Regulatory Brief by ECNE Research | 26 June 2026

This Week's Top Global Headlines

U.S.A

- **FDA clears first over-the-counter continuous glucose monitor for children:** FDA cleared Dexcom's Stelo Glucose Biosensor System as the first OTC continuous glucose monitor for children. The device is indicated for people aged two years and older who do not use insulin. FDA noted that the clearance used prior clinical study data and real-world evidence to understand expected device performance in pediatric users over the full sensor wear period. The decision is an important signal for consumer-accessible monitoring technologies, where usability, labelling, caregiver supervision, real-world evidence, and conditions of use are central to regulatory confidence. **More info here.**
- **FDA broadens access to over-the-counter naloxone nasal spray:** FDA approved Rextovy, a 4 mg naloxone hydrochloride nasal spray, for OTC use in the emergency treatment of opioid overdose. FDA said consumers may purchase the product without a prescription in pharmacies, convenience stores, and online, and noted that multiple approved formulations can expand access, support market availability, and encourage competition. The approval reinforces FDA's continued focus on direct public access to time-sensitive health products where clear instructions, usability, safety, and real-world use are central to impact. **More info here.**

EU

- **MHRA approves lower-dose needle-free adrenaline treatment for younger children:** MHRA approved a lower-dose version of EURneffy, an adrenaline nasal spray, for emergency treatment of serious allergic reactions in children aged four years and over. The 1 mg dose is indicated for children aged four years and above who weigh between 15 kg and 30 kg, extending access beyond the previously authorized 2 mg product for adults and older / heavier children. The update is relevant for pediatric access, usability, caregiver administration, and real-world emergency-use conditions. **More info here.**
- **EMA advances AI-in-manufacturing regulatory discussion:** EMA will hold a GMP-focused multistakeholder workshop on 30 June and 1 July 2026 to inform future guidance on artificial intelligence in medicines manufacturing. EMA states that the GMP/GDP Inspectors Working Group is organizing the workshop to help shape a risk-based approach to the use of generative AI in medicines manufacturing. This is relevant for manufacturers considering AI-enabled quality, manufacturing, or GMP applications. **More info here.**

APAC

- **China obesity therapeutics market remains a major regulatory watchpoint:** Reuters reported that Novo Nordisk plans to seek Chinese regulatory approval for oral Wegovy in

the coming months, while Eli Lilly's orforglipron could launch in China as early as late 2026 or early 2027 if approved. The regulatory and access implications are significant. Oral GLP-1 therapies may expand patient uptake, but market access will depend on pricing, supply, and health-system integration. **More info here.**

Deep Dive: Consumer Access Raises the Bar for Real-World Confidence

This week's updates point to a practical shift in regulatory strategy i.e., more products are moving closer to patients, caregivers, consumers, and real-world use settings. As that happens, regulatory confidence depends not only on whether a product works, but whether it can be used safely, correctly, and consistently outside traditional clinical environments.

In the U.S., FDA's clearance of the first over-the-counter continuous glucose monitor for children is an important medtech access signal. The decision reflects the growing role of home-based and consumer-accessible monitoring technologies, particularly where users may include children, caregivers, and non-specialist settings. In these cases, regulatory confidence depends not only on technical performance, but also on usability, labelling, instructions, caregiver understanding, and performance in the conditions where the product will actually be used.

FDA's approval of over-the-counter Rextovy points in the same direction from a public-health perspective. Naloxone is a time-sensitive emergency treatment, and broader non-prescription access may help reduce barriers in situations where rapid administration matters. But expanding access also raises practical expectations: instructions must be clear, the product must be usable by laypersons, and safety communication must support correct action under pressure.

In the UK, MHRA's approval of a lower-dose adrenaline nasal spray for younger children reinforces the same access-and-usability theme. Severe allergic reactions require fast action, often by parents, caregivers, teachers, or others outside formal clinical environments. A needle-free, age- and weight-appropriate option may reduce practical barriers, but its real-world value depends on clear instructions, appropriate patient selection, caregiver confidence, and reliable emergency-use performance.

EMA's upcoming AI-in-manufacturing workshop adds a different but connected layer. As AI moves into GMP and manufacturing environments, real-world confidence will depend not only on product innovation, but on the systems behind the product. Manufacturers will need to show that AI-enabled processes are governed, monitored, explainable, and controlled in ways that support quality and regulatory trust.

In China, the expected filing for oral Wegovy highlights how access challenges scale globally when major therapeutic categories become highly competitive and highly demanded. Oral GLP-1 therapies may expand uptake, but regulatory approval alone will not determine impact. Supply, pricing, real-world outcomes, and health-system integration will shape whether broader availability translates into meaningful use.

Taken together, this week's developments show that access is a usability, communication, manufacturing, governance, and implementation question. As products move closer to patients and consumers, regulatory strategy must account for how they will be used in practice. The strongest programs will be those that build evidence, labelling, communication, quality

systems, and post-market plans around real-world conditions from the start, showing that it can be used safely, appropriately, and confidently by the people who need it.

Why This Matters

It is no longer enough to show that a product works under controlled conditions. Sponsors also need to show that the product can be understood, accessed, used, monitored, and supported in the settings where real people will rely on it.

An over-the-counter glucose monitor for children depends on caregiver understanding, labelling, real-world performance, and appropriate use. OTC naloxone depends on rapid recognition, clear instructions, and confidence in emergency settings. A needle-free adrenaline treatment for younger children depends on caregiver readiness and reliable administration under pressure. AI-enabled manufacturing depends on governance, transparency, and quality controls that can withstand regulatory scrutiny. Therefore, products also need the evidence, instructions, systems, and communication needed to support safe and confident use.

For sponsors, this means real-world use should be considered much earlier in development. Labelling, usability, risk communication, human factors, post-market surveillance, supply, quality systems, and lifecycle evidence are no longer downstream implementation details. They are part of the regulatory strategy.

The strongest programmes will be those that can answer not only, “Can this product be approved?” but also:

- Can the intended users understand and use it correctly?
- Can risks be communicated clearly outside specialist settings?
- Can performance be sustained in real-world conditions?
- Can the supporting systems keep pace as access expands?

As more products move into homes, schools, pharmacies, consumer settings, and highly distributed care models, confidence will depend on more than availability. It will depend on whether the product can be used safely, appropriately, and consistently by the people who need it.

ECNE Insight

Consumer access should be designed and not assumed. As more products move into homes, pharmacies, schools, and other non-specialist settings, sponsors need to think beyond the regulatory decision itself. The real question is whether the product, evidence package, labelling, training, risk communication, and post-market systems are ready for the way the product will actually be used.

This is especially important for technologies and treatments that rely on lay users, caregivers, emergency decision-making, digital interfaces, connected monitoring, or distributed access models. In those settings, small gaps in instructions, usability, communication, supply, or follow-up can quickly become barriers to adoption and confidence.

Real-world use needs to be built into strategy early. At ECNE Research, we see this as a shift from approval-focused strategy to use-ready strategy. The strongest programs will not only show that a product can meet regulatory requirements. They will also show that the product can be

understood, trusted, and used safely in the real-world settings where patients, caregivers, clinicians, and health systems need it most.

On Our Radar

- **EU | 30 June - 1 July 2026 — EMA GMP workshop on artificial intelligence in medicines manufacturing:** EMA will hold a multistakeholder workshop to inform future guidance on the use of artificial intelligence in medicines manufacturing. This is a key event for manufacturers monitoring expectations around AI-enabled GMP processes, data governance, model oversight, transparency, accountability, and human supervision. **More info here.**
- **USA | 3 August 2026 — FDA comment deadline for draft guidance on communications with payors:** Comments are due by 3 August 2026 on FDA's revised draft guidance on drug and device manufacturer communications with payors, formulary committees, and similar entities. The guidance is relevant for teams developing healthcare economic information, value communication strategies, and evidence packages intended to support access and reimbursement discussions. **More info here.**