

Pharmaceuticals
 Healthcare
 Equity – India

India Pharmaceuticals

1QCY12 DMF filings: DRRD files Copaxone, Revlimid

- ▶ **Strong quarter both in terms of number and nature of filings. Indian DMF filing share increases to 50%**
- ▶ **Most large caps had a filing in 1Q12; largest by DRRD followed by LPC and SUNP. Cipla and Divi's have no DMF**
- ▶ **DRRD files Copaxone and Revlimid (complex generics), LPC likely among first-filers for Pristiq, GNP files sitagliptin**

Indian DMF share increases to 50% though flat yoy in 1Q12, but what is more interesting is that the nature of filings is strong with most large-caps filing one or more DMF (with the exception of Cipla and Divi's). Dr Reddy's has filed on glatiramer acetate (Brand Copaxone, USD3bn), lenalidomide (Brand Revlimid, USD3.2bn) and asenapine (Brand Saphris, USD150m). Other notable filings include Cadila's filing on salmeterol (aerosol filing), Ranbaxy's and Lupin's filing on fosamprenvir (HIV filing) and Glenmark's filing on sitagliptin. Sun Pharma has filed on hormonal injection ganirelix acetate and atorvastatin in this quarter.

Most large caps had a filing in 1Q12: The largest number of unique filings is from Dr Reddy's at 5 followed by Lupin at 4 and Sun Pharma at 3. Among other players, Aurobindo filed 3, Cadila 2, Ranbaxy, Glenmark, Torrent and Ipca 1. Small players with a large number of filings include Emcure (11) and MSN (5). Interesting filings among small players include Alembic's filing on prasugrel (third DMF after DRRD and Mylan), MSN/Emcure filing on zileuton (3 DMFs), Neuland on brinzolamide (ophthalmic filing).

Pristiq possibly a shared FTF filing with Lupin and three others: Among MNCs, Teva has filed on sitagliptin (Januvia, USD3bn) and desvenlafaxine (Pristiq, USD560m). Three other players – Apotex, Lupin and Wockhardt – too have filed on this product. We believe this could be a multiple FTF ANDA filing given earliest applications referring this product were invited by the FDA beginning on 29 February.

Niche filings likely to support DRRD pipeline beyond 2013: Dr Reddy's has sole DMF so far in glatiramer acetate and asenapine and is the third filer on lenalidomide (after Mylan and Apicore). Sandoz is FTF on Copaxone and Mylan/Natco second filer and Natco/Watson is FTF on lenalidomide. We believe these could be a material opportunity for DRRD as well given the size and complexity of the molecules. We would wait for an ANDA filing on these products, which could be a material positive development in terms of a US pipeline for DRRD.

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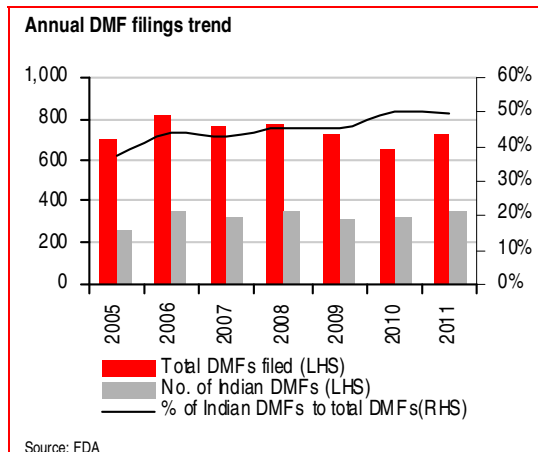
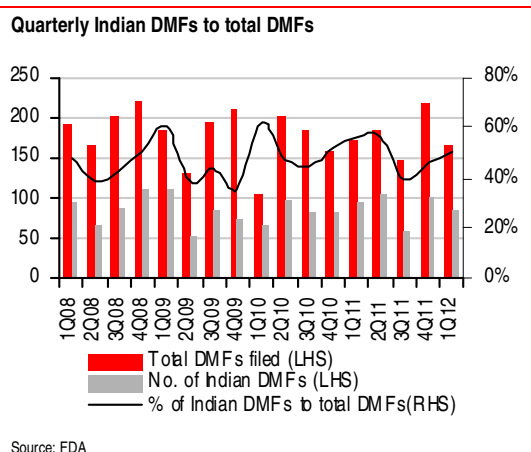
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Indian DMFs vs. Chinese DMFs

Period	Total DMFs filed	No. of Indian DMFs	% of Indian DMF to total	No. of Chinese DMFs	% 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%
1Q12	166	84	50.6%	23	14%

Source: FDA

DMF filing trend across few Indian companies

	2008	2009	2010	1Q11	2Q11	3Q11	4Q11	2011	1Q12
Dr. Reddy's Labs	13	11	12	2	9	1	2	14	5
Cipla	19	3	2	0	0	0	0	0	0
Ranbaxy	5	4	7	0	2	0	0	2	1
Sun Pharma	13	10	6	3	0	1	2	6	3
Lupin	16	12	7	1	3	0	2	6	4
Wockhardt	5	1	0	0	0	0	0	0	1
Zydus Cadila	9	9	4	4	1	1	2	8	2
Jubilant	5	6	5	5	0	0	2	7	2
Divi's Labs	3	2	1	1	0	0	0	1	0
Aurobindo Pharma	6	9	10	0	0	0	2	2	3
Glenmark	5	6	4	1	2	0	0	3	1
Biocon	2	0	1	0	0	0	0	0	0
Ipca Labs	8	7	8	0	0	1	2	3	1
Torrent Pharma	5	6	2	1	1	0	1	3	1

Source: FDA

Key Indian DMF filings (includes few first time filings [FTF])

Molecule	Brand	Company	DMF Filer	Total number of filers	Sales in USDm	Comments
Asenapine	Saphris	Organon	Dr Reddy's	Sole Filer	140	Sublingual tablet used for schizophrenia, earliest patent expiry in June 2015. NCE runs till Aug-14
Glatiramer Acetate	Copaxone	Teva	Dr Reddy's	Sole Filer	3000	Not FTF filing but strong due to complexity of the molecule. Big potential opportunity
Lenalidomide	Revlimid	Celgene	Dr Reddy's	3 (Mylan, Apicore, DRRD)	3200	Not FTF filing but strong due to complexity of the molecule. Big potential opportunity
Desvenlafaxine	Pristiq	Wyeth/Pfizer	Lupin, Wockhardt	5	560	Possible shared FTF filing by four-five players
Ganirelix Acetate	Antagon	Organon	Sun Pharma	Sole Filer	N.A	Injectable filing for treatment of infertility
Ethacrynic Acid	Edecrin	Aton	Cadila Healthcare	2	25	1st Indian DMF, small product. Patents expired
Brinzolamide	Azopt	Alcon	Neuland	6	110	1st Indian DMF, ophthalmic product. All patents expiring in April 2013
Estradiol Valerate	Delestrogen	JHP Pharms	Lupin	6	5	1st Indian DMF, hormonal product. Generics of Watson, Sandoz in market already. Can potentially file Natazia of Bayer.
Fosamprenavir	Lexiva	Viv Healthcare	Lupin, Ranbaxy	3 (Mylan is third)	150	HIV filing, earliest patent expiry in June 2018
Sitagliptin	Januvia/ Janumet	Merck	Glenmark	7	2900	Sun the other Indian DMF, earliest patent expiry in 2017
Acamprosate	Campral	Forest Labs	Emcure	8	25	2nd Indian DMF, patents expired
Dronedarone	Multaq	Sanofi	Unimark	2	300	NCE expires in June 2014

Source: FDA, HSBC estimates

Disclosure appendix

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