TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)

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REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

1. What are the principal statutes, regulations and competent authorities that govern the import, wholesale distribution, retail sale and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?

The legal frameworks governing the import, wholesale distribution, retail sale and export of therapeutic products are the following:

- Law No 423 'General Health Act', published in *The Gazette* (*La Gaceta*) No 91 on 17 May 2002 (the 'General Health Act');
- Executive Order No 001-2003 'Ruling of General Health Act', published in *The Gazette* Nos 7 and 8 on 10 and 13 January 2003, respectively (the 'Regulation of General Health Act');
- Law No 292 'Law of Pharmaceuticals and Pharmacies', published in *The Gazette* No 103 on 04 June 1998 (the 'Pharmaceuticals Act');
- Executive Order No 6-99 'Ruling of Law No 292 Law of Pharmaceuticals and Pharmacies', published in *The Gazette* Nos 24 and 25 on 4 and 5 February 1999, respectively (the 'Regulation of the Pharmaceuticals Act');
- Law No 265 'Establishing Self-Clearance for Importation, Exportation, and Other Customs Regimes', published in *The Gazette* No 219 on 17 November 1997 (the 'Customs Self-Clearance Act');
- Executive Order No 3-98 'Ruling of Law Establishing Self-Clearance for Importation, Exportation, and Other Customs Regimes', approved on 15 January 1998 and published in *The Gazette* No 31 on 16 February 1998 (the 'Ruling of Customs Self-Clearance Act');
- Central American Uniform Customs Code, published in *The Gazette* No 135 on 16 July 2008 (CAUCA IV);
- Ruling of Central American Uniform Customs Code published in *The Gazette* No 135 on 16 July 2008 (CAUCA IV);
- Central American Tariff System (Sistema Arancelario Centroamericano or SAC);
- Law No 842 'Law for the protection of consumers and user rights', published in *The Gazette* No 129 on 11 July 2013 (the 'Law of Consumers') as amended; and
- Executive Order No 36-2013 'Ruling of Law 842, Law for the protection of consumers and user rights', published in *The Gazette* No 192 on 10 October 2013 (the 'Ruling of Law of Consumers') as amended.

The foregoing is complemented by different administrative resolutions issued by the authority, governing the principles, requirements, guidelines and licensing applicable to the commercialisation of therapeutic products, based on the type of therapeutic product.

The following competent authorities are designated to supervise the importation, wholesale distribution, retail sale and export of therapeutic products:

The Ministry of Health (Ministerio de Salud or MINSA) coordinates, organises, supervises, inspects, controls, regulates, orders and oversees the healthcare system in general terms. MINSA is responsible for developing policies, plans, programmes, national projects and manuals on public health in all its dimensions, including therapeutic products commercialisation. Through the National Authority of Sanitary

Regulation (Autoridad Nacional de Regulación Sanitaria or ANRS), MINSA is the authority entitled to supervise the compliance of applicable regulations for the commercialisation and trade of therapeutic products. The ANRS has the faculties to issue rulings and regulations, and administrative disposition to update the regulatory framework for requirements licensing or permits related to therapeutic product commercialisation from the 'healthcare policy perspective'.

The General Directorate of Customs (Dirección General de Aduanas or DGA) is responsible for the administration of customs services for the control and facilitation of foreign trade, including the importation and exportation of therapeutic products.

The Ministry of Development, Industry, and Commerce (Ministerio de Fomento, Industria y Comercio or MIFIC) determines the prices for pharmaceuticals of human consumption (through the establishment of a maximum sale price per product, which must be observed by all participants in the supply chain). Along with the Directorate of Consumer Rights Protection (Dirección de Protección a los Consumidores and DIPRODEC), they continuously monitor compliance with pharmaceutical price control.

DIPRODEC is the authority that protects the rights of consumers and users, and ensures compliance with consumer laws.

2. How are therapeutic products classified for regulatory purposes (eg, prescription-only, over-the-counter, hospital-use and risk classes for devices) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is premarket review and approval required by a competent authority?

Under Nicaraguan law, therapeutic products are classified for regulatory purposes primarily according to their nature, intended use and applicable sanitary controls, with distinct legal consequences for their importation, distribution and commercialisation. The main categories include the following:[1]

Pharmaceutical products

- Prescription-only: These products may only be dispensed with a valid medical prescription issued by an authorised medical practitioner. Distribution and retail sales are restricted to licensed pharmaceutical establishments, and are subject to advertising and dispensing controls.
- Narcotic drugs and psychotropic substances: These products are subject to a special control regime, including specific import authorisations, quantitative restrictions, enhanced record-keeping requirements and prescription limitations to authorised medical practitioners, in addition to general pharmaceutical regulations.[2]
- Over-the-counter (OTC):[3] These products may be commercialised without a medical prescription and are not required to be sold exclusively through healthcare-licensed establishments. As a result, they may be offered by general retail outlets[4](eg, supermarkets and small stores). Pricing is subject to regulation and oversight by MIFIC and DIPRODEC.[5] The ANRS determines and issues the official list of products classified as OTC.

Medical devices

Medical devices, including in vitro diagnostic devices and other health technologies, are subject to sanitary registration and prior authorisation before importation or commercialisation. Regulatory requirements vary depending on the type of device, intended use and distribution channel.

[1] The categories described herein do not derive from an express statutory classification, but have been compiled by reference to the type of therapeutic product and the distinct regulatory and commercialisation requirements applicable to each category.
[2] Regulated under Title III Narcotic Drugs and psychotropic substances of the Pharmaceuticals Act.
[3] Defined in Pharmaceuticals Act, Art 80.
[4] Pharmaceuticals Act, Arts 59 d and 80.
[5] Ruling of Law of Consumers, Art 19.

In summary, each category is governed by distinct sanitary controls, licensing obligations and authorisation protocols, all of which are overseen by the ANRS through its respective specialised departments (eg, Pharmacy Division and Medical Devices Division). As a general requirement, premarket review and authorisation by the relevant ANRS division must be obtained before any product is imported or commercialised. Importation requirements may vary depending on the category of product and its intended purpose (eg, commercial distribution, professional use, personal use or clinical research). Administrative Resolution No 0024-2024 issued by the ANRS describes the importation requirements.

LICENSING, AUTHORISATIONS AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations or other official permissions are required for businesses to engage in the wholesale distribution of therapeutic products, and what key conditions (such as Good Distribution Practice, facility standards, personnel, insurance or financial guarantees) attach to them?

Under the Pharmaceuticals Act, pharmaceutical establishments[6] are the entities authorised to manufacture, distribute and commercialise therapeutic products. For distribution purposes, the Act classifies such establishments as 'importers or distributors',[7] defined as entities authorised to engage in the importation, storage and wholesale distribution of therapeutic products to licensed drugstores (pharmacies), hospitals and other authorised healthcare facilities.[8] In order to engage in distribution activities, distributors must obtain a prior sanitary operating license issued by the ANRS, typically following an inspection of the premises, which is valid for two years and subject to renewal upon expiration.[9]

Distributors must ensure that all therapeutic products they import or distribute hold valid sanitary registrations[10] prior to importation or commercialisation and, when applicable, obtain specific prior authorisations for controlled substances, such as narcotic drugs and psychotropic substances. Distribution activities must comply with relevant sanitary standards and good distribution practices. This includes maintaining proper facilities, ensuring suitable storage and transportation conditions to protect product quality, and appointing a licensed pharmacist as the technical and sanitary supervisor.[11] Specific requirements applicable to distributors are further set out in the Good Storage, Distribution, and Transportation Practices for Medical Supplies standard, issued by MINSA, as amended or updated from time to time.

Distributors are subject to ongoing supervision, record-keeping and inspection by the ANRS, and failure to comply with applicable requirements may result in administrative sanctions, including suspension or revocation of the operating authorisation.

4. Are there distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies or other retailers), and what key conditions attach to them?

Yes. Under the Pharmaceuticals Act, businesses that provide therapeutic products directly to consumers are subject to licensing requirements.[12] Pharmaceutical establishments engaged in direct dispensing to the public are classified as drugstores (pharmacies) and must be licensed by the ANRS.[13] Drugstores are defined as establishments dedicated to the dispensing and direct supply to the public of pharmaceutical specialties, among others, prescription medicines (including psychotropic products), general health

[6] Pharmaceuticals Act, Art 59.
[7] Pharmaceuticals Act, Art 59, b.
[8] *Ibid.*
[9] Pharmaceuticals Act, Art 64.
[10] Pharmaceuticals Act, Arts 60 and 61.
[11] *Ibid.*
[12] Pharmaceuticals Act, Art 59 c.
[13] Pharmaceuticals Act, Art 64.

supplies, cosmetics, personal hygiene products, herbal and homeopathic medicines, and compounded preparations, provided such products are registered and authorised by MINSA.[14]

Drugstores are required to obtain a sanitary operating license, comply with applicable sanitary and professional requirements, and operate under the technical supervision of a pharmaceutical technical responsible.

Note that OTC therapeutic products, as determined and listed by the ANRS, may be commercialised without the need for a pharmaceutical establishment license, and may therefore be sold by non-pharmacy retailers, subject to general sanitary and consumer protection rules.[15]

5. What rules govern the sale of therapeutic products to consumers over the internet (including social media and marketplace platforms)?

Nicaraguan law does not contain a specific legal framework regulating the sale of therapeutic products over the internet. The principles and rules set forth above may apply for therapeutic products sold over the internet.

IMPORT

6. What is the import-control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions, and routine or risk-based border inspections)?

As described in the response to Question 3, pharmaceutical establishments must obtain an importer license from the ANRS. Moreover, pharmaceutical establishments must also register as importers with DGA. Premarket control requires that therapeutic products hold a valid sanitary registration issued by the ANRS, evidencing compliance with applicable requirements on quality, safety and efficacy. Each importation of regulated therapeutic products requires a prior import authorisation, which are reviewed and approved by the competent ANRS division (eg, pharmacy or medical devices). Said authorisation is a prerequisite for customs clearance. Products subject to special control regimes, such as narcotic drugs and psychotropic substances, which require additional specific import authorisations, may be subject to quantitative controls. Administrative Resolution No 0024-2024 issued by the ANRS contains further information about importation requirements for therapeutic products.

From a customs perspective, therapeutic products must be declared and cleared by DGA in accordance with the Central American Uniform Customs Code and its regulations. Products must be classified under SAC, which determines the applicable tariff rates (VAT (impuesto al valor agregado or IVA), selective consumption tax (impuesto selectivo al consumo or ISC) and import duty (DAI)). Tariff treatment may vary depending on product SAC classification and applicable national or regional exemptions, including those derived from trade agreements or public health policies. The importation process of DGA must be carried out by a licensed custom agent of DGA.

Border control involves documentary verification and, where applicable, physical inspection of goods by the customs authority. Under the self-dispatch (*autodespacho*) regime, physical inspection is determined through a random selection mechanism, whereby shipments may be released without inspection or selected for customs' physical examination. Shipments not physically inspected at entry remain subject to selective post-clearance review, and failure to present required documentation gives rise to a presumption of customs violations.[16]

7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by mail), and what quantitative limits, prescription requirements, customs declarations, duties or other restrictions apply?

[14] See n 12 above.
[15] Pharmaceuticals Act, Art 59 d.
[16] These matters are governed by c II of the Ruling of the Customs Self-Clearance Act.

Under Nicaraguan law, consumers may import therapeutic products for personal use only, either by carrying them across the border as part of personal luggage or household goods, or by receiving them through personal shipments, subject to quantitative and regulatory limitations. Therapeutic products that enter through these channels may be authorised exclusively for the personal consumption of the interested individual and may not be commercialised, provided that the quantities do not exceed the maximum limits established[17] by the ANRS. Such cases do not generally require prior import authorisation. Customs declaration requirements apply, and the products remain subject to customs control and inspection. Applicable customs duties and taxes may apply unless an exemption is available (eg, duty-free allowance for goods in personal baggage).

Consumers importing prescription-only medicines for personal use must meet extra requirements.

In such cases, authorisation is limited to clinically indicated personal treatments and is subject to the submission of a valid medical prescription and supporting medical documentation, with quantities restricted to those consistent with the prescribed treatment. By contrast, OTC medicines and certain medical devices for personal or ambulatory use may be authorised for personal importation without a prescription, provided that they are classified as OTC and that quantities remain within the established limits.

Administrative Resolution No 0024-2024 issued by the ANRS contains further information about importation requirements of therapeutic products for personal use.

8. May foreign suppliers ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification or labelling obligations – if any – must they satisfy?

Nicaraguan law does not establish a specific regulatory framework permitting foreign suppliers to ship therapeutic products directly to consumers through e-commerce or mail-order sales as a commercial activity. Accordingly, such direct shipments are not authorised for commercial purposes unless conducted through a locally licensed importer, distributor or pharmaceutical establishment. Foreign suppliers may ship therapeutic products to consumers only under the personal-use importation regime, in which case the rules and limitations described in the response to Question 7 apply, including quantitative limits, prescription requirements when applicable, customs declaration and customs control. No local presence or platform registration is required for shipments admitted strictly under the personal-use exception.

9. How is parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual property rights, product relabelling or repackaging, and requirements to maintain original quality, safety and traceability?

Nicaraguan law does not establish an express legal framework specifically authorising or prohibiting parallel importation of therapeutic products. In practice, however, the sanitary regulatory system significantly constrains the feasibility of parallel importation. Therapeutic products may only be imported and commercialised if they hold a valid sanitary registration in Nicaragua, and distribution is limited to authorised importers or distributors recognised by the ANRS. For the purposes of the importation of therapeutic products in Nicaragua, the holder of the product or sanitary registration must grant a formal power of attorney authorising a specific local distributor or importer, which must be submitted to and approved by the ANRS as a prerequisite to lawful distribution.[18] As a result, a parallel importer that is not designated or authorised by the product or registration holder would generally be unable to obtain recognition as an authorised distributor, rely on an existing sanitary registration, or lawfully commercialise the product. Although the legal framework does not explicitly reference the exhaustion of intellectual property rights in relation to pharmaceuticals, the stipulation that distribution must be conducted by an authorised party designated by the rights holder effectively restricts parallel importation

[17] The quantitative limits currently in force are established in Administrative Resolution No 0024-2024, issued by the ANRS.
[18] See Administrative Resolution No 0031/2024, issued by the ANRS.

in practice.

EXPORT

10. Are there quantitative quotas, permits or other measures that restrict or condition the export of therapeutic products (eg, to mitigate shortages or address public health emergencies), and how are such measures administered and enforced?

As a general matter, Nicaraguan law does not establish permanent quantitative export quotas or a standing export-permit regime applicable to therapeutic products. Therapeutic products may be exported, provided that applicable sanitary and customs requirements are met.

Nonetheless, MINSA is vested with broad public health and sanitary powers that allow it to adopt measures to protect public health. These powers include the authority to regulate, limit or condition activities involving products subject to sanitary control, particularly in situations such as public health emergencies, epidemics, shortages of essential medicines or other circumstances that pose a risk to population health.[19] MINSA may lawfully adopt temporary and proportionate measures that affect the distribution and availability of therapeutic products within the national territory. While these measures are not framed as trade restrictions per se, they may indirectly restrict or condition exports, for example, by prioritising domestic supply, suspending sanitary authorisations or imposing special conditions on the circulation of certain products.

11. Is there any form of 'export-only' or 'dual-labelling' authorisation that permits the manufacture and export of therapeutic products not approved for domestic marketing, and if so, what standards, labelling or record-keeping obligations apply?

Nicaraguan law does not provide an 'export-only' regime or dual-labelling authorisation that would allow therapeutic products to be manufactured locally solely for export. As a general rule, therapeutic products manufactured, imported, distributed or commercialised in Nicaragua are subject to sanitary oversight and approval by MINSA and the ANRS, and must comply with applicable sanitary authorisation and quality standards, which also must be met for exportation activities (as further described in responses to previous questions).

Therapeutic products manufactured for export remain subject to sanitary supervision, and labelling or packaging practices must not compromise quality, safety or traceability, nor permit a diversion into the domestic market As of today, there is no dedicated pathway that expressly exempts export-only products from domestic sanitary controls or allows alternative ('dual') labelling regimes tailored exclusively to foreign markets.

LABELLING, TRACEBILITY AND PRODUCT INFORMATION

12. What local-language labelling, patient information, unique device identification, serialisation, anti-counterfeiting or traceability requirements must be met before imported therapeutic products may circulate domestically or before therapeutic products may be exported?

Therapeutic products for domestic distribution must have labels and patient information in Spanish, matching approved sanitary registration conditions.[20] Labels must allow the readable identification of the product. Information to be included may vary based on different elements (eg, type of therapeutic product, primary or secondary package, oral solutions and tablets). Typically, labelling should include the product

[19] General Health Act, Arts 7 and 80.
[20] Pharmaceuticals Act, Arts 16, 24 and 26.

name, active ingredients, dosage form, strength, batch number, expiration date, manufacturer and authorised importer or distributor.[21] There are no export-specific labelling requirements; labelling standards applicable to the validity of the sanitary registration also apply to exported products.

General sanitary requirements help to guarantee traceability and prevent counterfeiting by allowing only licensed therapeutic products to be traded, and ensuring batch and lot identification,[22] the expiration date, identification of the manufacturer and authorised distributor/importer, and record-keeping obligations applicable to manufacturers, importers and distributors.[23] Therapeutic products that do not comply with approved labelling, traceability or sanitary authorisation requirements may be detained, denied clearance or subject to administrative or criminal sanctions, as further described in the response to Question 14.

PRICING, REIMBURSEMENT AND MARKET ACCESS

13. Are there any price control, reimbursement, public procurement or stock/supply obligation regimes that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?

While Nicaragua does not operate a pharmaceutical reimbursement system applicable across all healthcare regimes, public procurement mechanisms, price regulation and the overall structure of healthcare financing may influence the distribution channels and availability of therapeutic products.

From a public procurement perspective, under the non-contributory public healthcare regime, healthcare services and medicines are provided free of charge to eligible populations through facilities operated by MINSA. In this context, therapeutic products may be supplied, by public procurement mechanisms, and by government purchasing and distribution of the products, among others. In parallel, Nicaragua also operates a contributory social security regime administered by the Instituto Nicaragüense de Seguridad Social (INSS). Moreover, individuals may access healthcare under a voluntary regime based on private payments, including coverage administered by INSS or by private insurers. These regimes involve different purchasing and supply arrangements, which may include direct procurement by healthcare providers, reimbursement arrangements within the social security system or out-of-pocket acquisition by patients in the private sector.

Regarding price regulation, OTC medicines are subject to maximum retail price controls and regulatory oversight by MIFIC and DIPRODEC, which may influence pricing structures and retail availability.

Although Nicaragua does not impose general statutory stockholding or supply obligations on private market participants, MINSA retains broad regulatory and emergency powers that may affect the supply and distribution of therapeutic products in exceptional circumstances, such as public health emergencies or shortages (as discussed in the response to Question 10).

Although these mechanisms are not strictly trade measures, the interactions among public procurement in non-contributory systems, contributory social security schemes, voluntary private-market options and price controls play a critical role in influencing market access, distribution strategies and product availability.

ENFORCEMENT, COMPLIANCE AND RECENT DEVELOPMENTS

14. What investigative powers, sanctions and remedial measures (administrative, civil or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?

In Nicaragua, compliance with rules governing the trade and distribution of therapeutic products is

[21] These matters are governed by Title II, cc II and III, of the Pharmaceuticals Act. Further details on labelling requirements are set forth in Resolution No 340-2014 (COMIECO-LXVII) on the Labelling of Pharmaceutical Products.
[22] Pharmaceuticals Act, Art 26.
[23] These matters are regulated under the Pharmaceuticals Act and the Regulation of the Pharmaceuticals Act. More specific requirements are established in Art 6, s A (Imports) and s D (Exports) of Administrative Resolution No 0024-2024, issued by the ANRS.

enforced through a multi-layered framework of administrative, civil and criminal powers, depending on the type of the non-compliance.

Administrative enforcement

On the other hand, MIFIC and DIPRODEC are empowered to monitor compliance with consumer protection and price regulations, particularly with respect to the sale and commercialisation of OTC therapeutic products, including the verification of compliance with maximum retail prices and lawful commercialisation practices.

DGA also plays an enforcement role by denying clearance or seizing therapeutic products that do not comply with applicable sanitary or import/export requirements.

If non-compliance is identified, administrative sanctions may apply, depending on the seriousness of the infringement affecting trade or distribution activities enforced by MINSA:

- Serious infractions[24] include manufacturing, importing, exporting, distributing, storing or commercialising therapeutic products without the required sanitary authorisation or registration, or handling products not legally recognised as medicines. Sanctions may include monetary fines of up to NIO 50,000 (approximately US$1,365) and seizure of products.
- Very serious infractions[25] include the manufacture, importation, distribution, commercialisation or possession of adulterated, expired, deteriorated or counterfeit medicines, or failure to comply with technical storage and handling requirements that endanger public health. Sanctions may include fines of up to NIO 100,000 (approximately US$2,730), seizure or destruction of products, suspension or cancellation of sanitary registrations, and temporary or permanent closure of establishments.

The said administrative enforcement is applied in a graduated and proportionate manner, and administrative sanctions may be imposed independently of civil or criminal liability. Administrative proceedings are subject to due process guarantees, including the right of the affected party to dispute the sanctions through administrative or judicial appeals, as applicable.

Civil enforcement

When breaches of trade or distribution rules harm a third party, the affected party may pursue civil claims for damages against the responsible operator, regardless of whether administrative sanctions have been imposed. Civil district courts are responsible for resolving the claim for damages, in the first instance.

Criminal enforcement

Certain violations of trade and distribution rules constitute criminal offences,[26] particularly where they involve the unauthorised manufacture, importation, exportation or commercialisation of therapeutic products; commercialisation of adulterated, expired, deteriorated or falsified medicines; or handling of controlled substances in quantities exceeding authorised limits.

In criminal cases, the process must initially be started in local courts. Generally, when the action involves the commission of a crime, this may be exercised through a prior complaint from a third party to the Public Prosecution Office. Once there are sufficient facts and elements to prove the commission of the crime, the Public Prosecution Office will file the accusation before the courts of justice.

Criminal sanctions may include imprisonment, fines and professional or commercial disqualification, as provided under the Criminal Code.

Enforcement will mainly involve administrative inspections, third-party complaints and corrective actions; criminal referrals are rare unless there are serious public health risks, repeated offences or intentional misconduct.

15. Is there recent case law, legislative or policy developments, noteworthy enforcement trends or

[24] Pharmaceuticals Act, Art 99.
[25] Pharmaceuticals Act, Art 100.
[26] These matters are governed under Title XIII Crimes against Public Health of the Criminal Code.

anticipated reforms that may significantly alter the regulation of trade, distribution or cross-border movement of therapeutic products in the future?
To the best of our knowledge, there are no recent headline decisions or major legislative reforms anticipated that would materially alter the regulatory framework for the trade, distribution or cross-border movement of therapeutic products in Nicaragua. Recent developments are primarily administrative and operational, including the progressive migration of sanitary import and registration procedures to online processing through platforms and periodic updates to ANRS administrative lists (eg, OTC classifications).