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Healthcare - India

Year Ahead 2024: Year of two halves with a better 1H

Price Objective Change

Positive momentum to sustain in 1H...

India healthcare particularly pharma had a standout year in CY23 with broad-based outperformance (33% vs. 20% for Nifty). This was led by improving US Gx sentiment, continued momentum in hospitals and earnings upgrade in pharma. The meaningful moderation in US Gx price erosion seems to stable going into 1HCY24 supporting margins and valuations for pharma stocks. While we remain optimistic for India Healthcare in the near-term, we believe a CY23 like earnings upgrade is unlikely given benign expectation on US Gx erosion and high gRevlimid base for FY24/FY25. As valuation for pharma are already at a 20% premium to long-term average (vs. discount at the start of CY23), we believe the scope for upside surprise is limited.

Not ignoring the risks in 2H

An election year in India could mean regulatory noise particularly given the government push toward Gx-Gx and state-specific action for healthcare services. While it might seem that investors are less sensitive to USFDA inspection news flow (given short-term stock reaction), higher incidence of adverse outcome that increase pipeline uncertainty is a key risk to valuations. Outside of regulations, we believe slower domestic pharma growth with increasing intensity would impact margins particularly given sharp re-rating in India focused stocks in CY23. Lastly, going into 2HCY24, the big gRevlimid hole post CY25 could increase focus on capital allocation decisions to replace gRevlimid contribution.

Reiterate Buy on DRRD

Dr Reddy's (DRRD) has re-rated on the back of improving US Gx environment and benefit from supply disruption particularly in injectables. However, adjusted for gRevlimid, valuation premium is well below most of the US focused peers (~8% vs. 10-25% for peers) on concerns related to competition in key products, limited pipeline visibility and uncertainty on its key facility, Bachupally that was inspected in Oct-end. While Bachupally is one its largest OSD facility, there is limited pipeline dependence that would make any adverse event just a sentiment negative (given its clear track record in recent years). We believe the competition in its key product was long anticipated and factored into estimates that will be offset by base business share gain (particularly in Mayne portfolio) and new launches. Moreover, we see DRRD 9% EPS CAGR FY24-26 being diversified with leverage from growth in India (double-digit growth from FY25), China contribution from new approvals and continued momentum in EMs. In our view, DRRD's ex-US growth is underappreciated by the street and can continue to support earnings with limited competition launches in US being upside drivers (we assume flattish US revenue ex-gRevlimid). We raise our PO on DRRD to Rs6570 (from prior Rs6000) on rolling forward to FY26, increasing target multiple from 25x to 26x, a premium to the long-term average.

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Healthcare

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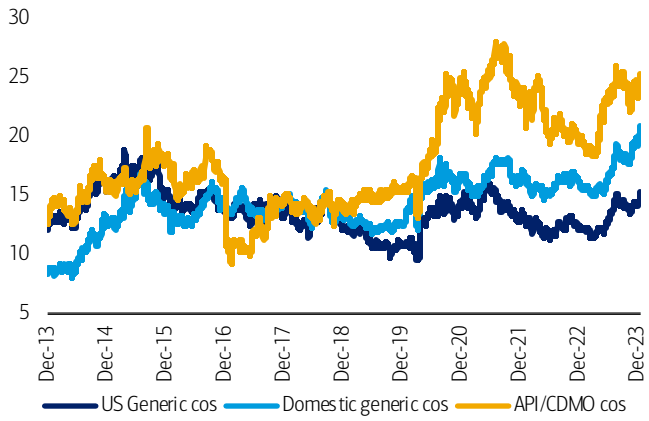
See Abbreviations at the end of this report

Remain selective – DRRD top pick

The India healthcare sector had a strong run in CY23 (Nifty Healthcare up 33% vs. 20% for Nifty) including the much-ignored US Gx stocks supported by improving sentiment on the industry and earnings upgrade across most stocks. While moderation in US Gx price erosion was surprise (low to mid-single digit vs. double digit at the end of CY22), the sector also witnessed re-rating on the back of improved near-term outlook and listing of pure-play domestic company (Mankind) at higher-than-average multiples.

Dr Reddy's (DRRD – PO Rs6570) has re-rated on the back of improving US Gx environment and benefit from supply disruption particularly in injectables. However, adjusted for gRevlimid, valuation premium is well below most of the US focused peers (~8% vs. 10-25% for peers) on concerns related to competition in key products, limited pipeline visibility and uncertainty on its key facility, Bachupally that was inspected in Oct-end. While Bachupally is one its largest OSD facility, there is limited pipeline dependence that would make any adverse event just a sentiment negative (given its clear track record in recent years). We believe the competition in its key product was long anticipated and factored into estimates that will be offset by base business share gain (particularly in Mayne portfolio) and new launches. Moreover, we see DRRD 9% EPS CAGR FY24-26 being diversified with leverage from growth in India (double-digit growth from FY25), China contribution from new approvals and continued momentum in emerging markets (EMs). In our view, DRRD's ex-US growth is underappreciated by the street and can continue to support earnings with limited competition launches in US being upside drivers (we assume flattish US revenue ex-gRevlimid).

Exhibit 1: Pharma (US gx, domestic, API/CDMO) 10 year EV/EBITDA
CDMO and domestic pharma cos trade at a premium to US gx names



Source: Bloomberg. Note: US gx cos include SUNP, ARBP, Cipla, DRRD, Zydus, LPC. Domestic cos include TRP, Alkem, Ajanta, Ipca, JB Chem, Alembic. API/CDMO cos include Divis, Laurus, Syngene

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Exhibit 2: BofA vs consensus earnings estimate for DRRD
We are 6-8% higher vs street on DRRD's FY24/25 EBITDA

		Sales (Rs Bn)		EBITDA (Rs Bn)		EBITDA margin (%)		EPS (Rs)	
		FY24E	FY25E	FY24E	FY25E	FY24E	FY25E	FY24E	FY25E
DR REDDY'S LABS	BofA	273	291	83	86	30.6%	29.5%	330.2	344.6
	BBG Cons	275	293	78	81	28.3%	27.8%	315.2	325.7
	Variance	*-1%*	*0%*	*8%*	*6%*	*231bps*	*176bps*	*5%*	*6%*

Source: Bloomberg, BofA Global Research

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Exhibit 3: Valuation summary for pharma stocks
SUNP trades at a premium to other US gx stocks on specialty focus, domestic stocks have higher valuation vs US gx

Company	Rating	Mkt Cap ($ Mn)	P/E		P/E ex-gRevlimid		EV/EBITDA		EV/EBITDA ex-gRevlimid		RoE	
			FY25E	FY26E	FY25E	FY26E	FY25E	FY26E	FY25E	FY26E	FY25E	FY26E
Sun Pharma	Neutral	37,850	29.2	26.9	30.8	28.3	19.9	17.6	21.0	18.5	15.5	14.8
Divi's Labs	U/P	12,893	54.4	40.0			37.9	27.8			13.4	16.2
Cipla	U/P	12,578	23.3	23.0	31.3	29.0	14.3	13.7	18.6	16.8	15.0	13.5
Dr Reddy's	Buy	11,709	17.0	16.4	26.6	24.0	10.4	9.5	15.4	13.3	17.6	15.8
Mankind	U/P	9,983	40.6	34.5			28.3	23.6			19.0	18.6
Torrent Pharma	Neutral	9,644	41.5	31.3	41.5	35.3	21.7	17.2	21.7	18.8	24.4	26.8
Zydus Lifscience	Neutral	8,625	19.9	19.8	23.6	23.6	12.8	12.3	15.0	14.4	16.1	14.4
Aurobindo	Buy	7,874	15.5	13.9	17.4	15.9	9.2	7.9	10.1	8.8	12.6	12.4
Lupin	U/P	7,654	34.8	28.4	34.8	34.7	17.9	15.0	17.9	17.3	11.8	12.8
Alkem Labs	U/P	7,570	32.7	29.2			24.9	22.0			13.9	12.2
Gland Pharma	Buy	3,909	25.7	22.1			16.3	13.8			12.4	12.6
Biocon	Buy	4,091	35.1	17.8			12.1	9.0			6.8	10.7

Source: Bloomberg, BofA Global Research

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Exhibit 4: Estimates changes
Summary of revisions in key estimates for DRRD

Stock	Sales		EBITDA		EPS		Comments
	FY24E	FY25E	FY24E	FY25E	FY24E	FY25E	
DRRD	-1%	0%	-1%	2%	-1%	2%	Building in higher India growth basis mgmt commentary but lower US on comp in large products

Source: BofA Global Research

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Exhibit 5: PO change and commentary
PO change for DRRD

Stock	Old PO	New PO	Comments
DRRD	6,000	6,570	Roll-fwd to FY26, increased multiple from 25x to 26x that is premium to LT avg

Dr Reddy's ADR PO changes to US$79.00 (from prior US$73.00)
Source: BofA Global Research

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US Gx – A blip, a cycle or structural change?

Post the double-digit erosion levels and covid inventory de-stocking in CY22, last year was as a year of comeback for US generics with positive surprise on the price erosion trend. USFDA adverse outcomes related supply disruptions as well as financial distress among mid-size players drove drug shortages to all time high. We witnessed companies optimizing portfolio (pushback on pricing for low margin drugs) leading to moderation in price erosion through the year. In our view, the sustainability of the pricing behavior through CY23 and limited signs of trend reversing atleast in the near-term does provide comfort on valuations. While not a blip, we believe the turn of the generic pricing cycle would depend on competitive landscape i.e continued supply disruption or aggressive pricing behavior by existing/new players for higher share.

India pharma companies indicate low-to-mid-single digit price erosion in US Gx with trend continuing to remain stable in the near-term. This is also reflected in strong US revenue growth (ex-gRevlimid) of 9% FY24E vs. flattish trend over FY19-23. The share gains in disrupted products and lower price erosion led to meaningful earnings upgrades in stocks in CY23. **In our view, consensus estimate built a fairly stable price environment in FY25-26 with mid-single digit erosion that would limit a repetition of the earnings upgrade cycle seen last year.**

Exhibit 6: Pharma companies commentary on erosion trends
India pharma cos note better pricing trends and do not indicate any signs of reversal in trends

Company	Commentary
Alkem	Price erosion in the US market has slowed down from high teens in last year to mid-single digit (5-6%) currently
Zydus	Expecting mid-single digit price erosion
LPC	We've seen a level of stabilization at mid-single-digit level on our baseline products
DRRD	Price erosion, we are finding the trends to be stable. So, if we look at the last few quarters, we have seen price erosion moderating, and we are now seeing it around the same level.
ARBP	Price erosion has moderated and continues to be neutral (low single digit)

Source: Company earnings transcripts

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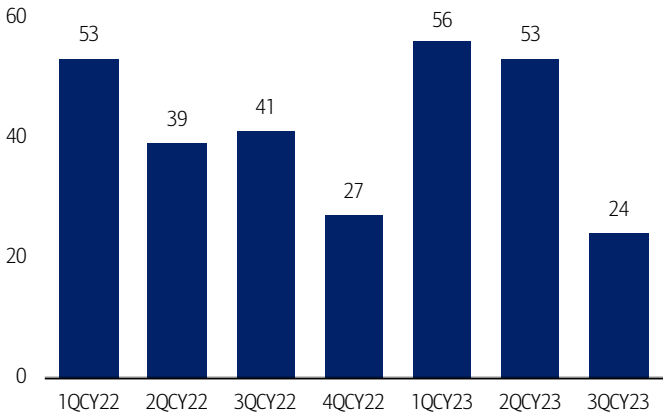
Why can't this be structural change in US Gx?

The surprising moderation in US Gx erosion has led to the question on how long we can see the current pricing trends sustain. In our view, there is limited visibility on the price erosion trend beyond a few qtrs. and the underlying factors that drove the improvement last year could be viewed as transient. Hence, we do not see the improvement in US Gx environment as structural, but a cycle driven by shift competitive intensity. A few of these factors are discussed below:

- While the extended price erosion in US Gx (started in CY16) led to financial distress and exits/bankruptcies in early CY23, we have not seen a reduction in capacity as these have been acquired by existing players.
- Further, the consolidation has not been significant enough with risk of aggressive pricing in a fragmented manufacturer base continuing to persist.
- Existing players have rationalized their generic portfolio to exit loss-making or low-margin products. However, the discontinuation of supplies hasn't really led to withdrawal of ANDA (permanent reduction in supply) therefore, continuing to provide an opportunity to re-enter the market as pricing improves.
- Lastly, USFDA inspection should continue to normalize in CY24 with continued supply disruption on adverse inspection supporting pricing environment. However, the uncertainty on pipeline monetization due to increased regulatory action on facilities will offset any benefit from better pricing leading to earnings downgrades and de-rating (as seen in CY18).

Exhibit 7: # product exits by top 20 gx players based on IQVIA
There have been exits on the base portfolio of CY21 end



Source: IQVIA. Note: Calculated for top 20 companies by US gx revenue as per IQVIA

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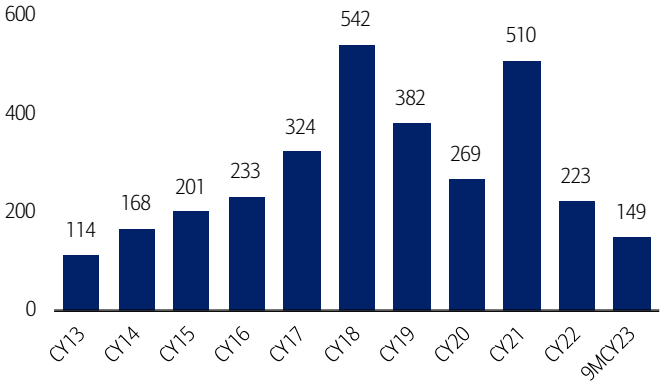
Exhibit 8: ANDA withdrawal trend
ANDA withdrawals is lower than CY21 levels which highlights the risk of discontinued supplies through portfolio rationalization coming back



Source: USFDA.

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Exhibit 9: Financial distress related exits and companies with stretched balance sheets
We saw some companies exiting or rationalizing portfolio due to financial distress; however, some merely saw ownership change. Few other large players have high leverage and are at risk of financial distress

Company	Company Description	Status last year	Current status	US gx business size (MAT Sep23)	# generic products (Nov-23)	9MCY23 YoY growth	Exits seen
Bankruptcy filing or ownership change							
Endo Pharma	US based generics and specialty pharma co	Filed Chapter 11 bankruptcy in Aug-22 due to litigation pressure from its now discontinued opioid business as well as steep erosion in US gx business. The company is now officially up for bidding with hearing scheduled in 2HCY23	Received interest from its lenders which includes investment firms Oaktree Capital Management, Silver Point Capital, and Bain Capital. However, DoJ has objected the proposed sale. If the proposed sale is completed, would imply that overall exit would not happen even if portfolio rationalization does happen	1,480	106	-15%	10 exits in CY23, 6 new launches
Akorn	US based generic pharma manufacturer	Filed Chapter 11 bankruptcy back in 2020 but closed one of its manufacturing facilities in July 2022 and filed Chapter 7 bankruptcy hence ceasing operations in Feb-23	All plants closed	300 (MAT Mar-23)	0		80+ product exits but small products
Apotex	Founded in 1974, generic company based out in US supplying primarily to US markets	SK Capital acquired Apotex in Apr-23. Possibility of portfolio rationalization for profitability	Apotex hasn't made many product exits post change in ownership. It has also launched new products	1,120	117	-11%	4 exits post Mar-23, 7 new launches
Athenex	US based specialty and generic pharma cos that sources drugs from different manufacturers and sells primarily in US markets	Athenex filed for Chapter 11 Bankruptcy in May-23	Assets to be sold in deals valued at $41mn to creditor Oaktree Capital Management and Sagent Pharmaceuticals. Sagent has acquired over 30 products from Athenex; closed 2 facilities	95 (MAT Jun-23)	0		Exited all products but many of these (30 products) transferred to Sagent
Sagent	US gx company with focus on injectables	Nichi-iko sold Sagent to a company backed by Gland Pharma's previous promoters in Mar-23. Earlier Nichi-Iko wrote down the value of the Sagent group by a total of $366m during 9MFY23	Sagent has expanded its portfolio since the ownership change by taking over the certain products of companies discontinuing operations	240	77	-11%	11 exits post Mar-23, 10 new launches
Lannett	Lannett, founded in 1942, develops, manufactures, packages, markets, and distributes generic pharmaceutical products for a wide range of medical indications.	Lannett filed for Chapter 11 bankruptcy in May-23. In December 2022, Lannett announced plans to close two research and development centers in Philadelphia, as well as eliminate 64 jobs, about 11 percent of its workforce.	Lannett emerged out of bankruptcy proceedings in July-23. It will now operate as private company under pre-petition lenders	430	63	-3%	9 exits post Mar-23, 2 new launches
Mallinckrodt	Ireland based both generic and branded drugs manufacturer	Filed Chapter 11 bankruptcy. It had first filed for bankruptcy in 2020. Missed $200mn payment due for settlement in June-23. Planned to conclude bankruptcy proceedings in 4QCY23	Completed financial restructuring in Nov-23	600	25	43%	0 exit, 1 large launch
Companies with high leverage							
Alvogen	Iceland based private pharma co		S&P Global Ratings (Jun-23) has a negative outlook for the company with a B- rating. It has $240mn debt due in early CY24. S&P has placed the company under CreditWatch	800	42	14%	Exited 8 products in CY23, launched 3 new drugs
Amneal	One of the largest US based generic pharma		Amneal currently has a leverage of 4.6x (even though down from 5.3x in CY22 end). It has $2.5Bn term loan due in May-25	2130	218	2%	Exited 15 drugs, launched 21

Exhibit 9: Financial distress related exits and companies with stretched balance sheets

We saw some companies exiting or rationalizing portfolio due to financial distress; however, some merely saw ownership change. Few other large players have high leverage and are at risk of financial distress

Company	Company Description	Status last year	Current status	US gx business size (MAT Sep23)	# generic products (Nov-23)	9MCY23 YoY growth	Exits seen
	company. Also has presence in biosimilars and in international markets						drugs in CY23, closed one facility in New York

Source: IQVIA, Media Reports, BofA Global Research

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Drug shortage elevated but improving

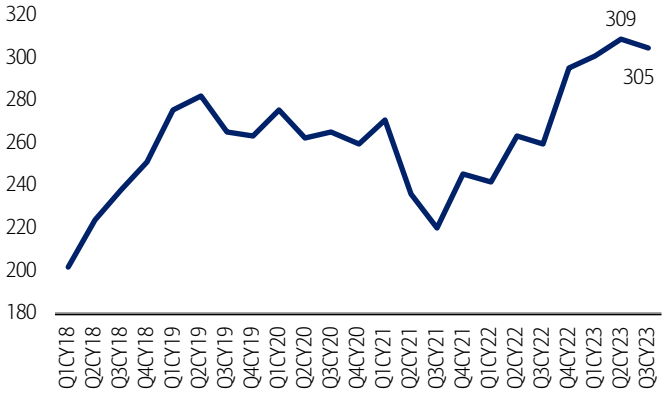
Drug shortages in the US touched the highest levels since CY14 to over 300 active shortages in 2QCY23. This shortage situation was a result of adverse USFDA outcome related supply disruption, bankruptcies as well as portfolio rationalization/ exits due to deterioration in profitability. We did see better pricing environment as well as share gains for other players in disrupted products on back of the drug shortages. However, we have started seeing some green shoots with 3QCY23 active shortages lower vs 2Q particularly with lower proportion of tougher to resolve injectable shortage.

USFDA has also highlighted efforts to address and prevent the shortages. These include incentivizing use of quality management maturity (QMM) practices, expediting drug ANDA/ supplement approvals, expedited inspections as well as collaboration with foreign regulatory authorities. USFDA noted that it was able to prevent 210 small molecule shortages in CY22 through these approaches. The agency also called out benefits from requirements related to early notification of supply disruptions or discontinuations in enabling it to resolve the shortage situation. We saw the USFDA allow import of oncology drugs from China's Qilu which were unapproved in US, allow Accord Pharma to supply 2 key oncology drugs (cisplatin, methotrexate) even as it continues to be under Import Alert. It also issued a guidance for drug compounders for oral antibiotics to alleviate shortage of oral amoxi.

Our analysis of sales gains by coverage companies in disrupted products also indicates peaking of gains. We do expect drug shortages to come down over next few quarters aided by continued USFDA efforts, scale-up by other players in these products as well as return of some of the impacted players (e.g. SUNP's Albut/Ipatrop share gains).

Exhibit 10: No. of drugs in active shortage

#drugs in active shortage seems to have peaked basis 3QCY23 data



Source: ASHP (American Society of Health System Pharmacists)

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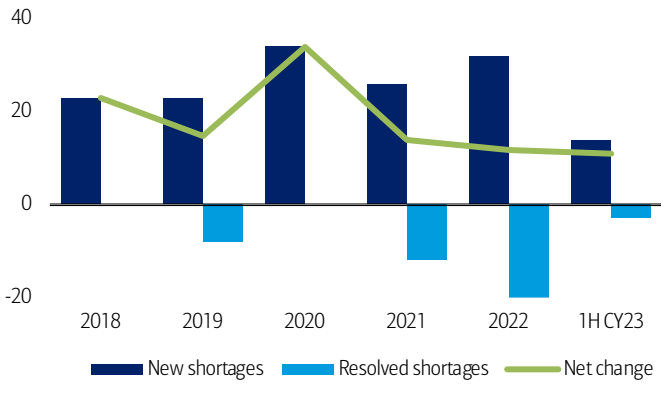
Exhibit 11: #new and resolved molecule shortages by year

Net shortages at the end of June-23 trending lower vs CY22



Source: IQVIA Drug Shortage Report Nov-23

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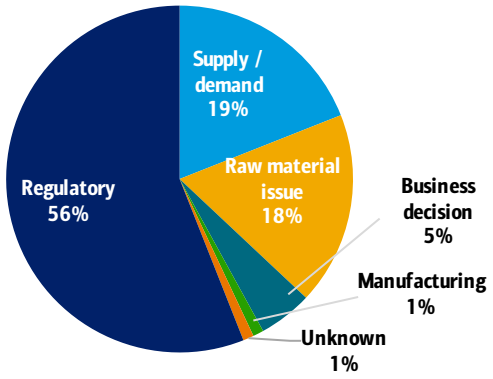
Exhibit 12: Drugs in shortage by reason (2022)
Quality / compliance related issues have been the major cause for drug shortages



Source: University of Utah Drug Information Service

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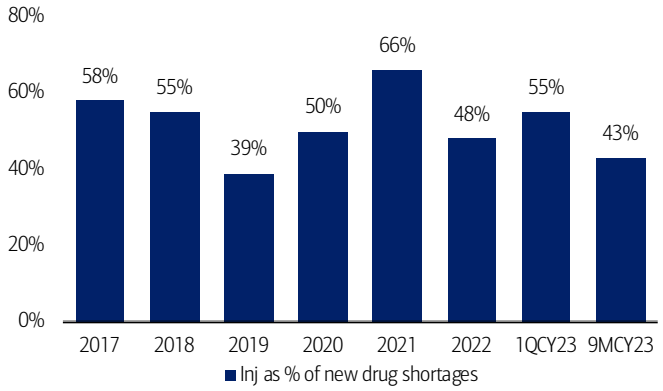
Exhibit 13: Injectables as % of drugs in shortage
Injectable shortage as % of total drugs in shortage has come off over past few months



Source: ASHP (American Society of Health System Pharmacists)

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Exhibit 14: Disrupted products trends for Indian US gx players
While some of the disrupted product gainers continue to witness inch up in sales, some have already seen peaking

	Disruption	4QCY22	1QCY23	2QCY23	3QCY23	Oct-23	Comments
ARBP							
Spironolactone	Accord product		136	202	185	173	Sales peaked in 1QFY24
Azacitidine	Accord product		222	421	608	745	Sales still growing
Methotrexate	Accord product	111	675	2,709	3,575	3,063	Sales peaked in 2QFY24
Aripiprazole	Accord product	112	236	424	542	438	Sales peaked in 2QFY24
Sertraline HCL	Accord product	106	153	152	143	157	Sales still growing
Digoxin	Accord product	109	191	195	196	181	Sales peaked in 2QFY24
Vecuronium Br	Halol product	115	133	135	166	152	Sales peaked in 2QFY24
Mirtazapine	Mohali product	112	114	105	107	102	Disruption started 4QFY23/1QFY24 - muted gain
Pantaprazole Sod	Mohali product	108	110	113	112	120	Disruption started 4QFY23/1QFY24 - muted gain
DRRD							
Glimepiride	Accord product	108	152	160	133	107	Sales peaked in 1QFY24
Azacitidine	Accord product	101	120	129	129	124	Sales stable
Desmopressin	Accord product	117	163	163	124	105	Sales peaked in 1QFY24
Zydus							
Spirinolactone	Accord product	111	296	375	446	371	Sales peaked in 2QFY24
Methotrexate	Accord product	130	593	908	725	646	Sales peaked in 1QFY24
Atorvastatin CA	Mohali product	116	168	421	253	173	Sales peaked in 1QFY24
Cipla							
Sertraline HCL	Accord product	124	192	202	143	116	Sales peaked in 1QFY24
Pirfenidone	Accord product	127	311	279	305	246	Sales peaked in 4QFY23
SUNP							
Mesalamine (Pentasa)	Mohali Product	109	91	57	11	4	Disruption started 4QFY23/1QFY24 - sharp decline
Pantoprazole Sod	Mohali Product	113	113	98	54	22	Disruption started 4QFY23/1QFY24 - sharp decline
Mirtazapine	Mohali Product	176	127	121	73	44	Disruption started 4QFY23/1QFY24 - sharp decline
Atorvastatin CA	Mohali Product	71	91	60	42	12	Disruption started 4QFY23/1QFY24 - some decline
Testosterone Cyp	Halol product	74	2	0	0	0	No recovery yet
Albut Suf/ Ipatrop	Halol product	109	58	81	295	378	Recovery in 2QFY24
Desmopressin Ace	Halol product	110	30	16	28	34	No significant recovery yet

Source: IQVIA, BofA Global Research. Note: Sales indexed to Oct-22

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USFDA news flow unlikely to abate

Post the covid lull, we did see pickup in USFDA inspections last year but the overall trend of foreign inspections in FY23 (ending Sep-23 for USFDA) is still materially below pre-pandemic levels. But the gap in foreign inspections for ex-India facilities is even larger with number of inspections for Indian facilities materially picked-up in the last year (but still below the FY18-19 peak). The notable adverse actions that we saw in the last year (including late CY22) are import alerts for SUNP's Halol facility, Accord's injectable unit as well as OAIs/ WLs impacting launches for Cipla (Goa, Pithampur), SUNP's Mohali and

BIOS' Malaysia facilities. Zydus, ARBP, GLAND & DRRD maintained its track record of clear inspections, while LPC was able to resolve outstanding WL/OAI for some of its key facilities. However, the stock reaction to adverse outcome was more sedate vs. the past given visibility in near-term earnings (aided by gRevlimid and base business gains) even as key launches are delayed.

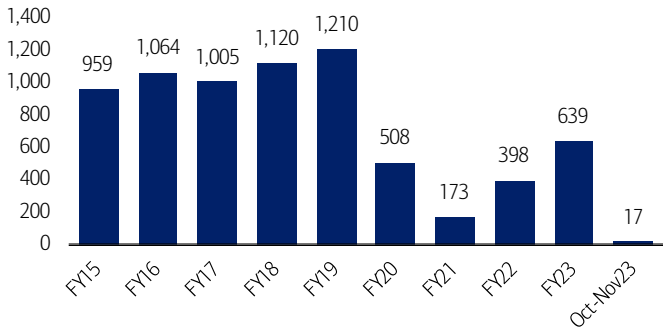
While we expect routine inspection to continue into CY24, there are some critical inspections/outcomes that will be closely watched given the impact on pipeline and earnings. Further, we would watch for pickup in China inspections (restarted only in Apr) which could also potentially result in supply disruption opportunities for Indian players with cleared facilities.

Risk from facilities due for inspection or outcomes awaited: While USFDA has completed inspection for most of the facilities that had not been inspected since before the pandemic, one key facility that remains in Aurobindo's Eugia Unit III (its largest injectable facility). Outcome for DRRD's Bachupally OSD facility inspected in Oct-23 with 10 observations will also be key to watch with an OAI being a sentimentally negative event even though minimal earnings impact given no large filings from the plant. Now that USFDA has cleared much of its inspection backlog, we could see the agency focus on routine inspections and most of the facilities that were cleared in 2HCY21/ CY22 would become due for inspection again. The base case for investors will be positive outcome given recent inspection and thus a negative outcome for a facility key for earnings could impact investor confidence.

Resolution of adversely impacted facilities: Given the large number of adverse USFDA action seen, investors would also watch for resolution of impacted facilities or site transfer of key products. SUNP had recently indicated resumption of supplies from its Mohali unit, and we expect to see market share pickup in its largest product from the facility. Cipla's two large facilities Goa and Pithampur are under warning letter, similarly BIOS' Malaysia facility re-inspection is also a key event.

Exhibit 15: Foreign inspections conducted by USFDA

#USFDA inspections have gone up in FY23 but still below pre-covid levels



Source: USFDA. Note: Fiscal year ends on Sep 31st per US FDA

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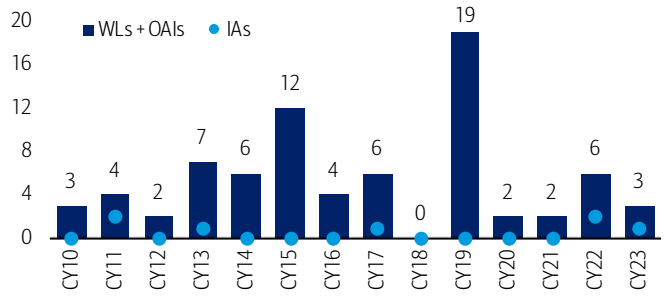
Exhibit 16: US FDA adverse outcome trend

We saw pickup in adverse USFDA outcomes in end CY22 as well as some in CY23



Source: Company Reports, BofA Global Research. Note: Data for 11 Indian companies

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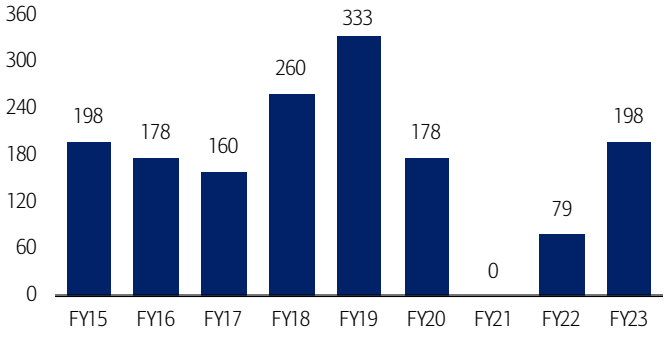
Exhibit 17: India USFDA facility inspections
#USFDA inspections for Indian facilities saw uptick in FY23 and are back at FY15-17 levels...



Source: USFDA. Note: Fiscal year ends on Sep 31st per US FDA

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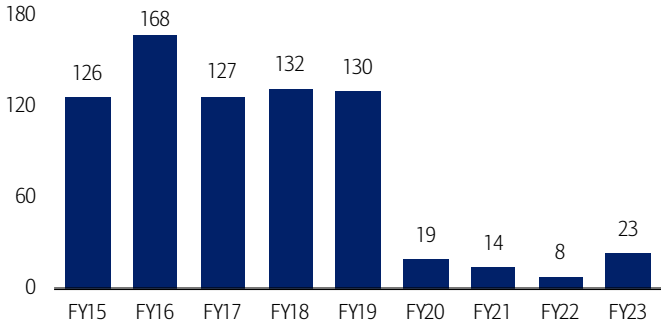
Exhibit 18: China USFDA facility inspections
...However, China facilities are yet to see inspection by USFDA and could lead to additional drug shortages



Source: USFDA. Note: Fiscal year ends on Sep 31st per US FDA

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Exhibit 19: Key facilities due for inspection
Most pending facilities since pre-covid have been inspected (ARBP Unit-IV key pending) but facilities inspected in 2021/22 will also become due for inspection in 2024

Company	Facility	Operations	Last inspection	Status
Lupin	Unit -3, Pithampur	Formulations	Oct-18	EIR received, key facility for inhalers
SUNP	Baska	API + Formulations	Mar-19	Smaller plant but critical given Halol/Mohali under IA/OAI
SUNP	Dadra	API + Formulations	Mar-19	Smaller plant but critical given Halol/Mohali under IA/OAI
Aurobindo	Unit-IV, Sangareddy (Eugia III)	Formulations	Nov-19	Largest injectable facility
LPC	Goa	Formulations	Sep-21	VAI issued in Dec-21
DRRD	Duvvada	Formulations	Oct-21	Received EIR in Feb-22
LPC	Novel labs (new Jersey)/Somerset	Formulations	Mar-22	VAI issued in July-22
Zydus	Vadodara, Gujarat (Dabhasa)	Formulations	Mar-22	Liva Healthcare injectable facility, 5 obs in last inspection; EIR received in May 2022
DRRD	FTO-SEZ - Process Unit - 01, Srikakulam	Formulations	Jul-22	EIR received after 2 observations
Zydus	Moraiya	Formulations	Aug-22	EIR received in Nov-22
Gland	Dundigal	Sterile injectables	Aug-22	Form-483 with 1 observation, EIR received in Jan-23
LPC	Unit-I, SEZ, Nagpur	Injectables	Oct-22	Received EIR in Feb-23

Source: Company Reports, BofA Global Research

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Exhibit 20: Pending facilities from last inspection (including ones with pending action post Form 483)
SUNP, CIPLA and BIOS had adverse outcomes in recent inspections of key facilities and progress in resolution will be key for their US gx earnings

Company	Facility	Operations	Last inspection	Status
ARBP	Unit-I, Sangareddy	API	Aug-21	Warning Letter received in Jan-22
LPC	Tarapur	API unit	Apr-22	Received WL after 2022 inspection
Glenmark	Monreo	Sterile injectables	Apr-22	17 observations and later classified as OAI in Aug-22
SUNP	Halol	Formulations	May-22	Import Alert received in Dec-22
Glenmark	Goa	Formulations	May-22	Received Warning Letter in Dec-22
Glenmark	Baddi	Formulations	Jun-22	Placed under Import Alert from Oct-22
CIPLA	Goa	Formulations	Aug-22	OAI received in Nov-2022
SUNP	Mohali	Formulations	Aug-22	Received form 483 with 6 observations, classified as OAI
Biocon	Bangalore	Formulation, biosimilar	Aug-22	11 observations received, critical for Beva and rh-Insulin
Torrent Pharma	Indrad	Formulations	Sep-22	Received OAI status in Jan-23
LPC	Pune biosimilar centre	Biosimilars	Oct-22	Form 483 with 17 observations issued
SUNP	Mohali	Formulations	Nov-22	OAI received, placed undr Consent Decree
Accord	SEZ facility	Formulations (Injectables and OSDs)	Nov-22	Issued Form 483 with 11 obs leading to Import Alert in Jun-23, the co received another Warning Letter for the same facility in Nov-23 as FDA found Accord's responses inadequate
Cipla	Pithampur	Formulations	Feb-23	Classified as OAI in Aug-23 and received warning letter in Nov-23
BIOS	Malaysia	Formulation, biosimilar	Jul-23	OAI issued in Oct-23, earlier issued a CRL - key for Aspart & rH-Insulin
ARBP	APL HC Unit IV (Unit-X), Nellore	Formulations (orals)	Sep-23	Issued Form 483 with 1 observation
DRRD	Survey No. 41, Bachupally	Formulations	Oct-23	Form 483 issued with 10 observations - key facility
DRRD	Biologics facility, Bachupally	Biologics	Oct-23	Form 483 issued with 9 observations in PAI

Source: Company Reports, USFDA, BofA Global Research

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China competition – small base but cost advantage

Data by US Census Bureau indicates significant pickup in pharma imports from China with its value contribution in US imports reaching 9.6% vs. 1% in CY21. We would point that this data could be slightly misrepresentative since it includes API, US gx as well as organs, cultures etc. Part of the pickup in pharma imports from China in the last year was associated with import of oncology drugs that were in shortage due to supply disruption.

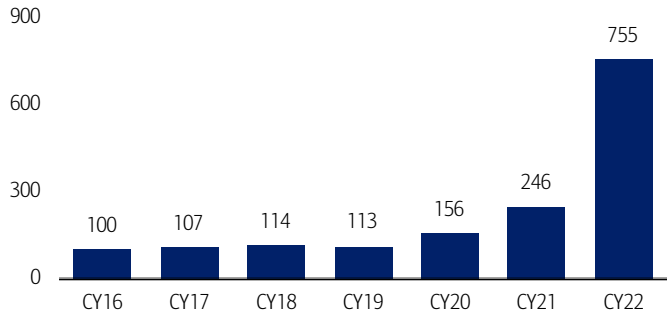
ANDA approvals by China companies increased have been increasing since CY17 (but still below Indian peers) with cos using approved ANDAs for faster approvals for generics in the domestic market. However, we do see pickup in China's US gx presence based on the IQVIA data with pick-up in ANDA approvals in CY22. We see a step-up in US gx sales for two China players - Solco Healthcare and Meitheal Pharma. While the current US gx base for China based players is small, the cost advantage from end-to-end supply chains makes them a credible competition particularly in injectables and commodity OSDs. We will watch out for scale up in front-end presence by China players as well as step up from existing players to gauge the impact on pricing.

Solco Healthcare headquartered in the US and founded in 2010 is a fully owned subsidiary of China based Prinston Pharma and Zhejiang Huahai. Zhejiang Huahai was the first China company to receive USFDA clearance for finished formulation. One of the company's key API facilities was placed under import alert due to NDMA impurities, which was lifted in Nov-21 and led to launch of 16 products over CY22-23 with a current portfolio of 50+ US gx products. Few of its largest products include sartans like losartan pot, valsartan. The company's end-to-end integrated play does have a cost advantage which could imply aggressive pricing for share gain. For instance, Solco launched Losartan Potassium in Jan-22 and reached ~30% market share in Nov-23. The company also calls out its robust pipeline.

Meitheal Pharma, founded in 2017 is a fully owned subsidiary of Nanjing King Fried based out of China. The company today has a portfolio of 50+ US gx injectables of which ~25 have been launched over CY22-23. Few of its top products include enoxapirin/ heparin, daptomycin, regadeneson, micafungin and has gained significant share in these products. Further, the company announced in Oct-23 that it has expanded its portfolio through asset purchase agreement by parent company which will take its total products to 82.

Others: Hepalink the largest heparin API manufacturer also entered the US market and launched 2 products heparin and enoxa. Other Chinese players like Yichuang Humanwell Pharma, Jiangsu Hansoh also supply in the US gx market through a partner.

Exhibit 21: US Pharma imports from China
US pharma imports from China in 2022 were 3x of CY21 levels



Source: US Census Bureau, Atlantic Council

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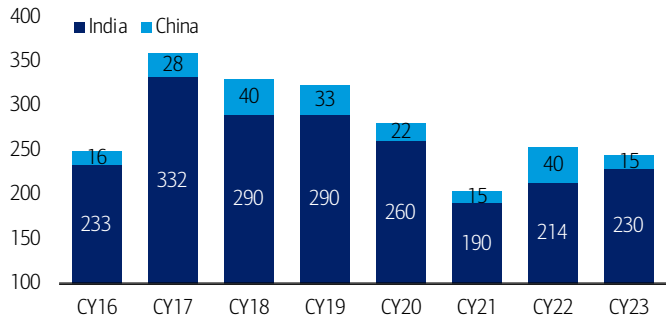
Exhibit 22: ANDA approval trends for China and India
China approvals saw pickup in CY22 though CY23 trends are running lower



Source: USFDA, BofA Global Research

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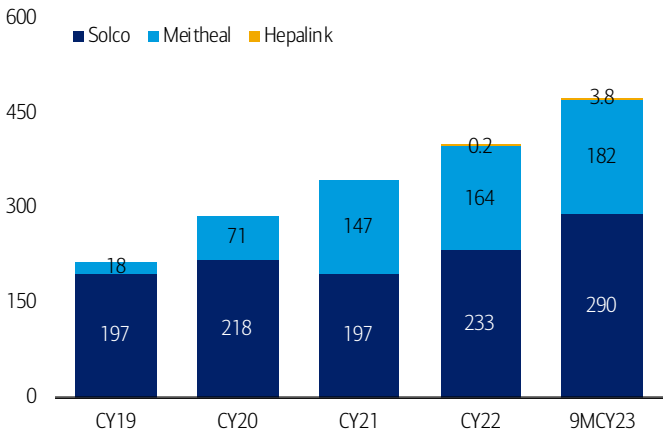
Exhibit 23: IQVIA sales trend for Chinese players
Significant uptick in US gx sales of Hepalink, Meitheal



Source: IQVIA

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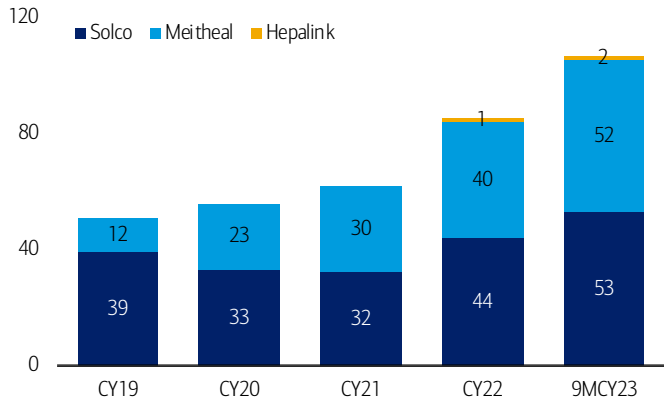
Exhibit 24: #products sold by China players
Solco and Meitheal have significantly ramped up their product portfolio in US gx particularly



Source: IQVIA

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US Gx – What are we building for DRRD?

While **DRRD** is expected to see impact from competition in two of its largest products gSuboxone, gVascepa we do expect this to be offset by scale-up of its Mayne portfolio including share gains in gNuvaring (up from 3% last qtr to 10% in Dec-23). While the company does not share any details on its pipeline, it does indicate 25-30 material launches over FY25-27 including limited competition injectables. We build in FY25 quarterly run rate at 1HFY24 level not giving benefit from any large launches in our assumptions. While gRevlimid contribution would continue till Jan-26 (~$400Mn pa as per BofAe), from 2HCY24 we expect focus to increase on the pipeline to offset the large contribution post settlement expiry.

Exhibit 25: Concentration risk (ex-gRevlimid)
DRRD is relatively better placed vs peers on US gx concentration risk

Company	LTM Top 5 concentration	LTM Top 10 concentration	Rolling 3M Top 5 concentration
Cipla	60%	72%	52%
Zydus	42%	52%	45%
DRRD (ex-Mayne)	35%	45%	35%
LPC	31%	44%	40%
SUNP	23%	34%	48%
ARBP	12%	22%	12%

Source: IQVIA

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Exhibit 26: Large existing generic products – contribution and risks
gSuboxone, gVascepa and gNuvaring competitive environment key to watch

Company	Product	FY24 US revenue contribution (BofAe)	FY25 US revenue contribution (BofAe)	FY25 growth (%)	Competitive scenario
DRRD	gSuboxone	7%	5%	-21%	Largest product with limited competition (5 players currently) with 1 player than has recently launched - erosion and share loss built in our est. Teva has also settled with innovator for Jan-25 launch
DRRD	gVascepa	4%	4%	-9%	6 players in market currently but Zydus and Strides (in partnership with Amneal) have approval and are expected to launch
DRRD	gNuvaring	2%	2%	23%	Mayne portfolio product - DRRD is gaining share but we have so far built in 8% share for FY24 (risk to the upside)

Source: BofA Global Research

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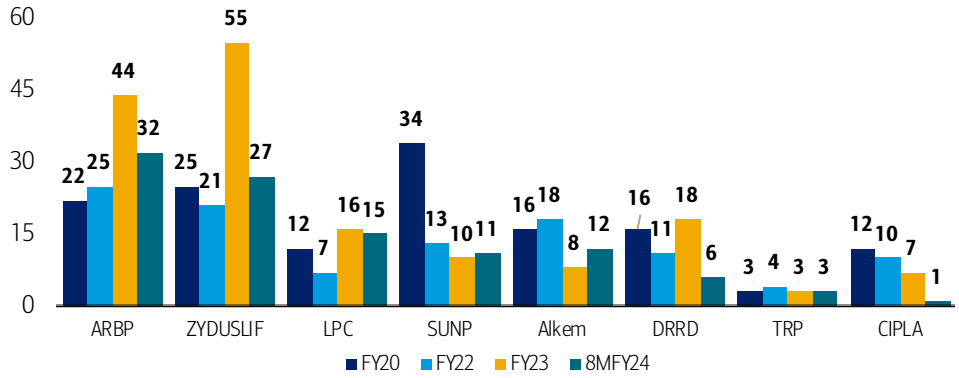
Exhibit 27: Approval trend for coverage companies
DRRD FY24YTD approvals tracking lower vs FY23 but expected to pickup



Source: USFDA

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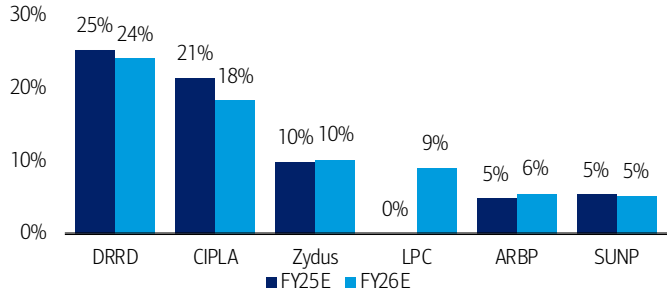
Plugging the big hole in CY26

The big debate that could emerge in US gx stocks in 2HCY24 is replacing gRevlimid revenue starting Jan-26 (patent expiry). Post patent expiry, we could see multiple other generic launches leading to share loss and sharp price erosion with focus shifting towards filling the large gRevlimid hole.

Exhibit 28: gRevlimid contribution to US revenue for coverage cos
gRevlimid is a meaningful revenue contributor for DRRD



Source: BofA Global Research

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The three key avenues being explored by Indian US gx companies include complex generics (including GLP-1 generics, inhalers, injectables), biosimilars and specialty products. While complex generics will be an area of focus for all generic companies, Indian companies have been late entrants in biosimilars (besides Biocon). We expect DRRD to focus on complex generics, biosimilars while specialty will be a tough area to crack with fewer participants.

Complex generics big enough to fill gRevlimid hole?

The intensifying competition in OSDs had led to most players explore limited competition complex generics opportunities including respiratory, injectables including peptides, long acting injectables, drug device combinations, etc. Given multiple filers for most products, large limited competition approvals may be tough to come by and hence, pipeline progress will be keenly watched by street.

DRRD in its Jun-22 analyst day noted that 40% of its pipeline for US business includes injectables/ sterile products. It also has 25+ complex products in pipeline across drug-device combos, peptides, long acting injectables and RTUs. Even in its most recent earnings call DRRD cited readiness to launch in semaglutide/ teripatide in key markets

(including US) once patent expires. Given DRRD does not share product specific details, large launches are likely to be upside risk to street estimates.

Cipla has 3 complex products undergoing clinical trials with filings targeted in FY24 and FY25 which includes gSymbicort. It is also working on few peptide products and already has a platform in place given its launch of lanreotide and Lupron depot. The company has indicated launching a few peptide products starting 4QFY24.

ARBP's complex pipeline includes peptides (13 DMFs submitted, 10 ANDAs filed) as well as 3 depots using its own technology (for microsphere and nano). It is also working on respiratory pipeline and has filed 1 MDI (not seen a launch as yet).

Lupin has called out pipeline in respiratory as well as peptides. It expects to file the long-acting injectable gRisperidone in the current fiscal and has also filed Liraglutide. It has also partnered with Caplin Point for injectable launches.

However, in our view, it would be tough to plug the gRevlimid hole through complex gx launches alone.

Exhibit 29: Complex or large pipeline products
Most players have complex generic opportunities

Product	Brand	Expiry	Comments
Liraglutide	Saxenda	2023	Teva, SUNP, Orbicular, BIOS in litigation, DRRD also working on it
Liraglutide	Victoza	2026	Sandoz, Teva and Viatris settled. Sandoz launch expected in Jun-24. Hikma, SUNP, Biocon in litigation. DRRD also working
Semaglutide	Ozempic	2032	Viatris has FTF; Other filers are Rio, Aurobindo, Sun, Sandoz and Zydus. DRRD also working
Semaglutide	Wegovy	2032	Viatris has filed (FTF)
Teriparatide	Forteo	2025	Apotex, Teva approved in Nov-23; DRRD in litigation (filed in 2022), SUNP in litgation (filed in Aug 21), Amphastar filed but hit with CRL (action expected 1QCY24)
Risperdal Contra	Risperidone	Expired	LPC guided for filing in 3QFY24. Teva and Luye Pharma also have brands competiting Risperdal Contra
Budesonide-formoterol	Symbicort	2022-29	Viatris received approval for its generic Breyna in Dec-23. Cipla guided for 3QFY24 filing
Mirabegron	Myrbetriq	May-24 for one patent, other patents under litigation	Contingent on litigation. Current patent for innovator expires Mar-24. District court declared another patent that extends life to 2030 invalid but innovator will appeal the decision. Zydus has 180 day shared exclusivity. LPC settled with innovator and received FDA approval, Sandoz, Teva and Torrent have also filed
Baricitinib	Olumiant	2029-32	ARBP received tentative approval

Source: BofA Global Research

Biosimilars – too big to ignore?

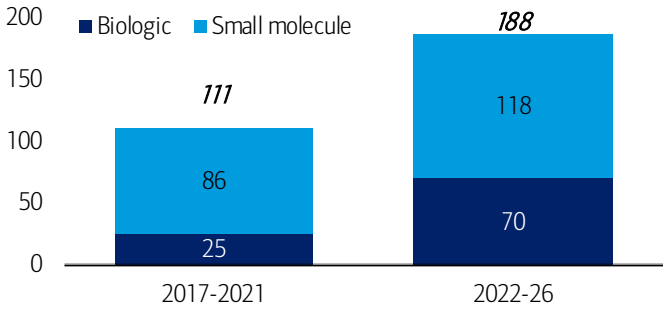
Biosimilars is an area of growth for gx companies given lower erosion levels and higher proportion of drug LoEs being biologics over the next decade. While there are concerns over biosimilar pricing going the generic way particularly with the possibility of USFDA granting interchangeability status without additional studies, we see many innovators de-prioritizing biosimilars thus increasing the opportunity size for gx players. The much-awaited bHumira launch was a disappointment for biosimilar players with Abbvie defending its market share aggressively and biosimilar share at <2% of retail prescriptions. This highlights the challenge in pharmacy benefit drugs, where pricing is not the only driver for market share and the aggressive stance by innovators.

Among India players, BIOS has the largest biosimilar portfolio with four commercial launches in the US (including bHumira) and four expected launches over coming few years contingent on USFDA inspections (Beva, bAspart,rH-insulin) and bEylea (litigation). While BIOS has been able to gain share in its existing products post the acquisition of front-end from its partner, the pipeline execution has been disappointing with delay in approvals and compliance issue in its facilities.

Apart from Biocon other Indian gx players are late entrants in the space. LPC and ARBP are the ones with possibility of US launch by FY26 while DRRD could make its front-end biosimilar entry in FY27 (vs partnered presence currently). Cipla, SUNP, Zydus have shared very little details on their biosimilar program for developed world. ARBP while late entrant, could be a credible player in the space given its portfolio of 14 biosimilars and cost-efficient play that could enable is generate 70%+ gross margins even in products where it is late entrant. Apart from updates on its Europe filings, we could see

ARBP file 1-2 biosimilars in US over FY25/26 (beva, one opthal biosim). The company expects CY26/27 to mark inflection for its biosimilar business. Any biosimilar updates from DRRD will also be closely watched given it has the largest gRevlimid contribution which increases focus on FY27 pipeline.

Exhibit 30: Biologic vs. small molecule LoE in developed markets ($bn)
Biologics will form a higher proportion of LoE opportunity – 37% in 2022-26 vs 23% in 2017-21 - too big an opportunity to ignore



Source: IQVIA – Global Use of Medicines 2022

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Exhibit 31: Biosimilar progress for Indian companies
Biocon is the only Indian player with a big biosimilar exposure, LPC and ARBP entry expected over FY25-26, DRRD inflection expected in FY27

Company	Comments
Biocon	Largest Indian biopharmaceutical player by revenue with good presence across regulated as well as unregulated markets. 4 products already launched in US, 4-5 launches expected in next 5 years with Bevacizumab (bAvastin), Aspart, rH-insulin launch in FY25 (contingent on facility clearance); bEylea, bProlia and bStelara launch in FY26 or later
Lupin	Expected entry in US biosim with PegG launch post USFDA facility clearance; ongoing on body injector trials, completed enrolments for ph-3 global study for bLucentis. Launched bEmbrel in India, Japan and EU and plans to launch in few other markets through partnerships.
Zydus	Largest biosimilar pipeline among Indian players but monetization largely from EM
Sun Pharma	Late entrant in biosimilar play; expects 1st biosim to hit the market in 2028-30 (2nd wave of biosims)
Cipla	JV with Kemwell Biopharma for biosim dev and commercialization; limited details shared on biosim plans so far but launched 1st biosim (bevacizumab) in Europe
Aurobindo	14 biosims in development under CuraTeQ sub with a TAM of US$50Bn across oncology and immunology assets. Late FY25-26 EU launch expected for 3 biosims. Signed a LoI with MSD for Biologics CDMO with expected commissioning in FY26 and revenue contribution from FY27. In-licensed bStelara from BioFactura (completed Ph-1 study)
Dr Reddys	Launched PEG-GCSF in US in partnership with Fresenius. PAI for bRituximab (partnered) concluded with 9 observations. Expects to launch ~5 biosimilars globally (including US) over the next 2-3 years. The inflection in biosimilar business is expected from FY27 from possible US launch with its own front-end.

Source: BofA Global Research

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Specialty – a tough game to crack:

While Indian companies have tried to foray into specialty (i.e branded business in developed markets) over the years, the model of operation and success-rate has varied widely. Most specialty efforts have been through business development, but we have also seen companies invest in building their NCE/NBE pipeline (Glenmark, Dr Reddy's, Lupin) largely focused on out-licensing these assets. Glenmark Pharma (Not covered) is a company where the investment in NCE/NBE has been penalized given the delay in monetization and continued cash burn on R&D. Dr Reddy's and Cipla have shifted their strategy to focus primarily on generics with the former divesting most of its portfolio (NCE development through self-sustaining model) and the termination of the specialty deal in case of Cipla. Lupin also took a Rs7Bn impairment on its specialty product Solosec after ramp-up being much slower than expected. The large failures in specialty execution and the huge investment required keeps most of these players except SUNP, Zydus out of the space.

Domestic – Risk to growth & regulations

The domestic branded domestic pharma market delivered a CAGR of 10% over FY14-23 per AIOCD however, the growth has slowed to 8.5% in the last three years, primarily driven by lower volume growth. The trend is even weaker this year with 8M FY24 growth as per AIOCD is tracking at 5.1% (MAT Nov-23 growth at 6.9%). While part of the weakness could be attributed to delayed seasonality, the data also shows particularly weak volume growth including chronic therapy segments. In our view, a key reason for the slower volume growth vs. the past has been the penetration of lower value Trade Generic and Generic-Generic segments in India that account for 15-20% of industry volumes. The government push toward expansion of its generic-generic store and recent noise on generic prescriptions does highlight the risk of faster shift towards the unpromoted generics. This could continue to weigh on already muted volume growth for industry over the medium term.

Pricing growth to be slower in FY25: The branded generic growth in recent years has also seen support from pricing (4-6% increase) with NPPA (National Pharmaceutical Pricing Authority) price ceiling on NLEM drugs being 10% over the past 2 years. **However, the lower WPI trend (-1.6% 8MFY24 vs 9.4% in FY23) and increasing competition in a lower volume growth market might make it tougher for companies to sustainably increase pricing to the same extent seen in recent years**. We see FY25 growth at lower end of 7-8% on a benign FY24 base and normal seasonality but pricing growth slowing down.

The key growth strategies for domestic formulations in CY24 in our view will include 1) **R&D in specialty/ niche molecules** (like of dydrogesterone by Mankind, biosimilars by Zydus, semaglutide for DRRD); 2) **in-licensing deals or collaborations with innovators** including drug-device combinations, digital diagnostics (eg. DRRD's digital platform for migraine), peptides (particularly weight loss area to be watched closely); 3) **scaling-up consumer health platforms** (TRP's recently launched platform, Mankind and Cipla already have large presence, DRRD focusing on ramping up nutraceuticals); 4) **acquisitions of brands particularly chronic focused** (JB Chem's recently announced acquisition of Novartis opthal portfolio).

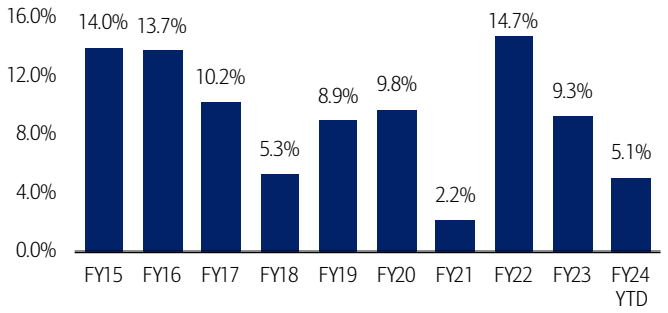
Weighing the regulatory risk – Is India ready for Gx-Gx?

The National Medical Commission (NMC) had put its regulation for Registered Medical Practitioners' (RMP) professional conduct in abeyance within 15 days of announcement after push back from stakeholder including pharma companies. The regulation provided guidance to avoid branded generic prescription by doctor by encouraging them to write Gx, non-proprietary, and pharmacological name. This would shift the decision on the choice of manufacturer from the doctor to the pharmacists who may not be qualified, and push drugs based on their incentive rather than drug safety/efficacy standards. The regulation also imposed restriction on RMPs participation in third-party events such as seminar, workshop, conference, etc. that involves direct or indirect sponsorships from pharma cos or allied health sector. The key pushback from doctors was on variability in quality standards of drugs sold in India, which could be detrimental to patient safety in case of generic Rx.

While NMC has put the RMP regulations on hold, we believe recent news reports highlights govt's focus on quality standard of drug manufacturing units in India. This also comes after a series of adverse events related to counterfeit/ substandard drugs. Earlier this month, DCGI instructed state drug controllers to obtain details from manufacturing unit under their jurisdiction including international certifications. The news report also indicates that the risk-based inspection by DCGI has pointed to deficiencies in current GMP regulation (last amended in 2005) and the need to relook at these. Any reform in quality standards would be viewed positively by the industry and help consolidate volumes towards quality manufacturers. However, the key question on any quality reform is the on-ground infrastructure to implement & monitor these regulations by state drug

controllers given ~10,500 units in India manufacturing FD/APIs. Progress on India's drug quality reforms will be key to assess pace of shift towards a more Gx prescription.

Exhibit 32: IPM growth trends
IPM growth has slowed down over past few years from the ~10% growth over FY14-23 with FY24 YTD growth tracking even lower at 5.1% YTD



Source: Pharmatrac (AIOCD)

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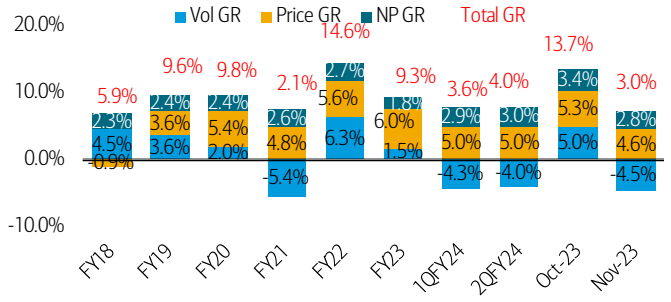
Exhibit 33: Branded generics industry growth drivers
IPM growth has been pricing driven over last 2-3 years with 4-6% pricing growth



Source: Pharmatrac (AIOCD)

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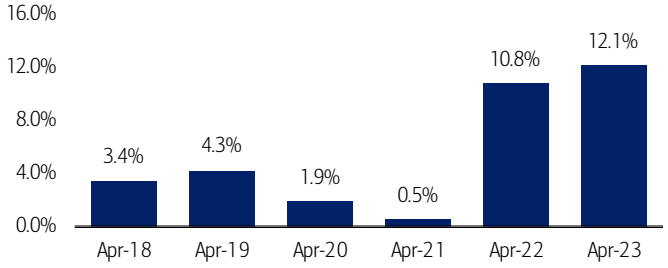
Exhibit 34: NPPA price revision for NLEM portfolio
Pharma cos benefited from 2 consecutive DD NLEM price hike ceiling



Source: PIB

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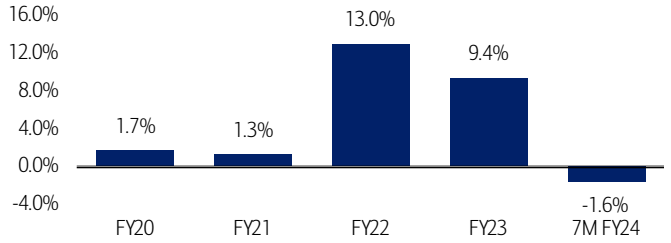
Exhibit 35: India WPI index
FY24 YTD WPI index tracking in negative implying that WPI linked NPPA NLEM price revision ceiling would be low for FY25



Source: RBI, Indian Economic Survey Dec-22

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Exhibit 36: Market share performance by top players
During the year Cipla, TRP, Mankind have gained share among coverage

Company	MAT growth	MAT Nov23 mkt share	MAT Nov22 mkt share	Mkt share change	Company	MAT growth	MAT Nov23 mkt share	MAT Nov22 mkt share	Mkt share change
IPM	6.9%				Torrent	10.1%	3.7%	3.6%	11
Sun Pharma	6.8%	8.5%	8.5%	-1	Alkem	9.2%	3.5%	3.5%	8
Cipla	12.4%	5.1%	4.8%	25	Mankind	11.2%	5.1%	4.9%	20
Dr Reddys	6.3%	2.9%	2.9%	-1	Macleods	12.8%	3.3%	3.1%	17
Zydus	4.4%	3.9%	4.0%	-9	IPCA	1.8%	1.9%	2.0%	-9
Lupin	5.6%	3.4%	3.5%	-4	Intas	8.3%	3.4%	3.3%	5

Source: AIOCD

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Exhibit 37: Company commentary on India growth levers
Most companies are looking at chronic therapy as a growth driver for India business and guiding for inline / higher tha industry growth

Co	Commentary
Cipla	Chronic contribution is improving. Highlights marketing and device and diagnostic initiatives. Has multiple in-licensing agreements across cardiac, diabetes, onco with a size of Rs5Bn+ in FY23
SUNP	Guides for higher than industry growth. Saw benefit from FF addition in FY23. Recent launch of a first in class drug for cerebral strokes & Cequa
Zydus	Guides for inline with industry growth. Growth to be aided by innovative portfolio. Zydus entered into co-marketing agreements for 2 of its innovative drugs.
LPC	Indicated stronger than industry growth in all therapy areas except diabetes and diabetes is also back on growth mode. Focus therapies include cardiac, diabetes, respi, gastro, anti-infectives
Alkem	Plan to increase chronic contribution from 15-16% currently to 20%+, Expects Alkem chronic business to grow at 2-2.5x market
TRP	Guides for outperformance vs industry with focus on market share improvement in key therapies, ramping up sales force productivity and growing recently launched consumer vertical
DRRD	Guidance of DD YoY growth from 4QFY24 with focus on licensing and collaborative initiatives. Some recent initiatives by the company include licensing deal with Hengrui (Pyrotinib), D2C platform Celevida for diabetic patients, launch of 'Nerivio' digital therapeutic product for migraine
Mankind	Plan to increase presence in chronic therapy areas particularly anti-diabetic, cardiac, CNS, respi, etc and expand presence in metro/tier-1 cities. Plans to leverage international standard API products for chronic therapies

Source: Company Reports, BofA Global Research

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Exhibit 38: Pharma companies' commentary on field force expansion in India
Companies don't indicate plans for large field force additions given headroom for productivity improvement from recent investments

Company	Commentary
Lupin	Added 1000+ reps in FY23 and 6 new divisions including one extra urban division. Plans to add ~500 reps every year
Zydus	Guided for MR addition in FY25 in a calibrated manner
Sun Pharma	Has increased its field force size by 10% from 11k level in FY22 end for geographic expansion and brand focus. Hasn't commented on further sales force increase
Torrent Pharma	FF expanded by 1500 MRs in FY23 including organic expansion and Curatio acquisition. Focus now on productivity ramp-up
DRRD	No plans to grow field force but could see need based addition in case of more innovative product launches
Alkem	Has been adding ~1000 MRs every year for the past few years but believes no substantial field force addition required over the next few years

Source: Company Reports, BofA Global Research

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Capital allocation – CY24 to be more action packed?

While CY23 did see mid-sized deals and bolt-on acquisitions in the sector, it was lower than the deals seen in CY22. There were a few notable deals in the sector – Sun Pharma's acquisition of Concert Therapeutics ($576Mn+milestone payments & royalties), Nirma group's acquisition of majority stake in Glenmark Lifesciences (~$650-700Mn for Glenmark's 75% stake), IPCA's acquisition of Unichem (~$190Mn including open offer) and more recently JBPharma's acquisition of Novartis' ophthalmology portfolio in India (~Rs11bn). Despite cash rich balance sheets, M&A activities by our coverage pharma companies were more bolt-on including DRRD's Mayne portfolio acquisition ($100Mn), Zydus Liqmeds acquisition ($87mn), SUNP's minority stake acquisition in Lyndra Therapeutics ($30mn), ARBP acquisition of Pfizer/ Viatris branded portfolio in Indonesia ($48mn). We also saw noise in the media around Cipla's potential promoter stake sale.

The strong FCF generation from gRevlimid contribution over the next two years and already robust balance sheet will keep investor focus on capital allocation strategy and their ability to generate value from M&A deal. This will be particularly crucial given shareholder return through dividend remains modest in the sector. We remain optimistic on M&A in the sector in CY24 with areas of interest being domestic pharma (and consumer wellness) assets particularly in chronic segment, specialty assets would be of interest for some players and select biosimilar or injectable assets. Value accretion from these deals will be crucial with investors likely to credit companies with strong historical track record on M&A and opportunities with strategic fit.

Steady eddie margin for most parts

Pharma stocks rallied in CY23 aided by better US gx pricing, new launches as well as gRevlimid contribution driving higher than expected margins. We witnessed margins for most US focused stock being higher than expected with gross margin expansion on

lower raw material costs, PLI benefit being higher and a much better pricing environment in the US. While companies continued to invest in field-force expansion, SG&A in India (& US specialty) and R&D, EBITDA margins performance was reset higher for FY24. However, as the gRevlimid contribution and US Gx pricing moderation is factored in the base, we are unlikely to see broad-based improvement in margins for pharma companies.

Who could see surprise in consensus earnings? We believe DRRD is the best placed for consensus earnings upgrades with street EBITDA estimates 6-7% below BofAe. In our view, while street is incorporating margin risks from competition in its large US gx products, it is not accounting for Mayne portfolio ramp-up or pick-up in ex US growth (particularly India). Further, given DRRD does not share pipeline updates early on, any large, limited product approval will imply consensus earnings upgrades against possibility of downgrades in case of launch delays vs guided timelines in some other cos.

What could be the risks to FY25 margins?

US price erosion trend: After the earnings surprise in CY23 on lower price erosion, we assume mid-to-high single digit base business decline for Indian US gx cos. While there is visibility on the moderate pricing trend continuing into 1HCY24, any reversal in trend due to higher competitive intensity is a key risk to our assumption for US Gx growth for DRRD.

R&D trajectory: While the focus on complex generics/ biosimilars should keep R&D spend elevated, slow progress on the pipeline could lead to higher margins. However, we believe progress on pipeline development is crucial for medium-term growth particularly with the revenue loss post Jan-26 from Revlimid patent expiry.

Domestic market dynamic: While we expect moderation in domestic market growth in FY25 on lower pricing growth. We build 9+% YoY growth for DRRD in FY25 (i.e higher than IPM growth). If the industry continues to see modest volume growth, we could see cos step-up SG&A spend in India to maintain and grow share. In our view, increased competitive intensity as most companies focus on increasing chronic share and grow higher than industry could weigh on margins.

Abbreviations used

ANDA	Abbreviated New Drug Application
API	Active Pharmaceutical Ingredient
CDMO	Contract Development and Manufacturing Organisation
DCGI	Drug Controller General of India
DMF	Drug Master File
DRHP	Draft Red Herring Prospectus
DRRD	Dr Reddys Lab
EIR	Establishment Inspection Report
EM	Emerging Market
FTF	First to file
GMP	Good Manufacturing Practice
Gx	Generics

IPM	Indian Pharmaceutical Market
IPO	Initial Public Offering
LoE	Loss of Exclusivity
MAT	Moving Annual Total
MSD	Merck Sharp & Dohme
NBE	New Biological Entity
NCE	New Chemical Entity
NCR	National Capital Region
NDMA	N-nitrosodimethylamine
NMC	National Medical Commission
OAI	Official Action Indicated
OSD	Oral Solid Dosage
PDUFA	Prescription Drug User Fee Act
PLI	Production Linked Incentive
RMP	Registered Medical Practitioners
RoW	Rest of World
RTU	Ready to Use
Trx	Prescriptions
USFDA	United States Food and Drug Administration
VAI	Voluntary Action Indicated
WL	Warning Letter
WPI	Wholesale Price Index

Exhibit 39: Stocks mentioned
Prices and ratings for stocks mentioned in this report

BofA Ticker	Bloomberg ticker	Company name	Price	Rating
DRYBF	DRRD IN	Dr. Reddy's	Rs 5842.2	B-1-7
RDY	RDY US	Dr. Reddy's	US$ 70.22	B-1-7

Source: BofA Global Research

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Price objective basis & risk

Dr. Reddy's (DRYBF / RDY)
Our PO is Rs6570 is based on 25.8x 1-yr fwd P/E on ex-gRevlimid business (15-20% premium to LT multiples) and net present value (NPV) of Rs303/share for gRevlimid. We value the core business at a premium to other peers given the diversified growth strategy and superior return. While the US is a significant driver, the dependence for incremental core earnings growth is lower than peers and limits the downside risk. We value the ADR at $79 (exchange rate of Rs83), in line with primary.

Downside risks are 1) deterioration in core margins due to slower growth, 2) adverse regulatory outcome on its key US facilities, 3) lower-than-expected revenue potential from gRevlimid impacting the NPV.

Analyst Certification

I, Neha Manpuria, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or view expressed in this research report.

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APR - Healthcare Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
	Adicon Holdings	XADKF	9860 HK	David Li
	Aier Eye Hospital	XAEOF	300015 CH	David Li
	Amvis Holdings	XEPSF	7071 JP	Ritsuo Watanabe
	Angelalign Technology Inc	AGLFF	6699 HK	David Li
	APM Human Services	XBZXF	APM AU	Lyanne Harrison
	Apollo Hospital	XWQAF	APHS IN	Neha Manpuria
	Asahi Intecc	AHICF	7747 JP	Ritsuo Watanabe
	Aurobindo	XLZFF	ARBP IN	Neha Manpuria
	Australian Clinical Labs	XAUKF	ACL AU	Lyanne Harrison
	Autobio Diagnostics Co Ltd	XQDXF	603658 CH	Sandra Sun
	AVITA	AVHHL	AVH AU	Lyanne Harrison
	AVITA	RCEL	RCEL US	Lyanne Harrison
	Baiyunshan	GZPHF	874 HK	Sandra Sun
	Bangkok Chain Hospital	BKKFF	BCH TB	Charti Phrawphraikul
	Bangkok Dusit Medical Services	BDUFF	BDMS TB	Charti Phrawphraikul
	Beijing Tongrentang Co., Limited	BJTGF	600085 CH	David Li
	Biocon	XLOFF	BIOS IN	Neha Manpuria
	Bumrungrad Hospital	BUHHF	BH TB	Charti Phrawphraikul
	Cansino Bio	CASBF	6185 HK	David Li
	Chugai Pharm.	CHGCF	4519 JP	Koichi Mamegano
	Chularat Hospital Group	XOCOF	CHG TB	Charti Phrawphraikul
	CSL Limited	CMXHF	CSL AU	Lyanne Harrison
	Daiichi Sankyo	DSKYF	4568 JP	Koichi Mamegano
	Daiichi Sankyo	DSNKY	DSNKY US	Koichi Mamegano
	Dr. Reddy's	DRYBF	DRRD IN	Neha Manpuria
	Dr. Reddy's	RDY	RDY US	Neha Manpuria
	EBOS Group Limited	EBOSF	EBO NZ	Lyanne Harrison
	EBOS Group Limited	XEBOF	EBO AU	Lyanne Harrison
	Eisai	ESALF	4523 JP	Koichi Mamegano
	Everest Medicine	XMLKF	1952 HK	David Li
	Fisher & Paykel Healthcare	XPAXF	FPH AU	Lyanne Harrison
	Fisher & Paykel Healthcare	FSPKF	FPH NZ	Lyanne Harrison
	Fortis Health	XFFTF	FORH IN	Neha Manpuria
	Frontage	FGHQF	1521 HK	David Li
	Gland Pharma	XGLPF	GLAND IN	Neha Manpuria
	Glenmark Life Sciences	XWDPF	GLS IN	Neha Manpuria
	Gushengtang	GSHTF	2273 HK	David Li
	Huadong Medicine	XCPDF	000963 CH	Ethan Cui
	Hygeia Healthcare	HYHHF	6078 HK	Ethan Cui
	Imeik	ZMITF	300896 CH	Ethan Cui
	Innovent	IVBXF	1801 HK	David Li
	Integral Diagnostics	ITGDF	IDX AU	Lyanne Harrison
	Jinxin Fertility	JXFGF	1951 HK	Ethan Cui
	Jinyu Bio-Tech	XMTDF	600201 CH	David Li
	Joinn Lab	XQTSF	6127 HK	David Li
	Kangji Medical	KMHLF	9997 HK	David Li
	Medley	XEQNF	4480 JP	Ritsuo Watanabe
	MicroPort	MCRPF	853 HK	Sandra Sun
	Mindray	XDVVF	300760 CH	Sandra Sun
	Nanosonics Limited	NNCSF	NAN AU	Lyanne Harrison
	Olympus Corp.	OCPNF	7733 JP	Ritsuo Watanabe
	Ovctek	XOCKF	300595 CH	David Li
	Pharmaron	PHBBF	3759 HK	David Li
	Polynovo	CALZF	PNV AU	Lyanne Harrison
	Praram 9 Hospital	XPNHF	PR9 TB	Charti Phrawphraikul
	ResMed Inc	RSMDF	RMD AU	Lyanne Harrison
	ResMed Inc.	RMD	RMD US	Lyanne Harrison
	Sawai Group Holdings	SWGHF	4887 JP	Ritsuo Watanabe
	Shionogi	SGIOF	4507 JP	Koichi Mamegano
	Shionogi	SGIOY	SGIOY US	Koichi Mamegano
	Sino Biopharm	SBMFF	1177 HK	David Li
	SMS	SMSZF	2175 JP	Ritsuo Watanabe
	Sonic Healthcare Limited	SKHCF	SHL AU	Lyanne Harrison
	Sosei	SOLTF	4565 JP	Koichi Mamegano

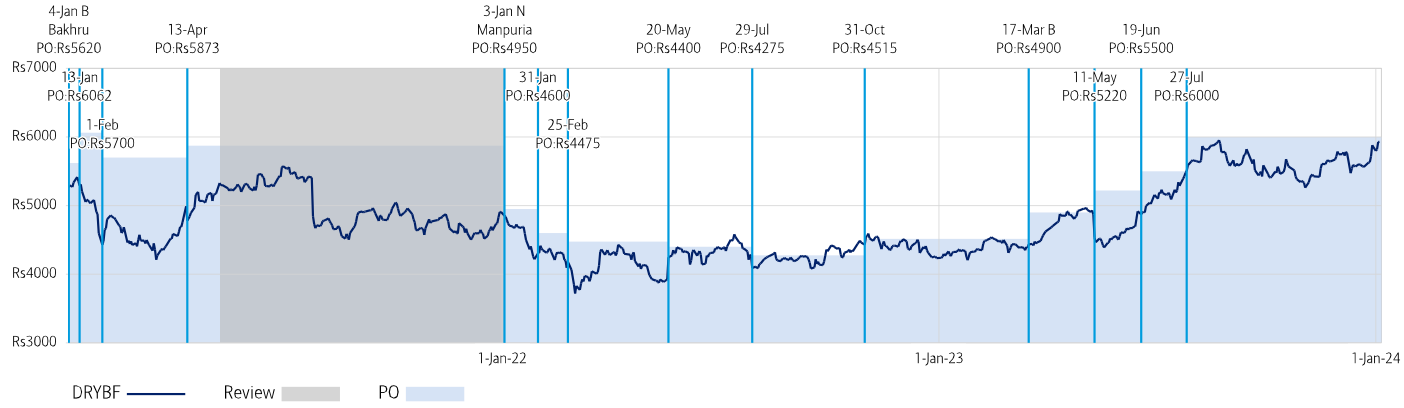
APR - Healthcare Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	Sun Pharma	XPUCF	SUNP IN	Neha Manpuria
	Takeda Pharm.	TKPHF	4502 JP	Koichi Mamegano
	Takeda Pharm.	TAK	TAK US	Koichi Mamegano
	Terumo	TRUMF	4543 JP	Ritsuo Watanabe
	TigerMed	HTMDF	3347 HK	David Li
	Torrent Pharma	TOPHF	TRP IN	Neha Manpuria
	TRYT	XHXTF	9164 JP	Ritsuo Watanabe
	Wuxi Apptec	WUXIF	2359 HK	David Li
	Yifeng Pharmacy	XYHCF	603939 CH	Ethan Cui
	Yunnan Baiyao	YBAIF	000538 CH	Sandra Sun
	Zai Lab	ZLAB	ZLAB US	David Li
	Zai Lab	XCDZF	9688 HK	David Li
	Zhifei	XCHOF	300122 CH	David Li
NEUTRAL				
	Ansell Limited	ANSLF	ANN AU	Lyanne Harrison
	Astellas Pharma	ALPMF	4503 JP	Koichi Mamegano
	Astellas Pharma	ALPMY	ALPMY US	Koichi Mamegano
	Beigene	XBETF	6160 HK	David Li
	Beigene	BGNE	BGNE US	David Li
	JMDC	JMDCF	4483 JP	Ritsuo Watanabe
	Kyowa Kirin	KYKOF	4151 JP	Koichi Mamegano
	Max Healthcare	XMHLF	MAXHEALT IN	Neha Manpuria
	PHC Holdings	PHCCF	6523 JP	Ritsuo Watanabe
	Pien Tze Huang	XUVHF	600436 CH	Sandra Sun
	Ramsay Health Care Limited	RMSYF	RHC AU	Lyanne Harrison
	Sigma Healthcare Limited	SIGGF	SIG AU	Lyanne Harrison
	Topchoice Medical	XZDXF	600763 CH	Ethan Cui
	WuXi Biologics	WXIBF	2269 HK	David Li
	Zydus Lifesciences	XMQLF	ZYDUSLIF IN	Neha Manpuria
UNDERPERFORM				
	Ain Holdings	AINPF	9627 JP	Ritsuo Watanabe
	Alkem	XAMLF	ALKEM IN	Neha Manpuria
	Asymchem Laboratories	XALPF	002821 CH	David Li
	Baiyunshan	XOUFF	600332 CH	Sandra Sun
	Beijing Wantai Biological Pharmacy	XBHIF	603392 CH	David Li
	Cipla	XCLAF	CIPLA IN	Neha Manpuria
	Cochlear Limited	CHEOF	COH AU	Lyanne Harrison
	CSPC Pharmaceutical	CHJTF	1093 HK	Ethan Cui
	Divis Laboratories	XXQPF	DIVI IN	Neha Manpuria
	Hansoh	HNSPF	3692 HK	David Li
	Hengrui Medicine	XMOKF	600276 CH	David Li
	Joinn Lab	JOLCF	603127 CH	David Li
	Lupin	XEFSF	LPC IN	Neha Manpuria
	M3	MTHRF	2413 JP	Ritsuo Watanabe
	Mankind Pharma	XDXZF	MANKIND IN	Neha Manpuria
	Medipal Holdings	MEPDF	7459 JP	Ritsuo Watanabe
	Ono Pharm.	OPHLF	4528 JP	Koichi Mamegano
	Otsuka HD	OTSKF	4578 JP	Koichi Mamegano
	Otsuka HD	OTSKY	OTSKY US	Koichi Mamegano
	Pharmaron	XLYGF	300759 CH	David Li
	Shanghai United Imaging	XCAOF	688271 CH	Sandra Sun
	Sinopharm	SHTDF	1099 HK	David Li
	Sysmex	SSMXF	6869 JP	Ritsuo Watanabe
	TigerMed	XHTHF	300347 CH	David Li
	Wuxi Apptec	XLUHF	603259 CH	David Li
RVW				
	IHH Healthcare Berhad	IHHHF	IHH MK	Paul Dewberry
	IHH Healthcare Bhd	XFAHF	IHH SP	Paul Dewberry

Disclosures

Important Disclosures

Dr. Reddy's (DRYBF) Price Chart



B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

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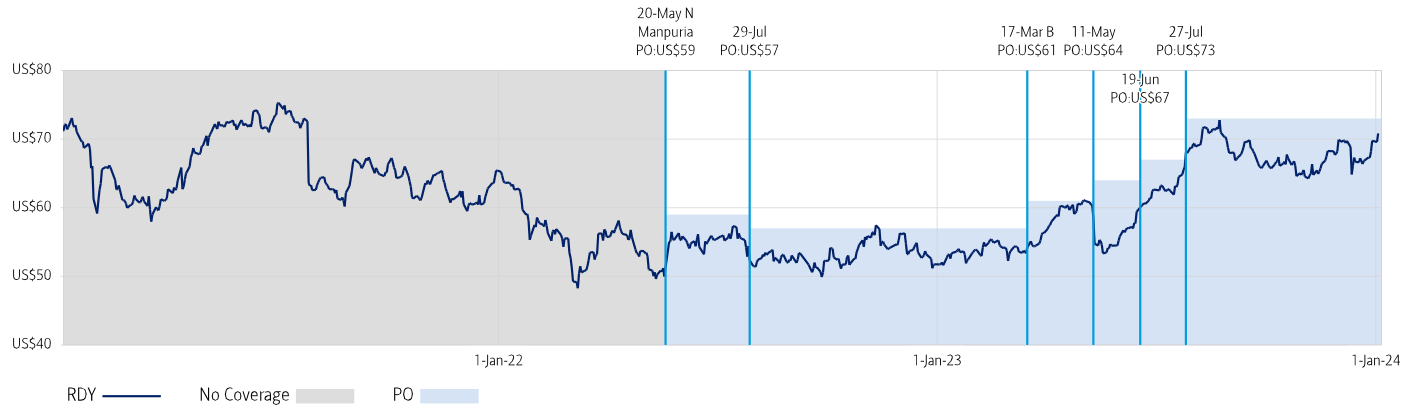
Dr. Reddy's (RDY) Price Chart



B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

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Coverage Universe	Count	Percent	Inv. Banking Relationships [R1]	Count	Percent
Buy	234	60.94%	Buy	115	49.15%
Hold	80	20.83%	Hold	36	45.00%
Sell	70	18.23%	Sell	29	41.43%

Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships [R1]	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
Hold	832	23.54%	Hold	454	54.57%
Sell	807	22.84%	Sell	383	47.46%

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Investment rating	Total return expectation (within 12-month period of date of initial rating)	Ratings dispersion guidelines for coverage cluster[R2]
Buy	≥ 10%	≤ 70%
Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

[R2]Ratings dispersions may vary from time to time where BofA Global Research believes it better reflects the investment prospects of stocks in a Coverage Cluster.

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