

This is the sixteenth edition (week ending 12-Jul-26) of our Pharma Weekly – In Case You Missed It. Key developments in the past week:

1) BMS's Krazati (Adagrasib) failed its confirmatory Phase 3 trial in mutated metastatic colorectal cancer, missing both progression-free survival and overall survival endpoints, thus creating uncertainty around conversion of its accelerated approval in the indication (read-through for Syngene).

2) Celltrion and Teva's Truxima (Rituximab) became the first interchangeable Rituximab biosimilar approved by the USFDA, enabling substitution with Rituxan (read-through for Dr Reddy's).

3) Vertex Pharmaceuticals agreed to acquire Crinetics Pharmaceuticals for \$10bn, gaining Palsonify—a newly approved potential blockbuster oral treatment for acromegaly, alongside Crinetics's endocrine pipeline (read-through for Anthem).

4) Vera Therapeutics's Trutakna (Atacicept) received USFDA approval for IgA nephropathy (IgAN), becoming the first dual BAFF/APRIL inhibitor for the disease, adding a new competitor to Novartis's Vanrafia in the rapidly expanding IgAN market (relevant for Anthem).

5) Teva has partnered with Samsung Bioepis to commercialize OPUVIZ (Aflibercept - biosimilar to Eylea) in Canada; Samsung Bioepis will manufacture and supply the product (relevant for Biocon).

6) Eli Lilly's Foundayo continues to see a muted launch, with weekly prescriptions remaining at ~20,000 over the past five weeks, well below Novo Nordisk's oral Wegovy, despite broader PBM coverage (relevant for Divi's). Meanwhile, Novo Nordisk launched its oral Wegovy in the UK through private pharmacies, expanding access ahead of potential NHS availability.

7) A US court dismissed most of Amgen's counterclaims and defenses against Regeneron in the ongoing Eylea (Aflibercept) biosimilar patent litigation, although Amgen's marketed biosimilar (Pavblu) remains on the US market as the underlying patent case continues (Biocon has a settled launch date).

8) Novo Nordisk launched Awiqli (once-weekly insulin) in India for adults with type 1 and type 2 diabetes, with India becoming the seventh country where Novo has launched the product. The product is priced below comparable daily basal insulin on a per-week basis and will compete with Sanofi's Lantus and insulin glargine products from Eris and Lupin.

9) WuXi Biologics received USFDA Pre-License Inspection (PLI) clearance for its MFG8 drug substance facility in China, which houses twelve 4KL single-use bioreactors, supporting commercial manufacturing of a potential blockbuster autoimmune therapy (relevant given the scale of the capacity being added).

10) Amneal and Adalvo announced USFDA acceptance of their NCE-1 ANDAs for generic Tirzepatide autoinjectors referencing Mounjaro and Zepbound.

11) Novo Nordisk has partnered with Vivani Medical to develop NPM-139, an ultra-long-acting Semaglutide implant for obesity designed for once- or twice-yearly dosing, with a Phase 1 trial set to begin in coming weeks.

12) The National Pharmaceutical Pricing Authority (NPPA) has fixed retail prices for 39 new drug formulations across therapies, including cardiovascular, diabetes, antibiotics, oncology, and HIV.

13) The CDSCO has proposed restricting the extension of established brand names to medicines with different active ingredients, aiming to reduce patient confusion and medication errors.

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

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News flow – Indian Pharma

- 1) Granules India has secured sole First-to-File (FTF) status for its ANDA for generic Lumryz (Sodium Oxybate ER oral suspension), marking its second sole FTF opportunity in the US complex generics market.
- 2) Fermenta Biotech has received FSSAI approval for its plant-based Vitamin D3 (VITADEE Green) for use in health supplements, nutraceuticals, and food products, enabling its use in fortified foods and beverages in India.
- 3) Amneal Pharma filed a US patent infringement lawsuit against Alembic Pharma, alleging that Alembic's proposed generic Crexont (extended-release Parkinson's therapy) infringes 29 patents covering the product's formulation and treatment methods.
- 4) Biocon announced the publication of Phase 3 trial data supporting Yesafili (Aflibercept), showing comparable safety, efficacy, and immunogenicity to Eylea in diabetic macular edema, ahead of its planned US launch.
- 5) Novo Nordisk launched Awiqli (once-weekly insulin) in India for adults with type 1 and type 2 diabetes, with India becoming the seventh country where Novo has launched the product. The product is priced below comparable daily basal insulin on a per-week basis and will compete with Sanofi's Lantus and insulin glargine products from Eris and Lupin.
- 6) Dr Reddy's will delay commercial supplies of generic semaglutide after certain batches failed specifications due to an API-related issue. OneSource Specialty clarified that the delay will not materially impact its operations, as demand from other customers remains strong and capacity expansion is underway. Torrent Pharma initiated a precautionary recall of select Semalix injection batches manufactured by Dr Reddy's.
- 7) Lupin Pharma recalled 2.5mn bottles of prednisolone acetate ophthalmic suspension due to the presence of a foreign substance, with the USFDA classifying the action as a Class II recall (probability of serious adverse health outcomes is remote).
- 8) Suven Life Sciences will present five scientific posters at Alzheimer's Association International Conference (AAIC) 2026, including updates on its Phase 3 Masupirdine program for Alzheimer's agitation and Usmapride Phase 2 program.
- 9) ChrysCapital-led acquirers received acceptance for only 40 shares in the mandatory open offer for Novartis India, at Rs860.64/share, as most minority shareholders declined to tender after the stock rallied well above the offer price.
- 10) Orchid Pharma partnered with Pharmasyn HSC to commercialize Exblifep in Russia, with Orchid supplying the finished product. The agreement represents a potential \$178mn opportunity over the first 10 years, subject to regulatory approval.
- 11) PharmaTrac raised its CY26 IPM growth forecast to 11.3% (from 8.1%) on the back of strong 1HCY26 performance, led by chronic therapies such as cardiac (18.8%), anti-diabetes (16.1%), and nutritionals (13%). Generic Semaglutide sales in India plateaued in June after the initial post-patent surge, while Novo Nordisk's innovator brands (Wegovy/Ozempic) maintained strong traction.
- 12) Krka and Laurus Labs commenced construction of their Hyderabad JV manufacturing facility, which will include finished dosage manufacturing and an R&D centre, with an initial capacity of 3bn tablets/year (expandable to 10bn tablets/year) targeted for completion in ~2 years.

News flow – Global innovators, CDMOs, and generic players

- 1) Ascletis Pharma submitted two USFDA IND applications for ASC36 (once-monthly to once-quarterly amylin receptor agonist) and ASC36_35 (once-monthly amylin/GLP-1/GIP dual agonist combination) for obesity, expanding its next-generation ultra-long-acting obesity pipeline.
- 2) Bristol Myers Squibb's confirmatory Phase 3 KRYSTAL-10 trial of Krazati (Adagrasib) + Erbitux in KRAS G12C-mutated metastatic colorectal cancer failed to meet its co-primary endpoints of progression-free survival and overall survival. The company is now focusing on larger NSCLC opportunities where two pivotal trials are underway (relevant for Syngene).

- 3) Fosun Pharma licensed Greater China rights to Junshi Biosciences's anti-IL-17A antibody roconkibart (JS005) for psoriasis, paying CNY215mn upfront, with up to CNY1.12bn in milestones plus double-digit tiered royalties.
- 4) Altimmune is preparing to initiate a Phase 3 trial of its dual GLP-1/glucagon agonist Pemvidutide in MASH in 2HCY26, following positive FDA discussions and encouraging Phase 2b data.
- 5) Celltrion and Teva's Truxima (Rituximab) became the first interchangeable Rituximab biosimilar approved by the USFDA, enabling substitution with Rituxan (read-through for Dr Reddy's).
- 6) Vertex Pharmaceuticals agreed to acquire Crinetics Pharmaceuticals for \$10bn, gaining a newly approved potential blockbuster Palsonify, approved oral treatment for acromegaly, alongside Crinetics's endocrine pipeline (relevant for Anthem).
- 7) Eli Lilly's Foundayo's launch continues to be muted, with weekly prescriptions remaining at ~20,000 over the past five weeks, well below Novo Nordisk's oral Wegovy, despite broader PBM coverage.
- 8) Novo Nordisk launched its oral Wegovy (Semaglutide) in the UK through private pharmacies, expanding access to patients seeking a non-injectable weight-loss option ahead of potential NHS availability.
- 9) Hengrui Pharma and Kailera Therapeutics reported positive Phase 3 results for its oral GLP-1 HRS-7535 in obesity and type 2 diabetes, supporting planned China NDA filings, although the obesity study showed high rates of nausea and vomiting.
- 10) Biohaven reported positive Phase 1 data for its myostatin inhibitor BHV-2000, showing preservation of lean muscle mass during weight loss, positioning the asset as a potential competitor to Eli Lilly's Bimagrumab in the emerging muscle-sparing obesity market.
- 11) Vera Therapeutics's Trutakna (Atacicept) received USFDA approval for IgA nephropathy (IgAN), becoming the first dual BAFF/APRIL inhibitor for the disease, adding a new competitor to Novartis's Vanrafia in the rapidly expanding IgAN market (relevant for Anthem).
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- 13) Amneal and Adalvo announced USFDA acceptance of their NCE-1 ANDAs for generic Tirzepatide autoinjectors referencing Mounjaro and Zepbound.
- 14) Teva has partnered with Samsung Bioepis to commercialize OPUVIZ (Aflibercept - biosimilar to Eylea) in Canada; Samsung Bioepis will manufacture and supply the product (relevant for Biocon).
- 15) Novo Nordisk has partnered with Vivani Medical to develop NPM-139, an ultra-long-acting semaglutide implant for obesity designed for once- or twice-yearly dosing, with a Phase 1 trial set to begin in coming weeks.
- 16) The USFDA expanded approval of Astellas/Pfizer's Padcev + Merck's Keytruda to all patients with muscle-invasive bladder cancer (MIBC) regardless of cisplatin eligibility, making it the first perioperative regimen approved for the broader MIBC population.
- 17) A US court dismissed most of Amgen's counterclaims and defenses against Regeneron in the ongoing Eylea (Aflibercept) biosimilar patent litigation, although Amgen's marketed biosimilar (Pavblu) remains on the US market as the underlying patent case continues (Biocon has a settled launch date).

Key regulatory developments

- 1) The National Pharmaceutical Pricing Authority (NPPA) has fixed retail prices for 39 new drug formulations across therapies, including cardiovascular, diabetes, antibiotics, oncology, and HIV, thus capping the maximum retail price of these medicines.
- 2) A bipartisan US House bill proposed a major overhaul of the 340B drug pricing program, introducing stricter patient eligibility, hospital reporting requirements, and establishing a data

clearinghouse, while temporarily suspending manufacturers' 340B rebate models for four years.

3) India's drug regulator (CDSCO) proposed restricting the extension of established brand names to medicines with different active ingredients, aiming to reduce patient confusion and medication errors.

4) The USFDA resumed publishing Complete Response Letters (CRLs), releasing 14 new CRLs, after a pharmaceutical company challenged the policy over potential disclosure of confidential information.

5) The USFDA and industry concluded BsUFA IV negotiations for CY28-32, eliminating the annual Biosimilar Product Development (BPD) fee, avoiding additional application fees for submissions with clinical data, and introducing a discounted fee structure for simultaneous biosimilar filings.

6) Germany approved healthcare reforms, including higher mandatory rebates from drugmakers, tighter limits on hospital cost increases, and a 15.5% statutory manufacturer discount to curb insurance costs.

7) The Union Health Ministry, India has reclassified oral medicines containing >12% ethyl alcohol (in packs over 30mL) under Schedule H1, ending over-the-counter sales and mandating prescription-only dispensing with stricter licensing and record-keeping requirements to curb misuse.

8) The USFDA proposed a rule allowing hub-and-spoke drug manufacturing networks operating under a single quality system to register as one establishment, while tightening registration requirements for certain foreign API and drug manufacturers to improve supply-chain transparency and oversight.

USFDA inspections/inspection outcomes

Piramal Pharma received an Establishment Inspection Report (EIR) from the USFDA for its Sellersville, US manufacturing facility, thus confirming successful closure of the inspection.

Management commentary

1) Glenmark's CMD Glenn Saldanha said innovation, out-licensing deals, government initiatives, international partnerships, and sustained R&D investment will be key to the next phase of growth for Indian pharma, highlighting the industry's shift beyond generics toward novel therapies and specialty products.

2) Dr Reddy's Chairman Satish Reddy said the company is reinvesting gRevlimid windfall profits into biosimilars, CDMO, consumer health, and innovative products while calling for patient capital, regulatory reforms, AI adoption, government R&D grants, and deeper domestic supply-chain capabilities to accelerate India's transition from generics to innovation-led pharma.

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

Final Approval: gRimso-50 (Stira), gBekyree (Annora Pharma), Dapsone (Macleods), gOfev (Humanwell)

Tentative Approval: gJanumet (Ajanta Pharma), gVemlidy (Laurus Labs)

Management changes/Corporate actions

1) Laurus Labs announced that Aruna Bhinge ceased to be an Independent Director effective 6-Jul-26 upon completion of her second consecutive term.

2) Suven Life Sciences approved the incorporation of wholly-owned subsidiary Suven Neurosciences in Singapore, and the re-appointment of Dr Vajja Sambasiva Rao as an Independent Director for a second five-year term.

3) Morepen Labs announced the resignation of Bhola Prasad, General Manager – Process Engineering & Technology Transfer, a Senior Management Personnel, effective 6-Jul-26.

4) Natco Pharma appointed Gnanadeva Chalapathy Gudipati as Senior Vice President - Analytical R&D and Madhava Rao Karicherla as Vice President - Formulation R&D (Kothur Unit), effective 6-Jul-26.

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- 5) Mankind Pharma approved the divestment of its wholly-owned subsidiary Broadway Hospitality Services and the incorporation of a wholly-owned subsidiary in the Netherlands to hold R&D assets and support business development in niche therapies.
- 6) Marksans Pharma agreed to acquire Germany-based ABCnow GmbH for a total consideration of €0.9mn, a Germany-based pharmaceutical company with front-end sales, marketing, and distribution capabilities across the German healthcare market.
- 7) Torrent Pharma fixed 17-Jul-26 as the record date for issuing shares to JB Chemicals shareholders under the approved merger, based on the exchange ratio of 51 Torrent shares for every 100 JB Chemicals shares.
- 8) Natco Pharma approved an investment of up to Rs14bn in its South African subsidiary and to increase its stake in Adcock Ingram from 35.75% to 49% through a Rs10.7bn share acquisition.
- 9) Blue Jet Healthcare raised Rs8bn through a Qualified Institutional Placement (QIP), allotting 15.81mn shares at Rs506/share to qualified institutional buyers.
- 10) Emcure Pharma's subsidiary Gennova Biopharmaceuticals agreed to divest its mRNA business to Immunoscience Life Science through a slump sale for a cash consideration of Rs1.4bn.

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