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REGULATIONS AND OPPORTUNITIES IN KEY LATIN AMERICAN MARKETS: PERU

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 new webinar. After doing one this week on Uruguay, then Colombia, then Brazil, today it's time to finish with Peru. I remind you that next week we are going to publish the second edition of our report on Latin America, in which we analyze the regulatory frameworks of the different countries in the region, as well as the current market situation in all these countries. In the chat you will surely be able to see the link in which you can prescribe to receive it.

During this webinar, as we did in previous ones, you can ask questions whenever you want. They don't have to wait for the end. If you use the Zoom Q&A option I will see them, and if they are connected with the topic we are talking about at the moment I will try to add them.

To talk about Peru today we have two panelists that I am very sure will complement each other very well. First I'm going to introduce Maritza Reátegui. She is a specialist in Life Sciences and intellectual property and a partner of Rodrigo, Elías & Medrano Abogados. Maritza, let's see if we can hear you well.

Maritza Reátegui: Perfect.

Alfredo: Are you there?

Maritza: Yes, there I am. Good morning to all.

Alfredo: Good morning, Maritza. Thanks for being here. We also have Andrés Vázquez, president of Cann Farm. He is an entrepreneur with many years of experience in agribusiness in Peru and the region, and I also know first-hand that he has been driving the development of the cannabis industry in Peru for several years now. Andrew. You are silenced. See if we can hear you.

Andrés Vázquez: Hello Alfredo. Hello good day. Hi Maritza. Many thanks to you and *MJBiz Daily* for the opportunity.

Alfredo: Thank you both for being here. I also remind the audience that if there are unanswered questions we use a LinkedIn group called *Marijuana Business Daily* in Spanish, which they can join and ask questions later.

So let's start with Peru. For me, Peru is a rather curious case in Latin America, at least to this day, because despite not having completely regulated its cannabis law, I understand that some regulations are still missing, as it already allows imports, it became one of the countries which is bringing more interest in the region. Peru is like a magnet today.

Many countries want to export. Peru as of today does not export but it does import. That is why it is one of the favorites. We will see later in today's conversation what the long-term perspective is, whether Peru is destined to be a long-term importer or not. Let's start by going specifically to what is happening now, which is that Peru is importing medicinal cannabis products and in the imminent it is expected to import even more.

Let's start with you Maritza, what is it that, at a regulatory level, at least companies in the region or in other countries can export to Peru?

Maritza: Alfredo, in Peru much progress has been made on the issues of the regulation of cannabis for medicinal use this year. Despite the pandemic, regulation has been implemented a lot and the authorities have been very proactive in granting licenses and health records. Indeed, Peru, starting with the State, has been the first to import raw materials linked to cannabis, basically on the subject of CBD. It is the State through the Digemid pharmacies that has already been made available to the consumer public.

There is also an importation of raw material by the private sector to be used and disseminated through different dispensing establishments, call them pharmacies or drugstores. In other words, it is already a reality that cannabis products are being imported for medicinal use in Peru.

There are two ways to do this import. If you do it as a finished product, you have to generate a health record. The truth is that there are two very simple categories; one as a medicine and the other as a natural product. Basically the difference between the two is at the marketing level, which in one case you will be able to indicate that it is for the treatment of a disease and in the other case that it contributes to the treatment of a disease.

Another issue that is also interesting, which does not require sanitary registration, is the importation of raw material to make master formulas in the country. There are already different marketing licenses that not only the Digemid pharmacy, which is the regulatory authority, which is already dispensing raw material, but there are already other pharmacies in Peru that are obtaining their license to deliver to users master formulas with imported raw materials also from the private sector.

Alfredo: Maritza, one question, when you talk about raw material, what kind of raw material can it be? Could it be the flower? Does it have to be an excerpt, at least? Can it be either of the two?

Maritza: For import purposes, you have to differentiate between what is CBD and THC. If it is greater than 1% THC, we are talking about psychoactive cannabis, according to our local regulation, which is very similar to regional regulations.

When you are going to import a psychoactive, you have to generate a special import certificate, as it works worldwide for the whole issue of psychoactive substances. When it is a product that is not considered a psychoactive, you can do the import without having these authorizations as a psychoactive and basically with a letter of agreement from the regulatory authority you can do this import.

By directly answering your question, raw material is currently imported to make master formulas. There is still no discussion on the subject, whether it may be the subject of the flower or not, but basically the import is to have the raw material ready for the realization of master formulas.

Alfredo: With which, in practice, what has been imported until now for magisterial formulas is already the extract ready to be used in the pharmacy, dilute it, bottle it.

Maritza: It is correct. Both the State have carried out this import and the private sector is also carrying out this type of import.

Alfredo: Then, we are going to talk more, Maritza, about the issue of product registration, the difference between one type of registered product and the other, and the requirements to also register these products. I'm going a little bit to Andrés now. Andrés, I want to ask you why, in practice, the first product available to patients was imported by the State, what is the outlook today, and in the coming months what type of product is expected to be available.

Andrés: According to the dialogue held with government entities last year, on the one hand, given that the implementation of the regulation took so long with respect to the enactment of the law - remember that the law is from November 2017 and the The regulation comes out in February 2019 - the pressure that this public sector had was such that they made a very executive decision of them to start a first import.

Why of that type of product? The truth is that as a new product, a new industry as in many countries, the authority looked for something that was probably less complex to handle and that is why it was inclined to work only with a CBD extract. Regarding the perspectives, according to the information, it is not official but let's say-

Alfredo: A review with that. This product went on sale in December, if I remember correctly, right? Sales of that first product began.

Andrés: December of last year, that's right.

Alfredo: Until now, is it the only thing that has been available at the level of commercial products for patients in Peru?

Andrés: That's right, in the formal market it is the only thing that has been available until now.

Alfredo: The prospects then?

Andrés: Regarding the perspective, on the one hand, comment that from conversations with the authority it is inferred that this offering of a product for sale by Digemid meets their mandate to seek to give patients access, but understands that when later there are products in the private sector and different types available to patients, the Digemid will not necessarily be competing in some way with the private sector with these products. Since it is also very aware of the price at which this product came out, which has been a product that has a significant subsidy load behind to be able to reach that price to the public.

Alfredo: Is the subsidy from the State that has it or from the company that simply offered a low price?

Andrés: The price in a public administration can be revised, if it was a low price, indeed, but at the same time the additional cost for the finished product is very low. This is clearly not a pricing structure that normally any private sector company would charge.

Alfredo: If we talk about what are the next prescriptions that patients will receive for products available in Peru, what do you think it will be? Master forms? Registered products that private companies are going to import?

Andrés: What is very clear is that the most agile way to make the product available to patients is the master formulas since, as Maritza commented, the product itself does not require a health registration. Therefore, the import is faster. Today, for example, any company with an import license could be managing or executing an import of raw materials, because it does not need to wait until it has had a sanitary registration. I think that's what Maritza was referring to. On the other hand, the finished product, you must first have approved the sanitary registration by Digemid and only then can you import it.

As of today there are three products, if I remember correctly, with registration. These three products can be imported in the form of a finished product, but there may be countless suppliers that are proposing raw materials to the market. The raw material will surely go to pharmacies, some of which have already made their interest public and the commercial route they will follow. In this way it is very likely that the first products we see will be masterful for patients. Certainly the products that have registration, we should see them on the market soon.

Alfredo: Maritza, we are going to clarify a bit the difference at the regulatory level between master formulas and registered products. Starting with magisterial formulas, Andrés commented that it seems to be the most agile thing to make available to patients, but I imagine that it is not just any pharmacy that can dispense this type of product, right? If we start with master formulas, can you give us a review of what requirements are there to import this raw material and then to distribute it in Peru?

Maritza: Okay. The import of the raw material can be given either psychoactive or non-psychoactive. Let us remember that for Peru it is a psychoactive when it has a greater percentage of 1% of THC. It has started in the market, which is usual, for the simplest thing, which is for non-psychoactive cannabis.

The raw material of non-psychoactive cannabis, you can carry out the import. The process you have to follow is the following; The patient who is going to have this cannabis product must first have registered on the website of the Ministry of Health, which is a very simple registration, in five minutes. They only ask for general information. That patient goes to the doctor, who are the doctors who specialize in cannabis issues who are already prescribing.

Since last year there are many companies and academia that have started training many health professionals on cannabis issues. That patient goes to a health professional, gives him the prescription. That patient who is already with his patient record goes to the pharmacy. Not everyone can sell at the pharmacy; You have to have a license to make compounds and to be able to market cannabis products, which is also a very simple process.

Alfredo: Is it something specific to cannabis, this of the magisterial formulas?

Maritza: You have to have a marketing license for cannabis issues. According to the latest statistics that we have verified in the Digemid, there are already more than five pharmacies that already have the marketing license, apart from the pharmacy of the regulatory authority, which is the Digemid. The patient approaches, in the pharmacy they verify that they have the prescription, that it is in the patient registry and immediately the product with cannabis is granted. It is a very simple process in the country and it is working very well.

Alfredo: One question, Maritza. You said that there are at least five pharmacies that already opened, at the regulatory level, the possibility of giving the patient magisterial formulas with cannabis. I imagine that for pharmacies, beyond the possible commercial agreements they make with their raw material suppliers, for the pharmacy cannabis is a raw material, right? Pharmacies in principle can buy it from different companies, right?

Maritza: That is correct, Alfredo. You can buy it from different companies right now because cannabis production licenses have not yet been granted in the country, there is no local supplier. In principle they are using foreign suppliers. This is definitely why it is a master formula, because it is made by a pharmaceutical chemist in the dispensing establishment. Obviously, the raw material, depending on the commercial agreements they have, they will be able to acquire from different suppliers.

Alfredo: So I imagine the prescription is not for a branded product, right? The prescription will say CBD 5%, THC as much, and then the pharmacist will prepare that according to the specification that is there.

Maritza: That is correct, Alfredo. That is the situation of a magisterial formula. That is why it does not have a sanitary registry, because the sanitary registry is when you already do something standardized and in a massive way for a marketing issue throughout the country. It is right.

Alfredo: There is no registration but there is a specific authorization that the pharmacy must have in order to dispense this type of product, plus a special import permit if it is a psychoactive product, right?

Maritza: It is correct. When we are already talking about psychoactive substances, all the regulations that already exist at the international level on issues related to psychoactive substances are activated. You have to generate the import and export health certificates of the country of origin. Additionally you have to have your import license. Regarding the commercialization and import licenses, the Digemid has also been collecting them. Let's say that the panorama is opening up, that it is a conducive environment, ideal now so that one can already establish drugstores, establish production centers in the country, because the regulatory authority on the issue of cannabis for medicinal use is fully implementing by The whole issue of importation and marketing is part of the health ministry, which is the first thing that comes out, the whole import issue.

From there, the second stage is everything related to the issue of local cannabis production with production licenses, security protocols and all the regulations that are similar in Latin America.

Alfredo: I understand. Already in practice, for magisterial formulations there is a limitation today to enter flower to Peru, right? Because I imagine that pharmacies do not have the equipment to do the extraction and everything else, to then make the magisterial formula. Would it be possible, for example, for a Peruvian doctor to prescribe a flower with, I don't know, 10% CBD, to give an example simply? The pharmacy uses raw material flower and deliver it only to the patient.

Maritza: Alfredo, that situation would be ideal. The idea is to open the market to the extent that this market is regulated as well. Current regulation does not prohibit it. It does not indicate it either, but we could have an open possibility on that subject.

Alfredo: Let's see, Andrés.

Andrés: These are conversations that we have had with Maritza in the past. As a lawyer, obviously I am not going to question its legal interpretation there. The will is the authority there. It is the one that was manifesting throughout the implementation of the regulations that the dried flower was not available in the country.

Now, how did you translate that will into the standard? That's another thing. Obviously there may have been some spaces, but that was the will of the authority all the time. In fact, that is why even in the production and export part we also touched a lot on the issue of whether it is possible to import flowers and the position of the authority was always negative.

Alfredo: Let's talk a bit about the product registration issue then. First, Maritza, at the regulatory level, what is the difference between the different types of products that can be registered in Peru? Then, Andrés, maybe you can tell us a little about your practical experience of having already achieved the registration of all three products that are already registered in Digemid.

Maritza: Yes. That question is interesting, Alfredo, because you have two possibilities in the country to register cannabis products for medicinal use. The category that we all know is that of drugs. In the case of medicines, you have to present the clinical studies of safety and efficacy like any medicine. You also have another option, which is the natural product for health use, which basically you have to do is present a monograph that accredits the traditional uses of that product.

When asked, which of the two categories? First, if you have the safety and efficacy clinical studies. If you want to promote that product for the treatment of a disease, the recommendation is that you register it as a drug, but if you want to promote it not as a drug but as a traditional use of the product, you can do so through the category of natural product.

It will depend a lot on the information you have to present the dossier and also how you want to market that product, because there are probably products registered in other countries that can fall into these two categories. It will already be a commercial decision of how you want to promote the product in the country.

Alfredo: I understand. Maritza, I imagine that the one that is registered, that has clinical trials to demonstrate safety and efficacy for a specific indication, is it obviously registered for that indication and then it could be prescribed off-label? That is, for other indications of the same product or would it be restricted to that use?

Maritza: Yes. In Peru we currently have four sanitary records granted. One of the drugs is Sativex, which is registered almost in most Latin American countries. The other three products are considered natural products.

Regarding drug issues, it must be borne in mind that one of the regulatory requirements is that you have a certificate of free sale. That is why it has been so easy for Sativex to be registered in the country in a record time also of six months, very fast, being the first drug in cannabis. It is because it has already been registered in other countries with high health surveillance and had a certificate of free sale. When you register in other countries, it already comes with the indications registered in those countries of high health surveillance.

Regarding the question that you ask me regarding off-label, that will depend, like any other type of medicine, not only on cannabis issues, that it is a prescription with a different indication than the one that the product has. It will be under the responsibility of the health professional, as always happens with any type of category of medicine.

Alfredo: I understand. The other type of registry, not for which Sativex entered as a common and current medicine, but the other one of traditional use that you called it, can this also be prescribed in principle for any condition or is it registered to treat refractory epilepsy in children and just for that? For example.

Maritza: The regulations do not discriminate, neither the law nor the regulations determine that they will only be for these indications. It will depend a lot on what you certify in the health registration dossier. The regulation does not establish any limitation. You only, if you have the clinical safety and efficacy studies that prove that it is for a special indication, they have to grant it to you.

For natural products, except to the extent that you accredit traditional uses in the monograph, those indications should also be accepted. Likewise, there is a document that has been published by the regulatory authority, by Digemid, where it says, “Look, in these indications we consider that there is enough scientific evidence worldwide, that in these indications it is feasible”, but if you present information in your dossier that certifies that there are more additional indications that have been recommended by the regulatory authority, you could also present them.

Alfredo: Good. Andrés, if you want, then tell us a little about how the registration process was and also if in practice it seems to you that there are advantages or disadvantages of one type of registration or another. For example, I imagine that capable that has implications for the promotion of the product or the disclosure of the product in the medical, scientific community, whether it is one or the other registry.

Andrés: Yes, certainly. In our experience, the time Maritza mentions is indeed a good time, and not because of a cannabis problem; It is a real situation in Peru that the process of sanitary registration of health products takes a long time. It took us eight months to get the first record. We went, as we mentioned, for the category of natural product for health use, which is the name of that category. Basically, we estimated that in a new situation it would be much easier for the authority to evaluate a product in that category than a drug option.

As for the advantages and disadvantages. Generally, a general advantage in the country, which I do want to limit because it is very important, is that the regulations give full responsibility and freedom to the medical professional to prescribe the product. That is why, as Maritza said, the medical professional could evaluate, prescribe a product, medicine, for a condition different from that of the sanitary registry, as well as the natural product could be used for a multiplicity of clinical conditions.

Between the two, basically there is a comparison, some advantages and disadvantages, if you want, in terms of how you do the promotion, obviously subject to the rules of the legal framework not only health but what is consumer protection. As for whether or not one is free to present a specific health benefit, no. In the case of the natural product, only one can refer to the traditional uses or the recommended uses. Can't one emphasize-

Alfredo: Andrés, forgive me for interrupting you. There I imagine that the communication will be, "CBD has been shown to be useful for such and such in such and which country", but not my specific product, right? Because if you don't have clinical trials I can't say, "My brand is the one indicated for such an indication." That can't be done with natural ones, right?

Andrés: Especially not in publications that are in any case massive. You cannot direct the patient to promote the product. Obviously, in closed meetings, one on one with the doctors, traditionally the medical visit, a company can present the general information to the doctor and has the freedom one by one to the professional to explain if their product has had any additional evidence to the one that is in the health registry.

What is very important is that the Peruvian regulation protects the patient as it protects the consumer who is not technically specialized from receiving information about a particular product.

Maritza: There it would also be good to specify, complete what Andrés has indicated, that all cannabis products, whether they are medicines or natural products, are all with a prescription. There it is important that the regulation on advertising issues establishes that any product with a medical prescription, whether it is a product with cannabis or not, advertising can only be aimed at health professionals.

There we also have a discussion with the regulatory authority, because it has placed the products that it has granted with a withheld medical prescription, when in reality the natural product products for health use that have been requested are only with CBD and do not have more than 1 % THC; therefore, they are not psychoactive.

The issue of this withheld prescription is badly granted by the regulatory authority, because it should only be a prescription withheld for products that are psychoactive that are greater than 1% THC. We understand that as it is a new issue for the regulatory authority and they are also learning about this issue, this situation should be corrected in the short term as well. The important thing to note is that all the products provided are with a prescription.

Alfredo: Then we are going to talk about cosmetics, food and others, Maritza. Meanwhile clarify, in case someone does not have much idea of how it works in Peru. All these products, even if they are only with CBD, is only under medical prescription; It is not something you buy at a gas station when I go to refuel.

Maritza: It doesn't happen like in Uruguay. [laughs]

Alfredo: No, in Uruguay it is also with a prescription.

Andrés: Yes. Comparing, Alfredo, with the presentation of Brazil the other day, it is also important to understand as a general framework that the regulation of cannabis in Peru is the regulation of a category of products that are framed within the health regulation usually. It is not a specific and special regulation for cannabis with all its own rules.

That is why Maritza's opinion is very relevant, in the sense that one has to understand cannabis regulation but one has to understand the Peruvian regulatory framework in general of the health sector.

Maritza: Perhaps to complement also, which is one of the questions that you are going to ask today, "If I already have my dossier ready, I have my sanitary registration in Brazil, in Colombia, in Uruguay", it will definitely be much easier to access the sanitary registration in Peru, because you already meet one of the conditions which is a certificate of free sale and which has already been evaluated by another regulatory authority.

This is what basically happens with products that are manufactured in Canada or the United States, that sometimes these categories do not require sanitary registration. There you have a situation that if the certificate of Good Manufacturing Practices, who is going to issue it to me? The FDA? Who issues it to me? If you already have a health record, it is much easier to access health records in other countries in Latin America.

Alfredo: Maritza, you mentioned a key issue and it is quality requirements. Good Manufacturing Practices, for example. Let's start back with magisterial formulas, what kind of requirements are there to export the raw material to Peru to be used by a pharmacy as raw material for magisterial formulas? Does the exporter, for example, need Good Manufacturing Practices? If yes, certified by whom. Then we go to the registered products and if there is a difference between one category and another of registered products in terms of the need for Good Manufacturing Practices.

Maritza: In Peru there is a regulation. Sometimes it is more flexible on some topics and not on others. If we do the simile, because notice that the regulation in Peru is a mix between the health part and the agricultural part. Then we will talk about the production part, which is different from what Colombia and other countries are.

When we talk about a certificate of Good Manufacturing Practices for raw materials, they do not ask for them in general for the entire research pharmaceutical industry. We do the simile because we do a lot to regulate pharmaceutical products. For raw materials the Good Manufacturing Practices certification is not required, but it is something that we always recommend to customers. The regulatory authority, even though it is not in the standards, sometimes says, "Give me some quality document", and usually the quality document that is used is the certificate of Good Manufacturing Practices of the raw material. That is when we already import only raw materials.

When we import a finished product and we do not have a certificate of free sale, because it is not a product granted with sanitary registration in another country, the previous regulation is very flexible in that part and tells you, "Well, they do not have a certificate of free sale; then present a contract of manufacture to order that will replace this certificate of free sale ". There you do have to present the GMP; You have to present the certificate of Good Manufacturing Practices for the product that you are going to bring. There you fill in the part that I do not have a sanitary registration and you complement the issue that it is a quality product.

Alfredo: Andrés, I don't know if you want to complement something with regard to the quality issue and if I don't ask you, Andrés, why so far the authorizations that are registered under natural products, let's call him, are all for CBD? Again, is it a bit of a precaution from the authority to start first with CBD and see how it works then THC or is it more--? Why aren't there any with THC yet? Beyond Sativex, registered as a conventional medicine, let's call it.

Andrés: Starting with the last, I think that is clearly that. There is a learning curve between authority, all entrepreneurs. I see that the authority is starting to work directly on formulations that are probably lower risk, that get a little bit easier to evaluate. This will surely evolve and I believe that very soon we will be able to see a record with THC already approved for the Peruvian market.

Regarding the requirements, an important one that I think will be relevant, in parallel with the certificates, is the certificate of analysis. The authority is being meticulous in reviewing the scope, depth and parameters that are presented for the products in the certificates of analysis, which will support each batch of product that is imported into Peru during the regular processes.

I do recommend that there be a thorough evaluation of the manufacturer's practice in terms of its quality control testing, if it uses a third party lab, if that third party lab is licensed. Practically the more robust that CoA is, as it is called, I think the registration process will be much easier.

Alfredo: There is a question whether for magistral there is some kind of limit of THC, for example, in the concentration. I take this opportunity to do it in general, does the legislation establish some type of THC limit in some type of product?

Andrés: No.

Alfredo: The only differentiation between psychoactive and non-psychoactive, the implication that it has is how easy it is to import and export, according to the certificates that are needed, right?

Andrés: Yes.

Alfredo: In theory too, non-psychoactive products should be able to be prescribed by the doctor with a simpler prescription than psychoactive products, right? Is that the other difference?

Andrés: That's right. Yes. Actually, when one works with special prescriptions and the retained prescription, there are other implications also for pharmacies in terms of inventory balance reports and how they have to declare whether they have inventory or not of psychoactive product. It does have certain operational implications, but that is why there is differentiation, for the psychoactive, not psychoactive, in terms of ease of access.

Maritza: That question is also interesting, Alfredo, completing a bit what Andrés has indicated, because the difference between the two, between a simple recipe and a special recipe that is psychoactive, is that it is very bureaucratic, because it has to generate three recipes; one stays with the doctor, another stays with the patient, another stays at the pharmacy. In pandemic situations, which we live all over the world, that patient ends up contaminated by something else, going to doctors. He ends with COVID-19, finally, to be able to acquire his prescription for a psychoactive.

This question is important because the regulatory authority understands that it wants to have control over this situation, on the issue of the medicinal use of cannabis, but the issue of technology and the issue of applications can be implemented there. I want to know from the moment the raw material is imported, to which patient it is reaching and all this bustle can be done through computer applications. The State does not establish over-regulation and has control over the entry of raw material, which is also of interest to the importer and the pharmacy establishment.

Currently the Digemid has released special rules for the pandemic issue, which indicate that the recipes can already be digitally or you can take a photo of the recipe to avoid all this trekking of going to various places and you can receive the product directly. It is an opportunity not only for the cannabis sector, but in general for the pharmaceutical industry sector, to be able to use these applications now that Digemid is creating a special regulation, as I suppose it must be happening in most countries on patient protection issues.

Alfredo: Speaking of control, let's move on to an issue that caught my attention with the Peruvian legislation, which is the registry of patients who use cannabis. I understand now in the middle of the year, there are already more than 6,000 registered, of which two are me, because I wanted to see how it worked and I put some false information and I registered in 10 seconds. With which, I do not understand very well what that record is for. I understand that it is something necessary for the patient to later obtain his prescription; otherwise the doctor cannot prescribe.

What is the point of having this record? I imagine that there is no record for other types of medicines in Peru, that there is a need to have a record of the patient, such medicine.

Andrés: Let's see, there we can have different opinions of reason. There is an issue that is seen a lot in the application of these regulations, and that is that the State has taken great care that the regulations follow the indications of the law. The law mentioned the need for records. By the time it is implemented, surely the authority has made a record in the simplest way possible, because in reality there are no records of other drugs in practice. That facility to which you have alluded I believe that it shows that the authority has precisely sought how to comply with the regulations with what the law commands, but at the same time not to make it even more complicated.

Now, it does have implications on the issue of access that have not yet been resolved, because it is assumed that the pharmacy at the time of dispensing should have the possibility of verifying if the patient is in the registry, which implies that you give it to private pharmacies access to that database online. Although the registry is simple, that can have certain complications in the matter of access that the authority will have to solve.

Alfredo: Capable that it has nothing to do with it, but in Uruguay, speaking of a totally different issue that is access to cannabis for non-medical use, for so-called recreational use, there pharmacies have access to the registry of people who are registered for access but do not have access to names or personal identification. It works with the fingerprint. I imagine that Peru will not want to go so far with this registration issue.

I imagine it may have had some political implications as well, that maybe it was easier to say, “We are going to legalize medical cannabis, but we have it well controlled with a registry.” With that, those who opposed were easier to convince.

Andrés: It’s a lot out there. Those of us who have been on the issue from the beginning seeing how it changed, in reality it is that those who brought this rule out at the level of Congress have been groups of patients and families of patients putting pressure on Congress. It has not been a government initiative.

Obviously, Congress produced a law addressing that need, but it has tried to cover itself as much as it could because it was not of its own accord . Surely it is related to what you say, «How do I attend to this need of the population, but protecting the issue as much as possible?»

Alfredo: Maritza, do you want to add something to the subject of the patient registry? If we don’t move on to a more interesting one capable

Maritza : No, just what we all already know. There are many prejudices related to the cannabis issue. That is why sometimes our authorities are trying to over-regulate and in this way they are feeling more in control of the situation of the entry of this medicinal product with cannabis.

The truth is that I repeat that this issue could be achieved with traceability with these applications that exist. It would be ideal because it does not over-regulate, it does not establish more regulations and the State has control over the entry of these products, either as raw material or as a final consumer product. So it finally reaches the patient. It allows the commercialization and importation to flow, the products to reach patients and the State has control, without there being over-regulation on the subject.

Alfredo: Andrés, ask for you and then another for Maritza. For you Andrés, what are the next steps to wait, now that there are already several import licenses? I understand that there are already a few for products that are already registered, so why are these products not in Peruvian pharmacies tomorrow? What steps are missing to make those products available?

Then, Maritza, let’s move on to the topic of food and cosmetics, there are a few questions about it.

Andrés: As for why not yet, there is a process. There are certain stages that some are loaded with bureaucracy and others are simply commercial stages that have been covered so that these licensed importers can make products available, they can have imported products.

In particular, there was an issue that worries me greatly, and that is that although you see today, I understand, around 17, something like that, import licenses, that with the additional number that Maritza mentioned, we are only talking about five licenses at the retail level. There is a disproportion at the end in the distribution channel. We need more dispensing point licenses that can really move the market.

I am sure, without having reviewed which are the additional ones that have already been granted, that none of them are in the provinces. Finally there are patients all over the country. We need pharmacies and distributors to apply their licenses so that we can achieve the capillarity that the network needs nationwide.

Alfredo: Maritza, to extend the conversation on the topic of cosmetics and food, there is a question that says, "The products that are currently on the market, at least those that the company imports," we are not going to burn it, " that are sold without a prescription, what category would they fall into? The illegal category or is there some type of cannabis product that can be sold without a prescription in Peru today? "

Maritza: None. If we talk about final consumer products, it has to be with a sanitary registration, unless it is on the subject of magisterial formulas that we had been talking about. Regarding cosmetics, it is interesting too, Alfredo, because we do not regulate ourselves under a local standard. We apply an Andean Community regulation for the four member countries of the Andean Community, which are Ecuador, Colombia, Peru and Bolivia.

At the Andean Community level, we have these cosmetic decisions that do allow the use of cannabis as an ingredient for cosmetic products. So much so that Colombia and Ecuador have been granting health notifications for cosmetic products. The only one that does not apply is Peru, but for a matter of local interpretation. We consider that on the subject of Andean decisions it is sufficient for Peru to start marketing and begin to acquire and import cosmetic products with cannabis themes. There is no limitation.

One of the arguments indicated by the regulatory authority is that the law we have on the medicinal and therapeutic use of cannabis had not been discussed, and cosmetics had not been included. We say, "Sure enough, it doesn't have to include--"

Alfredo: Because it is for other things.

Maritza: Yes , because it is for medicinal use. Not only do I not have to include cosmetics in the law on the medicinal use of cannabis, but I cannot, because this is already regulated in a supranational norm, which is the Andean Decision that applies to the four countries.

Specifically, what this Andean Cosmetics Decision tells you is that the authorities have to apply two international lists to determine that you can use an ingredient for cosmetics, whether it be cannabis or not, which is the United States PCPC and the CosIng of the European Economic Community. In both, cannabis is allowed as an ingredient. One of them is more restrictive than the other, but it is allowed in both.

Alfredo: Now, there are those who interpret that in CosIng it is more difficult to justify the use of products derived from the cannabis plant. With synthetic CBD there would be no problem, but if it is derived from the plant maybe yes, because it is the plant included in the 61 Convention on Narcotic Drugs, right?

Maritza: That's right. That's right, Alfredo. That is why I said that one of the CosIng listings is more restrictive, because it allows you to use the seed from the beginning, while the PCPC allows it in all versions. What is established in the decisions? They indicate that the regulatory authorities can choose the list they want, according to what is in Decision 526. Colombia has used the least restrictive, Ecuador has used the least restrictive, which already has 10 health notifications of cosmetic products granted, and let's not even talk about Colombia, which is increasing that number of cosmetics every time. Bolivia has not yet applied it, but it is about to apply the issue of cosmetics.

What I want to tell you is that it is effectively only a matter of interpretation and that the regulatory authority feels confident of being able to grant this type of health notifications in Peru.

Alfredo: So what is lacking is the political and administrative will for them to be implemented, and with that, cosmetics could begin to be marketed in Peru, if I understand correctly.

Maritza: That is correct, yes.

Alfredo: What about the food?

Maritza: Food, yes there is no specific regulation on the DIGESA issue. DIGESA, when you make a sanitary registration of food and beverages in general, if there is no local standard, you are guided by the Codex Alimentarius, which is an international standard that establishes which ingredients are allowed for food. In principle, if cannabis is allowed as an ingredient for the category of product that you have, an implementation of a local regulation would not be necessary, apart from when we are talking about CBD foods. We are never going to talk about THC.

The way is ready, but DIGESA, which is the authority in charge of the issue of food and beverages, still has not participated in any of the meetings related to cannabis issues. Let's say the topic is fine--

Alfredo: Now, there are several countries that say that if CBD is a medicine, something that even goes under medical prescription, then it should not be a food. For now they say, "Hemp seed oil, that's no problem. It's like olive oil, but not CBD, because it has an effect that will not be the effect of THC, but it does have an effect on health. , so it should only be prescribed by a doctor. "

In Peru, do you see the possibility that CBD would also, if there was political and administrative will, be allowed for food?

Maritza: Yes. Yes, it is viable.

Alfredo: Andrés, I don't know if you want to add something-

Maritza: Unlike Andrés, I am much more permissive in the regulatory part. I am guided by what the norm says.

Alfredo: I expected the opposite. Generally the lawyers are the ones who say not always [laughs]. Andrés, I don't know if you want to add something on the topic of cosmetics and food. If not, we have 15 minutes left. Let's move on to the issue of production in Peru. Because for now we have been talking about what Peru can import and how to import it and others, but Peru's regulations are not only for importing; is that you are simply applying this part first. Much of the regulation is actually dedicated to production in Peru. If you want, we can go to that topic, unless you have something specific about cosmetics and food.

Andrés: The only thing, to tell you that I am sure that in your audience you have Digemid officials, because they are writing to tell me that there are already provincial pharmacies in Peru with a request for a marketing license, and that the pharmacies will have access to your patient registry. So you have a good audience.

Alfredo: Welcome the audience of the Digemid then. Let's talk about local production. Until today, correct me if I am wrong, there is no license issued to produce anything in Peru, but it is expected that they can be granted. Let's start a bit with the big picture of what you expect in the coming months in regards to this.

Andrés: I have the same information, there is none issued. It is important to clarify that in Peru the regulations give three production license options. There is a production license that is a production license without cultivation, where a pharmaceutical laboratory - remember, a requirement for a production license to do so - a pharmaceutical laboratory can apply to that license to import an extract and from it formulate and manufacture a specific product . That is one option.

The second option is the production license with cultivation, which allows the same but also from the seed to manage your crop, make your extraction and then have a finished product. The third is an option called a production license with cultivation for seed production, which is in the regulations specifically for that issue. Given these first two categories, without culture and with culture, what you would expect to see is that at any moment there will be a local pharmaceutical laboratory with a production license without culture.

Why see it first? One, because there are a greater number of pharmaceutical laboratories dedicated to that part of the chain, which is their specialty. A pharmaceutical company is not normally a farmer. Second, because the steps to get to the license are fewer. There is one less step because you do not have to go through the Ministry of Agriculture. You go for the security issue with the Ministry of the Interior and then to the Digemid.

Alfredo: There Andrés, could that type of license import the flower, for example?

Andrés: Again, as Maritza said, when reading the regulation, a prohibition is not read. We know that the will of the authority was that there should be no flower, but when one reads the regulation-- In fact, many chapters of the regulation talk about cannabis and its derivatives, and cannabis in the definitions is the plant, the flower, its parts. A reading of the rule tells you, "Hey, the flower too." What the authority is doing today shows that obviously in the interpretation they also translate their will.

In principle, it should be to import extracts without any differentiation in how refined they are, and the laboratory can finish the process already with that production license without culture.

Alfredo: Good. Maritza, correct me if I'm wrong. I understand that both for this type of process that Andrés spoke of manufacturing, as well as for cultivation, it is not just anyone who can apply for a license. It's not, "I have a field and I don't know what to do with the field. I'm going to see if I can plant cannabis," right? They are precisely laboratories, or I don't know what the specific term is like in Peru, I don't remember it now, who-

Andrés: Pharmaceutical laboratories.

Alfredo: Exactly, who are the ones who can apply for these licenses. What implications does that have? I mean, how many of these are there in Peru? There are five? Are there 5,000? An approximate number, and if there is a company very interested in going to grow crops in Peru but it is not a pharmaceutical laboratory, obviously, what would it have to do? Be careful that you are silenced, Maritza.

Maritza: Thank you. Yes, that differentiation is important to verify the times when you want to start business in the country. We, unlike the region and the closest that is Colombia, has differentiated those that have agricultural issues and those that are pharmaceuticals. We have a mix of both. Two areas that were totally separate, now because of the cannabis issue they have to be together, or perhaps a little more similar to the regularization that exists in Paraguay and very different from what exists in the regulation of Colombia, Uruguay, Chile, from other countries.

In principle, if you want to produce cannabis in the country, you must first have your health authorization as a pharmaceutical laboratory. There you have a first fence, let's say. Once you have your sanitary authorization as a laboratory, you have two options; Either you make your laboratory from scratch in the pharmaceutical country or you buy a third party, and it depends on your time and the investments you want to make.

Once you have your sanitary authorization as a laboratory, you can apply for your production license. As Andrés explained well, it can be with cultivation, without cultivation or with seed. Once you have this topic you can close. There perhaps also the question that they always ask us is if there is any limitation of territory, of quantity. The standard does not establish any limitation. In any part of the territory of Peru you can do it and it does not establish a limit of the cultivation range.

Perhaps the issue where you will not be able to access, for example, are the security protocols that the Ministry of the Interior can grant you. Of course, if you want to grow your cannabis in an area of Vraem, which is a drug trafficking zone, you will probably not be able to comply with the security protocol standards and the Ministry of the Interior will not grant you security protocols. That would be the situation now that we have.

That is the differentiation that exists at the regional level because, as we indicated at the beginning, what the State has sought is to try to make it as restrictive as possible. That is why we, unlike Colombia, from the closest countries, do not yet have a production license, because you have to comply with this previous step of having your sanitary authorization as a laboratory, granted by the regulatory authority.

Andrés: There is another issue that is also a difference with other regulations. One cannot go to applications with a project. I am referring to a project where this is what I am going to do, you give me the license and then I invest. Here the route is that you have to, in the evaluation process, you have to demonstrate the investment that is made. You cannot say that you are going to do the labs; you have to have it built, operational. If you are going to present yourself to the security protocol, it is not enough to say what you are going to put; you have to implement it. There's an issue that again is a-- You have to manage investment risk, because first you invest, then you have a license.

Alfredo: Andrés or Maritza, I understand that there is still some small, or perhaps not so small, regulation missing to finish implementing the whole production issue, right?

Without going into much detail about what specific regulations are missing, what prospects do you have in terms of these missing regulations being published and how far are they limiting the lack of these regulations to be issued today?

Andrés: If you want, Maritza, I'll start, let's say last. In limiting, they don't really limit-- There is a way to get to the production license right now, yes; yes you can get there. You have no shortage of rules to get there, but you have fewer tools, because there are rules that have not been issued that could make it easier for you to meet all the requirements.

I emphasize, for example, one that has to do with the origin of the seeds. Today, the only way is to go for a seed via importation in one of the two countries with which we have a phytosanitary protocol, the United States or Colombia. The regulation establishes that we should also have the source of these seedbeds similar to that of Colombia, but it has not been regulated. We cannot use it; you can only use the other one.

There is also a separate agricultural standard for non-psychoactive cannabis, hemp, which has not been published either. You don't have this route either but, let's say, you have a way to get there. Now, the other thing is that in terms of expectations, there is much rumor of an intention that there be modifications in the regulations.

Alfredo: What kind?

Andrés: The information that has circulated is that there are some that are basically administrative clarifications, others that would have to do with some additional limitations in the agricultural part and others, let's say that are affecting access, the possibility of product categories or types of recipes. It is not a public document, but it is the information that has been rumored.

Alfredo: Maritza, there are several pieces in motion then, right? For what has to do with production, that something can already be postulated, but some rules need to be defined. When do you expect the system to be oiled? Let's say.

Maritza: The regulation of cannabis for medicinal use is already in the production license. There should be no changes on that topic. What is pending are lower-level regulations such as, for example, the issue of the seed source. Basically the seed source is to establish a local data bank of the seeds that exist here in the country, and to be able to proceed. There is no such regulation, the deadline is not established. Unlike Colombia, which has already closed the issue of the seed source, in Peru the guidelines have not even been given to begin with the issue of the seed source.

This issue is very important, because Peru is a country with a plant variety. You can protect genetics through intellectual property. Recently INIA, which is in charge of agricultural research issues, has just released an entire guidance document for intellectual property issues. We cannot miss this opportunity to have a seed source on cannabis issues for the protection of plant varieties. Peru could also be an exporter of seeds. This is an opportunity that the Ministry of Agriculture and the State should take advantage of.

Then it is pending, as Andrés commented, we currently have phytosanitary protocols with Colombia and with the United States for the importation of seeds. There is no limitation. If you want to import seeds from the Netherlands, from other countries, the phytosanitary protocols are established. There is no limitation in this part, only that there has probably been no need to import seeds from other countries in order to implement sanitary protocols with other countries.

While it is true, there is always that the regulation can be changed. The framework to facilitate and provide this legal security for all investors who are already in the country, and for those who come, is that the general guidelines that are already established in the regulations and in the law for medicinal use are not modified. of cannabis.

It is important, as Andrés mentioned and outlined, that we still do not have a regulation for the use of hemp for industrial uses. That is also a great opportunity for the country that cannot be missed. Hemp regulation was probably included in the medicinal and therapeutic use of cannabis, but in reality hemp has many industrial uses, not only related to medicinal issues. Yes, it is an opportunity and a new regulation should be applied on this issue, which is still outlined.

Andrés: Sorry.

Alfredo: We have two minutes left.

Andrés: I agree with Maritza because obviously the government has a pending task to align its positions, because just as it happens in other countries, where governments are looking for sources of reactivation of the economy, once this pandemic is over, we would all expect hemp be one of the ways of reactivation, a new crop to diversify agriculture in the country. That regulation should fall under its own weight.

Maritza: Besides, there are also interesting topics on the issue of reactivation even for rural areas. There are some nice projects that are being carried out on agricultural research topics with areas to make handicrafts and make looms linked with threads made with hemp themes. Cute. Not only do they promote the area, but you also generate special products for export and generate wealth in those countries where you have the theme of handicrafts for textile uses. Peru is well known for the manufacture of many handicraft textiles. You generate super interesting added value in agricultural research topics as well.

Alfredo: We have one minute left to say goodbye. Maybe the last one, if you want to guess, when do you expect to see the first crop in Peru? And with that they say goodbye.

Maritza: I think it's not a matter of guessing; I think that this year we should have it.

Alfredo: This year?

Andrés: This year, sir.

Alfredo: This year. Many thanks to both of you, Maritza and Andrés.

Andrés: Thank you Alfredo. Many thanks to *MJBiz*. Maritza, see you. Bye.

Maritza: Bye.

Alfredo: Bye.

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