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TECHNICAL BARRIERS TO TRADE OF PHARMACEUTICAL PRODUCTS IN CENTRAL AMERICA

Technical barriers to trade of pharmaceutical products in Central America

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ACRONYMS

CR	COSTA RICA
HN	HONDURAS
GT	GUATEMALA
ES	EL SALVADOR
NC	NICARAGUA
PN	PANAMA
WTO	WORLD TRADE ORGANIZATION
PAHO	PANAMERICA HEALTH ORGANIZATION
AACCUE	ASSOCIATION AGREEMENT BETWEEN CENTRAL AMERICA AND THE EUROPEAN UNION
SICA	CENTRAL AMERICAN INTEGRATION SYSTEM
TBT	AGREEMENT ON TECHNICAL BARRIERS TO TRADE
TRIPS	WTO- AGREEMENT ON TRADE-RELATED TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS
NRA	NATIONAL REGULATORY AGENCY
RTCA	CENTRAL AMERICAN TECHNICAL RULES

INTRODUCTION

Pharmaceutical industry has traditionally stood out for its capacity for innovation, while the Law constantly faces the challenge of staying up to date to adjust to development, trade transformation and human needs. Pharmaceutical Companies are frequently facing difficulties with the entrance of their products in Central America market; these challenges are mostly related to the regulations and requirements associated to product standards, registration, and approval processes. Through different regulations and agreements, the countries have tried to establish international strategies to reduce technical barriers to trade in this industry. These processes are necessary to facilitate access to medicines to the countries. These efforts have been oriented towards the need to guarantee the agility of trade and access to effective and safe medicines. In this way, national regulatory systems seek alternatives to improve economic development and public health.

In Central American, efforts have been made through international agreements and treaties, to harmonically regulate legislation. However, even though the legislation exists (RTCAs), the harmonized interpretation of these regulations has not been reached at the implementation level. This situation hinders the approval processes to market the pharmaceutical products.

This legal analysis study aims to clearly determine what are the main challenges in the region in this regard. With this panorama outlined, decisions can be made to guarantee the improvement of the regulatory systems and the approval processes of pharmaceutical products, to harmonize the technical-administrative processes and, in turn, guarantee the population access to safe and quality medicines.

This document consists of the following parts; firstly, the Central American regulatory framework is presented, going from international treaties and conventions to the particularities of each jurisdiction. Secondly, an analysis of the situation of each country is carried out; specifically, the legislation, process, cost, duration, and the main challenges faced in each jurisdiction. Thirdly, the main challenges of the central American region are analyzed. Fourthly, a case study of Panama is carried out, due to its situation regarding the interpretation of regulations, which is currently affecting the approval of pharmaceutical products, consequently the access of medicines to their population. Fifth, a brief analysis of intellectual property regulation and linkage of patent protection and data test information. Sixthly, the importance of taking High Standard Authorities and Reference Authorities as a parameter is mentioned, in order

to harmonize the criteria for the interpretation of regulations in the region. Finally, the conclusions of the research and future perspectives are presented.

I. LEGAL FRAMEWORK. OVERVIEW OF THE CENTRAL AMERICAN REGULATIONS FOR PHARMACEUTICAL PRODUCTS.

In this section, the legal framework of international conventions and treaties is presented. Among them: the AACUE, the TBT of the World Trade Organization and the Central American Integration System (SICA). These three agreements establish the normative bases that give rise to the special regulations that seek access to medicines, not creating unnecessary obstacles to trade and the application of the harmonized law. Each of the representative aspects from said international conventions and treaties, is detailed below.

1. PROVISIONS ON MEDICINES ESTABLISHED IN THE ASSOCIATION AGREEMENT BETWEEN CENTRAL AMERICA AND THE EUROPEAN UNION (AACUE IN SPANISH)[1]

Title IX of the AACUE establishes the list of the Central American Technical Rules (RTCA in Spanish) that apply to medicines and related products, which are as follows:

1. RTCA of good manufacturing practices for human use medicines, including the verification guide.
2. RTCA of requirements for health registration of human use medicines.
3. RTCA of natural products: Quality assurance. Requirements for natural product registration. Good manufacturing practices for laboratories that produce natural products. Labeling.
4. RTCA of labeling of pesticides for domestic and industrial use.
5. RTCA of registration of pesticides for domestic and industrial use.
6. RTCA of human use medicine stability study.

According to Article 305[2] called "Trading Technical Barriers" of Title IX of the AACUE, the Parties agree that Member States of the European Union will ensure that Central American products legally placed in the market of one of said Member States of the European Union (EU) may also be traded in the other Member States of the EU, provided that the products have the same level of protection of the legitimate interest of stakeholders (principle of mutual recognition). In addition, when there are

[1] 02_anexo-xx-lista-de-reglamentos-tecnicos-centroamericanos-rtca-en-proceso-de-armonizacion (2).pdf

[2] 00_parte-iv-titulo-ix-integracion-economica-regional (3).pdf

harmonized regional import requirements, the EU products must comply with regional requirements to be firstly traded and imported legally in the Republic of the Central American (CA) Party. Based on this Agreement, when a product is covered by a harmonized legislation and needs to be registered, the registration in one of the countries of Central America must be accepted by the other countries of Central America once internal procedures had been performed.

Article 306[3] called "Sanitary and Phytosanitary Measures" of Title IX of the AACUE establishes the sanitary and phytosanitary measures for free trading of merchandise in CA and the EU. This provision also intends to ensure the mutual recognition of assurance performed by the countries of Central America at any Member State of the EU.

2. Provisions of the Agreement on Technical Barriers to Trade (TBT)

The purpose of the Agreement on Technical Barriers to Trade (TBT Agreement) is that technical rules, regulations, and assurance assessments are not discriminatory and do not create unnecessary barriers to trade. This Agreement also recognizes the right of the Members of the World Trade Organization (WTO) to apply measures to comply with legal regulatory objectives such as health and environmental protection or people safety.

Based on the above, Article 2[4] called "Preparation, adoption, and application of technical rules by government institutions" of the Agreement on Technical Barriers to Trade (TBT) establishes that Members must ensure that technical rules that create unnecessary barriers to international trade are not prepared, adopted, or applied. In addition, technical rules must not be more trade restrictive than necessary to achieve legitimate objectives, considering the risks of not doing so.

Under the TBT Agreement, governments must ensure that TBT measures do not discriminate foreign products (in favor of national producers) or foreign producers. Products imported from any member country will be treated "as favorably" as "similar local products" and products from any other country are treated.

On the other hand, transparency is one of the pillars of the TBT Agreement, which anticipates three main elements: notifications, information services, and publication prescriptions. Therefore, through the WTO Secretary, governments must notify the other Members about all measures that may significantly affect trading between Members and that are not based on relevant international regulations.

[3] 00_parte-iv-titulo-ix-integracion-economica-regional (3).pdf
[4] https://www.wto.org/spanish/docs_s/legal_s/17-tbt.pdf

3. Provisions on medicines established by the Central American Integration System mechanisms

Rules for joint negotiation of prices and purchase of medicines in Central America and the Dominican Republic

Within the Central American Integration System framework (SICA), the Council of Ministers of Health of Central America (COMISCA) was created to address regional health issues (acronyms in Spanish). Based on the above, the rules for joint negotiation of prices and purchase of medicines in Central America (CA) and the Dominican Republic (DR) was approved. Its purpose is to establish a procedure to negotiate prices and purchase of medicines for CA and DR health ministries, secretary, or social security offices. These rules intend to give access to quality, safe, and efficient medicines at prices lower than individual acquisitions, unifying prices for the region.

Therefore, the joint negotiation is made at the regional and national level. In this way, at the regional level, planning, pre-qualification of companies and products, pricing negotiation, and medicine award are processes performed together with the COMISCA Secretary, advised by the Subregional Technical Commission for Medicines (CTSM in Spanish). On the other hand, at the national level, each country or entity that estimated the purchase of medicines under this mechanism is responsible for contracting the negotiated prices and awarded bidders.

Contracts between health institutions and pharmaceutical companies are covered by the SICA Legal Security in accordance with the Protocol of Tegucigalpa.

II. Central America´s Sanitary Registration Framework by country

While every Central American country has developed their own norms regarding commercialize of pharmaceutical products, there is an ongoing effort to harmonize general requirements and advance common standards at a regional level.

One of the important aspects in the Central American regulatory legislation is that it is possible to carry out a mutual recognition of the sanitary registries of the products, namely, the health authority of each of these countries that it is part of the Central American Technical Regulation RTCA 11.03.59:18 Pharmaceutical Products. Medicines for Human Use. Sanitary Registration Requirements" Annex II: Mutual Recognition of Registration could carry out a sanitary registration based on a product previously registered and evaluated in another Central American country to obtain a more

expeditious registration and with fewer requirements. However, the sanitary registration must always be evaluated in each country according to national legislation.

Below we present a list of the key regional regulations affecting sanitary registrations and import into Central America. Additionally, refer to annex 1 for an overview of sanitary requirements applied, and Terms used by Central American countries on pharmaceuticals products imported from the European Union and annex 2 for Technical notes and requirements for the importation of pharmaceutical products.

1. COSTA RICA

Costa Rica´s Sanitary Registration Framework is comprised by the following regulations: i) General Health Law (Law Nr. 5395); ii) Recognition of the Evaluation and Approval of final reports of Clinical and non-Clinical Studies by the Regulatory Authorities of reference as evidence for the Sanitary Registration of Medicine (Nr. 39433-S); iii) Regulation for the authorization for the import and acquisition of unregistered medicines (Nr. 36358-S).

General requirements

Sanitary registration
Competent authority: Ministry of Health (Ministerio de Salud)

Registration process: 1) Registration of PoA (it could take 2-3 months) at Ministry of Health 2) Filing application and required documents at the digital system; 3) Examination (it could take 6-12 months); 4) Objections (If apply), the applicant will have ten days to response with the possibility of two questions to the examiner by the system and extension of time of ten days; 5) The examiner will review the information/documents and grant or refused the sanitary registration 6) If the registration is refused it could be the possibility to file a revocation action (3 days after the notification) with the corresponding arguments or an appeal action (5 days after the notification) that will be examinate by the Director of the Health Ministry or the legal Department of the Ministry of Health.

Procedure: sanitary registration can be completed online at www.registrelo.go.cr. Digital signature is required.

Cost: €470.

Duration: 12- 18 months/ uncertain.

Validity: 5 years.

Main challenges: The main obstacle faced by companies in CR is the approval period of the processes, whether they are new applications, renewals, or post-registration changes. Currently, CR is one of the slowest countries in the approval process; however, transparency during the process is highlighted since the applicant can be informed of the delay reasons, for example, the shortage of examiners. In addition, the digital system has made it possible to guarantee the priority principle of applications.

CR has a functional digital system; however, improvements should be made. The limitations of the current system have not yet been improved.

As a counterpart to the digitization of the processes, access to examiners has deteriorated. At present the system offers a single query possibility for clarifications through the digital system.

Institutional instability due to political changes has increased, hindering proposals and improvement initiatives.

2. El Salvador

El Salvador´s Sanitary Registration Framework is comprised by the following regulations: 1) Medication Law (enacted by the Legislative Decree Nr.1008); 2) Legislative Decree on Fees for Services and Licenses for Health Facilities Applicable to the National Drug Administration (Nr. 417); 3) General Regulations of the Medication Law (Legislative Decree Nr. 245); 4) Special Regulation for the Recognition of Foreign Sanitary Registrations (Legislative Decree Nr. 34); 5) Data Protection Regulation for Testing New Pharmaceutical Products (Legislative Decree Nr. 65).

General requirements

Sanitary registration.

Competent authority: National Drug Administration (Dirección Nacional de Medicamentos or DNM)

Registration process: Registration of PoA at DNM 2) Filing application and required documents at the digital system; 3) Examination; 4) In case the examination of the application has been favorable, it continues with the filing of the physical dossier at the offices of the DNM and withdrawal of the sanitary registration of the product. 5) If the application is refused, the law neither the drug regulations regulate a procedure that may be filed. However, by supplementary application of the Administrative Procedures Law (LPA), a revocation and appeal could be filed.

Procedure: the application can be submitted online at https://portalenlinea.medicamentos.gob.sv/

Cost: €470.

Duration: 1-2 months and 10 working days for cases where the recognition of a foreign registration is requested.

Validity: 5 years.

Main challenges: El Salvador political instability has affected the national system and a pro-national industry trend has been perceived. The digitization of the system has been partially lost; since it has become a hybrid process, as only part of the process can be done digitally.

Another of the difficulties that applicants face is that the renewal processes have basically become new registration applications since the authority requests information that has already been provided in the initial application. Furthermore, access to evaluators is very limited.

3. GUATEMALA

Guatemala´s Sanitary Registration Framework is comprised by the following regulations: 1) Health Code (enacted by the Legislative Decree Nr. 90- 97 of the Congress of the Republic of Guatemala); 2) Law for the Simplification of Administrative Procedures and Requirements (enacted by the Legislative Decree Nr. 05-2021 of the Congress of the Republic of Guatemala); 3) Amendment to the Value Added Tax Law regarding generic medicines (enacted by the Legislative Decree Nr. 27-92 of the Congress of the Republic of Guatemala); 4) Regulation for the sanitary control of medicines and related products and its reforms (Government Agreement Nr. 712-99); 5) Advertising, promotion and information on medicines and pesticides for domestic use, Technical Standard 39-2020 of the Ministry of Public Health, and Social Assistance; 6) Technical standard to request and authorize certificates of free sale of Pharmaceutical and Related Products (Nr. 03-2020 of the Ministry of Public Health and Social Assistance); 7) Technical standard for distributors (Nr. 48-2020 of the Ministry of Public Health and Social Assistance); 8) Technical Standard for the Homologation of the Sanitary Registration of Medicines and Vaccines (Nr. 07-2023 of the Ministry of Public Health and Social Assistance); 9) Regulation on the Identification of Pharmaceutical Products (Nr. 21-2002 of the Ministry of Public Health and Social Assistance); 10) Technical Standard for the Sanitary Registry of Pharmaceutical Products (Nr. 65-2010 of the Ministry of Public Health and Social Assistance).

General requirements

Sanitary registration.

Competent authority: Ministry of Public Health and Social Assistance MSPAS (Ministerio de Salud pública y asistencia social)

Registration process: 1. Registration of the POA in favor of the pharmaceutical chemist responsible (regent) in the corresponding authority (it could take 1-2 weeks). 2. Payment of the corresponding fee. 3. Preparation of the physical application file with all the requirements. 4. Once the application file is submitted, it goes through a process of verification of documents and requirements that can take from 1-2 months until the issuance of the product registration certificate. If for any reason the resolution is unfavorable, the administrative remedies of the Law of Administrative Litigation, Decree 119-96 of the Congress of the Republic of Guatemala are applicable. The delay time to resolve the administrative appeal is approximately 2 months.

Procedure: Applications cannot be carried out online, the requests are entered in physical form. https://www.mspas.gob.gt/institucional/acerca-del-mspas

Cost: €50.

Duration: 1-3 months.

Validity: 5 years.

Main Challenges: In Guatemala there is no digital system, the registration process is carried out manually by filing physical documents. Additionally, the approval period of the processes, whether they are new applications, renewals, or post-registration changes is long and uncertain.

4. HONDURAS

Honduras's Sanitary Registration Framework is comprised by the following regulations: 1) Health Code (enacted by the Legislative Decree Nr. 65-91); 2) Regulation for the Sanitary Control of Products, Services and Establishments for Sanitary Interest (enacted by the Legislative Decree Nr. 318-2005); 3) Vaccine Law (enacted by the Legislative Decree Nr. 288-2013);¸4) Regulation for the sanitary control of products, services, and establishments of sanitary interest; 5) National list of essential medicines LNME 2018-2020.

General requirements

Sanitary registration.

Competent authority: Health regulatory agency ARSA (Agencia de Regulación sanitaria)

Registration process: 1) Submission of the application and required documents either online or physical form; 2) Review of documents by ARSA (may take 6-12 months); 3) Submission of documents or modifications (if applicable), the applicant will have ten days to respond; 4) the authority will review the information/documents and will grant or deny the sanitary registration.

Procedure: Applications could be carried online or could be file on physical form. https://www.arsa.gob.hn/tramitesl-pf/

Cost: €470

Duration: 8-12 months.

Validity: 5 years.

Main challenges: The main obstacle faced by companies in Honduras is the approval period of the processes, whether they are new applications, renewals, or post-registration changes. Even though the system offers the possibility of paying additional special rates to speed up processes the delays persist indefinitely. Another of the difficulties that applicants face is that the renewal processes have basically become new registration applications since the authority requests information that had already been provided in the initial application. Additionally, Honduras does not have a Regulation for biological medicines and the regulation for the registration of chemical synthesis medicines must be used.

5. NICARAGUA

Nicaragua´s Sanitary Registration Framework is comprised by the following regulations: 1) Law on Medicines and Pharmacies (Nr. 292); 2) Executive Decree N°6-99: Regulations to Law N°292, Law on Medicines and Pharmacies; 3) Executive Decree No. 23-2022: Reforming Executive Decree No. 6-99: Regulation of Law No. 292, Law on Medicines, and Pharmacies; 4) Administrative Resolution N°003-2021 Registration Process before the National Authority of Sanitary Regulation (ANRS); 5) Resolution N°444-2021 and N°446-2021 for good manufacturing practices and sanitary registration. Council of Ministers of Economic Integration (COMIECO); 6) Administrative Resolution N°003-2021 Registration Process before the National Authority of Sanitary Regulation (ANRS); vii) Administrative Resolution 139-2004 Charging of the fee for the recognition of the sanitary registration made by distributors and importers of pharmaceutical products for sanitary surveillance; 7) Administrative

Resolution No. 001-2023 Procedure for Powers of Attorney before the ANRS (National Authority of Sanitary Regulation.

General requirements

Sanitary registration.

Competent authority: Ministry of Health (Ministerio de Salud)

Requirements: 1) Registration of the PoA at the National Authority of Sanitary Regulation ANRS. 2) Preparation of the application and filing with all the requirements. 3) Pre-valuation request: Once the information is completed, the pre-valuation of the product is requested, then a payment order for the service is generated and the user goes to the Pharmacy Directorate with the payment order to make the payment at the Ministry of Health (MINSA) cashier's office to later enable the receipt of payment made on the platform. 4) Pre-valuation review: Once the application has been paid, the pre-valuator will start the review and determine the acceptance or rejection of the application. -Rejection: In case of rejection the applicant will be able to visualize the reasons for the rejection of the authority and response with the modifications or missing information. - Acceptance: Once the pre-evaluation is approved, the dossier is generated, and the application form is printed. 5) Filing the Dossier and Start of Dossier Evaluation: The applicant must appear at the Pharmacy Department of the General Directorate of Health Regulation with the dossier approved in the pre-evaluation. The dossier is received by the examiners who proceed to perform the exhaustive evaluation of the dossier and the sample analysis to obtain the sanitary registration certificate.

Procedure: Applications could be carried online or could be file on physical form. However, if the authority will request the original documents, these must be submitted. https://karplus.minsa.net.ni

Cost: € 66 and € 80for the analysis of the product.

Duration: 6-12 months.

Validity: 5 years

Main challenges: Political instability in Nicaragua has made the approval processes highly uncertain. The health authority has increased requirements and additional information to what is established in the regulations. There is no digitization of the system or access to the authority or examiners at all. There is a lot of uncertainty and lack of transparency in the processes. Due to these difficulties, Nicaragua is at risk of losing access to medicines.

6. PANAMÁ

Panama´s Sanitary Registration Framework is comprised by the following regulations: 1) Law 1 of 2001 Medicines and other human health products; 2) Decree 178 Regulation to the Law Nr. 1 of 2001 Medicines and other human health products; 3) Resolution Nr. 1655; 4) Executive Decree to regulate the protection of the information contained in test data and other undisclosed data to obtain the Sanitary Registration of medicines, publicity, and transparency measures (Nr. 1389); 5) Executive Decree to regulate the standards for stability studies, as set forth in law 1 of January 10, 2001 (Nr. 197); 6) Executive Decree Nr. 105 that amends the Executive Decree Nr. 178, as amended by Executive Decree Nr. 319, which regulates Law Nr. 1 of January 10, 2001; 7) Executive Decree Nr. 340 for the Sanitary registration of biological and biotechnological products; 8) Executive Decree Nr. 32 that modifies Executive Decree Nr. 340, which modifies Chapter V of Title II of Executive Decree Nr. 178 regarding the Sanitary Registration of Biological and Biotechnological Products; 9) Executive Decree Nr. 321 that regulates the Sanitary Registration and Handling of Radiopharmaceuticals; 10) Executive Decree Nr. 303 regulating the registration of Orphan Drugs; xi) Executive Decree Nr. 290 that regulates article 26 of Law Nr. 1 of January 10, 2002, on Homeopathic Medicines; 11) Executive Decree Nr. 331, which amends and adds articles to Executive Decree Nr. 178, regarding modifications and notifications of the Sanitary Registry; 12) Resolution Nr. 331 that establishes new provisions on the information of excipients that must be declared in the package insert and monograph of Medicines for Human Use; 13) Executive Decree Nr. 95 for the Regulation to the Law 1 of 2001 Medicines and other human health products.

General requirements

Sanitary registration[5, 6]

Competent authority: National Directorate of Pharmacy and Drugs of the Ministry of Health *(Dirección Nacional de Farmacia y Drogas del Ministerio de Salud)*

Registration process: 1) Registration of PoA 2) Previously of filing the application it is required to send the samples to SPECIALIZED INSTITUTE OF ANALYSIS of Panamá with the information of the product (formulas, analysis method) for the corresponding examination (if apply -depends of the type of product-). 3) Filing application and required documents at the National Directorate of Pharmacy and Drugs of the Ministry of Health or the digital system; 3) Examination: In case that the file does not have all the requirements the examiner will notify the owner to complete the all the requirements in a timeframe of 180 days otherwise the application will be withdraw.; 4) In case the

[5] https://www.minsa.gob.pa/direccion/direccion-nacional-de-farmacia-y-drogas
[6] Own research.

examination of the application has been favorable, it continues with the examination and verify the results of the analysis by the SPECIALIZED INSTITUTE OF ANALYSIS of Panamá (if apply -depends of the type of product-). 5) With the approval of the examination the file must be reviewed by the Sanitary registration department, and they will grant the sanitary registration.6) If the application is refused, the law neither the drug regulations regulate a procedure that may be filed. However, by supplementary application of the Administrative Procedures Law (LPA), a revocation and appeal could be filed.

Procedure: Applications could be carried online or could be file on physical form https://faddi.minsa.gob.pa:8443/control_principal/ [7]

Cost: €490 official fees and €.1400 for the analysis of the product by SPECIALIZED INSTITUTE OF ANALYSIS of Panamá.[8]

Duration: 6-12 months.

Validity: 5 years.

Main challenges: Panama´s main challenge is the current criteria of the national authority, regarding the requirements of the apostilled certificates of good manufacturing practices and the non-acceptance of digital certificates issued by high standard authorities, such as EMA, which will be further explained in the next section.

III. MAIN CHALLENGES TO TRADE OF PHARMACEUTICAL PRODUCTS IN CENTRAL AMERICA.

This section presents the main challenges to trade of pharmaceutical products in Central America. Through different interviews with pharmaceutical companies, the main challenges in this regard are determined. The foregoing proves that in the region it is necessary to harmonize technical-administrative processes, reduce their duration, update the legal framework, make technical changes to internal policies, among others.

1. Establishing the challenges

To gain comprehensive insights of the main challenges currently faced by the companies in the pharmaceutical industry, we have conducted a series of interviews

[7] https://faddi.minsa.gob.pa:8443/control_principal/
8 Euro exchange rate as of June 2023.

with eight key pharmaceutical companies which manufactures and import products to Central America, international trade experts and FEDEFARMA.

The interview section of this legal review analysis offers a qualitative analysis of the challenges and opportunities related to the main challenges to commerce of medicines in Central America. By conducting open dialogues with the people on the first front of the companies dealing with these challenges, we have gathered first-hand perspectives and deeper understanding of their perspectives and experiences on the main challenges in the region.

The objective of the interview was to identify and clarify the main challenges for the entrance of medicines into the market. The interviews were carried out through video calls, where participants were interviewed on the following question:

a) Regarding regulatory issues and based on your own experience; what are the main obstacles faced by pharmaceutical companies when marketing their products in CA?

b) Concerning the health authorities and government entities of the region, which do you consider to be the most critical aspects where substantial changes are required to improve the registration processes of pharmaceutical products?

2. Interviews Results

The following sections will present the key findings drawn from the interviews, providing an overview of the main challenges. The findings presented are based on the information provided by the interviewees; furthermore, it is important to state that all the interviewed subjects coincided on the six following points:

2.1 Lack of harmonized criteria in the interpretation of the Regulations. A true harmonization of the legislation in force in the region has not yet been achieved. The National Regulatory Agencies are not aligned in the interpretation of the RTCA and national regulations are frequently applied over regional regulation. In the interviews, it was determined that there is no opening for regulatory entities to apply internationally harmonized criteria, such as the Reliance Criterion. In the different countries, the good practices implemented by the reference authorities are not executed, hence it is the examiner's criteria and the national authority that prevails over what is established by the regional regulations.

2.2 The approval time of the sanitary registration process is long and uncertain. The processes are long for new application, renewal, and post- registration changes. The uncertainty of the time frames of the approvals makes business planning difficult. There is no visibility during the process, which increases uncertainty.

In Honduras, for example, there is a process expediting system, in which the applicant, by paying additional fees, can expedite the deadlines for resolution of procedures. However, this additional payment is not working since the processes are just as slow and the promised approval time is not met. In some countries, the lack of human resources within regulatory agencies has an impact on timing: if they do not have enough examiners, processes will slow down.
The NRA do not implement criteria of priority or expediting of the approval procedure to effectively differentiate between new applications, renewals, or post-registration changes. Since priority criteria are not applied, renewals could be evaluated as new applications. In fact, the interviewees indicate that, in the renewal processes, the different national regulatory agencies request information that had previously been provided by the companies. The terms, therefore, are extended to a great extent. There is no expedited mechanism for administrative changes that do not affect the quality, safety, and efficacy of a medicine, for example, the reduction of shelf life or a change of distributor.

2.3 The application systems in the region are not completely digitalized. There is not a complete digitalization of processes for all the countries of the region. In countries where the process is fully or partially digitized, the interviewees state that there are no initiatives to improve the quality of the system. Finally, the interviewees indicate that, despite the fact that certain processes are digitized in some countries, there is no transparency, since the user does not have a progress scale to know the progress of the procedure.

2.4 Outdated regulatory framework. The current regulation is not adapted to the technological advances and innovative medicines. There is no regional regulation for biological medicines. The legislation in force in each country does not allow the recognition of digital documents or digital labeling inserts.

2.5 Political changes. Political changes generate instability in the countries, that results in a lack of continuity in improvement initiatives. For example, the interviewees mention that, when there are changes in government, frequently, there are changes in the interpretation of the regulations, which affects the

approval processes. In addition to this, there are initiatives from political parties, but when the government changes, they are not given continuity. In addition, certain governments have very clear lines of action in terms of supporting access to medicines or strengthening the regulatory system, while in others this may not be within their political agendas.

2.6 Inaccessibility of evaluators. Lack of access to examiners makes communication difficult during assessment processes. Access to evaluators could allow for the exchange of knowledge between the applicant and the examiner, as well as greater openness to the standardized interpretation of internationally defined criteria.

As a result of the COVID-19 pandemic, the States became more flexible; for example, virtual calls were easily held with the examiner. However, when the state of emergency ended, some NRA took a step back on this matter. There are countries, such as Nicaragua, in which companies are not received at the NRA offices, nor do they have access or any type of contact with public officials. Finally, the interviewees mention that the inaccessibility to the examiner undermines the right to clarification.

3. PANAMA CASE STUDY

Panama has a particular critical situation generated by an unfortunate criterion of the national authority, regarding the requirements of the apostilled certificates of good manufacturing practices and the non-acceptance of digital certificates issued by high standard authorities, such as EMA.

Panama has recently (2 years) ratified the Central American technical rules for pharmaceutical products. However, the interpretation of these rules and the request of addition documentation by the examiners in regards of the apostille and certified copies, is not according to the regulations and requirements applied at a regional level. The following two aspects are currently impeding the registration of pharmaceutical products in Panama:

Interpretation the apostille of certificates: Panamanian national authority is not accepting certified copies of the Certificate of Good Manufacturing Practices (GMP); instead, they are requesting the original certificate. Considering that this document is issued one single time, and it must be presented in all jurisdictions for the registration process, companies provide a certified copy of the original document in each jurisdiction, authenticated by a public notary, to comply with the requirement of national authorities in all countries. The argument of the Panamanian national authority

used to reject the certifications is that "the signature of the signatory of the document is not legalized"; However, the Central American Technical Rules establishes that companies can provide the legalized original certificate or the authenticated copy of the original document. In this case, the Panamanian authorities have misinterpreted the regional rule when they state that the authenticated copy must indicate that "the signatory signature is original/authentic." However, when public notaries or authorized officials issues a certify copy, they are validating that they have seen this copy and certified that it is a true and exact copy of the original document. The authentication of the signature of the official who issues and signs the certificate is made through legalization by the apostille and not by the public notary.

Digital certificates issued by high standard authorities: The national authority is requesting a physical certificate issued by the regulatory authority, signed, and legalized by the consul or apostille, rather than the EMA´s pharmaceutical product digital certificates, or Eudra GMP, issued by the official web sites of national authorities of members of European Union Agreements. These electronic certificates are issued and signed by regulatory authorities and the electronic signature can be verified to guarantee the identity of the issuer; therefore, a public notary can issue a certification that can be legalized by the means of the apostille.

Consequently, the national authority should not request that the certification specifically indicate that "the signature of the signatory is original"; since electronic signatures are valid and are digitally certified with their respective code.

Since the requirements mentioned above are impossible for companies to comply with, the approval of the sanitary registries is not being achieved. This situation can affect the access to medicines; thus, FEDEFARMA has made recommendations in relation to this issue, to provide clarity on Central American Regulations and to support both, companies, and the national authority of Panama in regulatory matters, as well as to identify improvements that allow compliance with regional regulations in a unified manner for the registration processes of pharmaceutical products.

4. INTELLECTUAL PROPERTY AND DATA TEST PROTECTION

Central America and Panama have extensive and complete legislation for intellectual property rights, shaped by national laws, international treaties, and conventions. All the countries of the region are signatory members of the main international IP conventions such as the Paris Convention, the Patent Cooperation Treaty, the Trademark Treaty and WTO- Agreement on Trade-Related Trade-Related Aspects of Intellectual Property Rights (TRIPS). However, there is no integrated system for a single registry of IP rights in the region and the requesting companies must process the protection of rights in each country under the application of national regulations.

In the field of drug commercialization and intellectual property, the linkage of patents with test data is the most relevant topic. Central American regulation originates primarily from the international principles and agreements established by the World Trade Organization in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS establishes the minimum standards for the protection of intellectual property rights that member states must guarantee, including the protection of patents and the protection of test data submitted for the approval of pharmaceutical products.

The Association Agreement between Central America and the European Union establishes that undisclosed data on the safety and efficacy of new pharmaceutical products, presented as part of the requirements for obtaining the sanitary registry, will receive national and most favored nation treatment; therefore, protection is granted based on national legislation, this was later implemented by the Free Trade Agreement between the Dominican Republic, Central America and the United States and the Trade Promotion Agreement between the United States and Panama (DR-CAFTA).

In this regard, the DR-CAFTA establishes the obligation of the Member States in three aspects: test data protection, patent binding and test data protection, and patent term compensation. Regarding test data protection, it is established that undisclosed information must be protected against all disclosure, except when necessary to protect the public. Regarding the link between patents and test data, the States agree to guarantee protection for the undisclosed data on safety and efficacy required for the marketing approval of new products for five years; only for cases in which this information is a requirement to obtain the sanitary registry. Furthermore, States must guarantee that marketing approval will not be granted to third parties before the expiration date of the patent, unless the consent of its owner is obtained.

Regarding patent protection, the parties agreed to guarantee compensation for the term of patent protection to compensate for unjustified delays in its granting (more than five years after filing the application or three years after requesting the

examination of the application), provided that the delay is not attributable to the applicant.

Even though there is no single registration mechanism for IP rights in the region, the legislation in force in the region and its interpretation in practice are functional and standardized.

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IV. CENTRAL AMERICA REGULATORY AUTHORITIES AND THE AUTHORITIES OF REGIONAL REFERENCE.

This section contains the evaluation principles that the WHO has applied to classify national regulatory agencies, according to their efficiency and performance. To do this, it classifies them as reference or high standard authorities. The main function of national regulatory systems is to protect public health by controlling the safety, efficacy and quality of medicines entering the market. PAHO promotes the approval of medicines to be based on solid scientific arguments, that the proposed benefits outweigh the risks, and that users receive adequate information on the use of the products.

1. NATIONAL REGULATORY AUTHORITIES OF REGIONAL REFERENCE

Due to the impact of regulatory systems in public health, the WHO through *Resolution CD50.R9* of 2010, established the designation of National Regulatory Authorities of Regional Reference (RNAr) as a recognition of their capacities.

The designation of National Regulatory Authority of regional reference recognizes the installed regulatory capacities in the Region and aims to promote the exchange of information on the regulation of medicines and biological products between countries.

Currently in Latin-American, only the following eight NRA have been appointed as RNAr:

1. ANMAT: Administración Nacional de Medicamentos, Alimentos y Tecnología Médica, Argentina.
2. ANVISA: Agencia Nacional de Vigilancia Sanitaria, Brasil.
3. INVIMA: Instituto Nacional de Vigilancia de Medicamentos y Alimentos, Colombia.

4. CECMED: Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos, Cuba.
5. ISP: Instituto de Salud Pública, Chile.
6. COFEPRIS: Comisión Federal para la Protección contra Riesgos Sanitarios, México.
7. Health Canadá, Canadá.
8. FDA: Food and Drug Administration, United States.

2. Global Benchmarking Tool GBT

Later on, in 2014, the WHO in the WHA67.20 67-2014 assembly, in its continuous effort to strengthen regulatory systems, agreed to evaluate regulatory systems by analyzing performance and plan improvements and developing the evaluation tool called Global Benchmarking Tool (GBT).

[9]The Global Benchmarking Tool (GBT) represents the primary means by which the WHO evaluates regulatory systems, as mandated by WHA Resolution 67.20 on Regulatory System Strengthening for medical products. The tool and benchmarking methodology enable WHO and regulatory authorities to identify *a) strengths and areas for improvement, b) facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address the identified gaps, c) prioritize IDP interventions; and d) monitor progress and achievements*.

[10]The GBT incorporates the concept of "maturity level" (adapted from ISO 9004) which allows WHO and regulatory authorities to assess the "maturity" of the regulatory system according to the following scale:

1. *Level 1, there are some elements of the regulatory system.*
2. *Level 2, evolving national regulatory system that partially performs some essential regulatory functions.*
3. *Level 3, stable, well-functioning and integrated regulatory system.*
4. *Level 4, regulatory system that operates at an advanced level of performance and continuous improvement.*

None of the regulatory authorities in the Central American region currently qualify as a reference authority. Under the GBT system of the WHO, the NRAs of Central America are classified with a level of maturity between 1 and 2, as stated by Dr. Coto from PAHO,

[9] https://www.who.int/tools/global-benchmarking-tools

[10] Herramienta Mundial De La Oms Para La Evaluación De Los Sistemas Regulatorios Nacionales De Productos Médicos, Revision VI, versión 1, Washington, D.C., 2020.

in his speech at the webminar *Regulatory Reliance, Strengthening of Regulatory Systems,* organized by FEDEFARMA [11].

The regulatory importance of establishing a mechanism that evaluates and establishes the level of maturity of national regulatory agencies lies in the fact that the interpretation criteria in the harmonization of laws adopted by authorities recognized as reference agencies should function as standard criteria for other agencies. Less mature regulatory authorities when making decisions could consider or give greater weight to the evaluations carried out by high standard authorities.

V. FINAL REMARKS AND RECOMMENDATIONS

Throughout this research, the international and national regulatory framework of the countries of the Central American region was analyzed. A qualitative investigation was carried out, in which, through interviews, it was possible to determine which are the main challenges that companies face in the process of approval of sanitary registrations of pharmaceutical products. In addition, a case study of the current situation in Panama was carried out, since an interpretation of already standardized norms, is generating a blockade in the approval of medicines and, consequently, affecting access to medicines in this country. Furthermore, a brief analysis of intellectual property legislation in the Central American region was carried out, focused on the regulation and linkage of patents and data test protection. Additionally, the criteria established by the WHO to classify regulatory agencies to determine their level of performance, based on four criteria, were exposed.

In relation to the regulatory framework and from the perspective of a legal analysis, the following was concluded:

1. Concerning the regional legislation (RTCA) it has been determine that there is no true harmonization in the interpretation and application of current legislation by the authorities. Each NRA interprets and applies regional regulations according to its criteria and national regulation; NRA are not aligned in the interpretation of the RTCA and national regulations are frequently applied over regional regulation.

[11] Webminar Reliance Regulatorio, Fortalecimiento de los Sistemas Regulatorios, El rol de la OPS en el fortalecimiento de los sistemas regulatorios nacionales, Dr.Coto, 29/05/2023.

2. The current regulation is not updated or in accordance with technological advances, in relation to innovative medicines and digital certificates, issued by high standard authorities.

3. There is no regional regulation for biological and biotechnological medicines.

4. There is no adequate implementation of the recognition mechanisms that adhere to what is established and aimed by the legislation.

5. Regarding the approval time of a sanitary registry, renewal or post registration changes, a classification of priority criteria for the approval of pharmaceutical products is not applied.

6. Relating to the approval of a sanitary registry, the legislation does not establish the application of internationally standardized principles for the approval of products. Consequently, NRA do not consider the application or use these principles during the evaluation and approval process.

7. Although there is a right to clarification during registration processes established by the law, there is not an adequate or efficient mechanism to execute it. The lack of access to examiners makes communication difficult during assessment processes.

RECOMMENDATIONS

In the realm of pharmaceutical trade in Central America, technical barriers have emerged as a critical challenge. In this section, we present recommendations that offer a pragmatic pathway to addressing these challenges. These suggestions result from the analysis of the unique regional dynamics and regulatory framework evaluated in the preceding sections.

1. The focus of public policies oriented towards economic development has displaced the implementation of public policies for public health. The Central American States must evaluate and reconsider their public policies towards public health, access to effective and safe medicines, and the strengthening and improvement of their regulatory systems.

2. Central America countries must devote greater efforts and resources to NRAs to implement improvement and strengthening strategies that allow them to evolve in areas such as the adequate digitization of processes and guarantee

necessary human resources that allow them to satisfy the demand for approval of medications that the public health system requires.

3. Regional public policies must be implemented to allow the proper execution of regional legislation and facilitate dialogue and initiatives to update existing legislation and implement new regulations that allow the region to build a regulatory framework in accordance with the requirements of international conventions and treaties.

4. It is necessary to promote the approach and active dialogue between the NRAs of the region and the High Standard Regulatory Authorities (EMA) and regulatory authorities of reference, that facilitate the exchange of knowledge and good practices, to encourage the NRAs to implement improvements in their operation and the implementation of internationally harmonized criterias.

5. Work should be done for the effective implementation of product recognition of the European Union; based on the commitment established in the AACCUE.

6. It is recommended to use the mechanisms established in the AACCUE to seek the effective harmonization of current regional legislation and monitor its proper implementation.

ANNEX I

Overview of Sanitary Requirements applied, and Terms used by Central American countries on pharmaceuticals products imported from the European Union

X General requirements, applicable to pharmaceuticals products covered in this Guidebook

• Applicable only to Health risk pharmaceuticals

Δ Applicable only to Biological Medicines

	CR	ES	GT	HN	NC	PN
Sanitary registration by the Ministry of Health of each country	X	X	X	X	X	X
Responsible professional and legal representative (Power of attorney for both) duly notarized and apostilled.	X	X	X	X	X	X
Pharmaceutical certificate of the product issued by the Health Authority of origin or Free sale certificate/good manufacturing practices duly notarized and apostilled	X	X	X	X	X	X
Manufacturing contract	X		X	X	X	
Complete quantitative and qualitative formula of the product	X	X	X	X	X	X
Product Monograph	X		X	X	X	X
Analysis methods validated according to the RTCA Pharmaceutical Products	X	X	X	X	X	X
Organoleptic, physical, chemical, biological, and microbiological specifications of the finished product that comply with the provisions of the RTCA Pharmaceutical Products	X	X	X	X	X	X
Labelling, insert, instructions and catalog of the product	X	X	X	X	X	X
Report of the Stability Study according to the RTCA Pharmaceutical Products	X	X	X	X	X	X
Clinical studies, Safety and efficacy studies.	X	X	X	X	X	X
Analytical standards: Primary standards or standardized raw materials & Standards for related substances and/or degradation products, when required by the methodology.	X	X	X	X	X	X
Samples					X	X

Declaration issued by the holder or the legal representative stating the name, information, and characteristics of the Pharmaceutical Product to be registered signed in original.			X			
Certificate of Good Manufacturing Practices of the conditioner issued by the competent authority (if a third party other than the manufacturer)	X	X	X	X	X	X
Sanitary license of the distributor			X			
Certificate of analysis of finished product issued by the manufacturer's quality control laboratory, signed in original and copy		X				
Technical sheet for waste disposal						X
Therapeutic equivalence studies	•	•	•	•	•	•
Information on the regulatory status of the product internationally	Δ	Δ	Δ	Δ	Δ	Δ
Quality, safety and efficacy information for biologics	Δ	Δ	Δ	Δ	Δ	Δ
The Certificate of Good Manufacturing Practices and Third-Party Manufacturing Contract (when applicable) must be submitted for all laboratories involved in the manufacture of the active ingredient(s), intermediate product and final product.	Δ	Δ	Δ	Δ	Δ	Δ

ANNEX 2

Technical notes and requirements for the importation of pharmaceutical products

Costa Rica

General requirements:

1. Medicine importer registration
   Competent authority: Ministry of Health
   Procedure: Importers must be registered with the Ministry of Health before being authorized and registered with the Association of Pharmacists.

2. Authorization of removal from warehouse of raw materials, primary forms of medicines and cosmetics, medicines, cosmetics, and medical equipment (Form of Authorization for Removal from Warehouse (FAD in Spanish)-Technical Note 57).
   Competent authority: Ministry of Health, Department of Drugs and Narcotics, Controls, and Registration
   Requirements: 1) Registration in the "Single Window for Foreign Trade (VUCE 2.0)" platform; 2) Digital signature; and 3) Installation of platform drivers.
   Procedure: 1) Log in the system and activate the username. 2) Log in the Technical Import Notes module. 3) Create a new procedure for the technical note. 4) Select the procedure to perform (Registered Product Standards, Other Unregistered Products, Clinical Studies, etc.). 5) Review the FAD for approval or rejection (by the Ministry of Health official).
   Specific requirements for drugs, narcotics, and psychotropic substances

3. Registration with the Costa Rican Drug Institution for Controlled Substance Imports

   Competent authority: The Costa Rican Drug Institution for Controlled Substance Imports
   Requirements: 1) Fill out the registration application form. 2) Submit the following documents: a copy of the corporate or personal identification card of the applicant, the company registration with the Commercial Registry, the original legal standing

document, respective legal stamps. 3) Fill out the signature registration card for the company legal representative.
Procedure: Submit the documents mentioned above to the competent authority.

4. Drug and narcotics import permits and seals (Technical Note 51) .
Competent authority: Ministry of Health, Department of Drugs and Narcotics, Controls, and Registration
Requirements: 1) Registration in the "Single Window for Foreign Trade (VUCE 2.0)" platform; 2) Digital signature; and 3) Installation of platform drivers.
Procedure: 1) Log in the system and activate the username. 2) Log in the Technical Notes module. 3) Create a new procedure for the technical note. 4) Select the procedure to perform (Registered Product Standards, Other Unregistered Products, Clinical Studies, etc.). 5) Review and approve the information (by the competent authority).

5. Authorization of precursor and chemical substances imports, including seals (Technical Note 58)
Competent authority: Costa Rican Drug Institution (ICD in Spanish), Ministry of the Presidency
Requirements: 1) Registration in the "Single Window for Foreign Trade (VUCE 2.0)" platform; 2) Digital signature; and 3) Installation of platform drivers.
Procedure: 1) Log in the system and activate the username. 2) Log in the Technical Notes module. 3) Create a new procedure for the technical note. 4) Select the procedure to perform (Registered Product Standards, Other Unregistered Products, Clinical Studies, etc.). 5) Review and approve the information (by the competent authority).

6. Requirement for destocking of precursors and chemical substances
Competent authority: Costa Rican Drug Institution (ICD in Spanish), Ministry of the Presidency
Requirements: 1) Import authorization application; 2) Original document or certified copy of the purchase invoice the substances that will be removed from warehouse; 3) Original document or certified copy of the bill of lading, air waybill, or transport document, as applicable.

Procedure: These documents must be submitted to the specialized unit of the Costa Rican Drug Institution (ICD).

El Salvador

General requirements:

1. Import permit for products regulated by the National Medicine Office (Invoice Endorsement)

   Competent authority: Center for Imports and Exports of El Salvador (CIEX El Salvador) and National Medicine Office (DNM) (acronyms in Spanish)

   Requirements: 1) DNM / CIEX El Salvador form. 2) Invoice signed and sealed by the respective pharmaceutical chemist, including the name of the product, presentation, expiration date, quantity, and registration number assigned by the DMN. 3) Establishment seal on invoice (applicable to the lab and drugstore). 4) Number of authorized importer/establishment or copy of annuity. 5) Registration certificates or number. 6) Technical and security sheets, including the chemical composition up to 70% (applicable only to chemical products and pharmaceutical raw materials for drugstores and labs).

   Procedure: 1) The procedure is made online through the single Window of CIEX El Salvador.

   Specific requirements for drugs, narcotics, and psychotropic substances

2. Authorization of import or export permits and endorsement of narcotics, psychotropic substances, and aggregates

   Competent authority: Center for Imports and Exports of El Salvador (CIEX El Salvador) and National Medicine Office (DNM) (acronyms in Spanish)

   Requirements: 1) Registration with the DNM as importer or pharmaceutical establishment and have the updated authorization. 2) Register the product to import. 3) Manage or keep the control system of specially regulated products updated. 4) Have an annual forecast for product or substance imports.

   Procedure: 1) The application is made through the CIEX system, submitting the documentation mentioned above.

Guatemala

General requirements:

1. Import permit for non-controlled medicines

   Competent authority: Ministry of Public Health and Social Assistance

   Requirements: 1) Payment receipt per import procedure (Slip V-CC-G-01 and Copy of Receipt 63A2). 2) Two simple, legible copies of original invoices signed (in blue ink) and sealed by the technical director, including the sanitary registration or mutual recognition number per each product to import.

   Procedure: 1) Payment of respective customs duties. 2) Request for right of procedure (obtaining Receipt 63-A2). 3) Registration of import application at the Document Reception and Delivery window. 4) The authority reviews the documents submitted and approves or rejects the procedure. 5) Issuance of the import permit.

   Specific requirements for drugs, narcotics, and psychotropic substances

2. Authorization for imports of psychotropic substances, narcotics, precursors, chemical substances, vaccines, and final users

   Competent authority: Ministry of Public Health and Social Assistance and Department of Regulation and Control of Pharmaceutical Products

   Requirements: 1) Import requirements mentioned in the current version of Form F-IP-r-0. 2) Current version of payment receipt V-CC-G-001.

   Procedure: 1) Submit the forms and documentation to the Department of Regulation and Control of Pharmaceutical Products. 3) The authority reviews the documents submitted and approves or rejects the procedure. 4) After approval by the unit, the company is registered, and the file is archived.

3. Application for import certificates

   Competent authority: Ministry of Public Health and Social Assistance and Department of Regulation and Control of Pharmaceutical Products

   Requirements: 1) Request of the import certificate, Form F-SI-f-06. 2) Payment receipt per current customs duties. 3) Password issued by the Food and Medicine Service Window. 4) Personal identification document. 5) If the person collecting the certificate is not the person who signed it, a letter signed and sealed by the applicant is required.

   Procedure: 1) Submit the forms and payment receipt to the Department of Regulation and Control of Pharmaceutical Products. 2) The authority reviews the documents submitted and approves or rejects the procedure. 3) After approval by the unit, the user must submit the other documents required to collect the certificates.

Honduras

General requirements:

1. Application for the official import certificate for psychotropic substances and narcotics

   Competent authority: General Sanitary Regulation Office (DGRS in Spanish)

   Requirements: 1) Application for import certificates

   Procedure: Fill out the application with the DGRS, including the following information: 1) Name of company regent or manager. 2) Name and address of importer and exporter. 3) Name of the pharmaceutical establishment represented. 4) Name of vendor. 5) Quantity. 6) Concentration if it is a finished product. 7) Name of product. 8) Date of entry. 9) Entry customs. 10) Shipping origin.

2. Requirements for drugstore sanitary license

   Competent authority: General Sanitary Regulation Office

   Requirements: Application for license, including the recovery fee and terms of procedure resolution.

   Procedure: 1) Application. 2) Power of attorney granted to the legal professional. 3) Copy of the articles of incorporation of the company or individual merchant, duly registered with the Commercial and Property Registry. 4) Copy of the identification card of the regent or medical director, as applicable. 5) Payment receipt for sanitary license services. 6) Blueprints of physical, electrical, drinking water, and wastewater installations of the establishment approved by the Municipality.

Nicaragua

General requirements:

1. Application for clearing customs authorization

   Competent authority: Ministry of Health

   Requirements: 1) Written, original document, and copy of the application addressed to the Pharmacy Director, including the number of each invoice, the manufacturing laboratory or exporter. It must be signed by the Import Manager of the import company/distributor or the national manufacturing laboratory.

   Procedure: 1) Written, original document and copy of the application. 2) Original document and copy of the invoice. 3) When the invoice includes psychotropic substances, narcotics, and precursors, it must include an additional copy of the import invoice and import permits. Psychotropics invoices must be submitted separately from the invoices of non-controlled products nationally and internationally.

2. Application for psychotropics and narcotics import permits

Competent authority: Ministry of Health

Requirements: 1) Application for the import permit submitted to the Reception Department of the Pharmacy Division.

Procedure: 1) Submit application. 2) Have the sanitary registry updated. 3) Have the sanitary license updated.

Panama

General requirements:

1. Import permit for controlled substances

   Competent authority: National Pharmacy and Drug Office

   Requirements: 1) Have the operating and special license updated for controlled substances. 2) Be up to date with the delivery of monthly and quarterly controlled substance reports. 3) Have the sanitary registration or registration document updated.

   Procedure: 1) Fill out the PIRE Form and submit it to the National Pharmacy and Drug Office. 2) Submit the payment receipt of service rates for this permit.

2. Application for the special license for controlled substances

   Competent authority: National Pharmacy and Drug Office

   Requirements: 1) Have the operating license updated. 2) Be current with the delivery of monthly and quarterly controlled substance management reports. 3) Have the security area approved for product storage.

   Procedure: 1) Fill out the LESC Form. 2) Submit the payment receipt of service rates for this permit.