A *reliance* journey by COFEPRIS

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Equivalence Agreements

2010

Framework Agreement for the Recognition of Regulatory Equivalence

2010

FDA–Health Canada Equivalence Agreement for Medical Devices and its amendment

2012

Japan Equivalence Agreement

2019

Amendment to the Framework Agreement on Equivalence

2020–2021

Agreement on the Recognition of Equivalence for Health Supplies and Its Amendment

2024

Adjustments to the import scheme and regulatory recognition

2025

New Agreement on Equivalence for Health Supplies

Framework Agreement for the Recognition of Regulatory Equivalence*

Establishes general provisions for recognizing that the **requirements, tests, evaluation procedures, and other controls** carried out by foreign health authorities are equivalent to those required by Mexican law

Published in the Official Gazette of the Federation on September 3, 2010

- Creates the legal concept of equivalence agreements.

- Establishes that recognition must be formalized through specific agreements published in the Official Gazette.

- Requires proof of equivalence in quality, safety, and effectiveness.
- Maintains COFEPRIS's authority to issue resolutions.

Significance

- First successful regulatory equivalence framework implemented by COFEPRIS.
- Sets a precedent for future agreements.

FDA–Health Canada Equivalence Agreement*

Published in the Official Gazette of the Federation on **October 26, 2010**

Recognizes as equivalent the requirements set forth in sections 179 and 180 of the RIS and the evaluation procedures conducted by the FDA and Health Canada.

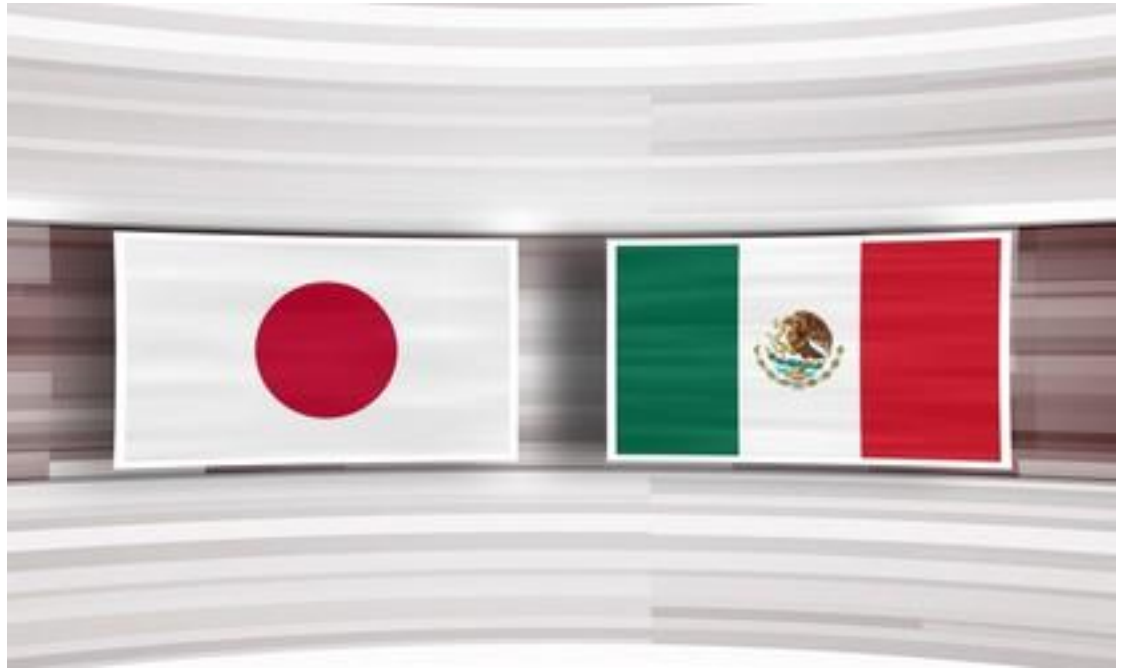
- First specific agreement issued under the Framework Agreement.
- Introduces expedited procedures for obtaining marketing authorizations.
- Allows the use of foreign regulatory authorizations as technical support.
- Reduces evaluation times by COFEPRIS.

Significance

- This represents the first formal regulatory equivalence framework for medical devices in Mexico.
- A precedent for future agreements.

Japan Equivalence Agreement*

Published in the Official Gazette of the Federation (DOF) on **January 25, 2012**



Recognizes as equivalent the regulatory requirements and evaluation procedures carried out by Japanese health authorities for marketing of medical devices.

- First equivalence agreement with an Asian regulatory authority.
- Recognizes regulatory evaluations issued by MHLW and PMDA.

- Applies primarily to moderate- and high-risk devices.
- Complements the FDA–Health Canada framework.

Amendment to the Framework Agreement *

Published in the Official Gazette of the Federation on **March 28, 2019**

Amends the 2010 Framework Agreement to incorporate regulatory recognition mechanisms based on international organizations, particularly WHO.

- It expressly incorporates WHO Prequalification Program.
- Expands the concept of regulatory equivalence.
- Allows for the recognition of assessments conducted by multilateral organizations.
- Modernizes the legal framework for equivalence.

Significance

It marks the transition from a model based exclusively on national regulatory agencies to one that incorporates international organizations.

Equivalence Agreement for Health Supplies*

Publication
DOF: January 28, 2020

Recognizes various requirements established at RIS and the evaluation procedures carried out by international reference regulatory authorities as equivalent.

Recognized authorities: FDA, Health Canada, EMA/European Commission, Swissmedic, TGA Australia, PAHO/WHO National Reference Regulatory Authorities, WHO Prequalification Program, and PIC/S member authorities.

Includes a section on **the import of drugs and medical supplies, whether or not they are registered in Mexico.**

Amendment
DOF: June 22, 2021

- Expands the operational scope of the agreement.
- Strengthens the recognition of foreign regulatory decisions.

- Simplifies documentation requirements.
- Consolidates the use of international standards.
- Reinforces the concept of reliance.

Significance

- It serves as a bridge between traditional equivalence agreements and the modern model of regulatory reliance.

Change to the import scheme without a sanitary registration*

PUBLISHED IN THE OFFICIAL GAZETTE OF THE FEDERATION ON SEPTEMBER 19, 2024

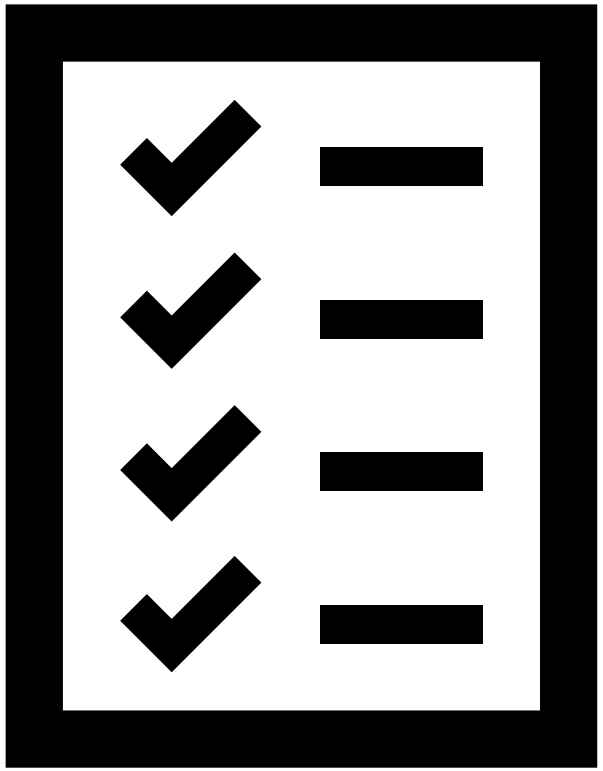
Purpose

To amend the extraordinary provisions related to the importation of drugs and medical devices without sanitary registration.

- Eliminates various extraordinary mechanisms implemented in previous years (import without sanitary registration).
- Reorganizes import requirements.
- Increases legal certainty.
- Maintains the historic FDA–Health Canada and Japan agreements in force.

Significance

Prepares the transition to the new model of equivalence and regulatory reliance in 2025.



New Equivalence Agreement for Health Supplies *

Published in the Official Gazette of the Federation on **June 11, 2025**

Purpose

Recognizes as equivalent various regulatory requirements and evaluation procedures carried out by reference regulatory authorities for drugs and medical devices.

Recognition of international bodies and schemes

- IMDRF member authorities.
- Medical Device Single Audit Program (MDSAP).
- ISO 13485 certifications.
- CE certificates issued by notified bodies.
- Documents issued by reference regulatory authorities.

Key changes

- Significantly expands the sources of accepted regulatory evidence.
- Reduces duplication of evaluation.
- Facilitates access to innovative medical technologies.
- Consolidates the regulatory reliance model.

Repeals the previous regulatory recognition mechanisms contained in the 2020 and 2021 agreements, as well as the 2019 agreement

This represents the most significant change in regulatory recognition since the creation of the equivalence system in 2010.

General Guidelines for the Application of the Expedited Regulatory Process *

Published in the Official Gazette of the Federation on July 18, 2025

Establishes the rules for granting health registrations through the **expedited regulatory pathway**, recognizing requirements, tests, and evaluations conducted by reference regulatory authorities and by the WHO Prequalification Program.

Key changes

- Establishes uniform rules for the application of the expedited pathway.
- Defines documentation requirements and eligibility criteria.
- Strengthens the use of reliance and avoids regulatory duplication.
- Allows for the use of evaluations conducted by reference regulatory authorities.
- Optimizes review times.

Repeals the Agreement published on **June 11, 2025**.

- Complements the historical equivalence framework for medical devices.
- Increases legal certainty and predictability for the industry.
- Represents COFEPRIS's transition from a regulatory equivalence framework to a comprehensive **reliance** model

A Reliance Journey by COFEPRIS - Part I (Prior to 2025)

Case Studies Practical Experience

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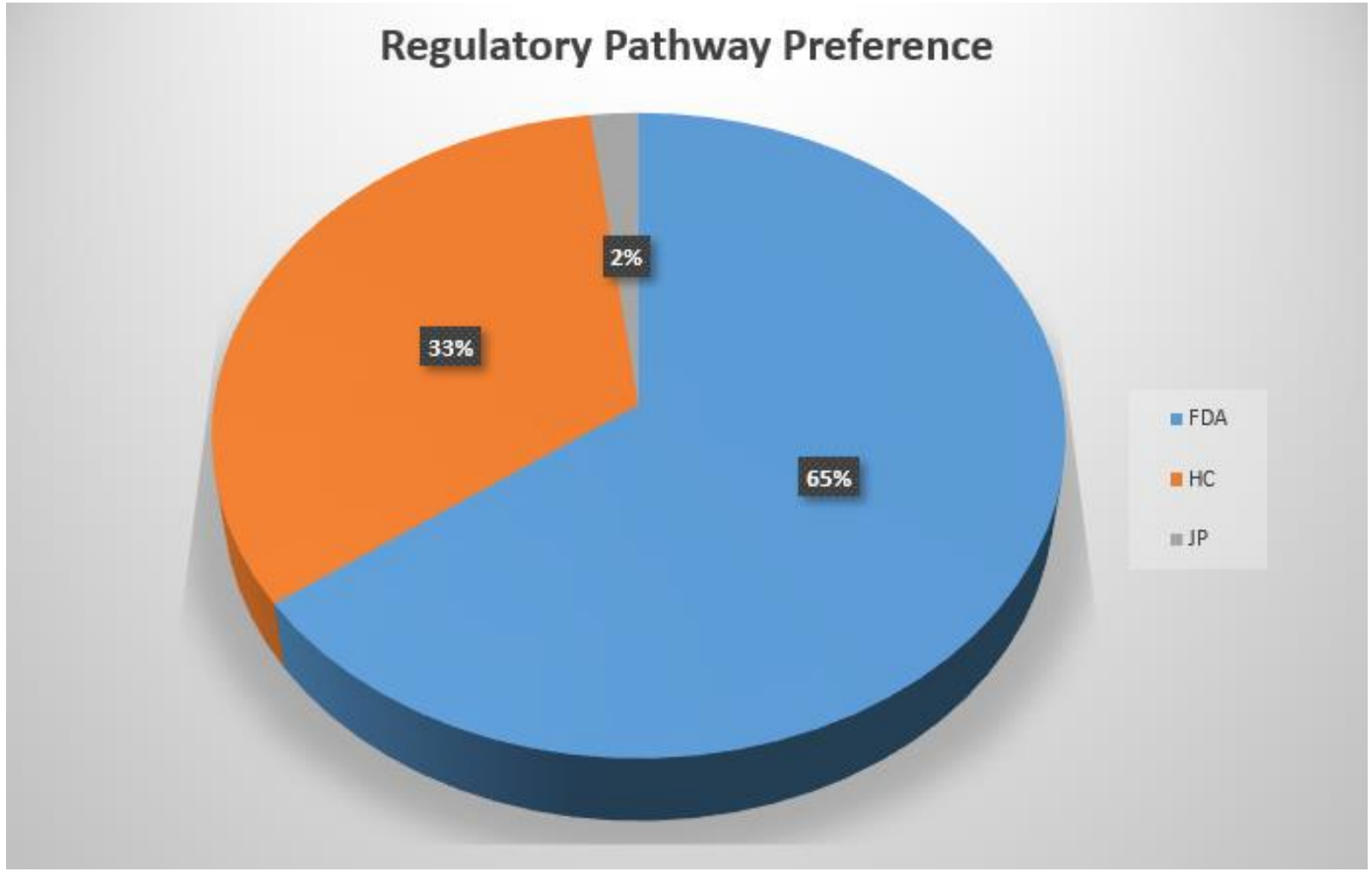
Regulatory Pathway Preference
2%
33%
65%
FDA
HC
JP

Equivalence Agreements USFDA, HC & PMDA

Pros

Provides confidence in authorizations granted by other recognized regulators and in the product.
It enables the reduction of technical requirements.
Regulatory pathway potentially more agile and expeditious.
Enhances quick access to medical technologies in the country.
Can improve regulatory efficiency and authority's use of resources.
Benefits international regulatory harmonization

Opportunities

Align assessment criteria to avoid preventions (clarity on requirements and continuous technical training).
Compliance on regulatory timelines.
Recognition of international documents.
Continuous regulatory training (regulator – regulated)
Accelerate the availability of innovative technologies within reach for doctors, patients and the market in general.

Case Study - A

- USFDA, Health Canada, and PMDA Equivalence Pathways – *Early Years*

  - **Regulatory requirements** were **largely aligned with** the provisions of **the equivalence agreements**, facilitating their implementation.
  - Although the submitted **dossiers** were **extensive**, **there was** mutual **understanding** between the regulated party and the authority regarding the submitted documentation and technical justification.
  - This context fostered **clearer interaction**, **reducing uncertainty** in the **evaluation** process.

- Result: **Greater efficiency** was observed in **obtaining** regulatory **approvals**.

Case Study - B

- USFDA Equivalence Pathway

  - **FDA approval** was obtained in the United States under the **"system"** approach, which integrated both the instrument and associated reagents.
  - The **local submission** involved **registering** the system **components separately**.
  - The **authority** recognized the scope of the USFDA approval and **granted** the **medical device registration for each component** with the same authorization within a reasonable evaluation timeframe.

- Result: This case demonstrates the effectiveness of the model when there is **technical alignment in** the **interpretation** of the **application**, allowing for a **more efficient evaluation.**

A Reliance Journey: Industry Experiences to Date – Part II Case Studies

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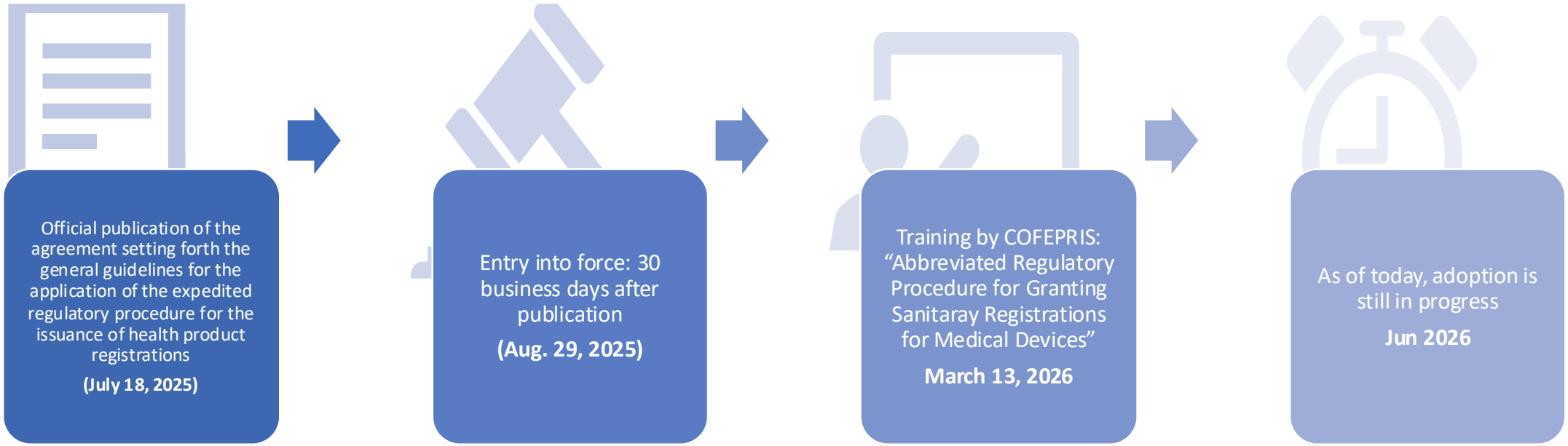
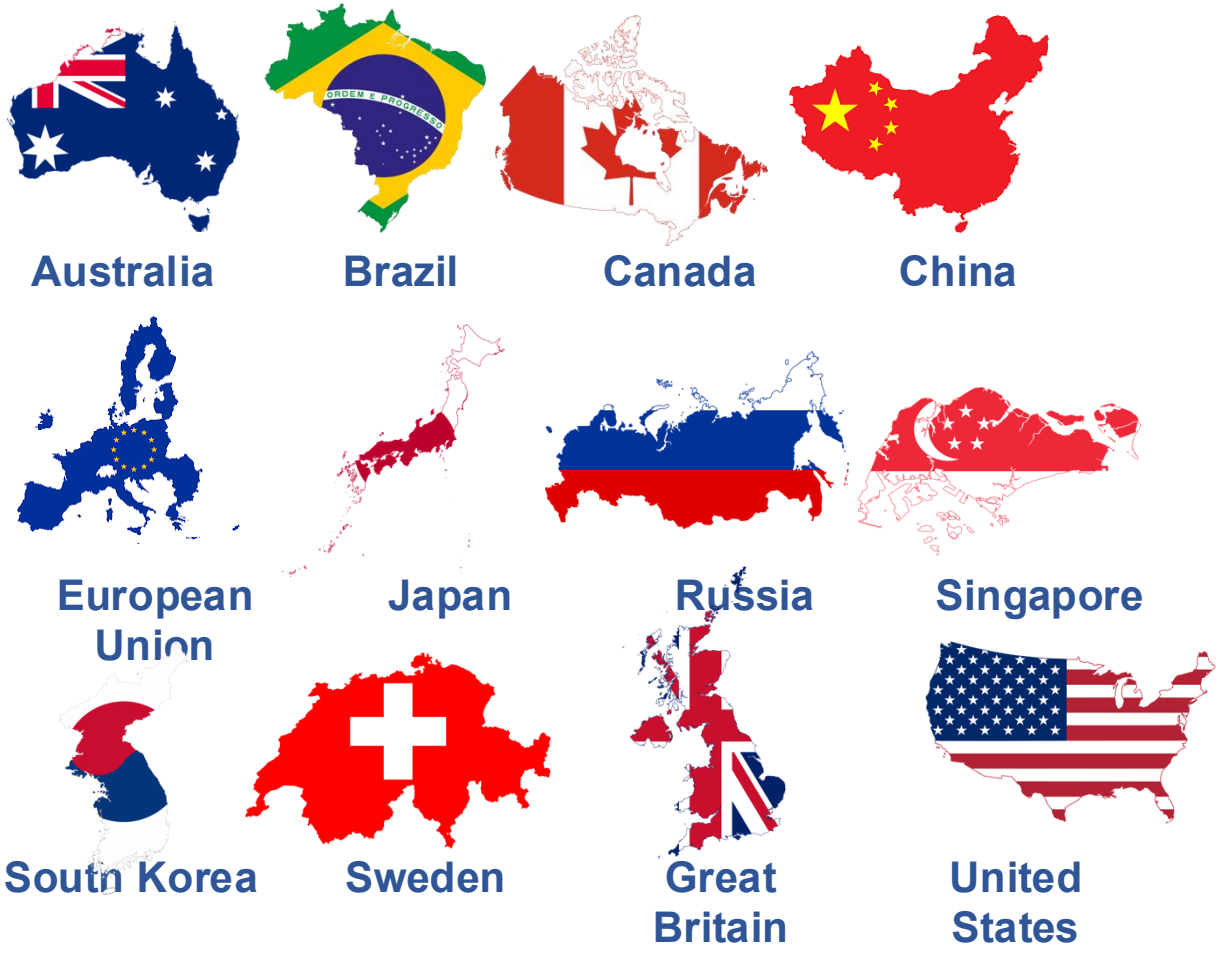
Industry experiences to date – Part II



IMDRF countries

The new agreement introduces a greater number of requirements, leading some stakeholders to prefer continuing to use the existing pathways based on the FDA, Health Canada, and Japan.



Benefits

1

This agreement contributes to the objectives of the USMCA.

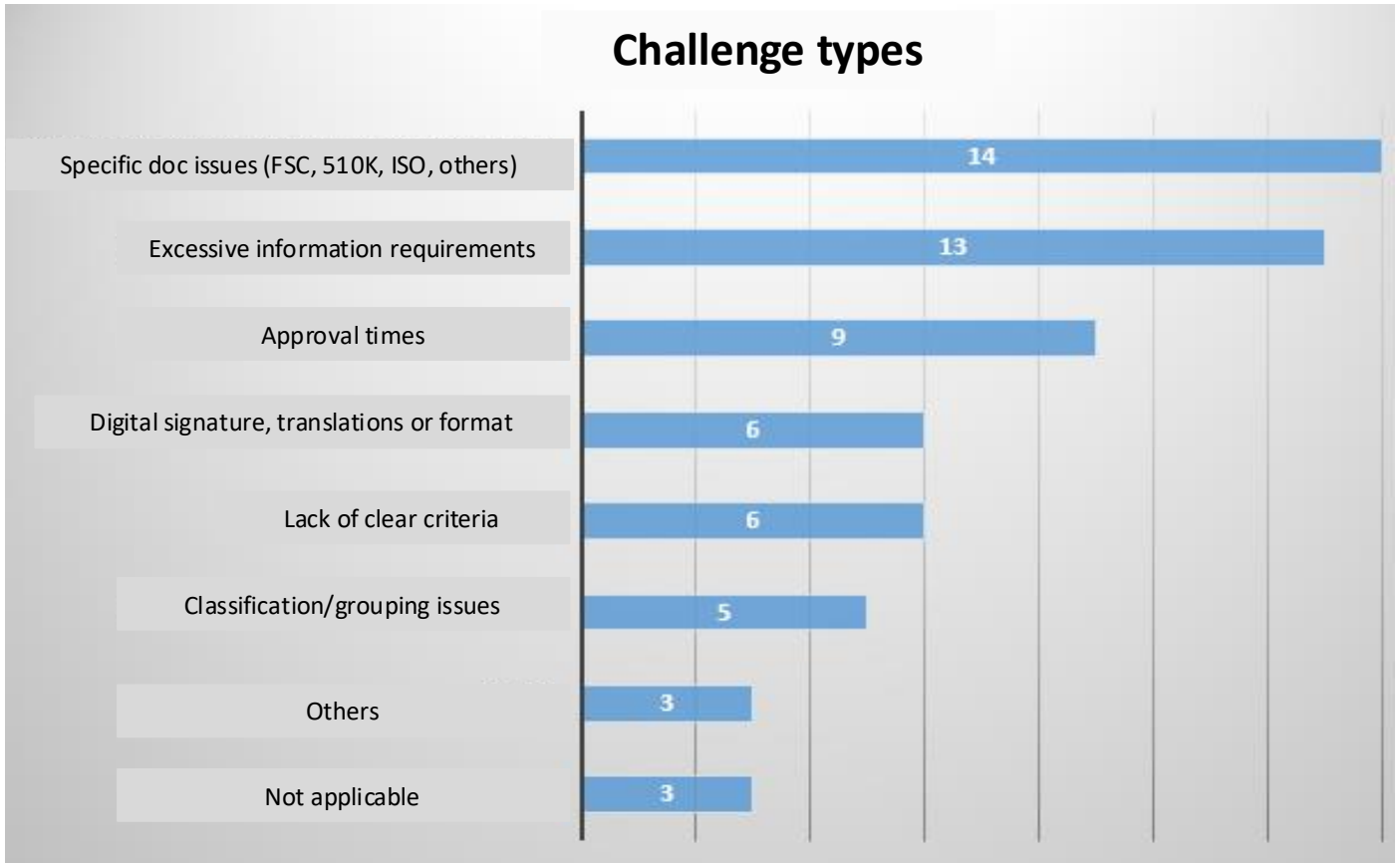
2

The update to the equivalence framework expands reliance on new countries, accelerating market access for the Mexican population.

3

It enables the accelerated approval of innovative technologies in the medical device sector.

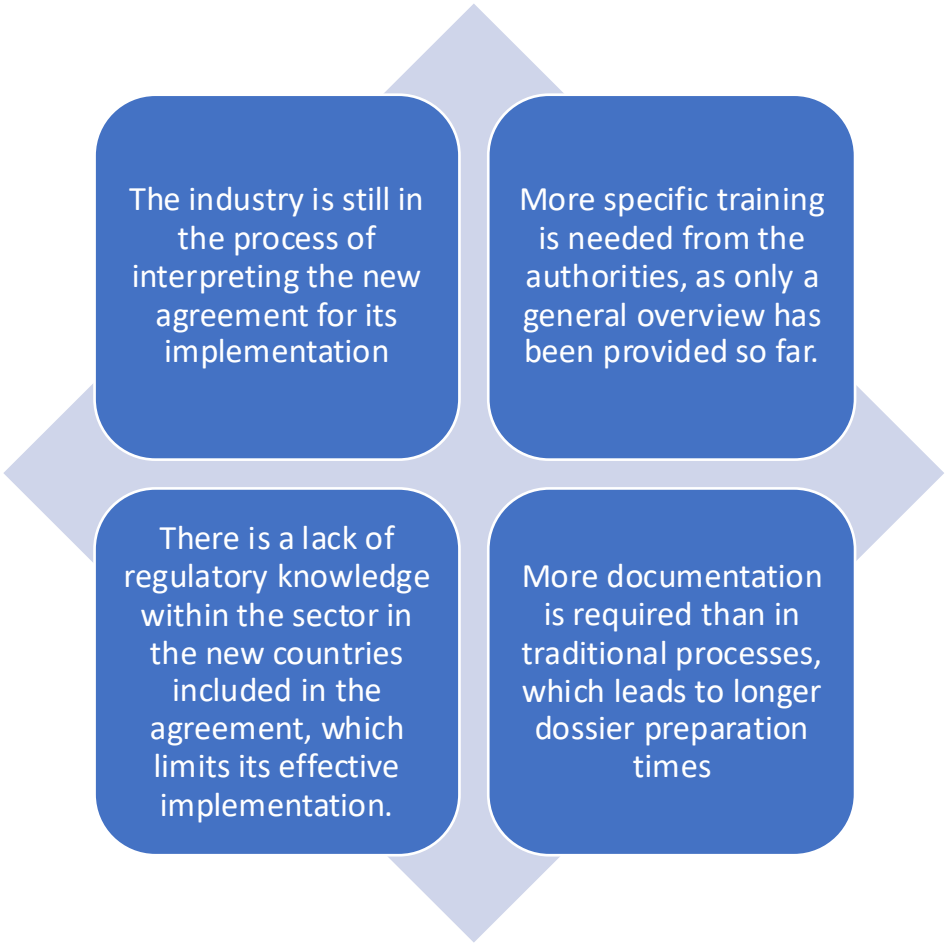
Findings | Case Studies



GAPS

- Lack of alignment in evaluation criteria
- Additional requirements
- Increased approval times
- Request for information not applicable

Challenges


The industry is still in the process of interpreting the new agreement for its implementation
More specific training is needed from the authorities, as only a general overview has been provided so far.
There is a lack of regulatory knowledge within the sector in the new countries included in the agreement, which limits its effective implementation.
More documentation is required than in traditional processes, which leads to longer dossier preparation times

Proposals

- Continue working on the development and implementation of country-specific checklists to ensure consistent application and interpretation of the new agreement by regulators and regulated entities.
- Explore with COFEPRIS how to prioritize the evaluation of these new registration applications.
- It is expected that, through digitization, COFEPRIS will achieve more accurate and efficient management of new registration applications.

Conclusions

As representatives of the medical device industry, we acknowledge that efforts are already underway to improve regulations and that we are now entering a phase focused on strengthening administrative management.