HEALTH REGULATIONS TO CONTROL DRUGS PRODUCT TRACEABILITY

ARCSA 30 Resolution
Official Registration Supplement 338 dated 26-Nov-2020
Status: in force

RESOLUTION ARCSA-DE-030-2020-MAFG

THE EXECUTIVE OFFICE OF THE NATIONAL AGENCY FOR HEALTH REGULATION, CONTROL AND SURVEILLANCE - ARCSA, DOCTOR LEOPOLDO IZQUIETA PÉREZ

CONSIDERING

That, The Constitution of the Republic of Ecuador in its article 360, states: "The system will guarantee, through the institutions that comprise it, the promotion of health, prevention and comprehensive, family and community care, based on primary health care; articulate the different levels of care; and promote complementarity with ancestral and alternative medicines. The Comprehensive Public Health Network will be part of the national health system and will be made up of an articulated set of state establishments, social security and other providers that are part of the State, with legal, operational and complementary ties ".

That, The Constitution of the Republic of Ecuador in its article 361, provides that: "The State will exercise the leadership of the system through the national health authority, will be responsible for formulating the National Health Policy, and will standardize, regulate and control all the activities related to health, as well as the operation of sector entities";

That, The Constitution of the Republic of Ecuador in its Art. 363 states: The State will be responsible for: "(...) 7. Guarantee the availability and access to quality, safe and effective drug products, regulate their commercialization and promote the national production and use of generic medicines that respond to the epidemiological needs of the population. In access to drug products, public health interests will prevail over economic and commercial ones. (...)";

That, The Constitution of the Republic of Ecuador, in its article 424, states that: "(...) The Constitution is the supreme norm and prevails over any other in the legal system. Public power norms and acts must maintain conformity with the constitutional provisions; otherwise, they will lack legal effectiveness (...) ";

That, The Constitution of the Republic of Ecuador, in its article 425, determines that the hierarchical order of application of the norms will be the following: "(...) The Constitution; international treaties and agreements; organic laws; ordinary laws; regional norms and district ordinances; decrees and regulations; ordinances; agreements and resolutions; and other acts and decisions of the public powers (...) ";

That, the Organic Health Law, in its article 6, establishes: "(...) It is the responsibility of the Ministry of Public Health, 18.- Regulate and carry out the sanitary control of production, import, distribution, storage, transportation, commercialization, dispensing and sale of processed foods, drug products and other products for human use and consumption; as well as the systems and procedures that guarantee their innocuousness, safety and quality (...) and other dependencies of the Ministry of Public Health (...) ";

That, the Organic Health Law, in its article 129, states that: "Compliance with the standards of health surveillance and control is mandatory for all institutions, agencies and

public and private establishments that carry out activities of (...) storage, transportation, distribution, marketing and sale of products for human use and consumption";

That, the Organic Health Law, in its article 130, prescribes that: "The establishments subject to sanitary control for their operation must have the permission granted by the National Health Authority. The operating permission will be valid for one calendar year ";

That, the Organic Health Law, in its article 131, orders that: "Compliance with the standards of good manufacturing, storage, distribution, dispensing and pharmacy practices will be controlled and certified by the National Health Authority";

That, the Organic Health Law in its article 137 provides; "Processed foods, food additives, drug products in general, nutraceutical products, biological products, processed natural products for medicinal use, homeopathic medicines and dental products, medical devices, biochemical and diagnostic reagents, hygienic products, pesticides for domestic and industrial use are subject to sanitary registration, manufactured in the national territory or abroad, for import, export, marketing, dispensing and sale, including those received as donations ";

That, the Organic Health Law, in its article 153, provides that: "All drug product must be marketed in legally authorized establishments. For public sale, a prescription issued by professionals authorized to do it, is required, with exception of over-the-counter drugs, (...). ";

That, the Organic Health Law, in its article 159, provides that "It is the responsibility of the National Health Authority to set, review and control the prices of medicines for human use and consumption through the National Council for the Setting and Review of Prices of Drug Products for Human Use, in accordance with the Law. Commercialization of the above-mentioned products without the fixing of prices is prohibited";

That, the Organic Health Law, in its article 173, states: "Every pharmaceutical establishment must have the technical responsibility of a professional chemist, pharmaceutical or biochemical pharmaceutical, who may have one or more pharmaceutical establishments under his technical responsibility, in accordance with what the regulation establishes. (...)".

That, Executive Decree No. 1033 signed on May 5, 2020, makes changes to the General Regulations of the Organic Law of the National Public Procurement System, in relation to the improvement of the procedures for the acquisition of drugs and strategic health supplies in order to exercise greater control, have adequate planning, guarantee the quality of public spending and avoid the shortage of health units that are part of the Comprehensive Public Health Network, RPIS;

That, Executive Decree No. 1033, signed on May 5, 2020, states in article 72 that; "Drugs are goods that consist of preparations or pharmaceutical forms contemplated in the definitions of drugs in article 259 of the Organic Health Law. For the acquisition of drugs, it will be necessary that they are within the current National Table of Basic Drug Products. Strategic health supplies constitute all types of products determined by the National Health Authority, within the framework of its powers, that are necessary and are directly related to the presentation of health services. (...)";

That, Executive Decree No. 1033 signed on May 5, 2020, establishes in its article 77 that: "Traceability control.- In the case of entities that make up RPIS, in the storage, distribution and delivery or dispensing service of drugs or strategic health supplies that is contracted, it will be monitored that in all transfer of the good the quality and health controls are complied with, being able to implement a traceability control mechanism for the monitoring of said goods, from the production of the drug or strategic good in health to the delivery or dispensing to the user or patient.

The traceability system will consist of the individual and univocal identification of each unit of the drugs and other strategic health supplies to be delivered or dispensed, which enables the monitoring of each unit through the entire distribution chain of said goods. Any irregularity in the quality, safety and efficacy conditions which is detected, will imply the immediate suspension of the contractual relationship and/or the application of the sanctions provided for in the respective agreement or purchase order, without prejudice to the sanctions contained in the other applicable regulations.";

That, in the Ministerial Agreement 0008-2017, signed by Dr. Verónica Espinosa Serrano Minister of Public Health, in which the document that establishes the National Drug Policy 2017-2021, signed on February 21, 2017, mentions among the strategic guidelines of this Policy, the following: "(...) 2. Ensure the quality and safety of drug products to protect consumers from associated risks. (...) 4. Strengthen drug product supply management planning. (...) 8. Strengthen transparency mechanisms in the pharmaceutical sector. 9. Strengthen the national production of drug products by increasing the volume of production and the diversity of the supply. ";

That, in the Ministerial Agreement 0008-2017, signed by Dr. Verónica Espinosa Serrano Minister of Public Health, which establishes the National Drug Policy 2017-2021, signed on February 21, 2017, in Chapter 5 Conceptual framework and analysis situation, 5.2.5.1 Counterfeit drugs, mentions:

- The Organic Health Law does not contain provisions regarding the counterfeiting of medicines. The second paragraph of article 157 mentions the following: "The National Health Authority [...] will periodically carry out post-registration controls and drug use studies to evaluate and control quality, safety and efficacy standards and sanction those who commercialize products that do not comply with said standards, falsify or adulterate pharmaceutical products.- [...] In April 2016, with Resolution ARCSA-DE-010-2016-GGG, the Sanitary Technical Standard for the control of products for human use and consumption subject to control and health surveillance considered falsified, adulterated or altered, in which the articulation and coordinated work with other State institutions is established to combat the commercialization of this type of products.
In the last quarter of 2016, the Judiciary sanctioned with prison, for the first time, the crime of counterfeiting drug products in Ecuador;

That, through Ministerial Agreement No. 0071-2019 Official Registration Special Edition No. 138, of November 25, 2019, the Minister of Health, Mgs. Catalina Andramuño Zeballos, Reforms the National Table of Basic Medicines and the annex that are part of the tenth revision issued by Ministerial Agreement No. 00037-2019;

That, through Ministerial Agreement No. 00010-2020, published in the Official Registration No. 590 of May 20, 2020, the Ministry of Public Health agrees to create the "Technical Commission of Strategic Goods in Health" which aims to periodically analyze and update the list of strategic goods in health;

That, the World Health Organization, urges its member countries that: "it is necessary that there is a system that guarantees the integrity of the supply chain of drug products to ensure the value of the same, in the prevention of diseases and in treating patients. Pharmacists are specifically trained and educated health professionals who have the corresponding authorization to manage the dispensing of medicines to users and carry out the appropriate tasks to guarantee the safety and effective use of medicines. As healthcare professionals, pharmacists have an important role in improving access to healthcare and reducing the gap between the potential benefit of medicines and the real value obtained, and they should be part of any

health system in its broadest sense. In addition, the increasingly complex and diverse nature of the functions of pharmacists in health systems and in public health, demands a continuous maintenance of their competencies as health professionals with up-to-date experience and skills ";

That, through Technical Report No. VCPPE-CGTVYCP-2020-196, dated November 13, 2020, the General Technical Coordination for Surveillance and Subsequent Control, mentions:" The traceability system for drugs and medical devices is a necessary platform for the subsequent control of establishments and post registration control of products, due to the fact that the information of the products will be available in real time, allowing more efficient control";

That, through Technical Report No. ARCSA-DTEEMCNP-028-2020- dated November 17, 2020, the Technical Directorate of Preparation, Evaluation and Continuous Improvement of Regulations, Protocols and Procedures justifies the preparation of a normative body that covers the particular needs that derive from the issuance of a national traceability system for products for human use and consumption, especially in the field of medicines and medical devices; as well as the requirements and criteria for its gradual implementation in phases at all levels, both public and private;

That, by means of the Legal Report ARCSA-DAJ-028-2020-MCGT, the Director of Legal Advice, validates the present normative project and establishes that it is feasible and in accordance with the Law, to issue the "SUBSTITUTE SANITARY TECHNICAL REGULATION THAT ESTABLISHES THE GUIDELINES FOR CONTROL OF THE TRACEABILITY OF MEDICINES, BIOLOGICAL PRODUCTS AND
MEDICAL DEVICES; without affecting the prohibitions established in article 131 of the Organic Administrative Code;

That, through Personnel Action No. 163 dated July 8, 2020, governs as of July 9, 2020, the Board of Directors of the National Agency for Regulation, Control and Sanitary Surveillance ARCSA, Doctor Leopoldo Izquieta Pérez, in use of his powers and attributions conferred by the Law, issues the appointment to Dr. Mauro Antonio Falconí García, as Executive Director of the National Agency for Regulation, Control and Sanitary Surveillance - ARCSA, Resolution No. DIR-ARCSA-001-2020 dated July 7, 2020 and based on the Minutes of the Board of Directors No. DIR-ARCSA-001-2020 held on July 7, 2020; responsibility that he will exercise with all the duties, rights and obligations that the position demands.

In accordance with the powers contemplated in Article 10 of Executive Decree No. 1290, published in the Official Registration Supplement No. 788 of September 13, 2012, amended by Executive Decree No. 544 of January 14, 2015 published in Official Registration No. 428 dated January 30 of the same year 2015, the Executive Director of ARCSA.

RESOLVED:

ISSUE THE SUBSTITUTE SANITARY TECHNICAL REGULATIONS THAT ESTABLISH THE GUIDELINES FOR THE CONTROL OF THE TRACEABILITY OF MEDICINES, BIOLOGICAL PRODUCTS AND MEDICAL DEVICES

CHAPTER I

PURPOSE AND SCOPE OF APPLICATION

Art. 1.- Purpose.- The purpose of this technical health regulation is to establish the guidelines for the implementation, monitoring, and control of the traceability of drugs, biological products, and medical devices in the country.

Art. 2.- Scope of application.- This technical health regulation is of mandatory application and compliance for all natural or legal persons, national or foreign, under public or private law that intervene in the distribution chain of the medicine, product

biological or medical device from its production or import until the dispensing or delivery of the product to the patient in the pharmacies of the Comprehensive Public Health Network (RPIS), Private Complementary Health Network (RPC) and in private pharmacies.

This technical regulation applies to all national or imported medicines, biological products and medical devices that are marketed in the national territory and have the Ecuadorian sanitary registry.

CHAPTER II
ABBREVIATIONS AND DEFINITIONS

Art. 3.- For the purposes of these regulations, it will be understood by:

Aggregation.- Process that allows associating the identification code of each logistics unit (corrugated box, pallet, container, etc.) with the CUTs of primary and / or secondary packaging contained in it to facilitate the registration of logistics movements in the computer traceability system.

Good Storage, Distribution and/or Transport Practices (BPA/BPD/BPT).- Constitute a set of mandatory minimum standards to be met by the establishments described in Article 2 of Resolution ARCSA-DE-002-2020-LDCL, published in Official Registration Special Edition 455, dated 19 March 2020, whose activity is the storage, distribution and/or transport, of the products referred to in the said legislation; facilities, equipment, operating procedures, organization, personnel and others, intended to ensure the maintenance of the characteristics and properties of the products during storage, distribution and/or transport.

Two-dimensional code.- Two-dimensional codes have a matrix structure consisting of small squares or points called modules that are organized into a square mesh and unlike barcodes have the advantage of storing more information. QR and Data Matrix codes are located on this category.

Unique Traceability Code (CUT) .- It is the identification code or unique code of the product according to the GS1 international standard, which must include the GTIN code, plus a unique serial number made up of up to 20 alphanumeric characters, the batch number, and the expiration date. In the case of medical devices, the UDI will be used as a CUT in accordance with the International Medical Device Regulators Forum - IMDRF, which must include the GTIN code, batch number, expiration date and serial number for implantable medical devices. The inclusion of the CUT shall be made in the secondary packaging, or in its primary packaging when the product does not have secondary packaging.

DCI- International Common Denomination of the active principle. Applies only for drug products indications.

Medical device for human use.- These are articles, instruments, appliances, artifacts, or mechanical inventions, including their components, parts, or accessories, manufactured, sold or recommended for use in diagnosis, curative or palliative treatment, prevention of an illness, disorder or abnormal physical condition or its symptoms, to replace or modify the anatomy or a physiological process or control it. They include amalgams, varnishes, sealants, and more similar dental products.

Any instrument, appliance, implement, machine, application, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used alone or in combination, to human beings, for one or more of the specific medical purposes (s) of:

- Diagnosis, prevention, monitoring, treatment or relief of the disease;

- Diagnosis, monitoring, treatment, relief or compensation for an injury;
- Research, replacement, modification or support of anatomy or a physiological process;
- Life support or maintenance;
- Conception control;
- Disinfection of medical devices
- Provision of information through an in vitro examination of samples from the human body;

And it does not exert the primary action foreseen by pharmacological, immunological, or metabolic means, in or on the human body, but which can be assisted in its role through portals.

Distribution.- Set of activities that are carried out from when the product is produced or dispatched by the manufacturer or company until it is purchased by the dispensing location or the consumer.

Dispensing.- Pharmaceutical act of providing one or more medicines to a patient, usually in response to the presentation of a prescription prepared by an authorized professional. In this act, the pharmacist informs and guides the patient about the proper use of said medicine. These are important elements of this guidance, including the emphasis on compliance with the dosing regimen, the influence of food, interaction with other medicinal products, the recognition of potential adverse reactions and the conditions of preservation of the product.

Packaging or primary packaging.- Packaging within which the finished dosage form is placed, or the container that is in direct contact with the product.

Packaging or secondary packaging.- This is the external box or case containing the primary container inside. It corresponds to the minimum commercial or hospital unit containing the product labelling information required and approved in the Health Registry.

Pharmaceutical logistics and storage companies.- They are establishments authorized to provide logistics, storage, distribution and/or transport services of the products described in Article 1 of Resolution ARCSA-DE-002-2020-LDCL, published in Official Registration Special Edition 455, dated March 19, 2020, must comply with the Good Practices of Storage, Distribution and Transport determined by the National Health Authority. They shall operate under the representation and technical responsibility of a Pharmaceutical Chemical or Pharmaceutical Biochemist and shall obtain the corresponding operating permission.

Label - Written, printed or graphic information that adheres or is printed both on the internal or primary packaging, as well as on the external or secondary packaging that identifies or characterizes the products (It does not refer to the stickers superimposed on the hashtag). The label must contain information related to the identification, technical description, indication and proposed use of the products, which must be in accordance with the regulations applicable to the type of product.

Private pharmacy.- They are pharmaceutical establishments authorized for the retail sale of medicines and other authorized products, which give attention to the general population and that can be installed in urban areas and rural areas.

Expiration or expiry date.- Date specified on the primary carton and secondary packaging of a product and up to which it is expected to remain within its technical specifications if stored properly.

Unique identification.- Unique code consisting of a combination of numbers and/or letters through which you can track the complete history of each finished product unit, individually.

Unique Identifier of Medical Devices (UDI).- This is a series of numeric or alphanumeric characters that is created through an accepted standard of device identification and encoding. Allows unequivocal identification of a specific medical device on the market. The UDI consists of the Device Identifier (DI) plus the Production Identifier (PI). The UDI will comply with the guidelines determined by the International Forum of Medical Device Regulators (IMDRF).

The ARCSA or the Agency - Refers to the National Agency of Regulation, Control and Sanitary Surveillance -ARCSA, Doctor Leopoldo Izquieta Pérez.

Drug product.- It is any preparation or dosage form, whose composition formula expressed in units of the international system, consists of a substance or mixture of substances, with weight, volume and constant percentages, prepared in pharmaceutical laboratories legally established, packaged or labeled to be distributed and marketed as effective for diagnosis, treatment, mitigation and prophylaxis of a disease, physical abnormality or symptom , or the restoration, correction or modification of the balance of the organic functions of humans and animals.

By extension this definition applies to the association of substances of dietary value, with therapeutic indications or specially prepared foods, which replace special dietary regimens.

Lot/serial number.- Designation by codes, numbers, letters, or a combination of the previous ones, of the lot/series of the product, which allows to make the identification and traceability of the same.

Global Commercial Item Number (GTIN).- This is the Global Commercial Item Number, used to uniquely identify a product or service. The GTIN identifies product types at any packaging level (e.g. e.g., consumer unit, inner package, box, dunnage).

Biological product or biological medicine.- It is that medicine for human use and consumption obtained from microorganisms, blood or other tissues, whose manufacturing methods may include one or more of the following elements:

- Growth of microorganism strains on different types of substrates.
- Use of eukaryotic cells.
- Extraction of substances from biological tissues, including human, animal and plant.
- Products obtained by recombinant DNA or hybridomas.
- The propagation of microorganisms in embryos or animals, among others.

They are considered biological medicines:

- Vaccines
- Processed blood products and related products;
- Biotechnological and biosimilar drugs, and
- Other biologics such as:

- Allergens of biological origin.
- Immune serums
- Others that the health authority determines, prior to the fulfillment of the requirements established for its categorization.

Comprehensive Public Health Network (RPIS).- It consists of the articulated set of state establishments, social security and other providers belonging to the State, with legal, operational and complementarity links.

Complementary Private Health Network (RPC).- It is the set of private institutions providing

health services, health insurance and prepaid medicine companies operating in the country, whether for profit or not-for-profit.

Serialization - A process that allows each primary and/or secondary package to be uniquely identified by printing a two-dimensional code or applying a sticker to enable unit traceability of the products.

National Traceability System.- The national traceability system is composed of domestic or foreign pharmaceutical laboratories, laboratories that manufacture domestic or foreign medical devices, importers of medicines, biological products and medical devices, distributors and representative houses that market medicines, biological products and medical devices, pharmaceutical logistics and storage companies, health facilities of the national health system (RPIS and RPC) including pharmacies located within these establishments , private pharmacies and patients or users involved in this management model of distribution of medicines, biological products and medical devices.

Traceability Computer System.- It is an information system intended to identify individually and uniquely each of the products to be marketed, as well as to track them throughout the distribution chain, from their production to the dispensing or delivery to the patient or end user.

GS1 System (Global System One)- It is a set of standards that enables efficient management of the multisectoral and global supply chain, by unequivocal identification of products, shipping units, goods, locations, and services. Facilitates e-commerce processes including full track and trace.

Traceability.- It is the ability to individually identify the origin and different stages of production and distribution of a product, up to the dispensing or delivery to the patient or end user.

Sanitary Registration Holder - The natural or legal person in whose name the sanitary registration certificate is issued and is legally and technically responsible for the quality of the product in the country.

Commercial unit - Product unit that corresponds to the initial level of aggregation and is formed by the box or packaging of the product (secondary packaging) containing the GTIN commercial identification code.

CHAPTER III
OF THE NATIONAL TRACEABILITY SYSTEM

Art. 4.- National Traceability System.- The national traceability system is composed of domestic or foreign pharmaceutical laboratories, laboratories that manufacture domestic or foreign medical devices, importers of medicines, biological products and medical devices, distributors and representative houses that market medicines, biological products and medical devices, pharmaceutical logistics and storage companies, health facilities of the national health system (RPIS and RPC) including pharmacies located within these establishments , private pharmacies and patients or users involved in this management model of distribution of medicines, biological products and medical devices.

As a result of the logistic movements of the product, an information system is generated which allows tracking of drugs, biological products, and medical devices through the distribution chain, all the way to the patient. These movements must be reported to the competent authority through the computerized traceability system used for this purpose.

Art. 5.- Traceability begins with the laboratories that manufacture or import medicines, biological products, and medical devices, who must report to the Agency, through the traceability computer system, the CUT that is granted for the traceability of each of the commercial units of the products that are the object of this resolution.

The holders of the sanitary registrations of these products must ensure the inclusion of the CUT on the secondary packaging, or on its primary packaging in case there is no secondary packaging, so that it can be clearly identified and read at all stages of the supply chain of the product. In the case of medical devices, the UDI will be used as a CUT in accordance with the International Medical Device Regulators Forum - IMDRF, which must include the GTIN code, lot number, expiration date and serial number for implantable medical devices.

Art. 6.- Identification codes generated in the different aggregation logistics units such as corrugated boxes, pallets, containers, etc., must follow international GS1 standards of commercial marking and serial identification, so that all information described in Article 19 can be obtained through electronic information capture devices, such as scanners or other technological devices available for this purpose.

Art. 7.- All logistic operations and movements carried out with the drug, biological product and medical device during its reception, storage, distribution, transportation, and commercialization must be registered in the traceability computer system through the CUT by the members of the national traceability system.

Art. 8.- For RPIS establishments, the contracted company or logistics operator must implement traceability, including monitoring the process of receiving, storing, distributing, transporting, dispensing and/or delivering medicines, biological products and medical devices to the patient or end user.

Pharmaceutical establishments and medical device establishments that market drug products, biological products and/or medical devices to public and private pharmacies must implement traceability and record the movements of their products in the traceability computer system that ARCSA generates for this purpose.

Art. 9. - In all the different stages of the logistics chain from production, importation, commercialization, storage, distribution, transportation up to dispensing or delivery to the patient or end user, the logistics operator providing services to the RPIS must have access to all traceable information in all the units corresponding to this chain, such as: pallets, corrugated or sales units; which must be coded, with global identifiers of commercial items according to GS1 international standards, in such a way that all the information of their content can be obtained through electronic information capture devices such as scanners or other technological devices available for that purpose.

Art. 10.- For the dispensing or delivery of the products for human use and consumption described in these regulations, public or private pharmacies must establish the mechanisms established in these regulations to guarantee their traceability, reflecting information on the dispensing and balances of the products for each unit dose dispensed or delivered to the patient or end user, as the case may be. Similarly, the information of the dispensing or delivery must be recorded in the traceability computer system implemented by the Agency for the purpose.

Art. 11.- The traceability computer system should allow the end user or patient to verify, through portable and easily accessible tools, the history, and data of the product dispensed or delivered, using the Unique Traceability Code found on the secondary or primary packaging, as appropriate.

CHAPTER IV
UNIQUE IDENTIFICATION

Art. Coding and labeling of drugs, biological products, and medical devices - Drugs and biological products must have a unique identification or code on the primary and/or secondary packaging, as appropriate, in accordance with the GS1 international standard, which must include the GTIN code, plus a unique serial number consisting of up to 20 alphanumeric characters, the lot number and the expiration date. In the case of medical devices, the UDI will be used as CUT.

In the case of medical devices, the UDI will be used as a CUT in accordance with the International Medical Device Regulators Forum - IMDRF, which must include the GTIN code, batch number, expiration date and serial number for implantable medical devices.

Art. 13.- The encoding generated with the information described in the previous article should be placed on the packaging using the two-dimensional CUT, which will contain the information for traceability and be displayed in a visible place.

Art. 14.- Whenever the dimensions of the package allow it, in addition to the two-dimensional CUT, the GTIN information, the expiration date, the lot and the unique serial number in the case of the medicine must be stated in humanly legible language.

For medical devices the traceability mechanism will comply with GS1 international standards for which the product must contain the unique identifier of UDI medical devices.

Art. 15.- The unique traceability code must be printed on the primary and/or secondary packaging, as appropriate, identifying the commercial unit, or, if not, a sticker or adhesive containing the information necessary for traceability may be placed. This sticker or adhesive must have inviolability characteristics that prevent easy removal. Any breakage, removal, fingerprint, replacement, or mark that involves an attempt to breach the integrity of the sticker or adhesive must be communicated to the ARCSA for the corresponding control and analysis to be carried out according to its competences.

Art. 16.- The unique traceability code must be placed printed or by a sticker or sticker preferably on a flat surface, avoiding coated surfaces or any material that hinders or prevents the reading, identification and capture of all the product information indicated above. The single traceability code should not impede or overlap with labelling information required by law and approved in accordance with regulations for the issuance of the sanitary registry.

Art. 17.- For the inclusion of the traceability code in secondary and/or primary packaging, as appropriate, of domestic or imported medicines, biological products and medical devices, the holder of the health register must do so in establishments authorized for this purpose by ARCSA, which must comply with Good Manufacturing Practices or Good Practices of Storage, Distribution and/or Transport.

Art. 18.- Holders of health records of imported medicines, biological products and medical devices must include traceability codes in the primary or secondary packaging of each of the products, as appropriate, at the time of entry to the establishment authorized for storage, distribution and/or transport, after nationalization, where applicable (in case the products do not bring the CUT from the country of origin).

Art. 19.- The information generated in the traceability computer system when capturing the traceability code that is included in the primary or secondary packaging of the

product, as appropriate, should consider at least the following:

a. Date, time, origin and destination of the transaction or logistical movement of the product;
b. Invoice number or identification of the transaction document of the logistics movement;
c. Lot or serial number, as applicable;
d. Product expiration date as applicable;
e. Name and identity card of the patient and/or recipient of the medicinal product, biological product, or medical device; and
f. Commercial product code (GTIN) must be related to the drug product, biological product, or medical device:

I. Sanitary registry number
II. Product Name
III. International Common Name (DCI) for drug products only
IV. Commercial presentation
V. Description of dosage form (drug product only)
VI. Strength (drug products only).

Art. 20.- When the drug product, biological product or medical device is delivered directly to the patient at his home or place of residence (for priority groups), the following information must also be recorded in the computer system:

a. Recipient's home address
b. Delivery date and time
c. Invoice number or identification with patient data
d. Name and identity card of the person receiving the product.

Art. 21.- Natural or legal persons involved in the process of receiving, storing, marketing, distributing, transporting, and dispensing or delivering medicines, biological products and medical devices must have the technological devices to capture the unique identification code and other elements or codes that allow traceability to be carried out along the distribution chain until reaching the patient or end user.

Art. 22.- Of the records of logistics movements.- All actors that are part of the scope of these regulations must record in the traceability computer system the logistical movements detailed below, without prejudice to other movements that may be informed through the system and that are required for their proper management and operation:

a. Quarantined product;
b. Product Release.
c. Distribution and reception of the product to the downstream player in the distribution chain;
d. Distribution and reception of the product to the previous actor in the distribution chain;
e. Distribution / delivery of the product to the patient;
f. Product cancelled (due to damage, breakage or damage resulting from transportation and distribution);
g. Stolen or lost product;
h. Transfer between own warehouses or warehouses;
i. Expired or expired product;
j. Returns for quality issues;
k. Re-entry of the product into stock;
l. Product withdrawn from the market (in the face of the issuance of a health alert or voluntary withdrawal notified to ARCSA);
m. Product withdrawn for destruction (product near to expire); and
n. Product intended for clinical trial.

CHAPTER V
FROM THE CENTRALIZED DATABASE

Art. 23.- Central Database - The traceability computer system shall have a database where all the records generated as a result of the logistic movements of the products involved in the supply chain shall be stored, in accordance with the provisions of these regulations. The administration, maintenance and improvement of the computer system and database will be the responsibility of ARCSA, which will maintain a backup of the information contained therein.

Art. 24.- The traceability computer system should allow only authorized personnel of the Agency as well as authorized personnel of the National Health System, income to view transactions and their status, statistical reports, indicators, and updated alerts, in order to execute actions of prior control, internal control and / or subsequent control.

Art. 25.- Security parameters.- The traceability computer system must contain security parameters, restrictions and alerts that at least allow:

a. Identify duplications of codes and errors that may occur with respect to product information.
b. Alert unauthorized logistics operations.
c. Verify the legitimacy of the distribution chain.
d. To become aware in the shortest time of any irregularity, anomaly and/or deviation of the relevant unique codes.
e. Ensure that no establishment accesses information from the distribution process corresponding to transactions of other establishments of which they are not part.
f. Archive traceability codes for products that have been delivered or dispensed to the patient or end user, preventing the product that has completed the traceability process from re-entering the distribution chain.
g. Protect information to prevent misuse of patient personal data in accordance with laws and regulations governing the purpose.

Art. 26.- The traceability computer system must be able to receive the required up-to-date information from all movements made in the distribution chain for proper storage and management. The computer system used by the actors described in the scope of these regulations must be compatible with the traceability computer system of the regulatory authority.

CHAPTER VI
OF SANCTIONS

Art. 27.- The sanitary registry or the certificate of good practice or rigorously superior, in accordance with the provisions of article 141 of the Organic Law on Health, or the law that does its times, shall be suspended from checking for non-compliance with these technical health regulations, a situation that will be maintained until effective compliance by the administered; without prejudice to any civil and criminal actions.

Art. 28.- The sanitary registry or the certificate of good practices or strictly superior, according to the provisions of article 141 of the Organic Law of Health, or the law that takes its place, shall be cancelled in case two (2) suspensions are proven in the same fiscal year; without prejudice to the civil and criminal actions that may be applicable.

GENERAL PROVISIONS

FIRST.- In the event that affectations have been reported to the characteristics of medicines, biological products and medical devices occurring during the process of

storage, distribution or dispensing; or that they are defeated or close to winning; the person responsible for the custody and safeguarding of the good storage conditions of these products in the pharmaceutical establishment or in the health establishment, must coordinate the final disposal thereof with the supplier. The traceability computer system should allow the recording and traceability of operations related to the final disposal activities of medicinal products, biological products and medical devices covered by this provision.

SECOND.- The holders of the health records of medicines, biological products and/or medical devices contracted by the RPIS, are responsible for including the traceability code and reporting it to the ARCSA, through the traceability computer system. The traceability code may be printed or attached by means of a sticker / adhesive, on the primary or secondary packaging as appropriate.

THIRD.- When any fraudulent information related to the unique product traceability code is detected it must be communicated to the ARCSA for the corresponding control and analysis to be carried out according to its competences and proceeded in accordance with law.

TRANSITIONAL PROVISIONS

FIRST.- Suppliers for the RPIS of medicinal products or biological products established by the national health authority for the first phase of implementation of traceability shall have a period of up to six (6) months from the publication in the Official Registration of these regulations, in order to comply with the guidelines set out in this resolution.

SECOND.- Suppliers for the CPR and private pharmacies of medicines or biological products established by the national health authority for the first phase of implementation of traceability shall have a period of up to twelve (12) months from the publication in the Official Registration of these regulations, in order to comply with the guidelines set out in this resolution.

THIRD: The suppliers for the RPIS of medicines or biological products that the national health authority establishes for the second phase of implementation of traceability, will have a term of up to twelve (12) months from the publication in the Official Registration of the present regulation, to comply with the guidelines established in this resolution.

FOURTH.- Suppliers for the CPR and private pharmacies of medicinal products or biological products established by the national health authority for the second phase of implementation of traceability shall have a period of up to eighteen (18) months from the publication in the Official Registration of these regulations, in order to comply with the guidelines set out in this resolution.

FIFTH: The suppliers for the RPIS of medicines or biological products that the national health authority establishes for the third phase of implementation of traceability, will have a term of up to eighteen (18) months as of the publication in the Official Registration of the present regulation, to comply with the guidelines established in this resolution.

SIXTH: The suppliers for the PRC and private pharmacies of the medicines or biological products that the national health authority establishes for the third phase of implementation of traceability will have a term of up to twenty-four (24) months as from the publication in the Official Registration of this regulation, to comply with the guidelines established in this resolution.

SEVENTH: The suppliers for the RPIS, RPC and private pharmacies of medical devices that the national health authority establishes for the fourth phase of implementation of traceability, will have a term of up to twenty-four (24) months from the publication in the Official Registration of this regulation, to comply with the guidelines established in this resolution.

EIGHTH - Within one hundred and twenty (120) days from the publication of this regulation in the Official Registration, the National Agency for Regulation, Control and Health Surveillance - ARCSA will acquire the computer system for the control of the operations involved in the distribution chain of the drug, biological product or medical device from its production or importation to the dispensing or delivery of the product to the patient.

NOVENA.- Within one hundred and twenty (120) days from the publication of these regulations in the Official Registration, ARCSA shall issue the corresponding instructions for the application of the traceability computer system and any instructions required to be modified with the entry into force of these regulations.

REFORM PROVISION

FIRST: Replace literal j of article 27 of Resolution ARCSA-DE-002-2020-LDCL, published in Official Registration Special Edition 455, dated March 19, 2020, by which the Technical Sanitary Regulations on good storage, distribution and/or transportation practices for pharmaceutical establishments and establishments of medical devices for human use are issued, with the following text:

"j) Printing area - In this area printing activities may be carried out using the inkjet system or any other printing system applicable to the products mentioned in Article 1 of these regulations; this area must have the standard operating procedures for the activities to be carried out and shall be under the supervision of the technical manager of the establishment.

In this area, processes that affect the integrity or sealing of the primary and secondary packaging of the products, as well as processes that affect the stability of the products, such as shrink-wrapping, shall not be carried out, unless this process is authorized in the sanitary registry. In case solvents are handled for the inkjet printing process, this area must have a ventilation system, including air injection and extraction.

In this area, only the printing of the following information may be made, with prior notification to ARCSA:

a. For Medical Devices

1. Sanitary registry:
2. Legends such as: "Before using this product, see enclosed insert / use manual", "Sterile", "Disposable or non-reusable product", "Free product prohibited for sale", "Prohibited for sale", "Protect from light", and other legends described in current regulations, and;
3. Unique Traceability Code (CUT).

b. For drug products:

1. Retail Price (PVP)
2. Legends such as: "Medical Sample, Not for Sale", "Free Medicine, Not for Sale", "Not for Sale", and other legends described in current regulations, and;
3. Unique Traceability Code (CUT).

The information not contemplated in paragraphs a and b must be printed by the manufacturer according to what is approved in the sanitary registration.

Only the CUT of drugs, biological products and medical devices may be included in this area by means of a sticker or adhesive.

SECOND.- Include the following text after the Twelfth General Provision of Resolution ARCSA-DE-008-2018-JCGO, published in Official Registration 257, dated June 7, 2018, whereby the Substitute Technical Sanitary Regulation on good manufacturing practices for pharmaceutical laboratories is issued:

"Thirteenth: National pharmaceutical laboratories that have the Good Manufacturing Practices certification may include in the packaging area the unique traceability code for their products and third party products.

DEROGATORY PROVISION

Resolution ARCSA-DE-013-2020-MAFG, by which the Technical Sanitary Regulations establishing the mechanisms for the control of traceability applicable to medicines and strategic health supplies, published in Special Edition of Official Registration 948, dated September 2, 2020, is expressly repealed.

FINAL PROVISION

The General Technical Coordination of Certifications, the Coordination of Subsequent Control through the corresponding Directorates of ARCSA and the Information Technology Directorate of ARCSA, each of them within the scope of their competencies, are entrusted with the execution and verification of compliance with this resolution.

This resolution shall become effective as of its publication in the official registration.

Given in the city of Guayaquil, on November 17, 2020.

Dr. Mauro Antonio Falconí García
EXECUTIVE DIRECTOR OF THE NATIONAL AGENCY FOR REGULATION, CONTROL AND SANITARY SURVEILLANCE - ARCSA, DOCTOR LEOPOLDO IZQUIETA PÉREZ.