Action Plan 2026 – 2030

Upon a thorough review of priority areas common to the Coalition's Principal Members, agreement was reached to include the following ones to focus our resources towards their advancement via maintaining or creating *ad hoc* working groups:

Transverse Topics
Strengthening of Good Regulatory Practices including Regulatory Impact Assessment - capacity building
Global Public Consultations – World Trade Organization (Technical Barriers to Trade Notifications): ePing System
Public Consultations - effective participation
Utilization of International Standards: participation in local committees at National Standards Bodies
Medical Device Single Audit Program (MDSAP) - acceptance and affiliation
Reliance: regulatory frameworks, implementation and capacity building
Certificate to Foreign Government (CFG)/Free Sales Certificate (FSC) & apostille – electronic versions and alternate options
Electronic Instructions for Use (eIFU) – regulatory framework to broaden utilization
Country of Origin – differentiation among custom and regulatory purposes
Technical Topics - capacity building
National Regulatory Authorities Performance Metrics - transparency
Digital Health: SaMD, Artificial Intelligence, Machine Learning – regulatory frameworks

Country specific topics to be supported by the Coalition were also agreed upon:

Argentina
Implementation of New Regulatory Frmework - Reliance

Brazil

Non-sterile implants
Technical Service for Medical Equipment
Conformity Assessment - INMETRO: retesting, recertification, labeling
Lease of eltrical-medical equipment (establishments'operation license)
Regulation for Oxigen Generators as Medical Devices to be used at health facilities as per RDC 751/2022

Canada
Implementation of Reliance
UDI
MDSAP - Add Manufacturers

Chile
New Law + Regulatory Framework
Post-market Surveillance

Colombia
Apostille requirements
Update Regulatory Framework for MDs & IVDs
Regulatory Framework for Reliance
Regulation of Good Manufacturing Practices

Ecuador
Counterfeit & Smuggling
Post-control vigilance & PAHO's Regulatory Agency Assessment Guidelines

Mexico
COFEPRIS Backlog
USMCA Revision
Labeling
Guidelines for Submission under new Abridged Processes

Peru
Accesorioes Regulation
Sample Retains
Technical Documents - Handwriten signatures + 2 Years validity
Local labeling
Sanitary licenses issued for Legal manufacturer
Documents translation to Spanish
Risk Class I - notification
Contact lenses publicity

United States of America
Medical Device User Fee Ammendments 2028 (MDUFA VI)