Coalición Interamericana de Convergencia Regulatoria
SECTOR DE TECNOLOGÍA MÉDICA

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Inter-American Coalition for Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

June 4, 2021

Considerations of the Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector Regarding G/TBT/N/ECU/498

Ecuador (ARCSA) - Health Regulations for the Control of Traceability of Medicines - Resolution ARCSA-DE-030_2020_MAFG

Summary

On 11 January 2021, the Ecuadorian government notified to the WTO as **G/TBT/N/ECU/498** (English / Spanish) **Health Regulations for the Control of Traceability of Medicines - Resolution ARCSA-DE-030_2020_MAFG** (English / Spanish) published by the Ecuadorian regulatory authority – the National Agency for Regulation, Control and Sanitary Surveillance (Agencia Nacional de Regulación, Control y Vigilancia Sanitaria - ARCSA).

The medtech industry position is that the Resolution should be withdrawn for the scope of medical devices at this time and the regulatory process be reinitiated from the beginning employing Good Regulatory Practices for the following reasons:

1) **Resolution is Not Aligned with IDMRF Criteria:** The Resolution mandates a two-dimensional (2D) barcode inconsistent with IMDRF/UDI WG/N7FINAL:2013. It also requires the application of the code for situations inconsistent with the IMDRF documents and incompatible with practical experience. It, and its new revision already underway, also includes several other unclear provisions.

2) **Implementation Timelines Unrealistic:** The 180 day window between the Resolution's publication and its enter-into-force date of May 25, 2021 are unrealistic based on the experiences of regulatory authorities in other countries and by the lack of clarity of the new provisions. The proposed extended deadlines are also unrealistic.

3) **Implementation Costs are Disproportionate**

4) **Good Regulatory Practices Not Employed:** This technical regulation was not developed following GRP as the Ecuadorian government has now ratified via the U.S.-Ecuador TIC Protocol on Trade Rules and Transparency (English / Spanish) and as reinforced by Ecuador's commitments via the World Trade Organization, Technical Barriers to Trade Agreement. (English / Spanish).

Background

UDI – Unique Device Identification

The International Medical Device Regulators Forum (IMDRF) has established guidance for the development and usability of Unique Device Identification (UDI) for Medical Devices via the following three documents:

IMDRF Document	Title
IMDRF/UDI WG/N7FINAL:2013	UDI Guidance Unique Device Identification (UDI) of Medical Devices
IMDRF/UDI WG/N48 FINAL: 2019	Unique Device Identification system (UDI system) Application Guide
IMDRF/UDI WG/N53 FINAL:2019	Use of UDI Data Elements across different IMDRF Jurisdictions

The relevant IMDRF reference for this position paper is in the first of these documents, IMDRF/UDI WG/N7FINAL:2013.

The relevant definitions from this document (Section 5) are as follows:

Term	Definition
UDI – Unique Device Identification	The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is comprised of the UDI-DI and UDI-PI. Note: The word “Unique” does not imply serialization of individual production units.
UDID – UDI Database	The UDID contains identifying information and other elements associated with the specific medical device.
UDI System	The UDI System is the framework for: 1) UDI production , 2) UDI application on the label or on the device, and 3) UDI Database (UDID) fundamental contents

AIDC – Automatic Identification and Data Capture	A technology used to automatically capture data. AIDC technologies include bar codes, smart cards, biometrics and RFID.
HRI – Human Readable Interpretation (HRI)	Human Readable Interpretation is a legible interpretation of the data characters encoded in the UDI Carrier
UDI Carrier [Also known as AIDC Carrier, or the Carrier]	The UDI Carrier is the means to convey the UDI by using AIDC and, if applicable, its HRI. Note: Carriers can include ID/linear bar code, 2D/Matrix bar code, RFID, etc.. [The UDI Carrier is the AIDC + the HRI]

Examples of UDI/AIDC Carriers permitted by the IDMRF include:

Linear (1D) barcode 2D/Data Matrix/QR barcode RFID

(See Annex 1 for additional information on UDI structure and examples of labeling using UDI.)

The other relevant portions of IMDRF/UDI WG/N7FINAL:2013 are as follows:

> "2. Introduction
>
> This guidance provides a framework for those regulatory authorities that intend to develop their UDI Systems that achieves a globally harmonized approach to the UDI. The framework can be used at a local, national, or global level such that these systems are implemented without regional or national differences. This guidance is intended to provide a high-level conceptual view of how a global UDI System should work. It is recognized that further additional guidance may be needed once these core concepts are accepted.
>
> The fundamental concepts of a globally harmonized UDI System include:
>
> a. the UDI and UDI Carrier are based on standards,

b. a UDI applied to a medical device anywhere in the world should be able to be used globally and to meet the UDI requirements of its regulatory authority,

c. national or local identification numbers should NOT be a substitute for UDI,

d. regulatory authorities should not specify the procedure for modifying these UDI standards

e. the UDID core elements should not be modified,

f. the UDID should use the Health Level Seven International (HL7) Structured Product Label (SPL) and web-based interface for data submission,

g. every medical device needs to be identified by a UDI, unless it is exempted

The UDI System is intended to provide a single, globally harmonized system for positive identification of medical devices. Healthcare professionals and patients will no longer have to access multiple, inconsistent, and incomplete sources in an attempt to identify a medical device and, its key attributes. The UDID is a designated source for additional information. It is critical to note that the benefits of UDI can only accrue if all stakeholders, from the manufacturer to healthcare providers and patients, use UDI throughout their workflow systems.

Therefore, it is imperative that all stakeholders be educated about the development and use of a UDI System.

A globally harmonized and consistent approach to UDI is expected to increase patient safety and help optimize patient care by facilitating the:

a. traceability of medical devices, especially for field safety corrective actions,

b. adequate identification of medical devices through distribution and use,

c. identification of medical devices in adverse events,

d. reduction of medical errors,

e. documenting and longitudinal capture of data on medical devices."

Particularly important is the following IMDRF criteria:

"8. UDI Carrier

8.5 No particular AIDC methods should be required by a regulatory authority. Globally accepted AIDC methods based on ISO standards that have been adopted by the global organization (e.g., GS1, HIBCC or ICCBBA) shall be used."

This means that regulatory authorities should not limit the AIDC method (including the UDI Carrier).

(See Annex 1 for more information on GS1, HIBCC and ICCBBA).

Resolution No. ARCSA-DE-030-2020-MAFG

According to Ecuador's notification to the WTO **G/TBT/N/ECU/498** of 11 January, 2021 (English / Spanish), the purpose of **Resolution No. ARCSA-DE-030-2020-MAFG of November 26, 2020** (English / Spanish) "is to establish guidelines for the implementation, monitoring and control of the traceability of medicines, biological products and medical devices in the country." Further, also according to the notification, the objective of the Resolution is the prevention of deceptive practices and consumer protection, information and labelling for human health protection or safety.

Timeline

The Resolution is set to enter into force in May 25, 2021, 180 days after publication in the Official Journal.

Industry Assessment

This new Resolution adds new requirements, complexity, unclear requirements, costs and will therefore unnecessarily restrict medical device trade.

In particular:

1. Resolution is Not Aligned with IDMRF Criteria

The Resolution requires the implementation of a Ecuadorian Unique Traceability Code (CUT) which is initially based on IMDRF/UDI WG/N7FINAL:2013 and GS1. However, the CUT goes beyond the IMDRF criteria and mandates the use of just the two-dimensional (2D) barcode option instead of allowing the use of any of the three primary UDI Carrier options the IMDRF allows in IMDRF/UDI WG/N7FINAL:2013 Section 8.5.

The Resolution does this in the following locations:

> "Chapter II
> ABBREVIATIONS AND DEFINITIONS
>
> Art. 3
>
> …
>
> 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."

> …
>
> CHAPTER IV
> UNIQUE IDENTIFICATION
>
> …
>
> 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."

This is problematic for the following reasons:

A. The IMDRF purposefully allows the various methodologies to ensure that identification systems currently in use throughout the medtech supply chain are not arbitrarily rejected.

B. There is no other regulatory authority in the world that has implemented such a limitation for medical devices. Ecuador is the only one and alone in this regard. There is no indication that this is a direction that the global community is shifting to.

C. The 2D barcode, while technically capable of capturing more information than a 1D linear barcode, is in practice much slower to scan. Its provision has been allowed as an additional option to facilitate the provision of information under circumstances and it was never intended to be the sole methodology. For high speed logistics operations including scanning of codes on products on conveyor belts, the time to scan a 2D barcode is significantly slower than for a 1D barcode.

D. No regulatory rationale has been offered as to the purpose of limiting the AIDC to a 2D barcode.

E. A significant portion of the medtech supply chain within and into Ecuador does not use a 2D barcode, and this Resolution does not demonstrate what regulatory purpose will be achieved through this exclusive imposition.

Additionally, below are comments that pertain to the Resolution as published and the revision to the Resolution already underway:

A. **The Resolution is not clear if the 1D bar code may still appear on the label. May both be present?**

B. CHAPTER III, Art. 8: **The Public Health Network is RPIS. This is a public system. The private equivalent is RPC. The latest draft removed the tracking of logistics for private.**

C. CHAPTER III, Art. 8: **Is the Ecuadorian database capable of accepting all the data that will go to them? Does everyone in the system have the equipment needed to do this? It seems the requirement for the Ecuadorian government to develop a database was removed in the latest draft.**

D. CHAPTER III, Art. 11: **What are** "portable and easily accessible tools, the history, and data of the product dispensed"**?**

E. CHAPER IV, Art 19: What does "should consider at least the following" mean? **Is it not mandatory?**

F. CHAPER IV, Art 22: "Transfer between own warehouses or warehouses" **This is an overly prescriptive requirement into company-specific operations. Industry needs to be able to manage product internally as necessary.**

G. The latest draft eliminates Chapter V "FROM THE CENTRALIZED DATABASED", **removing the requirements for Ecuador to have a system that will centralize information. What's happening here?**

H. The new draft includes in GENERAL PROVISIONS, after the Dispositions, the following provision "FOURTH.- The notification of information for medical devices contemplated in literal j) of article 27 of Resolution ARCSA-DE-002-2020-LDCL, published in the Official Gazette, Special Edition 455, dated March 19 of 2020, will be included in detail of modifications of the form in the Window. Only Ecuadorian and will be exempt from payment. " **It is not clear what this means.**

I. The new draft stipulates one year for industry to comply with phase 1, 1.5 years for phase 2, etc. Phase one now has one year instead of six months. **These timelines are still insufficient given the inconsistently with the international requirements and lack of regulatory clarity.**

J. The latest draft TRANSITIONAL PROVISIONS "SIX.- Until the Agency has a computer system to carry out the control of the traceability of medicines, biological products and devices doctors, the members of the National Traceability System must register the movements of the products subject to this regulation in the system traceability computer that they have for this purpose; logistics movements which will be verified by

the ARCSA through follow-up inspections. The characteristics of the ARCSA traceability computer system shall indicate in the instructions issued by the Agency for this purpose." **So Ecuador does not establish a date for themselves to have a system to process the data, but industry is required to keep the data for them?**

2. Implementation Timelines Unrealistic

The Resolution establishes unrealistic implementation timelines: international experiences have confirmed that it is not possible to implement the modifications required by the Resolution within twenty-four (24) months. As an example of implementation times: the U.S. Food and Drug Administration (FDA) implemented UDI over a seven (7) year period, as per the Compliance Dates for UDI Implementation published on the FDA's website.

3. Implementation Costs are Disproportionate

Estimated implementation cost per product type per company is USD 150,000 totaling USD 543 million for the entire sector, as assessed by ASEDIM (English and Spanish), a cost that surpasses the total Ecuadorian Medical Devices market value, which by 2019 accounted for USD 461 million, as assessed by ASEDIM (English and Spanish), 99% of which are imported, and a great portion of which originated in the United States.

4. Good Regulatory Practices Not Employed

This technical regulation was not developed following GRP as the Ecuadorian government has now ratified via the U.S.-Ecuador TIC Protocol on Trade Rules and Transparency (English / Spanish) and as reinforced by Ecuador's commitments via the World Trade Organization, Technical Barriers to Trade Agreement. (English / Spanish).

A. The broadest possible public consultation on the measure via notification to the WTO was not conducted, preventing the opportunity for the provisions of the measure to improve in efficacy and reduced impacts to trade.

B. This measure was not notified as a draft prior to final publication, precluding the opportunity for WTO member and affected stakeholder review and comment prior to publication.

C. A regulatory impact assessment (RIA) was not conducted evaluating various aspects of the measure, including the following:
   i. The regulatory efficacy of the measure in achieving its stated objectives.
   ii. A cost-benefit analysis of the measure.
   iii. Likelihood of the measure to decrease patient access to medical devices given that the costs of the devices will go up in order to comply with the Ecuador-unique technical requirements.

F. The requirements set by the Resolution can be applied to all listed essential medical products (*The Strategic Products List "Cuadro Nacional de Medicamentos Básico"* - CNMB) which accounts for 3,622 types of medical devices and does not comply with the proposed criteria to be

organized in phases, reducing the possibility of a greater participation of national and international suppliers as is generally desirable for a market-based public policy.

Public Consultation Context

The following section highlights the process and industry comments submitted to the Ecuadorian authorities to date on the Resolution and emphasizes the benefits that a fulsome GRP process including use of sound data, science and Regulatory Impact Assessment can bring to improve draft measures prior to their publication.

It is worth noting that throughout the process to develop the regulation (the process summarized here in English and Spanish), the private sector communicated with government counterparts and provided comments related to the draft regulations for traceability of medicines, strategic goods / medical devices during 2020 but none of the main observations made by the private sector (which are available here in English and Spanish), were accepted despite ARCAS's commitment in this regard, as was made evident throughout the various government-industry interactions. To the contrary, the initiative and project "Medicines within the reach of all" was maintained by the government without sufficiently evaluating the applicability of the measure with the reality of the country, both in terms or health (medical devices and medicines), and well as economic/trade.

The proposal for a limited bar-coding for the traceability system was kept in the adopted Resolution from November 2020, introducing the obligation for the industry to incur new operational costs that are overly trade restrictive for the stated purpose and also will not address the stated regulatory challenge of the situations faced by hospitals and medical units in Ecuador. Noteworthy, during the discussions held last year, the private sector had proposed that traceability be generated by reading either of the existing one-dimensional, two-dimensional or RFID modalities as established by IMDRF and that it be done through pilot projects in medical units, accompanied by the implementation of a hospital management system and inventory control, without the need for State and private sector actors to have to invest significant sums.

Despite the technical rationale and international experiences offered such as that from the US FDA, who implemented UDI over a seven (7) year period, as per the Compliance Dates for UDI Implementation published on the FDA's website, the industry input was not taken and the implementation of the traceability system via a two-dimensional code for medical devices in twenty four (24) months after the publication of the Resolution, as stated under General Provisions of the Resolution, was approved. In the assessment of industry, this implementation timeline is unrealistic for any party to comply with. In industry's estimation, the totality of these impositions will become insurmountable and unnecessary obstacles that lead to an eventual shortage of these products in the comprehensive public health network in Ecuador, affecting the access of patients to a wide variety of medical devices and supplies, the supply of which would be diminished.

Conclusion and Recommendation

For the abovementioned rationale, the medical technology industry is of the assessment that the adopted Resolution ARCSA-DE-030_2020_MAFG is a technical regulation that will cause unnecessary and severe restrictions to the trade of medical devices once it enters into force in May 25, 2021.

We therefore respectfully request that the (country name) and Ecuadorian authorities seek to review the Resolution's compliance with the WTO/TBT agreement, its development with the spirit and letter of the GRP principles the two governments have agreed to, for the government of Ecuador to withdraw the Resolution as it applies to medical devices, and to reinitiate the regulatory process from the beginning fully employing GRP including TBT compliance.

We remain available for continued technical dialogue toward resolution of this important matter.

Thank you for your consideration.

Sincerely,

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Annex 1

Additional information on UDI structure and labeling.

GS1 is a not-for-profit organization that develops and maintains global standards for business communication. The best known of these standards is the barcode, a symbol printed on products that can be scanned electronically. The GS1 system of standards provides for accurate identification and communication of information regarding products, assets, services and locations. Businesses can also combine different GS1 standards to streamline supply chain processes such as traceability.

HIBCC - the Health Industry Business Communications Council is an industry supported and internationally accredited nonprofit standards development organization. HIBCC develops standards that meet the unique requirements of the world's healthcare providers including for Auto-ID/bar code labeling and UDI Compliance to location identifiers and electronic commerce.

ICCBBA, the international standards organization responsible for the management and development of the ISBT 128 Standard, is a Non-State actor in official relations with the World Health Organization (WHO). For more information, please view ICCBBA's press release.

UDI Implementation Reality – AIDC How to identify/mark my medical device products?

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by GS1

GLI STANDARD GS1 PER LO UDI

IL CODICE IDENTIFICATIVO E LE INFORMAZIONI DESCRITTIVE

UDI Unique Device Identification	GS1 Standards Product Identification
DI Device Identifier (DI)	GTIN Global Trade Item Number
PI Production Identifier (PI) (if applicable)	AI Application Identifier (AI) • Expiration Date AI(17) - e.g. 141120 • Lot/Batch AI(10) - e.g. 1234AB • Serial Number AI(21) - e.g. 12345XYZ
Production Identifier data will vary by medical device type and manufacturer current practice.	
DI + PI = UDI	GTIN or GTIN + AI(s) = UDI

Unique Device Identification (UDI)

Ejemplo de etiqueta

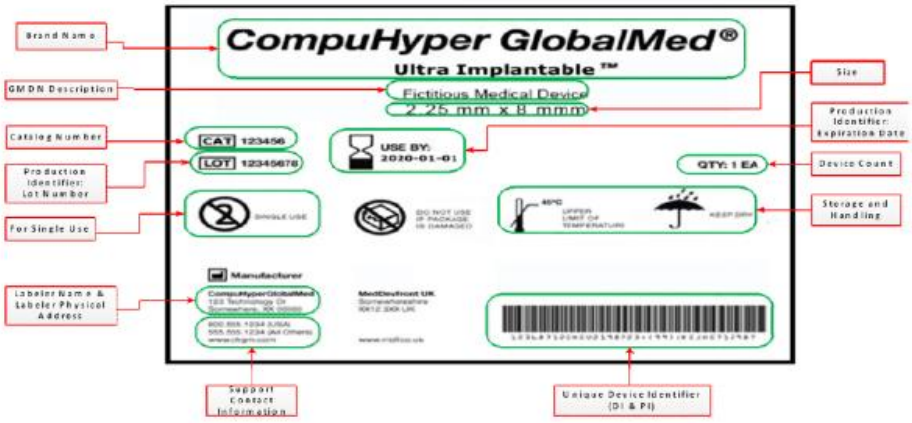

Figure 1 UDI Label. This is for illustration purposes only

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