Pharmaceuticals

Pharma Weekly – ICYMI

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Pharmaceuticals ▸ Sector Report ▸ **February 18, 2026**

NIFTY 50: 25,725

This is the sixth edition (week ending 15-Feb-26) of our Pharma Weekly – In case you missed it. Key developments in the past week: 1) The USFDA has accepted Biofrontera's supplemental NDA for Ameluz PDT in superficial basal cell carcinoma (primary competitor to Sun's Levulan in actinic keratoses). 2) Eli Lilly has built ~USD1.5bn worth of pre-launch inventory of its obesity pill – Orforglipron (USFDA target action date: 10-Apr-2026; read-through for Divi's). 3) Zoetis will launch Lenivia (Izenivetmab) in Europe and Canada in 1HCY26 and expects approval in the US in CY27 (read-through for Syngene). 4) Samsung Bioepis has secured a US launch date of Jan-27 for its Aflibercept (Eylea) biosimilar, while Sandoz has launched its Aflibercept biosimilar in Canada (read-through for Biocon and Lupin). 5) Keytruda has received USFDA approval as a second-/third-line therapy for ovarian cancer in combination with Paclitaxel (Zydus, Biocon, and Dr Reddy's are working on Keytruda biosimilars). 6) Eisai posted 22% YoY growth in global Dayvigo sales in 4QCY25 and has maintained its sales guidance for the year ending Mar-26 (relevant for Aarti Pharmalabs). 7) AstraZeneca's oral GLP-1 obesity pill showed positive Phase-2 results and will advance to Phase 3; Viking Therapeutics plans to rapidly advance its oral obesity drug into Phase 3 trials after supportive mid-stage data. 8) Novo Nordisk plans to expand its Ireland facility to manufacture oral Wegovy for markets outside the US; the company also plans to sell Wegovy in a vial presentation. 9) Celltrion plans to expand its biosimilar portfolio from 11 products currently to over 40 products over the next decade.

News flow – Indian pharma

1) Gilead has sued Cipla in the US to block its Descovy HIV drug copy via the 505(b)(2) pathway, alleging infringement of seven Tenofovir Alafenamide patents lasting till CY36. 2) Alkem MedTech will acquire up to 55% stake in Switzerland-based Occlutech for EUR99.4mn (~Rs10.7bn), entering the global minimally invasive cardiac device segment. 3) Emcure Pharma reported a fire at its Hinjawadi (Pune) Plant-I utility block, causing a temporary shutdown of ~5–7 days, with no injuries reported and losses covered by insurance. 4) The Gujarat Pollution Control Board granted interim relief to Piramal Pharma, allowing immediate resumption of operations at its Dahej plant after earlier closure directions. 5) Ipca Laboratories has commenced commercial production at its new Rs1.8bn greenfield API and drug intermediate facility in Hingani, Wardha. 6) Despite a ~37% price cut, Novo Nordisk's Wegovy sales in India remain weak (Rs110mn/month) as Eli Lilly's Mounjaro continues to dominate the obesity drug market. 7) South Africa's Competition Commission is probing multiple pharma suppliers, including firms linked to Micro Labs and Sun Pharma, over potential collusive tendering and pricing practices in public medicine supply. 8) USV acquired a 79% stake in Wellbeing Nutrition for Rs15.8bn, marking its entry into the fast-growing nutraceutical and D2C wellness segment. 9) Shilpa Medicare signed a long-term development and manufacturing agreement with Switzerland's NXI Therapeutics for a new chemical entity targeting autoimmune disorders. The company has also filed its ANDA for gRotigotine transdermal patch, marking its entry into the US transdermal segment with a USD112mn market opportunity. 10) Aurobindo Pharma's step-down subsidiary Acrotech Biopharma received USFDA approval of its NDA for ADQUEY (Difamilast) ointment, to treat mild-to-moderate atopic dermatitis. 11) Akums Drugs received its first UK MHRA approval for Rivaroxaban, marking its entry into regulated European markets. 12) OneSource Specialty Pharma and Hikma received Saudi regulatory approval to launch generic Semaglutide, which will be manufactured by OneSource and commercialized by Hikma. 13) Warburg Pincus and Mubadala are leading a USD1.8bn bid to acquire up to 74% stake in topical CDMO Encube Ethicals. 14) Natco Pharma has received CDSCO approval to manufacture and market generic Semaglutide injection in India. 15) Johns Hopkins University has partnered with Syngene to advance early-stage drug candidates using its SynVent platform. 16) The Supreme Court has refused to stop Zydus from selling its Nivolumab biosimilar and has asked BMS to pursue patent-infringement claims before the Delhi High Court. 17) Lupin and Zydus have settled with Astellas in the US Myrbetriq (Mirabegron) patent litigation.

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News flow – Global innovators, CDMOs, and generic players

1) Biofrontera's supplemental NDA for Ameluz photodynamic therapy (PDT) in superficial basal cell carcinoma was accepted by the USFDA, with a decision expected by 28-Sep-26 and the potential to become the first PDT indication for this skin cancer.

2) Eli Lilly has built ~USD1.5bn in pre-launch inventory of its oral GLP-1 obesity pill (Orforglipron) ahead of a potential USFDA approval in Apr-26.

3) Zoetis will launch Lenivia (Izenivetmab) in Europe + Canada in 1HCY26 and expects an approval in the US in CY27. Librela (Bedinvetmab) US sales declined by 16% in CY25 and by 32% YoY in 4QCY25. The company expects Librela-linked headwinds to continue into CY26 even as it expects the consequent impact on growth to moderate through the year.

4) Samsung Bioepis has secured a US launch date of Jan-27 for its Aflibercept (Eylea) biosimilar after patent settlements, while Sandoz has launched its Aflibercept (Eylea) biosimilar in Canada.

5) Merck's Keytruda and subcutaneous Keytruda QLEX have gained USFDA approval with chemotherapy (± Bevacizumab) for PD-L1 positive platinum-resistant ovarian cancer.

6) Eisai's Dayvigo reported JPY47.7bn in sales in the 9M ending Dec-25 (+18% YoY despite a price revision in Japan). It is expanding globally with approvals in 27 countries, with growth in Canada and China supporting the company's full-year guidance of JPY58bn.

7) AstraZeneca's oral GLP-1 obesity pill (Elecoglipron) showed positive Phase-2 results and will advance to Phase-3 (detailed weight-loss data was withheld). However, according to the trial protocol, the drug would have produced greater weight loss than placebo at the 26-week mark and also allowed more subjects to lose at least 5% of their weight at the same point.

8) Viking Therapeutics plans to rapidly advance its oral obesity drug VK2735 into Phase-3 trials after supportive mid-stage data. The experimental pill had helped patients lose 12.2% of their body weight over 13 weeks versus 10.9% for those who received a placebo.

9) Novo Nordisk plans to expand its Ireland facility to manufacture oral Wegovy for markets outside the US after strong early demand, supporting global supply expansion. The company also plans to sell Wegovy in a vial presentation to compete with Eli Lilly and expand access, after losing market share in the obesity drug market.

10) Celltrion plans to expand its biosimilar portfolio from 11 products to over 40 over the next decade, aiming to significantly grow global market share across multiple therapy areas.

11) Hims & Hers has halted sales of its compounded oral Semaglutide after regulatory scrutiny intensified, with the USFDA considering fines over a brief Wegovy copy launch, while Novo Nordisk separately sued for patent infringement seeking damages.

12) Alvotech reported positive PK similarity results for its Vedolizumab (Entyvio) biosimilar candidates AVT80 (subcutaneous) and AVT16 (intravenous), paving the way for regulatory filings.

13) A coalition of 42 US states has brought a new antitrust lawsuit accusing Novartis and its former generics division, Sandoz, of generic drug price-fixing and bid-rigging.

14) Biotech IPOs are reviving in the US, with four drugmakers including Agomab, Eikon Therapeutics, Spyglass Pharma, and Veradermics raising nearly USD1bn combined, signalling renewed investor interest after a prolonged sector slump.

15) Hengrui and Kailera advanced their oral obesity drug toward late-stage trials after promising mid-stage China data (up to 12.1% weight loss at 26 weeks), intensifying competition in the global GLP-1 segment.

16) Organon and Henlius have settled their US litigation with Roche/Genentech over their Pertuzumab (Perjeta) biosimilar.

17) GSK and Teva settled their decade-long US patent dispute over Coreg 'skinny-label' generics, dropping all claims and ending litigation that had major implications for generic drug labeling and infringement risk.

18) AbbVie has sued the US Department of Health and Human Services over the inclusion of Botox in Medicare drug price negotiations, arguing that the Inflation Reduction Act price controls are unlawful and seeking to block enforcement.

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19) CVS Caremark will drop Amgen's Prolia from key US formularies and prefer lower-cost Denosumab biosimilars, Ospomyv (Samsung Bioepis), and Stoboclo (Celltrion), from Apr-26.

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20) Eli Lilly has appealed a ruling on how the USFDA classified its obesity drug Retatrutide, a decision that could determine whether compounding pharmacies can make competing versions of the therapy.

21) STADA and Bio-Thera have received an EU approval for Gotenfia, a biosimilar to Simponi (Golimumab).

22) Bristol Myers Squibb has partnered with AstraZeneca's Evinova to deploy AI-driven clinical trial design tools globally to improve decision-making, cut costs, and accelerate drug development timelines.

Key regulatory developments

1) The US Department of Health and Human Services dropped its legal defense of the proposed 340B rebate pilot, scrapping the plan that would have allowed drugmakers to replace upfront discounts to hospitals with post-sale rebates, preserving existing hospital discount pricing for now.

2) The US FTC reached a landmark settlement with Express Scripts requiring major changes to rebate and formulary practices, including avoiding preference for high list-price drugs and expanding access to lower-cost medicines.

3) Drugmakers are opposing the USFDA's plans to simplify prescription-to-OTC switches, warning that the proposal could bypass physician oversight and raise safety risks.

4) China revised its Drug Administration Law to formally allow acceptance of overseas clinical trial data for drug approvals, enabling faster market entry and synchronized global launches while strengthening data exclusivity protections for innovators.

5) Pharma industry bodies in India met with the UP government to explore investments as the state pushes a pharma hub strategy via bulk drug and medical device parks, along with incentives to attract manufacturing.

6) A rise in drug prices in the UK, driven by the government's higher cost-effectiveness thresholds, could lift prices in other countries that use international reference pricing.

USFDA inspections/inspection outcomes

1) Jubilant Pharmova has stated that the USFDA has classified the Oct–Nov-25 inspection of its Montreal facility as OAI (Official Action Indicated), though operations have resumed following remediation.

2) The USFDA conducted a pre-approval inspection at Cipla's InvaGen facility in New York from 02-Feb-26 to 09-Feb-26 and issued two Form-483 observations.

3) Ipca Laboratories has stated that the USFDA has classified the inspection of its Tarapur API facility (01-Dec-25 to 05-Dec-25) as Voluntary Action Indicated (VAI).

4) USFDA inspections at Aurobindo Pharma's Eugia Unit-III (27-Jan-26 to 06 Feb-26) and Unit-VII Jedcherla (28-Jan-26 to 10-Feb-26) facilities concluded with 11 observations and 9 observations, respectively.

5) The USFDA has classified the inspection of Natco's Manali (Chennai) API facility (17-Nov-25 to 21-Nov-25) as VAI after issuing 7 Form-483 observations.

Key USFDA approvals (final + tentative): Indian pharma/global generic players competing with Indian players in the specific product

Final approvals: gCopaxone (Hybio), gRetin-A (Encube), gFlorinef (Hibrow Healthcare), gNeptazane (Ajanta Pharma), gBrilinta (Mankind), gBumex (MSN), gSolu-Cortef (Apotex), gNilstat (Steranco Healthcare), gLidoderm (US Pharma)

Tentative approvals: gGalafold (Aurobindo)

Management changes/corporate actions

1) Aurobindo Pharma appointed Dr Punita Kumar-Sinha as Non-Executive Independent Director for three years effective 09-Feb-26, while Dr Deepali Pant Joshi retired from the board effective 10-Feb-26.

2) Supriya Lifescience re-appointed Dr Neelam Yashpal Arora as Independent Director for a second term (25-Mar-26 to 24-Mar-31) and appointed Manish Panchal and Kothandaraman Hari as Additional Independent Directors effective 09-Feb-26.

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3) JB Chemicals & Pharmaceuticals' Vice President–Legal Himanshu Ranvah has resigned, effective 06-Feb-26.

4) Dr. Reddy's Laboratories' Sushrut Kulkarni has resigned as Global Head of IPDO (Integrated Product Development Organisation) and Senior Management Personnel, effective 08-May-26.

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5) Concord Biotech Limited appointed Paritosh Trivedi as Company Secretary, Compliance Officer, and Nodal Officer, effective 11-Feb-26.

6) Natco Pharma's CFO SVVN Appa Rao superannuated on 12-Feb-26. The company appointed Amit Parekh as CFO from 13-Feb-26, and named Kalakuntla Srinivas Rao as EVP–Pharma Division from 12-Feb-26.

7) Sanofi India's Senior Management Personnel Suresh Babu (Sales & Customer Engagement Head – Diabetes) resigned effective 12-Feb-26.

8) Lupin appointed Anand Kripalu as an Independent Director.

9) Aurobindo Pharma approved a scheme of amalgamation to merge Auro Vaccines Private Limited, its step-down subsidiary, into Curateq Biologics Private Limited, a wholly-owned subsidiary, subject to NCLT Hyderabad approval.

10) Natco Pharma approved the incorporation of a wholly-owned subsidiary, Natco Pharma Chile SPA, with an investment of up to USD300,000.

11) Biocon granted in-principle approval to acquire the remaining ~2% stake in its subsidiary Biocon Biologics from employees of the Biocon Group through preferential share allotment.

12) AstraZeneca Pharma India appointed Tanya Sanish as Company Secretary and Compliance Officer, effective 23-Feb-26.

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