



Dear Valued Client,

Welcome to the first edition of ANSEA Insights for 2026. As we step into the new year, the healthcare landscape is evolving rapidly, driven by value-based care, resilient health systems, and technological innovations. This edition highlights emerging trends such as continuous manufacturing, AI-driven therapeutics, integrated care models, and patient-centered regulatory frameworks that are shaping how pharma and MedTech companies deliver measurable value.

At ANSEA, we are committed to providing you with timely, actionable intelligence. Alongside insights into M&A activities, regulatory updates, and novel drug approvals, we examine the implications of these developments for companies navigating innovation, portfolio expansion, and strategic partnerships. Whether optimizing pipelines, embracing adaptive regulatory pathways, or exploring scalable operational models, our insights aim to guide your strategic decisions in a complex and rapidly changing 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 enter 2026, focus is shifting from incremental change to structural transformation. Across markets, leaders are prioritizing outcomes-based care, stronger system resilience, and smarter operational models that can scale under pressure. The common thread is clear: better health impact, delivered more efficiently, with measurable results. Below are three trends shaping near-term strategy and investment decisions globally.

1. Accelerated Value-Based Care Adoption

Value-based care is moving from pilots to scaled execution as providers seek measurable outcomes, cost containment, and improved chronic disease management. Leaders are increasingly prioritizing contracts that reward outcomes rather than volume, enabling more proactive, data-driven population health strategies.

- **Mandatory Bundles:** *Value-based care is scaling through Medicare's Transforming Episode Accountability Model (TEAM), an episode-based payment model linking hospital reimbursement to the quality and cost of defined surgical episodes. Starting Jan 2026 for five years, it introduces mandatory participation for selected hospitals across the select US regions. With graduated risk tracks, TEAM supports a phased move toward greater accountability. The model strengthens incentives for improved care coordination, post-acute transitions, and fewer avoidable readmissions.¹*
- **SDOH Integration:** *Embedding social determinants of health (SDoH) into routine care is enhancing value-based outcomes. North Carolina's NCCARE360 connects health systems with 1,000+ community organizations to screen for food, housing, and transport risks. When patients flag barriers, referrals are triggered instantly with closed-loop confirmation to providers. In 2025 pilots, 30-day readmissions dropped 22% for high-risk Medicaid patients, and participating systems reported \$4.2M first-year savings from fewer emergency visits.²*

2. Building Global Health System Resilience

Resilience is no longer a crisis-response concept, it is becoming a permanent health system design priority. Governments and global stakeholders are focusing on primary care, supply chains, and financing models that protect continuity of services. In 2026, countries that invest in resilience will be better positioned to manage outbreaks, workforce strain, and chronic disease burdens.

- **Primary Care–Led Resilience:** Building resilient health systems is increasingly anchored in primary care, financing reform, and service continuity rather than emergency response alone. Under the World Bank–supported National Health Compact framework, Kenya has committed to increasing public health spending toward 5% of GDP and expanding health insurance coverage from ~26% to ~85%, with subsidies for vulnerable populations. These reforms prioritize primary care strengthening, health workforce expansion, and financial protection as core resilience levers.³
- **Governance Reset:** Global health governance is being streamlined to reduce fragmentation and boost efficiency. In Jan 2026, WHO endorsed merging UN80 proposals with 30+ UN health entities, targeting 80% overlap reduction. Early steps include integrating UNAIDS programs and consolidating 15 regional offices into 5, enabling countries like Nigeria and Ethiopia to co-lead vaccine deals with 30% tech transfer. \$10B annual pandemic funding will flow through a single fund, cutting emergency response from 45 to 12 days, while low-income countries gain governance power, including veto rights over 20% of global health priorities.⁴

3. Pharma Pivot to Continuous Manufacturing

Pharmaceutical manufacturing is shifting toward faster, more flexible production models as the industry balances cost pressures with supply reliability. Continuous manufacturing is emerging as a strategic lever to shorten timelines, improve quality control, and scale output rapidly. In 2026, this trend will be critical for both operational resilience and competitive advantage.

- **Cycle Compression:** Continuous processes are reducing timelines and improving quality. Novartis moved Cosentyx production to continuous manufacturing in late 2025, cutting batch cycles from 120 to 21 days with real-time quality monitoring. Costs fell over 30% and batch failures dropped below 1%. Flexible output allows faster supply to key markets, potentially adding billions in revenue by 2027. However, this model concentrates operational risk, as system failures or regulatory re-validation can disrupt continuous output more sharply than traditional batch manufacturing.⁵
- **Smart Modular Plants:** Pfizer’s VERBATIM platform across U.S. and European facilities improved yields from 72% to 90% on top oral solid lines. Modular “smart factories” enable rapid product switches, cutting changeover from 14 days to 36 hours while maintaining near-total supply continuity. High-demand periods, like the 2025 holiday surge, were managed without stockouts. Continuous lines are now strategic assets for real-time demand response, making adaptable manufacturing a key competitive advantage in 2026.⁶

These trends highlight how healthcare and life sciences are evolving toward efficiency, resilience, and outcome-driven models. From value-based care and *social determinants of health (SDoH)* integration to resilient health systems and flexible pharma manufacturing, innovation is redefining delivery and operations. Organizations embracing these shifts will improve patient outcomes, optimize resources, and respond faster to market demands. 2026 is shaping up as a year where strategic adoption turns potential into measurable impact.

Pharma M&A Activity: Recent Deals and Insights

Pharma M&A in Q4 2025–Jan 2026 marked a strong resurgence, with total strategic deal value up **79% from 2024** levels. Big pharma dominated, targeting biotech innovators in oncology, neurology, and specialty care to address pipeline gaps and patent cliffs. Larger average deal sizes and high-impact therapeutics drove this momentum. Below are four standout transactions that reshaped the competitive landscape.⁷

- **Merck & Co. / Cidara Therapeutics:** Merck & Co. announced its acquisition of Cidara Therapeutics for \$9.2 billion in November 2025, strengthening its antifungal portfolio through Cidara's innovative drug-Fc conjugate (DFC) therapeutics. This strategic move addresses rising resistant infections while expanding Merck's leadership in infectious diseases. The deal is expected to accelerate regulatory approvals and provide access to new market opportunities. By integrating Cidara's platform, Merck positions itself to capture a larger share of the growing antifungal market.⁸
- **Johnson & Johnson / Halda Therapeutics:** In November 2025, Johnson & Johnson acquired Halda Therapeutics for \$3.05 billion, gaining access to Halda's Regulated Induced Proximity Targeting Chimera platform for oral targeted therapies in solid tumors. The acquisition strengthens J&J's oncology pipeline and supports faster market entry for differentiated treatments in immuno-oncology. By incorporating Halda's platform, J&J is poised to deliver more precise therapies to patients while maintaining a competitive edge.⁹
- **Johnson & Johnson / Intra-Cellular Therapies:** Johnson & Johnson completed the \$14.6 billion acquisition of Intra-Cellular Therapies in January 2026, marking the largest deal of the period. The transaction secures Intra-Cellular's neurology assets, including CAPLYTA for bipolar disorder and schizophrenia, supporting J&J's push into CNS therapeutics. This acquisition positions the company as a leader in neuroscience with blockbuster potential, offsetting revenue pressures from other patent expirations. By integrating these assets,

J&J strengthens its long-term growth in precision neurology and mental health care.¹⁰

- **Sanofi / Dynavax Technologies:** Sanofi acquired Dynavax Technologies for \$2.2 billion in early 2026, expanding its vaccine portfolio with Dynavax's CpG 1018 adjuvant technology. This addition enhances Sanofi's ability to develop next-generation vaccines and broadens its immunology offerings. The transaction supports faster vaccine innovation and strengthens the company's position in infectious disease prevention.¹¹

These deals highlight big pharma's focus on transformative acquisitions in oncology, neurology, and vaccines, prioritizing scale and strategic value over incremental additions. They reflect a deliberate push to bolster late-stage pipelines, expand innovative platforms, and address evolving patient needs. M&A activity is expected to remain robust in 2026, with precision medicine, specialty therapies, and high-impact technologies leading the way.

Regulatory Updates

Q4 2025–Jan 2026 saw landmark regulatory developments reshaping healthcare, digital health, and patient access worldwide. From AI integration in therapeutics to rare disease frameworks, flexible manufacturing, and healthcare system reforms, agencies are prioritizing innovation, patient empowerment, and efficiency. These updates signal a strategic shift toward adaptive, data-driven regulation with global influence.

- **MHRA Rare Therapies:** *The UK's MHRA introduced a new regulatory pathway for rare disease therapies in late 2025, spanning early engagement through post-market surveillance. In collaboration with HTA bodies and the NHS, the framework prioritizes flexible evidence generation to accelerate patient access while maintaining safety and system sustainability. Pharma benefits from proportionate licensing, reducing development burdens for orphan drugs, and enabling faster market entry. Globally, this guidance encourages international alignment, influencing EU and worldwide rare disease strategies through ongoing consultations.¹²*
- **FDA AI Framework:** *In December 2025, the FDA launched a comprehensive AI/ML regulatory framework, updating guidance for digital health tools and predictive algorithms in drug development. The framework, led by CDER and CDE, accelerates approvals for AI-driven diagnostics and personalized therapies while enforcing transparency in model validation. Providers gain validated tools for precision care, and pharma benefits from clearer pathways, reducing approval timelines by up to 30%. Industry-wide, it sets a precedent*

for ethical AI integration, shaping global standards including EMA and other jurisdictions.¹³

- **OBBBA Healthcare Overhaul:** *The One Big Beautiful Bill Act (OBBBA), signed in July 2025, triggers major CMS regulatory rollouts starting January 2026, transforming Medicaid, Medicare, and ACA frameworks. Expanding coverage timelines and streamlining eligibility, it empowers patients and reduces bureaucratic hurdles nationwide. Pharma faces recalibrated pricing and formulary dynamics, while providers gain flexibility in value-based care models. Globally, it serves as a precedent for bold reforms, influencing emerging markets' affordability and innovation strategies.¹⁴*
- **FDA Flexible CMC Approach:** *On January 11, 2026, the FDA introduced a "flexible approach" to chemistry, manufacturing, and controls (CMC) for certain biologics, easing rigid preclinical requirements. Led by CDER, the framework allows real-world data to supplement traditional testing, speeding Phase 3 transitions by 6–12 months for complex therapies. Biopharma can optimize supply chains and scale production faster, while patients gain earlier access to innovative treatments amid potential shortages. This regulatory shift modernizes FDA agility and aligns with non-animal testing trends for sustainable development.¹⁵*

These regulatory developments illustrate a shift toward adaptive, patient-centered, and innovation-driven frameworks. By integrating AI guidance, rare disease pathways, healthcare overhauls, and flexible manufacturing standards, regulators are enhancing access, accelerating approvals, and reshaping system incentives. Healthcare and pharma stakeholders must monitor these evolving policies closely to optimize strategy, maintain compliance, and capture opportunities in a rapidly changing global landscape.

Recent Drug Approvals: Advancing Patient Care

Regulatory developments from late 2025 into early 2026 signal a clear shift toward more adaptive, innovation-ready healthcare frameworks. Across markets, policymakers are tightening expectations on affordability and transparency while creating faster, clearer pathways for emerging technologies like AI and rare disease therapies. These updates will directly shape market access, evidence requirements, and go-to-market strategies for healthcare stakeholders in 2026¹⁶:

- **Kygevvi (doxecitine and doxribtimine, UCB, Inc, Nov 3, 2025):** *To treat thymidine kinase 2 deficiency in patients who start showing symptoms at age 12 or younger.*

- **Komzifti (ziftomenib, Kura Oncology/Kyowa Kirin, Nov 13, 2025):** For adults with relapsed or refractory acute myeloid leukemia with a susceptible nucleophosmin 1 mutation and no satisfactory alternative treatments.
- **Redempro (plozasiran, Nov 18, 2025):** To reduce triglycerides in adults with familial chylomicronemia syndrome.
- **Hyrnuo (sevabertinib, Bayer Healthcare Pharmaceuticals, Nov 19, 2025):** To treat locally advanced or metastatic non-squamous non-small cell lung cancer with activating HER2 tyrosine kinase mutations in patients who received prior systemic therapy.
- **Voyxact (sibeprenlimab-szsi, Nov 25, 2025):** To reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk for disease progression.
- **Lerochol (lerodalcibep-liga, Alnylam Pharmaceuticals, Dec 12, 2025):** To reduce LDL cholesterol in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia, as an adjunct to diet and exercise.
- **Nuzolvence (zoliflodacin, Innoviva, Dec 12, 2025):** For uncomplicated urogenital gonorrhea.
- **Cardamyst (etripamil, Milestone Pharmaceuticals, Dec 12, 2025):** To treat episodes of paroxysmal supraventricular tachycardia (PSVT) as a self-administered nasal spray for adults.
- **Exdensur (depemokimab-ulaa, GSK, Dec 16, 2025):** For severe asthma with an eosinophilic phenotype as an add-on maintenance therapy.
- **Myqorzo (aficamten, Cytokinetics, Dec 19, 2025):** For symptomatic obstructive hypertrophic cardiomyopathy.
- **Yartemlea (narsoplimab-wuug, Omeros Corporation, Dec 23, 2025):** For hematopoietic stem cell transplant-associated thrombotic microangiopathy.
- **Nereus (tradipitant, Vanda Pharmaceuticals/Eli Lilly, Dec 30, 2025):** Approved for motion sickness vomiting.
- **Zycubo (copper histidinate, Sentynl Therapeutics/Cyprium Therapeutics, Jan 12, 2026):** Approved for treating Menkes disease. Originally developed by Cyprium Therapeutics, with Sentynl completing final development and FDA submission. Cyprium retains eligibility for royalties and milestones on Zycubo sales.

Implications for Pharma and Med Tech Companies

The ongoing shift toward outcome-driven, resilient, and digitally enabled care continues to create strategic opportunities for Pharma and MedTech companies. Value-based care models, global health system strengthening, and social determinants integration are reshaping provider and payer interactions, while innovations in continuous manufacturing and modular production enable faster, more flexible supply chains. Regulatory advances, from AI/ML frameworks to rare disease pathways and comprehensive healthcare reforms—provide clearer pathways for approvals and market entry, and novel drug launches signal high-impact therapeutic opportunities across oncology, rare diseases, and specialty care. Companies that align portfolios with these trends, embrace adaptive regulatory strategies, and invest in scalable, patient-centered operational models can capture market share, accelerate innovation, strengthen partnerships, and lead in the evolving global healthcare ecosystem.

ANSEA supports organizations in navigating this transformation, 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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