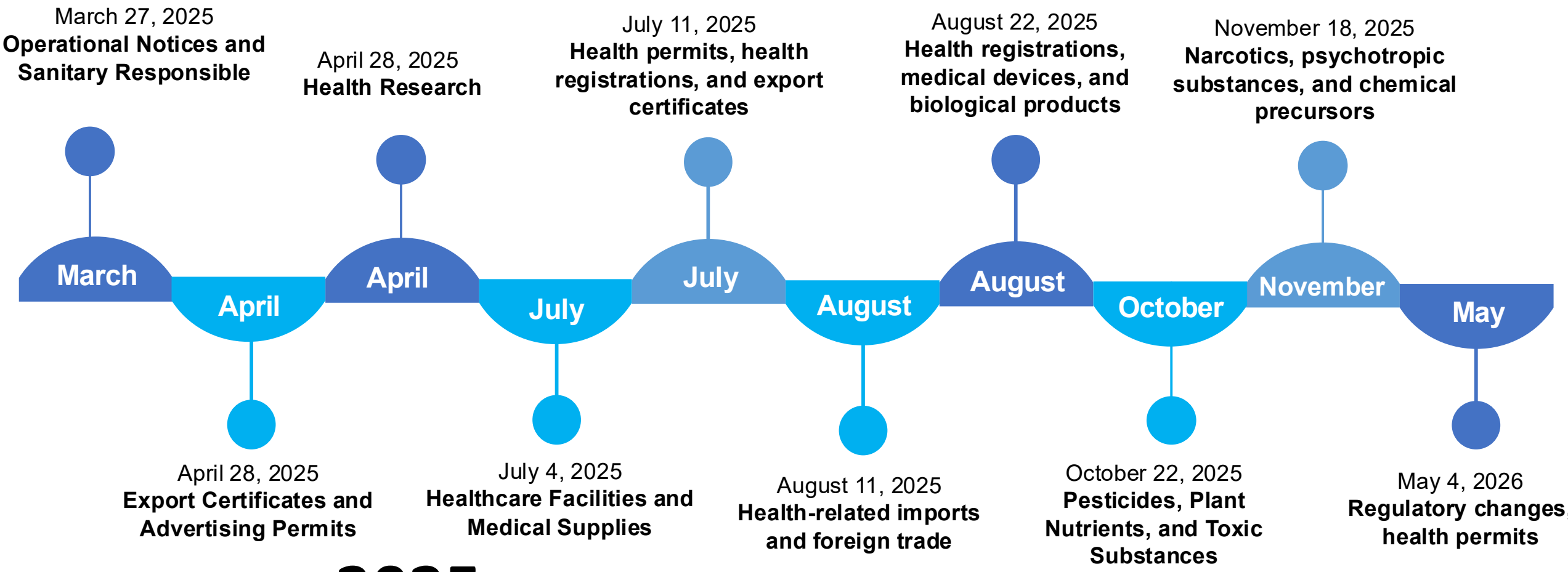
Regulatory Framework for Medical Devices in Mexico
What to Expect from the Latest Regulation Updates?

Ana Riquelme
Executive Director, AMID

COFEPRIS Simplification Agreements



2025 **2026**

Simplification Agreement March and April 2025*

March 27, 2025

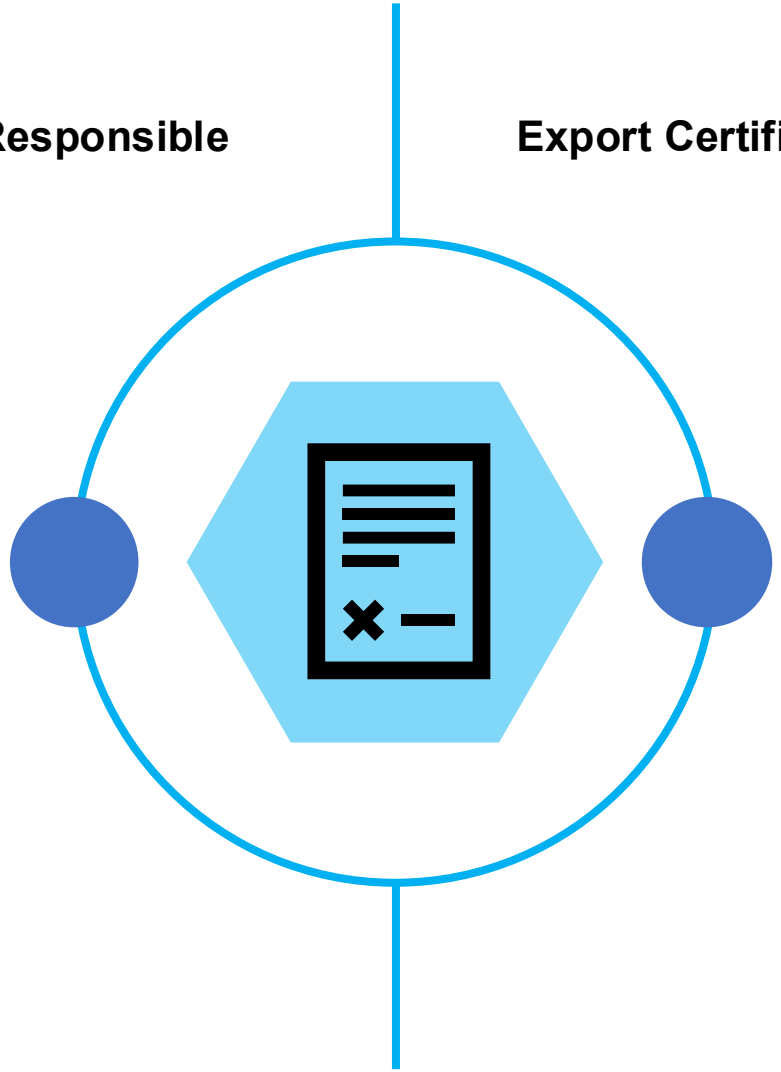
Notifications of Operation and Sanitary Responsible

Simplified Procedures

- Notifications of operation for health supply establishments.
- Amendments to notices of operation.
- De-registration of establishments.
- Registration, modification, and deregistration of sanitary responsibles.

Simplification

- Merging 10 identical procedures into 2.
- Elimination of paper forms.
- Elimination of requirements for deregistration of sanitary responsibles.



April 28, 2025

Export Certificates and Advertising Permits

Simplified Procedures

- Export certificates for regulated products.
- Health advertising permits.

Simplification

- Elimination of documentary requirements.
- Reduction of information required for filing applications.
- Simplification of foreign trade procedures.

Simplification Agreements April and July 2025*

April 28, 2025

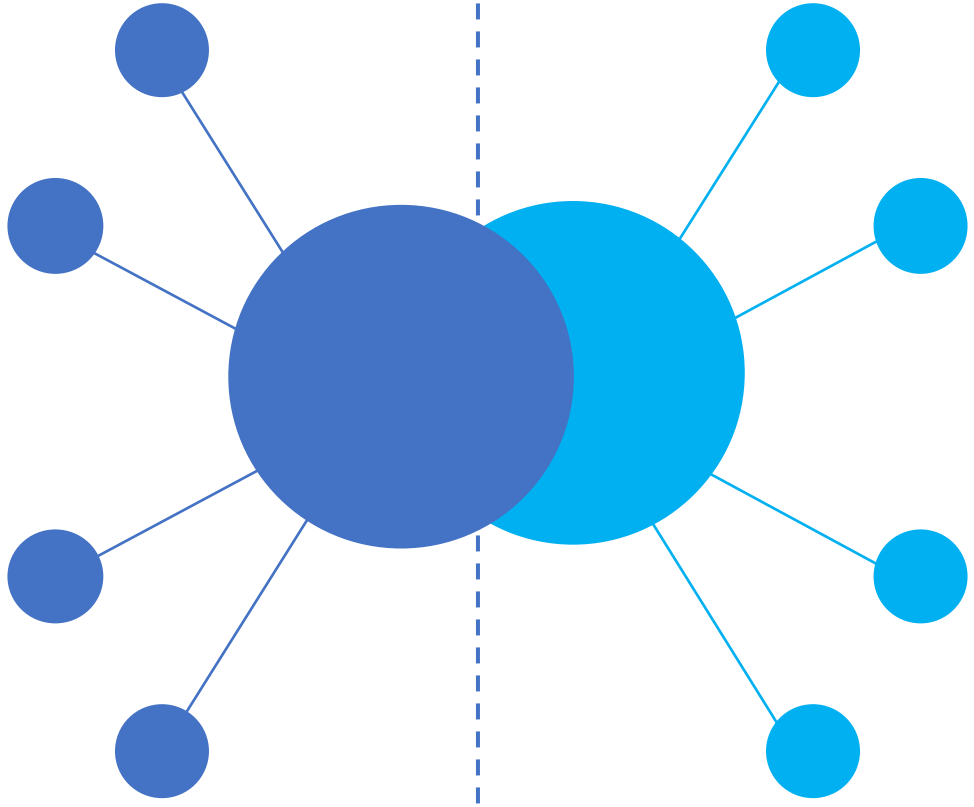
Health Research

Simplified procedures

- Clinical research protocols.
- Bioequivalence studies.
- Research with drugs and biologics.
- Amendments and modifications to protocols.

Simplification

- Elimination of documentation requirements.
- Simplification of amendments to authorized protocols



July 4, 2025

Healthcare Facilities and Medical Supplies

Simplified procedures

- Health licenses for healthcare facilities.
- Sanitary Responsible.
- Facilities Using Ionizing Radiation.
- Biological products.
- Notifications of operation.

Simplification

- Merging of multiple modalities.
- Elimination of redundant requirements.
- Immediate resolution for various notifications.

Simplification Agreements July and August 2025 *

July 11, 2025
Health Permits, Registrations, and Certificates

Simplified Procedures
- Amendments to health licenses.
- Certificates for export.
- Amendments to health registrations.
- Regulatory reports and health notifications.

Simplification
- Creation of immediate resolution procedures.
- Elimination of requirements issued by the authority itself.
- Conversion of authorizations into notifications.

Impact on medical devices
- Simplification of administrative modifications to the medical device registration.
- Reduced documentation burden for post-registration changes.

August 11, 2025
Health imports and foreign trade

Simplified procedures
- Importation of drugs and medical devices.
- Importation of raw materials and samples.
- International transport of tissues and cells.
- Amendments to import permits.

Simplification
- Single digital forms.
- Merge of import procedures.
- Reduction of physical requirements.
- Shorter response times.

Impact on medical devices
- Simplification for devices intended for clinical research and laboratory testing.
- Reduced documentation burden for imports.

Simplification Agreements for August and October 2025*

August 22, 2025
Health Registrations and Health Supplies

Simplified Procedures
- Health registrations for drugs and medical devices.
- Renewals of health registrations.
- Biological products.
- Health facility licenses.
- Export certificates.

Impact on Medical Devices

New consolidated procedures are created
- Sanitary registration of medical devices.
- Sanitary registration of low-risk medical devices.

Existing categories are merged
- Class I, II, and III health registrations.
- Domestic and foreign registrations.
- Low-risk devices.

October 22, 2025
Pesticides, Plant Nutrients, and Toxic Substances

Simplified Procedures
- Health registrations for pesticides and amendments.
- Health permits.
- Related permits.

Simplification
- Elimination of requirements and consolidation of identical procedures.
- Reduction of regulatory timelines.

Procedures are eliminated
- International regulatory equivalence categories.

Time reductions
- Class I: 30 → 20 days.
- Class II: 35 → 25 days.
- Class III: 60 → 35 days.
- Low risk: 30 → 15 days.
- Renewals: 120 → 45 days.

Simplification Agreements: November 2025 and May 2026*

November 18, 2025

Controlled Substances and Chemical Precursors

Simplified Procedures

- Import and export.
- Local procurement.
- Electronic special prescription books.
- Control logs.
- Appointment of inspectors.
- Regulatory notices.
- Activities involving chemical precursors and essential chemicals.

Simplification

- Implementation of the Comprehensive Substances System (SISUS).

May 4, 2026

Regulatory Changes and Health Licenses

Simplified Procedures

- Amendments to sanitary registrations and health licenses.
- Licenses for healthcare facilities.
- Licenses for facilities using ionizing radiation.
- Health certificates.
- Advertising permits.
- Foreign trade procedures.

Simplification

- Applications reduced to digital forms and fee payment.
- General reduction in processing times.

Impact on Medical Devices

- Administrative modification of the medical device registration
- Transfer of rights.
- Update of holder information.

Time savings

- Administrative modification of registration:
  - 22 → 15 business days.

Findings and Considerations

- Coordinated collaboration between the Agency for Digital Transformation and Telecommunications (ATDT) and COFEPRIS regarding the issuance of the agreements.
- The agreements combine regulatory simplification, digitization, and process redesign.
- All agreements completed their regulatory process in accordance with Article 36 of the National Law to Eliminate Bureaucratic Procedures.
- What was significant was not only the reduction of requirements but also the development of a new regulatory management model based on digital tools.
- The regulatory transformation unfolded sequentially: elimination of requirements → consolidation of procedures → digitization → reduction of processing times.
- The agreements reflect a shift from a model based on document review to one based on risk management.
- Regulatory simplification will only yield the expected benefits if technological platforms evolve at the same pace as regulatory changes.
- Implementation requires ongoing institutional coordination.
- Regulatory simplification should be viewed as an ongoing process rather than a set of isolated agreements.