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South Koreaâ??s Biosimilar Boom Enters High-Stakes â??Third Waveâ??

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Biosimilars are a central part of South Koreaâ??s biopharmaceutical strategy. As of 2024, more than 70 biosimilars have been approved by the Ministry of Food and Drug Safety (MFDS), placing the country among the leading biosimilar markets globally. This portfolio has been developed by around 15 companies engaged in biosimilar development and manufacturing, led by Celltrion and Samsung Bioepis. The market has expanded steadily since the first approval in 2012 and is projected to grow from around $530 million in 2023 to over $1 billion by 2027, at a CAGR exceeding 18â??20 per cent, according to ResearchAndMarkets reports. This growth has been supported by early government investment, regulatory guidance, and a focus on monoclonal antibodies and other complex biologics. Letâ??s look at the current biosimilar landscape in South Korea and what lies ahead.

South Korea has a growing biosimilars market. The country has taken an early and active approach to building this industry, allocating 35 per cent of its medical research budget in 2012 to support local pharmaceutical companies. In addition to funding and tax incentives, the government has also provided regulatory guidance to biosimilar developers. It is no surprise, then, that biosimilar activity has increased steadily since 2012, says L.E.K. Consulting report.

Based on 2024 data from the Ministry of Food and Drug Safety (MFDS) approvals have increased steadily over time. Since 2012, more than 70 biosimilars have been approved. In 2024 alone, 18 approvals were recorded, the highest so far.

Early activity included a mix of monoclonal antibodies and simpler biologics such as somatropin and insulin glargine (endocrine), along with darbepoetin alfa and epoetin alfa (hematology). Over time, development concentrated on monoclonal antibodies across key therapy areas. This included trastuzumab, rituximab, and bevacizumab in oncology, and adalimumab and etanercept in autoimmune diseases.

In later years, the pipeline expanded further to include ranibizumab and aflibercept in ophthalmology, as well as newer biologics such as eculizumab (hematology), ustekinumab and omalizumab (immunology), and denosumab (bone-related disorders). Activity in endocrine products such as insulin and peptide hormones remains limited.

The market is led by Celltrion and Samsung Bioepis. Other companies are also active. These include Dong-A ST, LG Chem, GC Pharma, Hanmi Pharmaceutical, and Daewoong Pharmaceutical. Their share is smaller, but they add to the pipeline and expand the overall market.

Apart from a strong domestic market, South Korean companies have also built a growing presence in global biosimilars. According to GlobalData's Pharmaceutical Intelligence Center, 24 biosimilars developed by Korean firms are approved across international markets, including 11 monoclonal antibodies. Another five products are in pre-registration across 10 therapy areas, indicating continued pipeline expansion. Around 15 companies are active in development.

South Korean firms have also built a presence in the European market. Between 2022 and 2024, India and South Korea together accounted for 11 per cent of biosimilar approvals by the European Medicines Agency, up from 8 per cent in the previous period, according to IQVIA.

What's next

The global biosimilars market is entering a new phase, often called the 'third wave.' Earlier waves focused on relatively simpler biologics. Now, the focus has shifted to high-value, highly targeted therapies, especially in immune-oncology and advanced immunology. These drugs are more complex, more expensive, and much harder to replicate making this wave both challenging and highly lucrative.

The most important segment in this wave is immune-oncology, particularly checkpoint inhibitors and targeted cancer antibodies. Drugs like Pembrolizumab (Merck's Keytruda) and J&J's Daratumumab (Darzalex) either activate the immune system or directly target cancer cells, such as in multiple myeloma.

Keytruda, with nearly $30 billion in annual sales, represents one of the largest upcoming biosimilar opportunities as it approaches its 2028 patent expiry. South Korean developers are already advancing pipelines. Samsung Bioepis is developing SB27, with global Phase 3 trials initiated in April 2024 alongside Phase 1 studies. Celltrion is advancing CT-P51, with Phase 3 trials in non-small cell lung cancer following FDA clearance in August 2024. Rophibio, an affiliate of Amicogen, has completed early development stages in collaboration with Avantor, and Chong Kun Dang is preparing entry through a licensing agreement with Singapore-based Favorex.

Daratumumab (Darzalex), whose patents begin expiring in 2026, is already seeing late-stage biosimilar activity. Celltrion is developing CT-P44, a biosimilar targeting both intravenous and subcutaneous formulations of the drug, which is used in the treatment of multiple myeloma.

In immunology, attention is shifting toward next-generation cytokine inhibitors, particularly Dupilumab (Dupixent). Unlike earlier TNF inhibitors, Dupixent targets IL-4 and IL-13 pathways and is used in atopic dermatitis, asthma, and other inflammatory diseases. With over $14 billion in annual sales and patent protection extending to around 2031, this segment represents a future battleground. Korean companies such as Chong Kun Dang, Daewoong, and Kyungdong are already positioning themselves as early entrants.

Another emerging area is ophthalmology, particularly treatments like Aflibercept (Eylea), used for retinal diseases. In this segment, competition is extending beyond pricing. Companies are focusing on formulation changes, including higher-dose versions that reduce injection frequency. Key players include Celltrion (Eydenzelt), Samsung Bioepis (Opuviz), and Sam Chun Dang Pharm., which is developing a high-dose approach.

A key enabler of this third wave is regulatory support. MFDS plans to introduce a streamlined biosimilar approval pathway from 2026, reducing review timelines from 420 to 295 days, introducing product-specific review teams, expediting GMP and GCP inspections, and increasing direct consultations. These changes are expected to shorten time-to-market and support faster pipeline execution, strengthening South Korea's position as a launch market.

Companies are also stepping up manufacturing capacity. On March 24, 2026, Celltrion committed 1.2 trillion won ($805 million) to expand its Incheon facility, alongside scaling its U.S. site to bring total capacity to 570,000 litres a year. On March 10, 2026, Samsung Biologics partnered with Eli Lilly to set up a new Gateway Labs site in Korea.

These moves come as the industry approaches a major turning point. By 2030, pharmaceutical companies are expected to lose over $236 billion in revenue as patents expire on around 190 drugs, including 69 blockbusters, putting nearly 46 per cent of sales at risk, according to Deloitte. South Korean companies are well-positioned to capture this opportunity.

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