Thera
HEALTH POLICY & ACCESS

let's create value together

THERA INSIGHTS · ISSUE NO. 04 OCTOBER 2026

From decision to delivery: closing the implementation gap

October's through-line was a question Thera keeps returning to: what happens between a decision and the patient? We launched Thera Quarterly on the implementation gap, our column examined how PAHO's new Revolving Fund can turn awards into access, and Global Biosimilars Week shifted the debate from approval to uptake. Across the region, a court ruling in Colombia and the rollout of new cancer medicines in Brazil tested the same idea. Let's create value together.

THERA IN ACTION

October brought a new flagship series, a new alliance and fresh engagement with Europe's translational-medicine ecosystem.

THERA QUARTERLY · OCT 5

Thera Quarterly launches with "The Implementation Gap"

Presented by Managing Director José Luis Cárdenas Tomažič, Thera's new thought-leadership series opens with a clear thesis: healthcare's main problem is not a lack of innovation, but the ability of health systems to adapt their institutions to it. Three signals frame the episode: access starts before reimbursement; misaligned incentives and fragmented budgets slow adoption; and buying a technology is not the same as implementing it. Its conclusion: "implementation capability may become the most important competitive advantage for healthcare systems."

Watch the episode →

ALLIANCE · OCT 13

Thera and REGNER join forces on health policy, access, compliance and governance

The alliance combines Thera's expertise in health policy, market access and regulatory affairs with REGNER's capabilities in compliance, integrity, governance, risk management and due diligence — connecting access strategy with the governance and execution needed for lasting change.

Read the announcement →

GLOBAL ECOSYSTEMS · HEIDELBERG · OCT 19–20

Sebastián Millar at Science Meets Industry Day: how Latin America can join innovation earlier

At this Heidelberg meeting on translational medicine, with participation from the German Cancer Research Center (DKFZ), the German Cancer Consortium (DKTK) and Germany's association of research-based pharmaceutical companies (vfa), Thera's Senior Strategic Advisor for Advanced Therapies & Precision Medicine focused on how discoveries become innovations that reach patients. His takeaway for the region: Latin America should engage upstream — through joint research, clinical studies and local capabilities — and become part of the ecosystems that create innovation, not only a recipient of it.

Read more →

THERATALKS · THIS MONTH

Watch on **YouTube** and follow on **LinkedIn**.

EPISODE 9 · OCT 19 · GLOBAL BIOSIMILARS WEEK

The future of biosimilars, regulatory convergence & sustainable patient access, with Aaron Josephson

A former senior FDA policy advisor and global biosimilars policy leader on how regulatory frameworks have matured, why reliance and convergence matter for Latin America, and why uptake still varies so widely after approval — arguing for a shift "from regulatory maturity towards policy and health system maturity."

Watch Episode 9 →

EPISODE 10 · OCT 28

Suicide prevention as a global public health challenge, with Dr. Guillermo Maligne

Thera's Senior Strategic Advisor for Medical & Scientific Affairs on why suicide has no single cause and why prevention must be system-wide: better data and surveillance, trained staff, accessible care, clear referral pathways, reduced stigma and responsible public communication.

Watch Episode 10 →

COLUMN OF THE MONTH · EL ECONOMISTA · OCT 16

The new PAHO Revolving Fund: from award to access

By José Luis Cárdenas Tomažič & Daniel López Lizama. On September 29, PAHO's Member States approved merging the Revolving Fund for Access to Vaccines and the Strategic Fund into a single Regional Revolving Fund, now spanning diabetes, cardiovascular, oncology, hematology and rare-disease products, as well as biologics where biosimilar competition exists. The column's core point: scale does not by itself create access. The real test is whether aggregated demand becomes tenders, tenders become purchase orders, and orders become medicines that patients receive on time.

The authors set out five conditions for sustainable participation — visibility of demand and supply risks, category-specific approaches, clear competition rules between originators and biosimilars, quality and supply performance across the full cycle, and integrity and traceability in tenders — and propose judging success by conversion metrics such as the share of awarded lines that receive orders, time to first order and on-time delivery.

Read the full column →

GLOBAL OUTLOOK · THIS MONTH

BIOSIMILARS · OCT 19–24

Global Biosimilars Week: moving the debate from approval to uptake

During this year's Global Biosimilars Week, led by the International Generic and Biosimilar Medicines Association under the theme "Realizing the global value of biosimilars," regulators, payers and global health experts focused on what slows adoption: fragmented demand and regulatory gaps in low- and middle-income countries, and procurement that rewards only the lowest price at the expense of reliable supply. Their policy asks included reliance pathways instead of redundant trials, multi-winner procurement and stronger pharmacovigilance. The week followed the FDA's October 13 final guidance on post-approval manufacturing changes for biosimilars and interchangeables, aligned with the international ICH Q5E standard — another step toward regulatory convergence.

Read more →

EMA & EU · REGULATORY INNOVATION · OCT

Europe tests faster and more coordinated pathways

On October 15, the EMA's scientific committee recommended the first medicine assessed through a phased review — in which data are evaluated as they become available — for metastatic pancreatic cancer, an area of high unmet need. The review piloted a mechanism foreseen in the EU's pharmaceutical reform. In early October, the European Commission also selected the first medical devices for a joint clinical assessment under the EU HTA Regulation, whose reports will inform national pricing and reimbursement decisions. Meanwhile, as it implements the new pharmaceutical legislation, the EMA is prioritizing transferable exclusivity vouchers for priority antibiotics, a regulatory sandbox and shortage management.

Read more on the EMA →

Read more on EU joint clinical assessment →

FDA · RARE DISEASES · OCT

FDA proposes a new framework for rare disease review

In a new policy statement, the FDA set out to make “fit-for-purpose” evidentiary expectations the norm for rare disease applications — with earlier patient input, greater use of external disease experts, risk-based manufacturing review and innovative trial designs — while keeping the legal standard for safety and effectiveness. With only about 5% of recognized rare diseases having an approved treatment, the shift matters well beyond the US: FDA decisions are a frequent reference for regulators across Latin America.

Read the framework →

MENTAL HEALTH · PSYCHEDELIC MEDICINES · OCT 15–25

Psychedelic medicines: governments prepare regulated pathways before approval

On October 25, Israel's Ministry of Health announced its first national clinical trial of MDMA- and psilocybin-assisted psychotherapy for chronic PTSD that has not responded to standard treatment. It will enrol hundreds of patients over about three years, in licensed clinics and without take-home doses, with the explicit aim of offering a regulated alternative to unregulated providers and building evidence. In the United States, the Veterans Health Administration said in mid-October that it has selected ten sites to prepare delivery of psychedelic therapies, should the first approvals arrive in 2027. The policy lesson travels: readiness — sites, trained teams, safeguards and evidence — has to be built before approval, not after.

Read more on Israel's trial →

Read more on US readiness →

WHO · GLOBAL GOVERNANCE · OCT 29

Seven candidates enter the race to lead WHO

WHO published the official list of candidates for its next Director-General, proposed by Qatar, Saudi Arabia, Belgium, Spain, Indonesia, China and Botswana. None was proposed by a Latin American country — a reminder that the region needs to make its priorities on access, financing and regulatory capacity heard in a process that runs through a candidates' forum in November, the Executive Board in January and the World Health Assembly vote in May 2027.

Read more →

SPOTLIGHT ANALYSIS

From decision to delivery: Latin America's pharmaceutical governance gap

October offered several snapshots of the same challenge. In Colombia, the Council of State ordered the government to formulate a new national pharmaceutical policy covering price regulation, shortages and procurement — a court stepping in where policy had stalled. In Brazil, the SUS began delivering nine newly incorporated cancer medicines through a phased rollout to treatment centres — the hard part that comes after incorporation. In Mexico, the consolidated purchase for 2027–2028, awarded in late September, covered 82% of codes but left 139 to be retendered. And at regional level, PAHO's newly integrated Revolving Fund promises scale for countries that pool demand.

For Thera, the common thread is the implementation gap. A ruling, an award or an incorporation decision is a decision, not access. What turns decisions into medicines in patients' hands is the institutional machinery in between: reliable price and supply information, predictable procurement rules, measurable conversion from award to delivery, and governance that can be audited. The region's opportunity is to treat that machinery as policy in its own right — designed, financed and evaluated — rather than as an afterthought.

LATAM IN FOCUS · THIS MONTH

COLOMBIA · PHARMACEUTICAL POLICY · RULING SEP 17, REPORTED OCT 16

Colombia's Council of State orders a new national pharmaceutical policy

In a ruling issued on September 17 and widely reported in mid-October, Colombia's Council of State largely upheld a lower-court decision in a class action brought by the Procuraduría, ordering the government to formulate a new national pharmaceutical policy — potentially updating CONPES 155 of 2012. A working group led by the Ministry of Health, with the national medicines price commission and Invima, must address price-control methodologies, shortages, public procurement tools and information systems, while oversight bodies follow up on possible overcharges.

Read more →

BRAZIL · CANCER CARE ACCESS · OCT 20

Brazil's SUS begins delivering nine new cancer medicines

Brazil's Ministry of Health began offering nine high-cost cancer medicines in the public health system on October 20, covering 13 indications — from breast, lung, prostate and kidney cancers to lymphomas and leukemias — and potentially reaching more than 116,000 people. The rollout starts at 20 treatment centres and is set to reach all remaining centres by year-end, with a target of 23 new oncology medicines. To make it affordable, the ministry combined direct price negotiation, a joint price-reduction agreement with states and higher transfers to fund services — a practical example of what it takes to move from incorporation to delivery.

Read more →

MEXICO & BRAZIL · REGULATORY RELIANCE · IN FORCE OCT 15

Mexico opens a fast-track registration route based on Brazil's Anvisa evaluations

Under a simplified procedure announced in September and in force since October 15, Mexico's regulator COFEPRIS recognizes Anvisa's evaluations as equivalent for new molecules, generics, biotechnological medicines, biosimilars and vaccines approved in Brazil — provided the product is identical and its Brazilian authorization is valid — with a decision due within 45 business days. It is the first time Mexico has relied on Anvisa's decisions, and a concrete step toward the regional regulatory convergence explored in recent TheraTalks.

Read more →

PAHO · ANTIMICROBIAL RESISTANCE · OCT 2

The Americas adopt a new Plan of Action on Antimicrobial Resistance 2027–2031

Closing the 63rd Directing Council on October 2, PAHO Member States adopted a regional Plan of Action on AMR with a One Health approach, covering surveillance, laboratory capacity, infection prevention and control, appropriate antimicrobial use, and access to diagnostics and vaccines. They also approved a 2026–2035 strategy on arboviral diseases such as dengue, chikungunya and Zika.

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From diagnosis to demonstrable impact — talk to Thera about your access and policy challenges.

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