# Open Consultations Working Group


Date

# Open Consultations WG Importance of Industry Participation

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

# Open Consultation WG

## Importance of Industry Shaping of Regulations

**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

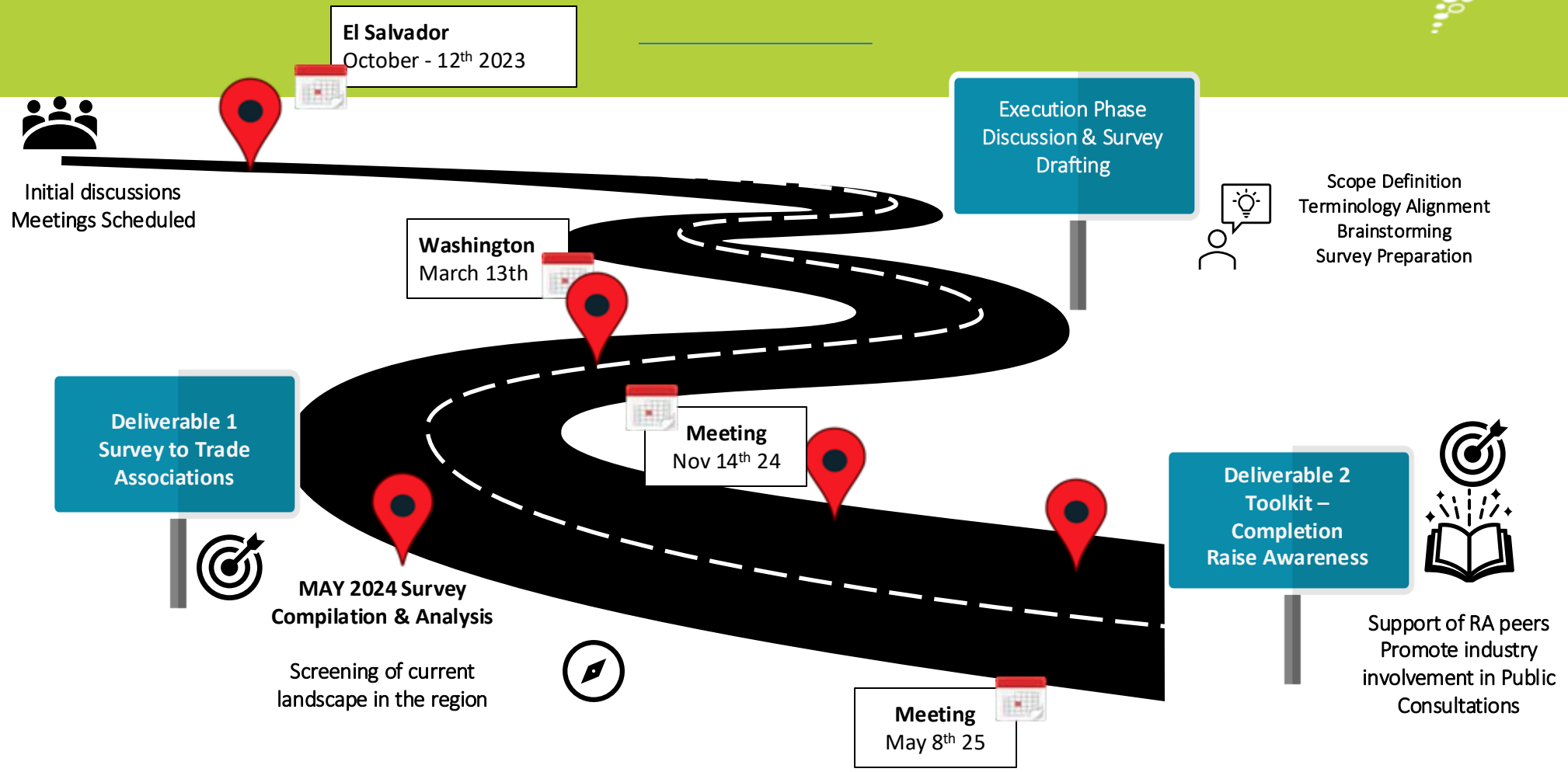
**Quality Feedback for Quality discussions with Regulators**

Avoid Company biases - Law hierachies - GRP

**Scope**: different scenarios are to be addressed

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

# ROADMAP


El Salvador
October - 12th 2023
Initial discussions
Meetings Scheduled
Washington
March 13th
Meeting
Nov 14th 24
Meeting
May 8th 25
Execution Phase
Discussion & Survey
Drafting
Scope Definition
Terminology Alignment
Brainstorming
Survey Preparation
Deliverable 1
Survey to Trade
Associations
MAY 2024 Survey
Compilation & Analysis
Screening of current
landscape in the region
Deliverable 2
Toolkit –
Completion
Raise Awareness
Support of RA peers
Promote industry
involvement in Public
Consultations

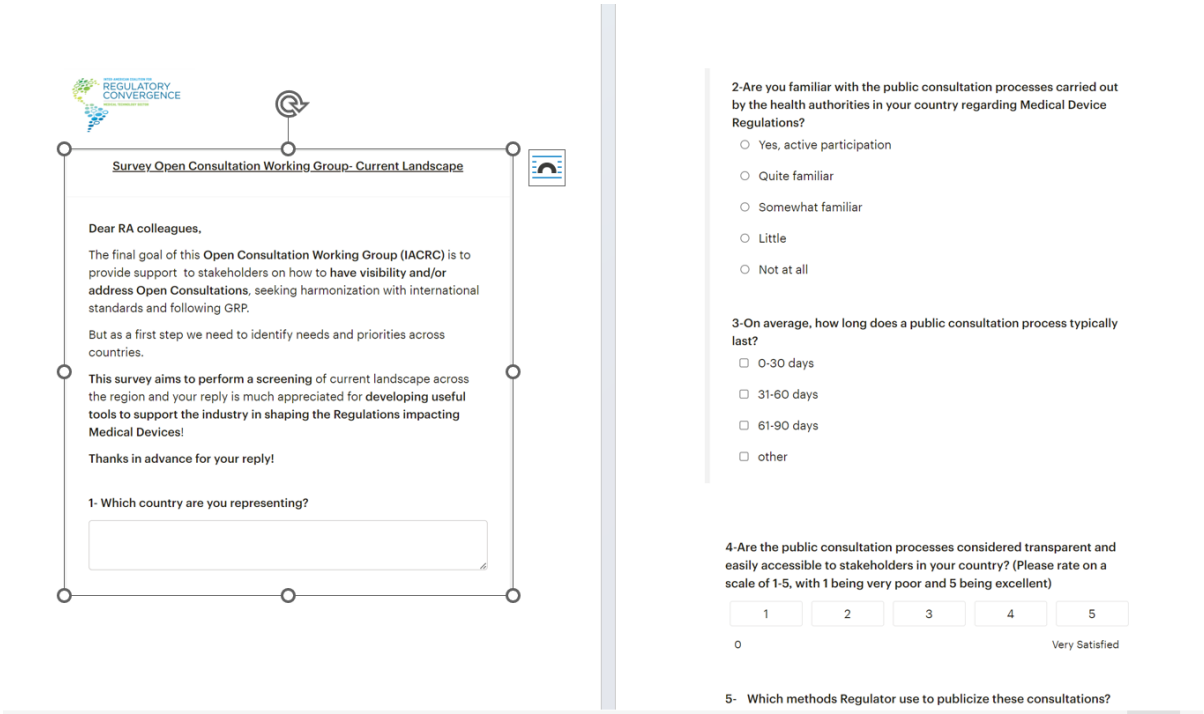

# Open Consultation WG

## 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?

Nov 2024

# Open Consultation WG

# **Toolkit**

## 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

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

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

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

| 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#/ |
| **USA** | FDA | https://www.regulations.gov/ |
| **PERU** | DIGEMID | https://www.digemid.minsa.gob.pe/webDigemid/publicaciones/normas-legales/ |
| **ECUADOR** | ARCSA | https://www.controlsanitario.gob.ec/matriz-de-proyectos-de-normativa-consulta-publica/ |
| **CANADA** | Health Canada | https://www.canada.ca/en/treasury-board-secretariat/corporate/transparency/acts-regulations.html |
| **COLOMBIA** | INVIMA | https://www.minsalud.gov.co/Normativa/Paginas/Proyectos-de-actos-administrativos.aspx |
| **Rep Dominicana** | DIGEMAPS | https://digemaps.gob.do/transparencia/consulta-publica/procesos-de-consultas-abiertas/ |

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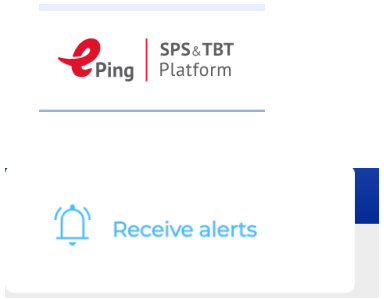
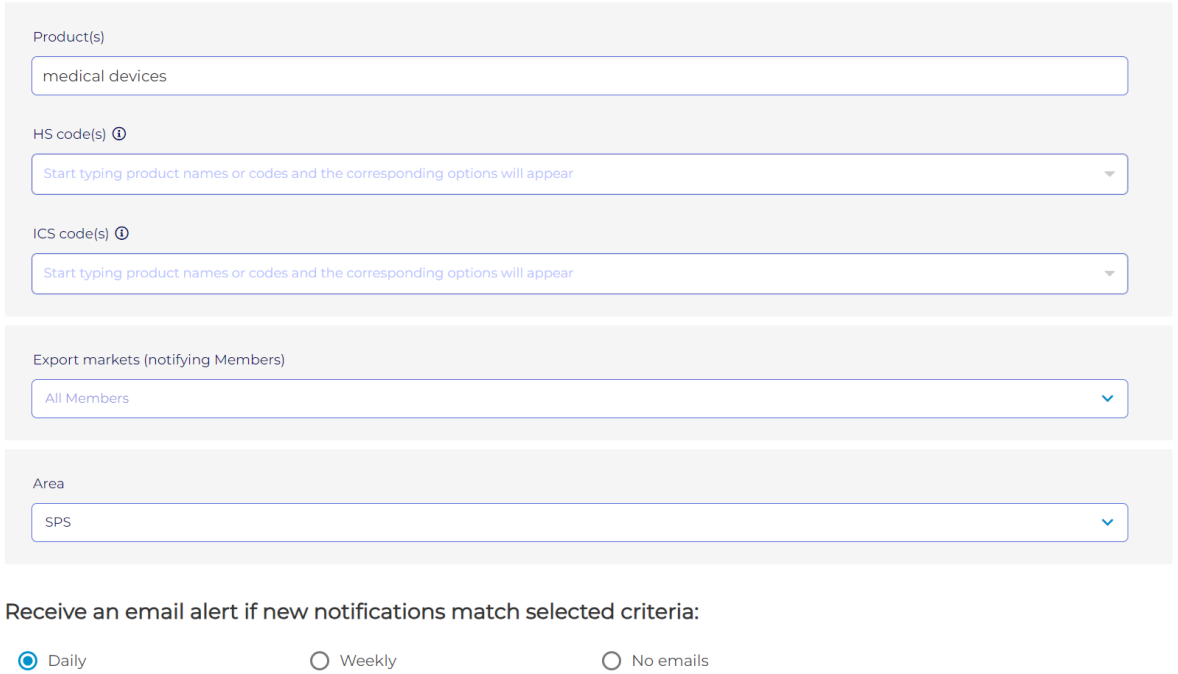
# Annex I- b - Tutorial e-ping Subscription

**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 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 |
|---|---|---|
| **IV. Autoridad Reguladora referencia (ARR):** Autoridad nacional o regional, o una institución confiable, como la precalificación de la OMS, a cuyas decisiones regulatorias o resultados de su labor regulatoria recurren otras autoridades con el objeto de fundamentar sus propias decisiones en materia de regulación; | IV. **Autoridad ~~Reguladora~~ regulatoria de referencia (ARR)**. Es una autoridad nacional o regional o una institución confiable como la precalificación de la OMS, a cuyas decisiones regulatorias o resultados de su labor regulatoria recurren otras autoridades regulatorias con el objetivo de fundamentar sus propias decisiones en materia de regulación. Para el caso de dispositivos médicos, se considera a las autoridades miembro del "Management Committee" del Foro Internacional de Reguladores de Dispositivos Médicos (IMDRF por sus siglas en inglés). | Alinear con la definición incluida en "Organización Panamericana de la Salud. Anexo 10. Buenas prácticas de utilización de decisiones regulatorias de otras jurisdicciones en la regulación de productos médicos: principios y consideraciones de alto nivel (55.º informe del Comité de Expertos de la OMS en Especificaciones para las Preparaciones Farmacéuticas). Washington, DC: OPS; 2022. Disponible en: https://doi.org/10.37774/9789275326763."<br><br>Para el caso de Dispositivos Médicos, se propone adicionar a las autoridadess regulatorias que forman parte del "Management Committee" de IMDRF, dado que este tipo de productos no están cubiertos en los criterios establecidos para las SRA. |

# THANK YOU

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