



Regulatory Brief by ECNE Research | 13 March 2026

This Week's Top Global Headlines

U.S.A

- **FDA launches new adverse event look-up tool:** The FDA has launched the Adverse Event Monitoring System (AEMS), a new unified platform for analyzing adverse event reports across drugs, biologics, vaccines, cosmetics, and animal food. FDA says the system is intended to improve transparency, modernize post-market surveillance, and eventually provide real-time reporting across all FDA-regulated product categories. Legacy systems to be replaced by AEMS include FAERS (FDA Adverse Event Reporting System), VAERS (Vaccine Adverse Event Reporting System), MAUDE (Manufacturer and User Facility Device Experience), HFCS (Human Foods Complaint System), and CTPAE (Center for Tobacco Products Adverse Event Reporting System). [More info here.](#)
- **FDA expands use of GSK's RSV vaccine:** The FDA has expanded the approved age range for Arexvy to include adults aged 18 to 49 who are at increased risk of lower respiratory tract disease caused by RSV. The decision broadens access to RSV prevention in younger at-risk adults and reflects continued regulatory attention to respiratory vaccine policy outside traditional older-adult populations. [More info here.](#)

EU

- **EMA safety committee updates product information for Ixchiq:** EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has recommended an update to the product information for Ixchiq, a live attenuated chikungunya vaccine, following review of a safety signal for aseptic meningitis. The committee concluded that the product information should be updated to reflect the latest evidence on this known neurological risk. Ixchiq's product information will now be updated to reflect that serious side effects, such as aseptic meningitis, have also been observed in healthy young adults. Previously, most reported cases had occurred in older people (over 65 years of age) or people with multiple long-term medical conditions. [More info here.](#)

APAC

- **Singapore and Malaysia formalize medical device regulatory reliance program:** Singapore's Health Sciences Authority (HSA) and Malaysia's Medical Device Authority (MDA) have announced full implementation of their Medical Device Regulatory Reliance Programme following a six-month pilot. From 1 March 2026, eligible HSA-registered devices may undergo faster review for access to the Malaysian market, while MDA-registered devices may benefit from shortened review pathways in Singapore. [More info here.](#)
- **India warns against direct or surrogate advertising of obesity medicines:** India's drug regulator, CDSCO, has issued an advisory warning companies against both direct and indirect advertising of prescription weight-loss medicines, including disease-awareness campaigns that could function as surrogate promotion. The advisory specifically warns against exaggerated efficacy claims, demand-inducing promotions, and campaigns that downplay the role of lifestyle interventions. [More info here.](#)

Deep Dive: Expanding Access Means Managing the Reality of Use

This week's headlines point to a more practical question than whether products can be approved: how do patients actually gain access to them safely, appropriately, and at the right time?

In the United States, the FDA's expansion of Arexvy to include adults aged 18 to 49 who are at increased risk of RSV-related lower respiratory tract disease is, at its core, an access story. It widens preventive options for a younger, clinically vulnerable population that previously sat outside the vaccine's approved age range. For patients, broader labeling can mean earlier protection and more targeted prevention. But it also means that health systems, clinicians, and manufacturers need to be ready for more nuanced real-world use, including identifying eligible subgroups and generating confidence in benefit beyond the original population.

At the same time, the FDA's launch of the Adverse Event Monitoring System (AEMS) has implications far beyond regulatory infrastructure. Better-connected safety monitoring supports access by helping products remain usable in practice. The more effectively regulators can identify, contextualize, and communicate emerging safety signals, the easier it becomes to maintain trust in therapies over time. In that sense, surveillance is not separate from access but is part of what sustains it.

In Europe, the update to Ixchiq product information makes this even clearer. Access is not simply a matter of keeping a product on the market; it is also about ensuring patients and clinicians are using it with the most current understanding of risk. When product information is updated quickly and transparently, access becomes better informed rather than simply broader.

Across Asia-Pacific, the access dimension is even more explicit. The Singapore–Malaysia medical device reliance program is a practical model for reducing avoidable delay in market entry, allowing eligible devices to move more efficiently between neighboring systems. This is a direct mechanism to shorten the path between regulatory readiness and patient availability. Meanwhile, India's warning against direct and surrogate advertising of obesity medicines addresses a different access problem: how to ensure that demand is shaped by clinical need rather than promotional pressure. In this context, protecting appropriate access is just as important as expanding it.

Taken together, these developments show that patient access in 2026 is becoming more conditional, but also more meaningful. It is not only about making products available. It is about making sure they are available to the right patients, with the right information, through the right channels, and with the right safeguards once they are in use.

Why This Matters

Access is becoming more than a question of approval. It now depends on whether products can be introduced, monitored, and communicated in ways that hold up in real-world care.

Broadening an indication, updating product information, streamlining device entry across borders, or restricting inappropriate promotion all affect the same outcome: whether the right patients can access the right products with confidence. These decisions shape not only availability, but also public trust, clinical uptake, and the practical conditions under which products are used.

For companies, this means patient access is increasingly influenced by what happens *around* the product i.e., surveillance systems, labeling updates, market entry pathways, and promotional controls. The organizations best positioned for sustainable access are those that plan for that full environment, rather than treating access as something that begins after authorization.

ECNE Insight: Designing for Sustainable Access

Patient access is often described as an endpoint. In reality, it behaves more like a system.

A product may be approved, but access can still be delayed, narrowed, or destabilized if safety communication lags, if market entry pathways are inefficient, or if demand is shaped in ways regulators consider inappropriate. The strongest organizations understand that access is not secured once but is maintained through a combination of evidence, communication, and operational readiness.

At ECNE Research, we see the value of designing for that reality from the outset. That means thinking beyond the approval milestone and asking whether the product can move efficiently into practice, whether the evidence will support confidence as use expands, and whether the surrounding strategy reinforces appropriate uptake.

In 2026, patient access is about getting products to market and also making sure they remain usable, trusted, and sustainable once they are there.

On Our Radar

- **EU | 18–20 March 2026 — EMA CAT meeting:** The Committee for Advanced Therapies (CAT) will convene in Amsterdam, continuing its work on assessing the quality, safety and efficacy of advanced-therapy medicines. [More info here.](#)
- **EU | 18 March 2026 — ICH M14 guideline becomes applicable in the EU:** The ICH M14 guideline on non-interventional studies using real-world data for safety assessment is set to become applicable in the EU, marking an important milestone for post-authorization evidence planning. [More info here.](#)
- **APAC (Australia) | 20 March 2026 — TGA consultation deadline:** Australia's consultation on the Annual Charge Exemption (ACE) Scheme Compliance Program closes on 20 March 2026. The outcome may affect how sponsors manage annual fees for non-marketed or low-volume products on the Australian Register. [More info here.](#)

The Friday Brief is curated by Elizabeth Weathers, PhD, RN, RGN, FAAN, Founder & CEO of ECNE Research. Follow ECNE Research on LinkedIn for ongoing insights in regulatory strategy, clinical evidence, and market intelligence.