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4Q CY11 Drug Master Files (DMF) filings update

- ▶ **Indian DMF share recovers to c46% of overall DMF filings in 4QCY11, breaking out of the recent slowing trend in filings**
- ▶ **Large generics filings seem to be stagnating; small players more aggressive registering an increase on yoy basis**
- ▶ **DRRD sole DMF on Prasugrel (potential FTF), Lupin files ophthalmic brimonidine**

Indian DMFs share jumped to c46 % (+22% yoy) of overall DMF filings in 4Q CY11 after witnessing a slower rate over the last few quarters. For the full year CY2011, Indian DMFs share in overall DMFs filings remained at similar 50% level as in CY2010 (c9% yoy growth). China's DMFs share of total DMFs fell from 20% in 4Q10 (18% in CY2010) to 16% in 4Q11 and CY2011. Global DMFs increased by c10% for CY2011.

Indian large cap generics filings seem to be stagnating: Barring DRRD which increased its filings in CY2011, most players' filings stagnated for the year as a whole. The number of filings from CIPLA and RBXY actually declined materially. DRRD CY2011 filings were strong at 14; SUNP and LPC filed 6 each, CDH 8, RBXY had 2 and CIPLA 0. TRP and IPCA each filed three DMF during the year. Small players like Hetero Lab, Alembic were the most active with DMF filings of c12-13.

4QCY11 noteworthy filings include Dr Reddy's sole filing on Eli Lilly's anti-thrombotic drug Effient (prasugrel), which has cUSD100mn sales in the US. This could be a potential first-to-file opportunity given no other DMF yet (though ANDA can only be filed after July 2013). Lupin continued its filing momentum in ophthalmics with a recent filing on brimonidine (Alphagan-P) used in glaucoma. Among mid caps, Ipca's filing on primaquine, Cadila's on erlotinib (Tarceva) and Torrent's on darfenacin (Enablex) are noteworthy. Other small players' filings including Hetero's DMF on etravirine (Intelence) and Gland Pharma's filing on agratroban and dalteparin (Fragmin) are the sole Indian DMF filings and hence potentially strong. Reliance Life Science filed two niche products including loteprednol etabonate (ophthalmic corticosteroid) and injectable nandrolone. Among MNCs, Apotex's filing on lansoprazole hints at a possible increase in competition in Prevacid generic (currently four players only). Mylan's filing on iloperidone (Fanapt) is also worth mentioning.

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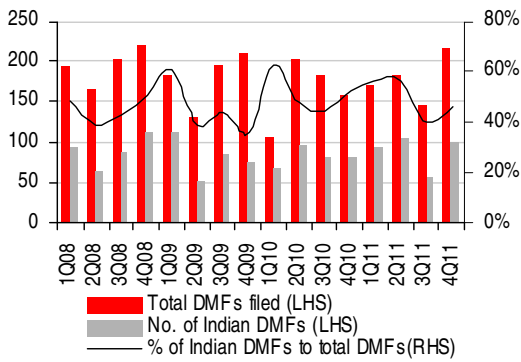
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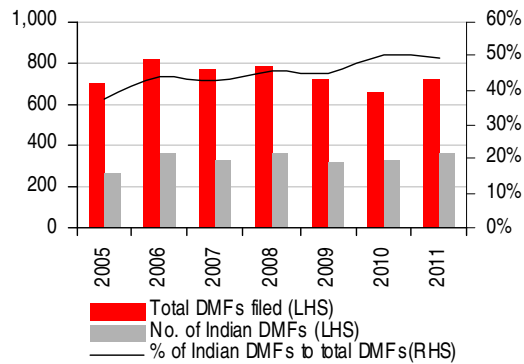
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Quarterly Indian DMF filings to total DMF filings



Source: FDA

Annual Indian DMF filings to total DMF filings



Source: FDA

Indian DMF filings vs. Chinese DMF filings

Period	Total DMFs filed	No. of Indian DMFs	% of Indian DMF to total	No. of Chinese DMF	% of Chinese DMF to total
2007	767	326	43%	115	15%
2008	782	356	46%	90	12%
2009	719	322	45%	94	13%
1Q10	106	66	62%	23	22%
2Q10	204	97	48%	28	14%
3Q10	183	81	44%	32	17%
4Q10	158	82	52%	31	20%
2010	651	326	50%	114	18%
1Q11	170	95	56%	26	15%
2Q11	183	103	56%	24	13%
3Q11	145	58	40%	28	19%
4Q11	219	100	46%	36	16%
2011	717	356	50%	114	16%

Source: FDA

DMF filing trend for major Indian companies

Company	2008	2009	1Q10	2Q10	3Q10	4Q10	2010	1Q11	2Q11	3Q11	4Q11	2011
Dr. Reddy's Labs	13	11	8	1	2	1	12	2	9	1	2	14
Cipla	19	3	0	2	0	0	2	0	0	0	0	0
Ranbaxy	5	4	0	0	1	6	7	0	2	0	0	2
Sun Pharma	13	10	0	3	2	1	6	3	0	1	2	6
Lupin	16	12	0	7	0	0	7	1	3	0	2	6
Wockhardt	5	1	0	0	0	0	0	0	0	0	0	0
Zydus Cadila	9	9	0	3	1	0	4	4	1	1	2	8
Jubilant	5	6	0	1	3	1	5	5	0	0	2	7
Divi's Labs	3	2	1	0	0	0	1	1	0	0	0	1
Aurobindo	6	9	1	3	6	0	10	0	0	0	2	2
Pharma												
Glenmark	5	6	0	0	4	0	4	1	2	0	0	3
Matrix Labs	13	6	0	4	6	7	17	0	0	0	0	0
Biocon	2	0	1	0	0	0	1	0	0	0	0	0
Ipca Labs	8	7	0	2	3	3	8	0	0	1	2	3
Dishman Pharma	2	4	0	0	1	0	1	1	0	0	0	1
Alembic	7	9	0	1	1	0	2	4	3	1	4	12
Torrent Pharma	5	6	0	1	1	0	2	1	1	0	1	3
Hetero Pharma	11	6	0	3	0	1	4	6	9	8	6	29

Source: FDA

Important DMF filings by Indian companies

Molecule	Brand	Company	DMF Filer	Total number of filers	Sales in \$ mn	Comments
Prasugrel	Effient	Eli Lilly	DRRD	sole filer	100	Potential FTF for DRRD
Argatroban	Argatroban	GSK	Gland Pharma	6	130	1st Indian DMF
Etravirine	Intelence	Tibotec	Hetero	2	180	1st Indian DMF
Primaquine	Primaquine	Sanofi Aventis	Ipca Lab	sole filer	<5	Generic
Loteprednol etabonate	Lotemax	Bausch and Lomb	Reliance Life Science	9	110	Sole Indian DMF filing
Nandrolone			Reliance Life Science	14	-	Sole Indian DMF filing
Daltepain	Fragmin		Gland Pharma	11	210	Sole Indian DMF filing
Erlotinib	Tarceva	OSI Pharma	Cadila Healthcare	8	550	
Brimonidine	Alphagan-P		Lupin	10	190	Ophthalmic filing
Darifenacin	Enablex	Warner Chilcott	Torrent	8	260	
Busulfan	Busulfex	Otsuka Pharma	Emcure	11	12	

Source: FDA

Disclosure appendix

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