April 20, 2023

CONSIDERATIONS OF THE INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE, MEDICAL TECHNOLOGY SECTOR WITH RESPECT TO THE PROPOSED CHILEAN DECREE THAT SUBJECTS "IMMUNOHEMATOLOGICAL REAGENTS" TO THE CONTROL OF MEDICAL DEVICES PROVIDED FOR IN ARTICLE 111 OF THE SANITARY CODE.

Precedents

The Chilean Ministry of Health (MINSAL) notified the World Trade Organization (G/TBT/N/CHL/624) 23 February 2023 for a public consultation of 60 days, the "Proposed Decree that submits "immunohematological reagents" to the control of medical devices provided for in Article 111 of the Health Code".

The Inter-American Coalition for Regulatory Convergence – Medical Technology Sector (IACRC) considers in its Mission the promotion of cooperation in the Western Hemisphere to achieve internationally aligned regulations, standards and requirements for conformity assessment of medical technology, within a continuous process of convergence, to maximize patient access to innovative, effective, life-saving and life-improving medical technologies.

We recognize and applaud Chile's decision to strengthen the regulatory framework for medical devices, including in vitro diagnostic reagents, as well as its decisive participation in international forums focused on regulatory convergence, such as the Global Harmonization Working Party.

In recent years, the World Health Organization has strengthened its efforts to promote the implementation of Good Regulatory Practices, including the use of international standards. Likewise, the promotion of Good Reliance Practices throughout the entire life cycle of products is intended to help countries facilitate access to health products for the care of their populations, as well as to make more efficient use of the resources of National Regulatory Agencies.

Complementarily, following the issuance of the 2017 Report on the Evaluation of Regulatory Impact Analysis conducted by the Organization for Economic Cooperation and Development (OECD) in its 2016 review of the Chilean Regulatory Policy, the Chilean government introduced the obligation to carry out regulatory impact analysis, as part of the regulatory development process. In addition to the APEC (Asia Pacific Economic Cooperation) recommendations, policy instruments are promoted and provided to facilitate the implementation of the World Trade Organization Agreement on Technical Barriers to Trade (WTO/TBT) in relation to Good Regulatory Practices.

With this background, we would like to present the following observations for your consideration, with the purpose of contributing to the objectives that Chile has set in terms of sanitary regulation, as well as to collaborate in the fulfillment of its international commitments in terms of Good Regulatory Practices.

Through the analysis of the document notified for comments, we found that several requirements related to Good Regulatory Practices do not seem to have been considered, which could risk overestimating the resources available to the regulatory authority for the Decree's implementation. The decree as proposed could also jeopardize the availability of these reagents in the country due to its implications for the regulated sector.

Among the aspects that we have identified as necessary to consider, and which are critical to the regulatory decision making, are the following:

- **Ex ante evaluation.** This step is required to analyze various options to guarantee the quality, safety and performance of these products, among which non-regulation, reliance or direct recognition of approvals by other reference regulatory authorities for the commercialization of this type of diagnostic reagents would be considered.
    - Regulatory impact analysis that considers feasibility (resources, infrastructure, etc.) and cost for the regulatory authority, as well as for the regulated sector, including the timeframe for implementation.

- **Open public consultation** at the local level and **regulatory authority response to comments**. The process to develop the proposed Decree included a call to some of the interested parties under the scheme of working groups in which several proposals were presented but not considered and without provision of rationale for doing so. The process to develop the measure did not include a local public consultation which would allow the exhaustive participation of the interested and affected parties and therefore, the possibility of having their comments considered was not provided.

These omissions, in addition to various technical aspects discussed in the body of this document, if not adequately resolved, will generate potential technical barriers to trade with negative implications for the availability of these diagnostic reagents in Chilean territory. The regulatory process utilized here also does not comport with Chile's support of the APEC Regulatory Reform agenda, Chile's commitments as a member of the OECD, Chile's support of the Summit of the Americas Declaration on Good Regulatory Practices, and Chile's various trade commitments, among them, the WTO TBT Agreement, the U.S.-Chile FTA and the CPTPP.

Positioning

The Inter-American Coalition for Regulatory Convergence – Medical Technology Sector (IACRC) respectfully requests that the Chilean government consider revising the draft Decree with a view to applying good regulatory practices:

- contemplating the use of international standards and references as its basis
- avoiding the implementation of duplicate requirements and promoting reliance practices
- conducting a full regulatory impact analysis that considers both the impacts for the regulator and the regulated sector, considering adequate transition periods, applicable to Chile, amongst other considerations.

This may allow the development of a regulation that meets the needs of the Chilean population, in the best technical and economic conditions.

Regarding the requirements established in the proposed decree and without prejudice to the request for the reinstatement of the process in its entirety, we propose the following modifications:

Original Text	Proposal and Rationale
ARTICLE THREE: [...] Additionally, the devices mentioned in article one shall be subject to an evaluation by the Institute of Public Health, referring to the performance of the products in terms of sensitivity and specificity".	Based on the Agreement on Technical Barriers to Trade, Article 6: Recognition of Conformity Assessment by Central Government Bodies, Section 6.1 *" Without prejudice to the provisions of paragraphs 3 and 4, Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures. [...]"*, as well as in Sub-Sections 6.1.1 *" adequate and enduring technical competence of the relevant conformity assessment bodies in the exporting Member, so that confidence in the continued reliability of their conformity assessment results can exist; in this regard, verified compliance, for instance through accreditation, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence;"* and 6. 1.2 *" limitation of the acceptance of conformity assessment results to those produced by designated bodies in the exporting Member."*, is requested to be amended to read as follows: *ARTICLE THREE: [...] Additionally, the devices mentioned in article one, which do not have a Conformity Assessment performed by an* Accredited *International Institution, shall be subject to an evaluation by the Institute of Public Health, referring to the performance of the products in terms of sensitivity and specificity.*

ARTICLE FIVE: Verification of conformity shall be carried out in accordance with Title IV of Decree No. 825, of 1998, of the Ministry of Health.	The Decree omits in the numbering of the articles the following ARTICLE FOUR, therefore, it is proposed to correct the numerical sequence, so that the current ARTICLE FIVE becomes ARTICLE FOUR and so on. Based on the same grounds included in the proposal for ARTICLE THREE, it is proposed: *ARTICLE FOUR: Verification of conformity shall be carried out in accordance with Title IV of Decree No. 825, of 1998, of the Ministry of Health, in cases where the devices do not have a Conformity Assessment carried out by an Accredited International Institution.*
ARTICLE SIX: The certificate of verification of conformity shall be granted by an entity authorized by the Institute of Public Health or, in its absence, by the Institute itself.	On the same basis as in the two previous cases, it is proposed: *ARTICLE FIVE: The certificate of verification of conformity shall be granted by an entity authorized by the Institute of Public Health or, in the absence thereof, from the same Institute, in cases where the device does not have the result of Conformity Assessment issued by an Accredited International Institution.*
TRANSITORY ARTICLE	Considering that there is no analysis of the existing capacities of the various entities impacted by the entry into force of this technical regulation, such as the Institute of Public Health, customs, the Regional Ministerial Health Secretariats, etc., it is proposed to review the deadlines required by each of them, as part of the Regulatory Impact Analysis referred to in previous paragraphs, in order to establish the appropriate one for the correct implementation of the regulation. Regarding the deadlines for conducting the Evaluation Process for the various types of diagnostic reagents, in addition to the above considerations regarding its applicability only for products that do not have a Conformity Assessment result issued by an Accredited International Institution, it is proposed to review the deadlines considering the analysis of the capabilities,

	according to the necessary Regulatory Impact Analysis, referred to in previous paragraphs.

We appreciate the opportunity to contribute with our comments to this process, reiterating our availability and commitment to work in coordination with all interested parties, for the review of these proposals, with the purpose of improving the effectiveness of the Decree, as well as the alignment of Chile with the applicable international references.