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ANSEA INSIGHTS

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Dear Valued Client,

Welcome to the April 2026 edition of ANSEA Insights. As the year progresses, the healthcare landscape is becoming increasingly **value-driven, selective, and execution-focused**, shaped by affordability pressures, evolving regulatory frameworks, and rapid advances in science and technology. This edition highlights key shifts including the scaling of AI across the healthcare value chain, structural changes in pricing and coverage, and the rise of high-impact therapies and platform-based innovation that are redefining how pharma and MedTech companies compete and deliver value.

At ANSEA, we remain committed to providing timely, actionable intelligence to support your strategic priorities. Alongside insights into M&A activity, regulatory developments, and recent drug approvals, we examine how these shifts are influencing portfolio strategy, access planning, and investment decisions. Whether navigating stricter value expectations, integrating regulatory and evidence strategies, or building scalable innovation platforms, our insights aim to support informed decision-making in an increasingly complex global healthcare environment.

As always, we appreciate your continued engagement and look forward to supporting your efforts to drive meaningful impact, innovation, and patient-centered outcomes worldwide.

Healthcare Trends to Watch

As healthcare systems **navigate 2026 amid ongoing cost pressures and structural change**, the focus is increasingly shifting from **piloting innovation** to **scaling solutions that deliver measurable value within financial and operational constraints**. Health systems are actively **reallocating resources** toward technologies and therapies that demonstrate **clear impact**, while **reassessing fragmented pilots and lower-value investments**. At the same time, **policy-driven pricing reforms**, **coverage redesign**, and **rapid scientific advances** are reshaping how care is delivered and accessed across markets. The result is a more **constrained but decisive operating environment**, where **efficiency, evidence, and impact** are critical. Below are three trends shaping **near-term strategy and investment decisions globally**.

1. AI Scaling Across the Healthcare Value Chain

AI is moving from experimentation to **embedded capability across healthcare and life sciences**, becoming a core lever for efficiency, speed, and decision-making.

- ***AI-Driven drug discovery & R&D transformation:*** *AI is shifting from supporting discovery to* ***actively generating clinical-stage assets****, with AI-designed drugs advancing into trials and reducing development timelines by* ***40–50% while improving early-stage success rates****. For example, collaborations such as the AI-driven drug discovery partnership between* ***Eli Lilly and Nvidia*** *are focused on building integrated AI platforms to accelerate molecule design and development. At the same time,* ***41% of companies are planning to automate core discovery workflows using AI agents****, signalling a shift toward partially autonomous R&D models rather than incremental augmentation.*[1]
- ***Operational AI & workflow automation:*** *Healthcare systems are moving from pilot programs* ***to enterprise-wide deployment of AI in operations,*** *particularly to address workforce constraints. Around* ***64% of leaders expect cost reductions through workflow standardization and 55% through workforce optimization,*** *with AI now embedded in triage, documentation, and administrative processes.*[2] *This marks a shift from experimentation to* ***AI as a core infrastructure layer supporting care delivery.***[3]

2. Intensifying Affordability Pressures and Structural Coverage Redesign

Cost containment is moving from reactive measures to **system-wide restructuring of pricing, reimbursement, and coverage**, directly shaping access and commercial models.

- ***Policy-driven drug pricing restructuring:*** *Governments are moving beyond isolated pricing controls to* ***more systematic and coordinated cost-containment frameworks,*** *with* ***350+ drugs expected to see price increases in 2026,*** *triggering expanded regulatory intervention. Existing mechanisms such as* ***international reference pricing*** *and* ***mandated rebates*** *are being* ***applied more aggressively and across a broader set of therapies,*** *signalling a shift toward* ***externally benchmarked pricing and tighter margin control across markets.***[3]

- ***Coverage redesign and access fragmentation:*** *Coverage is* ***not just selective, it is becoming more systematically constrained and explicitly value-driven across markets****. In the U.S., subsidy expirations and Medicaid changes could leave millions losing or downgrading coverage, with states tightening eligibility and benefits. Globally, health systems are* ***formalizing stricter eligibility criteria and prioritizing high-value interventions****, increasingly limiting access to high-cost therapies and shifting decisions earlier in the patient journey. For example, in India, access is often controlled through* ***package caps, preauthorization, and selective formularies****, but these mechanisms are being* ***applied more consistently and across a broader set of high-cost therapies****, reinforcing reliance on alternative financing models.*[4]

3. Expansion of High-Impact Therapies and Preventive Care Models

Innovation is increasingly concentrated in therapies that can **reduce the long-term impact of chronic diseases**, with payers and governments evaluating them as **system-level investments rather than standalone treatments**.

GLP-1 therapies as strategic health investments: *GLP-1 therapies are increasingly positioned as system-level interventions, with evidence showing benefits in* ***diabetes prevention and cardiovascular risk reduction beyond weight loss.***[4] *Adoption is accelerating, with* ***~11.8% of U.S. adults already using GLP-1s for weight loss and ~14% expressing interest,*** *indicating strong and expanding demand*[5] *This growth is expected to* ***intensify competition and amplify affordability pressures globally.***

- ***Shift toward broader value frameworks:*** *Health systems and HTA bodies are moving beyond traditional clinical endpoints to* ***multi-dimensional value assessment****, incorporating* ***equity, productivity, and social determinants of health*** *into decision-making. This reflects a shift toward* ***system-level and preventive value frameworks****, with models such as the*

U.S. VA Whole Health System demonstrating how more holistic approaches can be scaled across populations.[6]

These trends reflect a healthcare environment that is becoming **more selective, more outcome-driven, and more operationally disciplined**. AI is transitioning into core infrastructure, affordability pressures are driving structural changes in pricing and coverage, and innovation is increasingly focused on long-term disease impact. For pharma and medtech companies, this means competing not only on innovation, but on **demonstrated value, access strategy, and execution at scale**. In 2026, advantage will come from aligning innovation with system priorities, not operating ahead of them.

Pharma M&A Activity: Recent Deals and Insights

Pharma M&A activity in early 2026 reflects a shift from broad dealmaking to **fewer, high-conviction transactions focused on differentiated science and platform capabilities**. While total deal momentum remains strong, with Q1 deal value reaching ~$47 billion and multiple $5B+ transactions announced, companies are becoming more selective, prioritizing assets that can materially impact long-term growth. At the same time, **rising competition for a limited pool of high-quality, differentiated assets** and more disciplined valuations are shaping deal behavior. Deal structures are also evolving, with increased use of **milestone-based payments and contingent value rights (CVRs)** to balance risk and valuation uncertainty. Below are four standout transactions that highlight these dynamics.[7]

- ***Gilead Sciences / Tubulis (~$5B):*** *Gilead's acquisition of Germany-based Tubulis strengthens its oncology pipeline through access to* ***next-generation antibody-drug conjugate (ADC) platforms****, including assets targeting ovarian and lung cancers. The deal combines upfront and milestone payments and builds on prior collaboration between the companies. By integrating Tubulis as a dedicated ADC research unit, Gilead is prioritizing* ***platform-based innovation over single-asset acquisition****, enhancing precision oncology capabilities.*[8]

  Implication: *Signals growing competition in ADCs and continued shift toward targeted oncology platforms.*

- ***Novartis / Excellergy (~$2B):*** *Novartis' acquisition of Excellergy expands its immunology portfolio with a* ***next-generation anti-allergy biologic candidate****, strengthening its position amid increasing biosimilar competition to existing therapies like Xolair. The deal aligns with Novartis' broader strategy to deepen its U.S. footprint and invest in differentiated biologics.*[9]

Implication: *Highlights lifecycle management through pipeline reinforcement in competitive biologic markets.*

- ***Eli Lilly / Centessa Pharmaceuticals (up to ~$7.8B):*** *Lilly's acquisition of Centessa reflects a strategic move to diversify beyond its dominant metabolic portfolio into neuroscience, specifically sleep disorders. The deal includes contingent value rights (CVRs), linking payments to regulatory milestones, indicating a more risk-adjusted deal structure.*[10]

  Implication: *Demonstrates increasing use of structured deals (CVRs) to manage uncertainty in high-risk therapeutic areas.*

- ***Novo Nordisk / Vivtex (~$2.1B partnership):*** *Novo Nordisk's partnership with Vivtex focuses on developing* ***next-generation oral biologics for obesity and diabetes****, leveraging Vivtex's proprietary drug-delivery platform. The deal combines licensing, milestone payments, and royalties, with Novo Nordisk leading global development and commercialization.*[11]

  Implication: *Signals increasing investment in delivery platforms and intensifying competition in the obesity and metabolic therapy space.*

These transactions highlight a clear shift toward **precision dealmaking**, where companies prioritize differentiated platforms, high-impact therapeutic areas, and scalable capabilities over broad portfolio expansion. **While oncology remains a key focus, deal activity is broadening into neuroscience, immunology, metabolic diseases, and enabling technology platforms.** At the same time, evolving deal structures and increasing competition for high-quality assets are reinforcing a more disciplined, value-driven approach. In 2026, M&A is less about volume and more about **strategic fit, execution capability, and long-term value creation**.

Regulatory Updates

In early 2026, regulation is shifting from enabling innovation to actively shaping how innovation is evaluated, approved, and accessed across markets. Regulators are moving beyond standalone approvals toward **integrated, lifecycle-based frameworks** that link evidence generation, manufacturing, pricing, and post-market monitoring. At the same time, increasing alignment across agencies and the rise of digital-first regulation are redefining global expectations. These developments signal a transition toward **more coordinated, data-driven, and value-focused regulatory systems**.

- ***FDA biosimilar pathway simplification:*** *In March 2026, the U.S. Food and Drug Administration issued updated draft guidance streamlining biosimilar development by reducing the need for certain clinical pharmacokinetic (PK)*

and comparative efficacy studies. Developers can now leverage non-U.S. comparator data when scientifically justified, potentially reducing development costs by up to ***50% (~$20 million per study)*** *and shortening timelines. With biologics accounting for* ***~51% of drug spending despite only ~5% of prescriptions****, this shift directly targets affordability and access. For pharma, the pathway lowers development burden while maintaining scientific rigor, signaling a move toward* ***efficiency-driven regulation that actively supports cost containment****.*[12]

- ***FDA–EMA AI governance framework:*** *In January 2026, the U.S. Food and Drug Administration and European Medicines Agency jointly published "Guiding Principles of Good AI Practice in Drug Development," establishing the first transatlantic framework governing AI across the product lifecycle. The principles introduce expectations for* ***data provenance, validation, predefined change management, and continuous monitoring****, while aligning with upcoming enforcement under the EU AI Act in August 2026. This marks a shift from exploratory AI use to* ***formal governance and standardized compliance****, requiring companies to embed AI validation and lifecycle controls into development processes.*[13]
- ***EU HTA joint clinical assessment implementation:*** *The EU's Health Technology Assessment (HTA) regulation is now operationalizing, requiring developers to align regulatory and access pathways earlier in development. For products submitted after January 2025, evidence submitted to regulators must simultaneously support* ***Joint Clinical Assessments (JCA)*** *at the EU level, coordinated through the HTA Coordination Group. This reduces duplication across member states but increases upfront evidence requirements, signaling a shift from* ***post-approval reimbursement evaluation to parallel regulatory–HTA decision-making****. For pharma, this strengthens the need for early integration of clinical, economic, and real-world evidence strategies.*[13]
- ***Flexible manufacturing and lifecycle regulation (CMC):*** *Regulators are adopting more adaptive approaches to manufacturing and evidence generation, particularly for complex therapies. In early 2026, the U.S. Food and Drug Administration introduced greater flexibility in chemistry, manufacturing, and controls (CMC) for advanced therapies, allowing real-world and adaptive data to support development and regulatory decisions. This enables faster progression through development stages, particularly for cell and gene therapies, while shifting emphasis toward* ***post-approval monitoring and lifecycle evidence generation.***[14]

These regulatory developments highlight a shift toward lifecycle-based, value-driven, and globally aligned regulation. AI is moving into formal governance frameworks, HTA is becoming integral to regulatory strategy, and manufacturing pathways are becoming more flexible while increasing post-market accountability. At the same time, emerging markets are accelerating digital and adaptive regulatory models. For pharma and medtech companies,

success will depend on integrating regulatory, evidence, and access strategies early in development, as regulatory systems increasingly shape not just approval, but the speed, cost, and reach of innovation globally.

Recent Drug Approvals: Advancing Patient Care

Early 2026 drug approvals reflect a continued shift toward **targeted, high-impact therapies across chronic, rare, and specialty conditions**. Regulators are prioritizing treatments that improve patient adherence, address unmet needs, and deliver differentiated clinical value. Notably, several approvals highlight innovation in **drug delivery, first-in-class mechanisms, and rare disease therapies**, reinforcing a move toward more precise and patient-centric care. These developments will shape competitive positioning, pipeline strategy, and commercialization priorities across pharma and medtech.

- ***Adquey (difamilast, Otsuka Pharmaceutical / Acrotech Biopharma, Feb 12, 2026):*** *Approved for the treatment of mild-to-moderate atopic dermatitis in patients aged 2 and older. This non-steroidal PDE4 inhibitor provides a new topical option, offering improved safety and tolerability for long-term use in dermatology.*

- ***Yuviwel (navepegritide, Ascendis Pharma, Feb 27, 2026):*** *Approved to increase linear growth in pediatric patients with achondroplasia. As a CNP analog prodrug, it represents continued innovation in treating rare genetic growth disorders.*

- ***Loargys (pegzilarginase-nbln, Immedica Pharma, Feb 23, 2026):*** *Approved for Arginase 1 Deficiency, marking the first enzyme replacement therapy for this rare metabolic condition. The approval highlights growing focus on ultra-rare diseases and targeted metabolic interventions.*

- ***Bysanti (milsaperidone, Vanda Pharmaceuticals, Feb 20, 2026):*** *Approved for schizophrenia and bipolar I disorder. This atypical antipsychotic expands treatment options in CNS disorders, addressing ongoing demand for improved safety and efficacy profiles.*

- ***Awiqli (insulin icodec-abae, Novo Nordisk, Mar 26, 2026):*** *Approved as the first once-weekly basal insulin for type 2 diabetes, significantly reducing injection frequency from daily to weekly. This innovation is expected to improve patient adherence and long-term disease management.*

- ***Lifyorli (relacorilant, Corcept Therapeutics, Mar 25, 2026):*** *Approved in combination with nab-paclitaxel for platinum-resistant ovarian cancer. The*

therapy targets a high unmet need in oncology, offering a new option for heavily pretreated patients.

- ***Avlayah (tividenofusp alfa-eknm, Denali Therapeutics, Mar 24, 2026):*** *Approved for neurologic manifestations of Hunter syndrome (MPS II). This therapy addresses central nervous system involvement, a major unmet need in rare genetic disorders.*

- ***Icotyde (icotrokinra, Johnson & Johnson, Mar 17, 2026):*** *A first-in-class oral peptide targeting the IL-23 receptor for moderate-to-severe plaque psoriasis. The approval signals continued innovation in immunology and targeted biologic pathways.*

- ***Lynavoy (linerixibat, GlaxoSmithKline, Mar 17, 2026):*** *Approved for cholestatic pruritus in primary biliary cholangitis. The therapy improves symptom management and quality of life in chronic liver disease.*

- ***Foundayo (orforglipron, Apr 1, 2026):*** *Approved for chronic weight management in adults with obesity or overweight with comorbidities. This oral GLP-1–based therapy reflects continued expansion and competition in the metabolic and obesity treatment landscape.*

Implications for Pharma and Med Tech Companies

The ongoing shift toward **value-driven, selective, and digitally enabled healthcare systems** is reshaping strategic priorities for Pharma and MedTech companies. Increasing affordability pressures, coverage redesign, and expanded HTA frameworks are transforming provider and payer interactions, while the scaling of AI and platform-based innovation is enabling faster, more efficient R&D and operations. Regulatory evolution, from AI governance and lifecycle-based approvals to integrated evidence and access pathways, provides clearer but more demanding routes to market, and recent drug approvals highlight continued momentum in high-impact therapies across metabolic disease, oncology, rare conditions, and specialty care. Companies that align portfolios with these trends, integrate regulatory and access strategies early, and invest in scalable, patient-centric capabilities can capture market share, accelerate innovation, strengthen partnerships, and lead in an increasingly competitive global healthcare ecosystem.

ANSEA supports organizations in navigating this complexity, unlocking value through strategic insights, grounded analysis, and a deep understanding of the healthcare environment.

About ANSEA

ANSEA is a global healthcare consulting firm dedicated to improving patient outcomes for public and private sector institutions. Our expertise ranges from Commercial Planning, Market Access, Health Systems Research, Stakeholder Engagement and Health Economics and Outcomes Research. We provide innovative solutions and local insights to support clients worldwide.

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