

# Pharmaceuticals

## Q2 CY15 DMF Filings, A mellow quarter

- Q2 CY15 DMF filings reveal Indian companies have filed for 36% of total filings in Q2 CY15, much lower than the 45% aggregate in 2014 and 47% in 2013. Cumulatively Indian companies filed for 45 molecules in Q2 CY15 compared to 96 in Q1 CY15
- Cipla and Alembic file DMF on generics with low competition products – Ambrisentan and Azilsartan respectively. Cipla also filed Albendazole which is off patent but has no generic. Aurobindo, the only Indian filer for injectable for the quarter

- India's share of DMFs falls to 36% in Q2 CY2015:** India's share in overall drug master filings (DMF's) dropped to c36% in Q2 CY2015 (-48% YoY) after witnessing c50% share during the previous quarter. The total number of filings at 126 also decreased from 193 in the last quarter. We would not take the lull in Q2 filings as a trend given that at times such filings tend to be lumpy as reflected in Q1 which touched a new high for Indian companies.
- Few DMF filings across key companies:** Cipla and Aurobindo filed 3 DMF's each, Alembic and Lupin had 1 new filing each. Other Indian generic majors namely Dr Reddy's, Cadila, Glenmark, Torrent have no filings this quarter, while API suppliers like Divi's also had no additional filings for Q2. Sun Pharma had no new filings either during the quarter. Overall in 1H2015, Aurobindo and Sun filed a maximum 9 DMFs each followed by 8 each by Glenmark and Cipla. Lupin and DRL trail with 5 and 4 filings respectively.
- Cipla filed DMF on Ambrisentan (gLetairis) which has no generic players currently. The overall market is cUSD600m with key patent expiry towards end 2015. Another similar filing on a generic product is Cipla's Albendazole (gAlbenza). The product is off patent but has not yet genericized yet. We notice key filings from Cipla's in Q2 CY15 and 1H CY15 indicate initial outcome of renewed investment in R&D expenses at c6% of sales currently and expected to increase by 1% annually.
- Aurobindo has filed for Ranolazine (gRanexa) which is a sizeable USD510mn market split between innovator Gilead and Lupin. Esomeprazole (gNexium) saw increased competition with Aurobindo potentially entering the fray within the USD1.8bn market.
- Our preferred sectoral picks are Glenmark, Aurobindo, Cadila and Lupin.

### Financial Snapshot (Consolidated)

(Rs mn)	EPS		EV/EBITDA		P/E	
	FY16E	FY17E	FY16E	FY17E	FY16E	FY17E
Aurobindo Pharma	67.9	80.7	16.2	12.9	23.2	19.2
Cadila Healthcare	72.9	92.9	16.8	13.3	23.2	18.2
Cipla	22.7	29.0	18.3	14.6	28.7	22.4
Divi's Lab	80.0	97.8	17.3	14.3	23.3	18.9
Dr. Reddy's Lab	144.6	179.8	16.0	13.2	24.0	19.3
Glenmark Pharma	37.9	50.2	15.6	12.2	23.1	17.4
Granules India	6.9	8.4	8.2	7.1	11.5	9.4
Lupin	57.7	72.6	19.2	15.1	29.3	23.3
Sun Pharma	26.4	32.7	22.7	18.1	33.3	26.9
Torrent Pharma	53.4	64.3	16.5	13.5	23.6	19.6
Ipcalab	25.2	35.1	14.3	11.2	25.9	18.6

<b>Aurobindo Pharma</b>	BUY
CMP	Target Price
1,450	1,370

<b>Cadila Healthcare</b>	ACCUMULATE
CMP	Target Price
1,901	1,860

<b>Cipla</b>	HOLD
CMP	Target Price
641	640

<b>Divi's Lab</b>	HOLD
CMP	Target Price
1,863	1,960

<b>Dr. Reddy's Lab</b>	BUY
CMP	Target Price
3,732	3,600

<b>Glenmark Pharma</b>	BUY
CMP	Target Price
1,037	955

<b>Granules India</b>	ACCUMULATE
CMP	Target Price
82	85

<b>Lupin</b>	BUY
CMP	Target Price
1,886	1,752

<b>Sun Pharma</b>	HOLD
CMP	Target Price
872	820

<b>Torrent Pharma</b>	HOLD
CMP	Target Price
1,294	1,304

<b>IPCA Lab</b>	HOLD
CMP	Target Price
682	700

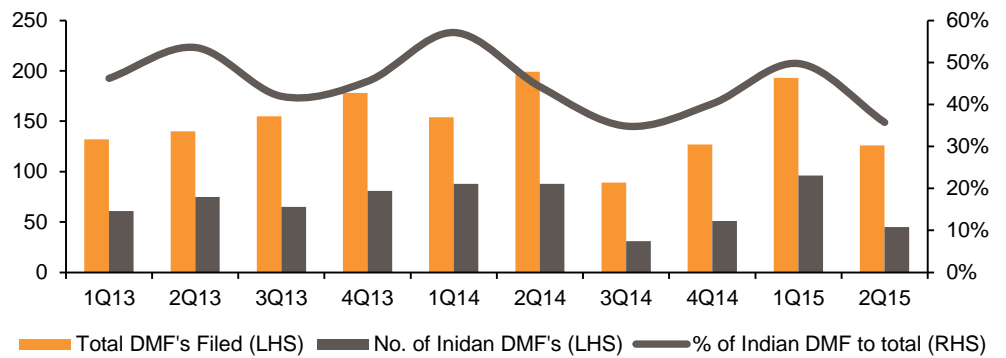
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**Exhibit 1: Quarterly Indian DMFs to total DMF's**

Period	Total DMF's Filed	No. of Indian DMF's	% of Indian DMF to total
1Q13	132	61	46%
2Q13	140	75	54%
3Q13	155	65	42%
4Q13	178	81	46%
<b>2013</b>	<b>605</b>	<b>282</b>	<b>47%</b>
1Q14	154	88	57%
2Q14	199	88	44%
3Q14	89	31	35%
4Q14	127	51	40%
<b>2014</b>	<b>569</b>	<b>258</b>	<b>45%</b>
1Q15	193	96	50%
2Q15	126	45	36%
<b>2015 YTD</b>	<b>319</b>	<b>141</b>	<b>44%</b>

Source: Company, Emkay Research

**Exhibit 2: Indian filings run rate**

Source: Company, Emkay Research

**Exhibit 3: Key Indian DMF filings during Q2 CY2015**

DMF Filer	Generic molecule (Brand)	Dosage Form	Genericized	US Annual Sales USD mn	Comments
Cipla	Albendazole USP (gAlbenza)	Tablet	No	105**	Product has gone off patent but has not been genericized yet. Other notable DMF filers are Sequent scientific, Uquifa and Unimark
Cipla	Ambrisentan (gLetairis)	Tablet	No	595*	Patent expires in 2015 and 2018. Likely that generic launch post key patent expiry by end 2015. Notable DMF filers Mylan, Watson and MSN labs
Alembic Pharmaceuticals	Azilsartan Medoxomil (gEdarbi/gEdarbyclor)	Tablet	No	37**	NCE exclusivity till Feb'16. Other Patent Expiry in 2025. No other notable DMF filers.
Aurobindo Pharma	Ranolazine (gRanexa)	Tablet; ER	Yes	510*	Lupin only generic to launch. Patents expiry through May'19. There are 10 other generic DMF filers
Sun Pharmaceutical	Tadalafil (gCialis)	Capsule	No	1,040	Key patent expiry in Nov '17 with at least 17 other DMF filers and one tentative approval. Sun had filed a DMF earlier in 2009 too.
Auro Peptides (Aurobindo)	Octreotide acetate (gSandostatin/ gSandostatin Lar)	Injectable	Yes	1650*	Sandostatin genericized with 7 generic players. However Sandostatin LAR has not yet been genericized with its last patent expiry in Jan' 17.
Aurobindo Pharma	Esomeprazole Magnesium (gNexium)	Capsule, Delayed Rel Pellets	Yes	1,876	Teva has already launched. Expect other generic players to follow suit in 2HFY16
Cipla	Olanzapine (g Zyprexa Zydis)	Tablet / Capsule / Injectable	Yes	120	Highly competitive with multiple generic launches in the market currently
AuroNext (Aurobindo)	Sodium Bicarbonate	Injectable	Yes	NA	Off patent. There are 6 other generic DMF filers.
Lupin	Darunavir Propanolate (gPrezista)	Suspension / Tablet	No	1831*	Lupin had filed a DMF earlier in 2011 too. Other notable generic DMF filers includes Cipla, Hetero, Mylan
Lupin	Atazanavir Sulfate (gReyataz)	Capsule / Powder	Yes	689	Teva has already launched. There are 3 other generic players having tentative approvals and para III filings for patents expiring in Jun 2017 and Dec 2018.

\* Global Sales \*\* Bloomberg global sales

Source: Company, Emkay Research

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BUY	Expected total return (%) (Stock price appreciation and dividend yield) of over 25% within the next 12-18 months.
ACCUMULATE	Expected total return (%) (Stock price appreciation and dividend yield) of over 10% within the next 12-18 months.
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SELL	The stock is believed to underperform the broad market indices or its related universe within the next 12-18 months.

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