Coalición Interamericana de Convergencia Regulatoria
SECTOR DE TECNOLOGÍA MÉDICA

Coalizão Interamericana de Convergência Regulatória
SETOR DE TECNOLOGIA MÉDICA

Inter-American Coalition for Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

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CONSIDERATIONS OF THE INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE, MEDICAL TECHNOLOGY SECTOR (IACRC) REGARDING

WTO/TBT NOTIFICATION G/TBT/N/CHL/536 OF 9 OCTOBER 2020

CHILEAN DRAFT LAW THAT MODIFIES THE SANITARY CODE (BULLETIN N ° 9.914-11) FARMACOS II NOVEMBER 2020

The Inter-American Coalition for Regulatory Convergence, Medical Technology Sector (IACRC) provides the following comments on the draft law modifying the Chilean Sanitary Code, aligned with the positioning of the Chilean Medical Device Association (ADIMECH), the Chilean Health Industry Suppliers Association (APIS).

INTRODUCTION

The current reform underway of the Chilean Sanitary Code by the Chilean National Congress (BULLETIN N ° 9.914-11 FARMACOS II, notified to the WTO/TBT as G/TBT/N/CHL/536 of 9 October, 2020) is important and has the primary objective of addressing modifications principally applicable to the pharmaceutical sector. The draft law however also seeks to establish a new regulatory framework for medical devices.

The medical technology industry has communicated with the Chilean government over the course of the development of the draft law that the medical technology sector and pharmaceutical sectors are significantly different and that proper establishment of the regulatory and ethical framework for the medical technology sector requires its own separate legislation aligned with the relevant international benchmarks for medical technology, among them the recommendations of the World Health Organization (WHO), the International Medical Device Regulators Forum (IMDRF), the Organization for Economic Co-operation and Development (OECD) and the Asia Pacific Economic Cooperation (APEC), as well as the treaty obligations of the World Trade Organization (WTO), the Pacific Alliance and also with Chile's various bilateral trade obligations including within the United States - Chile Free Trade Agreement. Annex I provides a summary of these international references.

The overarching concern identified with this draft law are that the legislative discussions within its development in the Congress have had the result of inappropriately applying pharmaceutical industry regulations that are inconsistent with the international benchmarks and regulatory requirements for the medical devices industry.

In this respect, the bill introduces administrative requirements that industry expects will impede the proper use of medical technologies in Chile, slow the process for medical technology regulatory review and approval resulting in anticipated delays for patients, create overly burdensome and unnecessarily trade-restrictive technical barriers to trade, and will require government resources for the regulatory authority (Institute of Public Health - ISP) and Ministerial Regional Secretariats of Health for the law's implementation for which this bill does not provide. Industry also anticipates that these regulatory limitations will translate into a disincentive for the incorporation of technological innovation in the Chilean health sector.

To date, the draft law has been approved by the Senate (Chamber of Origin) and the Chamber of Deputies, and it is currently being addressed by a Conference Committee, whose main objective is to reconcile the differences between the two Chambers.

PROCEDURAL NOTE

The Coalition (IACRC) expresses its appreciation to the Chilean government for having notified this draft law to the WTO Technical Barriers to Trade (TBT) Committee. This is especially the case given that the draft law is still within the legislative process, providing a side-by-side comparison of the four versions of the text under deliberation including the pre-existing legal code, Senate, House of Deputies and Committee versions. As the actual text that the Congressional Committee is discussing has since changed and may continue to change, jumping between the Senate, House of Deputies, and Committee text, the comments below pertain to both the measure text as notified as well as subsequent versions of the draft law as they are being considered.

We note also within our comments below that the overarching concern of the draft law is that its primary intent and focus is the pharmaceutical sector, but into which requirements for the medical technology sector have been introduced out of alignment with international benchmarks. One indicative consequence of this misalignment is that this this draft law was not notified to the WTO as applicable to the medical technology sector, and therefore many parties that track WTO TBT notifications for medical devices may not be aware of its existence. In fact, the description of content in the notification matches neither the scope of the draft law as it applies to the medical technology sector nor to the pharmaceutical sector.

Consistent with the intent of the requirements for WTO TBT notification providing opportunity for all parties including the regulated sector to submit comments within 60 days of notification, we respectfully request that this draft law be re-notified to the WTO TBT Committee applicable to the medical technology sector with the relevant description of content and corresponding 60-day comment period.

DESCRIPTION OF MAIN CONCERNS IDENTIFIED BY THE MEDICAL TECHNOLOGY INDUSTRY

1) Chilean definition of medical devices should be internationally aligned

Although the definition of "medical device" incorporated by the Chilean Ministry of Health in the draft law was originally in line with the WHO guidance and GHTF/IMDRF definition, the approved text in its current form adds to this international definition those devices associated with contraceptive control and the exercise of the reproductive rights of women as codified in three clauses of Chilean Law 21.030, which depart from the international definition. Annex II provides greater detail regarding the proposed definition in the draft law.

The international definition of medical devices had been widely discussed and elaborated through international cooperation with Chile's participation and is used globally and independent of national reproductive policies that vary by country.

The Coalition (IACRC) takes no position on the merit of the deviation, but simply notes that if this draft law is passed in its current form, the Chilean definition of "medical device" would deviate from the international definition, potentially creating foundational complications in the direction of medical device regulatory convergence with broader negative impacts for health sector and medical device market in Chile.

The Coalition (IACRC) recommends that: (1) for clarity, the draft law make explicit reference to the international base definition of the GHTF/IMDRF vs. only re-incorporating the current definition; and (2) that any Chile-unique measures be addressed via separate policy measure and not by a Chile-unique definition of medical device.

2) Restrictions by medical technology sector representatives inappropriate to the sector

Article 129 P of the draft law (see Annex III below) limits the interaction of "medical visitors" in public health establishments to the purchasing departments and only via pre-scheduled appointments with the express written approval of the establishment's management as determined in conformity to the provisions contained in the laws that govern the activity of lobbying in Chile.

The article also mandates the publication of visits approved by the director of the establishment in the electronic transparency portal. Additionally, this provision also applies to medical visitors that develop their activity in private health establishments (that provide for overnight patient stays), requiring them to register and publish the interaction and sharing this information to the Institute of Public Health (ISP).

It is essential to highlight that a central role of the medical device industry is to facilitate clinical advice and support of a particular technology. This highly technical support is usually carried out in surgery rooms, in diagnostic imaging centers, in laboratories, etc., through engineers or trained personnel who provide clinical or surgical aid to the medical staff of the health centers, carrying out training and

constant advice to treating physicians, nursing teams, technicians and operators, as well as administrative support, to supply medical devices in an adequate and timely manner.

In practice, the application of this legislative requirement will generate unnecessary administrative burden in public hospitals, but most importantly, it does not consider the nature of support and technical advice that defines the relationship between the providers of medical devices and the professionals of the health care centers which is different from the role of the medical representative of the pharmaceutical industry. Incorporating the medical devices representatives in this standard could seriously and negatively affect the effective operation of a medical device of how it is used, and consequently affect patients.

3) Entry into force and transitional provisions for the implementation of the regulation are insufficient for both the medical device regulatory authority as well as for the medical device industry

The draft law provision for Transitory Provisions is included in Annex IV a summary for which is provided here.

Article 1 a) requires that the regulatory authority **(Institute of Public Health – ISP)** develop and publish **within six months** the full package of implementing regulations to operationalize the law and define how the regulated sector must comply with it following the law's passage.

Article 1 b) requires that medical device manufacturers, importers and distributers register themselves with the government within six months following the law's passage (prior to the deadline for ISP to publish the corresponding regulations).

Article 1 c) requires that **companies** provide to ISP the **notification of all** of the [Class I and Class II] medical devices that they wish to provide to the Chilean market **within one month** of the publication of the regulations (i.e. seven months following the law's passage).

Article 1 d) requires that **distributers submit** to ISP the **device technical dossier application** for **all** devices that they wish to provide to the Chilean market **within six months** from the enactment of the law **(i.e. prior to the deadline for ISP to publish the applicable regulations)**.

Article 1 e) requires that **companies** provide to ISP the **device technical dossier application** for **all** of the [Class III and Class IV] medical devices that they wish to provide to the Chilean market **within one year** of the publication of the regulations (i.e. 18 months following the law's passage).

The stipulated deadlines must be linked to the regulatory authority's ability to develop and publish the technical regulations following internationally aligned good regulatory practices and the derivative requirements of the regulations. The fulfillment of these deadlines will result in a difficult burden for ISP to bear as an institution that does not have an on-line system for medical devices and only eleven (11) professionals to develop all of the technical regulations and conduct all of the activities of review,

registration and approval of medical devices as well as to conduct good manufacturing facility inspections in Chile.

The increase in regulatory authority mandate this draft law introduces would be significant for any country, even with sufficient authority capacity. However it is important to highlight that, with the exception of just five product categories[1], there are currently no medical devices registered in Chile and that this will be the first time that all medical devices will be required to be reviewed and approved by ISP.

These deadlines of the draft law in its current form are not aligned with the WHO guidance, the experience of regulatory authorities in other countries, and the experience of the global medtech industry. An overarching concern is that a timely regulatory implementation of the law seems unlikely which would introduce negative consequences such as the unavailability of products and supplies for procedures, impacting healthcare delivery quality and patient access.

Even with an immediate increase to ISP resources, sufficient time must be allotted to ISP allowing them to: hire professionals with medical technology experience, train authority staff on medical technology, implement the internal regulatory procedures and good regulatory practice protocols following the relevant international benchmarks.

The Coalition (IACRC) recommends that, barring the establishment of separate legislation specifically applicable to, and appropriate for effective regulation of the medical technology sector following international benchmarks:

1) The regulatory authority (ISP) and the private sector be provided sufficient transition time to implement the provisions of the draft law and its regulations;
    a. The transition period for Transition Article 1 a) be extended to not less than **two years following the publication of the law**;
    b. The transition period for Transition Article 1 b) be required within **six months following the publication of the applicable technical regulations**.
    c. The transition period for Transition Article 1 c) be extended to not less than **one year following the publication of the technical regulations**.
    d. The transition period for Transition Article 1 d) be extended to not less than **one year following the publication of the technical regulations**.
    e. The transition period for Transition Article 1 e) be extended to not less than **three years following the publication of the technical regulations**.

2) The regulatory authority (ISP) be provided sufficient resources to conduct the increased scope of its mandate under this bill, following international benchmarks, in particular:

[1] Needles, syringes, gloves, condoms, select diagnostics

a. Permanent increase in authority budget;
b. Hiring of professionals with medical device experience;
c. Training on medical technology regulation;
d. Implementation of an ethics compliance program and training on ethical conduct;
e. Engagement in the international medical device regulatory convergence activities:
    i. International Medical Device Regulators Forum (IMDRF);
        1. Medical Device Single Audit Program (MDSAP)
        2. Medical Device Single Review Program (MDSRP – in development)
    ii. Pan American Health Organization (PAHO);
    iii. International standardization of medical technologies (ISO, IEC, et al).
f. Implementation of OECD/APEC recommendations for foundational good regulatory practices;
g. Implementation of WHO recommendations for medical device regulatory authorities;
h. Implementation of compliance with international trade obligations regarding development of technical regulations, including the provisions of the WTO/TBT Agreement and bilateral WTO+ provisions;
i. Implementation of WHO policy of regulatory reliance, decreasing the need for Chile/ISP-specific resources.

We remain available to answer any questions regarding this contribution.

Sincerely,

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Annex I

International References for Medical Technology Regulatory Frameworks

- World Health Organization Model Regulatory Framework for Medical Devices including In Vitro Diagnostics Medical Devices
  - **Stepwise Principle**, ensuring that medical device authority mandate is commensurate with allocated resources and budget, prioritizing basic regulatory functions, and leveraging the;
  - Principle of **Regulatory Reliance**, accepting the regulatory outcomes of qualified foreign medical device authorities to economize national health resources

- International Medical Device Regulators Forum (IMDRF)
  - IMDRF documents, including;
  - The IMDRF definition of "Medical Device" in document **GHTF/SG1/N071:2012** and as referenced in **IMDRF/SAMD WG/N10final:2013**, and;
  - The IMDRF/GRRP WG/N47:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices
    - Appendix A: Use of Standards in Meeting Essential Principles

- Medical Device Single Audit Program (MDSAP)

- World Trade Organization – Technical Barriers to Trade Agreement

- OECD/APEC – Good Regulatory Practices
  - APEC-OECD Integrated Checklist on Regulatory Reform
  - OECD Best Practices Principles for Governance of Regulators
  - Supporting the TBT Agreement with Good Regulatory Practices Implementation Options for APEC Members

- APEC Principles for Codes of Ethics and Ethical Environments in the Medical Technology Sector
  - APEC Kuala Lumpur Principles for Codes of Ethics in the Medical Device Sector
  - APEC Vision 2025: Promoting Ethical Environments in the Medical Device and Biopharmaceutical Sectors
  - APEC Resource Guide: Government Strategies to Encourage Ethical Business Conduct

Annex II

Article 1 Number 9 Definition of Medical Device

Below is the Chamber of Deputies version of the text as notified (Original Spanish with English translation provided) which is the version the Congressional Committee has currently incorporated

MODIFICACIONES INTRODUCIDAS EN EL SEGUNDO TRÁMITE CONSTITUCIONAL POR LA CÁMARA DE DIPUTADOS (Column 3 – page 36 of notified pdf in Spanish)	**AMENDMENTS INTRODUCED IN THE SECOND CONSTITUTIONAL PROCEDURE BY THE CHAMBER OF DEPUTIES** (English Translation)	**Industry Comment**
Numeral 9 - Ha pasado a ser 14, modificado en el siguiente sentido: - Ha reemplazado el artículo 111 bis por el siguiente: "Artículo 111 bis.- Definición de dispositivo médico. Se entenderá por dispositivo médico cualquier instrumento, aparato, implemento, máquina, equipo, artefacto, implante, reactivo para uso in vitro, software, material u otro	Number 9 - It has become Number 14, modified in the following sense: - It has replaced article 111 bis by the following: "Article 111 bis.- Definition of medical device. A medical device shall be understood to be any instrument, apparatus, implement, machine, equipment, device, implant, reagent for in vitro use,	

artículo similar o relacionado, que cumpla con las siguientes condiciones copulativas: 1. Que no se trate de las sustancias descritas en los artículos 95 inciso primero, 102 y 106 de este Código. 2. Que no logre su acción principal en el cuerpo humano por mecanismos farmacológicos, inmunológicos o metabólicos, aunque pueda ser ayudado en su función por tales mecanismos. 3. Que su uso previsto en los seres humanos, individual o combinadamente, se refiera a uno o más de los siguientes fines: a) Diagnóstico, prevención, monitoreo, tratamiento, alivio o cura de una enfermedad. b) Diagnóstico, monitoreo, tratamiento, alivio, cura o compensación de un daño o lesión. c) Investigación, reemplazo,	software, material or other similar or related article that meets the following copulative conditions: 1. That it is not about the substances described in articles 95, first subsection, 102 and 106 of this Code. 2. That it does not achieve its main action in the human body by pharmacological, immunological, or metabolic mechanisms, although it may be helped in its function by such mechanisms. 3. That its intended use in human beings, individually or in combination, refers to one or more of the following purposes: a) Diagnosis, prevention, monitoring, treatment, relief, or cure of a disease. b) Diagnosis, monitoring, treatment, relief, cure or compensation of damage or injury.	

modificación o soporte de un proceso anatómico o fisiológico.	c) Research, replacement, modification, or support of an anatomical or physiological process.	
d) Soporte o mantenimiento de la vida.	d) Support or maintenance of life.	
e) Control de la concepción y el ejercicio de los derechos reproductivos de las mujeres consagrados en la ley N° 21.030[1].	**e) Control of the conception and exercise of the reproductive rights of women enshrined in Law No. 21.030[1].**	
f) Desinfección de dispositivo médico.	f) Disinfection of the medical device.	
g) Suministro de información para propósitos médicos o diagnósticos a través de un examen in vitro de especímenes derivados del cuerpo humano.”.	g) Provision of information for medical or diagnostic purposes through an in vitro examination of by-product specimens of the human body.”	
[1] Ley N° 21.030. Regula la Despenalización de la Interrupción Voluntaria del Embarazo en Tres Causales.	[1] Law N ° 21,030. Regulates the Decriminalization of the Voluntary Interruption of Pregnancy in Three Causes.	Deviation from international definition of **GHTF/SG1/N071:2012** As recognized by the International Medical Device Regulators Forum (IMDRF)

Annex III

Article 129 P of the Latest Committee Version of the Draft Law

Below is the Senate version of the text as notified (Original Spanish with English translation provided) which is the version the Congressional Committee has currently incorporated

TEXTO DESPACHADO EN EL PRIMER TRÁMITE CONSTITUCIONAL POR EL SENADO (Column 2 – page 36 of notified pdf in Spanish)	**TEXT DISPATCHED AT THE FIRST CONSTITUTIONAL PROCEDURE BY THE SENATE CHAMBER** (English Translation)	**Industry Comment**
"Art. 129 P: Los visitadores médicos sólo podrán desarrollar su actividad en los establecimientos públicos de salud ante el Comité de Farmacia o de Abastecimiento, en conformidad a las disposiciones contenidas en las leyes Nos 19.886 y 20.730. Los directores del establecimiento deberán adoptar las medidas para la realización transparente, no discriminatoria y periódica de esta actividad, sin afectar las atenciones de salud de los pacientes. Lo dispuesto en el inciso anterior regirá también para los visitadores de dispositivos	Article 129 P: **Medical representatives** may only carry out their activity in public **health establishments** with the **Pharmacy or Supply Committee**, in accordance with the provisions contained in **Laws No. 19.886** and **20.730.** The Directors of the establishment shall adopt the measures for the transparent, non-discriminatory, and periodic performance of this activity, without affecting the health care of patients. The provisions of the preceding paragraph shall also apply to medical sales representatives	The legislative intent of this paragraph was directed at the pharmaceutical sector by using the term "**medical visitors**". As such, this term is not defined more precisely to clarify intent of applicability to sales representatives, technicians, specialists, maintenance service providers. **Pharmacy or Supply Committee** means in this context purchasing departments – although it is not clear why this Committee would be appropriate for the medical technology sector.

médicos. Con todo, el Director del establecimiento mediante resolución fundada, podrá autorizar que la actividad de los visitadores médicos de medicamentos y dispositivos se realice ante otro funcionario, siempre que no afecte la atención de salud de los pacientes y en conformidad a las disposiciones contenidas en las leyes N°s 19.886 y 20.730	for medical devices. However, by means of a formal written authorization providing justification, the Director of the establishment, may authorize that the activity of the medical sales representatives for drug products and medical devices is carried out with other establishment staff, provided that it does not affect the health care of patients and in accordance with the provisions contained in the Laws No. 19.886 and 20.730.	**Chilean Law No. 19.886** is the Chilean Lobby Law – requiring scheduling of meetings in advance. **Chilean Law 20.730** is the Public Tendering Law.
Las disposiciones de este artículo se aplicarán también a los prestadores institucionales privados que cuenten con atención cerrada de salud, en cuyo caso la actividad de los visitadores médicos se desarrollará ante los mencionados comités o su equivalente, sin perjuicio de la facultad del director respectivo de autorizar la realización de dicha actividad ante otro integrante del equipo de salud.”	The provisions of this article will also apply to private institutional providers that have closed health care, in which case the activity of medical visitors will be limited to the aforementioned Committees or their equivalent, without prejudice to the power of the respective director to authorize carrying out this activity before another member of the health team.	The above provisions apply to all public health facilities. This provision here applies to private sector points of care that allow for overnight patient stays (“closed health care”). The regulatory burden of Article 129 P, as it applies to both the public and private sector health providers is inappropriate for the medical technology sector which is required to provide: • Highly technical support in

		surgery rooms, in diagnostic imaging centers, in laboratories, etc., through engineers or trained personnel who provide clinical or surgical aid to the medical staff of the health centers; • Training and constant advice to treating physicians, nursing teams, technicians and operators, as well as administrative support to supply medical devices in an adequate and timely manner.

Annex IV

TRANSITORY PROVISIONS

Below is the Senate version of the text as notified (Original Spanish with English translation provided) which is the version the Congressional Committee has currently incorporated

TEXTO DESPACHADO EN EL PRIMER TRÁMITE CONSTITUCIONAL POR EL SENADO (Column 2 – page 162 of notified pdf in Spanish)	**TEXT DISPATCHED AT THE FIRST CONSTITUTIONAL PROCEDURE BY THE SENATE CHAMBER** (English Translation)	**Industry Comment**
DISPOSICIONES TRANSITORIAS Artículo primero.- La presente ley entrará en vigencia a contar de la fecha de su publicación, salvo las siguientes materias:	TRANSITORY PROVISIONS Article 1.- This law will enter into force as of the date of its publication, except for the following matters:	
a) Las disposiciones contenidas en los artículos 111 al 111 novies del Código Sanitario entrarán en vigencia a contar del sexto mes posterior a la fecha de su publicación, mismo plazo en el que se dictarán los reglamentos complementarios de la misma.	**a) The provisions contained in articles 111 to 111 novies of the Sanitary Code shall enter into force as of the sixth month after the date of their publication, the same term in which the complementary regulations thereof shall be issued.**	Recommend that ISP be allotted at least **<u>two years</u> with sufficient ISP resources** to draft these regulations, following OECD/APEC/WHO good regulatory practices, WTO/TBT, using international guidance documents (IMDRF) and international standards.
b) Inscripción de los	b) Registration of the	Recommend that this be

establecimientos que fabriquen, importen y distribuyan **elementos de uso médico**, indicando listado de productos, seis meses desde la entrada en vigencia de la ley.	establishments that manufacture, import, and distribute **the elements for medical use**, indicating a list of products, six months as of the entry into force of the law.	required within **six months following the publication of the technical regulations**.
c) Notificaciones exigidas para **elementos de uso médico**, un mes desde la entrada en vigencia del respectivo reglamento.	c) Notifications required for the **elements for medical use**, one month as of the entry into force of the respective regulation.	Recommend that this be required no less than **one year following the publication of the technical regulations**.
d) Autorización sanitaria de establecimientos distribuidores de **elementos de uso médico**, debiendo ingresar las solicitudes correspondientes, antes de seis meses desde la entrada en vigencia del respectivo reglamento.	d) Sanitary authorization of establishments distributing the **elements for medical use**, having to submit the corresponding applications, within six months as of the entry into force of the respective regulation.	Recommend that this be required no less than **one year following the publication of the technical regulations**.
e) Respecto del registro de **elementos de uso médico** y autorización sanitaria de establecimientos que los fabriquen, se deberá ingresar las solicitudes respectivas dentro de los doce meses siguientes a la entrada en vigencia del respectivo reglamento.	e) Regarding the registration of the **elements for medical use** and the health authorization of the establishments that manufacture them, the respective applications shall be submitted within the twelve months following the entry into force of the respective regulations.	Recommend that this be required no less than **three years following the publication of the technical regulations**.
...	...	