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DISRUPTION SERIES
(VOL 12: Pharmaceutical industry)

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Disruption is inevitable: We are prepared

We at Ambit are constantly trying to stay ahead of the curve by drowning out the noise and looking ahead. In keeping with our long term investment thesis, we like to stay up to date with not just the present impediments faced by your portfolio companies but also long term disruptions which can hit these companies. Hence we will regularly come out with our thoughts on disruptions in your portfolio companies/ sectors and for the twelfth volume of this series we have chosen **Indian Pharmaceutical Industry with special focus on Lupin and Torrent Pharma**

A disruptive technology/ innovation is one that helps create a new market and value network, and eventually goes on to disrupt an existing market and value network (over a few years or decades), displacing conventional wisdom or technology. This note takes a closer look at Lupin and Torrent Pharm within the Pharmaceutical industry with a focus on key disruptions that may lie ahead in this fast evolving industry.

Lupin: Moving up the value chain

Chemistry Professor to Entrepreneur

Mr. Desh Bandhu Gupta or DBG as he was famously known - started Lupin in early 1960s. Born in Rajgarh, Rajasthan, DBG completed his M Sc. in Chemistry and started his career as a teacher in Birla Institute of Technology and Science (BITS), Pilani. He later moved to Bombay in early 1960s and started Lupin with a sum of Rs5,000 which he borrowed from his wife. The company initially focused on Folic acid and Iron tablets for Government of India's Mother and Child health program and later moved on to Anti-Tuberculosis (TB) drugs which formed up to 36% of the company's revenues by 2001. The company also ventured into Cephalosporin and Cardiovascular categories.

Bold moves in the 21st Century

With the start of the new century, Lupin made some bold moves which accelerated revenue growth and propelled the company into a different orbit over the next 10 years. **(1) Entry in the US Market –** Transition from low cost to Branded generics in the US when no other Indian manufacturer had been able to establish a meaningful presence in the category. **(2) Change in India business strategy -** Focus on Chronic from Acute therapies and Formulations from API **(3) Entry into Japan (back then, 2nd largest Pharma market globally)** – Lupin became the first international generics company to gain a foothold in Japan. The above efforts resulted in 23% revenue CAGR from FY04 to FY17.

Interesting Fact –

The name of the company was after a flower – Lupinus, commonly known as lupin or lupine – known to survive in infertile soil

Lupin Today

Around the year 2015-16 Lupin started facing increased headwinds in its US business due to increased generic competition, generic price erosion and customer consolidation. This was accentuated by spate of USFDA observations that followed, thus impacting the company's financial performance in the last few years. Over the years Lupin tried to work on compliance issues and address these, which was visible in the number of clearances received in CY20 before COVID struck. In-licensing strategy helped Lupin gain expertise in select therapies while incurring less capital and the same is being used to enter new-geographies. Lupin is working on building a strong franchise of inhalation product and biosimilars which will fuel the next leg of growth for the company.

In-Licensing of brands

Under in-licensing deal, a company gets a license to market a product of another company for a particular region by paying a royalty or profit-sharing agreement, without any kind of patent infringement.

Torrent Pharma: Building on niche capabilities

Focus on niche segments

Prior to starting Torrent Pharma, the founder – Mr. Uttambhai Nathalal Mehta – worked as a Medical Representative for Sandoz for 15 years. Founded as Trinity Laboratories, the company had to change its name to 'Torrent' after it was sued by another company with a similar name. UN Mehta initiated the concept of Niche Marketing starting with Trinicalm Plus– a tranquiliser in Central Nervous System (CNS) segment and subsequently forayed into Cardiovascular segment. Torrent expanded its business by entering erstwhile USSR in 1980s where it enjoyed 1st mover advantage. It was able to scale up the business to Rs170Cr in 2-3 years. The disintegration of USSR in 1992 disrupted the company's operations and affected its plans to enter other geographies. It took 2-3 years to recover ~Rs200Cr stuck in USSR.

Foray into international markets

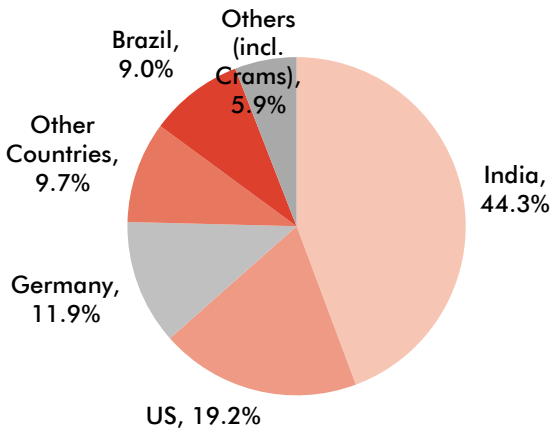
The company resumed its foray into international market by setting up subsidiaries in Germany and Brazil. It further acquired Pfizer's generic subsidiary - Heumann Pharma – to build on its presence. But the company, however, was late compared to other Indian peers like Lupin in entering US market, which it started exploring in 2010. Currently, US, Brazil and Germany are the largest overseas market for Torrent Pharma ***(Refer to Exhibit: 1)***.

At one point, the erstwhile Soviet Union contributed to 70% of revenue and ~90% of profits for Torrent Pharma. The key learning from the crisis for the promoters was to diversify. - Source

Adding capabilities in domestic market

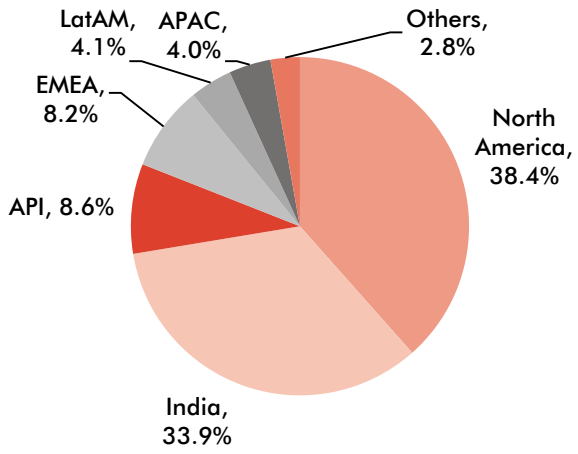
India continues to be the largest market for Torrent contributing 44% revenue. The company has made few big acquisitions in the past to acquire leading brands and add capabilities. Acquisition of domestic business of Elder Pharma and Unichem were two big acquisitions the company undertook. While Elder's portfolio helped increase share in Women's health and pain segment, the Unichem portfolio was a synergic fit in Torrent's chronic heavy portfolio adding top brands like Losar (Cardiovascular) and Unienzyme (GI). Torrent has thus grown ***its India sales @ 20% CAGR since FY14.***

Exhibit 1: India is the single largest market for Torrent



Source: Ambit Asset Management, Company

Exhibit 2: NA and India are the largest markets for Lupin



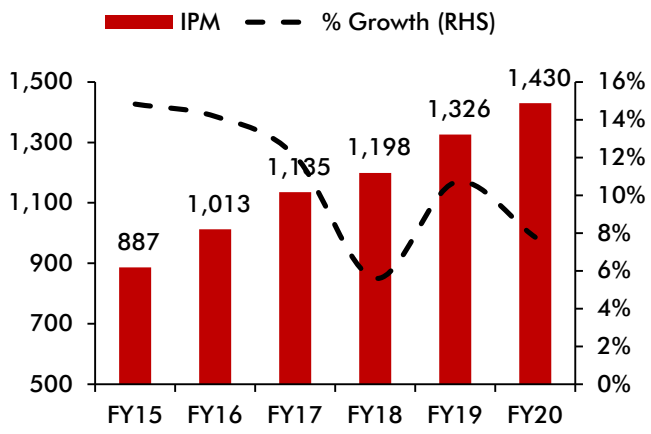
Source: Ambit Asset Management, Company

Indian Pharma Industry – Story in Charts

The type of diseases are often categorized into 3 categories –

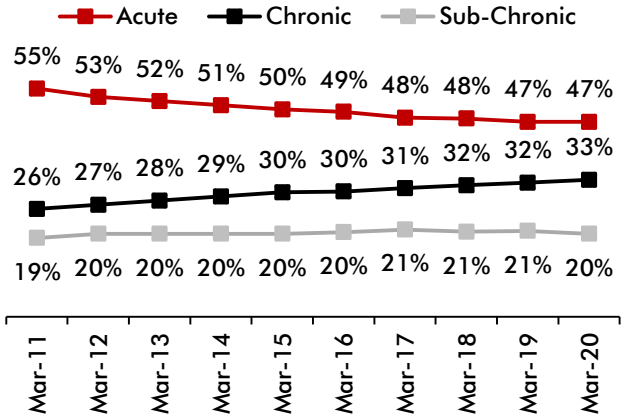
1. **Acute –** Illnesses which develop suddenly because of a virus or infection and last for a short period of time, often few days or weeks.
2. **Chronic –** Illnesses which develop slowly and last for a longer duration of time, often lifetime, mainly attributed to lifestyle changes.
3. **Sub-Chronic –** Diseases that fall between acute and chronic and last for a medium duration for 6-12 months.

Exhibit 3: Indian Pharma Market (IPM) has grown at a CAGR of 10% in the last 5 years



Source: Ambit Asset Management, AIOCD

Exhibit 4: India has been an Acute heavy country due to high instance of infections, but that's changing



Source: Ambit Asset Management, AIOCD

Exhibit 5: Lupin and Torrent Pharma are leaders in top Chronic therapies

IPM Market Share	**13.3%**	**10.1%**	**6.1%**	**11.0%**	**8.6%**	**7.7%**	**6.7%**	**4.8%**	**13.2%**	**6.6%**
	Chroinc			**Sub-Chronic**					**Acute**	
Therapy	**Cardiac**	**Anti-Diabetic**	**Neuro / CNS**	**Gastro Intestinal**	**VMN**	**Respiratory**	**Derma**	**Gynaecological**	**Anti-Infectives**	**Pain/ Analgesic**
Rank 1	Sun Pharma	Abbott	Sun Pharma	Abbott	Mankind	Cipla	GSK	Abbott	Alkem Labs	Sun Pharma
Rank 2	**Torrent**	USV	Intas	Sun Pharma	Abbott	**Lupin**	Glenmark	Cadila	Aristo	Cadila
Rank 3	**Lupin**	**Lupin**	Abbott	Alkem Labs	**Torrent**	Cadila	Sun Pharma	Sun	Cipla	IPCA

Source: Ambit Asset Management, AIOCD, Research Reports

Exhibit 6: Strong growth in leading Chronic Therapies

		Growth % YoY			
Therapies	*% share*	**FY17**	**FY18**	**FY19**	**FY20**
Anti-Infective	*14%*	4%	1%	6%	10%
Cardiac	*13%*	11%	6%	13%	12%
Gastro Intestinal	*11%*	10%	6%	9%	8%
Anti-Diabetic	*10%*	19%	12%	15%	11%
Vitamins/ Nutrients	*9%*	10%	4%	9%	9%
Respiratory	*8%*	9%	8%	8%	13%
Pain / Analgesics	*7%*	10%	4%	8%	10%
Neuro / CNS	*6%*	10%	6%	10%	9%
Derma	*7%*	12%	10%	11%	7%
Gynaecological	*5%*	11%	4%	9%	6%

Source: Ambit Asset Management, Company

Exhibit 7: India and US constitute the largest market for Indian Pharma Companies

FY20 Sales (Rs Cr)	**Company**	**API**	**India**	**US/NA**	**RoW**
32,838	Sun	6%	30%	33%	31%
23,099	Aurobindo	13%	-	50%	37%
17,517	Dr. Reddy	15%	17%	37%	32%
17,132	Cipla	4%	40%	24%	32%
15,375	**Lupin**	**9%**	**34%**	**38%**	**19%**
14,253	Cadila	3%	27%	44%	26%
10,641	Glenmark	10%	31%	30%	29%
8,344	Alkem Labs	-	67%	27%	7%
7,939	**Torrent**	**-**	**44%**	**19%**	**37%**

Source: Ambit Asset Management, Company, Screener.in

Challenges for 'Pharmacy to the world'

1. Supply chain disruption in the advent of e-pharmacies

a) Supply chain of Indian Pharmaceutical market is extremely fragmented with ~85,000 distributors (largest distributor having ~3% market share). Each retailer has to depend on up to 30-40 distributors for sourcing of required products. There is a need for simplification and digitization of this framework which would lead to better efficiency, and cost saving for the end consumers. E-Pharmacies have been trying to do just that, receiving a boost during lockdown (some growing30% MoM) despite lower discounting. Possible disruption that could arise out of e-pharmacies' increased penetration :

i. **Margin pressure for Drug manufacturers –** Currently, ~30% margin is passed on by manufacturers of which a retailer is able to get 18-20% margins ***(Refer to Exhibit: 10)***. E-Pharmacies are estimated to have ~2-3% market share. A larger pie of the market (15-20%) would give them bargaining power over manufacturers and increase their margin. Consolidation among e-pharmacies themselves could lead to further pricing pressure for manufacturers, as it happened in the US post 2017.

ii. **Generic Substitution at pharmacy level –** There has been indication by the government to amend D&C Rule 65 (11A) ***(Refer Callout)*** which would enable generic substitution for drugs at the pharmacy level. This could be a risk for leading Branded drugs with high market share as new brands could partner with e-pharmacies and capture market share from leaders.

iii. **Real-time market data** – Ability to provide real-time market data once they reach a scale would make their presence irreplaceable for drug manufacturers.

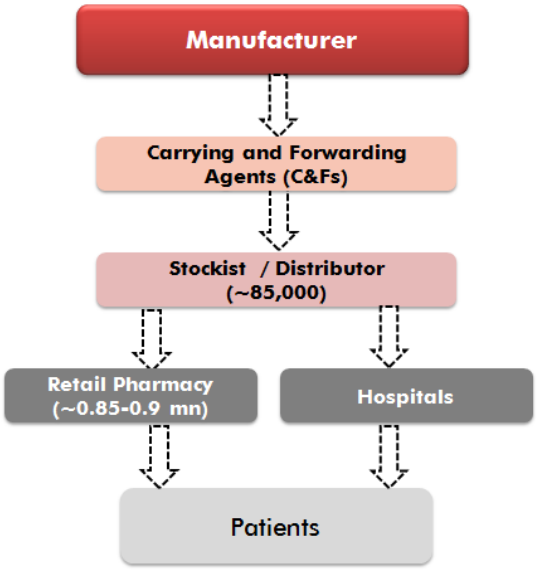
However, e-pharmacies will have to address a few key challenges, like building infrastructure for same-day delivery (even within hours) to deliver Acute drugs which are often needed within hours. They may also face strong resistance from AIOCD (The All Indian Origin Chemists & Distributors) which is an association of pharma distributors and retailers and is a politically powerful body.

D&C Rule 65 (11A) prohibits pharmacy level substitution of one drug with any other preparation containing the same substance

Could Pharma companies create a separate e-commerce channel?

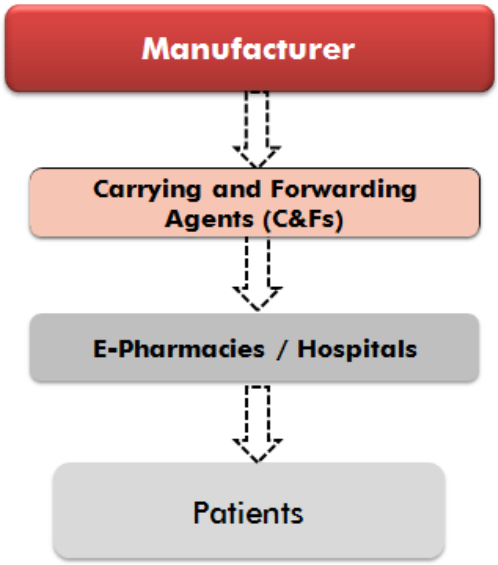
Building their own e-commerce channel could be another growth driver for pharma companies leading to higher customer touchpoints & real-time data. They could also roll-out a subscription based model for chronic therapies on the same platform.

Exhibit 8: Current Supply Chain components...



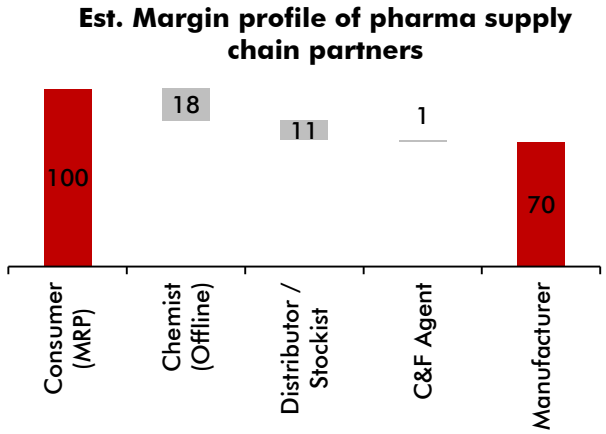
Source: Ambit Asset Management

Exhibit 9: ... and what it could evolve to



Source: Ambit Asset Management

Exhibit 10: Market share gain will allow e-pharmacies to grab higher margin share from channel & manufacturers



Source: Ambit Asset Management

Exhibit 11: E-Pharmacies in India

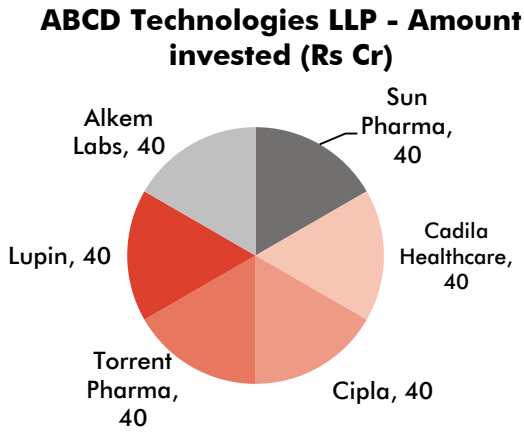
Company	Amount Raised* (USD mn)	Founding Year
Pharmeasy	652	2015
1mg	191	2015
Myra Medicines**	129	2014
Medlife*	57	2014
Netmeds#	99	2010
Practo	228	2008
Medplus	318	2006

*Source: Ambit Asset Management, Crunchbase * - Acquired by PharmEasy, # - Acquired by Reliance Retail, ** - Acquired by Medlife*

b) ABCD Technologies LLP – a collaborative investment by Top Indian Pharma Companies

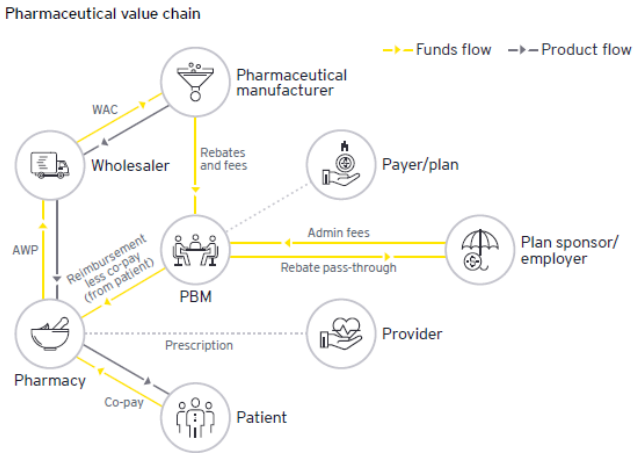
Realizing the need to digitalize the supply-chain infrastructure, a few leading Indian pharma companies, including Lupin and Torrent Pharma, have invested in a healthcare services firm ABCD Technologies LLP. It will act as a vehicle for then to acquire assets in the space of Business Intelligence, Market Research and Digital healthcare services applications which will enable modernization and digitalization of a largely physical infrastructure. This may also enable the companies to use real-time drug sales and inventory data to reduce inefficiencies and better time product launch. ABCD has already made two acquisitions in the area by acquiring **(1)** Pharmarack – a B2B healthcare tech platform – which will enable them to start their own Digital-first distribution company. **(2)** AIOCD Pharmasoftech AWACS – a market research firm. Additionally, there is interest from other leading pharma companies too to partner in this Digitalization drive. This will give them much better bargaining power over traditional distributors / stockists, improve margins and help fend off threat from e-pharmacies backed by Reliance / Amazon. However, any possible clamp down from government or the regulator remains a risk.

Exhibit 12: Companies that have so far announced investment in ABCD Technologies LLP



Source: Ambit Asset Management, Company

Exhibit 13: Pharma supply chain in the US is much simpler when it comes to product flow



Source: Ambit Asset Management, EY-Parthenon

2. **Extensive price controls in India, US and other global markets –** Drug prices across most of the regions globally are subject to direct or indirect price controls. With increasing political pressures and budget constraints post COVID, there is pressure on governments to reduce healthcare expenditure which could weigh negatively on drug prices in the highly competitive generics market.

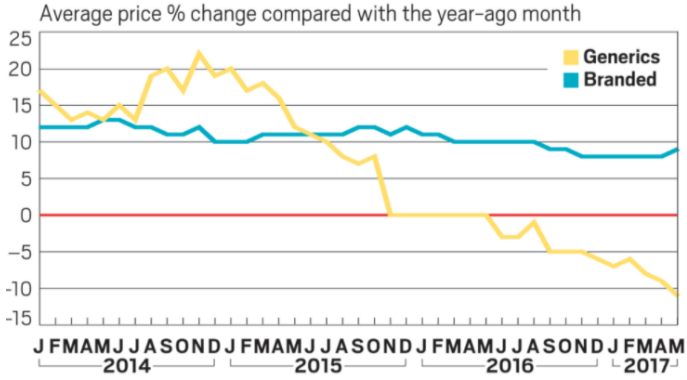
   In India the prices of drugs that feature in the National List of Essential Medicines (NLEM) are regulated. The price controls are as follows –
   - **a)** Upper price ceiling for drugs featuring in NLEM is fixed as per the average Market price of all brands with >/= 1% market share. An Annual increase in line with the Wholesale Price Index (WPI) is allowed.
   - **b)** For drugs not featuring in NLEM list, an annual increase of up to 10% is permitted. In the past, there have been proposals to link this too to WPI which would severely impact pharma pricing in the country.

   The US Generics market witnessed sharp price erosion from FY16 which impacted the revenue of Indian Manufacturers ***(Refer to Exhibit: 16)***. This was due to –
   - **a)** **Increased Generic competition –** Increased ANDA approval rate (40 approvals/ month in 2012 to 65/moth in 2017) following the Generic Drug User Fee Amendment (GDUFA) by the FDA led to increased approval in similar therapies resulting in higher competition and price erosion.
   - **b)** **Customer Consolidation –** Consolidation of Channel partners resulted in much more bargaining power and lower prices for the manufacturers.

   Indian Pharma companies have started to differentiate their offerings from me-too generic products in export markets while focusing on new product launches in the Indian market***. Lupin is focusing its R&D efforts on specialty products and biosimilars while Torrent Pharma is focusing on therapies like Anti-Diabetics, Derma and Gynaecology products and plans to increase new product contribution to 3.5-4% from current 2.5%.***

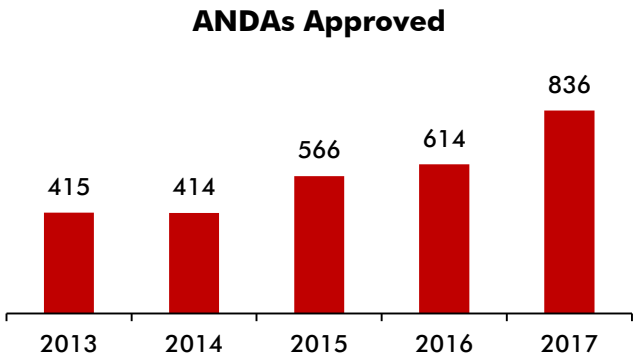
UK's National Health Service (NHS) recently approved a drug Zolgensma manufactured by Novartis, which is used to treat a rare, genetic disease that causes paralysis. ***It has a reported list price of Rs18Cr (£1.79 mn) per dose.***
-Source

Exhibit 14: Sharp fall witnessed in Generics price in US



Source: Ambit Asset Management, cen.acs.org

Exhibit 15: Led by ~2x ANDA approvals in 4 years...



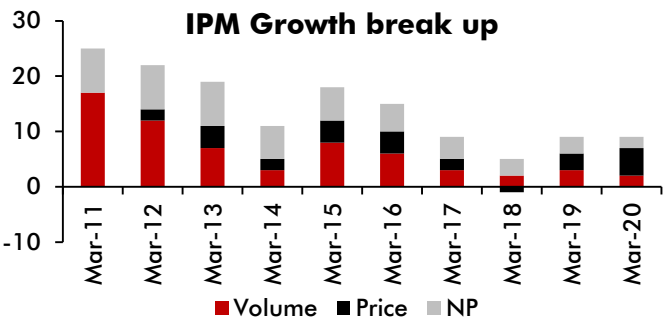
Source: Ambit Asset Management, IQVIA, FDA ANDA Approval Data

Exhibit 16: ... sharply impacting US revenue of Indian cos

US Sales (US$ mn)	FY11	FY16	5yr CAGR	FY17	FY20	5yr CAGR
Sun Pharma	495	2,066	33%	2,052	1,487	-10%
Aurobindo Pharma	255	935	30%	1,010	1,622	17%
Dr. Reddy's	471	1,139	19%	946	924	-1%
Cadila	209	614	24%	554	893	17%
Lupin	441	871	15%	1,207	800	-13%
Glenmark	186	371	15%	553	444	-7%
Cipla	170	324	14%	392	553	12%
Torrent Pharma	25	408	74%	201	206	1%

Source: Ambit Asset Management, Research Reports, Company

Exhibit 17: Growth led by Volume and New launches



Source: Ambit Asset Management, AIOCD

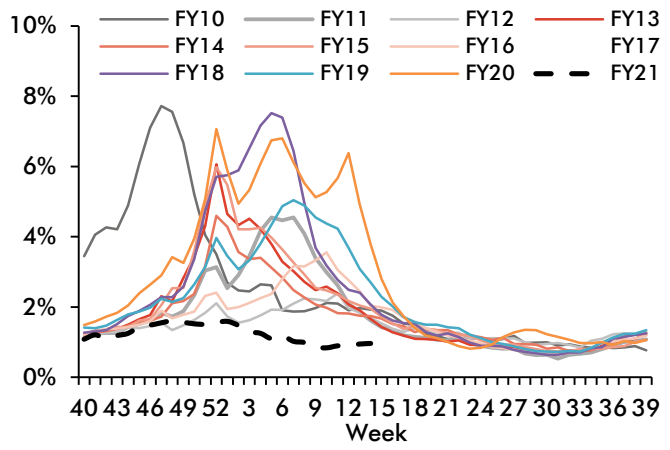
3. **Evolving diseases and infections –**Flu (Influenza) is a major infectious disease threat in US, leading to 6-8Lac hospitalization and 50-60k deaths annually. The current flu season, however, has been one of the weakest (measured in terms of number of people infected) this century ***(Refer to Exhibit: 18)*** which impacted the sale of anti-influenza drug (Tamiflu for Lupin) ***(Refer to Exhibit: 19)***. This, in large parts, can be attributed to COVID-19 related curbs like social distancing, mask wearing, etc. Similar trend was witnessed in India where Respiratory and Ophthalmology segment sales were impacted this winter ***(Refer to Exhibit: 20)***. Less outdoor activities resulted in lower Eye and Asthma ailments, which usually trigger in the winter season, as people were less exposed to Allergens.

   Tropical and developing countries like India have a larger share of Acute therapy due to higher incidence of infectious diseases compared to developed nations like US, UK where the Chronic share is much larger. This trend in India has been reversing over the years and was further accentuated during the COVID outbreak when better hygiene practices led to lower instances of infectious diseases.

   Any swift lifestyle change because of endemics / pandemics like COVID may end up impacting the sales of such Acute drugs and Acute heavy companies and thus render the investment in R&D and Marketing of drugs like Tamiflu redundant. ***Torrent Pharma and Lupin are relatively more Chronic focused with 52% / 58% respectively compared to acute heavy companies like Alkem Labs.***

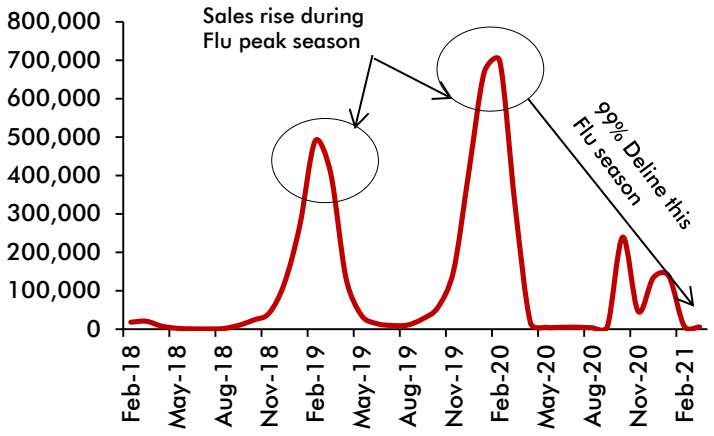
"The coronavirus has essentially muscled aside flu and other bugs that are more common in the fall and winter. Scientists don't fully understand the mechanism behind that, but it would be consistent with patterns seen when certain flu strains predominate over others" – Source

Exhibit 18: Weakest flu season when compared on % visits for Influenza-Like-Illness symptoms



Source: Ambit Asset Management, CDC

Exhibit 19: Oseltamivir Phosphate (Tamiflu) prescription for Lupin declined sharply due to lower incidence of influenza



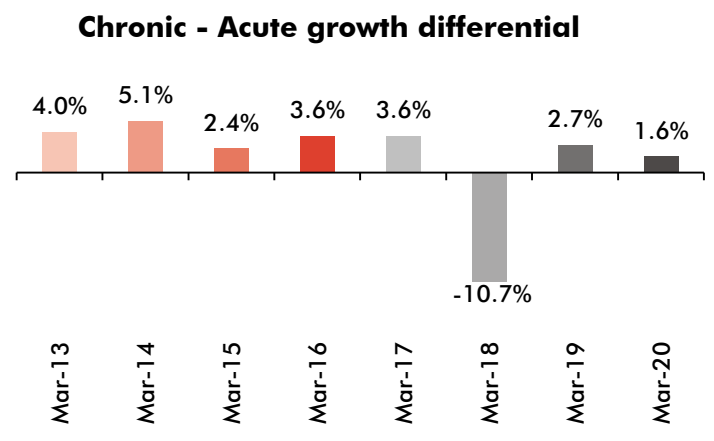
Source: Ambit Asset Management, Bloomberg

Exhibit 20: YoY Growth (%) in select therapy in IPM

Therapy	Dec'19	Mar'20	Jun'20	Sep'20	Dec'20	Mar'21
IPM	9.2	10.1	-5.2	1.1	6.4	5.3
Anti-Infective	19.9	10.7	-17.4	-6.2	4.2	-1.8
Cardiac	0.3	15.1	9.3	14.2	14.3	7.4
Gastro-Intestinal	7.2	8.2	-7.9	0.7	11.1	15.2
Anti-Diabetic	8.2	12.9	6.5	5	7.3	3.4
VMN	9.1	8.8	-6.2	9.5	14.7	14.3
Respiratory	**14**	**18.2**	**0.4**	**-8.2**	**-7.2**	**-16.6**
Pain/Analgesics	9.4	7.6	-12.9	-6.6	1.1	7.2
Neuro/CNS	8.7	10	2.3	3.1	6.4	7.3
Gynaecological	8	4.5	-14.5	-3.8	3.2	11.8
Ophthalmology	**6.4**	**2.3**	**-19.2**	**-10.1**	**-4.8**	**2.8**

Source: Ambit Asset Management, AIOCD

Exhibit 21: Increasing share of Chronic therapies due to faster growth in the last few years



Source: Ambit Asset Management, AIOCD

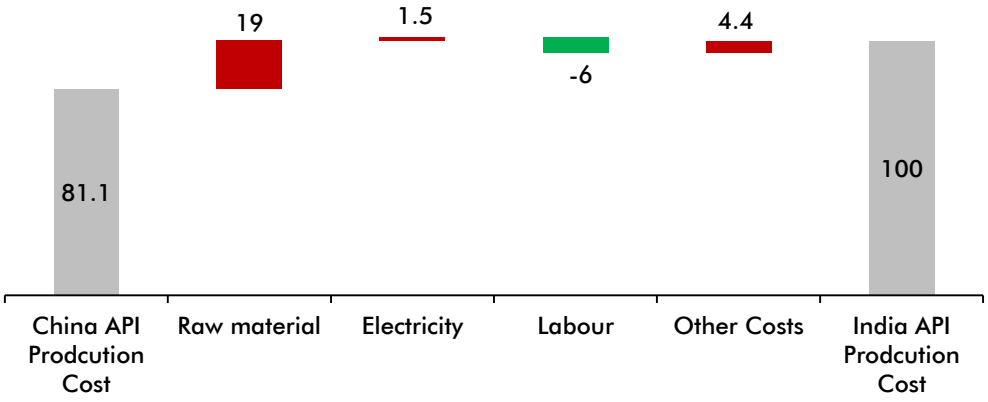
4. **Emphasis by governments / companies on localized manufacturing / backward integration –** In light of COVID and the subsequent supply-side challenges faced, many countries witnessed shortfall of critical medical supplies for which they were relying on overseas suppliers. Therefore, there is increasing focus – from governments and corporates – on making the supply-chain more localized rather than centralized. While USA has been vocal about shifting base of essential medicines from countries like India / China to the US, India is also looking to reduce dependence on China in sourcing APIs and KSMs (Key Starting Materials). We see two possible disruption from these efforts –

   a) While the requirement to shift manufacturing base to US / Europe in lieu of exporting from India may dissipate the cost advantage for Indian exporters, it'll act as a nudge to forward integrate in those geographies where they currently rely on a local partner for distribution by sharing up to 40-60% revenue.

   b) Extensive focus on- becoming self-reliant and backward integration may lead to companies incurring capex which may seem lucrative in the near term but not hold investment case in longer term once government subsidies are rolled back. Highly commoditized materials like APIs / KSMs, where India is looking to develop its strong base are sensitive to pricing pressure from China which enjoys better Raw Material availability.

Torrent Pharma does not have any meaningful API sales. It does not plan to make additional investments in API in the next 2-3 years and intends to utilize existing capacities first. For Lupin, API revenue constitutes ~9%.

Exhibit 22: Lower cost of production in China has enabled them to gain market share by offering competitive prices while maintaining margins



Source: Ambit Asset Management, KPMG

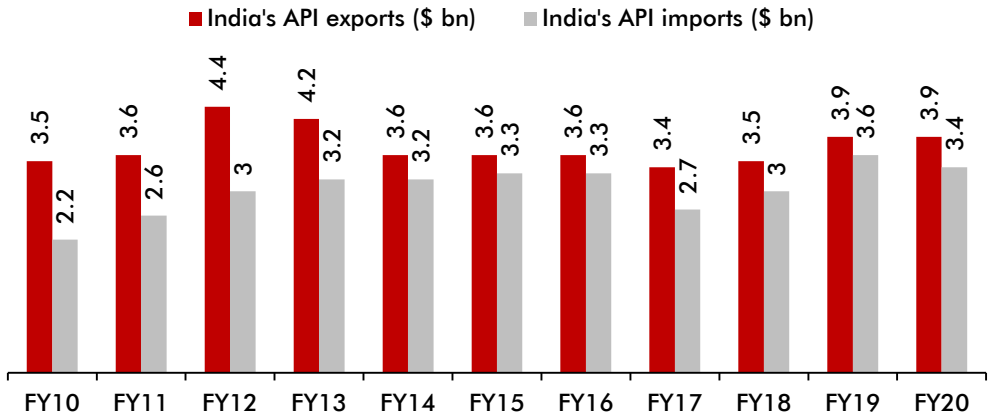
5. **Lengthy environmental clearance for API manufacturers –** Setting up an API plant in India requires Environmental Clearance (EC) the process for which can be extremely tedious. Some of the major challenges in acquiring an EC currently are –
   a) Lengthy timeline of 18-24 months
   b) Public hearing requirement for which the timeline is long and there is no limitation on participation
   c) Modernization of existing plant, too, requires environmental clearance. The timelines are so long that by the time approval is received the technology is obsolete

In addition to introduction of PLI Schemes, industry veterans believe that these challenges too need to be addressed in-order to promote API manufacturing in India. This step itself will lower the cost of production for the industry by 10-15%. Most of these challenges, according to the experts, are being addressed in the

new draft Environment Impact Assessment (EIA) 2020 proposed by the Union government. However, the same is facing challenges at present and any further delay would hamper the prospects of the industry.

Any incremental easing of norms will allow Indian manufacturers to backward-integrate and increasingly source locally, reducing supply chain constraints.

Exhibit 24: While India is still a Net exporter of APIs, the imports are catching up fast growing @ 4.4% CAGR in last 10 years compared to 1% CAGR for exports

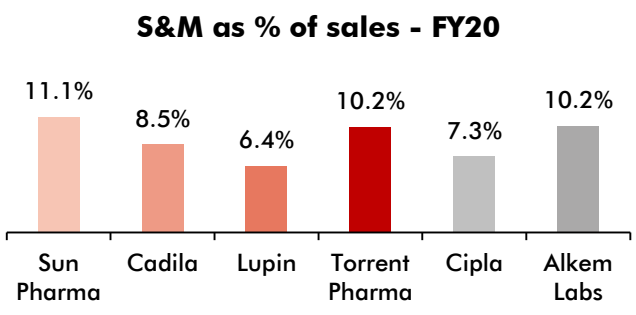


Source: Ambit Asset Management, DGCIS

6. **Evolving marketing trends which may render existing infra redundant –** Medicines in India are not allowed to be advertised like other products. Pharma companies employ Medical (Sales) Representatives or MRs for Sales and promotion of their products. These MRs visit Doctors and Medical practitioners in person to explain them about the new brand launched and its benefits. COVID had disrupted this entire ecosystem when in-person consultation with doctor was not possible. As a result, Top Brands continued to gain as the doctors continued to prescribe those while new launches struggled to break through impacting revenue from New Products for Pharma companies.

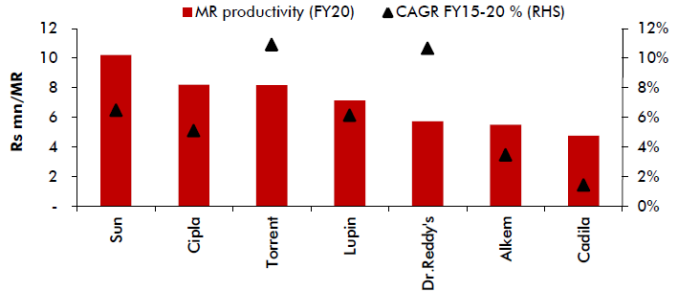
   Even after COVID normalizes, multi-channel interaction will be the new way ahead where companies will use a mix of in-field Marketing Force and Digital Tools to interact with Doctors. This is likely to disrupt the existing marketing infrastructure and the earlier spends made by companies to develop the same. There may however be some cost savings from such Digitalization, but the extent of the same will depend on the agility with which each company acts.

Exhibit 25: Relatively higher S&M spend for India focused companies



Source: Ambit Asset Management, Company

Exhibit 26: Torrent's MR productivity has improved considerably in the last 5 years



Source: Ambit Capital Research

7. **Emergence of other cost-efficient Global manufacturing hubs –** In, 2015, the World Trade Organization (WTO) granted a 17 year extension of a 2001 waiver to Least Developed Countries (LDC) which enabled them to manufacture generic version of patented drugs. Bangladesh has been one of the key beneficiaries of this exemption which, in addition to favorable government policies, saw its phamra industry output grow 1,000x from 1982 making it the biggest white collar employer in the country. Under the waiver, Bangladesh as an LDC, can also export these generic versions of patented drugs to other countries – like Myanmar, Vietnam and Kenya – where those drugs aren't covered by patents or where compulsory licences are issued to treat diseases like cancer or HIV. Weak IP laws in Bangladesh have also enabled local firms to develop their own technology base by imitating or reverse engineering foreign technology.

   While Bangladesh will exit the LDC status in 5 years by 2026, it has the potential to develop its manufacturing and challenge Indian counterparts on cost efficiency and technology. Additionally, emergence of other such LDC countries could impact export revenue from smaller EMs for Indian Manufacturers.

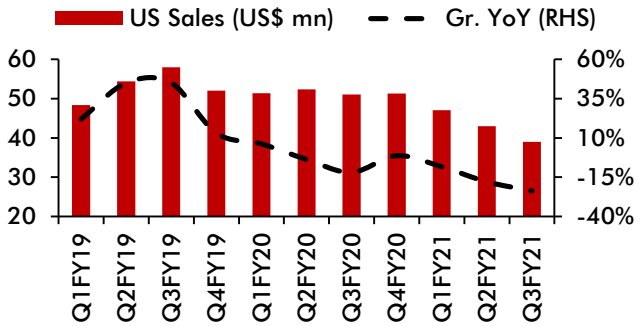
8. **USFDA related regulatory compliance –** USFDA, in the last few years, has increased scrutiny of overseas drug manufactures which resulted in sharp increase in compliance actions against facilities of Indian Manufacturers. This has accentuated post the detection of nitrosamine impurities in *Sartan* drugs. While these impacted New product launches and increased compliance cost cost, it also served as a lesson in GMP (Good Manufacturing Practices) to pharma companies which will lead to long term process realignment and better capabilities to manufacture more complex drugs.

   Lupin and Torrent Pharma currently have 5 and 3 facilities, respectively under OAI/WL awaiting USFDA clearance. With resumption of USFDA inspection post COVID, these facilities are expected to be inspected within the next two quarters. Lack of clearance would impact new product launches from these plants and increase the remediation cost in the near term. Moreover, this would also have a negative impact on Lupin which suffered a spate of OAI/WL in the previous few years and is believed to have undertaken strict process and compliance changes.

*If a **Warning Letter (WL)** is issued, new approvals from that particular facility are halted.*

*In case of an **Import Alert**, even existing products from that facility cannot be imported to the US.*

Exhibit 27: Torrent's US sales have been on a declining trend due to lack of new product launches & price erosion



Source: Ambit Asset Management, Company

Exhibit 28: Facilities currently classified as OAI /WL for Torrent Pharma and Lupin

Torrent Pharma		Lupin	
Plant	**Status**	**Plant**	**Status**
Indrad	WL	Mandideep (Unit-1)	WL
Dahej	OAI	Tarapur	OAI
Levittown	WL	Goa	WL
		Indore (Pithampur) - Unit-2	WL
		Somerset	OAI

Source: Ambit Asset Management, Company

At Ambit we believe in wealth creation by long term equity investment and through the power of compounding. We constantly try and stay ahead of the curve on what may possibly impede the growth of our portfolio companies. We do a long term scenario analysis on what could be the possible disruptions for Indian Pharma Manufacturers, especially Lupin and Torrent Pharma. ***In our view: (1) Fast evolving disease / illnesses (2) Adverse pricing regulations (3) Supply chain disruption due to technology and e-pharmacies (4) USFDA compliance challenges*** *will be the things to watch out for in the case of Lupin and Torrent Pharma over the next decade.*

Appendix

Glossary

1. **API (Active Pharmaceutical Ingredient) –** API means the active ingredient which is contained in the medicine. There are the key ingredients that make the drug effective against a particular ailmetn. Eg, Paracetamol is an API

2. **Excipients (Inactive components) –** The inert ingredients which are combined with drug substances to create a dosage form product. Excipients may affect the rate of absorption, dissolution, metabolism & distribution in humans or animals

3. **Dosage Forms –** Refers to pharmaceutical preparations or formulations in which specific mixture of drug substances (API) & inactive components are presented in a particular configuration.

4. **Chronic -** Illnesses which develop slowly and last for a longer duration of time, often lifetime, mainly attributed to lifestyle changes.

5. **Sub-Chronic -** Diseases that fall between acute and chronic and last for a medium duration for 6-12 months.

6. **Acute -** Illnesses which develop suddenly because of a virus or infection and last for a short period of time, often few days or weeks.

7. **In-Licensing -** Under in-licensing deal, a company gets a license to market a product of another company for a particular region by paying a royalty or profit-sharing agreement, without any kind of patent infringement.

8. **NLEM -** In India, under the provisions of Drug Pricing Control Order (DPCO) 2013, the prices of drugs that feature in the National List of Essential Medicines (NLEM) are regulated by the regulator National Pharma Pricing Authority (NPPA).

9. **US FDA -** The United States Food and Drug Administration (US FDA) is a federal agency of the Department of Health and Human Services that regulates a wide range of products including human and veterinary drugs; vaccines and other biological products; medical devices, etc.

10. **Warning Letter -** If a Warning Letter (WL) is issued by the FDA to a particular facility, new approvals from that particular facility are halted.

11. **Import Alert -** In case of an Import Alert to a particular facility, even existing (earlier approved) products from that particular facility cannot be imported to the US.

12. **Generic Product –** A drug marketed under it chemical name. It generally refers to small molecule products approved by the FDA under an ANDA.

13. **Branded Product –** A drug marketed under a brand name. Typically, refers to products approved under an NDA, though products approved under an ANDA may also be marketed with a brand name.

14. **New Drug Application (NDA) –** Application by a drug sponsor to the FDA for approval required to market a new drug in US. Detailed document includes drugs details & process to manufacture. After submission, FDA has 60 days to decided whether to file it or review or reject it.

15. **Abbreviated New Drug Application (ANDA) –** It contains data for the review and potential approval of a generic drug product. Generic drug applications are called "abbreviated" because they are not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness to demonstrate its product is bioequivalent.

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