Pharmaceuticals

Pharma Weekly – ICYMI

This is the fifteenth edition (week ending 5-Jul-26) of our Pharma Weekly – In Case You Missed It. Key developments in the past week:

1) Shilpa Medicare has partnered with Orion Pharma to commercialize an intravenous Nivolumab biosimilar in Europe, with Orion securing exclusive commercialization rights while Shilpa will receive milestone payments and long-term supply revenues. Separately, Unicycive Therapeutics received a second USFDA CRL for Oxylanthanum Carbonate (OLC) due to third-party manufacturing deficiencies, with no concerns raised on efficacy or safety.

2) Evommune's EVO756 failed Phase 2b trial in chronic spontaneous urticaria (CSU). The company continues to evaluate the drug in Phase 2b atopic dermatitis (3QCY26 data readout) and plans to begin a Phase 2b migraine prevention study shortly (read through for Piramal Pharma).

3) Apotex became the first company to receive a Health Canada approval for generic Wegovy (Semaglutide) for chronic weight management. The product, Sevmia, was developed with Orbicular Pharmaceutical Technologies (read through for Dr Reddy's).

4) Samsung Bioepis reported positive global Phase 3 results for its Keytruda (Pembrolizumab) biosimilar, becoming the first company to demonstrate Phase 3 equivalence to the reference product (read through for Zydus, Dr Reddy's and Biocon).

5) AbbVie's Rinvoq (Upadacitinib) received a positive CHMP opinion for non-segmental vitiligo, moving closer to becoming the first systemic treatment for the condition in the EU, subject to European Commission approval (read through for Divi's and Anthem).

6) Novartis has reduced out-of-pocket costs for eligible US patients taking Kisqali (Ribociclib) as part of a broader access program after the drug was included in the first round of Medicare price negotiations (relevant for Divi's).

7) The Centers for Medicare & Medicaid Services (CMS) has clarified that beneficiaries already receiving Part D coverage for GLP-1s for non-obesity indications (type 2 diabetes, obstructive sleep apnea, or metabolic dysfunction-associated steatohepatitis) are not eligible for the Medicare GLP-1 Bridge Program, which is intended only for obesity-related coverage.

8) Morepen Laboratories has commenced commercial supplies under its Rs8.25bn CDMO contract, completing the first dispatch worth ~Rs500mn in 1QFY27. The company expects ~Rs2.25bn of additional supplies in 2QFY27.

9) Lupin is exploring the sale of its Brazilian subsidiary Medquímica for ~BRL300mn. The business reported FY25 revenue of BRL235mn and a loss of BRL112mn, and has remained loss-making since its acquisition in 2015.

10) Sandoz and Hybio Pharmaceutical announced that the USFDA accepted, for review, their generic Tirzepatide applications referencing Mounjaro and Zepbound, positioning both companies among the leading contenders to launch the first generic Tirzepatide products in the US.

11) A US federal court granted Amgen a preliminary injunction, blocking Colorado's first-in-the-US price cap on Enbrel (Etanercept). The ruling prevents the state from enforcing the $600 weekly dose price cap, citing potential irreparable harm to Amgen while the legal challenge proceeds (Organon has an approved biosimilar of Enbrel in the US).

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

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Additional News flow – Indian Pharma

1) Glenmark Pharmaceuticals has initiated a multi-country Phase 3 trial of Trastuzumab rezetecan in HER2-positive platinum-resistant ovarian cancer, with India becoming the first market to begin enrollment. The ADC was licensed from Hengrui Pharma in Sep-25 for commercialization across licensed markets outside China, the US, Europe, Japan, and certain CIS countries.

2) Lupin is exploring the sale of its Brazilian subsidiary Medquímica for around BRL300mn. The business, acquired in 2015, reported FY25 revenue of BRL235mn and a loss of BRL112mn, and has remained loss-making since its acquisition.

3) Morepen Laboratories commenced commercial supplies under its Rs8.25bn CDMO contract, completing the first dispatch worth ~Rs500mn in 1QFY27. The company expects ~Rs2.25bn of additional supplies in 2QFY27.

4) Mankind Pharma partnered with Denovo Sciences to launch an AI-driven drug discovery program, combining AI-driven molecular generation and prioritization platform with Mankind's R&D and clinical development capabilities to accelerate early-stage drug discovery, improve quality of lead candidates and move strong development potential candidates ahead.

5) Corona Remedies commissioned its EU-GMP approved hormone manufacturing facility in Ahmedabad, increasing in-house hormone production capacity by ~20%. The facility will manufacture tablets, soft gel capsules, ointments, and gels.

6) The Delhi High Court restrained Finecure Pharmaceuticals from manufacturing or selling Pantopacid, holding they are deceptively similar to Sun Pharma's Pantocid. Finecure has been allowed four months to liquidate its existing inventory.

7) Shilpa Medicare partnered with Orion Pharma to develop and supply an intravenous Nivolumab biosimilar for Europe. Orion will hold exclusive commercialization rights, while Shilpa will receive milestone payments and long-term supply revenues.

8) Aurobindo Pharma has completed the $250mn acquisition of Lannett following FTC approval, with Lannett becoming a wholly-owned subsidiary of Aurobindo Pharma USA. The company will commence the integration process immediately.

9) Lupin received EMA approval to expand the label for NaMuscla to include children aged 6-11 years (≥20kg) and adolescents (12-17 years) with non-dystrophic myotonic disorders, along with approval for new 62mg and 83mg capsule strengths.

10) India's pharmaceutical exports grew 6.6% YoY to $5.3bn in Apr-May '26, despite exports to the US (-6.3%) and West Asia North Africa (-0.4%) declining. Growth was driven by vaccines (+37.5%) and bulk drugs (+13.6%), along with strong demand from ASEAN, LatAm, Africa, and Europe.

News flow – Global innovators, CDMOs, and generic players

1) Novo Nordisk's oral Wegovy continued to dominate the oral obesity market with ~149,000 weekly prescriptions versus ~19,800 for Eli Lilly's Foundayo for the week ended 26-Jun-26, while Lilly maintained 59.5% share of the overall US obesity market led by strong Zepbound prescriptions.

2) Sandoz and Hybio Pharmaceutical announced that the USFDA accepted for review their generic Tirzepatide applications referencing Mounjaro and Zepbound, positioning both companies among the leading contenders to launch the first generic Tirzepatide products in the US, subject to approval.

3) Evommune's oral MRGPRX2 inhibitor EVO756 failed to meet the primary endpoint in a Phase 2b trial in chronic spontaneous urticaria (CSU). The company continues to evaluate the drug in a Phase 2b atopic dermatitis trial (data readout expected in 3QCY26) and plans to initiate a Phase 2b migraine prevention trial shortly (read through for Piramal Pharma).

4) The European Commission approved Enhertu (Trastuzumab deruxtecan) as the first HER2-directed tumour-agnostic ADC for previously treated HER2-positive unresectable or metastatic solid tumours with no satisfactory treatment options.

5) USFDA reviewers recommended against allowing seven peptides for pharmacy

compounding, citing insufficient evidence of safety and efficacy. The recommendations will be reviewed by the Pharmacy Compounding Advisory Committee on 23-24 Jul-26, with the FDA making the final decision.

6) Unicycive Therapeutics received a second Complete Response Letter (CRL) from the USFDA for Oxylanthanum Carbonate (OLC), with the agency again citing third-party manufacturing deficiencies that were identified in the previous CRL and raising no concerns on the drug's efficacy or safety (relevant for Shilpa Medicare).

7) Apotex became the first company to receive a Health Canada approval for generic Wegovy (Semaglutide) for chronic weight management. The product, Sevmia, was developed in partnership with Orbicular Pharmaceutical Technologies (relevant for Dr Reddy's).

8) Samsung Bioepis reported positive global Phase 3 results for its Keytruda (pembrolizumab) biosimilar, becoming the first company to demonstrate Phase 3 equivalence to the reference product (read through for Zydus, Dr Reddy's, and Biocon).

9) Lonza will expand its ADC payload-linker and HPAPI manufacturing capacity at its Visp, Switzerland site, with commercial operations expected in 2028. The company also expanded its partnership with an unnamed US biopharma to include commercial manufacturing for two biologics programs, with options for two more.

10) Sandoz launched Sandoz Direct, its first US direct-to-consumer platform, enabling eligible self-pay patients to purchase Omnitrope (Somatropin) directly, bypassing traditional pharmacy channels.

11) A US federal court granted Amgen a preliminary injunction, blocking Colorado's first-in-the-US price cap on Enbrel (etanercept). The ruling prevents the state from enforcing the $600 weekly dose price cap, citing potential irreparable harm to Amgen while the legal challenge proceeds (Organon has an approved biosimilar of Enbrel in the US).

12) AbbVie's Rinvoq (Upadacitinib) received a positive CHMP opinion for non-segmental vitiligo, moving closer to becoming the first systemic treatment for the condition in the EU, subject to European Commission approval (read through for Divi's and Anthem).

13) Novartis has reduced out-of-pocket costs for eligible US patients taking Kisqali (Ribociclib) as part of a broader access program after the drug was included in the first round of Medicare price negotiations (relevant for Divi's).

Key regulatory developments

1) The US's Centers for Medicare and Medicaid Services (CMS) clarified that beneficiaries already receiving Medicare Part D coverage for GLP-1s under non-obesity indications (such as type 2 diabetes, obstructive sleep apnea or MASH) are not eligible for the Medicare GLP-1 Bridge program, which is intended to expand access for patients seeking coverage solely for obesity.

2) The USFDA selected Eli Lilly, Regeneron, Fujifilm, Cellares, Amneal, Kyowa Kirin, and Kriya Therapeutics for its PreCheck Pilot Program, aimed at accelerating US drug manufacturing by enabling early regulatory engagement and potentially reducing manufacturing review timelines by up to 14 months.

3) The Philippines FDA plans to introduce priority review lanes for locally manufactured medicines as part of a broader government strategy to reduce reliance on imports, strengthen domestic pharmaceutical manufacturing, and improve medicine security.

4) The Indian government amended the Drugs Prices Control Order (DPCO), 2013 to simplify drug pricing rules. Manufacturers launching the same formulation of an NPPA-approved product within 12 months will no longer require separate price approval, while the reforms also introduce pack-based pricing flexibility, reduce overcharging liability subject to compliance, and strengthen disclosure and record-keeping requirements.

5) The Indian government brought cell & gene therapies, including stem cell, gene therapy, and xenograft products, under the Centrally License Approving Authority (CLAA) framework to ensure uniformity in regulatory standards across the country.

6) The Indian Health Ministry proposed extending Periodic Safety Update Report (PSUR) requirements for new drugs, requiring six-monthly reports for the first two years, annual reports for the next two years, and once every three years thereafter.

USFDA inspections/inspection outcomes

1) Ajanta Pharma received an Establishment Inspection Report (EIR) from the USFDA for its Paithan, Maharashtra manufacturing facility with a Voluntary Action Indicated (VAI) classification following an inspection conducted from 13-Apr-26 to 21-Apr-26.

2) Rubicon Research received two Form 483 observations following the first USFDA inspection of its Pithampur, Madhya Pradesh facility since its acquisition. The company said the observations were procedural, unrelated to data integrity, and reiterated plans to commence commercial operations from 1QCY27.

3) Lupin received an Establishment Inspection Report (EIR) from the USFDA for its Somerset, New Jersey manufacturing facility with a Voluntary Action Indicated (VAI) classification following an inspection conducted during 13-Apr-26 to 17-Apr-26.

4) OneSource Specialty Pharma received one Form 483 observation following a routine USFDA inspection of its Sterile Product Division facility in Bengaluru, conducted from 22-Jun-26 to 30-Jun-26.

5) Glenmark Pharmaceuticals received six Form 483 observations following a USFDA GMP inspection at its Goa manufacturing facility conducted from 22-Jun-26 to 30-Jun-26. The company said the observations were procedural, with no data integrity or repeat observations, and does not expect any impact on commercial product supplies.

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

Final Approval: gXarelto (Mankind), gXarelto (Micro Labs), Selenious Acid (Zydus), gZortress (I3 Pharma), gDifferin (Unique), gGadavist (GE Healthcare), gRifadin (Novitium Pharma)

Tentative Approval: gJanumet (Zydus), gProtonix (Jubilant)

Management changes/Corporate actions

1) Morepen Laboratories elevated Sanjay Suri from Whole-time Director to Managing Director, effective 1-Jul-26, to jointly lead the company's operations alongside Chairman and Managing Director Sushil Suri.

2) JB Chemicals announced the retirement of Pradeep Kumar Singh (President - Global Business) and Suresh Bhise (Vice President - IT), effective 30-Jun-26.

3) Emcure Pharmaceuticals announced the retirement of Kuber Jagdale, President - API Business, effective 30-Jun-26.

4) Syngene appointed Siddharth Mittal as Managing Director and CEO, succeeding Peter Bains. Siddharth joins from Biocon, where he served as MD and CEO.

5) Laurus Labs approved the appointment of Dr Shekhar Chintamani Mande and Sutapa Banerjee as Independent Directors for a five-year term, effective 2-Jul-26.

6) Natco Pharma announced the retirement of Nadella Malleswara Rao, Vice President - Operations (Pharma Division, Kothur), effective 30-Jun-26.

7) Strides Pharma Science agreed to sell a majority stake in its wholly-owned subsidiary Pivot Path to a consortium led by Ascent Capital and Vintage Classic for Rs1bn, alongside a Rs500mn primary capital infusion into Pivot Path. Post-transaction, Strides will retain a 19.95% stake in the company.

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