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This Week's Top Global Headlines

U.S.A

- **FDA selects Dexcom as the first participant in its TEMPO digital-health pilot:** FDA selected Dexcom as the first manufacturer to participate in the Technology-Enabled Meaningful Patient Outcomes (TEMPO) pilot. The Dexcom Glucose Health Program will continue to be evaluated for intended uses connected to the CMS Innovation Center's ACCESS model, including screening for prediabetes and type 2 diabetes, monitoring metabolic and nutritional status, and providing patients and healthcare professionals with real-time data and AI-enabled insights. Participating manufacturers will collect, monitor, and report real-world data relating to patient outcomes. **More info here.**

EU

- **EMA recommends twelve new medicines and eight indication extensions:** At its 20–23 July meeting, EMA's Committee for Medicinal Products for Human Use recommended twelve new medicines for approval and eight extensions of therapeutic indication. Positive opinions included Susvimo, a refillable ocular implant delivering ranibizumab for wet age-related macular degeneration; Icotyde, the first oral medicine targeting the interleukin-23 receptor for plaque psoriasis; three new treatments for primary hypercholesterolemia or mixed dyslipidemia; Nezglyal for cerebral adrenoleukodystrophy; Zokovea for post-exposure prophylaxis of COVID-19; one biosimilar; and three generic medicines. CHMP also adopted negative opinions for three applications and supported updated compositions for four COVID-19 vaccines targeting the XFG variant. **More info here**.

- **European Commission publishes AI transparency guidance:** The European Commission published final guidance on the transparency obligations applying to certain providers and deployers of AI systems under Article 50 of the EU AI Act. From 2 August 2026, applicable AI systems must inform individuals when they are interacting directly with AI. Providers of generative systems must also support the detection of AI-generated or manipulated content through machine-readable marking, while additional disclosure requirements apply to areas including deepfakes, emotion recognition, and biometric categorization. For healthcare and life-sciences organisations, the immediate task is to map where AI is being used across patient-facing, clinician-facing, operational, educational, and product-related workflows — and determine which transparency obligations apply. **More info here.**

APAC

- **Australia's TGA updates GLP-1 safety warnings for rare vision disorder:** Australia's Therapeutic Goods Administration updated product warnings across the GLP-1 receptor agonist class due to the potential risk of non-arteritic anterior ischaemic optic neuropathy, a rare but severe eye disorder associated with possible permanent visual impairment. The update covers high-profile medicines used primarily for type 2 diabetes and obesity, including Ozempic, Wegovy, Mounjaro, Saxenda, and Trulicity. For healthcare and life-sciences organisations, the immediate task is to ensure that product information, patient counselling, prescriber communication, and pharmacovigilance systems are updated quickly enough to support safe use as demand expands. **More info here.**

Deep Dive: Evidence Strategy Meets the AI Transparency Era

This week's developments highlight that evidence is becoming more dynamic, more visible, and more accountable.

The clearest signal comes from the European Commission's AI transparency guidance. As Article 50 obligations begin to apply, healthcare and life-sciences organizations will need to identify where AI is being used across patient-facing, clinician-facing, educational, operational, and product-related workflows. This is not just an IT mapping exercise. It is a regulatory, clinical, communications, and governance exercise.

AI changes the evidence question because it changes where decisions are made and how information is presented. If a patient is interacting with AI, if a clinician is being supported by AI-generated output, or if educational or product-related content is AI-generated or manipulated, transparency becomes part of the trust infrastructure. Organizations will need to know not only whether a system works, but whether users understand when AI is involved, how outputs are generated, what risks are being managed, and which obligations apply alongside MDR, IVDR, data-protection, and sector-specific requirements.

FDA's selection of Dexcom as the first participant in the TEMPO digital-health pilot adds another layer. The pilot connects digital-health product evaluation, real-world evidence generation, measurable patient outcomes, and payment through the CMS ACCESS model. For digital-health developers, the evidence bar is no longer only technical performance. It is whether the technology can support meaningful outcomes in routine care, generate data regulators and payers can trust, and fit into clinical and patient workflows.

Together, the AI transparency guidance and TEMPO pilot show where regulatory strategy is heading i.e., evidence needs to be clear enough for regulators, credible enough for payers, practical enough for clinicians, understandable enough for patients, and structured enough to support oversight over time.

The same principle appears in the other headlines. EMA's July CHMP recommendations show the breadth of evidence packages now moving through European review, from medicines and implants to biosimilars, generics, vaccines, rare disease, and indication extensions. Australia's TGA update on GLP-1 safety warnings shows how quickly product information, prescriber communication, patient counselling, and pharmacovigilance systems must adapt when use expands and new safety concerns emerge.

The common thread is that evidence is becoming less static. It is no longer something generated once, submitted once, and then left behind. Evidence now has to move through digital tools, AI-enabled workflows, payer models, safety updates, patient communications, clinical settings, and post-market systems.

If AI, digital health, and real-world access are becoming part of the pathway, evidence strategy has to become more transparent, connected, and adaptable. The strongest organizations will be those that can show not only that their products work, but that the evidence behind them can be understood, trusted, updated, and used in the real world.

Why this Matters

AI and the digital health movement are making evidence more visible to more people. Evidence is no longer only reviewed by regulators behind a submission portal. It is increasingly embedded in digital tools, patient interfaces, clinician workflows, payer models, product communications, safety updates, and post-market systems.

As AI-enabled and digital-health products become more common, organisations will need to explain not only what the evidence shows, but how the evidence is generated, interpreted, governed, updated, and communicated.

This creates a practical challenge for healthcare and life-sciences teams. Regulatory, clinical, quality, data, vigilance, market access, medical affairs, and communications functions can no longer work in isolation. The same evidence may need to support multiple audiences and decisions, including:

- regulatory review;
- transparency obligations;
- payer and reimbursement discussions;
- clinical workflow integration;
- patient understanding;
- product information updates;
- pharmacovigilance and safety monitoring;
- and real-world performance assessment.

The risk is that evidence is not structured in a way that others can understand, trust, or use. Evidence strategy needs to include transparency strategy. That means asking early where AI is used, who will rely on the output, what needs to be disclosed, how performance will be monitored, and how evidence will stay reliable as products, systems, and risks evolve.

The organizations best positioned for this next phase will be those that can connect evidence generation with governance, communication, and lifecycle oversight from the start.

ECNE Insight

Do not let AI become a separate evidence workstream.

That is the practical risk we see for healthcare and life-sciences organizations. AI governance, digital-health evidence, regulatory strategy, reimbursement planning, clinical workflow, and

post-market oversight are often managed by different teams. But the evidence they rely on is increasingly connected.

If those teams work in parallel but not together, important questions can be missed:

- Is the intended use aligned across regulatory, clinical, and access stakeholders?
- Is the AI-enabled output understandable to the people who will rely on it?
- Are transparency obligations reflected in product communications and workflows?
- Can real-world outcomes data support both regulatory confidence and payer decisions?
- Are safety, performance, and product information updates connected after launch?

At ECNE Research, we see the opportunity as integration.

The organizations that move fastest will be those that connect the evidence to the decisions it needs to support in a cross-functional way i.e., across regulatory review, reimbursement, clinical adoption, product communication, and lifecycle oversight.

In the AI transparency era, the real advantage is not just having better tools. It is having a clearer, more connected evidence strategy behind them.

On Our Radar

- **USA | 29 July 2026 — FDA Cellular, Tissue, and Gene Therapies Advisory Committee:** The committee will discuss Capricor's biologics license application for deramiocel, an allogeneic cardiosphere-derived cell therapy proposed for cardiomyopathy in Duchenne muscular dystrophy. **More info here.**
- **EU | 2 August 2026 — EU AI Act Article 50 transparency obligations begin to apply**: Providers and deployers of applicable interactive and generative AI systems will need to comply with new disclosure, marking, and transparency requirements. This is especially relevant for healthcare and life-sciences organizations using AI across patient-facing, clinician-facing, educational, operational, or product-related workflows. **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.**