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What's Next? Five Things To Look Out For In July

Ustekinumab Set To Roll Out Across Global Stage; GGB Awards Deadline Looms

by **Dean Rudge**

Generics Bulletin previews the most noteworthy and anticipated events for July 2024.

Stelara Biosimilars Could Move In Europe...

Late this month, biosimilar competition to Janssen's Stelara (ustekinumab) blockbuster treatment for autoimmune diseases can begin to roll out across Europe, with the expiry of a key European supplementary protection certificate covering the biologic brand.

At the beginning of 2024, European ustekinumab biosimilar frontrunners Stada and Alvotech revealed plans to launch their partnered Uzpruvo rival to Stelara "as soon as possible" following the expiry of the Stelara SPC. (Also see "[Stada And Alvotech Eye Launch Date For Ustekinumab After EU Approval](#)" - Generics Bulletin, 10 Jan, 2024.)

In the race to compete, Celltrion became recently the fourth firm to win a positive opinion from the European Medicines Agency for a Stelara biosimilar. The Korean firm's Steqeyma version was just endorsed by the agency's Committee for Medicinal Products for Human Use at its June meeting.

Alvotech and Stada's Uzpruvo, as well as Samsung Bioepis and Sandoz's Pyzchiva, have both now seen their positive opinions converted into final approvals. Meanwhile, Amgen also holds a positive CHMP opinion for its Wezenla version, which should convert imminently into a pan-European marketing authorization. (Also see "[...And Amgen Makes Three: Another Ustekinumab Biosimilar Gets Go-Ahead In EU](#)" - Generics Bulletin, 26 Apr, 2024.)

Stelara brought in \$10.858bn for Johnson & Johnson in 2023, according to the figures reported by the originator, with this total up 11.7% over 2022's \$9.723bn. In the US, sales grew by 9% to \$6.966bn; while internationally, the brand achieved \$3.892bn in sales, a 16.7% improvement over 2022. (Also see "[A \\$10bn Target: Stelara Sales Break Barrier Ahead Of Biosimilar Launches](#)" - Generics Bulletin, 26 Jan, 2024.)

...While Ustekinumab Action Expected In Korea

Biosimilar competition to Stelara is also set to materialize in a further major global market this month.

Samsung Bioepis plans to launch its Epyztek biosimilar in its native Korea this month, a spokesperson for Samsung confirmed to *Generics Bulletin*, coming in at a discount of around 40% to the reference brand.

Confirming the details of a recent *Korea Biomedical Review* article, after the firm released details to local media, Samsung Bioepis indicated that it will begin marketing its 45mg/0.5ml pre-filled syringe ustekinumab biosimilar from July – at a price of around KRW1.3m (\$940).

Set to launch directly by Samsung Bioepis, without the aid of a sales or commercialization partner, the biosimilar will enter a market valued roughly at around KRW42bn per year, according to reports.

“With the launch of Epyztek, Samsung Bioepis now offers a total of nine biosimilar products in Korea, with five being sold directly by the company,” the *Korea Biomedical Review* article notes.

Earlier this year, Fuji Pharma's Stelara biosimilar – in-licensed from developer Alvotech – was listed on Japan's National Health Insurance price list for reimbursement.

Lupin Plots Completion Of Trade Generics Carve Out

This month, Lupin will complete a deal to carve out its domestic trade generics business to Lupin Life Sciences Limited, a wholly owned subsidiary of the company – becoming the latest Indian player to flag up the growing importance of trade generics in the country.

Announcing the deal earlier this year, Lupin said that the deal – carving out the unit as a going concern, on a slump sale basis – was intended to “achieve agility, better focus and growth of trade generics business,” as well as “to increase business by investing in new launches and penetrating underserved markets.” (Also see "[Lupin Sharpens Focus With Carve-Out Of Indian Trade Generics Business](#)" - Generics Bulletin, 3 Apr, 2024.)

Last month, Lupin entered into a business transfer agreement with Lupin Life Sciences to formally carve out the business effective 1 July.

The Indian firm's trade generics business – which achieved sales of around INR2.78bn (\$33m) in Lupin's most recent financial year, representing around 2.5% of total company turnover – was worth around INR721m, Lupin said.

Trade generics have received renewed attention in India in recent years, thanks to the Indian government's focus on providing economical drugs through “Pradhan Mantri Bhartiya Janaushadhi Kendras”, or public medical retail outlets.

Last year, Dr Reddy's entered into the trade generics business in India with the launch of a new dedicated division, 'RGenX'.

Pharmexcil Looks For Boost In CIS Markets

The Pharmaceuticals Export Promotion Council of India, Pharmexcil, will – in collaboration with the Union ministry of commerce – this month send a delegation to Kazakhstan, Tajikistan, and Uzbekistan.

Taking place from 22-30 July, the initiative aims to expand the market for Indian generics and active pharmaceutical ingredients in the Commonwealth of Independent States (CIS), “especially with the emerging business opportunities in the region.”

Pharmexcil has organized a comprehensive visit to the capital cities of three countries, including Almaty (Kazakhstan), Dushanbe (Tajikistan), and Tashkent (Uzbekistan).

“As part of the business delegation, buyer seller meets will be organized at each country along with meetings with the regulatory officials and prominent trade associations. We are proposing to invite business delegates from neighbouring countries as well for B2B meetings with the Indian delegation.”

GGB Awards 2024 Entries Deadline Looms

Interested parties have until 22 July to submit their entries to the Global Generics & Biosimilars Awards 2024, celebrating achievements undertaken in the generics and biosimilars between 1 September 2023 and 31 July 2024. (Also see "[One Month Remains To Enter 2024 GGB Awards](#)" - Generics Bulletin, 21 Jun, 2024.)

Once the entries have been evaluated by our panel of independent expert judges and the winners selected, our prizegiving ceremony will then take place at the Hotel NH Milano Fiera on Wednesday 9 October, during CPhI Worldwide week.

In a recent podcast, *Generics Bulletin* editors Dave Wallace and Dean Rudge spoke about how companies can enter and attend the awards – both of which remain free of charge – as well as offering tips for entries and discussing the reasons why off-patent industry players might want to

be involved in the event. (Also see "[Podcast: The Global Generics & Biosimilars Awards 2024](#)" - Generics Bulletin, 1 May, 2024.)