HSA Health Sciences Authority

IMDRF International Medical Device Regulators Forum

29th IMDRF 2026

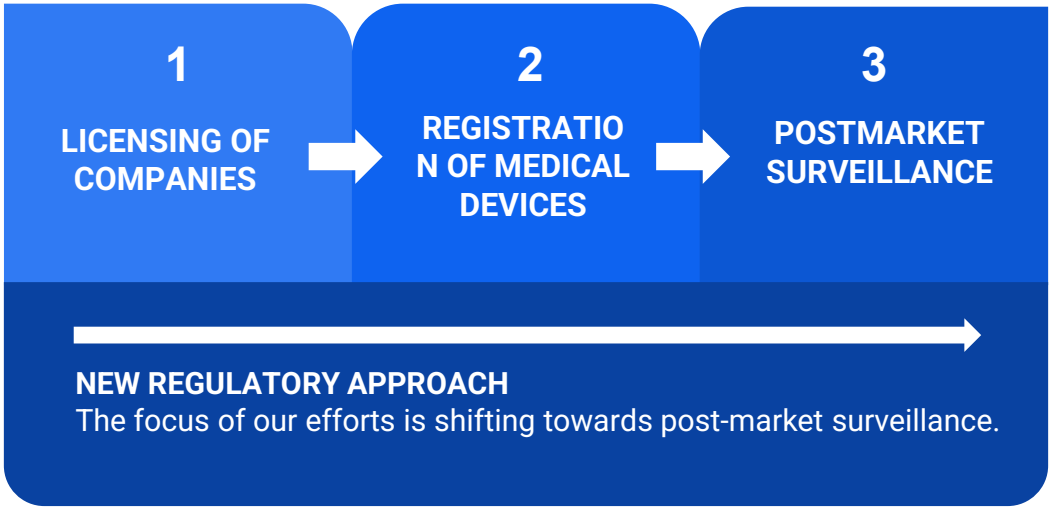
Day 2 - IMDRF Stakeholder Forum | 10 March 2026

PRESENT OF MEDICAL DEVICES REGULATION IN ARGENTINA

"Towards a modern and dynamic approach which is based on risk, evidence and international cooperation"

Lorena Terrizzano, Eng.
National Director - National Institute of Medical Devices
ANMAT - ARGENTINA

ARGENTINE REGULATORY SYSTEM: POSTMARKET SURVEILLANCE AS A CENTRAL PILLAR



TOWARDS AN EX POST FOCUSED REGULATORY MODEL

Ex post regulation is based on ongoing vigilance, once the product is on the market.

ARGOS System -> Argentine platform to report adverse events and field safety corrective actions
-> Focus is on promoting a culture of reporting

This model allows us:

- to detect long-term problems
- take fast corrective actions
- facilitate promotion of innovation and access to state-of-the-art technologies

NEW REGULATION

Regulation n° 8799/25
To establish a simplified licensing regime for manufacturers or importers of low and moderate risk medical devices.

Regulation n° 236/26
To establish a New Registration System to pursue the simplification and streamlining of class I and II medical devices imports and marketing.

Regulation n° 4446/25
To eliminate the step of a previous authorization for importing said medical devices.

RELIANCE AND INTERNATIONAL COOPERATION

We understand **“reliance”** as the strategic use of information, evaluations and decisions adopted by other competent regulatory authorities, always maintaining sovereign responsibility for our decisions.

Agreement on Reciprocal Trade between **Argentina and the U.S. Bilateral Relations.**

Reliance does not imply a delegation of responsibilities, but rather a more intelligent way of performing the regulatory function in a global environment.

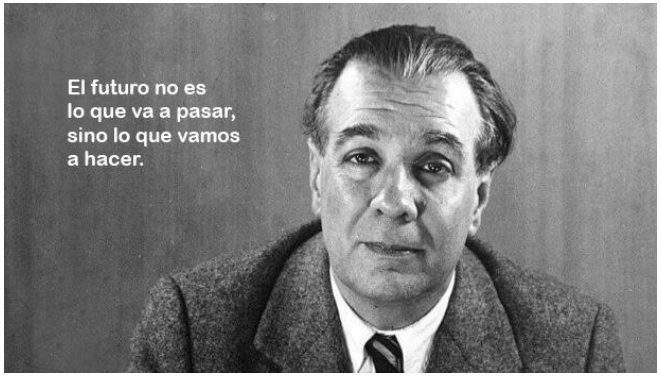
THE FUTURE ENVISIONED

CONCLUSIONS

We are committed to building a streamlined regulatory system that:

- is based on risk, evidence and trust,
- goes along with innovation without compromising the safety of patients.

Our focus will be set on strengthening postmarket surveillance, deepening international cooperation and continuing to align our regulations to global standards.



"Future is not what will happen, but rather what we are going to do".

Jorge Luis Borges

Thank You!