example, large international companies in the industry that have announced that they will no longer make large investments to set up in the country and that they prefer to follow a model of less capital investment.

Also, from what you hear talking to local businessmen. The situation for the small businessman, who has his license, but still does not have the necessary capital to develop his project, has become much more difficult than a while ago, without a doubt.

César, starting with you, I put you in a role perhaps a little difficult to start the conversation and it is, imagine that a small businessman or even medium-sized businessman is listening to you, that what he has are licenses, land, a very nice PowerPoint presentation but still couldn't get started with much more than that, what should he do?

**César:** Thank you Alfredo. Actually, as we all know, this has been an issue that has impacted all companies. In general, small entrepreneurs now, after there has already been an experience with companies that started their processes, have a much bigger challenge in this regard.

We understand that, for example, in Colombia banks are not yet ready to finance small entrepreneurs, which means that what remains as in any other industry, the venture capital market, starting with friends, with family, then with angel investors, as it is known in the investment world.

As the project progresses and is able to show milestones that are attractive to investors and the risk is diluted, it is most likely that it will reach capital from a venture capital or a private equity fund, not necessarily international but local, who are also interested in the industry and who are also learning like all of us what are the advantages and what are the attractions of being able to enter this industry.

This to speak on the capital side, but also today there is much talk of private debt, not debt that we typically know that banks can help us or help entrepreneurs, but private debt with specialized debt funds that have. They have been entering the Latin American industry that they have been understanding and that they have also been making certain investments with a completely different risk.

When we talk about capital we all know that the risk is much higher, there is no collateral and the profitability is also tremendously high. When we talk about debt, what will happen is that everything that the fund is willing to put into a company or all the cash flow that it is going to put has to be backed, let's say there is a good mix to decide, then the Entrepreneurs have had to invest a good amount to be able to support that debt that they are going to acquire.

Without a doubt, the issue of financing is a challenge in this industry particularly, but also because of what has been happening in recent times with the pandemic issue, although there were many interested funds, international funds interested in reaching Latin America clearly what has happened has been delaying a little both the interest of investors and the development of companies and the development of those milestones that are important to show investors.

**Alfredo:** César, I'm going to come back to you with the financing issue, but I want to go over to Camilo a bit. César mentions milestones that can be shown to begin to develop confidence among investors that what the company has is not just a piece of paper. Camilo, what are those milestones that companies in Colombia can show?

**Camilo:** I think you have to focus on looking beyond licenses. Licenses are the runway, but they do not guarantee that you will have a good flight. Without them you cannot start the plane, but you have to go further. I would give the following practical advice to companies that are venturing into this and the first is to make a realistic economic model. This industry is very dynamic and prices have changed enormously, drastically in the last two years.

I remember two years ago, for example, that we were doing a study with Fedesarrollo, a kilo of CBD isolate could be in the \$ 7,500 and today we see that a kilo of CBD isolate could be in \$ 750. These prices fluctuate from month to month, but the oversupply in the market and the commoditization of these products has generated pressure where it is important to have a realistic financial model before starting the business to ensure that it will be sustainable.

Number two would also invite you to consider certain regulatory milestones that are necessary to access different market categories. There are market categories such as bulk products, that is, distillates, refined oils, isolated, but there are also finished products in the areas or in the categories of cosmetics, topicals, food and beverages, medicines and nutraceuticals or phytotherapeutics.

Each of these market categories has a different regulatory complexity that must be mapped very well not only in the country where it is produced, but also in the country where it is intended to commercialize and this in order to estimate a time to reach the market. If, for example, a category has a regulatory complexity of 24 months, that must be taken into account in the financial model.

Third, I think it is very important to have some corporate law milestones that give investors peace of mind, prepare for a small investment at the startup level, what are my regulatory licenses? What are the real estate assets that I can have? Do I have a rental property or do I have a purchased property? How do I have structured my schedule of incentives for employees or consultants? which is important to investors.

Above all, how am I going to structure corporate financing given the challenges in banking the system? How will the money flow and how will I be able to meet my obligations? I think you have to land and go to very practical terms so as not to fall into the trap of selling a promise, without that promise being prepared to be realized.

**Alfredo:** Thank you Camilo. Ana, César and Camilo spoke of certain milestones and obviously it is not the same to export medicinal cannabis to Germany than to have the possibility of marketing a cream in Colombia, just thinking again of these companies that still do not have the necessary capital to have a truly GMP laboratory and power comply with everything that is needed to be able to export to the European Union.

What milestones do you think these entrepreneurs can think of in order to start having success stories, even if they are not exporting to Germany?

**Ana:** Yes, I really agree with Camilo on the business model. I feel that the business model is the first thing to really structure and understand what are the capabilities that each of these companies have and what part of the production chain they really want to focus on. What we have seen is that this is an extremely long production chain and several of the companies from the beginning wanted to do the entire production chain.

Now what we are seeing not only in this industry, but in other industries, is specialization. One of the big questions that these small entrepreneurs could ask them is, what part of the chain do you want to do? Do you want to do it all? Is there something that really gives you the right to win in any of the stages of the production chain and why not start thinking about collaborations? Which is one of the issues that we are also seeing that are moving a lot within this industry.

**Alfredo:** For example, what kind of collaborations?

**Ana:** Collaborations within the production chain, collaborations on the issue of cultivation and extraction, for example, collaborations on distribution and production models, we don't necessarily have to do from cultivation to commercialization, it is really understanding what part of the chain in which you want to specialize and what type of partner are with whom you would also like to start generating a network.

**Alfredo:** With specialization, César, capital becomes more accessible, right?

**César:** Yes, I completely agree with Ana in what she mentions. I believe that we have all heard for a long time about vertically integrated companies and these business models that have been successful in the United States and Canada, but I believe that it is also worthwhile that, for example, in Latin America we begin to specialize in what we really know how to do. and in what we have plenty to do.

That I think could clearly have a positive impact on the cash needs that companies are looking for, a company or a project that is looking only to expand its cultivation and have improvements in the production process is different and not think about what it also wants to have. an extraction laboratory and also wants to export and also wants to have a marketing point in Europe.

I think that there are clearly some very good examples, probably some others who have the financial muscle to do that will follow, but the whole situation has also led us to rethink a bit, as Ana says so well, from where we can really have an advantage. We at Bastion in particular are convinced of the potential of the industry, however we see that it may not be as fast as we were all expecting here in Latin America.

We are going to have to wait a little longer, we are going to have to wait for the market to really start to react. That those \$13,000 million of which we have spoken or of which the experts speak in making those market projections, are really beginning to occur, because so far they are only expectations of a market potential that can be given and we need that to begin to advance in different ways.

**Alfredo:** César, while we wait, obviously there are many businessmen who have already run out of family and friends to ask for money for the project and who suddenly, because they were too ambitious in what they thought they would be able to do, at the end of the day they are unable to show these milestones that even the minors are talking about, what is that businessman, César, doing now?

**César:** Yes, I think there are two ways. In Latin America we have not yet seen that the issue of mergers and acquisitions has started in good shape because the industry is not yet mature enough or at the point where they start buying from the small ones, but that sooner or later is going to happen, the Large producers are going to concentrate on what they know how to do and are going to start, or buy small producers, or make this type of agreement as Ana mentioned.

Commercialization agreements, collaboration agreements to enter a much more efficient production chain, but in the event that this is not the scenario of some of these small ones that have already invested, I think it could continue working with a little more patience, I insist, on the agricultural issue.

There are many verticals on the subject that can still be explored. The issue of seeds, the issue of...

**Alfredo:** Genetic registry? For example.

**César:** Exactly. Where there is still not much development, I think the potential is great and where I also think that Latin America has a very large asset. All the countries in Latin America are known precisely for having economies based on agriculture. I believe that there may also be a differentiator with respect to the other countries that are doing this in the world.

**Alfredo:** Have you not seen any projects in Colombia already working at scale operations in what has to do with the use of hemp for food, or have they?

**César:** I don't know them, at least I do.

**Ana:** No.

**Alfredo:** Camilo, you mentioned the financial part. If you want to add something, obviously welcome, but if not, I already asked you Camilo, when you were talking about the financial part, about the difficulties in accessing financial services, how does this affect the different types of companies? Does it affect the international company or the small entrepreneur equally or differently?

Are the solutions that can be found the same for everyone or does it also depend on each company?

**Camilo:** It affects all companies, depending on their size and focus in a different way, but I think it is a generalized issue. It affects when it comes to attracting investment, it affects, above all, when it comes to monetizing investment. That is, that investment in foreign currency can enter the country.

There are very strict controls of foreign trade laws and compliance requirements of money laundering laws in Colombia, which basically make it difficult to bring foreign currency if it is not done through banks, which is the only alternative there is. Without a doubt, an operation that is more focused on the domestic market may have some alternatives. Banco Agrario, which is a state bank in Colombia, has the mandate to serve the cannabis sector.

This can be a good solution for small entrepreneurs who are focused on the domestic market, on raising capital in the country and selling in the country. This solution has a very big limitation, which is that they do not have what is called a "correspondent bank" in international markets, where investors or clients can make a consignment of money to bring to the country--

**Alfredo:** In this case we are talking about 100% Colombian pesos.

**Camilo:** Yes, pure Colombian pesos.

**Alfredo:** What if this imaginary businessman was lucky, or more than lucky, successful, and got the investor from the United States, for example, who is willing to send him a million dollars or whatever he needs to set up his laboratory? How can that be done?

**Camilo:** It is an issue that must be analyzed depending on each case, but my advice would be, "Go to a good law firm, with good financial consultants that will allow you to design a solution that can allow you to bring those resources to Colombia."

They are complex waters to navigate, because depending on whether your investor is in the United States and if your focus is on the psychoactive market, you may have much greater limitations than if, for example, your investor is in Europe and you are focused on the non-psychoactive sector. Each case is different, but what I do believe is that it is good money invested in professional advice, which can help you structure a solution that meets all the requirements.

**Alfredo:** César, do you want to add something regarding the issue of how to bring money to Colombia?

**César:** Yes. The truth is that this is an issue that has affected the industry forever, it is not recent and I do not see a change, at least in the next few months. A lot of work has been done in the financial sector, as Camilo, Banco Agrario and BBVA mentioned well, conversations have also been held with Finagro, as a second-tier bank.



Even private equity funds with offices in Colombia or Latin America, but whose capital comes from the United States or Europe, have tried to find schemes that allow a flow of that cash much more expeditiously and quickly, but as well as Camilo mentions, it is something that must be analyzed in detail in each particular case.

I have had the experience of participating in some of those transactions, in which some very interesting investment vehicles have been created, but with all the rigor that both local law and the law of the country where the silver comes from requires in this regard. . In Canada there are also mechanisms that companies that have made this type of capital injection into the country have used, which I think can also be observed.

My conclusion or my recommendation in that sense would definitely be in this regard, but also in all aspects, professional support is always required in an accompaniment by experts to help them reach the desired end. Returning a little to the initial topic that Camilo commented regarding financial models, it seems to us that excessive valuations I believe that no one is buying them today.

Investors became tremendously sophisticated and knowledgeable about the industry, continuing to think that we are going to sell a project because in Latin America we are the ones who can grow the cheapest at \$ 0.15 or \$ 0.20, etc., with life margins of 80 % I think that this may be a good theory to put on the investment deck, but the reality is that no company at this time in Latin America can prove it.

The financial models, to conclude on that point, serve from a perspective such as understanding very well what the business metrics are, however, you must be very careful when you really believe what the value of a company can be given by this methodology of Discounted cash flow, I think you have to fine-tune the details a bit and understand that investors are going to take a next step, which is due diligence.

Where they are going to review absolutely all the legal, financial, corporate, etc. aspects and they are going to find perhaps certain difficulties in reaching those numbers as large as those that were seen at some time, we must not ignore that either.

**Alfredo:** Thank you César. Ana, let's move on to what can be sold. From what I understand in Colombia what is currently available to patients, in terms of medicinal cannabis, are two registered products. One is Sativex, that is manufactured in the United Kingdom.

The other available product was registered by Procaps, a Colombian company, and is a product with CBD. But in addition to the registered products that I understand require demonstrating safety and efficacy for a specific condition, Colombia has the great advantage that it also allows magisterial formulas with individualized prescriptions that they also started recently.

What is public knowledge is that Khiron is the only company that is already providing this type of product to patients and passed the first thousand prescriptions. First of all, I ask you to correct me if I made a mistake there in this description, but also to tell us a little more about the ways to get to these two types of products, whether registered or magisterial formulas, and the advantages, disadvantages, of each of these.

**Ana:** You are correct at this moment we have both alternatives and patients in Colombia have both alternatives we have the path of the magisterial formulas and the finished products. Let's start with the master formulas, the master formulas not only in Colombia, but in other parts of the world have been like the gateway to the path of finished products.

Not in vain and that is special and I want to emphasize that in Colombia, the quality that is being requested for these master formulas and all the licenses and guides that INVIMA is asking us for the BP, BPM, etc. inspections, are very rigorous for quality issues. Let's not forget that these are products that are going to patients, these are not products that are going to the consumer, but they are going to patients with specific indications. A special emphasis on the issue of quality.

On the subject of master formulas, at this time we saw a route that worked the parallel. First, the regulatory agency, INVIMA, working on the entire issue of regulations, announces in 2017 that there will be some guides, December 2019 finally the inspection guides come out and that is where that race begins a little for the whole issue of the BP, and in parallel we as an industry are standardizing processes, acquiring all licenses, all quality issues.

Defining which are those formulations that are really going to make an impact on the patient. It's nice to say that from the pharmaceutical industry point of view, four years after you get a license you are being able to offer a therapeutic alternative. Normally in the pharmaceutical industry you are spending between seven and ten years, from starting from scratch, until putting a product on the market. Really four years with some flats on regulatory issues and so on that have been working closely with INVIMA, but I really believe that Colombia is a pioneer in this regard and we will continue to advance.

That in the subject of magisterial formulas and in the subject of finished products, already within the pharmacological norms there are established and within the INVIMA if some paths are established that could speed up these registrations and we also take Brazil, UK and even Portugal as an example, which are opening some parallel paths for finished products. As a pharmaceutical industry we see that this has to be the finished product.

Magisterial formulas are an entry way, but all the research and development that we are betting on in a culture that is absolutely patient-oriented, is in finished products with a specific indication and specific compositions. To round off the idea, at this time patients have the option of magisterial formulas with an excellent quality from the hand of all medical education that surely we will also talk a little about that.

Seeing a not too distant horizon of already finished products as Procaps and Sativex did right now, also a couple of years ago in the Colombian market.

**Alfredo:** I think we lost Camilo. Ana, if I understand you well, it seems you think that for now, these two paths will continue in parallel, that of master formulas and that of finished products, but you think that the medium or long-term objective should rather be, from the point of view of the patient, more products registered for certain medical conditions.

**Ana:** Without a doubt Alfredo. What we really see is how-- Again, this is the entry point, but how should we accelerate two issues, one from a regulatory point of view and work together, as has been done with INVIMA and with the different agencies of the government. How can you work together to really speed up those pathways to patient end products?

Number two, hand in hand with scientific societies and doctors, how do we also accelerate research to have local data and our own data that also support us in those in those local registries?

**Alfredo:** Now Ana, from the point of view of the company or perhaps an entrepreneur who is just trying to see which way to go, an advantage that magisterial formulas have is that they can be prescribed, in principle, for anything, they do not have a specific disease to which they are limited. What advantage does the finished product have that it can only be prescribed for something very specific for which it was registered?

**Ana:** Actually, that is a very good question and on the subject of magisterial formulas it is something that has also been talked about, not only in Colombia, but around the world, but really the finished product what is behind it is research and clinical support from the proper molecule.

At this time, under Colombian regulations, what we are giving in the master formulas are high quality processes aligned with all GMP's, but the research data is not as specific as it can be in a finished product. The finished product continues to be the best alternative and that is why we are focusing our research efforts on finished products, being the master formulas a gateway.



**Alfredo:** César, do you want to add something there in this part of master formulas versus finished products? Camilo, welcome back.

**César:** Alfredo yes, I definitely believe that the industry in Latin America, the great beginning as Khiron already did, for example, was to enter on the side of the master formulas and I believe that evolution should be through the products of added value, understood as finished products, not only from a medicinal point of view, but also from everything that is related, such as the cosmetic issue and the issue of foodstuffs that will surely also arrive.

**Alfredo:** Camilo, we lost you for a few moments, we were in the debate, to call it that somehow, between master formulas versus finished products and I don't know if you want to add something there from a business point of view, what perspective do companies have when they face this decision?

**Camilo:** Yes, I would go back to something that Ana mentioned a few minutes ago, which is the international trend towards specialization. In that vein, I think it is important that regulation is as flexible as possible to allow companies to choose their path and choose where in the value chain they can focus. César has also pointed out that Latin America and Colombia in general have a great competitive advantage in agricultural production.

In this sense, we can see countries like Uruguay that are taking advantage of this competitive advantage to export cannabis flower, whether it is non-psychoactive or psychoactive, both as raw material to process abroad, or as a finished product for end patients.

I think that is something that Colombia is ready to give as part of the discussion of updating local regulations, especially given the drop in prices of what is the gene and all its derivative products, because although the finished products are Very interesting, they have a long time to market, as Ana pointed out. It may take four, six, or eight years to obtain the necessary permits to market a drug.

Meanwhile, companies need oxygen and need to generate income, to maintain that appetite of investors in a very complex global situation, where not only do we have a consolidation of the industry that begins in 2019 at a global level, but we also have the effect of COVID on the overall economy, causing investors to want to move their capital to safe havens and assets.

The truth is that, I think it is important to consider all the alternatives, specialization is super interesting. Colombia has an opportunity to generate added value that at this moment I do not consider it is taking advantage of, which is to develop different genetic varieties in the thousands of microclimates that exist in the country. Colombia is a country with a privileged geographical position in the Andes, they divide it into three, in an Ecuadorian context. This generates thousands of endemic microclimates and extremely high biodiversity.

Why not bet on thinking of a strategy that can also allow us to capitalize on that? As California is doing, generating an origin appeal program, for different varieties that have different characteristics.

**Alfredo:** Ana, connecting with what Camilo said about that need I imagine that also types of products that are simpler to start selling, or that require less time to obtain all authorizations, are cosmetics, true?

There is also some question that the audience is already asking regarding food in Colombia, cannabis-based foods. Also as the audience we have is from various countries and all the countries want to export, several ask how they can do to export this type of product to Colombia. There are several questions. Look, where do you want to start? César and Camilo, maybe you can start thinking about this as well.

**Ana:** On the subject of cosmetics. Let's start with that one. On the subject of cosmetics, we see extremely large differences with medical cannabis. Basically, for cosmetics, it is more a health authorization that is being given, rather than the registry as such, and we do not need all the data of scientific evidence and support, research and clinical trials, which is behind a drug that goes directly to the patient.

In cosmetics it can be a much simpler process. I am not an expert on the subject of cosmetics, but I know that it is a much simpler process. There has been a relative growth in Colombia. I focus on the second, which is the export issue. There are endless different themes there, but I emphasize two main ones. One, knowledge of the regulatory channel for both entry and exit to the countries. Two, the quality issues that the products have to meet.

Something that we have understood over time and one of the great learnings is that this regulatory route must be connected between countries, that what is allowed to take out of a country must be what is allowed to enter another country, that when I am talking about the threshold of the psychoactive, it is the same from the beginning as from the exit, that when I speak of the pesticides that a country is referring to me, I must be able to also test them in my home country.

That regulatory path, really, has a supremely detailed watermark and all teams need to rally around that to understand both entry and exit.

Not surprisingly, I go back and place a lot of emphasis on the issue of quality, because when we are looking at the different governments and the different regulatory agencies, Colombia is no exception. They are asking us to behave like pharmaceuticals. They are asking us that if we want to make a registered product and eventually want to enter the reimbursement system of the Colombian health system, we must ensure quality for these patients.

For the second export question, the two clear issues is, entry and exit regulatory landscape. Two, high quality standards of products.

**Alfredo:** César, Camilo, do you want to add something regarding this? If not, we will talk about the issue of exports from Colombia to other countries.

**César:** Yes. I just wanted to say that what-- This particularity connects very well with the interest of investors in monetizing their investment.

When we talk about the time to market being so long, what immediately translates that is that there are going to be companies in which the generation of income, profitability and cash will probably go very hand in hand with that time to market.

In that sense, that is why today one of the first questions that investors generally ask us is, "Is it already a company that is selling? How much is it selling? Where is it selling? What is the definition? Of market it has? Or is it simply making non-commercial exports or shipments, it would be for scientific purposes, and so on.

I think that this is transcendental in the sense of how I am, understanding the business model in which I want to participate.

**Alfredo:** There is a slightly funny question, but this connects with the next topic which is exports. Someone asks, "What is happening with all the raw material that is being grown in Colombia? If practically nothing is being exported, at least not THC."

I have put it this way a little funny and then we go into more detail. What is happening with everything that is being cultivated in Colombia today?

**Ana:** If you want, I can take it.

**César:** Brave.

**Ana:** Yes. At this moment for us that raw material is already being produced and now that we recently received our EU-GMP, we are already on the verge of being able to export this raw material, mainly to European markets.

We are following this raw material in 2-1, already in production, for commercial purposes, after our EU-GMP certification. Two, to continue studying and standardizing all the different formulations that we want to produce.

**Alfredo:** Would you say Ana, that obtaining EU-GMP certification by a health agency of the European Union, is today the bottleneck, let's call it more important to be able to export THC or is it one of many, And after this come other challenges ahead?

**Ana:** I think it is one of the most important milestones and more than a bottleneck, I would say that it is an objective of a company.

We, as Clever Leaves from the beginning, established within our business model, that was the vision that was had from the beginning, where we wanted to go.

If we go back to the beginning of the conversation, in what sounds important in that design of that business model. That vision of us wanting to touch European lands and for that, what do we need? We need to establish an ecologically friendly, large-scale, low-cost cultivation and what are the certifications that we must have.

It took us four years, it is not an easy or simple process and it requires very high levels of investment and foreign capital, but here we are. Four years later, we have an EU.GMP that will allow us to enter different markets.

**Alfredo:** César, Camilo, when we talk about exports, the first thing we think is, "export medical cannabis to Europe."

I imagine this is not the only option, for companies that are suddenly realizing that obtaining EU-GMP was more difficult than they initially imagined. What alternatives do these companies have today?

**Camilo:** Yes, okay. For example, a question that those who are entering the business have to ask themselves is whether they want to be in the psychoactive or non-psychoactive market. They have very different regulatory treatments, the complexity of the psychoactive is much higher, the times to obtain permits as well. It is more difficult to access financial services if you are focused on that sector.

Another alternative is to focus on non-psychoactive cannabis, where if you map well the requirements of the country of destination and that is what I agree with Ana. You have to carry out an operation designed to comply with the regulatory requirements of where you want to sell, not only with those of the country in which you are operating.

You can plan an operation, where you can reach some exports a little earlier. That said, since there are not so many regulatory barriers, it is more competitive, because prices behave in a different way, it is more similar to a commodity, and you have to have an operation where you pay close attention to controlling your production costs.

**Alfredo:** Is that why the exports that are seen the most in Colombia so far have been CBD, CBD isolate or CBD products that are usually sold in the country of destination as a food supplement, or not as a medicinal pharmaceutical product?

**Camilo:** What we see in the market is that they are exports in bulk, to be processed later. The figures and statistics do not allow us to see for what use it is going, but that opportunity exists and I think that this is a very interesting market for Colombia to return to-- One of the interesting categories is bulk, high quality derivatives at a competitive price.

**Alfredo:** Camilo, you mentioned something super important and I think that now it is clearer in the industry, but that a while ago it was not so obvious, and it is thinking more about the requirements of the destination country and the buyer's specifications, and not only what can I do in my country, what can I grow.

That, without a doubt, is very true. Taking that into account, Camilo or anyone, what advantages and disadvantages do you think that the current Colombian regulation presents to precisely export to countries that perhaps have higher or lower quality requirements, or different ones?

I want to know if you have any opinion regarding, what is Colombia lacking in that regard? That does not mean that Colombia has to change it, but that the businessman who is in Colombia has to take it into account, that only by complying with the Colombian requirements it will not reach certain countries and it will be missing certain things, or perhaps Colombia it does have certain requirements that already help it to enter other markets.

**Ana:** I think that Colombia, we are a country-

**Camilo:** In terms of advantage. Alfredo, I believe that Colombia already has a tough regulatory framework. Calm Ana, go ahead.

**Ana:** No, go on, please.

**Camilo:** I think Colombia already has a mature regulatory framework, that's an advantage. Also that the authorities have expressed great interest in updating it and a great willingness to talk with the industry to really understand the dynamics of international markets and how these trends affect producers in the country.

There is an inter-institutional effort, where many actors have been part of a conversation to modify a decree that is in progress. I think this is a plus, a government that is willing to make changes so that regulation evolves to address bottlenecks or issues that were perhaps thought of in one way, but later developed in another.

**Alfredo:** There is an interesting question that I had never asked myself, it seems to me that the answer is, "No", but it is better if Ana or one of you answers it. Someone asks if the EU-GMP requirement is a barrier that is protectionist in approach, to protect the more expensive European crops.

The answer is that, "No", because GMP is just the normal in the pharmaceutical industry, is the standard and it is not something special that someone has invented it to protect the European cannabis industry.

**Ana:** Yes, totally. That, as you say, is a requirement of the pharmaceutical industry, there are very few pharmaceutical industries in Colombia that have an EU-GMP. Clever Leaves is the only company that has EU-GMP within Colombia. This is a requirement so that patients can be reassured that what they are receiving is really a quality medicine.

Under no circumstances is this a barrier, these are the regulatory routes that any pharmaceutical product has to follow.

**César:** Yes. It is clearly a barrier to entry in the industry. There is no talk of being something exclusive, but it must necessarily be considered if the actors want to participate in pharmaceutical issues.

**Ana:** Exactly.

**Alfredo:** We can comment a little on the topic be to be that I think has begun to be seen more in Colombia. Agreements between different companies that were perhaps not so common before. Now, some have even been publicly announced. From a business point of view, what are the arguments behind these types of agreements? What types of agreements are being seen between Colombian companies?

**César:** I would say that this is an essential and normal part of the development of any industry. Again we go back to what we talked about at the beginning, that perhaps all the actors cannot dedicate themselves to being involved in absolutely all the steps of the industry value chain, and on the contrary, there must be specialists.

That, at the end of the day, I think generates many more positive issues for the industry in general and for the Latin American region in general, facing the world. We have already seen what Canopy did when he left, but left a very established JV here in Latin America, and what other greats are doing.

In our opinion, I believe that these collaborations or those types of agreements are the ones that will allow these small entrepreneurs to really have the visibility they need and be able to bring their businesses to an optimal point from the business point of view and financial.

The greats and those who have done all this extremely interesting work of paving the way in Latin America, I think they have done it very well. We are all aware of the huge investments, as Ana said well, that are needed to achieve EU-GMP certification, to be able to be in international markets and put your products on the shelves wherever you want to be, and so on.

There is also the possibility of, again, being a good genetics producer, or being a good seed producer and supplying the rest of the market. Not only think about European markets or Israel, etc., but I believe that in Latin America we have a tremendously interesting market, which perhaps we have not seen with the same interest, as is generally seen reaching Germany and other European countries.

**Alfredo:** We have a little more than 10 minutes left. Camilo, if you want to add something and if not, we will also go on to the subject of possible changes that may come in Colombia. Did you want to add something, Camilo?

**Camilo:** Yes, I would add one thing. For example, in the case of Natura and what we have thought is that, precisely the specialization will require that more people be served. Natura was not only born to supply but to supply any brand that needs inputs in its products.

Call yourself products to make your own finished products, or if regulation permits, one can come up with a point of offering white label solutions.

It is an inevitable trend, internationally with solutions that allow the others to focus on the part of the value chain, where they really want to focus. A brand should focus on marketing, building its brand, distribution and can--

[sound break]

**Alfredo:** Camilo, the sound cuts you off a bit.

We are going to move on to the last topic, which is the possible changes that may come in the regulation in Colombia. I think the main thing, as I understand it, is a draft decree, which has been in draft format for at least a year now, but which could bring, when it is approved, if it is approved one day, several changes and I have listened to whom He says that he will bring more controls, who says that he will bring fewer controls and obviously, I imagine that it is not so easy to simplify if it is more or less controls.

We have 10 minutes left. We will try to give an overview if possible of this draft decree. I don't know if César or Ana, who dares to start? We already lost Camilo.

**Ana:** Within the credit draft, we really hope and trust that the government at this time becomes more flexible and access issues can be opened up a little more. It comes with some additional regulations on control issues, but for us it really is a vote of confidence that we are giving the government to speed up and, above all, to shorten the times a bit, especially on the issue of quotas.

**Alfredo:** César, what have you been hearing in the industry that the draft decree affects me?

**César:** I think that what we are all waiting for in the industry is that there are finally some standards so that, for example, the issue of exports can be dynamic and much more expeditious. We understand that every time there is an export, regardless of what the purpose is or what country it is going to reach, many particularities need to be reviewed, the industry--

**Alfredo:** Specifically, what could you on the Colombian side to facilitate exports? This is something that yesterday was also a topic of conversation in the Uruguay panel, which is asking the Uruguayan government to facilitate exports.

I understand that it is necessary to facilitate exports as much as possible from the country of origin, but then, anyway, we still have the requirements of the country of destination.

That, I think is what we sometimes forget. The requirements of the destination country are often complex and the government of the country of origin can do little about that. What concrete things could change in Colombia to make exports easier?

**César:** I think the process needs to be definitively standardized, I would say that.

**Ana:** On our side, we consider that the flexibility in the geographies and the annualization of the quotas are two points that will definitely favor the times of entry to the different markets.

**Alfredo:** Camilo, we lost you a few moments, here you are back, we are talking about the draft decree project, I don't know if you want to add something of your vision of the subject, what kind of impact it could have on the industry if this new one is approved decree.

**Camilo:** Without a doubt, it would be a substantial improvement over the regulation that we have or it would have several issues, I think that two very great opportunities is to allow the export of flowers, I think that would open a category for Colombian producers to participate in a very large category in the market, you have to have a debate on how to do it, so that it is well done.

Undoubtedly, it is a category that, for example, in Germany or the United States we see that in finished medicinal product, it represents more than 50% of sales. This is an interesting opportunity, especially in the face of the United States elections, where the legalization of medical cannabis, at the federal level, may be a campaign issue.

**Alfredo:** Do you see a real possibility that, before the end of the year, to put a date, the export of flowers will be approved, or is it just a wish of the industry that is currently unrealistic?

**Camilo:** I think it is a conversation that is being held at a technical level, there is an important disposition on the part of the interlocutors, at least, with whom we have spoken, to understand the technical reasoning, that they could allow that, but Let's see, it is something that does not change overnight, but I think it is a very great opportunity for Colombia.

We are seeing it, for example, in the recent exports of Uruguay, I think there are already two and a half tons exported to Europe in recent months.

**Alfredo:** Yes, it is. With regard to the issue of quotas, what can you change specifically to make this easier for companies? What can the government do, specifically, to streamline the quota allocation process? Again I ask myself, is the difficulty in the bureaucratic process of obtaining a quota, or is the difficulty in proving to the government that one has a buyer for a psychoactive product, or both?



**César:** I would say that it can be a little of both, especially from the point of view of exports and to which country are you thinking of taking what you want to send, but in addition there is something that in my opinion is always there, although there is not much talk and it is still the issue of what the industry means in our country and the development and evolution that we have had, but there is still a lot of resistance to this change and to accept an industry that has evolved and that represents a great opportunity.

I think that, in my opinion, it's like a bit of, "We want to get into the industry, but maybe not so head-on," and that's why the process is not so clear, or the quotas, for example, are not so clear.

**Alfredo:** Ana, do you want to add something? Camilo?

**Ana:** Yes. Two issues on the issue of quotas, an opportunity that we also see is the quotas for mother plants. Actually, it is something that could be discussed and again the flexibility in the quotas depending on the country of destination.

That, really, is something that can substantially delay the processes when you have to change from Germany to Brazil, from Germany to Peru, or from Canada. This subject of geographic flexibility can undoubtedly also be a very interesting subject.

**Alfredo:** A question for you, Ana, who is here ... Sorry. Then we close with final comments. Recommendations for small companies that want to get EU-GMP based on the experience of Clever Leaves, what can you recommend? In a minute.

**Ana:** Recommendations from the beginning and as I said, it is to have that clear vision that they want to do it. The total emphasis is on the issue of quality and the focus of the business. Quality is going to be the main thing here and knowing that they are going to be a little more extensive processes, more complex processes that are going to have to have a preparation long ago, years ago, but without a doubt, at the end of the road it will be a grand market opening.

From the beginning, having it as a business focus, from the beginning when they start to design that model, that deck of investors as they spoke now, is to have it there, it is to have it as the main focus and to start preparing on issues of process and operational capacity from day one. It is not a process-

**Alfredo:** César and Camilo-- Sorry.

**Ana:** Yes, go ahead. That it is not a process in itself.

**Alfredo:** To finish. Cesar and Camilo, here is someone who says that the new decree should facilitate banking and transportation issues, both local and international. Is this something that can be facilitated by decree or is it relatively out of the hands of the government and there is not much that can be done by decree to facilitate access to banks and international transportation, especially?

**César:** I believe that the part of access to banks is clearly in the interest of the government and should be promoted by the government. In the decree, I have not seen that it has been mentioned and deepened deeply on the issue of access to the financial system.

However, as we said at the beginning, this may not be a short-term development, and it may take a long time and a couple of years for us to get to that point. In the United States, we still see great difficulties in accessing the financial system.

**Alfredo:** Camilo?

**Camilo:** Alfredo, for me it is a more international issue. The issue of access to banking has to do with the legislation of the United States and that still illegal status of marijuana as a controlled substance and that financial services do not feel comfortable entering to provide their services there.

Colombian banks that have a presence in the United States, either because they list products in the capital markets or have agreements with correspondent banks, make the decision based on a risk assessment not to participate.

I think the Colombian government could help by offering a solution with the Banco Agrario, I think that would be possible. Offering a solution for an international account of the Agrarian Bank that allows monetizing resources, but by decree I see it complex. I would emphasize that the government has had a very receptive attitude to the industry, it is a fluid conversation and they are always willing to listen.

I think that makes Colombia a very interesting place to continue investing, to continue believing, because not only did we have one of the first regulations, but the government is actively interested in monitoring it and understanding those regulations, what economic and practical effects they are having.

**Alfredo:** We have to go. Before saying goodbye, remind all the participants that we have this group that we made on LinkedIn to precisely exchange opinions and comments on these topics. It's called *Marijuana Business Daily* en Español.

Also take the opportunity to tell you that next week we will publish the second version of our report on the situation of the industry in Latin America and there are also several answers to many of the questions that were planted here. With that, I am saying goodbye and I leave you for a few last words and closing.

**Camilo:** Thank you very much Alfredo, Ana and César. A pleasure to share the panel with you. To all those who want to enter this business I would give one last recommendation, perhaps they consider the possibility of joining a union, we have to build a community, we have many common problems and if we help each other to have a well-regulated industry that behaves Okay, and be a good corporate citizen, I think we'll all go further.

**César:** Thank you Alfredo. Thanks Ana, Camilo. To all the participants for this space and this opportunity. I believe that definitely in the cannabis industry there is an opportunity. My suggestion would be that we be patient, keep working and build what we all want to see from this industry, that the time will surely come when we can finally enjoy so much hard work that we have done.

**Ana:** Alfredo, César, Camilo, really thank you very much. Very interesting conversation.

My final message is nothing more to say that Colombia has an immense opportunity, as a country we have an opportunity on our feet to be able to achieve worldwide, something that very few will be able to achieve. Let us persist, we have already done it, we have shown what we are made of and that will surely not be too big for us either.

Let's move on, we are on the right track.

**Alfredo:** Okay, Ana to close. Thank you all. Until next time.

**César:** Thank you.

**Ana:** Thank you.

**Camilo:** Bye. Thank you all.

**Ana:** 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.*