# Pharmaceuticals

## Pharma Weekly – ICYMI



**This is the twenty-fourth edition (week ending 6-Sep-26) of our Pharma Weekly – In Case You Missed It. Key developments in the past week:**

**1) Aurobindo Pharma's US subsidiary, Lannett, has launched the generic equivalent of GSK's Advair Diskus (Fluticasone Propionate/Salmeterol) in the US in 100/50mcg and 250/50mcg strengths, marking the first commercialization from Aurobindo's inhalation pipeline (relevant for Cipla which has an approval for all three strengths).**

**2) Aspen's CEO, Stephen Saad, said the company expects to launch generic Semaglutide in FY ending Jun-27, with the Canadian launch dependent on API supplies from Dr Reddy's. Aspen expects to have greater clarity regarding supplies from Dr Reddy's in Sep-26. Aspen has also submitted its generic Semaglutide for approval in South Africa and is pursuing registrations in Brazil and other emerging markets.**

**3) Cipla's US subsidiary, InvaGen, has entered into an exclusive licensing and supply agreement with Qilu Pharma for a biosimilar to Keytruda (Pembrolizumab) in the US. Qilu will handle development, regulatory registration, and supply, while Cipla will commercialize the product (relevant for Zydus, Dr Reddy's, Ipca Labs, and Biocon).**

**4) Lupin's EMEA and Emerging Markets President, Thierry Volle, stated that the company intends to double its sales base in the region over a five-year period. The growth plan relies on expanding specialty care, making selective biosimilar investments, and advancing complex generics to establish EMEA as a major business division.**

**5) AstraZeneca and Daiichi Sankyo's Enhertu (Trastuzumab Deruxtecan) plus Pertuzumab has received EU approval for first-line treatment of unresectable or metastatic HER2-positive breast cancer. In the Phase 3 trial, the combination reduced the risk of disease progression or death by 44%, with median progression-free survival of 40.7 months (relevant for Cohance Lifesciences).**

**6) The USFDA has approved Stelara (Ustekinumab) for moderately to severely active ulcerative colitis in pediatric patients aged 2 years and older, following its Apr-26 approval for pediatric Crohn's disease. Stelara has received Orphan Drug Designation for this indication (relevant for Biocon).**

**7) Eli Lilly has cut the cost of the two lowest tablet strengths of Foundayo, with self-pay prices starting at $149/month for 2.5mg (vs $199 earlier) and $199 for 5.5mg (vs $299 earlier). Commercial insurance coverage can bring the monthly cost down to around $25 (relevant for Divi's).**

**8) Medicare's GLP-1 Bridge program has seen strong initial uptake, with ~600k seniors enrolling since its 01-Jul-26 launch and saving $216mn on weight-loss medicines. ~3.8mn Medicare beneficiaries are eligible for the Bridge program (temporary program that lets eligible Medicare Part D beneficiaries get specific weight-loss medications for a flat $50 co-pay per month).**

**9) RPG Life Sciences's MD, Ashok Nair, said the company plans to deploy the remaining Rs5bn of its Rs7bn committed capital over the next 12 months toward acquisitions to strengthen its manufacturing and API capabilities. He expects API to play a larger role going forward, while domestic formulations continue to grow ahead of the market, and targets Rs20-25bn revenue by CY30.**

**10) The USFDA has stepped up oversight of compounded GLP-1 drugs, establishing an import alert to block potentially poor-quality Semaglutide and Tirzepatide APIs while allowing compliant manufacturers to continue imports. The agency also flagged fraudulent compounded products, dosing errors, and use of unapproved Semaglutide salt forms.**

*Further coverage of Global innovators, CDMOs, and generic players on the next page*

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## News flow – Indian Pharma

1) Cipla has entered into an exclusive license and supply agreement with Sino Biopharmaceuticals for TQB2102 (Rolditamig Deuteruxtecan), an HER2 bispecific ADC. Cipla will hold exclusive development and commercialization rights across India, South Africa, and five other emerging markets, while Sino will manufacture and supply the drug.

2) Torrent Pharmaceuticals has commenced Phase 2 supply integration of its acquired Curatio portfolio, expanding distribution of dermatology and pediatric skincare products across its authorized stockist network. The 97 integrated products will follow existing trade margins and payment terms, with Torrent continuing to directly manage saleable, non-saleable, and quarantine stock returns.

3) Aurobindo Pharma's US subsidiary, Lannett Company, has launched the generic equivalent of GSK's Advair Diskus (Fluticasone Propionate/Salmeterol) in the US in 100/50mcg and 250/50mcg strengths, marking the first commercialization from Aurobindo's inhalation pipeline (relevant for Cipla which has an approval for all three strengths).

4) Zydus announced positive topline results from the Phase 2(b) trial of Saroglitazar Mg in MASH, which enrolled 189 patients and met its primary endpoint of steatohepatitis resolution without worsening of fibrosis at week 52, with a 26.5% treatment difference. The study also showed improvements in liver histology, steatosis, inflammation, and ballooning.

5) Zydus Lifesciences has agreed to pay $5.9mn as settlement related to the generic pharmaceuticals pricing antitrust litigation pending before the US District Court for the Eastern District of Pennsylvania.

6) Sun Pharma has signed an agreement with the US government to adopt MFN pricing for its innovative medicines, aligning US prices with the lowest prices in other developed markets, including for future innovative launches. The agreement provides tariff exemptions on innovative products for more than two years, while Sun Pharma will contribute 71.4 tonnes of Clindamycin and 6.75 tonnes of Doxycycline to the US Strategic API Reserve.

7) Cipher Pharmaceuticals received a favorable ruling from a New York federal court, which denied Sun Pharma's petition to partially vacate the arbitration award and confirmed Cipher's ownership of clinical data used for Sun's Canadian launch of Absorica LD.

8) Cipla's US subsidiary, InvaGen Pharmaceuticals, has entered into an exclusive licensing and supply agreement with Qilu Pharmaceutical for a biosimilar to Keytruda (Pembrolizumab), in the US. Qilu will handle development, regulatory registration, and supply, while Cipla will commercialize the product (relevant for Zydus, Dr Reddy's, Ipca Labs, and Biocon).

9) RPG Life Sciences's wholly owned subsidiary, RPG Active Pharma, has agreed to acquire the API and intermediates business of Raghava Life Science for Rs1.35bn through a slump sale, funded by the recent Rs2.43bn equity infusion from InvAscent. The acquisition provides access to an EU-GMP-approved 300kl facility and 29 API molecules, with the business generating Rs190mn revenue in FY26 and revenue potential of ~Rs2bn at full utilization.

10) Cohance Lifesciences has agreed to acquire a controlling stake in ADC-focused CRDMO Aruka Bio for $5mn and invest an additional $13mn in NJ Bio. The transactions will increase Cohance's stake in NJ Bio from 56% to 67.3%. Aruka Bio will focus on the ADC pipeline and partnership initiatives under NJ Bio's founder, Dr Naresh Jain.

11) MSN Laboratories has been barred from launching its generic Cabometyx (Cabozantinib) in the US until 15-Jan-30, after the US Court of Appeals for the Federal Circuit upheld three key patents held by Exelixis. A separate trial over another formulation patent is scheduled for Nov-26, which could potentially extend exclusivity to Feb-32.

12) Suven Life Sciences has completed enrollment in its global Phase 3 study of Masupirdine (SUVN-502) for agitation associated with Alzheimer's dementia, with 424 patients randomized versus the planned 375. The last patient last visit is expected by Dec-26, database lock by Mar-27, and topline results by May-27.

13) Lupin voluntarily recalled 5,082 tubes of Clobetasol Propionate cream in the US after the product failed content uniformity specifications. The affected batch was manufactured at Lupin's Pithampur facility, and the FDA has classified the nationwide recall as Class II.

14) Fosun Pharma has sold a 4.55% stake in Gland Pharma for Rs21.2bn through block deals at an average price of Rs2,827 per share. The stake sale reduced Fosun Pharma's holding in Gland Pharma to 47.22% from 51.77%.

15) Sun Pharma secured a favorable final determination from the US International Trade Commission (ITC), which found that Biofrontera's RhodoLED XL system infringes certain Sun Pharma patents and rejected Biofrontera's invalidity defenses. The ITC issued limited exclusion and cease-and-desist orders restricting the import and sale of infringing products in the US for the remaining patent terms.

### News flow – Global innovators, CDMOs, and generic players

1) Novartis has paused eight clinical trials of its experimental CAR-T therapy rap-cel in autoimmune and neurological disorders after three patients died from a severe immune response, while studies of rap-cel in cancer patients are continuing. Bristol Myers Squibb has also paused autoimmune trials of its CD19-targeted CAR-T therapy zola-cel as a precaution following transient, reversible inflammatory events.

2) AstraZeneca and Daiichi Sankyo's Enhertu (Trastuzumab Deruxtecan) plus Pertuzumab has received EU approval for first-line treatment of unresectable or metastatic HER2-positive breast cancer. In the Phase 3 trial, the combination reduced the risk of disease progression or death by 44%, with median progression-free survival of 40.7 months (relevant for Cohance Lifesciences).

3) The USFDA has approved Stelara (Ustekinumab) for moderately to severely active ulcerative colitis in pediatric patients aged 2 years and older, following its Apr-26 approval for pediatric Crohn's disease. Stelara has received Orphan Drug Designation for this indication and is the first approved non-TNF alpha-targeting monoclonal antibody for both major forms of pediatric inflammatory bowel disease (relevant for Biocon).

4) Eli Lilly has cut the cost of the two lowest tablet strengths of Foundayo, with self-pay prices starting at $149/month for 2.5mg (vs $199 earlier) and $199 for 5.5mg (vs $299 earlier). Commercial insurance coverage can bring the monthly cost down to around $25 (relevant for Divi's).

5) Medicare's GLP-1 Bridge program has seen strong initial uptake, with ~600k seniors enrolling since its 01-Jul-26 launch and saving $216mn on weight-loss medicines. About 3.8mn Medicare beneficiaries are eligible for the Bridge program (temporary program that lets eligible Medicare Part D beneficiaries get specific weight-loss medications for a flat $50 co-pay per month), according to an estimate from the health policy research organization Kaiser Family Foundation.

6) Novo Nordisk's Wegovy pill and Eli Lilly's Foundayo prescriptions increased 3% and 8% week-on-week to ~181k and ~44k, respectively. The oral pill accounted for 35% of total Wegovy prescriptions as overall Wegovy scripts rose 2.7% to 513.5k, while Zepbound scripts increased 1.6% to ~772k.

### Key regulatory developments

1) The Federation of Pharma Entrepreneurs (FOPE) has opposed an NPPA proposal that could hold manufacturers solely accountable for medicine overpricing while exempting retailers, hospitals, and nursing homes from prosecution. FOPE argued that responsibility should also lie with downstream sellers who determine the final transaction price, while AIOCD welcomed safeguards protecting chemists and other trade members from prosecution for manufacturer-driven pricing violations.

2) The USFDA issued 55 new and revised product-specific guidances (PSGs) to facilitate generic drug development, including 18 guidances for complex products and more than 30 for products with no approved ANDAs. The batch covers areas such as targeted oncology drugs, a first-in-class dipeptidyl peptidase 1 (DPP1) inhibitor, PARP inhibitors, Ferumoxytol and Benzoyl Peroxide, and Tretinoin, providing clearer bioequivalence and development pathways for potential generic entrants.



3) The USFDA has stepped up oversight of compounded GLP-1 drugs, establishing an import alert to block potentially poor-quality Semaglutide and Tirzepatide APIs while allowing compliant manufacturers to continue imports. The agency also flagged fraudulent compounded products, dosing errors, and use of unapproved Semaglutide salt forms. As of

31-May-26, FDA had received 990 adverse-event reports linked to compounded Semaglutide and 730+ for compounded Tirzepatide.

### USFDA inspections/inspection outcomes

1) Cohance Lifesciences's formulation (FDF) plant at Shamshabad, Telangana, underwent a USFDA inspection from 27-Aug-26 to 04-Sep-26, which concluded with four Form FDA 483 observations.

2) Gland Pharma's VSEZ Sterile Oncology Formulations and API facilities in Visakhapatnam underwent a routine USFDA inspection from 24-Aug-26 to 01-Sep-26, which concluded with zero Form FDA 483 observations.

### Management commentary

1) Natco's CEO, Rajeev Nannapaneni, said the company is looking beyond the US as global generic competition intensifies, with a focus on geographic expansion and moving further up the value chain while remaining primarily a generics company. He highlighted the 49% stake in Adcock Ingram as a long-term diversification opportunity, with the combined pipeline expected to create value over the next 2-3 years, while India is expected to be a key growth driver, led by Semaglutide.

2) RPG Life Sciences's MD, Ashok Nair, said the company plans to deploy the remaining Rs5bn of its Rs7bn committed capital over the next 12 months toward acquisitions to strengthen its manufacturing and API capabilities. He expects API to play a larger role going forward, while domestic formulations continue to grow ahead of the market, and targets Rs20-25bn revenue by CY30. Nair also sees the Indian GLP-1 market as being in its early stages, with potential to reach ~Rs40bn in the next 3-4 years.

3) Aspen's CEO Stephen Saad said the company expects to launch generic Semaglutide in FY ending Jun-27, with the Canadian launch dependent on API supplies from Dr Reddy's. Aspen expects to have greater clarity regarding supplies from Dr Reddy's in Sep-26. Aspen has also submitted its generic Semaglutide for approval in South Africa and is pursuing registrations in Brazil and other emerging markets, with plans to eventually manufacture the product in South Africa.

4) Lupin's EMEA and Emerging Markets President, Thierry Volle, stated that the company intends to double its sales base in the region over a five-year period. The growth plan relies on expanding specialty care, making selective biosimilar investments, and advancing complex generics to establish EMEA as a major business division.

### Key USFDA Approvals (Final + Tentative): Indian Pharma/global generic players competing with Indian players in the specific product

**Final Approval:** gPomalyst (Sandoz, Cipla, Dr Reddy's, SPIL), gSuprep Bowel Prep Kit (Macleods), gEntresto (Aurobindo)

**Tentative Approval:** gNuplazid (Teva)

### Management changes/Corporate actions

1) Orchid Pharma appointed Arjun Dhanuka, currently a Non-Executive Non-Independent Director, as Whole-Time Director of the company.

2) Kwality Pharmaceuticals approved the regularization of the appointment of Swanith Kapoor as Non-Executive Independent Director for a 5-year term through Jun-31 and the reappointment of Aditya Arora as Whole-Time Director for a 5-year term through Sep-31.

3) Gufic Biosciences has promoted Ami Shah to Head – Legal, while she will continue as Company Secretary and Compliance Officer and KMP. Pinak Padhya has been promoted as President – Sales and Marketing, with both changes effective 2-Sep-26.

4) Procter & Gamble Health approved the reappointment of S Madhavan as Independent Director for a 5-year term, effective 15-Nov-26.

5) Aarti Pharmalabs's Senior Management Personnel, GM Naidu, Manufacturing/Sr General Manager, has resigned, with his resignation received on 10-Jun-26. He will be relieved from the company's services effective close of business hours on 31-Aug-26.

6) Aurobindo Pharma's wholly owned subsidiary, Apitoria Pharma, has incorporated Avogent Lifesciences as a new wholly owned subsidiary in India. The new entity has an initial share capital of Rs50mn and will undertake pharmaceutical manufacturing and marketing operations in India and overseas.

7) Mankind Pharma has completed the sale of its 100% stake in Broadway Hospitality Services to AKRK Projects LLP and its partners on 31-Aug-26. Accordingly, Broadway Hospitality Services has ceased to be a wholly owned subsidiary of Mankind Pharma with effect from 31-Aug-26.

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