12th Meeting (Hybrid)

Working Group: Open Consultation

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

OPEN CONSULTATION

Industry active participation

One standard, one test, accepted everywhere for any medical technology scope

– EXECUTIVE COMMITTEE

Importance of Industry Shaping of Regulations

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Open Consultation WG

Main Objective: provide support to stakeholders on how to gain visibility and/or address Open Consultations, seeking harmonization with international standards and following GRP.

Sources of information - available - updated – filtered - relevant

Quality Feedback for Quality discussions with Regulators

Avoid Company biases - Law hierachies - GRP

Scope: different scenarios are to be addressed

Different scenarios in different countries : Subsidiary / distributor/ consultant / Trade Association

ROADMAP

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Initial discussions
Meetings Scheduled

El Salvador
October - 12th 2023

Execution Phase
Discussion & Survey Drafting

Scope Definition
Terminology Alignment
Brainstorming
Survey Preparation

Washington
March 13th

Deliverable 1
Survey to Trade Associations

MAY 2024 Survey
Compilation & Analysis

Screening of current landscape in the region

Meeting
Nov 14th

Deliverable 2
Toolkit –
Preparation
Raise Awareness

Support of RA peers
Promote industry involvement in Public Consultations

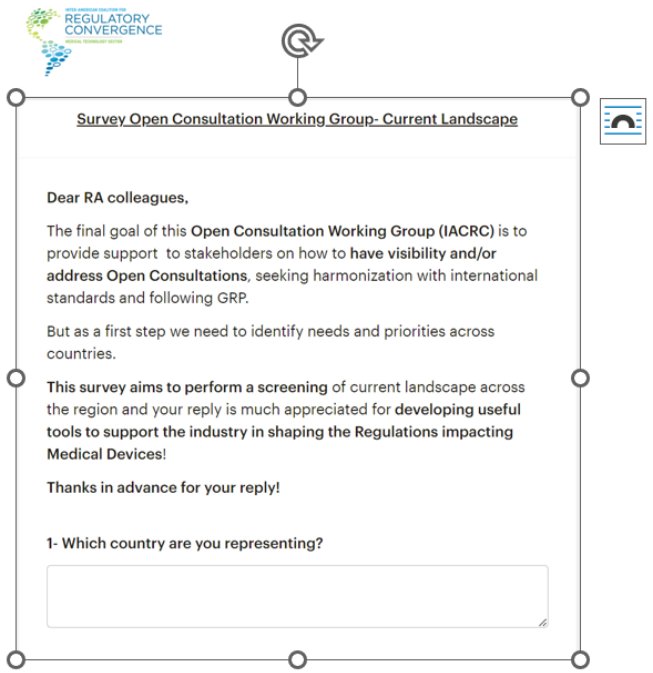
May 2024

Open Consultation WG Survey

Survey Goal: screening of current landscape across the region

Addressed Topics:

- **Familiar with OC?**
- **Visibility-Sources?**
- **Usual Participation**
- **OC Period**
- **OC Transparency**
- **Method to publicize**
- **Method to gain visibility**
- **HA responsiveness to feedback**



Survey Open Consultation Working Group- Current Landscape

Dear RA colleagues,

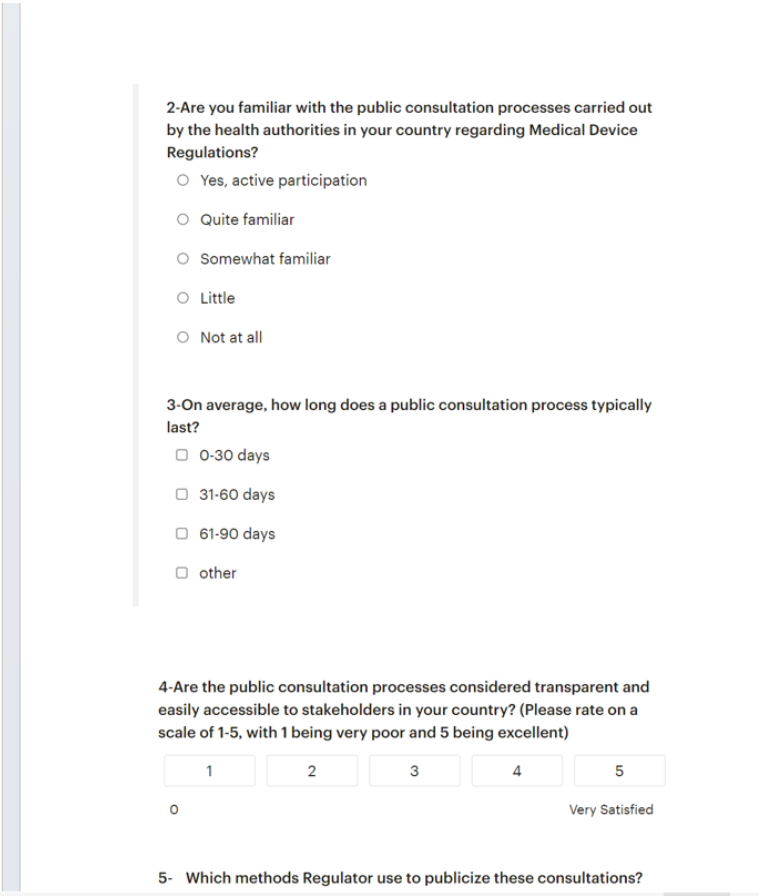
The final goal of this **Open Consultation Working Group (IACRC)** is to provide support to stakeholders on how to **have visibility and/or address Open Consultations**, seeking harmonization with international standards and following GRP.

But as a first step we need to identify needs and priorities across countries.

This survey aims to perform a screening of current landscape across the region and your reply is much appreciated for **developing useful tools to support the industry in shaping the Regulations impacting Medical Devices**!

Thanks in advance for your reply!

1- Which country are you representing?



2-Are you familiar with the public consultation processes carried out by the health authorities in your country regarding Medical Device Regulations?

- Yes, active participation
- Quite familiar
- Somewhat familiar
- Little
- Not at all

3-On average, how long does a public consultation process typically last?

- 0-30 days
- 31-60 days
- 61-90 days
- other

4-Are the public consultation processes considered transparent and easily accessible to stakeholders in your country? (Please rate on a scale of 1-5, with 1 being very poor and 5 being excellent)

1	2	3	4	5

0 Very Satisfied

5- Which methods Regulator use to publicize these consultations?

Open Consultation WG Survey

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Información general sobre respuestas

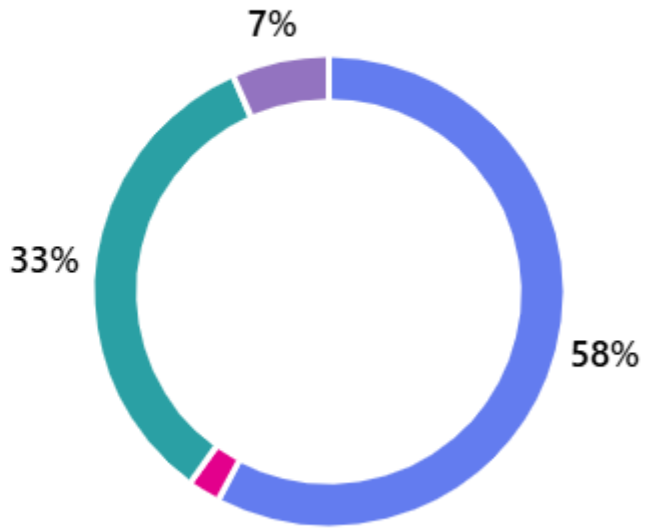
Activo

Respuestas	Tiempo promedio	Duración
45	03:32	138 Días

Open Consultation WG
Survey- OC Industry Participation

3. Do you usually participate/contribute to address draft regulations in:

Domestic Open Consultations	26
International Open Consultations	1
Domestic and International Open Consultations	15
No	3



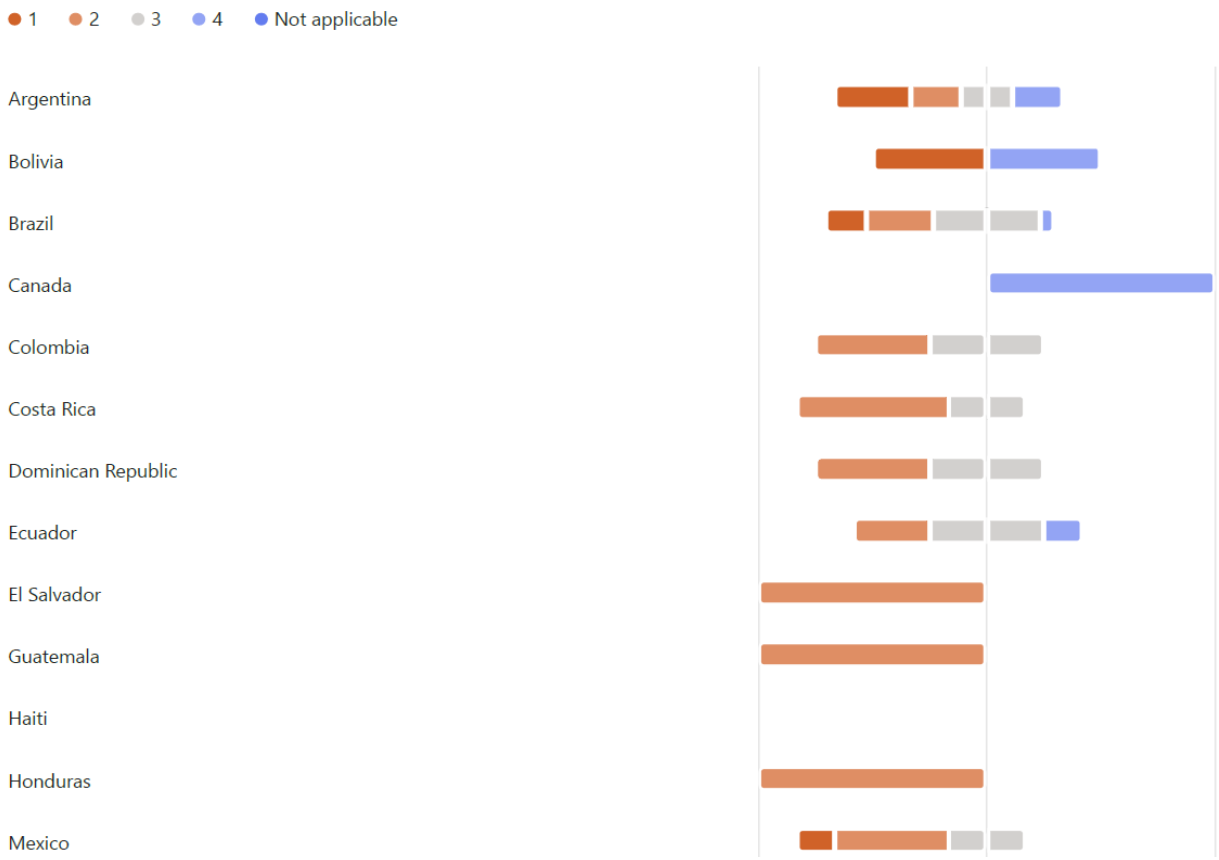
Open Consultation WG
Survey- Results- Visibility

Regulator Publication

Industry Visibility

Open Consultation WG
Survey- HA Responsiveness

12. Are the health authorities responsive to the feedback received during the public consultation processes? (Please rate on a scale of 1-4, with 1 being very low and 4 being very high)



Nov 2024

Open Consultation WG Toolkit

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

BECOME AWARE

Active/ Passive search: Subscribe to email alerts from e-ping, search national portals.
See instructions for e-Ping subscription & list of portals per country. ATTACHMENT 1.

DRAFT INITIAL ASSESSMENT

a. Is the issuing country signatory to Good Regulatory Practices agreements? Is the draft notified via e-ping?
b. Is the deadline for commenting aligned with GRP? If not, ask for an extension.
c. Is there an overlap with other domestic regulations?
d. Is there an overlap with other international regulations?
e. Is the regulation necessary ?
f. Is reliance or recognition possible?
g. Is it possible to implement?
h. What's the cost of implementing? *See impact assessment & include relevant stakeholders*
i. What is the benefit of implementing?
j. Is an impact assessment from the Health Authority available? *See HA obligations-Refer Literature ATTACHMENT 2-*
k. Is the implementation timeline feasible?
l. Map stakeholders to participate in the assessment & include their perspective.
m. Recognize or create an effective communication channel with the authorities to guarantee engagement in future discussions.
n. Set a follow-up strategy after comments submission

PREPARE COMMENTS

a. Always refer comments/suggestions to internatio|nal or domestic regulation.
b. Structure your comments clearly and objectively, highlighting the most relevant points. ATTACHMENT 3
c. Prioritize the mitigation of risks, effects, and negative impacts identified.
d. Seek alignment with international standards and practices in the same or similar sectors.
e. List the positive and negative impacts perceived with the draft in the Public Consultation and summarize the proposed contributions to minimize negative impacts and highlight the positive impacts expected by incorporating the proposed contributions into the regulation.

After the contribution proposal is finalized, review the initial assessment.

SUBMIT & FOLLOW-UP

-Ensure compliance with the contribution format determined by the HA promoting the Public Consultation and adherence to the deadline set by the HA and accepted submission channels by the HA.
- Seek HA PoC to discuss feedback on OC.
- Grant feedback is processed and replied by HA

FOLLOWING UP POST-PUBLIC CONSULTATION
Follow up with the regulatory body and explore all available social and sectoral participation options to emphasize the contributions and their importance to society or the sector.

MONITOR THE ADHERENCE TO GRP

Toolkit Attachments

	Supporting STAGE	ATTACHMENT
Attachment 1	Step 1- BECOME AWARE	e-Ping Subscription Tutorial & List of Regulators´ webpages (links) by country
Attachment 2	Step 2 - DRAFT INITIAL ASSESSMENT	Reference background Literature on Good Regulatory Practices OC to refer /consult.
Attachment 3	Step 3 - PREPARE COMMENTS	AdvaMed Table Format example & Directions on how to complete this Table to submit comments to Regulators.

Annex I.a - List of Regulators´ webpages & Links to Open Consultation publication sites

https://www.interamericancoalition-medtech.org/regulatory-convergence/quick-links/medical-device-regulatory-authorities/

Country	Regulator	Webpage
ARG	ANMAT	https://opinionpublica.anmat.gob.ar/Home
MEX	MEXICO	https://www.cofemersimir.gob.mx
BRA	BRAZIL	Consultas Públicas – Anvisa https://antigo.anvisa.gov.br/consultas-publicas#/
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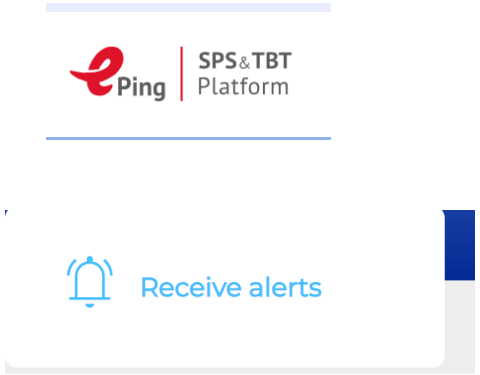
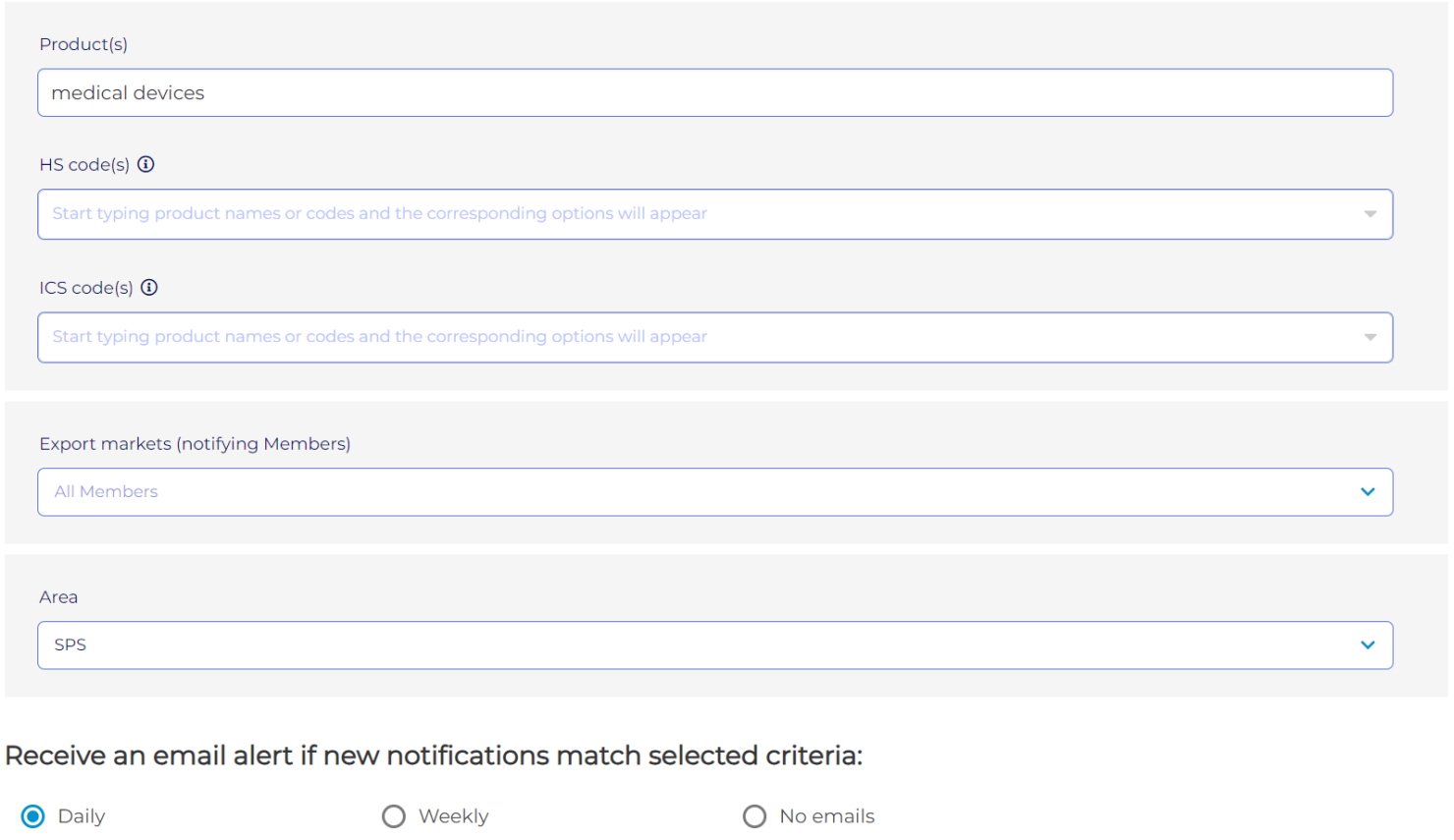
Annex I- b - Tutorial e-ping Subscription

1- Create an Account: https://epingalert.org/en/Account/Registration

2. Select products and markets of interest to receive alerts





Annex II – Reference Literature – GRP on Open Consultations

High Level Checklist to follow in each Phase

Phases

- **Prior to start / During planning process**
- **During the regulatory process**
- **After the regulatory process**

Annex II – Reference Literature – GRP on Open Consultations

Practical Checklist item by item

GOOD REGULATORY PRACTICES CHECKLIST TECHNICAL REGULATIONS Section I. Prior to the start of the regulatory process / During the planning process											
DISCIPLINE TYPE	**OBLIGATION**	**LEGAL GROUND**						**WAS IT FULFILLED?**		
		USMCA Chapters 11, 28	**CPTPP Chapters 8 y 25**	**PA Chapters 7, 15 *BIS***	**TBT Agreement**	**LGMR**	**LIC**	**Yes**	**No**	**N/A**
1. Technical Regulations - National Treatment	1.1 Does the proposed technical regulation establish the characteristics of a product or the processes and production methods related to them, including the applicable administrative provisions?	11.1	8.1.1	7.3	Annex 1, paragraph 1	N/A	4 subsection XVI			
	1.2 Does the proposed technical regulation establish terminology, symbols, packaging, marking or labeling requirements applicable to a product, process, or production method, or does it deal exclusively with them?	11.1	8.1.1	7.3	Annex 1, paragraph 1	N/A	4 subsection XVI			
	1.3 Is the instrument referred to in questions 1.1 or 1.2 mandatory?	11.1	8.1.1	7.3	Annex 1, paragraph 1	N/A	4 subsection XVI			
	1.4 Did COFEPRIS ensure that the technical regulation provides imported products from any of Mexico's trading partners no less favorable treatment than that accorded to similar products of national origin?	11.3.1.a	8.4.1	7.3	2.1	8, subsection III	12 (fourth paragraph)			
	1.5 In the technical regulations that have as scope the prescription of the products, did COFEPRIS define such products based on the properties of use and application of the products?	N/A	N/A	7.3	2.8	N/A	12 (fifth paragraph)			
	1.6 In the technical regulations that have as scope the prescription of products, did COFEPRIS avoid defining products based on their design or descriptive characteristics?	N/A	N/A	7.3	2.8	N/A	12 (fifth paragraph)			
2 **Technical Regulations - Preparation**	2.1 Did COFEPRIS carry out an adequate assessment of the technical regulation, including a regulatory impact analysis of the potential impacts of the technical regulation?	11.5.1.a	N/A	N/A	N/A	2 subsection XV; 71	34 subsection X			
	2.2 Did COFEPRIS carry out an evaluation of alternative measures that could be applied instead of the technical regulation?	11.5.1.b	N/A	N/A	2.2	69 subsection II	32 subsection I			

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Annex III – Formatting & Directions How to Submit Comments to HA

- Then assess item by item, each sentence in the Regulation following this table format below.

Instructions:

- ✓ Strikethrough the text to be deleted and in ~~red color~~
- ✓ Underline the new text to be added and in blue color
- ✓ Provide rationale for this change indicating GRP- Regulation to be aligned with - etc

Particular Comments

Statement/Dice	Should be replaced by/Debe decir	Rationale / Justificación
Articulo 1. El presente Acuerdo tiene por objeto establecer las disposiciones que debe observar la Comisión Federal para la Protección contra Riesgos Sanitarios para utilizar y reconocer las decisiones de otras Autoridades Reguladoras de Referencia y del Programa de Precalificación de Medicamentos de la Organización Mundial de la Salud para el registro sanitario y el ciclo de vida de los insumos para la salud.	**Articulo 1.** El presente Acuerdo tiene por objeto establecer las disposiciones que debe observar la Comisión Federal para la Protección contra Riesgos Sanitarios para utilizar y reconocer las decisiones de otras Autoridades Reguladoras de Referencia y del Programa de Precalificación de Medicamentos, de Dispositivos Médicos y de Reactivos de Diagnóstico in *vitro*, de la Organización Mundial de la Salud para el registro sanitario y el ciclo de vida de los insumos para la salud.	Se propone agregar el Programa de Precalificación de la OMS para Dispositivos Médicos y Reactivos de Diagnóstico *in vitro*.

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE MEDICAL TECHNOLOGY SECTOR

THANK YOU

MAGDALENA FERRARI DEL SEL

RA LEAD - POLICY SPECIALIST

JOHNSON & JOHNSON MEDTECH

mferrar8@its.jnj.com

ROBERTA MELE MAZZA

CADIEM ROCHE DIAGNOSTICS

SANDRA LIGIA GONZÁLEZ

Executive Secretary

LETICIA FONSECA

Executive Sub-Secretary

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