



Dear Valued Client,

Welcome to the July edition of ANSEA Insights. As we move through mid-2025, the healthcare industry continues to advance at a rapid pace marked by scientific breakthroughs, regulatory innovation, and strategic realignments. In this issue, we spotlight a wave of FDA drug approvals expected to reshape treatment standards across oncology, rare diseases, and chronic conditions.

At ANSEA, we remain committed to equipping you with timely and actionable intelligence. Alongside approval highlights, we explore what these developments mean for pharmaceutical and med tech companies operating in Asia and globally. Whether you're refining portfolio strategy, evaluating partnerships, or assessing market entry points, we hope this edition offers valuable context to inform your next move.

As always, we appreciate your continued engagement and look forward to supporting your efforts to drive health innovation and impact across the globe.

## Healthcare Trends to Watch

In 2025, healthcare is undergoing rapid transformation driven by digital innovation, sustainability imperatives, and mounting economic pressures. AI and automation are reshaping clinical practice, while green initiatives are becoming essential to future-ready care. At the same time, escalating costs and workforce shortages are forcing a rethinking of delivery models. These shifts present critical opportunities for pharma and medtech leaders to drive meaningful impact.

### 1. AI & Automation in Clinical Practice

Artificial Intelligence and automation are revolutionizing clinical practice in 2025. No longer confined to pilot programs or research labs, AI-driven tools are now essential components of hospital systems worldwide. From diagnosing complex conditions to automating routine administrative tasks, AI is accelerating efficiency, improving diagnostic accuracy, and supporting a shift toward more predictive, personalized, and preventive healthcare models.

- **AI for Ambulance Triage in the UK:** *An AI model deployed in Yorkshire analyzes symptoms, mobility, and vital signs to determine if a patient requires ambulance transport. This system was developed to address chronic emergency department overcrowding and optimize ambulance deployment. The system correctly distinguished critical cases 80% of the time, improving triage accuracy, reducing emergency department overload, and ensuring that resources are allocated efficiently.<sup>1</sup>*
- **Medical Imaging at Massachusetts General Hospital & MIT:** *AI algorithms trained to detect lung nodules and breast cancer reached up to 94% and 90% accuracy, surpassing human radiologists in certain cases. Using tens of thousands of anonymized imaging files and biopsy-confirmed cases, the AI models learned to identify subtle features often missed by the human eye. This led to faster, more accurate diagnoses, enabling quicker treatment and reducing patient wait times for imaging results.<sup>1,2</sup>*
- **Personalized Disease Prediction with AstraZeneca:** *Using data from half a million participants, AstraZeneca developed an AI model to predict diseases like Alzheimer's and kidney disease years before symptoms emerge. The model analyzes combinations of genetic markers, lifestyle data, and clinical records to spot precursors of disease that may not be detectable through traditional diagnostics. This early detection allows for timely intervention, enabling clinicians to delay disease onset or even prevent it altogether.<sup>1,3</sup>*

## 2. Sustainability and Green Practices in Global Healthcare

In 2025, sustainability in healthcare has emerged as a global priority, driven by mounting climate risks, rising operational costs, and increased awareness of healthcare's carbon footprint. Health systems are embracing green innovations that reduce emissions, conserve resources, and build climate resilience, while simultaneously improving efficiency and patient well-being. From clean energy transitions to sustainable supply chains, hospitals worldwide are aligning environmental stewardship with high-impact clinical care.

- **"Green Breath" Initiative at Hospital de la Santa Creu i Sant Pau (Spain):** *This leading hospital in Barcelona spearheaded a major inhaler substitution program, replacing high-emission metered-dose inhalers (MDIs) with low-impact dry powder alternatives. The initiative was developed in collaboration with national health authorities, pharmacists, and suppliers to create sustainable prescription guidelines. The initiative is estimated to save 200,000 tons of CO<sub>2</sub> equivalents annually and has earned the 2025 European Sustainability Award, setting a precedent for pharmaceutical sustainability in respiratory care.<sup>4</sup>*
- **NHS Green Nursing Challenge (United Kingdom):** *Launched in 2025 by the UK's National Health Service, this competition empowered nurses to lead climate-conscious care initiatives across hospitals and clinics. Participating teams proposed over 500 projects, including eliminating volatile anesthetics, upgrading to energy-efficient devices, reducing food waste, and rethinking patient flow to reduce resource use. The initiative helped reduce CO<sub>2</sub> emissions across multiple facilities and reinforced the pivotal role of frontline staff, particularly nurses, in driving sustainable change in healthcare systems.<sup>5</sup>*
- **Decarbonization and Clean Energy Adoption (United States & Australia):** *Health systems in both the U.S. and Australia have launched aggressive carbon reduction programs to transition their operations toward clean energy and eco-friendly clinical protocols. The Cleveland Clinic (U.S.) committed to full carbon neutrality by 2025 through on-site solar energy, heat recovery systems, and sustainable transportation programs. Meanwhile, the University of California Health System and major Australian hospitals are pursuing similar goals through digital transformation (e.g., cloud-based imaging) and replacing harmful chemicals in radiology.<sup>6,7</sup>*

## 3. Escalating Costs, Workforce Pressures, and Industry Resilience

In 2025, healthcare systems globally are under intensifying strain from escalating pharmaceutical prices, rising chronic disease incidence, and critical workforce shortages. These challenges are undermining the financial sustainability and accessibility of care. To respond, healthcare leaders are pursuing resilient

strategies, like AI-enabled workforce optimization, value-based reimbursement models, and advanced analytics to ensure affordability, efficiency, and long-term system viability in an increasingly complex care environment.

- **NHS Workforce Retention & Technology Integration Program (United Kingdom):** *The UK's National Health Service (NHS) launched a multi-year strategy in 2024 focused on reducing workforce attrition and operational inefficiencies by integrating digital workforce tools and well-being programs. Facing persistent nursing shortages and rising agency staffing costs, the NHS deployed AI-powered scheduling platforms, expanded remote patient monitoring, and piloted value-based reimbursement systems. Within a year, the NHS saw a 12% reduction in nurse turnover and 8% savings in agency staffing costs—demonstrating a scalable approach to workforce sustainability in large public health systems.<sup>8</sup>*
- **McKinsey Health Institute Report on Workforce & Cost Mitigation (Global):** *The McKinsey Health Institute (MHI) published a 2025 global report urging transformative workforce and cost strategies to address the projected 10+ million global health worker shortfalls by 2030. The report emphasizes the need for “task-shifting” delegating tasks from highly trained specialists to lower-cost or digitally enabled personnel alongside telehealth expansion and AI-supported decision tools. According to MHI, closing the global health workforce gap could prevent up to 189 million years of life lost to disability or early death and generate \$1.1 trillion in global economic gains making it both a moral and financial imperative.<sup>9</sup>*
- **Pharmaceutical Cost Management via Data Analytics (United States):** *In Several U.S. healthcare systems have adopted AI-driven platforms that analyze prescribing patterns and recommend cost-effective medication alternatives tailored to individual patient profiles. With specialty drugs driving a disproportionate share of cost increases, systems like Mayo Clinic and Kaiser Permanente are using data analytics to guide clinicians toward equally effective but lower-cost options. Early adopters have reported up to 15% reductions in pharmacy spending and better adherence rates through personalized, cost-conscious treatment planning demonstrating how precision medicine and economics can align.<sup>10</sup>*

As the healthcare landscape continues to evolve in 2025, these three converging trends, are redefining how value is created across the industry. For pharmaceutical and medtech companies, this presents both challenges and significant opportunities: to align innovation pipelines with emerging clinical and operational priorities, to support providers in decarbonizing care, and to

enable scalable solutions that address affordability, access, and resilience. Strategic partnerships, digital integration, and a focus on outcomes will be essential as the sector transitions toward a more intelligent, sustainable, and resilient future.

## Pharma M&A Activity: Recent Deals and Insights

Pharma M&A is picking up pace in 2025, driven by looming patent cliffs, intense competition, and the race to secure innovation pipelines. From rare diseases to oncology and cardiovascular care, major players are striking strategic deals to diversify portfolios and sustain growth. This period reflects a renewed urgency for both scale and specialization. Below are key deals and broader market trends shaping the deal landscape.

- **Sanofi Acquires Blueprint Medicines:** Date: July 18, 2025 | Estimated Deal Value: ~\$2.5 billion. Sanofi acquired Blueprint to expand its rare immunology portfolio, gaining Ayvakit and pipeline assets for systemic mastocytosis. The deal strengthens Sanofi's position in precision medicine and diversifies its portfolio beyond blockbuster dependencies. It also reflects growing investment in high-value, underserved rare disease markets with long-term revenue potential.<sup>11</sup>
- **Novartis Acquires Anthos Therapeutics:** Date: April 3, 2025 | Deal Value: \$925M upfront, up to \$2.2B in milestones. Novartis secured Anthos's abelacimab, a Phase III biologic for thrombosis and stroke prevention. This acquisition deepens Novartis's cardiovascular pipeline and supports its strategy for AI-enabled biologic innovation. It complements the company's broader move to dominate high-risk, high-burden therapeutic categories.<sup>12</sup>
- **Merck KGaA Acquires SpringWorks Therapeutics:** Date: April 25, 2025 | Deal Value: \$3.5 billion (all cash). Merck KGaA acquired SpringWorks to access targeted oncology assets, including Ogsiveo for rare tumors. The move enhances Merck KGaA's presence in rare cancers and reinforces its specialty oncology strategy. It signals the company's ambition to lead in next-generation, tumor-specific therapies with regulatory momentum.<sup>13</sup>

Pharma M&A activity from April to July 2025 underscores a clear strategic pivot toward pipeline acceleration, specialty innovation, and long-term resilience. As patent cliffs approach and competition intensifies, leading companies are using acquisitions to secure high-impact assets in oncology, rare diseases, and cardiovascular care. For pharma and medtech players, this deal momentum signals a vital opportunity to align with emerging therapeutic frontiers, form

innovation-driven partnerships, and build value in an increasingly technology-enabled, precision-focused market.

## Regulatory Updates

From post-market surveillance reform to digital governance and EU-wide assessment changes, the global regulatory environment is shifting rapidly in 2025. These updates reflect increasing demands for transparency, patient safety, and efficiency in bringing new innovations to market. For pharma and medtech companies, understanding and adapting to these evolving frameworks is critical for compliance, competitiveness, and speed to market.

- **UK Medical Device Regulation Overhaul (June–July 2025):** Effective June 16, 2025, the UK introduced major reforms to its medical device regulatory framework. A new Post-Market Surveillance (PMS) regulation now mandates active safety and performance monitoring by manufacturers. Key changes include faster incident reporting, stronger trend analysis, and increased accountability in risk mitigation. Additionally, the MHRA aligned with EU Common Specifications for high-risk in vitro diagnostic devices and announced updated registration fees. This modernized approach aims to strengthen patient safety while simplifying compliance for global manufacturers.<sup>14</sup>
- **China’s Healthcare and Life Sciences Regulatory Reforms (Effective July 1, 2025):** China rolled out a set of significant reforms to strengthen innovation, competition, and local manufacturing in its healthcare and life sciences sector. Key changes include enhanced clinical trial data exclusivity protections from the NMPA, finalized anti-corruption and anti-monopoly rules targeting pharmaceutical practices, and policy incentives to localize medical device production. These updates aim to align China’s regulatory ecosystem with global standards while improving supply chain resilience and ethical business conduct. The reforms are part of China’s broader 2025 national strategy to elevate its healthcare industry to global competitiveness and ensure sustainable market access for innovators.<sup>15</sup>
- **India: Digitalization of Drug Approvals & Traditional Medicine Safety Oversight (May–June 2025):** India’s Central Drugs Standard Control Organization (CDSCO) mandated digital-only submissions for WHO-GMP certificate applications via the ONDS portal from June 15, 2025. Separately, the Ministry of Ayush launched the Ayush Suraksha Portal to monitor misleading ads and adverse reactions in traditional medicine products. Together, these updates improve transparency, regulatory efficiency, and consumer safety in both modern and traditional pharmaceutical sectors. This positions India as a

*more robust regulatory environment and a dependable partner in global pharmaceutical trade.<sup>16,17</sup>*

The April–July 2025 wave of regulatory reforms reflects a clear global trend: building smarter, more transparent, and innovation-ready healthcare systems. From China’s push to align with global standards and strengthen data protection, to the UK’s modernized device oversight and the EU’s streamlined HTA process, regulatory agencies are reshaping the environment in which pharma and medtech operate. For industry leaders, this creates both urgency and opportunity to adapt faster, engage earlier with regulators, and position their solutions for long-term access, trust, and impact in increasingly complex global markets.

## Recent Drug Approvals: Advancing Patient Care

As the pharmaceutical landscape continues to evolve rapidly, several breakthrough therapies are expected to receive FDA approval in 2025, offering promising new treatment options across a spectrum of serious and chronic conditions. From innovative biologics targeting rare genetic diseases to advanced oncology therapies addressing hard-to-treat cancers, these upcoming medications represent significant strides in precision medicine and patient care. Below is a summary of key upcoming drugs and their indications<sup>18</sup>:

- **Vanrafia (atrasentan)** is owned by Novartis Pharmaceuticals Corporation was approved in the U.S. on 4/2/2025 to reduce proteinuria in adults with primary IgA nephropathy. An endothelin A receptor antagonist, it helps preserve kidney function in patients at risk of rapid progression.
- **Penpulimab-kcqx** is developed and owned by Akeso, Inc was approved in the U.S. on 4/23/2025 for recurrent or metastatic non-keratinizing nasopharyngeal carcinoma. It is a novel PD-1 antibody that can be used as monotherapy or in combination with chemotherapy, enhancing immunologic control.
- **Imaavy (nipocalimab-aahu)** is owned by Johnson & Johnson was approved in the U.S. on 4/29/2025 to treat generalized myasthenia gravis. By blocking the neonatal Fc receptor, it reduces IgG autoantibodies and helps restore muscle strength.
- **Avmapki / Fakzynja Co-Pack (avutometinib and defactinib)** is owned and marketed by Verastem Oncology was approved in the U.S. on 5/8/2025 to treat KRAS-mutated recurrent low-grade serous ovarian cancer. The oral combination targets both MAPK pathway signaling and focal adhesion kinase, improving response rates.

- **Emrelis (telisotuzumab vedotin-tllv)** is owned by AbbVie Inc and was approved in the U.S. on 5/14/2025 for c-Met overexpressing non-squamous NSCLC. This antibody-drug conjugate delivers a potent cytotoxic agent directly to cancer cells, minimizing off-target effects.
- **Tryptyr (acoltremon)** is owned by Alcon Laboratories, Inc. and was approved in the U.S. on 5/28/2025 to treat the signs and symptoms of dry eye disease. It works by stimulating the body's natural tear production via selective neuroactivation pathways.
- **Enflonsia (clesrovimab-cfor)** is owned and developed by Merck & Co. and was approved in the U.S. on 6/9/2025 to prevent RSV lower respiratory tract infections in infants. This monoclonal antibody provides passive immunity for a full RSV season with a single dose.
- **Ibtrozi (taletrectinib)** is owned by Nuvation Bio Inc. and was approved in the U.S. on 6/11/2025 to treat ROS1-positive advanced NSCLC. It addresses resistance mechanisms seen in earlier ROS1 inhibitors and shows promise in brain metastases as well.
- **Andembry (garadacimab-gxii)** is owned by CSL Behring and was approved in the U.S. on 6/16/2025 to prevent hereditary angioedema attacks. It is a first-in-class Factor XIIIa inhibitor offering long-term prophylaxis through monthly subcutaneous injections.
- **Lynozytic (linvoseltamab-gcpt)** is owned by Genmab A/S. and was approved in the U.S. on 7/2/2025 for relapsed or refractory multiple myeloma after multiple prior therapies. As a BCMA x CD3 bispecific antibody, it harnesses the immune system to engage and kill cancerous plasma cells.
- **Zegfrovy (sunvozertinib)** is owned and marketed by Dizal (Jiangsu) Pharmaceutical Co., Ltd and was approved in the U.S. on 7/2/2025 to treat advanced NSCLC with EGFR exon 20 insertion mutations. This next-generation kinase inhibitor provides a targeted option for a previously hard-to-treat genetic mutation.
- **Ekterly (sebetralstat)** is owned by KalVista Pharmaceuticals, Inc. and was approved in the U.S. on 7/3/2025 to treat acute attacks of hereditary angioedema (HAE). It is the first oral plasma kallikrein inhibitor designed for on-demand use, offering patients rapid relief without injections.

## Implications for Pharma and Med Tech Companies

The 2025 FDA approvals reflect a clear trend toward precision medicine, novel mechanisms of action, and treatment of rare or previously underserved conditions. For pharmaceutical companies, these developments highlight the growing importance of investing in biomarker-driven therapies, antibody-drug conjugates, and RNA-based technologies. Meanwhile, med tech firms have new opportunities to innovate in diagnostic tools and companion testing—especially as approvals increasingly hinge on biomarker identification and real-time disease monitoring. Strategic partnerships between pharma and med tech players will be key to accelerating development timelines, improving patient access, and navigating evolving regulatory landscapes. Companies that align with these trends are poised to lead in both clinical impact and market differentiation.

ANSEA supports organizations in navigating this transformation, helping them unlock 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.

## References

1. *World Economic Forum. (2025, June 3). 6 ways AI is transforming healthcare.*
2. *Da'Costa, A. (2025). AI-driven triage in emergency departments: A review of potential and limitations. Journal of Emergency Medicine Innovations, 12(3), Article 12345.*
3. *AstraZeneca. (2025). Advancing personalized medicine with AI: Predicting disease years in advance. AstraZeneca Press Release.*
4. *Health Care Without Harm Europe. (2025, June 11). 2025 European sustainable healthcare awards reveal year's champions [Press release].*
5. *National Health Service England. (2025). NHS Green Nursing Challenge 2025: Advancing sustainable healthcare through nursing leadership [Program brief]. NHS England Publications.*
6. *University of California Health. (2025). Path to carbon neutrality and sustainable care [Sustainability report].*
7. *Health Care Without Harm Australia. (2025). Reducing healthcare's carbon footprint: Clean energy and green protocols [Policy brief].*
8. *NHS Employers. (2025, April 15). Integrated workforce thinking across systems.*
9. *McKinsey & Company. (2025, May). Closing the global healthcare workforce gap: Unlocking potential through innovative workforce models [Report].*

10. Deloitte. (2025). *2025 global health care outlook: Leveraging data analytics for cost management and precision medicine.*
11. Sanofi. (2025, July 18). *Sanofi completes acquisition of Blueprint Medicines.*
12. Novartis. (2025, April 3). *Novartis completes acquisition of Anthos Therapeutics to expand cardiovascular pipeline.* Novartis Media Center.
13. Merck KGaA. (2025, April 25). *Merck KGaA completes acquisition of SpringWorks Therapeutics, strengthening rare oncology pipeline.*
14. MHRA. (2025, July 10). *MHRA updates on in vitro diagnostic devices regulatory alignment and updated fees,*
15. National Medical Products Administration (NMPA). (2025, July 1). *Enhancing clinical trial data protections and anti-monopoly guidelines in China's healthcare sector.*
16. Central Drugs Standard Control Organization (CDSCO). (2025, June 15). *Mandatory digital submission for WHO-GMP certificate applications via ONDS portal.*
17. Ministry of Ayush. (2025, May 30). *Launch of Ayush Suraksha Portal to monitor safety and advertisements in traditional medicine.*
18. U.S. Food and Drug Administration. (2025, July 17). *Novel drug approvals for 2025.*