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Health Check

Q2 2019

Foreword

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We are delighted to bring you the launch edition of Health Check, a quarterly publication on key trends in pharma and life sciences, which is also one of Grant Thornton's focus sectors. As a result of serving dynamic clients in this space, we have a deep understanding of emerging trends, challenges, disruptions and other issues.

It will not be an exaggeration to say that India has the potential to be one of the pharma superpowers of the future. Low cost of production and increasing expenditure on R&D have led to competitive pharma exports from India reaching USD 19.13 billion in FY 19. Government's 'Pharma Vision 2020' aims to make India a global leader in end-to-end drug manufacturing. Increasing private sector investments in R&D and acquisition are driving the sector's growth. In FY 19, the largest Indian pharma companies invested 7% of their sales in R&D. This edition covers an in depth sectoral analysis of H1 2019 including export sales, R&D pipeline, tightening liquidity, product mix, price capping, focus on quality management, controlling production cost, among others.

We have also covered the impact of regulatory announcements on the sector besides hot topics of debate including challenges in quality management, price capping, warning letters from USFDA, impact of reduction in corporate tax rates, etc.

Overall, the industry has strong growth prospects with a solid pipeline for new drugs in various markets. The government is moving forward in its aim to make healthcare affordable to every citizen and this can only bring good tidings to the entire healthcare value chain.

H1 – April to September 2019, Q1 – April to June 2019, Q2 – July to September 2019

Introduction

The Indian pharma industry recorded an average performance in Q2 2020 with top 10 listed pharma companies * showing an average increase in revenue of 14% over Q2 2019. These companies also maintained an average of 14% PBT (Profit Before Tax) on turnover for the quarter. Some of the reasons contributing to the quarter's results include increase in turnover from the US market, lower inventory holding in the distribution channel of stockists on account of liquidity remaining tight in the Indian market, product recalls in the US market and impairment losses.

The Indian pharma companies also strengthened their position in the US with higher drug approvals from the US Food and Drug administration (FDA) than any other country in 2019. From a quality perspective, Indian pharma companies received some warning letters from the US FDA regarding quality practices based on audits. While warning letters do not result in a ban on products, these will delay approval of other drug applications. Increasing drug recalls in the US indicated that quality management is a challenge in regulated markets.

In India, the healthcare industry did not receive much attention in the Union Budget 2019 presented in July. However, budget allocation for the Ayushman Bharat Yojana, India's universal healthcare programme, saw a whopping 167% increase to INR 6,400 crore. Transactions in the life sciences space have also picked up in H1 2019-20, with small-mid Indian pharma companies looking to acquire global pharma assets.

* Cipla, Aurobindo, Torrent, Cadila, Sun Pharma, Glenmark, Lupin, Dr. Reddys, Alkem Labs, Piramal

Industry overview

The Indian pharma industry faced a challenging environment in 2019. Amid talks of slowdown in other industries, pharma has maintained reasonable revenue growth at 14%*.

While top line growth was slower in Q1 at 13%, Q2 growth in revenue marginally increased to 14%. PBT for the top five companies had negative growth of 7% in Q2 FY20 over Q1 FY 20 owing to one-time litigation losses, impairment losses, etc. All of these factors combined with continued lower volumes in Indian channel sales on account of tight liquidity resulted in lower profitability.

* increase in H1 FY20 revenue over H1 FY19 of top 10 listed companies in terms of turnover

The Indian pharma industry has evolved over the years from selling generic drugs in India, investing in R&D to developing niche drugs and selling in highly regulated markets overseas.

In FY 2018-19, 67% of the revenue of the top 10 pharma companies came from exports. Pharma exports from India were USD 19.13 billion in FY 19 registering a growth of 10% over the previous year. As per data published by the Pharmaceuticals Export Promotion Council of India, 30% of these exports were to the US.

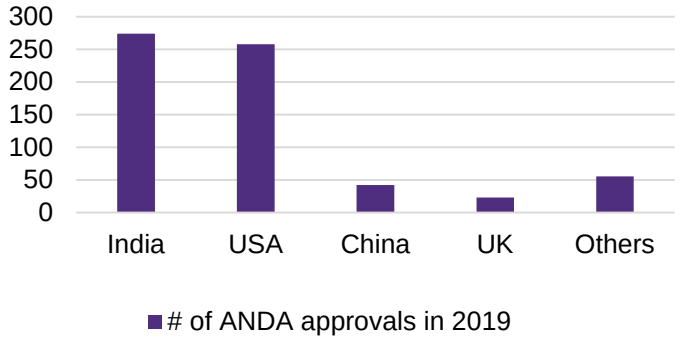
A closer analysis of Indian pharma companies in the US would indicate a strong new generic drug pipeline.

* https://pharmexcil.com/uploads/tradestatistics/Countrywiseexports201819.pdf

India's dominance in regulated markets

The US story: Out of 597 ANDAs* (generic drug applications) approved by the USFDA from January 2019 to September 2019, 274 approvals were given to Indian pharma companies comprising 42% of approvals.

This makes India the **largest receiver of generic drug approvals in 2019** (up to September 2019).



* ANDA: Abbreviated New Drug Application

It is also interesting to note **that Indian companies are now receiving more generic approvals than American companies in the US.**

Year	India approvals %	USA approvals %
2019	42%	42%
2018	38%	38%
2017	40%	40%

For the last three years, India has always come a close second to the US in terms of the number of generic drug approvals in recent past years. The growth in approvals in 2019 is commendable, particularly in the light of protectionist trade policies being implemented in the US recently.

Innovation and quality are growth drivers

The Drug Controller General of India (DCGI) approved 15 new drugs in India in 2019 (up to September).

Year	Number of new drug approvals
2019*	15
2018	26
2017	8

* 2019 data up to 30 September 2019

This year, neuro/mental health drugs received the highest number of approvals at 27% closely followed by anti-infectives. Other therapeutic categories include oncology, diabetes care, respiratory, female health, among others.

Source: DCGI

Central Drugs Standard Control Organisation (CDSCO) performs random sample testing of old and newly launched drugs to check drug quality. Alerts are issued for any drugs that fail quality tests. In September, alerts were issued for 21 drugs out of 1,134 drugs that were tested

Details on sample testing for April-September 2019 are provided below

Month	Tested	Alerts	%
April	1,095	29	2.6%
May	821	33	4.0%
June	843	25	3.0%
July	988	18	1.8%
August	951	28	2.9%
September	1,134	21	1.9%
Total	**4,737**	**125**	**2.7%**

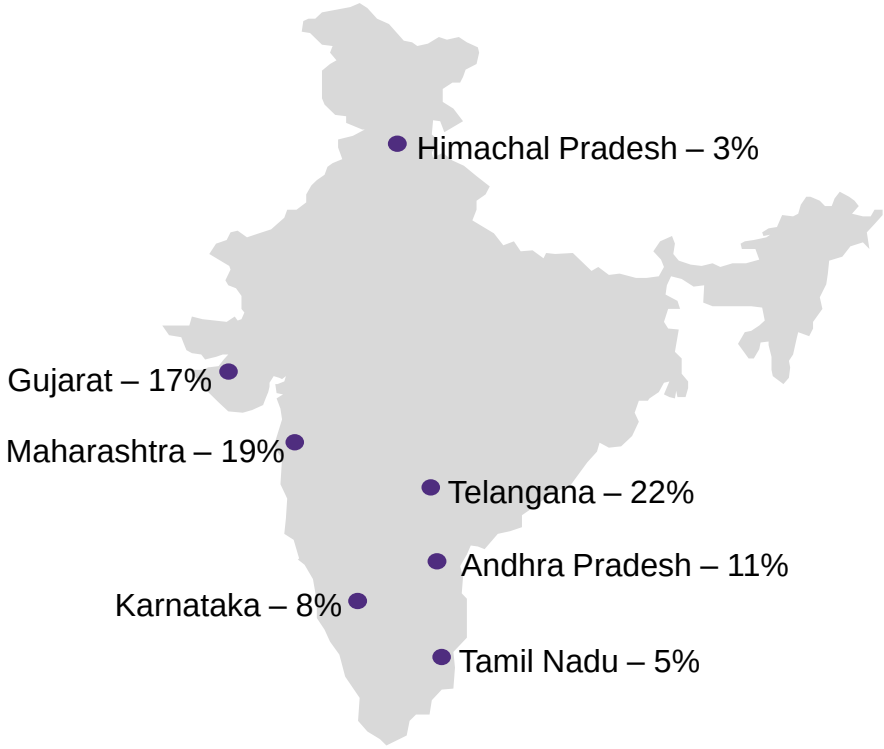
Pharma hubs in India

While the government's Pharma Vision 2020 aims to make India a global pharma manufacturing hub, the industry expertise in India seems to be geographically concentrated in the states of Telangana, Andhra Pradesh, Gujarat, and Maharashtra.* These 4 states account for 69% of India's approved manufacturing sites.

A pharmaceutical industrial park is being set up outside Hyderabad, Telangana, over 19,000+ acres of land. It is expected to attract investment of INR 64,000 crore and provide employment to 1.5 lakh + people.

* Number of USFDA approved manufacturing sites Source: USFDA

USFDA approved sites in India:



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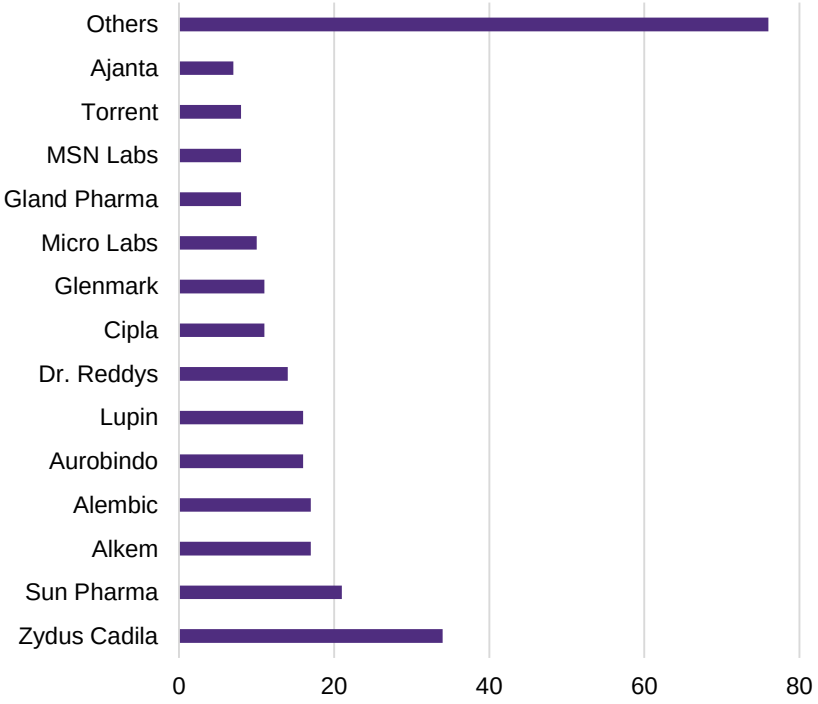
Leading players: Drug approval tracker

Zydus Cadila led the industry with 34 USFDA approvals received in 2019 (till September) followed by Sun Pharma with 21 approvals.



Zydus Cadila and Sun Pharma appear to be catching up with Aurobindo Pharma in terms of receiving the highest number of USFDA generic drug approvals till date

Company	Over the counter	Prescription	Total
Aurobindo	25	328	353
Sun Pharma	18	283	301
Zydus Cadila	1	231	232
Lupin	1	188	189
Dr Reddys	21	161	182
Glenmark	2	152	154
Torrent	2	81	83
Cipla	1	76	77
Alkem	-	57	57
Grand total	**71**	**1,557**	**1,628**

Oral dosage forms leading the way

Deeper analysis of drug approvals of Indian pharma companies indicates that most of the **expertise lies in oral dosage forms** wherein 7 out of the 10 top listed pharma companies have over 70% of their approvals for oral dosage forms.

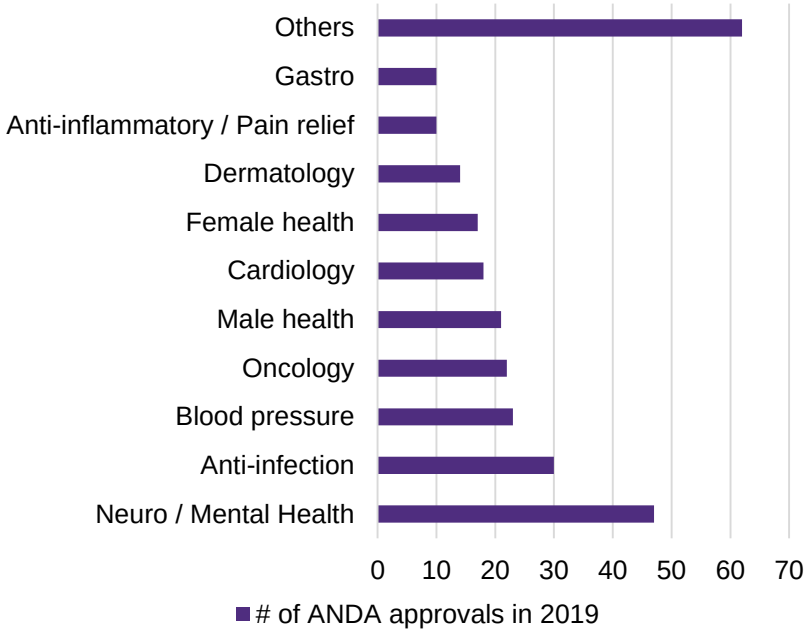
Oral	Injectable (incl. IV/ IM)	Topical	Others	Total	Orals %
1,313	164	91	61	**1,629**	81%

Cipla and Piramal, being the exceptions, obtained 25% and 45% of their approvals from injectables/intravenous dosage forms respectively. Glenmark obtained 30% of its approvals from topical dosage forms.

Top five pharma companies: Aurobindo, Sun Pharma, Cipla, Dr. Reddys, and Lupin invested 7% of their consolidated turnover on R&D in FY 2018-19.

Wide spectrum of therapies

While Indian pharma expertise seems to lie in oral dosage forms, it covers a broad spectrum of therapies covering cancer to common cold.



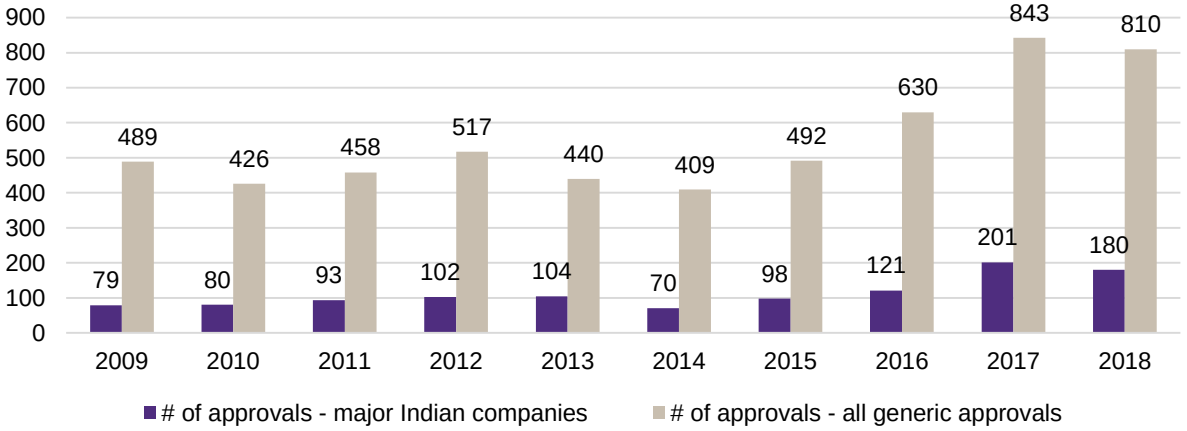
As an industry, Indian pharma companies have maintained focus on generic drugs versus new drugs or biologics

Indian pharma companies did not receive approvals for new molecules in 2019. 19 out of 28 (68%) approvals were received by American companies.

Indian pharma companies also did not receive any biologics licence approvals (biologics drugs) in 2019. 62% of approvals were granted to American companies.

Increasing pace of drug approvals

- Analysis of the top 9 listed Indian pharma companies also shows that the pace of approvals has picked up from 2016 going from an average of 61 approvals a year between 2001 and 2015, to an average of 167 approvals per year (from 2016 to 2018).



2017 saw record number of approvals

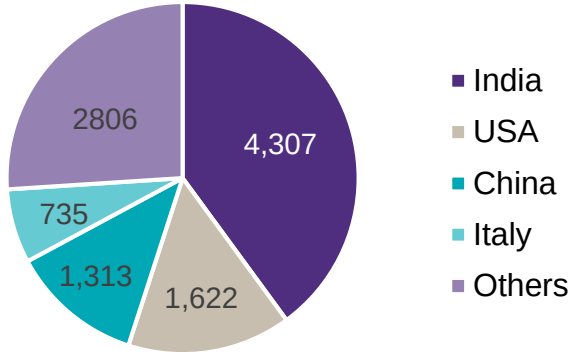
- 2017 saw a record number of approvals in line with the USFDA's general approval rate, which spiked in 2017 under the Trump administration.
- The reasons for the higher number of approvals include revised goals for the FDA in approving generic drugs from 75% approvals within 15 months in 2016 to 90% approvals within 10 months* from 2017.

* Goals for approval of standard original ANDAs revised under GDUFA II

India's leadership in API manufacturing

India is a significant supplier of active pharmaceutical ingredients (API*) to the US. 40% of approved active Drug Manufacturing Files (DMF) up to 30 September were held by Indian companies. DMFs are approvals from the USFDA which permit an API to be used in an application for a new drug or new generic drug.

Number of active DMFs



However, India continues to rely heavily on China for sourcing of APIs for its own production of finished drugs; the industry imports around 85% of active ingredients from China. The API industry continues to face challenges on account of dependency on formulation approvals, increasing demand for biologics based and protein based molecules as opposed to the traditional synthetic/chemical APIs, together with backward integration by most formulation manufacturers which reduces demand for exclusive API manufacturers.

* Drugs are usually made of 1-3 key active ingredients known as APIs.

Source: USFDA, Trade Promotion Council of India

Challenges in quality management

Challenges in quality management

The USFDA performs annual site inspections of approved manufacturing facilities with 3 outcomes:
NAI: No Action Initiated (clean report); **VAI**: Voluntary Action Initiated (minor audit observations); **OAI**: Official Action Initiated (serious audit observations)

While India is a significant contributor to drugs sold in the US, compliance to the USFDA's stringent quality management norms remains one of the key challenges facing the industry. Quality-related observations were found in 64% of inspections concluded in India in 2019 (up to September 2019)

Region	Inspection outcome			% of inspections with no observations
	No observations	Minor observations	Serious observations	
US	166	174	20	46%
India	49	74	13	36%
China	18	57	7	22%
Canada	18	26	-	41%
Germany	9	19	1	31%
Japan	7	18	-	28%
Others	40	72	7	34%
Total	**307**	**440**	**48**	

17 warning letters were issued to Indian pharma companies in 2019. The US and Canada lead on quality management with an average of 44% inspections conducted with 'no observations'.

Quality enforcement action

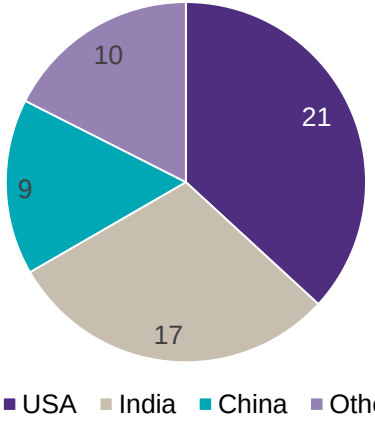
Quality enforcement action may take the form of warning letters, drug recalls, cancellation of registration or criminal proceedings

- **Warning letters** are an intimation on serious audit observations; however, they do not always result in prohibitive action from the USFDA. Usually, it means that pending drug applications may be put on hold till the observations are addressed.
- **Product recalls** may be voluntary or FDA mandated. They may arise out of FDA inspections, but most often they are voluntary arising out of a company's internal quality procedures.
- **Cancellation of site license** occurs where issues raised through warning letters or through other inspection observations are not adequately rectified.
- **Criminal proceedings** for any criminal activity.

17 warning letters were issued to Indian pharma companies in 2019. The US and Canada lead on quality management with an average of 44% inspections conducted with 'no observations'.

63% of warning letters issued are for CGMP* violations

Number of warning letters by country in 2019



* CGMP: Current Good Manufacturing Practices

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Drug recalls

In 2019, 62 recall events by Indian pharma companies were mostly (56%) due to CGMP deviations and quality check failures.

Reason	# of recalls	%
QC failure	19	30%
CGMP deviations	16	26%
Label	6	10%
Defective container / delivery system	5	8%
Others	16	26%
Total	**62**	

5 of the 62 (<10%) recalls are serious class I recalls - reasonable probability that use will cause serious adverse health consequences or death - which largely arise out of contamination.

The major recalls by Indian companies in were: Losartan (Q1 FY20), Estradiol (Q2 FY 20) and Ranitidine (Q3 FY20).

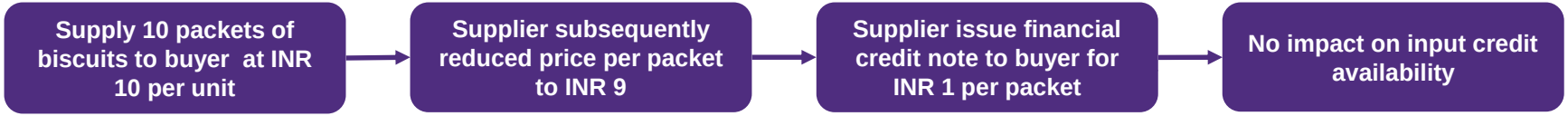
Regulatory update

Goods and Services Tax (GST): Striving for simplification

The healthcare sector was one of the most challenging sectors with regards to the implementation of GST. Recent announcements and judicial precedence are helping build tax and operational efficiency along with efforts from the authorities and industry players.

Below is the relevant clarification issued recently on availability of input tax credit on promotional schemes:

Sr.no.	Scheme	Example	Remark
1.	Free samples	Free samples of manufactured or trading products issued to doctors/ physicians	Input credit not available
2	Gifts	Gifts with brand logo like T-shirts/ pens/ mugs / writing pads provided to doctors/ employees / clinics	Input credit not available
2.	Buy and get free offer	• Scheme of 'Buy 3 product and get 1 free' • Single price charged in consideration for all products	Input credit available
3.	Discounts including 'Buy more, save more' offers	**Discounts known at the time of or before supply like:** - On purchase of INR 10,000, discount of flat 10% - Volume discount on purchase of 1 lakh packets of biscuits during the year, discount of 15% by issuance of credit note	Input tax credit available if discounts agreed before or at time of supply



No impact on availability of input credit when secondary discounts are provided as per recent circular explained below

GST: Striving for simplification

- The clarification regarding impact on availability of input tax credit for expired drugs as explained below provided relief to sector for efficient approach.

Credit Note (CN) time limit	Remark
CN issued up to 30 September of next financial year	• Manufacturer/supplier to reverse GST liability as mentioned in Credit Note • Dealer /buyer to reverse ITC attributable on expired goods as per Credit Note from manufacturer
CN issued after 30 September of next financial year	• Dealer / buyer may raise fresh invoice for return of such expired goods, basis which ITC to be reversed on such procurement by the supplier / manufacturer

- Ab intio withdrawal of clarification on post-sale discount will impact differently depending upon business operations.
- As a step towards procedural improvisation, a single authority mechanism introduced to enhance export and GST refund process. Further, an initiative has also been proposed for automation to fast track refund claims.
- The progressive approach with the clarifications on anti-profiteering would reduce complexities for the sector. Further, procurement of taxable capital goods and maintenance for providing exempt healthcare services increases cost, hence suitable mechanism to be introduced to reduce tax cost.
- The authorities appear to be determined for continuity of progressive action with the proposed simplified return and by waiving compliances for two years for job work which is a common practice in the sector. Further, relaxation from annual return for small players and resolving system-related glitches would help in enhancing productivity of the sector.

Direct tax: Moving the needle

On the direct tax front, the impact of reduced tax rates vis-à-vis existing rate of 25%-30% would have significant impact on industry players looking for a breather. In some cases, this will strengthen operational approach. However, the following issues should be addressed:

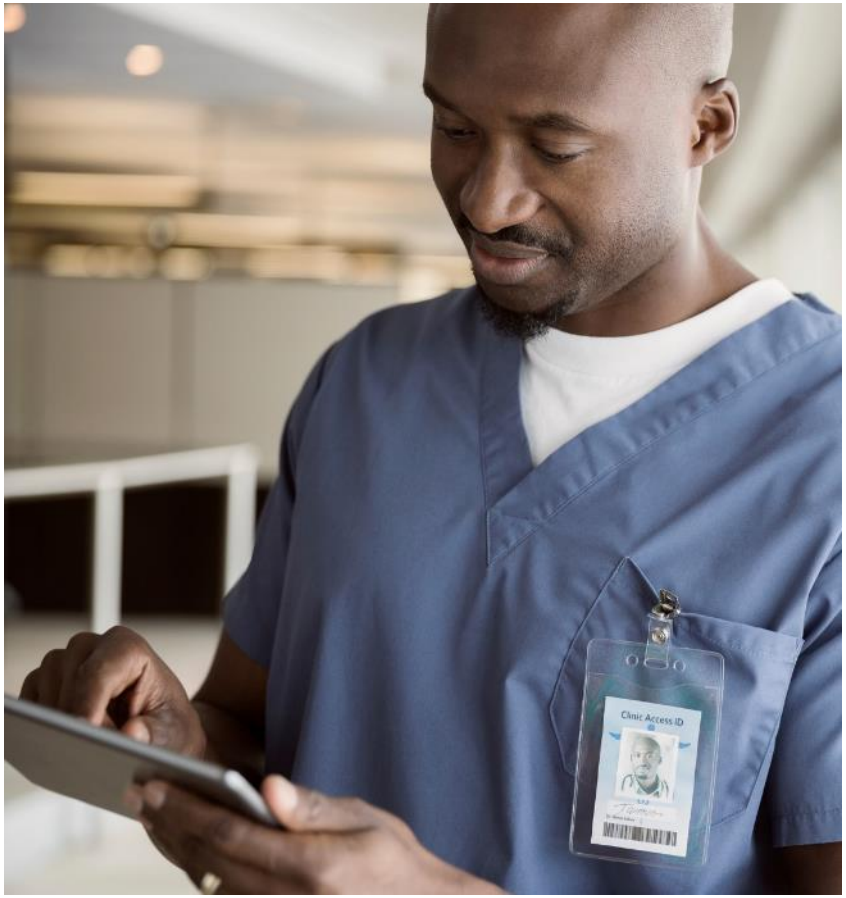
- Would MAT credit lapse if lower corporate tax rate is opted?
- Authorities have clarified that the companies opting for lower tax rate will have to forgo MAT credit under new tax regime. However, ambiguity amongst stakeholders still exists as ordinance is silent on adjustment and carry forward of accumulated MAT Credit against normal tax liability.
- Deferred tax asset-related challenges
- Company opting for new tax regime will have to reinstate the Deferred Tax Assets as per revised tax structure. However, this would be required only once the company opt for new rates.
- Losses pertaining to specified deductions from losses brought forward from previous year:
- Benefit of tax losses arising out of specified deduction/ additional depreciation, etc. will have to be forgone where the company choses amalgamation or demerger, such losses will not be available to the amalgamating/ resulting company. Thus, the company needs to evaluate real benefit of lower tax rate before adopting the same.

  – **Change in rate/computation method of depreciation**: Additional unabsorbed depreciation on new plant and machinery available to manufacturing units will lapse from 1 April 2019. Corresponding adjustment to the written down value of the such block of asset as on 1 April 2019 shall be allowed in prescribed manner.

Direct tax: Moving the needle

  - **Impact of violating any of the conditions for availing lower tax rate:** Companies need to critically evaluate the option to avail lower tax rate under new tax regime. In case any of the conditions for availing lower tax are violated, it is proposed that the benefits of lower tax rate shall stand withdrawn from the year of violation and in future. Going forward, the company will never be allowed to take benefit of reduced tax rates in future.

- Non-corporate entities such as LLP, etc. are still subject to tax at a higher rate (i.e. 30%) as compared to companies. Hence, there is room for streamlining the same in order to offer fair tax regime to all irrespective of legal form.



Budget update

Key Budget announcements

- INR 62,659.12 crore outlay for the health sector in the 2019-2020 fiscal, an increase of 15% from the revised outlay of fiscal 2018-19 of INR 54,302 crore
- Budget allocation for the Ayushman Bharat Yojana has seen a whopping 167% increase from INR 2,400 crore to INR 6,400 crore in FY 2019-20.
- Nil customs duty on import of raw materials, parts, or accessories for manufacture of artificial kidney, disposable sterilised dialyzer and micro-barrier of artificial kidney with a view to promote domestic manufacturing

Market size of health sector to increase three-fold to INR 8.6 lakh crore by 2022

Expected CAGR of 22% to reach INR 26 lakh crore by 2022

Government expenditure to reach 2.5% by 2025 from 1.4% in 2018

Emerging trends in India

Price capping on cancer drugs

The MRP of 526 anti-cancer drugs has been reduced in 2019. Reduction in MRP has been in the range of 0.5% to 91% per drug (**45%** per drug on average). The government is committed to making cancer drugs more affordable for the Indian patients and multiple steps have been taken in this area. The National Pharmaceutical Pricing Authority (NPPA) which has the responsibility for monitoring and regulating drug prices in India has reduced the MRP of cancer drugs thrice in 2019, adding new branded drugs to the list each time.

The reduction in MRP was accompanied with a capping of trade margins (difference between the price at which the manufacturer sells to stockists and the retail price) to 30% with a view to ensure affordability of anti-cancer drugs.

In addition to cancer drugs, the prices of 140 new drugs was capped by the NPPA in 2019 with a view to improve affordability for the common man.

Trade margin capping at 30%

Another form of drug price control in India is through the **capping of trade margins** for non-scheduled drugs. Currently, the prices of non-scheduled drugs can be increased by up to 10% per year.

In April, the Department of Pharmaceuticals (DoP) had proposed a few options on drug price capping including:

Capping of trade margins of non-scheduled drugs to 43%

Flat capping of 100% on trade margins of all drugs

Capping for only five therapeutic segments where trade margins were believed to be highest: anti-infectives, pain /analgesics, gynecological, gastrointestinal, and respiratory.

The trade margins on cancer drugs had already been capped at 30% with a view to make these more affordable. The industry norm has been to typically provide 10% margin to stockists and 20% margin to retailers; however, it is believed that actual margins are significantly higher for some drugs.

India is not the first to walk the path of trade margin capping, countries like South Africa, Mauritius, Ecuador, etc. have regulatory provisions for setting the maximum retail mark up.

Source: World Health Organisation

Pharma freebies to healthcare providers

Hon'ble Union Health Minister, Dr. Harsh Vardhan informed Parliament on 12 July 2019 that pharma freebies to doctors would invite disciplinary action, not just on doctors, but also on CEOs of pharma companies indulging in unethical drug marketing practices. Unethical practices include exchange of gifts, pecuniary benefits, travel facilities, hospitality, monetary grants and some medical research grants.

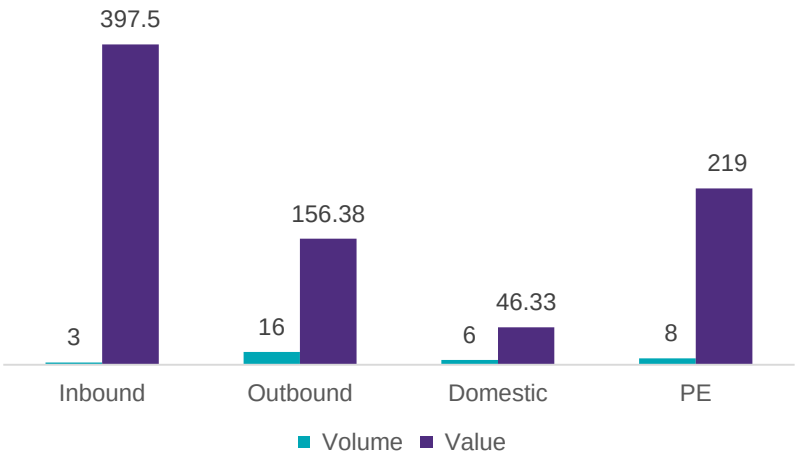
Currently, only doctors face disciplinary action by the Medical Council of India (MCI) under the Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulation, 2002 for unethical marketing practices. Under the Uniform Code for Pharmaceutical Marketing Practices (UCPMP), the Managing Director/CEO of a company is ultimately responsible for ensuring adherence to the Code. The UCPMP is a voluntary Code for marketing of drugs, including medical devices, for the Indian pharmaceutical industry. Under the Code, complaints may be registered with Indian pharmaceutical manufacturing associations regarding unethical marketing practices followed by companies in their interactions with healthcare providers.

It remains to be seen what shape the disciplinary action against CEOs of pharma companies will take.

Transaction update

M&A and PE

Deal summary



2019	Volumes	USD million
M&A	25	600.21
PE	8	218.90
	33	819.11

Notes: 2019 refers to period of Jan to August 2019

The sector witnessed around 33 deals between January and August 2019, picking up after recording low level of activity in similar period in 2017 and 2018. In terms of composition, M&A deals witnessed significant amount of outbound transactions though in terms of deal value in-bound transactions aggregated to higher overall deal value than outbound transactions. Except for couple of relatively large transactions, the deal making was concentrated in smaller value band ranging up to USD 50 million.

The critical driver for M&A and specifically outbound transactions has been Indian players aiming to add product pipeline or newer markets to beat increasing pricing pressures. We see such trend continuing in future contributing to increased deals in this space.

Top M&A deals

Acquirer	Target	USD m	Deal type	% stake
Apotex Inc. - Apotex Pty Ltd.	Strides Shasun Ltd(Strides Pharma Global Pte) - Arrow Pharmaceuticals	282	Acquisition	100%
Upsher-Smith Laboratories, LLC	Dr Reddy's Laboratories Ltd. - Neurology products: Tosymra and Zembrace	110.5	Acquisition	100%
TAKE Solutions Ltd.	DataCeutics, Inc.	45	Acquisition	100%
TAKE Solutions Ltd.	KAI Research, Inc.	27	Acquisition	100%
Strides Shasun Ltd. - Strides Pharma Inc.	Vensun Pharmaceuticals Inc.	18	Acquisition	100%
Ipca Laboratories Ltd.	Ramdev Chemical Pvt. Ltd.	15.5	Acquisition	100%
Suven Life Sciences Ltd.	Rising Pharmaceuticals, Inc. and its subsidiaries	15	Acquisition	100%
Kemwell Biopharma Pvt. Ltd.	Stempeutics Research Pvt. Ltd.	13.8	Minority stake	N.A.

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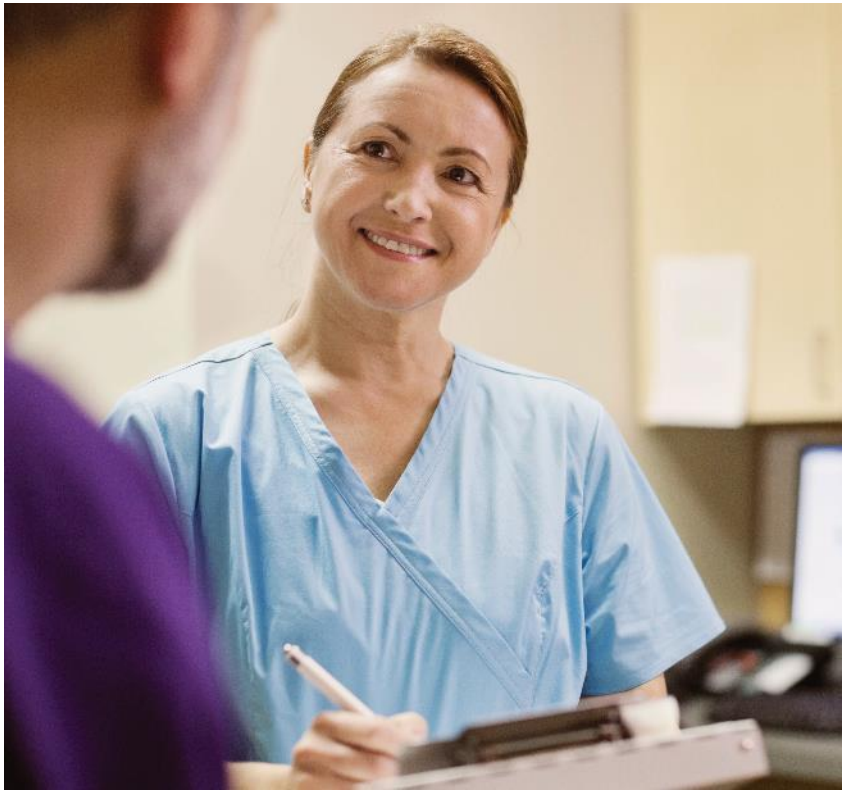
Top PE deals

Investor	Investee	USD m	% stake
General Atlantic	Rubicon Research Pvt. Ltd.	100	N.A.
Affirma Capital	Tirupati Medicare Ltd.	50	N.A.
Eight Roads Ventures, F-Prime Capital Partners	Caplin Point Laboratories Limited	30.6	N.A.
TPG Growth	Solara Active Pharma Sciences Limited	30	N.A.
Iron Pillar, Perceptive Advisors, Romulus Capital and Kalaari Capital	Vyome Therapeutics Inc.	22	N.A.
Eight Roads Ventures and Anterra Capital	Ashish Life Science Pvt. Limited	6.3	N.A.

Key trends which may drive deals in this space in future

- The Indian market is impossible to be ignored given its economic prospects and consumption pattern. Foreign companies view India as a potential significant contributor of future sales and so they are serious about making large investments in the country. Also, India's domestic market is particularly promising for global player looking to launch new products.
- With increasing regulatory accountability and USFDA getting more stringent, high-quality manufacturing assets will command a premium.
- Biotech industry, with its cost advantages, could be another significant growth driver for local development of biosimilars for the global market.
- Bioinformatics, stem cell research and medical devices could present new opportunities for growth.



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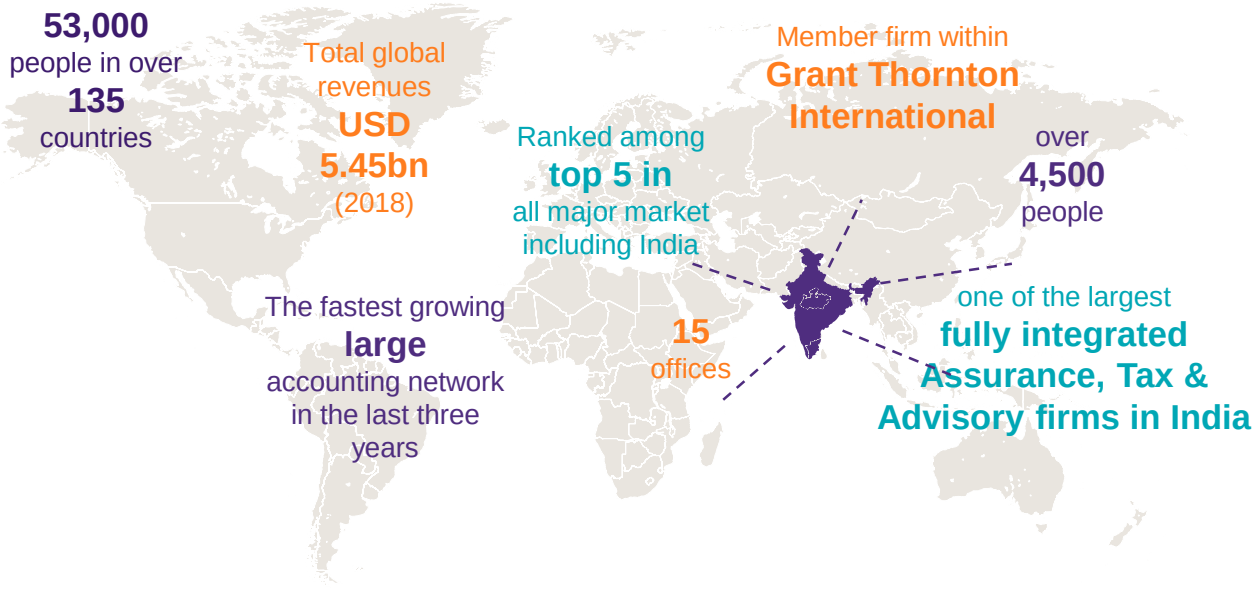

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Bagmane Tech Park, C V Raman Nagar,
Bengaluru – 560093
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CHANDIGARH
B-406A, 4th Floor, L&T Elante Office
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Chandigarh 160002
T +91 172 4338 000

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7th Floor, Prestige Polygon
471, Anna Salai, Teynampet
Chennai 600018
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DEHRADUN
Suite no. 2211, 2nd floor
Building 2000, Michigan Avenue
Doon Express Business Park
Subhash Nagar, Dehradun – 248002
T +91 135 2646 500

GURGAON
21st Floor, DLF Square
Jacaranda Marg, DLF Phase II
Gurgaon 122002
T +91 124 462 8000

HYDERABAD
7th Floor, Block III, White House
Kundan Bagh, Begumpet
Hyderabad 500016
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KOCHI
6th Floor, Modayil Centre point
Warriam road junction, M.G.Road
Kochi 682016
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KOLKATA
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5th Floor
Kolkata 700017
T +91 33 4050 8000

MUMBAI
16th Floor, Tower II, Indiabulls
Finance Centre, SB Marg,
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MUMBAI
Kaledonia, 1st Floor,
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Sahar Road, Andheri East,
Mumbai - 400 069

NOIDA
Plot No. 19A, 7th Floor
Sector – 16A
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