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SECTOR UPDATE | Sector: Pharmaceuticals

Pharma – US approvals watch

New approvals lack bite; DRL key beneficiary

In this report we look at FDA approvals in Q1 so far to gauge the traction in US business as new product approval remains key to sustainable growth within the context of benign price erosion. Compared to some of the previous such checks (most recent in Nov'23), data suggests aggressive filers like Aurobindo and Zydus are notably absent when it comes to gathering meaningful approvals. On the other hand, Dr Reddy's and to some extent Gland have got decent approvals in April and May that can support base business ex Revlimid in the case of former. Mid-sized and small players like Alkem, Torrent, Alembic and Ajanta have had a lackluster quarter with no major approval. This is in continuation of what we wrote in Nov'23, about lack of any large or meaningful approvals coming in for small and mid-sized players (except possibly Strides and Caplin in this iteration). While we understand US environment remains supportive in the form of lower price erosion, it may turn for worse relatively quickly; hence fresh approvals assume importance, and which is missing in most of the players. Below we summarize some of the key approvals and impact/outlook for respective US businesses in Q1.

- **Aurobindo** – Unusually weak quarter for new approvals as none of the ~8 approved ones likely to be a major contributor in Q1; Eugia base business and Revlimid could be key drivers in such a case.
- **Alembic** – Mix of derma, onco tablet approvals but none exciting; Sacubitril Valsartan approved but unlikely to be launched anytime soon
- **Alkem, Ajanta & Torrent**– No major approval and expect US performance to be driven by volume gains if price erosion remains stable QoQ; Alkem has launched Suprep in Q1 which would act as a support.
- **Dr Reddys'** – A better approval quarter after a fairly long period as DRL got 4 CGTs (competitive generic therapy or <3 generics) which should aid US on top of Revlimid performance.
- **Lupin** – Mirabegron (Q4 approval) and generic Oracea (Doxycycline) should drive US performance and expect amongst highest sequential growth rates in US amongst large generic companies

Q1 FY25 US business outlook – existing business assumes significance

We expect generic companies like Dr Reddys' and Lupin to clock a better US performance QoQ as 1) DRL is supported by several CGT approvals and 2) Revlimid was off to a seasonally weak start to CY24 that should reverse or stabilize in Q1 3) Lupin has Mirabegron launch and Oracea approval that would drive growth apart from Spiriva. In the rest of the generic plays, expect existing business to assume significance as none of the companies (IPCA too has started with ordinary set of approvals) have pocketed any meaningful approvals.

Overall view – Torrent investment thesis intact; Alkem, Indoco preferred bets to play likely acute rebound in H1

Torrent continues to be a preferred pick as smaller NLEM share implies lack of WPI linked price hike impact to be minimum while efforts to grow US and Brazil shoulder the growth burden away from domestic business. Also, post Q4 results, we had upgraded Alkem as reckon 10-11% domestic growth on weak base of FY24 is achievable with optional margin upside if Pen G prices head lower. In the same vein, Indoco's top Azithromycin brand is likely to rebound on back of better acute season; stability in US and key approvals in Europe should aid earnings making it attractive at ~15-16x FY25 EPS.

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Pharma – US approvals watch

Exhibit 1: US ANDA approvals since Apr'24 (approvals in bold are meaningful in our view)

Company	ANDA	Comments
April'24		
Alembic Pharma	Clindamycin Phosphate	Fully commoditized topical gel
Torrent Pharma	Teriflunomide	Multiple Sclerosis drug of Sanofi that has been hit with waves of generic competition since Mar'23
Strides Pharma	Fluoxetine Hydrochloride	Generic of Lily's anti-depressant Prozac which is fully genericized
Lupin	Valbenazine	Lupin, along with Teva & Sandoz has settled and launch is in 2038
Gland Pharma	**Eribulin Mesylate**	**First generic with IQVIA tallied sales of ~US$90mn but Gland does not appear in litigation and patent goes out in 2027 so unlikely to launch/partner before then**
Aurobindo	Ibuprofen	OTC of J&J's Motrin; unlikely to be meaningful
Lupin	**Doxycycline**	**First generic of Oracea used for anti-inflammatory lesions with IQVIA size of US$130mn; Lupin prevailed in litigation and has launched in April and should be a meaningful addition to US portfolio**
Laurus Labs	Gabapentin	Fully commoditized oral tablet for neuropathy, epilepsy
Dr Reddys'	**Doxycycline**	**CGT approval and like Lupin, likely to be a decent addition to US business**
Alkem	Cefprozil	Oral anti-biotic fully genericized
Aurobindo	Betamethasone Dipropionate	Derma gel/ointment that has more than 15 players
Dr Reddys'	**Calcitonin Salmon**	**CGT designated (DRL is 3rd generic) injectable used to treat Osteoporosis; IQVIA sales probably below US$100mn (based on Endo's approval release highlighting US$170mn IQVIA sales in Sep'21)**
Mankind Pharma	Haloperidol	Oral tablet used for nervous conditions but fully commoditized
Caplin Point	Ofloxacin	Anti-biotic fully genericized across all dosage forms - Caplin has approval for ophthalmic dosage
Torrent Pharma	Doxycycline Hyclate	Fully genericized anti-biotic
Gland Pharma	Tranexamic Acid	Used for bleeding control, approval marks entry in a crowded market
Aurobindo	Haloperidol	Oral tablet used for nervous conditions but fully commoditized
Aurobindo	Minoxidil (For Men)	Foam based treatment for hair loss, fully commoditized
Lupin	Loteprednol Etabonate	Corticosteroid used for eye inflammation but insignificant size at US$59mn per IQVIA
Gland Pharma	**Cetrorelix Acetate**	**Injectable used during IVF treatment with IQVIA sales of US$130mn; Gland is the 4th generic and could be a useful addition**
Alembic Pharma	Diazepam	Old injectable used for anxiety disorders; unlikely to be meaningful approval
Zydus Life	Tretinoin	Acne cream approval paves way into a very crowded market
Alembic Pharma	Tretinoin	Acne cream approval paves way into a very crowded market
Glenmark	Acetaminophen; Ibuprofen	OTC combination of Paracetamol and Ibuprofen with IQVIA sales of US$84mn and 6 generic players

Pharma – US approvals watch

Granules	Colchicine	Oral capsule for gout flares which is fully genericized
Aurobindo	Colchicine	Oral capsule for gout flares which is fully genericized
Dr Reddys'	Esomeprazole Magnesium	OTC generic of Nexium for acid reflux; too crowded a market
May'24		
IPCA	Etodolac	Anti-inflammatory tablet for mild pain & not meaningful
Laurus	Oseltamivir Phosphate	Generic Tamiflu tablet which no longer offers any opportunity; seasonal product too contributing between Nov-Feb
Gland Pharma	Plerixafor	Niche injectable used for collecting stem cells from bone marrow, Gland can see modest 1-1.5% addition to US business which may not move the needle at consol level
Lupin	Travoprost	Ophthalmic approval with 6 players and US$77mn IQVIA estimated size - could be a niche addition but subsumed at a US business level
IPCA	Levocetirizine Dihydrochloride	Fully competed antihistamine
Dr Reddys'	Edaravone	CGT designated injectable for nervous system, but small size precludes any benefit
Gland Pharma	Edaravone	Limited competition but small size precludes any meaningful benefit
Dr Reddys'	**Vasopressin**	**Yet another CGT approval of which DRL was already selling authorized generic; could be a decent addition given the large size though it has 6-7 approved generics**
Zydus Life	Dapsone	Gel dosage with several generics and small size
Strides Pharma	Sevelamer Carbonate	Tablet dosage dominates market but unlikely to make a meaningful contribution to Strides given >10 generic players
Zydus Life	Dexamethasone	Mature steroid with wide applications but very large no of generics
Dr Reddys'	Omeprazole; Sodium Bicarbonate	DRL got a CGT approval for suspension but given the large no of players in acid reflux market reckon CGT designation may not be of significance
Ajanta Pharma	Prochlorperazine Maleate	Nervous/CNS approval but is fully commoditized
Lupin	Midostaurin	Likely IQVIA sales under US$100mn and 2-3 tentative approvals; product is under patent going out in 2030 with little clarity on settlements and launch timelines
Aurobindo	Fluticasone Propionate	Nasal spray for respiratory conditions but underlying molecule is fully genericized
Aurobindo	Oseltamivir Phosphate	Generic Tamiflu suspension which is no longer a meaningful opportunity
Glenmark	**Brimonidine Tartrate; Timolol Maleate**	**Generic Combigan used to treat eye pressure; approval implies additional competition for Indoco and a niche addition to Glenmark with 6-7 generic players**
Indoco	Pregabalin	Highly genericized peripheral neuropathy approval
IPCA	Quetiapine Fumarate	Nervous/CNS approval but is fully commoditized
Strides Pharma	**Sucralfate**	**Per Strides, a complex suspension product with IQVIA size of US$120mn and 6 generic players -**

Pharma – US approvals watch

		could be a decent addition to Strides US portfolio
Invagen (Cipla)	Lanreotide Acetate	Cipla is the only approved generic and has a CGT designation for its 505b2 product in a market worth >US$500mn
Zydus Life	Theophylline	Asthma tablets already commoditized
IPCA	Irbesartan	Hypertensive approval and negligible contribution
IPCA	Gabapentin	Fully commoditized oral tablet for neuropathy, epilepsy
Caplin Point	**Phenylephrine Hydrochloride**	**A CGT ophthalmic approval with IQVIA pegged size of US$32mn**
Alembic Pharma	Sacubitril; Valsartan	Patented heart failure drug: settlements or launch timelines not clear with >15 filers. Novartis has indicated no generic launch in 2024
Laurus Labs	Sacubitril; Valsartan	Patented heart failure drug: settlements or launch timelines not clear with >15 filers. Novartis has indicated no generic launch in 2024
Jun'24		
Dr Reddys'	Arformoterol Tartrate	Generic of the Brovana brand earlier acquired by Lupin; unlikely to add substantially to the US as already > 10 approvals
Alembic Pharma	Methotrexate Sodium	Anti-inflammatory and chemo tablet but highly competitive
Aurobindo	Tofacitinib Citrate	Blockbuster patented arthritis drug of Pfizer who has settlements with at least 3 cos and likely launch by Dec'25; Aurobindo has been sued over 2 patents and most likely launch not before Dec'25
IPCA	Alendronate Sodium	Used for Osteoporosis but highly genericized

Source: FDA, YES Sec; Approval data between April 1 and June 4, 2024

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