

DECEMBER

Date	Headline and Source	Link	Summary
1 st December	CDSCO Panel approves Roche Products Polatuzumab Vedotin for Injection-30mg per vial for Diffuse large Bcell lymphoma Medical Dialogues, December 01, 2024	CDSCO Panel approves Roche Products Polatuzumab Vedotin for Injection-30mg per vial for Diffuse large Bcell lymphoma	The Subject Expert Committee (SEC) functional under the Central Drug Standard Control Organisation (CDSCO) has approved Roche's proposal for the additional indication of diffuse large Bcell lymphoma (r/r DLBCL) for Polatuzumab Vedotin for injection (Polivy) 30 mg/vial with the condition that the drug should be prescribed only for the patients who are not eligible for transplant procedure as certified by the tumor board of the hospital.
2 nd December	BioPharma's Transformative & Strategic Outlook 2025 BioSpectrum India, December 02, 2024	BioPharma's Transformative & Strategic Outlook 2025	During September and October 2023, The Organisation of Pharmaceutical Producers of India (OPPI) and EY conducted primary research with the CXOs of the leading Indian and global multinational pharma companies, contract research development and manufacturing outsourcing organisations (CRDMOs), startups, patient advocacy groups, and other organisations to understand their perspective about the potential ambition for the pharma and healthcare sectors in the country for India@100.
3 rd December	Delhi HC Upholds AstraZeneca's Tagrisso Patent, Imposes Rs 7L Fine on Habitual Infringer for Knockoff Production Medical Dialogues, December 03, 2024	Delhi HC Upholds AstraZeneca's Tagrisso Patent, Imposes Rs 7L Fine on Habitual Infringer for Knockoff Production	The patent (IN 297581) protects the drug's composition and grants AstraZeneca exclusive rights to manufacture and sell Osimertinib in India until 2032. Advertisement AstraZeneca's patented compound, Osimertinib, is used to treat specific types of non-small cell lung cancer (NSCLC) and is marketed under the brand name Tagrisso.
4 th December	Pfizer India and Goa Government Launch Project Parivartan to Combat AMR and Strengthen Infection Control The CSR Universe, December 04, 2024	Pfizer India and Goa Government Launch Project Parivartan to Combat AMR and Strengthen Infection Control	Pfizer India, in partnership with the Government of Goa, Goa Medical College (GMC), Directorate of Health Services (DHS), and Americares India Foundation, has launched Project Parivartan, an initiative to enhance infection prevention and control (IPC) across Goa's public healthcare facilities. Supported by Pfizer's CSR program, the project aligns with India's National Action Plan on Antimicrobial Resistance (AMR) and the World Health Organization's global health priorities.

8 th December	Pfizer Gets CDSCO Panel Nod To Import 20 Valent Pneumococcal Conjugate Vaccine Medical Dialogues, December 08, 2024	Pfizer Gets CDSCO Panel Nod To Import 20 Valent Pneumococcal Conjugate Vaccine	This came after the vaccine major Pfizer presented the global immunogenicity data of all subjects vis-vis immunogenicity data of Indian subjects for 20Valent Pneumococcal Conjugate Vaccine (20vPnC) and the immunogenicity data of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P. 13 valent.
9 th December	AstraZeneca partners with Qure.ai to contribute in early Lung Cancer detection with AI New Indian, December 09, 2024	AstraZeneca partners with Qure.ai to contribute in early Lung Cancer detection with AI	A key highlight of the event was the announcement of a strategic partnership between AstraZeneca and Qure.ai, a leader in artificial intelligence applications in healthcare. Mohammed Yahya, Director of the CEO's office at Qure.ai, underscored the pivotal role of AI in lung cancer diagnosis, particularly in its early stages, where survival rates are significantly higher.
9 th December	Eli Lilly to launch diabetes, obesity drug in India next year The Times of India, December 09, 2024	Eli Lilly to launch diabetes, obesity drug in India next year	Eli Lilly, the US pharmaceutical giant that gained widespread attention globally with its weight-loss treatments, plans to launch its blockbuster drug Tirzepatide in India in 2025. India presents a promising market, with a large and growing population, rising disease burden from obesity, diabetes, and cancer, and an increasing health expenditure.
10 th December	Eli Lilly to launch its obesity drug at competitive price in India in 2025 Business Standard, December 10, 2024	Eli Lilly to launch its obesity drug at competitive price in India in 2025	US pharma giant Eli Lilly which plans to bring its obesity and diabetes drug Tirzepatide (or Mounjaro) to India next year, says it will price it "competitive and appropriate". A company spokesperson told Business Standard that they have received the marketing authorisation from relevant authorities for both Type 2 diabetes and obesity indications.
11 th December	AstraZeneca-Daiichi Sankyo Datopotamab deruxtecan gets USFDA Breakthrough Therapy Designation for previously treated advanced EGFR-mutated non-small cell lung cancer Medical Dialogues, December 11, 2024	AstraZeneca-Daiichi Sankyo Datopotamab deruxtecan gets USFDA Breakthrough Therapy Designation for previously treated advanced EGFR-mutated non-small cell lung cancer	AstraZeneca has announced that Datopotamab deruxtecan (DatoDXd) has been granted Breakthrough Therapy Designation (BTD) in the US for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor mutated (EGFRm) nonsmall cell lung cancer (NSCLC) with disease progression on or after treatment with an EGFRtyrosine kinase inhibitor (TKI) and platinum-based chemotherapy.
12 th December	Novo Nordisk, SKIMS forge strategic partnership to advance clinical trials	Novo Nordisk, SKIMS forge strategic partnership to advance clinical trials	Novo Nordisk India Private Limited and SheriKashmir Institute of Medical Sciences (SKIMS), Soura have signed a landmark Memorandum of Understanding

	Daily Excelsior, December 12, 2024		(MoU) to embark on a strategic collaboration focused on advancing clinical trials in India.
13 th December	SKIMS, Srinagar, Novo Nordisk ink MoU to advance clinical trials in India Medical Buyer, December 13, 2024	SKIMS, Srinagar, Novo Nordisk ink MoU to advance clinical trials in India	Novo Nordisk India Pvt. Ltd. and SheriKashmir Institute of Medical Sciences (SKIMS), Soura have signed a landmark Memorandum of Understanding (MoU) to embark on a strategic collaboration focused on advancing clinical trials in India.
16 th December	CDSCO panel approves AstraZeneca's Protocol Amendment proposal for Anticancer Drug AZD5305 study Medical Dialogues, December 16, 2024	CDSCO panel approves AstraZeneca's Protocol Amendment proposal for Anticancer Drug AZD5305 study	The Subject Expert Committee (SEC) functional under the Central Drug Standard Control Organisation (CDSCO) has approved the drug major AstraZeneca's proposal for the protocol amendment of the clinical trial titled A randomised 2 cohort double blind placebo-controlled phase III study of AZD5305 in combination with physicians choice new hormonal agents in patients with HRRm and non-HRRm metastatic castration sensitive prostate cancer (EvoPARProstate01).
17 th December	Anil Matai reflects on 2024 as a pivotal year for India's pharma sector Express Pharma, December 17, 2024	Anil Matai reflects on 2024 as a pivotal year for India's pharma sector	As 2024 nears its end, the Organisation of Pharmaceutical Producers of India (OPPI) DG, Anil Matai, has shared a yearend reflection on the transformative developments in India's healthcare landscape. According to Matai, Director General of OPPI, the year has set the stage for a more patient-centric and innovation-driven future in the healthcare sector.
18 th December	Eli Lilly and Company gets CDSCO panel nod to import, market Tirzepatide Multiple Dose Pen Medical Dialogues, December 18, 2024	Eli Lilly and Company gets CDSCO panel nod to import, market Tirzepatide Multiple Dose Pen	The pharmaceutical major Eli Lilly and Company (India) has got the go-ahead from the Subject Expert Committee (SEC) functional under the Central Drug Standard Control Organisation (CDSCO) to import and market of Tirzepatide Multiple Dose Pen (additional of new presentation-KwkPen) 2.5 mg/0.6 ml, 5 mg/0.6 ml, 7.5 mg/0.6 ml, 10.0 mg/0.6 ml, 12.5 mg/0.6 ml, and 15.0 mg/0.6 ml in India, subject to the condition that the firm should conduct a Phase-IV clinical trial.
18 th December	MSD Pharmaceutical Gets CDSCO Panel Nod To study MK1084 Medical Dialogues, December 18, 2024	MSD Pharmaceutical Gets CDSCO Panel Nod To study MK1084	MSD Pharmaceutical has got approval from the Subject Expert Committee SEC functional under the Central Drug Standard Control Organisation (CDSCO) to conduct the phase 3 clinical study of the anticancer drug MK1084. This came after MSD Pharmaceutical presented

			phase 3 clinical study protocol no. MK1084004 version 00 dated 15 December 2023.
18 th December	Eli Lilly's Weight Loss, Anti-Diabetes Drug Mounjaro To Be Launched In 2025 News 18, December 18, 2024	Eli Lilly's Weight Loss, Anti-Diabetes Drug Mounjaro To Be Launched In 2025	Eli Lilly, a US-based pharmaceutical giant, plans to launch its drug, Tirzepatide, sold under the brand name Mounjaro, in the Indian market next year. Mounjaro, a weekly injectable drug by Eli Lilly for treating type 2 diabetes and obesity, competes with another high-profile drug, Ozempic (manufactured by Danish drugmaker, Novo Nordisk).
19 th December	Breaking Health News: Major Approvals and Controversies in Pharma Industry Devdis Course, December 19, 2024	Breaking Health News: Major Approvals and Controversies in Pharma Industry	Eli Lilly's Alzheimer's treatment has gained approval in China, joining the United States, Japan, and the UK as markets for Kisunla. This move diversifies options for patients following the earlier approval of Eisai and Biogen's Leqembi in January. CVS faces allegations of filling and billing for illegal opioid prescriptions, heightening scrutiny over its role in the opioid crisis.
19 th December	Global Health Advancements: Eli Lilly's Alzheimer's Treatment Gains Ground Devdis Course, December 19, 2024	Global Health Advancements: Eli Lilly's Alzheimer's Treatment Gains Ground	Eli Lilly's Alzheimer's treatment has been approved in China, marking the fourth major market to give the nod to Kisunla after the U.S., Japan, and the UK. This development offers a new option for patients following Eisai and Biogen's recently approved Leqembi.
19 th December	Merck in pact for Chinese obesity drug in nearly \$2 billion deal Money Control, December 19, 2024	Merck in pact for Chinese obesity drug in nearly \$2 billion deal	Merck CEO Rob Davis has previously indicated an interest in gaining more assets that lead to second and third generation approaches to treating obesity, diabetes and related diseases. Merck & Co. snagged a potential drug in the burgeoning market for obesity medications in a deal worth as much as \$2 billion.
23 rd December	India's CDSCO gives nod to sell 19 new drugs in 2024 Fortune, December 23, 2024	India's CDSCO gives nod to sell 19 new drugs in 2024	Sun Pharma's gynaecological drug Elagolix tablets, Bristol Myers Squibb (BMS)'s cardiology drug Mavacamten, lung cancer drug Brigatinib marketed under the brand name Alunbrig by Ariad Pharmaceuticals etc. are some of the new drugs approved in recent months and will be launched in India.
23 rd December	CDSCO Panel Approves AstraZeneca's Protocol Amendment Proposal For Anticancer Drug Volrustomig study	CDSCO Panel Approves AstraZeneca's Protocol Amendment Proposal For Anticancer Drug Volrustomig study	The Subject Expert Committee (SEC) functional under the Central Drug Standard Control Organisation (CDSCO) has approved AstraZeneca's protocol amendment proposal for study of Volrustomig in Women with High Risk

	Medical Dialogues, December 23, 2024		Locally Advanced Cervical Cancer (eVOLVECervical).
27 th December	AI, machine learning to help Indian pharma industry to pivot on innovation Daily Pioneer, December 27, 2024	AI, machine learning to help Indian pharma industry to pivot on innovation	Similarly, Organisation of Pharmaceutical Producers of India (OPPI) Director General Anil Matai said the industry is set for a profound transformation in 2025. Technological advancements like AI, machine learning and precision medicine are set to revolutionise drug discovery, manufacturing and patient care, he said.
27 th December	Weight Loss Drug Mounjaro to Be Launched in India in 2025; Know How It Tackles Obesity Times Now News, December 27, 2024	Weight Loss Drug Mounjaro to Be Launched in India in 2025; Know How It Tackles Obesity	US pharma giant Eli Lilly plans to bring its obesity and diabetes drug Tirzepatide or Mounjaro, to India next year and has said it will price it competitive and appropriate. According to news reports, the company has received marketing authorization from relevant authorities for both Type 2 diabetes and obesity indications.
30 th December	CDSCO Panel Approves Eli Lilly's Protocol Amendment Proposal for Antidiabetic Drug Retatrutide study Medical Dialogues, December 30, 2024	CDSCO Panel Approves Eli Lilly's Protocol Amendment Proposal for Antidiabetic Drug Retatrutide study	The Subject Expert Committee (SEC) functional under the Central Drug Standard Control Organisation (CDSCO) has approved the drug major Eli Lilly's protocol amendment proposal for the antidiabetic Drug Retatrutide (LY3437943) study.
30 th December	CDSCO Panel Approves AstraZeneca's Protocol Amendment Proposal To Study antihypertensive drug Baxdrostat Medical Dialogues, December 30, 2024	CDSCO Panel Approves AstraZeneca's Protocol Amendment Proposal To Study antihypertensive drug Baxdrostat	The Subject Expert Committee (SEC) functional under the Central Drug Standard Control Organisation (CDSCO) has approved the pharmaceutical major AstraZeneca protocol amendment proposal to study Baxdrostat Tablets 1 mg/2 mg.
31 st December	FOPE & PharmaState Academy host Session 12 of the PULSE series Express Pharma, December 31, 2024	FOPE & PharmaState Academy host Session 12 of the PULSE series	The event began with a keynote address by Anil Matai, Director General, OPPI India. He opened the session by addressing the importance of product safety and quality, highlighting the global recognition of India's pharmaceutical industry.
