



PHARMA MONTHLY

FEBRUARY 2023

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Key News for the Month

Company

- Lupin arm recalls 5,720 skin treatment cream tubes in US
- SII's cervical cancer vaccine to be available in market this month at Rs2000 for two doses
- Sun Pharma gets USFDA nod to market generic medication
- Sun Pharma recalls over 34k bottles of generic drug in US due to manufacturing issues
- USFDA issues CRL for Bevacizumab license application moved by Viartis: Biocon
- Natco Pharma submits application with USFDA for generic cancer drug
- Torrent Pharma forays into OTC segment with calcium supplement
- Max, Princeton Healthcare among 11 entities interested in SevenHills Hospital
- Aurobindo Pharma gets VAI classification, USFDA gives nod to two facilities
- Alembic Pharmaceuticals receives EIR for its Injectable Facility at Karkhadi
- Lupin receives an EIR from the USFDA for its injectable facility in Nagpur
- AstraZeneca gets CDSCO nod for drug to treat biliary tract cancer
- Glenmark gets USFDA nod for generic diabetes drug
- Cipla's Pithampur unit gets 8 observations from USFDA after inspection
- Sun Pharma acquires 26.09% stake in Agatsa Software, 27.39% in Remidio Innovative Solutions
- Biocon raises USD129mn from Kotak to fund biosimilars deal
- Venus Remedies gets marketing approval for cancer drugs from Uzbekistan, Palestine
- Wockhardt shuts the US manufacturing plant
- Bristol Myers Squibb to invest Rs800cr to set up facility in Hyderabad for drug development, IT
- Strides flagship facility in Bangalore receives USFDA inspection closure
- USFDA concludes inspection at Alkem Laboratories' Indore facility
- Wockhardt looks to roll out 2 vaccines from UK plant in 12 months as part of tie-up with Serum
- Dr. Reddy's Laboratories announces agreement to acquire Mayne Pharma's US generic prescription product portfolio
- Venus Remedies awarded Saudi GMP approval for all its production facilities in Baddi
- Granules gets USFDA nod to market generic medication to treat high blood pressure

Industry

- Thrust on R&D in Union Budget a welcome step: Pharma body
- Government steps up efforts to drive innovation in pharmaceutical sector
- Govt releases Rs166cr incentives under PLI scheme for pharmaceuticals
- Essential drugs list to soon include commonly used hygiene products

Global

- EU approves AstraZeneca Forxiga for use across the EU
- GSK announces results from 17-year retrospective study on US clinical trial diversity
- Pfizer's elranatamab receives FDA and EMA filing acceptance
- AstraZeneca enters license agreement with KYM Biosciences for CMG901, a Claudin-18.2 antibody drug conjugate
- Merck delivers vital data on evobrutinib

Tentative ANDA Approvals

Company	API	Strengths	Indications	Brand (Company)	Mkt Size
Glenmark Pharma	Saxagliptin Tablets	2.5/5mg	Used to lower blood sugar levels in patients with type 2 diabetes	Onglyza (AstraZeneca AB)	USD122.3mn (annual sales Dec 2022)
Zydu Lifesciences	Bosentan Tablets for Oral Suspension	32mg	Indicated for the treatment of pulmonary arterial hypertension (PAH) in pediatric patients aged 3 years and older	Tracleer (Actelion Pharmaceuticals US, Inc.)	USD16mn (annual sales Dec 2022)
Zydu Lifesciences	Canagliflozin Tablets	100/300mg	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	Invokana (Mitsubishi Tanabe Pharma Corporation)	USD660mn (annual sales Dec 2022)
Zydu Lifesciences	Gabapentin Tablets	300/600mg	Indicated for the management of Postherpetic Neuralgia (PHN)	Gralise (Almatica Pharma, LLC)	USD90mn (annual sales Dec 2022)
Zydu Lifesciences	Canagliflozin & Metformin Hydrochloride Tablets	50/500mg, 50/1000mg, 150/500mg and 150/1000mg	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	Invokamet (Mitsubishi Tanabe Pharma Corporation)	USD49.4mn (annual sales Dec 2022)

Source: Media Reports and Company Press Releases

Final ANDA Approvals

Company	API	Strengths	Indications	Brand (Company)	Mkt Size
Zydu Lifesciences	Sirolimus Tablets	1/2mg	Used to prevent rejection (anti-rejection medicine) in people 13 years of age and older who have received a kidney transplant	Rapamune (Pfizer Inc.)	USD69mn (annual sales Dec 2022)
Zydu Lifesciences	Pitavastatin Tablets	1/2/4mg	Used together with diet, weight-loss, and exercise to reduce the amount of fatty substances such as LDL cholesterol	Livalo (Kowa Company Ltd)	USD319mn (annual sales Dec 2022)
Caplin Point	Carboprost Tromethamine Injection	250mcg/mL Single-dose Vials	Indicated for treatment of postpartum hemorrhage due to uterine atony	Hemabate Injection (Pfizer Inc.)	USD55mn (annual sales Sept 2022)
Granules India	Losartan Potassium Tablets	25/50/100mg	Indicated for the treatment of hypertension in adults and pediatric patients	Cozaar Tablets (Organon LLC)	USD336mn (annual sales Dec 2022)

Source: Media Reports and Company Press Releases

BSE Health Care Index Price Performance				
Companies	Price	Change		
		1 M	6 M	12 M
Aarti Drugs Ltd	366	-8.8%	-15.2%	-19.6%
Abbott India Ltd	20192	-3.7%	7.6%	15.1%
Ajanta Pharma Ltd	1178	-2.5%	-12.9%	2.3%
Albert David Ltd	549	0.8%	0.8%	5.8%
Alembic Ltd	61	-9.2%	-16.9%	-31.4%
Alkem Laboratories Ltd	3176	5.6%	9.0%	-3.1%
Ami Organics Ltd	906	4.1%	-8.6%	4.2%
Anuh Pharma Ltd	84	-4.5%	-6.9%	-12.4%
Alembic Pharmaceuticals Ltd	510	-5.1%	-21.6%	-29.7%
Apollo Hospitals Enterprise Ltd	4401	3.8%	3.7%	-8.3%
Aster DM Healthcare Ltd	222	5.3%	-1.4%	29.9%
AstraZeneca Pharma India	3350	-0.2%	8.1%	28.5%
Aurobindo Pharma Ltd	463	12.5%	-14.2%	-26.0%
Bajaj Healthcare Ltd	345	-13.4%	-3.8%	-11.1%
Biocon Ltd	229	-2.1%	-24.5%	-34.4%
Bliss GVS Pharma Ltd	80	-0.2%	3.6%	9.6%
Caplin Point Laboratories Ltd	655	-4.1%	-13.62%	-1.9%
Cipla Ltd/India	906	-12.4%	-10.9%	-2.1%
Dishman Carbogen Amics Ltd	117	41.4%	0.2%	-29.4%
Divi's Laboratories Ltd	2826	-16.1%	-21.2%	-33.7%
Dr. Reddy's Laboratories Ltd	4311	-0.5%	2.4%	6.1%
Eris Lifesciences Ltd	640	4.3%	-7.8%	-5.0%
FDC Ltd	263	2.5%	0.3%	-2.8%
Fermenta Biotech Ltd	131	-23.0%	-26.3%	-46.1%
Fortis Healthcare Ltd	268	-3.4%	-7.2%	9.1%
Gland Pharma Ltd	1317	0.4%	-43.7%	-59.5%
GSK Pharmaceuticals Ltd	1335	6.0%	-8.6%	-12.2%
Glenmark Pharmaceuticals Ltd	429	15.5%	12.8%	-4.4%
Glenmark Lifesciences Ltd	375	-2.8%	-14.9%	-18.7%
Granules India Ltd	280	-3.9%	-7.3%	-3.6%
Gufic Biosciences Ltd	212	-3.2%	0.2%	3.9%
Gujarat Themis Biosyn Ltd	642	-9.2%	23.6%	90.5%
HealthCare Global Enterprises Ltd	280	0.3%	3.1%	22.8%
Hester Biosciences Ltd	1764	-0.7%	-15.6%	-19.5%
Hikal Ltd	295	-14.5%	-9.2%	-19.7%
Indoco Remedies Ltd	359	6.3%	0.4%	-8.4%
Indraprastha Medical Corp. Ltd	79	-5.3%	13.4%	19.5%
IND-Swift Laboratories Ltd	62	-4.8%	3.1%	-10.4%
IOL Chemicals and Pharma Ltd	285	-9.7%	-20.1%	-18.9%
IPCA Laboratories Ltd	808	-5.5%	-10.3%	-17.6%
J.B.Chemicals & Pharmaceuticals Ltd	1934	-4.3%	7.5%	19.6%
Jubilant Life Sciences Ltd	307	-9.0%	-12.3%	-22.9%
KIMS Ltd	1350	-10.3%	14.1%	6.4%
Kopran Ltd	110	-15.0%	-40.6%	-59.7%
Kovai Medical Center & Hospital Ltd	1921	12.2%	27.8%	24.4%
Krsnaa Diagnostics Ltd	359	-14.4%	-25.6%	-34.5%
Lal PathLabs Ltd	1988	-3.5%	-23.5%	-21.1%
Lasa Supergenerics Ltd	24	-6.4%	-31.0%	-45.2%

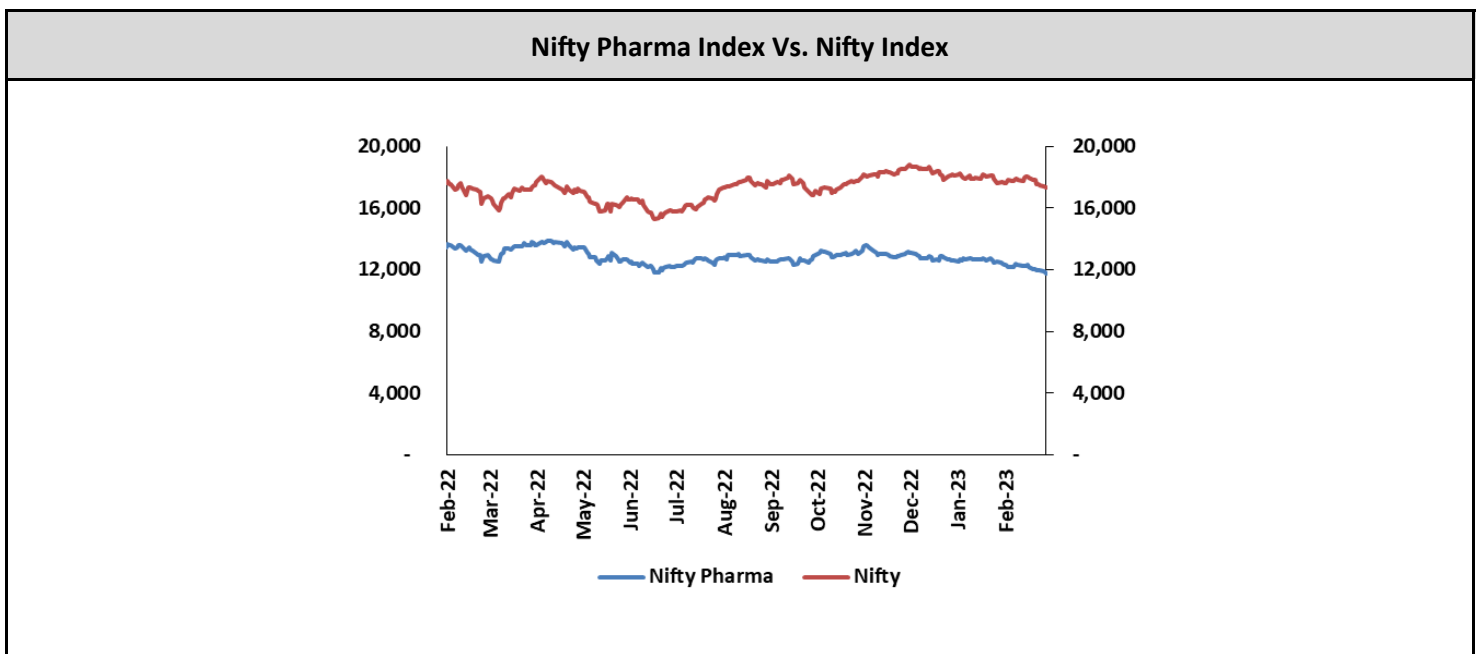
Source: BSE website; All prices are as on 28th Feb, 2023

BSE Health Care Index Price Performance				
Companies	Price	Change		
		1 M	6 M	12 M
Laurus Labs Ltd	314	-8.1%	-45.5%	-42.0%
Lincoln Pharmaceuticals Ltd	328	6.2%	15.6%	7.7%
Lupin Ltd	659	-10.2%	-0.5%	-11.6%
Marksans Pharma Ltd	67	6.6%	29.2%	43.2%
Max Healthcare Institute Ltd	430	-2.2%	14.8%	14.9%
Medicamen Biotech Ltd	609	-17.7%	-46.3%	-8.6%
Metropolis Healthcare Ltd	1310	-0.2%	-7.4%	-32.9%
Morepen Laboratories Ltd	25	-9.8%	-26.2%	-37.0%
Natco Pharma Ltd	538	1.0%	-12.6%	-38.0%
Nectar Lifesciences Ltd	17	-14.6%	-24.3%	-35.6%
Neuland Laboratories Ltd	1609	13.5%	31.8%	52.2%
NGL Fine-Chem Ltd	1290	-12.9%	-18.7%	-38.9%
Narayana Hrudayalaya Ltd	752	3.5%	7.3%	9.7%
Novartis India Ltd	601	-2.1%	-18.8%	-4.5%
Nureca Ltd	341	-11.3%	-65.9%	-75.3%
Panacea Biotech Ltd	120	-5.8%	-11.8%	-36.6%
Pfizer Ltd (India)	3795	-3.9%	-8.0%	-13.8%
Procter & Gamble Health Ltd	4669	16.2%	11.9%	2.1%
Poly Medicure Ltd	937	7.4%	6.9%	17.7%
RPG Life Sciences Ltd	858	12.9%	18.8%	73.4%
Sanofi India Ltd	5830	5.5%	-5.3%	-19.7%
Sastasundar Ventures Ltd	229	-11.9%	-34.3%	-41.1%
Sequent Scientific Ltd	62	-18.2%	-44.6%	-53.6%
Shalby Ltd	123	-15.6%	-0.3%	-1.6%
Shilpa Medicare Ltd	257	6.6%	-30.4%	-36.8%
Sigachi Industries Ltd	253	-20.1%	-7.5%	-15.9%
SMS Pharmaceuticals Ltd	69	-9.5%	-14.5%	-30.1%
Solara Active Pharma Sciences Ltd	360	-12.2%	-17.2%	-47.3%
SPARC Ltd	191	-0.9%	-16.7%	-29.0%
Strides Pharma Science Ltd	298	-0.3%	-9.8%	-6.9%
Sun Pharmaceutical Industries Ltd	957	-8.9%	9.0%	13.5%
Supriya Lifescience Ltd	200	-4.4%	-44.3%	-52.5%
Suven Life Sciences Ltd	56	-8.6%	-21.1%	-29.9%
Suven Pharmaceuticals Ltd	481	-1.0%	3.1%	-5.8%
Snycom Formulations (India) Ltd	6	-20.9%	-25.3%	-34.8%
Syngene International Ltd	581	2.3%	-3.9%	7.0%
Take Solutions Ltd	18	-18.6%	-31.2%	-39.0%
Tarsons Products Ltd	587	-13.2%	-24.0%	-2.32%
Thyrocare Technologies Ltd	452	-13.2%	-26.0%	-47.3%
Torrent Pharmaceuticals Ltd	1460	-5.6%	-5.2%	5.9%
TTK Healthcare Ltd	900	-6.5%	6.2%	32.8%
Unichem Laboratories Ltd	297	-9.4%	-2.7%	17.3%
Venus Remedies Ltd	165	1.1%	-23.6%	-42.8%
Vijaya Diagnostic Centre Ltd	376	-7.3%	7.6%	-10.6%
Vimta Labs Ltd	302	-16.1%	-19.0%	-5.1%
Windlas Biotech Ltd	256	7.3%	17.2%	5.1%
Wockhardt Ltd	187	-6.1%	-21.8%	-44.8%
Zydus Lifesciences Ltd	466	8.8%	23.3%	29.2%

Source: BSE website; All prices are as on 28th Feb, 2023

NIFTY PHARMA COMPANIES					
Company	Price (Rs)	Mcap (Rs mn)	Change		
			1 M	6 M	12 M
Abbott India Ltd	20192	429061	-3.7%	7.6%	15.1%
Alkem Laboratories Ltd	3176	379679	5.6%	9.0%	-3.1%
Alembic Pharmaceuticals Ltd	510	100257	-5.1%	-21.6%	-29.7%
Aurobindo Pharma Ltd	463	271319	12.5%	-14.2%	-26.0%
Biocon Ltd	229	274937	-2.1%	-24.5%	-34.4%
Cipla Ltd	906	7272989	-12.4%	-10.9%	-2.1%
Divi's Laboratories Ltd	2826	750148	-16.1%	-21.2%	-33.7%
Dr. Reddy's Laboratories Ltd	4311	717925	-0.5%	2.4%	6.1%
Gland Pharma Ltd	1317	216905	0.4%	-43.7%	-59.5%
Glenmark Pharmaceuticals Ltd	429	120994	15.5%	12.8%	-4.4%
Granules India Ltd	280	67748	-3.9%	-7.3%	-3.6%
Ipca Laboratories Ltd	808	205006	-5.5%	-10.3%	-17.6%
Laurus Labs Ltd	314	169217	-8.1%	-45.5%	-42.0%
Lupin Ltd	659	299778	-10.2%	-0.5%	-11.6%
Natco Pharma Ltd	538	98234	1.0%	-12.6%	-38.0%
Pfizer Ltd	3795	173615	-3.9%	-8.0%	-13.8%
Strides Pharma Science Ltd	298	26892	-0.3%	-9.8%	-6.9%
Sun Pharmaceutical Industries Ltd	957	2296164	-8.9%	9.0%	13.5%
Torrent Pharmaceuticals Ltd	1460	494283	-5.6%	-5.2%	5.9%
Zydus Lifesciences Ltd	466	471232	8.8%	23.3%	29.2%

Source: NSE website, Company Research; All prices are as on 28th Feb, 2023



Source: NSE website

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