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Health check

Q1 FY 21

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Foreword

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The healthcare industry is at the centre of a new world defined by the COVID-19 pandemic – be it healthcare delivery system that cares for those infected, while exposing themselves to the virus, or the drug manufacturing industry, which is racing towards finding a cure/vaccine for the disease.

The epicentre of the disease has shifted through 2020 and India may soon find itself on the top of the table.

The economic impact of COVID-19 on world economies, particularly India, can be a cause for concern. However, the pharmaceutical industry has maintained stable revenues in 2020 compared with similar periods last year.

In terms of performance, the major listed companies* had a flat revenue growth, both over Q1 of FY 20 and the immediately preceding quarter of Q4 FY 20.

The third edition of Health Check takes a closer look at:

- Opportunities for the pharma industry due to the ongoing pandemic
- Impact of COVID-19 on pharma and healthcare providers
- Government incentives available to the industry
- Summary of Grant Thornton's International Business Report findings from the healthcare sector

We hope you find this publication useful and informative.

*Top 10 listed companies by turnover

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The big picture

Industry overview

The slowdown in the Indian economy has also impacted the pharmaceutical sector. Annual financial year 2019-20 (FY 20) revenue grew by an average of 9% over FY 19* but it has remained relatively flat from Q4 FY 20 to Q1 FY 21.

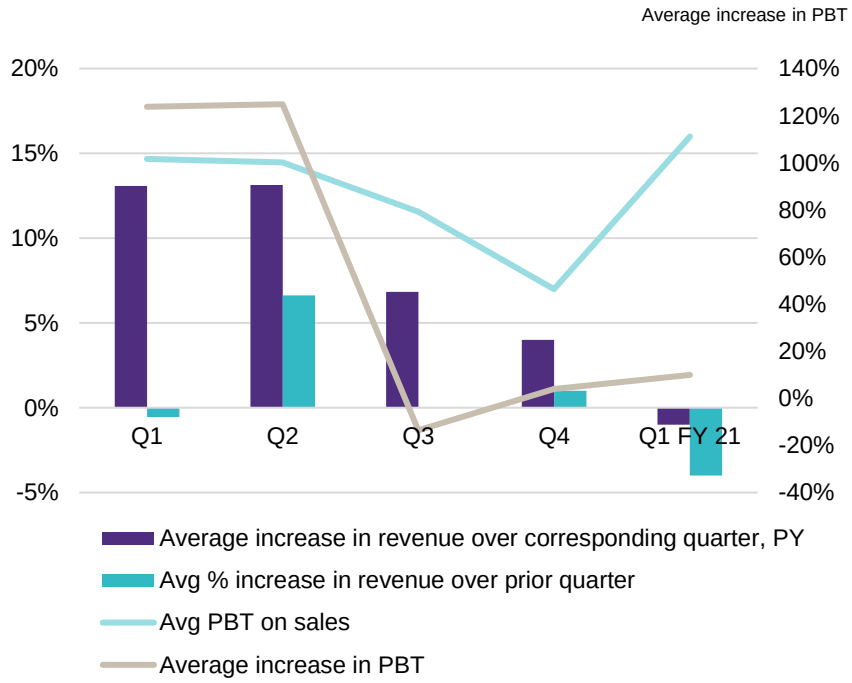
The strain on healthcare providers has been demonstrated through financial results of the top seven listed healthcare providers who posted 34% lower revenues in Q1 FY 21 compared with the corresponding quarter in FY 20.

Profit before tax (PBT) grew by 10% on average in Q1 over the corresponding quarter last year despite rising active pharmaceutical ingredients (APIs) cost, COVID-19-related slowdown etc.

The five-year CAGR of the top 10 listed companies was at 7%; however, the top three listed API manufacturers averaged a five-year CAGR of 14%. This underlines the growth opportunities available to the Indian API industry, especially combined with recent government incentives.

Overall, FY 20 was a difficult year for pharma with average PBT/income of 7% for the top 10 listed companies by turnover, which has consistently dropped in the last few months of the year.

Revenue and PBT growth in FY 20 and Q1 FY 21



* increase in FY 20 revenue over FY 19 of top 10 listed companies in terms of turnover

Grant Thornton's International Business Report

Grant Thornton International Business Report (IBR) is a half-yearly survey of business leaders from across the globe. Excerpts from the healthcare sector have been summarised below:

Economic optimism: It sharply declined from 60% in H2 2019 to 32% in H1 2020.

32%
in H1 2020

60%
in H2 2019

Investments in buildings and equipment: The percentage of respondents expecting an increase in investments in buildings and machinery dropped from 44% (H2 2019) to 19% in H1 2020.

Employment creation: The percentage of respondents expecting to create employment dropped from 45% (H2 2019) to 19% in H1 2020.

Constraints on account of shortage of finance: Nearly half (47%) of the respondents believed that shortage of finance was a major constraint in H1 2020, as compared with only 32% in H2 2019.

Data collection: The data for this release is from interviews conducted in May and June 2020 with chief executive officers, managing directors, chairpersons, or other senior executives from across sectors.

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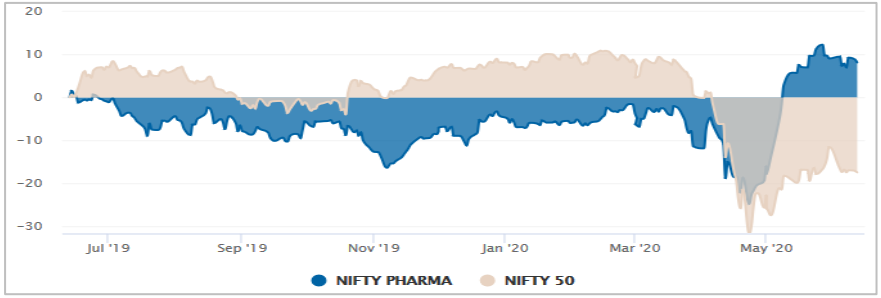
Pharma opportunities

COVID-19 opens avenues for India to emerge as the next pharmaceutical hub

Nifty pharma performance (2001-2020 YTD)

Nifty pharma vs Nifty 50 performance (YTD)

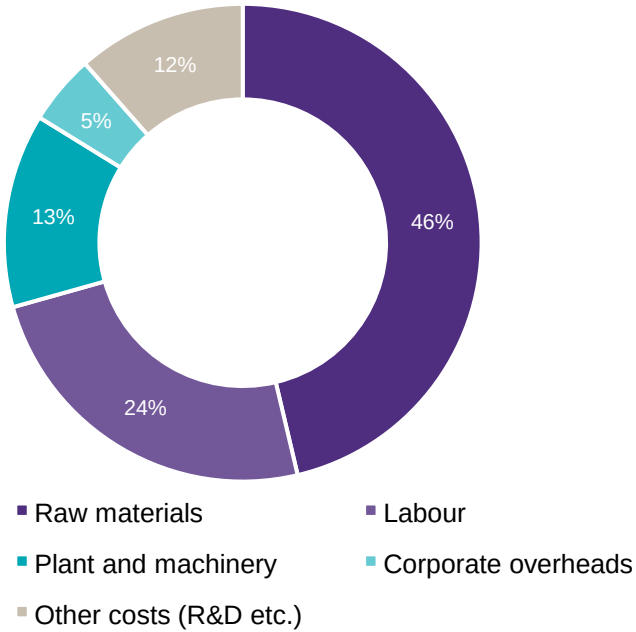


16.50% YTD (as on 30 April 2020) and 29.97% QTD returns on Nifty Pharma reflect the burgeoning state of the sector in India

- **The sector has been witnessing strong headwinds since 2015**
  - Slowdown in the US markets led to stagnation. During FY 17-19, there was just 2% growth in the US exports compared with 16% growth in other markets during the same period.
  - Rising number of Good Manufacturing Practices (cGMP) related observations and warning letters issued by the US Food and Drug Administration (FDA) to Indian players caused regulatory hurdles and increased compliance cost.
  - Capping of drug prices under the National List of Essential Medicines (NLEM) and other government initiatives, such as Jan Aushadhi Yojana, aimed at providing affordable medicines through the government channels
- **COVID-19 has made India rethink its strategy and focus on being self-reliant**
  - In March 2020, the government announced an INR 14,000 crore package to incentivise production of APIs in India which is anticipated to boost the bulk drug manufacturing industry by ~ USD 3.3 billion.
  - Considering the sudden spurge in demand of certain anti-malarial drugs, such as Hydroxychloroquine (and 11 other APIs) touted to be effective in treatment of COVID-19, the US FDA has lifted ban on certain facilities in India allowing it to export to 55 countries.
  - The US FDA has also fast-tracked approvals for other drugs, including Remdesivir allowing Indian companies, such as Cipla, Jubilant Life Sciences, Mylan and Hetero Labs to manufacture the drug under a licensing agreement with Gilead and export to 127 countries.

API manufacturers must focus on cost optimisation and process improvement initiatives to leverage new opportunities

Cost break-up for Indian pharmaceutical companies



Key challenges of the API industry

- **Concentrated supply chain:** ~70% of India's API demand is met from China. As a result, Indian API plants operate at 30-40% capacity utilisation. India is 100% dependent on China for APIs of certain drugs, such as Paracetamol, Metformin, Ampicillin, Ciprofloxacin.
- **Cost competitiveness:** Being an industry with wafer thin margins, Indian players are unable to compete with their Chinese counterparts due to relatively lower productivity, lower economies of scale and lack of government incentives unlike China.
- **High cash blockage:** Most of the API manufacturers in India have high inventory holding, i.e., they hold inventory for over 9-12 months. As a result, there is high cash blockage and working capital issues

Shifting industry focus

- **Cost optimisation:** Manufacturers will need to rationalise their input costs, labour and overheads as well as leverage automation and technology
- **Establish robust sales and operation plan:** A robust sales and operational plan needs to be created to improve the end-to-end supply chain
- **Inventory and working capital management:** Inventory comprises of ~40% of the total assets for the companies. Optimising inventory would be critical to release cash blockage and improve working capital

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Dealing with COVID-19

Global impact

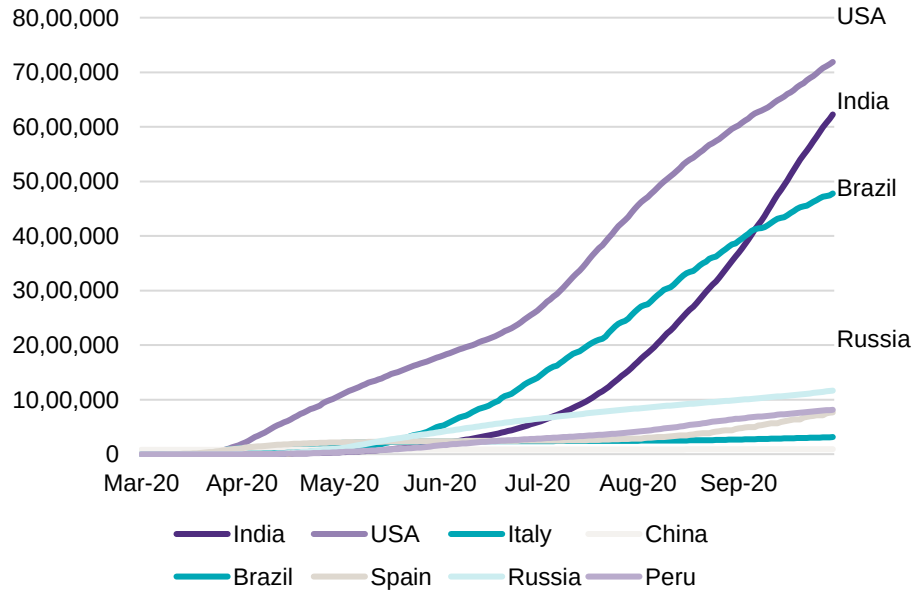
The global impact of COVID-19, including socio-economic, political, health, safety, etc., is yet to be widely documented but it has had far reaching consequences on all aspects of life.

The global epicentre of the disease has shifted over time from China in February to Italy in March and the USA subsequently.

While India's lockdown effectively slowed the spread of the virus up to May 2020, easing of travel and economic restrictions has led to a surge in the number of positive cases.

Currently, India is seeing close to 100k new cases per day. However, India has a relatively low mortality rate at 2% when compared with the world mortality rate of 4%. Countries with similar number of cases have experienced higher mortality with Brazil at 3% and the USA at 5%. As clearly indicated in the graph, it appears that India could have the highest number of COVID-19 positive cases in the future.

Total COVID-19 cases by country



Source: Ourworldindata.org; Data up to 30 September 2020

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Impact on the pharma sector

While India may soon be the country with the highest number of infections, it's per capita rate of infections continues to be lower than most countries as on 30 September 2020.

Country	Infections per 1 million population
India	3,771
USA	20,743
Brazil	20,938
Russia	7,447

The nationwide lockdown gave India time to ramp up its production of ventilators, personal protection equipment (PPE) and other sanitisation equipment to meet the increased demand. As per the press release of Press Information Bureau on 17 September 2020, India is the second largest producer of PPE kits with daily production capacity surpassing 5 lakh units.

India exported 23 lakh PPE to five countries, including the USA, the UK and the UAE, in July after the government relaxed export norms. This has substantially helped the country to position itself in the global market.

Similarly, in case of ventilators, indigenous production capacity has increased to 3 lakh per annum.

The healthcare industry has been in the middle of the COVID-19 storm since the onset of the pandemic. Supply chain disruptions, vaccine trials, finding viable cures, ramping up healthcare infrastructure, speeding up clinical trials and medical research are some of the challenges being faced by the industry.

Impact on the pharma sector (contd.)

The healthcare delivery system is being stretched in hotspots, including all major metros in India, due to the surging number of cases. Hospitals are facing stresses of providing quality treatment, managing risks of infection, staff safety, and increasing financial instability.

Governments are taking over private hospital beds and capping prices which results in lower ability of hospitals to recover costs. Costs for COVID-19 tests have been capped at INR 4,500. Creation of isolation wards to treat COVID-19 patients means hospitals cannot accommodate their regular patients which has resulted in financial strain on the system. 42 US hospitals have shut / filed for bankruptcy since the pandemic began.

Analysis of the FY 20 financial results of major listed hospitals showed a 10% YoY increase in revenues. However, it is possible that Q1 revenues may be impacted as majority of the lockdown and COVID-19 surge was in the first quarter of the year.

Telehealth volumes have also been significantly affected by COVID-19. In the USA, telemedicine visits accounted for 69% of total encounters in April, but has dropped to 21% in August 2020, which is still higher than pre-pandemic levels.

In India, the much-awaited Telemedicine Practice Guidelines were released in March 2020 with the higher volume of telemedicine consultations.

Our View

Telemedicine volumes increased significantly during the lockdown and have since corrected, partially. It remains to be seen if the popularity of telemedicine sustains. While there is a significant stretch on the healthcare and pharma industries during the pandemic, opportunities are also presented in terms of discovery of a vaccine/cure for the disease. Government incentives can also provide some impetus to investment activity for the industry to find the proverbial silver lining.

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Race for a vaccine

As on date, the US FDA has authorised only one drug – Remdesivir for use on an emergency basis.

Earlier approval given to Hydroxychloroquine was revoked after studies showed it was not likely to be effective in treating COVID-19. Indian Council of Medical Research (ICMR) continues to recommend its use as prophylaxis (by contacts of infected persons and healthcare workers).

Other drugs being researched for effectiveness include Favipiravir, Lopinavir and Ritonavir, some monoclonal antibodies and plasma therapy.

Contenders for vaccines

- University of Oxford with AstraZeneca's vaccine (called AZD1222 globally and Covishield in India) is undergoing phase III clinical trials; however, the trials have been suspended after a volunteer developed an unexplained illness.
- Covaxin, developed by Bharath Biotech in collaboration with the Indian Council of Medical Research (ICMR), has sought drug regulator's approval to start large scale phase III clinical trials
- Russia announced launch of clinical trials for a COVID-19 vaccine in August 2020.
- Drugmaker Dr. Reddy's Laboratories announced in September 2020 that it will distribute 100 million doses of Russia's Sputnik V COVID-19 vaccine in India after conducting final-stage human trials and receiving regulatory clearances here.
- As of September 2020, there were over 200 vaccine contenders globally.

Our View

The normal lifecycle of bringing a drug to the market is well over a decade. However, all the current contenders are existing drugs being evaluated for effectiveness in treating COVID-19, resulting in the accelerated timelines. The vaccine for COVID-19, irrespective of the timeline, will bring much relief. The National Expert Group on Vaccine Administration for COVID-19 tasked with drafting a roadmap for procuring, financing and distributing a potential COVID-19 vaccine decided that all procurement will be done centrally. However, India is yet to make any commitment of setting aside funds for procurement.

Government impetus to the pharma industry

Production-linked incentive

- The government, with the aim to achieve an Atmanirbhar Bharat, approved INR 6,940 crore package to boost APIs/key starting materials(KSM)/drug intermediaries (DIs) industries.
- Specific focus has been placed on fermentation-based products
- A drug security committee constituted by the Department of Pharmaceuticals has identified 53 key APIs/KSMs/DI for which the country is heavily dependent on imports.
- Support under the scheme will be provided for six years in case of fermentation-based products and five years for chemically synthesised products based on incremental sale of APIs/KSMs/DIs.

Category	Year 1–4	Year 5	Year 6
Fermentation based (starting FY 23)	20%	15%	5%
Chemically synthesised (starting FY 22)	10%		-

- Eligibility for the incentive scheme is based on:
  - Available only to manufacturers
  - Applicable only for greenfield projects
  - Threshold for incremental investment to be met
- FY 20 will be considered as the base year for computation of incremental sales.

Category	Target segments
Fermentation based	• Penicillin, Cephalosporin, Erythromycin, Potassium Clavulanate • Cyclins, Aminoglycosides, Steroids, Anti TB, Vitamins and neutraceuticals
Chemically synthesised	• Dicyandiamide, Para-aminophenol, 2-MNI, CDA • 23 other drugs

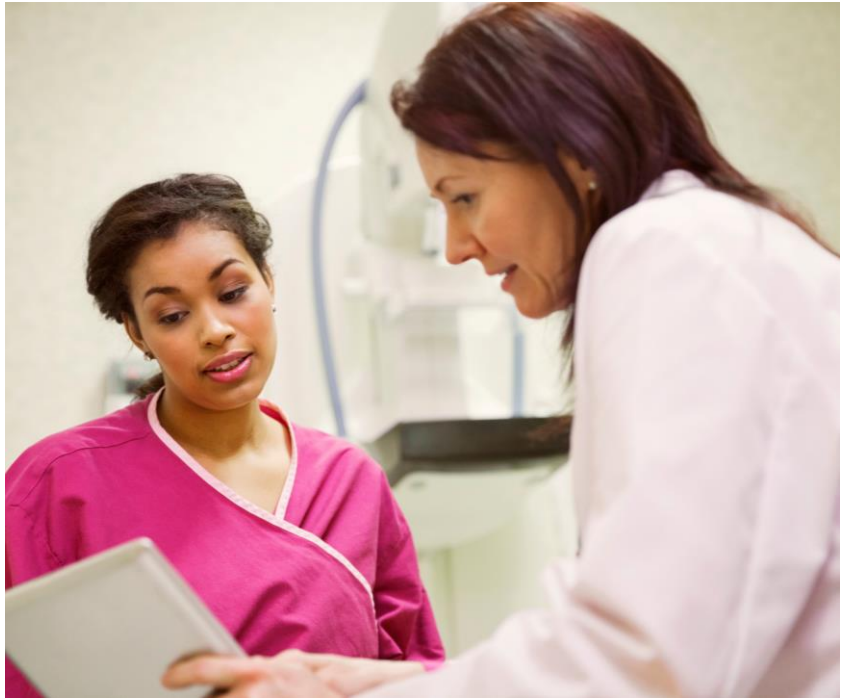
- The government is also offering grants-in-aid to set up three bulk drug parks with a maximum limit of INR 1,000 crore per park.

Production-linked incentive (contd.)

- The restriction on export of 26 drugs imposed in March 2020 was mostly lifted in April.
- The restriction on export of Hydroxychloroquine was also subsequently lifted in June 2020 provided manufacturers supplied 20% of their output to the domestic market.

Our View

The production incentive offered to the pharma industry could be a much-needed boost for growth. As many countries will be looking to de-risk their supply chains, the Indian API industry can tap into the opportunity. However, the investment required for a greenfield project could be a roadblock considering cash conservation is a priority due to the crisis.



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Other incentives for the sector

- The Indian medical device market is projected to register a CAGR of 14.8% and is expected to reach INR 86,840 crore in 2021-22. However, the share of the Indian market in the global market is only 1.6%. Currently, 86% of our medical device needs* are imported.
- **Incentive scheme:** It will extend 5% incentive on incremental sales (over base year FY 2019-20) of goods manufactured in India and covered under target segments, to eligible companies, for a period of five years.
- **Eligibility criteria:** Same as the API/KSM/DI schemes, i.e., available to manufacturers who meet incremental investment (INR 180 crore over three years) and sales thresholds.
- **Expected outlay:** INR 3,420 crore

* Source: Department of Pharmaceuticals

Target segments

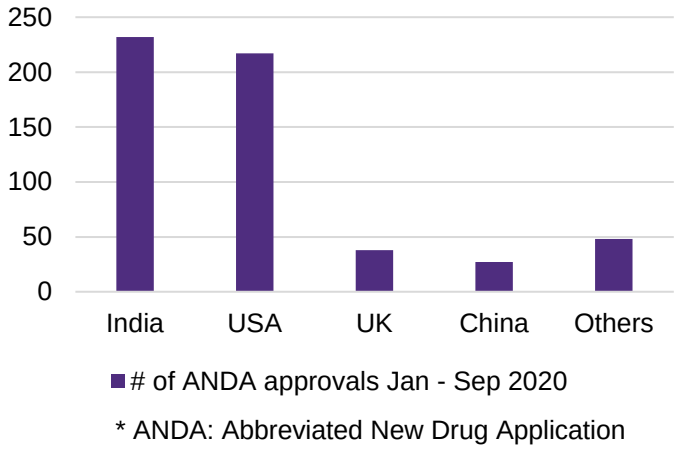
Cancer care/radiotherapy medical devices
Radiology and imaging medical devices and nuclear imaging devices
Anesthetics and cardio-respiratory medical devices
All implants including implantable electronic devices like cochlear implants and pacemakers

- Earlier restriction on export of PPE kits, including medical coveralls, masks (except N95 /FFP2 or equivalent), and face shields has been removed.
- Promotion of Medical Device Parks scheme also offers grant-in-aid to four medical device parks with a maximum of INR 100 crore per park or 70% of the project cost of common infrastructure facilities to be set up by the state governments.

New drug approvals

Investment in R&D paying off

India was the **largest receiver of generic drug approvals by US FDA in YTD January–September 2020,** with 42% of approvals. The US received 39% of generic drug approvals.



* ANDA: Abbreviated New Drug Application

In India, DCGI approved 26 new drugs in India in the first half of 2020.

This year, oncology and anti-infective drugs together received 42% of approvals in India.

A deeper analysis of the 237 generic drug approvals of Indian pharma companies in the year indicates that expertise lies in a few therapeutic uses, i.e. **anti-infectives and Central Nervous System / neuro medicines accounting for 32% of approvals** received.

Our View

Currently, R&D departments of many pharma majors are in the race to develop a COVID-19 vaccine or find effective treatment for combating the virus. This could result in some delays in filings and approvals for other drugs. Cancellation of elective procedures, healthcare backlogs can also delay completion of clinical trials for non-COVID drugs. This could require rethinking or redoing the R&D pipeline.

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Challenges in quality management

Challenges in quality management

The US FDA performs annual site inspections of approved manufacturing facilities with three outcomes:
No Action Initiated (NAI) - clean report
Voluntary Action Initiated (VAI) - minor audit observations
Official Action Initiated (OAI) - serious audit observations

While India is a significant contributor to the drugs sold in the USA, compliance to the USFDA's stringent quality management norms remains one of its key challenges. Quality-related observations were found in 76% of the inspections concluded in India in Jan–Sep 2020 on drug quality assurance.

Under the lens

Region	Inspection outcome			% of inspections with no. observations
	No observations	Minor observations	Serious observations	
US	58	94	10	36%
India	25	43	5	34%
Canada	3	10	3	19%
Germany	2	6	-	25%
Mexico	1	4	-	20%
Others	3	14	-	18%
Total	**92**	**171**	**18**	33%

Note: No inspections carried out between April – June 2020.

Eight warning letters were issued to Indian pharma companies in the first nine months of 2020 (all pertaining to CGMP violations).

63% of the warning letters issued during the January–September period were on account of unapproved or misbranded products related to COVID-19.

Majority of the six drug recalls by Indian companies in 2020 (up to September) were due to impurities seen in drugs (comprising Valsartan and Metformin)

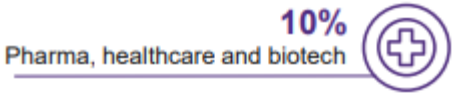
The major risk with receiving warning letters is delay in approval of other drug applications, which increases the pay back period on R&D investments.

Transaction update

Mergers and acquisitions (M&A), Private equity (PE)

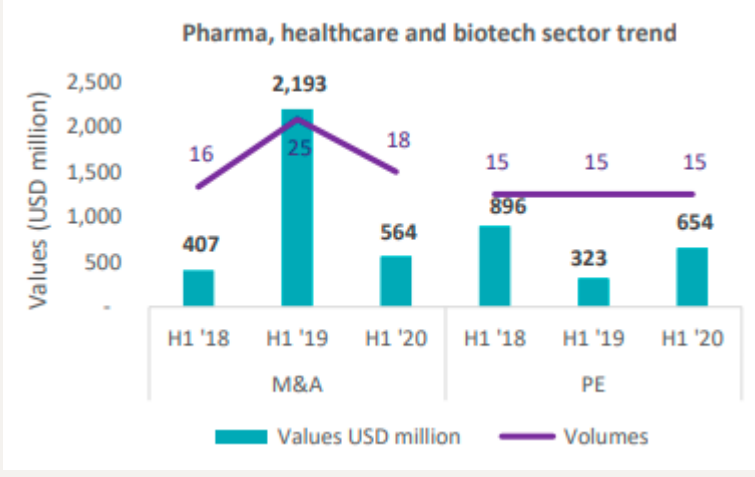
Deal Summary	Volumes		Value (USD million)	
	2019	2020	2019	2020
Outbound	11	2	136	28
Domestic	5	8	41	296
Inbound	2	3	393	197
Total M&A	**18**	**13**	**569**	**521**
Private Equity	7	9	249	476
Grand Total	**25**	**22**	**818**	**996**

Note: Deals where in reliable data for transaction value is not available, we have assumed the transaction value as USD 5 million



10% of inbound deals by volume in H1, 2020 were in the healthcare sector. 8% of outbound deals were in the sector.

- In H1 2020, the cross-border deal volumes were the lowest since 2011 while the deal values were third highest. The values were driven by Facebook's USD 5.7 billion investment in Jio Platforms. Barring this deal, the values were second-lowest.
- H1 2020 also witnessed the lowest individual inbound and outbound deal volumes since 2011.



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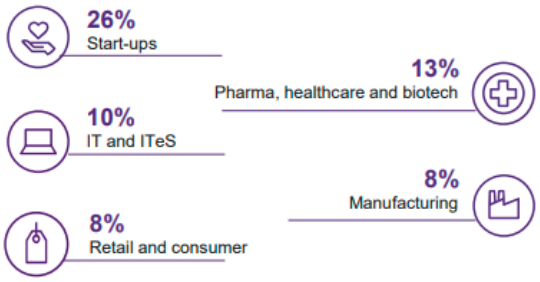
Deal highlights: Summary

- The pharmaceuticals sector witnessed 18 M&A transactions in H1 2020, valued at USD 564 million. These were the second lowest deal volumes and deal values recorded in the first six months since 2011. On the contrary, PE investments values recorded 102% increase with muted deal volumes compared with H1 2019.
- Overall, the sector saw only four deals valued at and above USD 100 million compared with seven such deals witnessed in H1 2019.
- While pharma and biotech segments dominated the overall deal activity within the sector, consolidations were seen in the primary healthcare segment and PE investors showed heightened interest in the medical devices segment.
- M&A deals within the sector were dominated by domestic consolidation with 67% of the total M&A deals volumes, while, inbound and outbound transactions saw three deals each.
- PE investments were primarily raised with a view of business expansion, growth acceleration, growing customer base, product innovation and developing new age technology to support the sector activity.

Share of top sectors by deal volume in H1 2020



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Top M&A deals

Top M&A deals - H1 2020				
Acquirer	**Target**	**Value (USD million)**	**Deal type**	**% stake**
Dr. Reddy's Laboratories Ltd.	Wockhardt Ltd.'s generics drug business in India and other countries	260	Acquisition	100%
Novavax Inc.	Serum Institute of India Pvt. Ltd.- Praha Vaccines a.s	167	Acquisition	100%
Aster DM Healthcare	e Wahat Al Aman Home Healthcare LLC	29	Acquisition	100%
Piramal Enterprises Ltd.- Piramal Pharma Solutions Inc.	G&W Laboratories Inc. - solid oral dosage drug manufacturing facility	18	Acquisition	100%
Hubei Biocause Heiien Pharmaceuticai Co. Ltd.	Granules-Biocause Pharmaceutical Co. Ltd.	16	Increasing stake to 100%	50%

Top PE deals

Top PE deals - H1 2020			
Investor	**Investee**	**Stake (%)**	**Value (USD million)**
The Carlyle Group	SeQuent Scientific Ltd.	74.0	210
ChrysCapital	Intas Pharmaceuticals Ltd.	3.0	132
CVC Capital	HealthCare Global Enterprises Ltd.	31.0	82
True North	Biocon Biologics India Limited	2.4	76
LeapFrog Investments, Sofina and Sequoia Capital	MedGenome Labs Pvt. Ltd.	N.A.	55

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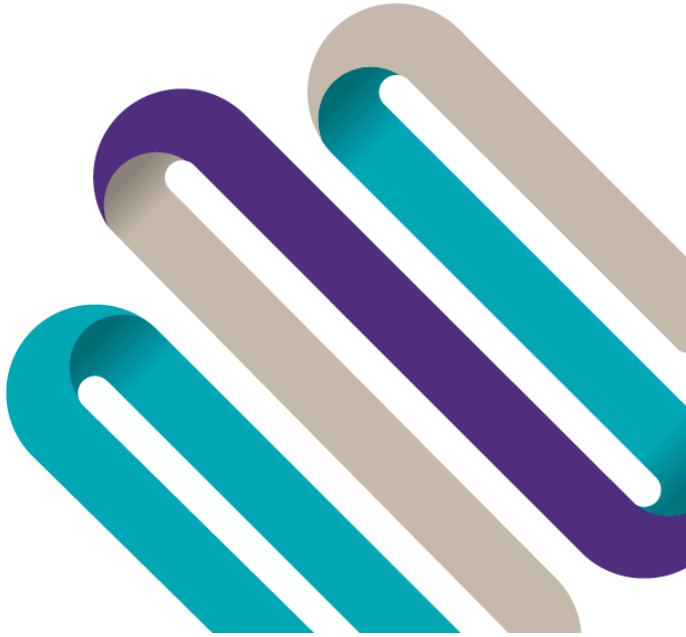

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