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ANSEA INSIGHTS

Newsletter 2025 | April Edition

Dear Valued Client,

Welcome to the latest edition of ANSEA Insights. As we enter into the second quarter of 2025, we are dedicated to keeping you informed and ahead in the dynamic healthcare landscape. Building on the success of our first edition, this issue continues our goal of sharing timely, relevant, and strategic updates that matter to your business.

At ANSEA, we are driven by a deep understanding of the forces shaping healthcare across Asia and beyond. In this edition, we focus on emerging trends, deal activity, regulatory shifts, and the latest drug approvals—offering you a concise view of key developments that could influence strategic decisions.

As always, we hope this collection of insights empowers your planning, sparks ideas, and strengthens our shared mission of advancing health outcomes across the region.

Healthcare Trends to Watch

Healthcare is evolving rapidly through breakthroughs in genomics, digital innovation, and pharmaceutical development. Genomic technologies are reshaping care from treatment to prevention, with major strides in personalized medicine. Emerging digital health trends—such as remote monitoring, telemedicine, and AI-powered diagnostics—are enhancing patient engagement and transforming chronic disease management. Meanwhile, GLP-1 receptor agonists are transforming into multi-disease therapeutics.

1. Genomics: Transforming Healthcare from Treatment to Prevention

Genomics is revolutionizing healthcare by shifting the focus from treating diseases to preventing them. By analysing genetic predispositions, healthcare professionals can identify risks early, enabling personalized prevention strategies, targeted therapies, and improved disease management. This approach is particularly impactful in cancer treatment, rare diseases, and neurodegenerative conditions like Alzheimer's, where early interventions can significantly improve outcomes. A few examples of advancement in genomics are stated below:

- ***Moderna & Merck's Cancer Vaccine Trials (Ongoing in 2025):*** *Developing individualized cancer vaccines based on genomic insights.[1] Moderna's platform uses next-generation sequencing to analyse tumour DNA mutations unique to each patient. The vaccine primes T-cells to recognize neoantigens, while Merck's Keytruda (pembrolizumab) removes PD-1-mediated immune suppression. Combined approach enhances cytotoxic T-cell activity against residual cancer cells post-surgery.*
- ***Genomics Australia (Launching 2025):*** *A government-funded initiative integrating genomic research into patient care to advance cancer and rare disease treatment.[2]*
- ***Genome UK Strategy (2022–2025):*** *Aims to sequence 500,000 genomes with £105M for rare disease research and £22M for equitable genomic access.[3] Moderna's platform uses next-generation sequencing to analyze tumor DNA mutations unique to each patient. The vaccine primes T-cells to recognize neoantigens, while Merck's Keytruda (pembrolizumab) removes PD-1-mediated immune suppression. Combined approach enhances cytotoxic T-cell activity against residual cancer cells post-surgery.*

2. **Telemedicine and Digital Health: Enhancing Access While Preserving Human Connection**

   The integration of digital tools into healthcare—such as telemedicine, AI-driven diagnostics, and electronic health records—is transforming how care is delivered. These technologies improve accessibility, continuity, and efficiency, particularly for chronic disease management and remote consultations. Yet, human interaction remains central to effective care. This balance of digital innovation with personal connection is reshaping patient journeys and healthcare systems around the world

   - ***LuxMed Mental Health Clinics Poland (2025):*** *Operating a 50/50 hybrid model, balancing digital and in-person consultations for convenience and personalized care.*[4]
   - ***BCG X (February 2025):*** *BCG X highlighted the development of smart implants and wearable devices that allow real-time monitoring of patients' health metrics. These innovations aim to enhance chronic disease management by integrating digital health tools with traditional care practices.* [5]
   - ***BioTrillion (2024):*** *BioTrillion developed a novel solution allowing remote blood pressure monitoring using a smartphone and selfie technology. This innovation reduces the need for frequent in-person visits while providing real-time health data and medical advice.*[6]

3. **GLP-1 Therapies Expand Beyond Diabetes: A New Era of Multi-Indication Dominance**

   In 2025, GLP-1 receptor agonists are no longer confined to diabetes management — they are redefining the future of chronic disease treatment. Originally developed for type 2 diabetes, these therapies have proven highly effective across a broad range of conditions, including obesity, sleep apnea, addiction, Alzheimer's disease, and non-alcoholic steatohepatitis (NASH). This expanding therapeutic scope is shifting treatment paradigms and potentially reducing the need for devices and surgeries traditionally used in diabetes and obesity care. Pharmaceutical companies are aggressively investing in expanding indications, making GLP-1s central to managing a wider spectrum of diseases.

   - ***Novo Nordisk's Semaglutide Expansion****: On January 28, 2025, the FDA approved Ozempic (semaglutide) for chronic kidney disease (CKD) in adults with type 2 diabetes, following studies showing a 24% risk reduction in kidney-related complications.*[7]

- ***Eli Lilly's Oral GLP-1 Breakthrough:*** *Eli Lilly's orforglipron, the first oral small-molecule GLP-1 agonist, completed Phase 3 trials (ATTAIN-1 results expected mid-2025) after Phase 2 data showed 14.7% weight loss at 36 weeks in adults with type 2 diabetes.*[8]

- ***Sanofi's Sustained-Release Innovation:*** *In February 2025, Sanofi received FDA approval for Merilog, a biosimilar to Novo Nordisk's NovoLog. While not a GLP-1 itself, Merilog's entry into a market facing GLP-1 dominance highlights how the insulin market is adapting amid this major therapeutic shift.*[9]

- ***Japan's Drug Pipeline Gains Pace:*** *In 2025, Japan's drug pipeline grew 5.6%, driven by a rise in domestic developers and led by cancer therapies. Otsuka Holdings became the second-largest contributor. Cancer dominates with 9 of the top 10 focus areas, while Alzheimer's remains absent.*[10]

Partners can harness these trends to drive innovation and patient-centric care. By integrating genomics, they can develop targeted therapies and predictive diagnostics. Embracing phygital models enables smarter care delivery and deeper patient engagement.

Pharma M&A Activity: Recent Deals and Insights

In 2025, pharma giants are making bold moves to future-proof their oncology pipelines. GSK targets treatment-resistant GIST, AstraZeneca bets on rapid in vivo cell therapies, and Sun Pharma secures a market-ready skin cancer drug—reflecting a clear focus on precision, speed, and commercial readiness.

- ***GSK Acquires IDRx, Inc. in a Deal Worth Up to $1.15 Billion:*** *GSK has acquired IDRx, a clinical-stage biotech firm focused on precision therapies for GIST. The deal includes IDRX-42, a next-gen TKI targeting all key KIT mutations in GIST. IDRX-42 aims to address resistance seen with current standard treatments. The asset is currently in Phase I clinical development. It has received FDA Fast Track and Orphan Drug designations. The acquisition boosts GSK's oncology portfolio with a focus on durable tumor control.*[11]

- ***AstraZeneca to Acquire EsoBiotec in a Deal Worth Up to $1 Billion:*** *AstraZeneca will acquire Belgian biotech EsoBiotec to strengthen its cell therapy capabilities. The deal includes $810 million upfront and up to $250 million in milestone payments. EsoBiotec's ENaBL platform enables rapid in*

vivo reprogramming of immune cells. This could significantly reduce cell therapy preparation time and complexity. The acquisition supports AstraZeneca's ambition in oncology and immune-mediated diseases. The deal brings transformative potential in solid tumors and will integrate into AstraZeneca's cell therapy unit.[12]

- ***Sun Pharma to Acquire Checkpoint Therapeutics in a $355 Million Deal:*** *Sun Pharmaceutical Industries has agreed to acquire U.S.-based Checkpoint Therapeutics for $355 million. The acquisition includes UNLOXCYT (cosibelimab-ipdl), an FDA-approved treatment for advanced cutaneous squamous cell carcinoma (cSCC). Sun Pharma will pay $4.10 per share, a 66% premium over Checkpoint's March 7 closing price. An additional $0.70 per share is contingent on European regulatory approvals. The deal aligns with Sun Pharma's strategy to expand its oncology portfolio and is expected to close in Q2 2025. Fortress Biotech, Checkpoint's controlling shareholder, will receive royalties on future cosibelimab sales.*[13]

Partners can leverage these M&As to fast-track innovation and fill critical pipeline gaps. By aligning with cutting-edge platforms like in vivo cell therapy or next-gen TKIs, they can stay ahead in competitive therapeutic areas. Strategic partnerships or acquisitions offer speed-to-market and differentiated assets. Monitoring these deals also reveals where investor and scientific momentum is heading next.

Regulatory Updates

Regulators are making pivotal moves with broad health implications. The FDA's flu vaccine meeting cancellation sparks concern amid a severe season, while new guidance on therapeutic equivalence supports faster generic approvals. EMA's AI tool qualification for MASH marks a leap in digital diagnostics.

- ***FDA's flu vaccine meeting cancelled, raising public health concerns (March, 2025):*** *The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting, which was set to determine flu vaccine strains for the upcoming season, was abruptly cancelled without explanation. This decision has sparked serious concerns, particularly as the current flu season has already led to 430,000 hospitalizations and 19,000 deaths. Experts warn that any delay in updating vaccines could significantly impact public health preparedness. Adding to the uncertainty, the CDC has also postponed a key vaccine advisory meeting, further fuelling worries about the government's ability to respond effectively to emerging health threats.*[14]

- ***FDA Releases Updated Guidance on Therapeutic Equivalence:*** *In March 2025, the U.S. FDA published updated guidance clarifying its framework for evaluating therapeutic equivalence (TE) between generic and brand-name prescription drugs. Aimed at pharmaceutical manufacturers, regulatory professionals, and healthcare providers, the guidance outlines the criteria used to ensure that generic drugs are clinically equivalent in effectiveness, safety, strength, dosage form, and administration route to their branded counterparts. The update reinforces FDA's commitment to transparent generic drug approval and supports faster access to cost-effective treatments.*[15]
- ***EMA Qualifies First AI Tool for Diagnosing MASH:*** *In March 2025, the European Medicines Agency issued a landmark qualification opinion for the first-ever artificial intelligence tool designed to support the diagnosis of Metabolic dysfunction-associated steatohepatitis, previously known as NASH. The AI-based technology analyses histological features from liver biopsy samples to objectively assess disease activity and progression in clinical trials. This qualification marks a major step in integrating digital innovation into liver disease diagnostics and enhances standardization and reproducibility in MASH assessments.*[16]
- ***Tariffs Reshape Global Pharma Supply Chains:*** *In 2025, the U.S. government—under former President Donald Trump—announced plans to impose tariffs of up to 25% on pharmaceutical imports, aiming to reduce reliance on foreign drug manufacturing and bring production back to the U.S. However, with deeply integrated global supply chains, especially between the U.S. and EU, such tariffs risk major disruptions. These tariffs could lead to global drug shortages, production delays, and rising costs, forcing companies to reassess sourcing and manufacturing strategies worldwide.*[17]

Partners can leverage regulatory shifts to accelerate innovation and market access. FDA's updated guidance on therapeutic equivalence opens doors for faster generic approvals and portfolio expansion. EMA's support for AI tools signals growing acceptance of digital diagnostics—ripe for strategic investment. Staying agile to regulatory trends enables proactive positioning and competitive advantage.

Recent Drug Approvals: Advancing Patient Care

In 2025, the FDA approved seven novel drugs never marketed in the U.S., marking a strong year for therapeutic innovation. Breakthroughs in cancer, pain, infections, and rare diseases reflect rising momentum in precision and non-invasive care. New mechanisms like ADCs, siRNA, and non-opioid therapies expand options for hard-

to-treat conditions. These approvals signal continued progress in addressing unmet clinical needs.[18]

- ***DATROWAY (datopotamab deruxtecan-dlnk)*** *was approved by the U.S. FDA on January 17, 2025, for adults with unresectable or metastatic HR-positive, HER2-negative breast cancer after prior endocrine and chemo treatment. The TROP2-directed ADC showed a 37% reduction in disease progression vs. chemo in the TROPION-Breast01 trial. This marks a significant advancement in targeted therapy options for heavily pretreated breast cancer patients.*[18]
- ***GRAFAPEX (treosulfan)*** *was approved by the U.S. FDA on January 21, 2025, for use in combination with fludarabine as a conditioning regimen before allogeneic stem cell transplantation in patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS)The approval offers a well-tolerated, effective alternative to traditional conditioning agents, improving transplant. outcomes in high-risk hematologic cancers.* [18]
- ***JOURNAVX (suzetrigine)*** *was approved by the U.S. FDA on January 30, 2025, for the treatment of moderate to severe acute pain in adults. As the first-in-class NaV1.8 inhibitor, Journavx offers a novel non-opioid approach to pain management, potentially reducing reliance on traditional opioids and associated risks.*[18]
- ***GOMEKLI (mirdametinib)*** *was approved by the U.S. FDA on February 11, 2025, for the treatment of adults and children with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas. This MEK inhibitor provides a targeted, non-surgical option for managing tumor burden in NF1 patients with limited treatment alternatives.*[18]
- ***ROMVIMZA (vimseltinib)*** *was approved by the U.S. FDA on February 14, 2025, for the treatment of symptomatic tenosynovial giant cell tumor (TGCT) where surgery would likely lead to worsened functional outcomes or severe morbidity. As an oral CSF1R inhibitor, Romvimza offers a non-surgical, targeted therapy for patients with limited treatment options.*[18]
- ***BLUJEPA (gepotidacin)*** *was approved by the U.S. FDA on March 25, 2025, for the treatment of uncomplicated urinary tract infections (uUTIs) caused by susceptible bacteria. As a first-in-class antibiotic with a novel mechanism of action, Blujepa addresses rising antimicrobial resistance and offers a new option for uUTI management.*[18]
- ***QFITLIA (fitusiran)*** *was approved by the U.S. FDA on March 28, 2025, to prevent or reduce the frequency of bleeding episodes in people with hemophilia A or B, with or without inhibitors. As the first approved U.S. therapy using siRNA for hemophilia, Qfitlia offers a once-monthly, subcutaneous treatment option that*

rebalances clotting, representing a major advancement in disease management.[18]

Implications for Pharma and Med Tech Companies

The trends and developments highlighted in this edition reflect a broader shift toward personalization, digitization, and accelerated innovation in healthcare. For pharmaceutical and med tech companies, this evolving landscape presents both opportunities and challenges.

The growing emphasis on genomics and precision medicine underscores the need to invest in targeted therapies and personalized care solutions. At the same time, the increasing adoption of digital health tools—from AI-powered diagnostics to remote monitoring—is reshaping how care is delivered and how patients engage with treatments. Regulatory bodies are also signalling greater willingness to innovation, offering faster pathways for approvals and support for new modalities, especially in areas like digital health and rare diseases. To stay competitive, companies must not only keep pace with these changes but also anticipate where the momentum is heading.

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.

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