

November 22, 2023

SECTOR UPDATE | Sector: Pharmaceuticals

Pharma – US approvals watch

Opportunity from new approvals remains weak

In follow up to our US approvals watch published in mid-August'23, we reassess US approvals data in the previous 3 months to understand the support from new launches. A look at fresh approvals suggests for most companies, barring Aurobindo and Zydus (yet again), approvals are either small in size or fully commoditized. While companies like Dr Reddys' might navigate on back of Revlimid, reckon smaller companies would need several meaningful approvals to generate sustained growth. In continuation of what we wrote in Aug'23, we do not notice any signs of larger/meaningful approval filtering through across wide spectrum of companies. While we understand US environment remains supportive in the form of lower price erosion, it may turn for worse relatively quickly; hence fresh approvals are what would lead to sustained growth outperformance which is missing in most of the players. Zydus (not Rated) continues to get good approvals while Aurobindo yet again banks on sheer volume. Mid-sized companies have got the odd, good approval (Alkem – Chantix, , Alembic – Combigan, Selexipag) but most of them continue to struggle. Reiterate preference for Ajanta, positive view on Indoco while a cautious stance on Alembic is warranted given the lack of quality injectables approvals.

- Aurobindo – As always garners large volume of approvals but has lesser number of meaningful ones compared to June-August period
- Alembic – Barring an ophthalmic approval (Combigan) in August and Selexipag in Oct'23, Alembic has not managed any decent onco/general injectable approval. Q3 performance would depend on volume gains in existing business and ramp up in Combigan.
- Alkem, Ajanta – No major approval and expect US performance to be driven by volume gains; Ajanta may have to contend with large sales of flu products in Q3 FY23
- Lupin & Dr Reddys' – Lupin US performance rests on Spiriva share gain coupled with strength of flu season (good start so far); continued lack of approvals may hurt as company reaches optimum market share in Spiriva. A similar assessment would hold true for DRL as Revlimid and benign pricing environment are helping offset weak new launch pipeline

Q3 US business outlook – A repeat of Q2 FY24?

Q2 FY24 had seen the full benefit of a benign US pricing scenario as many companies reported strong US sales driven by volume increase in existing products and lower price erosion. We expect a similar scenario to prevail in Q3 and this would ensure that lack of approvals across several players may offset by better volumes coupled with select shortage opportunities. We view current phase prone to sudden shifts in pricing environment which would impact US profitability accentuated by lack of approvals.

Reiterate preference for Ajanta; cautious on Alembic and neutral stays on Dr Reddys'

We continue to prefer Ajanta on few triggers like faster growth in branded business in Asia and Africa, 10-11% growth in domestic business and US turnaround after 2 tough years (ex-forex and flu-related sales in Q3 FY23). We had lowered rating on Indoco to ADD on back of continuous disappointment and too much to do in H2 FY24. On the other hand, Alembic is not getting support from large approvals that can propel US onto the next leg of growth and continues to rely on benign generic market to eke out volume expansion. Within the larger generic names, Lupin is supported by Spiriva traction though the market share gains may be gradual after the sprint since launch, thereby increasing dependence on US generic markets staying calm.

BHAVESH GANDHI

Lead Analyst

bhaves.gandhi@ysil.in



Exhibit 1: US ANDA approvals since Sep'23 (approvals in bold are meaningful in our view)

ANDA	Company	No of players	Opportunity size
Sep'23			
Loperamide Hydrochloride	Aurobindo	7	Fully genericized anti-diarrhea medicine; less than US\$15mn market size
Sevelamer Carbonate	Strides	7	Used to lower blood phosphate level; combined tablet + suspension market is ~US\$200mn per IQVIA and could be a good approval for Strides
Acetazolamide	Ajanta Pharma	11	Diuretic - helps lose salt/water; fully genericized
Ethinyl Estradiol and Norelgestromin	Zydus	4	CGT designated contraceptive transdermal patch with market size of US\$330mn - can be a good approval though reference drug is no longer available
Ibuprofen	Aurobindo	>10	Pain killer fully genericized
Chlordiazepoxide Hydrochloride and Clidinium Bromide	Aurobindo	9	Stomach ulcer drug - fully genericized
Chlordiazepoxide Hydrochloride and Clidinium Bromide	Alembic Pharma	9	Stomach ulcer drug - fully genericized
Norepinephrine Bitartrate	Caplin Point	10	Fully genericized low blood pressure med
Famotidine	Ajanta Pharma	>10	Stomach ulcer drug - fully genericized
Clindamycin Phosphate	Cadila	>10	Topical gel for acne fully genericized
Icosapent Ethyl	Strides	7	Additional generic Vascepa approval could mean competition for DRL though API procurement appears difficult
Topiramate	Aurobindo	>10	Not much left in this ER tablet for seizures
Dextroamp Saccharate, Amp Aspartate, Dextroamp Sulfate and Amp Sulfate	Sun Pharma	>10	CNS drug for attention deficit - innovator drug Adderall of Teva has been notably in shortages
Losartan Potassium; Hydrochlorothiazide	Granules	>10	Nothing left in this high blood pressure tablet
Oct'23			
Efavirenz; Emtricitabine and Tenofovir Disoproxil Fumarate	Strides	7	Anti-HIV drug fully genericized
Osetamivir Phosphate	Invagen (Cipla)	>10	generic Tamiflu - not much benefit except may be in ongoing seasonal flu
Sugammadex	Zydus	2 (+ 6 tentative approvals)	Amongst top sellers for innovator Merck used to reverse effect of muscle relaxants; few others have tentative approval but launch unlikely before Jan'26
Metformin HCL	Laurus	>10	Fully genericized anti-diabetes tablet
Eslicarbazepine Acetate	Alkem	4	Drug to treat partial epilepsy which may not be meaningful anymore
Selexipag	Alembic Pharma	2 (+2 TAs)	Anti-hypertensive tablet for which Zydus had 180-day shared exclusivity; Lupin has TA injectable approval; could be decent for Alembic with IQVIA sales of >US\$400mn

Piperacillin and Tazobactam	Aurobindo	>10	Anti-bacterial injectable fully genericized
Fosphenytoin Sodium	Gland Pharma	7	Anti-seizure injectable fully genericized
Apremilast	Glenmark	4 (+6 TAs)	Large Amgen psoriatic arthritis under patent; Sandoz and Zydus barred till Feb 2028 so Glenmark unlikely to launch anytime soon
Atorvastatin Calcium	Cadila	>10	Cardiac tablet fully genericized
Deferasirox	Aurobindo	>10	Highly commoditized tablet used to treat excess Iron in the body
Succinylcholine Chloride	Eugia Pharma	>10	Highly commoditized injectable used as an adjunct to anesthesia
Esomeprazole Magnesium	Granules	>10	Highly commoditized heart burn tablet
Fluorouracil	Alembic Pharma	>10	Highly commoditized oncology injectable
Fluconazole	Lupin	>10	Highly commoditized anti-fungal tablet
Testosterone Cypionate	Eugia Pharma	>10	Highly commoditized Testosterone hormone injection
Carmustine	Alembic Pharma	>10	Onco injectable but negligible market
Sutinib Malate	Natco	6	Off patent onco capsule; possibly niche market of <US\$100mn between 6 players
Febuxostat	Aurobindo	>10	Off patent tablet to lower Uric acid in the body; unlikely to be meaningful
Nitroglycerin	Aurobindo	5	Sublingual tablet for chest pain but too small in size
Dapsone	Alembic Pharma	>10	Topical gel with negligible market
Ondansetron	IPCA	8	Tablet to prevent nausea; unlikely to be meaningful
Mitomycin	Eugia Pharma	>10	Onco injectable but negligible market
Nov'23			
Midodrine HCL	Mankind	>10	Tablet to treat low blood pressure and too small in size
Neostigmine Methylsulfate	Eugia Pharma	>10	Injectable with negligible market
Fluphenazine HCL	Glenmark	>10	CNS tablet with negligible market
Lifitegrast	Eugia Pharma	2 (+2 TAs)	Ophthalmic drug to treat dry eye; Aurobindo was sued but case is dismissed with unclear launch time line. Would be a good addition to portfolio
Topiramate	Dr Reddys' (TA)	>10	Not much left in this ER tablet for seizures

Source: FDA, YES Sec; Approval data between Sep 1 and November 20, 2023

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YES Securities (India) Limited

Registered Address: 2nd Floor, North Side, YES BANK House, Off Western Express Highway, Santacruz East, Mumbai - 400 055, Maharashtra, India.

Correspondence Address: 4th Floor, AFL House, Lok Bharti Complex, Marol Maroshi Road, Andheri East, Mumbai - 400059, Maharashtra, India.

☎ +91 22 68850521 | ✉ research@ysil.in
Website: www.yesinvest.in

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Details of Compliance Officer: Name: Aditya Goenka,
Email id: compliance@ysil.in, **Contact No:** 022- 65078127 (Extn: 718127)

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