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Mid-Summer Edition: What Have We Learned Since March?

Welcome to a slightly different Friday Brief.

We are now deep enough into summer that inboxes are quieter, out-of-office replies are flourishing, and at least one person on every email chain is "just back" or "just heading off." So instead of another full regulatory roundup, we are using this week to step back.

Since March, The Friday Brief has tracked developments across FDA, EMA, MHRA, PMDA, WHO, TGA, HSA, and others. Different agencies, different geographies, different product areas; but several themes keep appearing.

The headlines have changed each week. The underlying message has been surprisingly consistent.

Regulatory strategy is becoming less about a single approval milestone and more about whether the evidence, systems, and infrastructure around a product are strong enough to support what comes next.

1. Approval is not the finish line

It is tempting to treat regulatory approval as the end of the race. It is more like getting through airport security. Important, sometimes painful, but still not the whole journey.

Across medicines, medtech, diagnostics, digital health, and advanced therapies, regulators are focusing more closely on what happens after a positive decision: safety monitoring, labelling, risk communication, manufacturing readiness, real-world use, and continued benefit-risk confidence.

The question is no longer only, "Can this product be approved?"

It is also, "Can confidence be maintained once the product reaches patients, clinicians, health systems, and the market?"

2. Evidence now has to do more jobs

Evidence used to have a relatively clear job: support the regulatory decision. Now it has a longer CV.

The same evidence may need to support regulators, payers, HTA bodies, clinicians, procurement teams, patients, and health systems. That means evidence needs to be credible, structured, reusable, and relevant to the decisions that come next.

Evidence can no longer be built for one meeting or goal. It needs to travel.

3. Lifecycle planning needs to start earlier

Post-market planning is not something to discover after launch, ideally while holding a coffee and looking alarmed.

Manufacturing readiness, quality systems, pharmacovigilance, product data, usability, labelling, human factors, and post-market evidence all need to be considered much earlier.

The strongest programs are approval-ready, use-ready, access-ready, and lifecycle-ready.

That shift matters because many programs do not stall at the first regulatory question. They stall when downstream evidence, access, safety, quality, or implementation questions were not anticipated early enough.

4. AI is everywhere, but trust is still the hard part

AI has been one of the clearest recurring themes this year. Regulators are interested. Industry is excited. Everyone has a slide deck.

But the regulatory question is not simply, "Can AI make this faster?"

It is:

- Can it be validated?
- Can it be explained?
- Can it be governed?
- Can humans remain meaningfully in control?
- Can the output be trusted?

AI may accelerate evidence generation, manufacturing, literature review, quality processes, and regulatory operations; but only if the governance keeps up.

Speed helps. Trust decides.

5. Innovations are moving closer to real-world users

More products are moving into homes, pharmacies, schools, community settings, and distributed care models. That changes the regulatory question.

It is no longer only whether the product performs in ideal conditions. It is whether the intended users can understand it, use it correctly, act on the result, and stay safe in real-world conditions.

For medtech, diagnostics, and digital health, usability, instructions, human factors, labelling, training, and post-market monitoring are becoming central.

6. Global alignment is improving, but complexity has not gone on holiday

FDA, EMA, MHRA, PMDA, WHO, TGA, and other agencies are often moving in similar directions: more lifecycle oversight, more attention to data quality, more interest in AI, more focus on post-market evidence, and more pressure to connect regulatory strategy with access.

But similar direction and some harmonization does not mean identical requirements.

Regional expectations still matter. Local evidence still matters. Timing still matters.

The mid-year takeaway

If the past few months have taught us anything, it is this:

Regulatory strategy is becoming less about getting to "yes" and more about building the evidence, systems, and confidence needed for what comes next.

Approval still matters. Of course it does.

But approval alone is not enough if the evidence does not support reimbursement, adoption, safety monitoring, manufacturing scale-up, real-world use, and continued confidence.

The advantage will go to teams that plan early for the full pathway, while building the evidence, systems, and flexibility needed to evolve as new data, risks, and access questions emerge.

So, as we head into the second half of 2026, we will keep watching the same big questions:

Can the evidence travel? Can the systems support scale? Can the product be used safely in the real world? Can confidence be maintained after approval?

With any luck, the second half of 2026 will bring clearer pathways, stronger evidence, and fewer acronyms. We will be watching closely…coffee in hand, sunscreen nearby, and acronym tolerance fully tested.

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.