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REGULATIONS AND OPPORTUNITIES IN KEY LATIN AMERICAN MARKETS: BRAZIL

WITH

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Alfredo Pascual: Hello. My name is Alfredo Pascual. I am an international analyst for *Marijuana Business Daily*. Welcome everyone to this webinar. After having done one on Uruguay and another on Colombia, Brazil is playing today. Tomorrow we are going to finish with Peru. Next week we will send the recordings of these sessions to all who registered, so stay tuned for an email that will arrive next week.

Also next week, I will take the opportunity to tell you that we are going to publish the second edition of our report on Latin America that analyzes the regulatory framework and the market situation in the main countries of the region. By the way, I also remember that we have a LinkedIn group called *Marijuana Business Daily* in Spanish where we can follow this exchange about the cannabis industry in Latin America, generally there are always questions to be answered.

Regarding this webinar, several people asked me why it is not in Portuguese, the answer is that the objective is that these webinars serve to exchange industry issues at the regional level and the rest of Latin America speaks Spanish. Anyway, whoever wants to ask questions in Portuguese, please do so, you can write it in the chat or better yet in the Q&A option that the Zoom application has, I may not be able to answer in Portuguese any more I can understand what I read.

With that I am going to introduce the panelists we have today who are excellent. I start with Camila Teixeira, she is CEO and founder of INDEOV. She has been facilitating access to cannabis products in Brazil for many years, surely they have several tips that she will be able to give us about what companies that want to sell their products to patients in Brazil should take into account. Camila.

Camila Teixeira: Hello. Nice to be here. First of all, I would like to thank Alfredo for the invitation and also the *Marijuana Business Daily*.

Alfredo: Thank you Camila.

Camila: This is the result of the communication cycle in our market and also being able to speak alongside people that I admire so much about the Brazilian market. Thank you very much.

Alfredo: Thanks to you. We also have José Bacellar, he is CEO of VerdeMed, an international company that is focusing on Brazil, more than anything on the pharmaceutical part, surely he will be able to explain, in much detail, how difficult it is to obtain a sanitary authorization from according to the rules that Anvisa created in December of last year.

José Bacellar: Hello, good morning everyone. Camila, Tarso, Alfredo. I also thank you for the invitation to participate in this panel. I'm sure that in the end everyone who is going to participate will understand a little more about our country, because we have specialists like Camila, Tarso and you who know the whole region. I look forward to a very productive hour for all of our audience.

Alfredo: Thank you José. We also have Tarso Araujo. He is now Director of Business Development for Entourage, a Brazilian company that is dedicated to the research and development of cannabis medicines. In addition, he is well known in Brazil for having directed a documentary that was very important called Illegal, which was surely very influential in normalizing the conversation around medical cannabis in Brazil. Tarso, a pleasure to have you with us.

Tarso Araujo: Nice to see you, Alfredo. Thank you so much for the invitation. A pleasure to be here with Camila, with José. We hope that we will have the opportunity to clarify a lot of things about the Brazilian market.

Alfredo: Thank you Tarso and thank you all three for making the effort to also speak in Spanish. Now moving on to the topic Brazil itself, most of the conversation in this webinar I think is going to be focused on the different categories of products that exist in Brazil. Many times we see that companies talk about the Brazilian market in general, but I think it is important to distinguish what we are talking about specifically.

In practice there are different possibilities for patients in Brazil, the most common being that of products that are not registered in the country and that patients can import individually if they have an authorization from Anvisa. Also the rules that Anvisa, the health agency, created in December last year to allow so-called sanitary authorizations that are products that do not have their proven effectiveness, but that are temporarily allowed to be marketed.

Of course also the possibility of registering medicines that are developed based on cannabis, which have their safety and proven efficacy through clinical trials, and there is one of that in Brazil. Also, it could even be said that there is a fourth access route, which is not less important, but it is not of a commercial nature and is the authorizations that individual patients have been obtaining through the justice, the courts in Brazil and also two patient associations.

We are going to start the conversation by talking about what is surely the most common form of access to medical cannabis in Brazil, which are unregistered products. By the way, because today we published, a little while ago, just an article about, precisely, how the number of authorizations has been increasing based on a response from Anvisa that I got a couple of days ago, in which you can see how it has grown this enormously, especially since 2018. If you want more details about this article you can find it on the MJBizDaily.com website.

With this on the screen, Camila, let's start with you at a rather generic level of, why is the number of these authorizations increasing and increasing rapidly?

Camila: We always know that the challenge of cannabis in all markets is one of communication. So in Brazil this week a newspaper article came out reporting about silent legalization, because it's true, since 2015 when we had resolution 17, we had very important milestones. 2015, of course, with this resolution we begin the legal path of access. This was due to enormous popular pressure that forced our agency to respond with the import authorization per individual, with compassionate use.

At this point, as Alfredo commented, we had the participation of Tarso, with the film or documentary, Illegal, which tells the story of people with the need to use cannabis for medicinal use. Of course, the response of this pressure, therefore, I invite everyone to watch why this film begins the history of Brazil.

Alfredo: Camila, one question, because that started many years ago, you could say that the first authorizations I think were from 2014, around 2014, 2015, however, the fastest growth has been seen above all from The end of 2018. That's when you see that this is really being pushed up, what happened there?

Camila: Communication was decisive, we had three communication vehicles here in Brazil from the main media, VEJA, Folha de São Paulo, Época, having specific journalistic columns to deal with the issue. That was very important, because it was monitored from the point of view of the media, the progress of access. The regulatory part, which was also very decisive last year, we had a table questioning the population about the different points of view of regulation.

In the last two years, we also had the entry of many companies, not like the direct import model, but also companies established here in Brazil with the specialty of access and of course, considerable investments by these companies in medical education to facilitate--

Alfredo: So that was also an important factor, precisely, starting to train doctors.

Camila: Exactly. That is a very important point. Today in Brazil, we only have 0.2% of the doctors doing the prescription, approximately 1,000 doctors, in reality there are approximately 450,000 doctors with the right to prescribe. It's nothing and medical education--

Alfredo: Is it much more than two years ago?

Camila: Yes, of course. It has been a process since 2015, but we have important progress and also the resolution, now, of 335 of 2020, this year, which simplifies the previous one of 2015, which makes the bureaucracy less for this access. Also a regulatory clarity with resolution 327 of 2019. That allows companies to import finished or semi-finished products here to Brazil, for distribution in pharmacies. That was very important, because we suffered from 2015 to 2019, as a lack of clarity, what we can do with this market.

So all that has contributed to a significant increase in demand. If we compare last year from January to June, we had for this same period, a 50% increase in demand, with today published by you a significant number of 11,317 active legal authorizations for direct importation. These are very important steps that we had in the last two years.

Alfredo: Tarso, do you want to add something about this process?

Tarso: Yes. I think there is another important factor out there, this investment by companies in medical education that Camila has mentioned and that I think is very important indeed. There is also a factor that has to do with communication, which was very important in 2019 and continues to be important now, at the beginning of 2020, which is the discussion itself on the regulation of cannabis products in Brazil.

It must be remembered that in 2019, throughout the year, there was a very intense discussion in the newspapers, about the regulation by Anvisa. William Dib, our predecessor, the former Anvisa director, has been very involved in this debate, he has participated in many events, he has given many interviews, always talking about the positive points of cannabis treatment.

I believe that this, coming from the director of Anvisa, has put many doctors who before were not so confident in prescribing, not only for clinical reasons, but for cultural reasons, in itself, for safety. I think they will stay more confident in making prescriptions and an indication that this had an influence is the fact that this quarter of 2020, which came out after regulation 327, in this period we had the largest increase in import applications since 2014. The medical class is more confident.

Alfredo: The curious thing about this is that in reality these authorizations, which increased rapidly even in 2020, did so under the rules that already existed before, that of individual importation. The rules that changed in December actually did not change that much in practice, since there is only one product registered or with sanitary authorization to date.

Tarso: There is another change, in January, at the end of January 2020. Anvisa changed a very important rule of how patients, doctors, patients had access to prescriptions, forgive me, until January 27, sorry, 20 from January. The prescription was analyzed one by one by Anvisa. She went to the conference, the milligrams per day, with the amount and many prescriptions did not go ahead.

Three important changes, one, now all import authorizations are done through the Brazilian government portal for all citizens, it is a more institutional way, safer from the patient's point of view, they managed to communicate with Anvisa.

After he leaves for Anvisa, Anvisa is the second change, Anvisa is no longer analyzing prescription by prescription to be sure that the doctor knows what he is doing, Anvisa is waiting, he only says, "Okay, I authorize, I do not authorize", one or the other who makes comment.

Third, it is possible to have a proxy, legally companies that want to work with patients in a legal way, can ask them for a proxy to represent them alongside the government. These are three things that changed in January, this is why the explosion of the prediction this year occurs because, as you say, the process has not changed, what has changed to have so much demand? The lawsuit is going through Anvisa, a prescription that took 60, 90 days to be approved, today there are prescriptions that are two days, just 20 days.

Alfredo: Besides, everything online?

Tarso: Everything online, everything with documents. It's a bureaucracy, it's not easy for patients, but the thing about being able to appoint an attorney for you through the process, there are companies that specialized in making this process faster and it's legal because everything that it was done before it was very on the line between the law and no.

Alfredo: All these authorizations are individual, so Camila, I imagine there are many patients who still have difficulty paying for these products, they have to pay for a shipment that is being sent to the individual patient, from another country, which, I imagine, it is not cheap, what advice would you have for companies that, from outside Brazil, are interested in this opportunity that the demand for individual patients from Brazil is growing, but that the system is still a bit complicated to navigate because it is individual patients who obtain authorizations to import.

Camila: Yes. If these companies hope to take advantage of the compassionate use resolution, they should not come to Brazil because changes are happening every day and these companies today, which are in Brazil, many of them are preparing for this new resolution that came out. in December, whatever it means to import finished or semi-finished products for sale in pharmacies. They have to keep in mind that you have to have a high investment to enter Brazil. If they want to take advantage of future opportunities.

Alfredo: You see Camila, that the future of Brazil is going to mean that most of the products that patients are going to buy will now be available in Brazil instead of importing one by one?

Camila: Yes, I see that. Of course, both models are going to be possible because in the end, if I am, for example, I have a product that is satisfactory for me, why can't I access tomorrow and this company is not necessarily going to come to Brazil. The part that these companies have to keep in mind is the complexity of the operation of this individualized export or the part that I see as much more complex, the part of adapting the companies to the new regulatory reality, which is much more difficult to operate. .

Alfredo: We are going to talk about sanitary authorizations, focusing only on compassionate use, the so-called compassionate use. The individual patient that matters. For the three of you, and if you want now first, Camila, what advice can you give to companies that have not yet exported anything to Brazil, to any patients and are at this moment realizing that they are missing an opportunity to send those products to individual Brazilian patients? Where should these companies start?

Camila: With high investment, with planning for the future to adapt to Brazil. You have to keep in mind that this is a pharmaceutical market, so there is a need for the part of an operational structuring in the face of this reality. They have to bear in mind that you have to have a very strong investment in education for doctors about the product because it takes at least six months, when they start operating in Brazil, for doctors to understand the products.

They have to bear in mind that there is a need for innovation because today we have approximately 120 companies in Brazil with different products, if it comes here with a product like the others, it will not be very effective.

Alfredo: José, get on the case.

José: I have a little more vision - The opportunity is Alfredo, the topic that I think is more about regulatory risks of a company that comes from the United States, for how long is compassionate authorization going to be allowed? I believe that Anvisa is doing a market test, to see what the effective demand is for all cannabis products, that is why direct importation became easier in January.

Because it is very difficult for us to supply the demand with a pharmacy product. I believe that for a long time it is possible to have both models. The issue of direct importation is that it is expensive, and propaganda in America is prohibited, you cannot promote products that are not registered with the CID. Many companies do, but it is not legal. He is also talking about something that can be closed very quickly, or even worse.

We are in a transition phase, I believe that is the way of thinking of Brazil, in direct importation. Brazil is-- Everything that has happened in Canada, the United States, which took 20 years, is happening in three years. In 2000 Canadians managed their right to plant, to have their plants at home, it took 10 years to have the commercial cultivation, until this beginning of this decade, where the market is established.

In the United States the same, California 96, then the state of Colorado. Justice always pushes patients until a situation of change is created, we are in this moment of transition. The sale of the product directly to the patient, I think it will continue for a long time, because no one is going to handle it and supply all the demand as a pharmaceutical product in such a short term, but it is a market that will always have--

The logistics issue is not that simple, and the legal issue also requires a lot of thought about what you are doing.

Alfredo: Tarso, what limitations do you see in compassionate use?

Tarso: I think so. In fact, the two models will coexist, but surely there are limitations to the import model for compassionate use. The big question we have is, how are you going to walk to the transition in 2021 when we have more products in pharmacies? Because surely the patients that today use imported products are probably going to continue for a few more months, perhaps a few years importing, because they are satisfied with these products.

We know that right there in the United States, where there is no prescription, in general patients are faithful to certain products, the same will probably happen here. The fact is that, in five years we did not exceed 20,000 patients. The same, with this faster rate of 2019, we had an average of 6,000 new patients per month. This, for the potential of the Brazilian market, is very small.

For example, there are forecasts that the Brazilian market would have up to three million, and 400,000 patients in three years. Three years after regulation, this is a giant potential compared to the 20,000, at most, that we have today. I think that outside, this maintenance of the growth rate of imported products, we will have comparatively elsewhere an increase in the consumption of products, bought in pharmacies.

The speed of penetration of these products to the market will be much broader, much greater than that of imported products, for a number of reasons. Camila has already pointed out, as well as José, the logistical issues, which do complicate.

It is obvious that if you are a new patient, that you are going to start consuming a cannabis product, your doctor gives you a prescription and says, "You can go out here on the corner and buy this product at the pharmacy, or you can go to the Anvisa website, fill out a form, send your prescription, make a request, wait for authorization, send a purchase order, wait for them to arrive, go to customs. The tendency is for people to buy at the pharmacy, so soon the prices are equivalent, how? Of course, we will probably have an economy of scale in the pharmaceutical part, this I think it will not take long to pass a price equivalence. When this is possible, the balance will probably fall more on the side of the products in pharmacy, how quickly will this transition that José mentioned? This is the big question, I would say.

Alfredo: Good, good analysis. Now, when the December Anvisa rules came out, which allowed these sanitary authorizations to be able to have products in pharmacies, many companies began to write their press releases, and say that they were going to enter the Brazilian market with this. It seemed like 50 companies were going to start registering products in Brazil.

The word is not to register, to obtain sanitary authorization to be able to have your products in Brazilian pharmacies. However, the months go by, there is still only one product that obtained a sanitary authorization, and on July 16 Anvisa replied that it did not have a single application to authorize a second product. With which, I fully share your analysis, that of the three, that in the long term the trend will be that the products that are in Brazilian pharmacies are the ones that will be sold the most.

There are still very few, there is only one in particular. The question for all three, starting with Camila now, is why is there still only one product and no application?

Camila: The biggest challenge we have today in Brazil for the companies that are selling, is to guarantee-- Have the GMP, that it has within a series of other documents. We are talking about a resolution, which also speaks of 15 resolutions, which refers to 15 more resolutions. It is a huge complexity. The biggest challenge for the companies is that I don't have GMP, and I don't have a way to guarantee the stability shield, specifically for Brazil, which is zone 4B.

Yes of course. This stability shield aims to guarantee that the product has its quality maintained, during shelf life. Do not go wrong with the unit and the temperature of these climatic zones of Brazil.

Alfredo: None of these things are required of products that go through compassionate use to individual patients. There are practically no quality requirements, other than that they are legal products. Legally produced products, and voila. There is no GMP, no stability tests, or anything. Some were very good, but others may also be very bad because there is no quality control for these products.

Camila: Yes. Today for companies to enter with compassionate use, they only need to send some documents that prove that they exist, so that Anvisa will list it as companies authorized to import in Brazil. It is much easier today in this model, which as we all commented, is going to happen for much longer.

Alfredo: José, we are still with you regarding the difficulties in obtaining a sanitary authorization in Brazil. The general question is, why so far only one?

José: First of all, only one, because only Prati-Donaduzzi that has registered a product, it is 200 milligrams, in a 30 ml bottle. Only they were ready with all the study of the requirements, why were they ready? Because they didn't start in 2019, or 2018.

Prati began his efforts with Anvisa in 2016. He negotiated with Anvisa the entire process during 2017, until he found the regulatory exit that was created in December. You can tell me, "The law is very frank or good for Prati." Only she is benefiting. Yes, but only she started this four years ago. La Prati was ready with its product, with all the demands that Anvisa has placed on this rule. The rule of sanitary authorization is something very Brazilian, we made Brazil the only country that has jabuticabas, it gives something bold, very sweet, excellent, this is the typical Brazilian jabuticabas, this must be left, a law that takes pieces of the pharma, pieces of herbal medicine, part of I don't know.

A category of cannabis-derived drugs was created, not the class of products.

Alfredo: You can't even call these products "medicines".

José: You can't, they are products, they are not drugs, they are products derived from cannabis, what else? There are no indications, it is that they are with a restricted prescription that, by the law of medicines, there is a restricted prescription, there is a clear indication for the use of products. It is typical of Brazil, it is a jabuticabera with its jabuticabas that is very complex for those who are outside to understand.

There is no other company, because it is very complex to understand all that as Camila said, 17 regulations, what do I know, 20 other RNCs that must be complied with, that's why--

Alfredo: That also José, to clarify one thing, that all those regulations that must be complied with, it is not that they are cannabis regulations, they are health regulations in general, pharmaceutical regulations in general and therein lies the difficulty.

José: I believe that Anvisa had the following in mind, there is no way to ensure this, but as a regulatory agency I want to have quality control over the products, I don't know if they are good, if it will work, if it has a therapeutic effect, no I know, but I want to guarantee that the production insurance is in place and we are going to give the company three years to prove that this is useful.

Prati has three years now, to prove that his 200 milligrams per ml, is going to have some therapeutic effect and if this is fulfilled in the case of Prati, in the next two, three years, he changes of sanitary authorization for pharmaceutical products in case of them with chemical, because it is an isolated product.

If one registers a product based on herbal medicine, the category is changed to herbal medicine. The Anvisa rule in truth, is a transition for pharmaceutical companies, not for cannabis companies, for the pharmaceutical company, starting in the production model that they know there, they launch their products, offer in the market to close direct import.

To close this purchase from patient to patient, as quickly as possible, because Anvisa does not control the quality, the Brazilians are consuming. It is a path that, in a year and a half, two years will have thousands of products, what will it be in five years? Only what they have proven to have therapeutic efficacy is a transition law, it is a transition rule of how to solve the problem.

For example, that has not resolved, that how they will accept MedicoCare or how it will resolve, there is no MedicoCare and voila, period. I believe that each country found a way to solve it. The cannabis issue in Brazil is not like in the United States, nor like in Canada, nor like in Colombia.

The perception of the plant is very difficult, we have a government that is against everything, it is a fight over a lot of prejudice. I believe that Anvisa has given an opportunity for the company, like us, everyone, like every team of participants to do this. Of course Alfredo, who is ahead are the farms, because she knows the processes, she has everything, but she doesn't have the raw material, it's 4B. It is not that simple to get to handle this whole process.

Alfredo: In short, the quality is really pharmaceutical, the only thing that it requires us to do is to check the efficacy through clinical studies temporarily, because it is a temporary system, both the rules are temporary, and the sanitary authorizations are also temporary. Tarsus, we go with you.

Tarso: I would like to clarify, complementing what they said. Brazil has surely adopted a pharmaceutical model.

There are advantages and disadvantages, as in everything, in this. I think the advantage is the safety of the patients. Quality control is very important to them, as it is for the recreational market, for example. If you buy some to go crazy, he will know if it works or not, for obvious reasons. Now a patient using Cannabidiol, for example, will not be sure that it works for months, until he realizes that, "Well, this doesn't work." Because, for example, we in the laboratory already buy imported products abroad, from China, for example. Cannabidiol products can be purchased from many sources.

When you buy it and do an analysis, you notice that there is not what is written on the packaging. This is common. In the United States this has happened a lot of times, and we know this happens. For patients, this is good news. Now, it is also clear that pharmaceutical development is expensive, it costs you a lot. Not only clinical trials, but manufacturing, the whole process has a quality control that makes things more expensive, and this comes at a cost, this is the downside.

Now, we also know that the neck of the bottle, in the case of sanitary authorizations, are; one, the GMP conditions required of any type of medicine in Brazil, and in many countries abroad as well. Mainly the 12 months of stability that is required of a new product on the market. The great neck of the bottle today is two months. That is why we do not have other registered products, or with a protocol request at this time, but this will pass.

Why did we get to this point? Because the global cannabis market was not ready for pharmaceutical demands, for a lot of reasons. Mainly due to the fact that the main cannabis market has started in the United States, outside of pharmaceutical requirements. Most of the available products were not made under GMP, and they did not do stability tests for tropical areas, because if we were from zone two or zone one, there would be stability testers, but there are not because no company of cannabis had thought that we would have a market of 210 million people in zone four E, which is the tropical zone. That is why we do not have stability tests at this time.

Alfredo: Even in other areas, I would tell you that there aren't that many either. Even in Canada, medical cannabis does not require stability testing. If they were made, it was to sell in Europe, not to sell in Canada.

Tarso: Exactly, but Alfredo, the companies that already had a medicinal approach already knew about this and were already preparing, but for different markets, for European markets, and not for the Brazilian market.

So we do not have the stabilities, but this is surely the destination of cannabis products for medicinal use, because although we have many possibilities of using more primitive extracts, with success, surely when we have a more massive consumption, we are going to look for one broader security, and what this gives us today not only in Brazil but abroad are products with higher degrees of quality control, with GMP, with stability. This is normal for a drug.

I think that even though we weren't ready, this is the future. In this sense, it is good that the Brazilian regulations are at the high standard, because that way we are already preparing in advance for what is the future of the therapeutic use of cannabis. In this sense, I believe that Brazil will be very well in the coming years, because we will have a park or a lot of companies that are qualified not only to provide products in the Brazilian market, but also for Latin America, and even for Europe, because the Products registered here before Anvisa are enabled for registration in Europe even.

If we have a product registered here, we can license it in Europe without great regulatory efforts, because what Anvisa requires of us is the same as Europe requires of companies there. I think that is the future.

Alfredo: José and Camila. Ahead.

José: I fully share the vision of Tarso and Camila, which makes it obvious to prescribers that Anvisa's assurance of having a drug, not medical cannabis. A drug that has gone through all the pharmaceutical rules is safer but we do not have the use of medicinal cannabis, the uses of free CBD gel, because we must also consider that this is from a natural product. The mass market is never going to be the pharmaceutical market, ever, because it is more expensive, more difficult to distribute. The important market, the demand that is there is for CBD, CBN, CBG, all derivatives in cosmetics, beverages, food, products for animals. This is not in Brazil.

Yeah sure, we fixed an important part. We are going to create an important small pharmaceutical market in the next three to five years because we are not going to have a cannabis blockbuster. They are small additional increments. The pharmaceutical market for cannabinoids will always be small markets, by definition. The raw material is all, all the APIs are not under patent. Therefore, the protection is thinner. There is no indication patent here.

The question is, when are we really going to have medical cannabis? When are we going to have what is happening in the United States, what is happening in Canada, what is going to happen in Mexico? On that side, Brazil is going to delay, it is going to be a beautiful pharmaceutical market, spectacular, safe, expensive, that nobody buys because only, even though the government buys, the consumer market is not there, the law is not.

Camila: You know I don't agree.

Tarso: Me neither.

Camila: Because I see as a trend, sharing with the vision of Tarso, which is a pharmaceutical trend in the world, because in the end we are talking about health. Thinking like this, we have here an agency that is the most respected; if not the most respected, one of the largest agencies in the world and that this product will always be under it for a long time. So the question of the guarantee of safety or quality is very decisive.

The FDA itself is much more repressive on this issue. Countries of Europe. So I see how Brazil-- I remember a talk I had with Tarso about two years ago about this issue, that it is a pharmaceutical reality and that we have an advantage in this. For example, we have the possibility of having this full spectrum product, yes. A tendency to have a little more flexibility in the form of access with a tendency not as restrictive as today is a possibility.

José: Camila, don't you think that patients have the right to plant their cannabis for consumption, without phytosanitary control? The product should be free, the gel should be free, not under Anvisa. As the Americans did, as the Mexicans are going to do, a consumer product. If Anvisa blunders for what goes into a cosmetic, we will never have a significant market of people in Brazil. It is very simple because this is an agricultural commodity. They are two different things.

Excellent that we have pharmaceutical quality products with indications, with prescriptions, but I think that people want to buy ointments, people want to buy shampoos, they want to wash their hair, they want to use CBD beard shaving products, and why not? What need is there for clinical trials to sell a cosmetic product or whatever? They are two different things. One thing is a medical claim. To make a medical claim you must have clinical tests.

I sold cleaning products in my life. If I want to put CBD in the cleaning product, in soap, why not? Is this prohibited? It is not in the United States and it will not be there because cannabis has to be free. We started with hemp and one day we will have the plant also regulated for everyone's consumption.

Alfredo: Let's get to what it is now, it's not what we want it to be. We all want it to be free; there is no--

José: This is going to be now. A change in Brazil will now be proposed to the law. We are not talking about the future.

Alfredo: Before going to the bill in the lower house, a question because we have many people from other countries who are obviously hearing that demand is increasing in Brazil, that there is also the opportunity to obtain sanitary authorizations for products and others. As you well know, most of the countries in the world that have regulated medicinal cannabis have an industry that wants to export. Brazil is one of the very few exceptions in the world, I think only Brazil and Poland, that all they want is to import, at least the raw material. Let's clarify a point.

José: This is going to change, Alfredo.

Alfredo: It will change, but before going to the bill, we leave that for the last 10 minutes. Now in five minutes and then we go to the bill that is in the deputies; which is a project. It still hasn't changed.

To this day, before things change, we are going to talk about what can be imported now. You will correct me, but I understand that for the products, leaving aside compassionate use, and sending one by one, for what has to do with sanitary authorizations, the products that are or will be In pharmacies in Brazil, what can be imported into Brazil, I understand that it has to be at least extracts.

The plant cannot be imported, nor its parts, nor the flowers, nor the crushed flowers. It has to be an extract. With which all the companies that go around the world planting and wanting to export their flower will not be able to export it to Brazil, unless you correct me if I am wrong.

Now what I ask of you is, tell me what it is that you can import to Brazil, because obviously if it cannot be cultivated commercially in Brazil, let's put aside Habeas Corpus and the associations that obtained their permits in court. If it cannot be grown commercially in Brazil, the raw material has to come from somewhere. Maybe Tarso, tell us what kind of raw material it has to be.

Tarso: Alfredo, at this time under 327, the current regulation, we can import extracts - Pharmaceutical ingredients, APIs, from CBD or THC, it doesn't matter, as long as they are made under GMP grade. You have to have a pharma grade.

Outside of this we can also import finished products; products already in their final bottles with packaging, with everything. In this sense, the product has to prove that it is made under GMP in a PIC / S member country, which is a pharmaceutical agreement, of pharmaceutical conventions, of harmonization of pharmaceutical conventions.

Alfredo: To clarify, Tarso, the place where this product is made has to be certified by a health agency in these countries. It is not enough that the product comes from this country; It must be GMP certified by the state health agency.

Tarso: Yes. For example, if I am going to import this from Albania, then Albania has to have either an Anvisa good practice certificate from Brazil or a good practice certificate from Albania if Albania is a PIC / S member, but I think no this. In this sense, Albania would not do, but--

Alfredo: All the certifications of private companies out there are useless, sometimes companies say, "I have GMP, this company certified me." That does not work.

Tarso: Sorry, José.

José: If you still do not have GMP in Colombia, EU-GMP Colombia, a certified plant in Colombia, is not a PIC / S country, it will not be exported from Colombia to Brazil. It is very complex.

Alfredo: One question, José, unless that facility in Colombia has been certified by an agency of the European Union, right?

José: No, because it is not PIC / S.

Alfredo: The agency of the European Union?

José: You have to require an inspection from the special Anvisa.

Tarso: Alfredo, these good practices of Anvisa are mandatory, but for a while you can have only the application and present the certification of good practices of this country, in case it is certified as a PIC / S member or certified under the legislation of a country PIC / S. For example, if the country is not certified but agrees with the certification, it has a certification, for example, from Germany, which is a PIC / S member, then this works.

What happens is that the great confusion, in fact, as you were talking about, is that there are many different GMP certifications. There are GMP certifications for food, cosmetics and pharma. Here in Brazil, only pharmaceutical GMP certifications are authorized for the production of cannabis products. Those for cosmetics or food are not available, they will not be accepted. These are the main import requirements and the products that can be imported.

Another important clarification. Many people ask me about THC content. Yes, it is possible to import assets, inputs and finished products with THC, but when they arrive in Brazil, the final product, if it has more than 0.2% THC, needs a special prescription, like morphine, for example. If it is less than 0.2%, you can write the prescription, which is also a controlled prescription that is retained in the pharmacy, but it is more normal. The one used, for example, for antibiotics.

Now, finally, this is important too. The pharmaceutical asset, if you import an input, this input must be allowed for export. For example, if you have an extract that is from a plant low in THC, but you concentrate it in the extract and the extract has more than 4%, for example, from Colombia you cannot export an extract with more than 1% to Brazil if you don't have psychoactive export quotas. If your extract is less than 1%, all good, but if it is more than one, even if its plant was originally hemp, it does not matter; you have to have the export quotas.

Alfredo: We have eight minutes left and we still have a big issue that is the possible changes in Brazil. Obviously, any of these issues would require a lot of development time, but now we are going to move on to what can change in Brazil, because obviously those who plan their businesses in this industry not only have to look at the situation today, but what can change .

Let's do a round, I ask you not very long, starting with Camila, then José, then Tarso, we have eight minutes left, to explain what can change in Brazil. It seems to me that this is focused on what is happening in the lower house today. Camila, do you want to start?

Camila: First of all, the question that we talked about previously, which has to do with this issue, is that my vision is that Brazil will have two paths. The part of the pharmaceutical industry, which I see with a greater global trend, of greater control of products, and that in Brazil today we have this path already developed. Of course, we have another possibility that I see, that this is the part of the silent legalization of Brazil. A series of developments that we already had due to social pressure.

Today we have approximately rights for high cultivation, two associations that can already grow their own crops. I see it as a trend that we have more developments, such as the possibility of growing hemp, for example, because we have a series of bills here in Brazil. One in particular is very developed, because we are very careful to listen to the opinion of everyone who is involved in this issue, in the ecosystem.

I, as well as José, for example, had the opportunity to speak on behalf of businessmen here in Brazil. As well as doctors, patients, researchers, lawyers and the entire ecosystem. This bill, which is focused at the moment on account of everything we are experiencing right now, is made as a social reflection of a social demand for a possibility of economic expansion, which Brazil has all the potential to develop. I see as two possible paths.

Alfredo: Thank you Camila. Let's move on to José. Finally, José, the content?

José: No. The expectation is simple. This month, a year ago, the deputies, as Camila has said, due to social pressure, on the Anvisa issue, on the issue of cannabis, a special commission was created in the Chamber of Deputies to analyze a new project. They worked for a year in the expectation that now, this August, the new cannabis law will come out. I think it will be two very important things. This is my expectation, I do not have access to the law, but I believe that we are going to have two critical changes. One, we are going to be able to produce THC, CBD in Brazil as the law of Colombia, with a caveat; that the production of psychoactive plants or for pharmaceutical use must have a direct link with the future production of medicines. This is a new, very new thing. Look, we are going to legally produce cannabis with THC in Brazil under license, everything. This is a change in the law.

The second is the free CBD, the making of industrial hemp a massive product of our agriculture and also the products that come, but this, Alfredo, is honestly an expectation. Let's see, first [cross talk].

Alfredo: Tarso, what is the expectation?

Tarso: The deputy rapporteur of the proposal said that he will publish the decree, the text of the project, in the last week of August. There are still many points that are being discussed mainly with patient groups and patient associations.

What is already defined is that there will be a differentiation of cannabis plants in terms of their THC concentration. Plants with less than 0.3% will have a calmer production regime. The safety requirements will be softer than in the case of products with more than 0.3% THC. There will also be a distinction, say the deputies, a distinction between the products that will be made for industrial hemp, for industrial production, for fibers, for textiles, for these things. There will be a forecast for crops for these purposes.

In this sense, these products will also have a softer difficulty to register and to cultivate. Products for the pharmaceutical market, even CBD products, even CBD crops for pharmacy purposes, will have to be under higher controls, of course.

Alfredo: Tarso, when? When do you think this can be approved?

Tarso: This is a more complex question, Alfredo, for two reasons. First of all, because we are still caught in COVID. In the initial forecast, the deputy was that this was going to be voted at least in the Chamber of Deputies this year, but with the delay of everything caused by COVID perhaps this will only come for a vote to the plenary next year. Then this has to go to the Senate and go back to the chamber.

If he returns to the chamber after changes in the Senate, everything has to be voted on one more time, and it is certain that they will make changes in the Senate because we know that this is a very complex and controversial issue.

It will happen? My bet is that yes, even because there is an interest of deputies from the so-called agronomic bench, which is the deputies who are involved with agronomic production in Brazil, which is, not by chance, the strongest bench in Brazil. There is no interest group broader than that of agronomists, agronomists, agro-industrial producers in the Brazilian congress. They are interested in approving this. I think it happens, but it is a very long process that I do not have much hope that it will take less than two years. I don't think that in 2021 we will have a new law. I do not think so.

Alfredo: Thank you, Tarso. Finally, because we have a minute left, Camila and José, a final word about the expectations of change in Brazil.

José: I agree with Tarso and that covers me. If the president has to pass the law, even if we approve everything, Bolsonaro has already declared that he is not going to plant cannabis in Brazil. In the separation into industrial hemp, psychoactive cannabis creates a hope that the president sees from only one part but, as Tarso says, a year and a half, two years to have the law.

Alfredo: Thank you, José.

Tarso: Now we don't know if we will have the same president up there.

[laughs]

Alfredo: Camila.

Camila: I am very optimistic in relation to everything that we are going through in Brazil. I see a market with this potential of 210 million patients who can benefit, as I mentioned, two possibilities in parallel that are being carried out in Brazil; pharmaceutical use, use of other products, each regulated by a specific ministry or agency. In potential, we know, the largest in Latin America, and that we have all the potential together to make this a reality. We have a lot of patience. That is a very determining factor

Alfredo: Thank you all three. It was spectacular. I would want many hours to speak on this subject, but we have an hour. So I thank you very much. Questions remain hanging around here. A very funny one, which I am going to do because it is very funny. They ask if Camila works for Big Pharma. I imagine not, at the moment. [laughs]

There is not time to answer other questions, but we have the LinkedIn group, which surely the panelists there may want to answer something else. There we can follow it. Thanks Camila, Tarso, José and see you next time.

Camila: Thank you very much.

Tarso: Thank you. Bye.

José: See you later. Thank you all.

Tarso: Thank you all.

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.