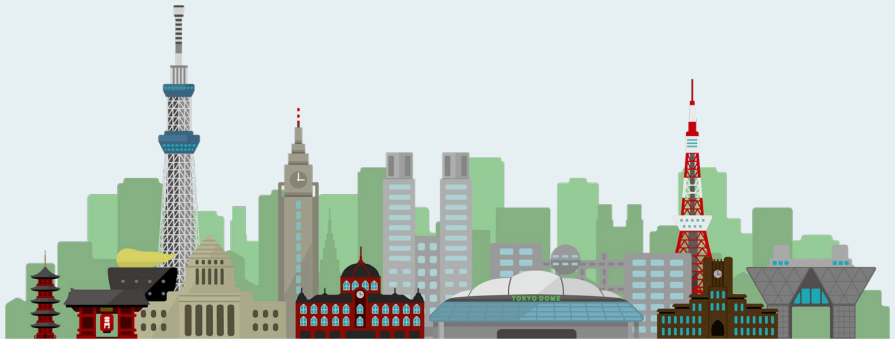
IMDRF International Medical Device Regulators Forum



Challenges in expanding reliance
ANMAT - Argentina

Lucas Duarte
International Affairs Analyst
March 10, 2025

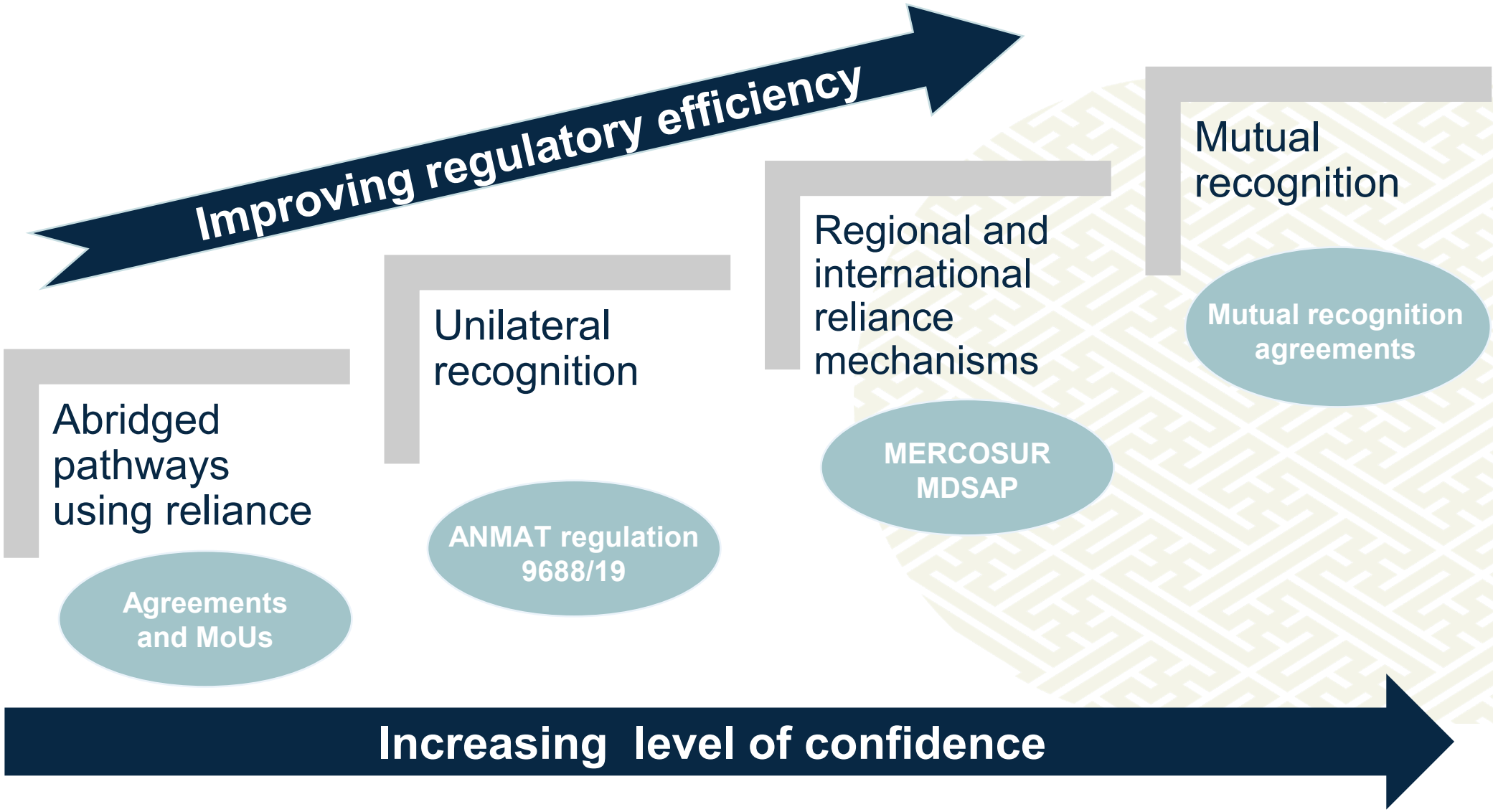
Reliance Framework in ANMAT

- **ANMAT Regulation 9688/19 on registration of medical devices**
- **Good Reliance Practices Manual**

  Provides guidelines for implementing reliance, strengthens the response capacity required by the regulatory framework, and addresses new technologies and good practices while promoting international regulatory cooperation.

- **ANMAT Strategic plan 2024-2027**

SO 1	Move towards streamlined proceedings, regulatory convergence and reliance practices criteria


Improving regulatory efficiency
Abridged pathways using reliance
Agreements and MoUs
Unilateral recognition
ANMAT regulation 9688/19
Regional and international reliance mechanisms
MERCOSUR MDSAP
Mutual recognition
Mutual recognition agreements
Increasing level of confidence

ANMAT regulation 9688/19 - We rely on NRAs that

1. hold monitoring functions and legislation in agreement with the Argentine regulatory framework;
2. comply with the international guidelines adopted by ANMAT, and
3. regulate products over which ANMAT has experience and knowledge on their use and existence on the market.

Accepted Free Sale Certificates


Australia


Brazil*


Canada


European Union


Japan


Israel


South Korea


Switzerland


United Kingdom


United States

FSC acceptance: What does it mean?

The product meets the established technical requirements

- ANMAT does not request extra tests or clinical trial repetition
- ANMAT does not require a manufacturing site inspection

Case study 1 Medical Device Class II

Endodontic barbed broaches

Registration process started on February 7, 2025 and finished on February 19, 2025

9 working days

Case study 2 Medical Device Class IV

PCL (polycaprolactone) dermal filler

Registration process started on March 03, 2024 and finished on May 05, 2024

54 working days

Medical Device Single Audit Program (MDSAP)

ANMAT has been an affiliate member since January, 2020

Acceptance of MDSAP audit reports

Inspection report exchange within MERCOSUR

ANMAT regulation 11419/2024 incorporates into the internal system Resolution GMC 3423 (amending Resolution 20/17), which governs the procedure for MERCOSUR Member States inspection report exchange.

Case study 1 - MERCOSUR exchange of reports

Non-active implantable medical devices site

- Report received on December 2, 2024
- GMP certificate granted on February 7, 2025

46 working days

Case study 2 - MDSAP audit report

Reusable instrument site

- MDSAP audit report received on December 18, 2024
- GMP certificate granted on February 28, 2025

33 working days

Mutual Recognition Agreement for Medical Devices ANMAT - ANVISA

Agreement for mutual recognition of Free Sale Certificates and certificates for foreign countries for Medical Devices (Risk Classes I and II) and IVD Medical Devices (Risk Classes A and B)

Agreement signed on November 8, 2023

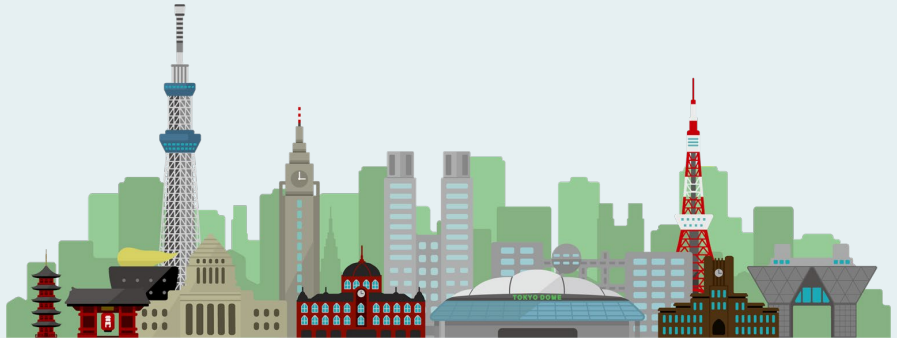
Reliance in a Post-market Setting

- Surveillance of other NRAs alerts
- REDMA
- MERCOSUR guide
- ARGOS public library

Benefits of reliance

- Cost and resource saving
- Shorter response times
- Faster market access
- Collaboration among agencies

IMDRF International Medical Device Regulators Forum



Thank you!

lucas.duarte@anmat.gob.ar
relaciones.internacionales@anmat.gob.ar