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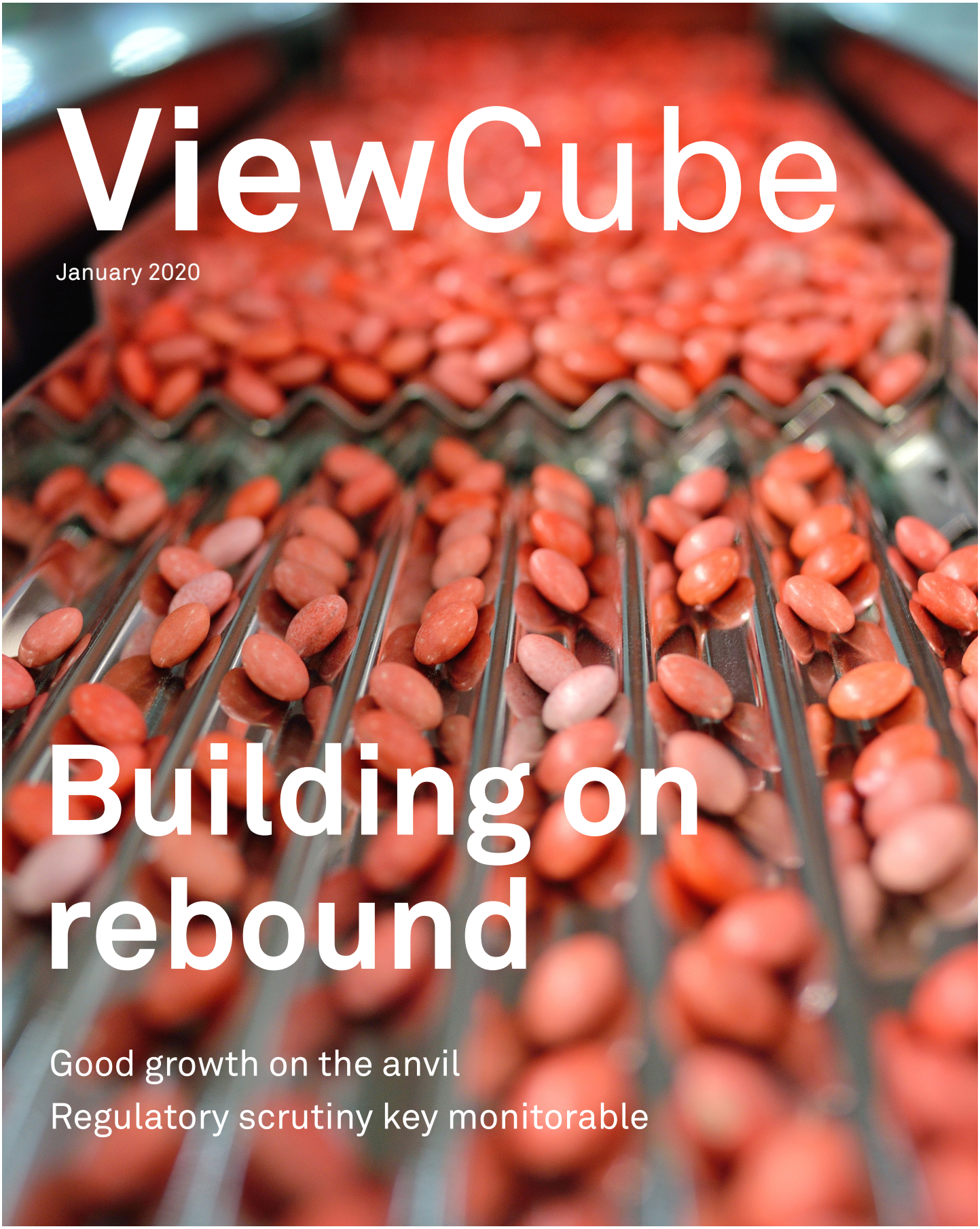

ViewCube

January 2020

Building on rebound

Good growth on the anvil

Regulatory scrutiny key monitorable

ViewCube is a compilation of sector views expressed during CRISIL's webinars. These include CRISIL's own views, that of stakeholders, and those emanating from a poll done during the webinar.

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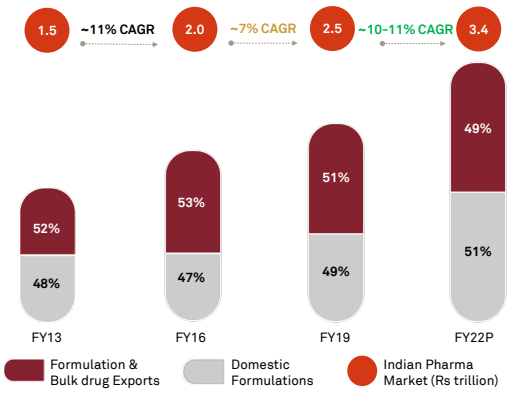
Our view

The pharmaceutical industry's fortunes have started looking up after two years of slowdown wrought by rollout of the Goods and Services Tax (GST) at home and pricing pressures in the export market. Driven by a sharp spurt in exports, the industry logged double-digit growth of 15% in fiscal 2019, signalling a return to the healthy ways of fiscal 2013-2016.

We expect double-digit growth of 10-11% to continue over the medium term.

Industry poised for good growth through fiscal 2021



Note: CAGR – Compound annual growth rate (INR terms); Exchange rate – Rupee depreciation of ~2% is assumed for years FY20, FY21, FY22
Source: Directorate General of Commercial Intelligence & Statistics (DGCIS), CRISIL Research

The domestic growth story has been largely stable, barring a few regulatory interventions such as pricing regulation on essential drugs in fiscal 2015 and GST in fiscal 2018.

Over the next two fiscals, domestic growth is expected to hold steady at 11-12%, driven by

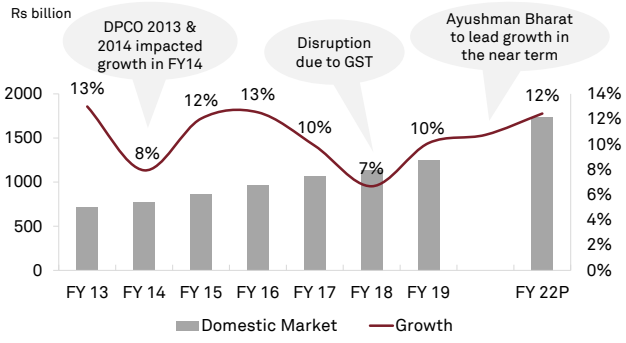
- Increasing healthcare penetration because of Ayushman Bharat, the government's flagship scheme
- Greater incidence of non-communicable diseases and ageing population
- Growing per capita income

Exports, which account for half of the industry's revenue, are also expected to clock a good compound annual growth rate (CAGR) of ~9% over fiscal 2019-2021, riding on

- Robust product pipeline as players look at niche and limited-competition products
- Rising generic penetration in European nations
- Indian players' focus on entering newer and smaller markets in Africa
- Short-term supply opportunity for bulk drug exports owing to Chinese disruption

Stable domestic growth expected in near term

Price controls on essential drugs to continue



Note: DPCO - Drug Price Control Order
Source: Industry, CRISIL Research

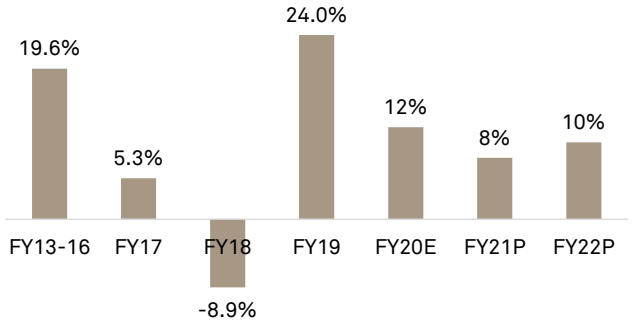
The **Ayushman Bharat Scheme** is expected to expand India's healthcare coverage from 35-40% at present. The government aims to set up ~1.5 lakh Ayushman Bharat health and wellness centres. Of these, ~20,000 centres have already been set up. In the near term, there could be certain challenges stemming from budgetary allocation, given the government's fiscal position. However, over the medium term, the scheme has the potential to lift the growth rate of the domestic pharma industry.

The **Jan Aushadhi Scheme**, which aims to sell cheaper generic generics drugs, is unlikely to have a significant impact over the medium term. From roughly less than 500 kendras during 2014, the scheme has now expanded to over 5,500 kendras. However, it has failed to take off in a meaningful way owing to non-availability of stock and issues related to supply. And this could have a negative impact on branded generic players in the long term, given a continuation of the government's focus on it.

The government regulates prices of essential medicines via the National List of Essential Medicines (NLEM). Currently, it regulates ~20% of the Indian pharmaceutical market. We expect this coverage to increase to ~23% by fiscal 2022. However, the government has recently excluded some drugs from the purview of the NLEM. Hence, any action on this front will be a key monitorable.

Indian pharma exports set to grow, driven by product diversification

Formulation exports (Regulated markets)



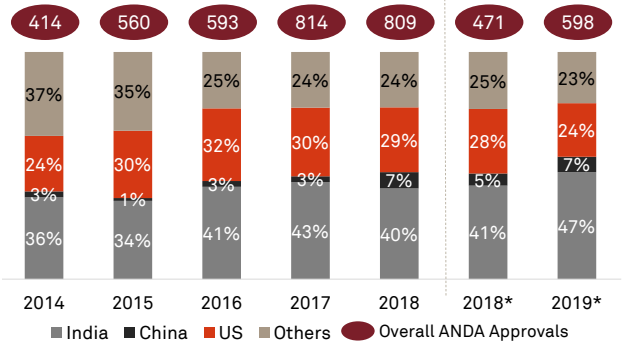
Source: Directorate General of Commercial Intelligence & Statistics (DGCIS), CRISIL Research

Formulation exports to regulated markets posted single-digit growth between fiscals 2016 and 2018, but bounced back to 24% in fiscal 2019, led by easing pricing pressure and increase in share of complex generics. These exports are expected to increase 10-11% annually over the next two years.

The improvement will ride on an easing in pricing pressures in the US, which accounts for ~37% of India's overall exports in this segment. During fiscals 2017 and 2018, price erosion in the US market had escalated as competition intensified, and wholesaler consolidation had reduced the bargaining power of Indian players.

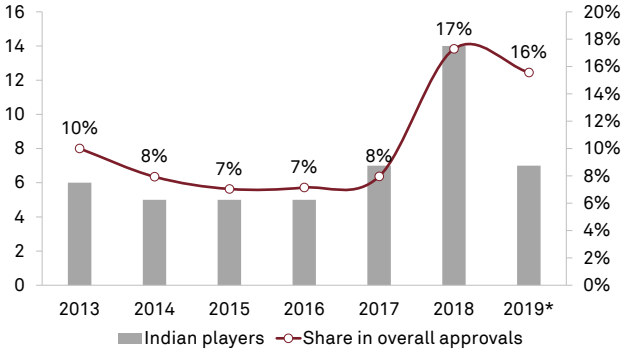
The easing in pricing pressures is evident from higher abbreviated new drug application (ANDA) withdrawals in 2018 and so far in 2019 as large generic players such as Teva, Mylan and Sandoz have exited non-core, non-profitable portfolios, providing volume opportunities for Indian companies. *(The way it works, a spurt in ANDA approvals means more intense competition as new players enter the fray, while more ANDA withdrawals means an easing in competition, and thereby less pricing pressure.)*

India's share in ANDA approvals improves



Note: 2019 - (Jan-Aug)*
Source: USFDA, CRISIL Research

Indian players' product filings via 505 b(2) (NDA) route increases

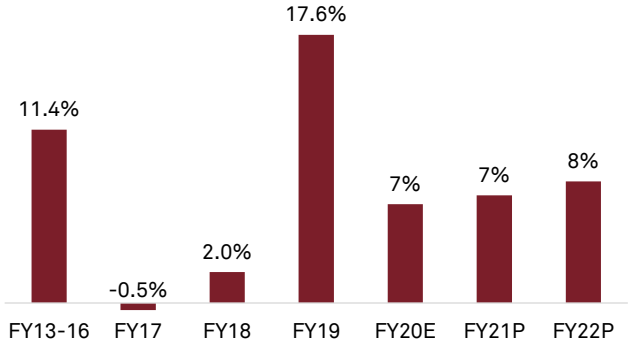


Note: 2019 - (Jan-Aug)*
Source: USFDA, CRISIL Research

Indian players are generally more selective when it comes to ANDA filings and are looking at ANDAs that match their skill sets. Despite this, India's share in total ANDA approvals remained at a record high of 40% in 2018.

Another interesting trend that will drive growth of Indian pharmaceutical companies is a sharper focus on 505(b) (2) filings – a hybrid between an ANDA and a new drug – and the number of approvals thereof. These filings offer the premium-end pricing advantage due to the complex nature of the drugs and limited competition. The 505 (b) (2) approvals were also at an all-time high at 17% in 2018.

Formulation exports (Semi-regulated markets)



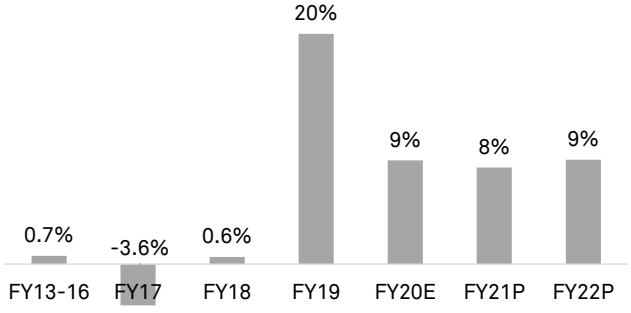
Source: Directorate General of Commercial Intelligence & Statistics (DGCIS), CRISIL Research

Indian exports to semi-regulated markets – where the share of individual countries is much more diffused, with Africa and Russia being the key markets – are also likely to witness good growth at 6-7% as Indian players are looking to penetrate deeper into relatively new markets.

For instance, in the first half of this fiscal, exports to Africa increased ~8%, driven by smaller African markets. Indeed, while Indian formulation exports to the top 10 African markets grew only 2%, exports to the rest of Africa grew 15%.

Chinese disruption to aid bulk drug exports

Bulk drug exports



Source: Directorate General of Commercial Intelligence & Statistics (DGCIS), CRISIL Research

India's exports to China increased by over 50% in the first half of this fiscal. India is clearly benefitting as China cracks down on polluting manufacturing plants and relocates those near cities to inland areas. There have also been concerns around quality with the recent Sartan and Ranitidine contaminations having originated in China. All this bodes well for India and we see some part of the supply chain for bulk drugs shifting to India over the next few years.

Patent expiry opportunity shifts in favour of larger molecules...

We expect patent expiries in the US market to increase in the medium term, especially in the bio-similars space. Also, the share of categories such as injectables and inhalation, which are relatively difficult to manufacture – and hence command higher pricing over simpler oral solids – to go up significantly.

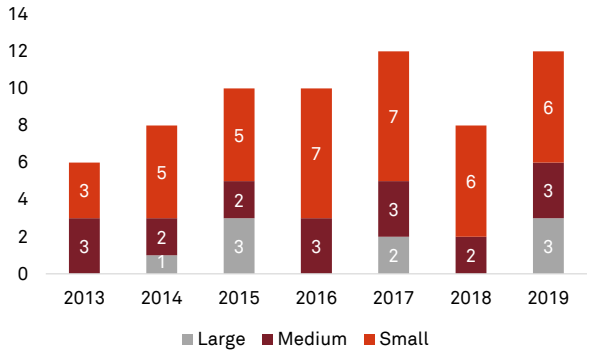
Indian players are capitalising on this opportunity by moving up the product profile and diversifying into manufacturing more complex and limited-competition products. For major Indian pharmaceutical players, the share of complex generic drugs, or specialty drugs, has increased substantially in terms of both volume and value.

...however, investments in biosimilars are limited

A biosimilar molecule requires 30 times the investment needed for a plain generic drug. This is because the manufacturing set up is different, has to be highly sterile, and requires clinical trials unlike chemical generics. Only three players have received approval for biosimilars in the regulated markets. Whether Indian pharmaceuticals will be able to emulate the success of chemical generics in biosimilars remains to be seen.

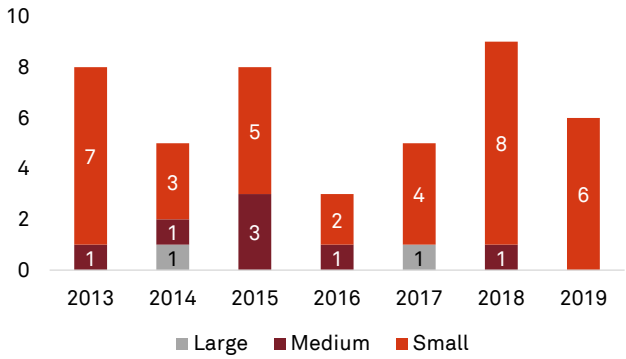
Increase in USFDA scrutiny – launch of 18% ANDA pipeline maybe delayed

Import alerts



USFDA data on calendar year basis
Source: US FDA, CRISIL Research

Warning letters



USFDA data on calendar year basis
Source: US FDA, CRISIL Research

This year has seen sharper scrutiny from the US Food & Drug Administration (USFDA), with warning letters and import alerts issued in the first nine months of 2019 already in excess of the full-year numbers of 2018. In fact, warning letters have more than doubled as of September 2019. However, the impact is more pronounced on smaller players (revenue of less than Rs 5 billion). For instance, in 2019, all import alerts were for smaller players.

A warning letter indicates the agency can initiate enforcement action, including withholding approvals for products/ ANDA involving the affected plant, until remedial action is taken for the products/ practices/ activities the authority deems to be in violation of the Federal Food, Drug, and Cosmetic Act.

In the case of import alerts, on the other hand, exports from the plant to the US are barred.

Such heightened regulatory action can impact especially the large Indian pharmaceutical companies who get as much as ~40% of their sales revenue from the US.

The situation is a throwback to 2015 when these players had seen growth in the US market drop – with a lag effect – as scrutiny intensified. It is likely to happen again because of delayed product launches, while the existing portfolio inherently witnesses a price drop. Of the large pharmaceutical companies' ANDA pipeline, 15% is from the impacted plants. These may, hence, be at risk because of likely delayed launches.

That said, at the industry level, the impact is expected to be limited compared with earlier years as the players have taken steps to minimise the risks with dual product filings from different plants, transfer of high-value products to unaffected plants through USFDA approval, and lower dependence on a single plant. Furthermore, the time of resolution is unlikely to be as prolonged as it was in 2015 because of fewer citations of data integrity issues.

Profitability of large pharma companies to narrow marginally, but remain healthy at 17-18%

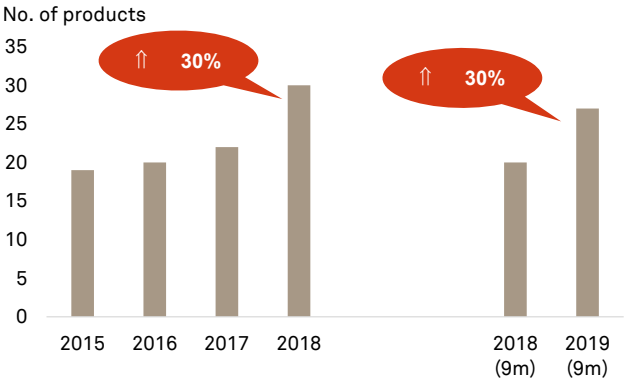
Despite moderation in growth, large pharmaceutical companies have managed to keep their profitability steady in the past few years. And how?

There have been two main factors:

1) Growing share of first-time generics (FTG), which saw a sharp increase of 30% in 2018 and the first nine months of 2019. FTG are those where there is no previous ANDA. This segment would have limited players, and hence, get better pricing at least in the short term.

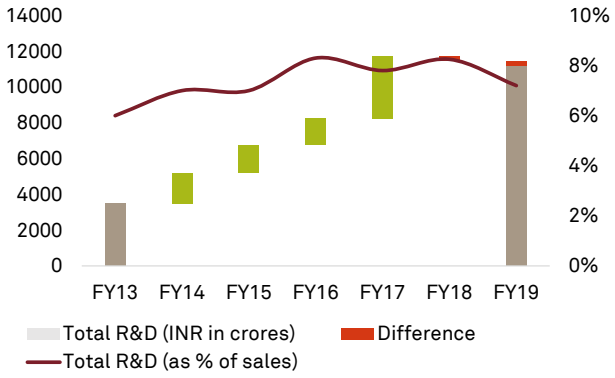
2) Research & development (R&D) expenses were rationalised by 100 basis points (bps) in fiscal 2019 and are likely to remain at this level. Players have cut down on products under R&D that may be commercially unviable. However, there may be some increase in costs given the regulatory impact.

Increase in FTG



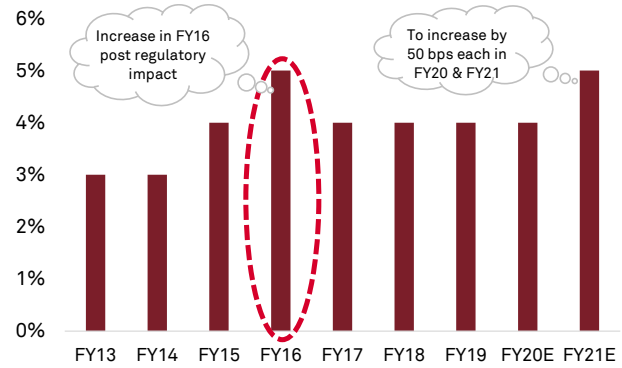
Source: US FDA; Calendar year

Rationalised R&D



Source: CRISIL Ratings; R&D: Research & Development expenses

Legal and consulting expenses



Source: CRISIL Ratings

Operating profitability is expected to remain healthy at 17-18% over fiscal 2010 and 2021. However, margin is expected to be lower by 50 bps over fiscals 2020 and 2021 because of increase in remediation costs for some players. We have considered the legal and consulting expenses as a proxy for the remediation costs. For companies that were impacted by regulatory issues, there has been a 100-200 bps increase in legal and consulting expenses as a percentage of sales in fiscal 2016.

Limited impact of USFDA scrutiny on mid-sized players

Mid-sized players have low presence in the US. Hence, the impact of increase in FDA scrutiny will be limited on them. However, their operating profitability fluctuates as these players are constrained by their scale and limited geographical diversity.

Mid-sized bulk drug players saw sharper

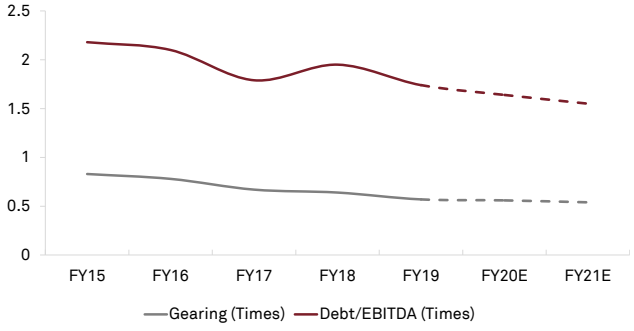
improvement in profitability in fiscal 2019 as they benefitted from product shortfall from China. The supplies situation has stabilised somewhat, and hence, the uptick in bulk drugs profitability is set to reverse in fiscals 2020 and 2021.

Resilient credit profile, backed by strong balance sheet

The capital structure of the sector is expected to remain robust and debt/ earnings before interest, tax, depreciation & amortisation (EBITDA) is expected to improve to about 1.7 times in fiscal 2021 from 1.75 times in fiscal 2019. Even when the sector was hit on multiple fronts in fiscal 2018, the debt metrics had only deteriorated marginally. The financial prudence of the sector is also reflected in increase in cash and bank balance to 13-14% of debt in fiscal 2019 from 8-9% historically, thus giving it headroom for mergers and acquisitions.

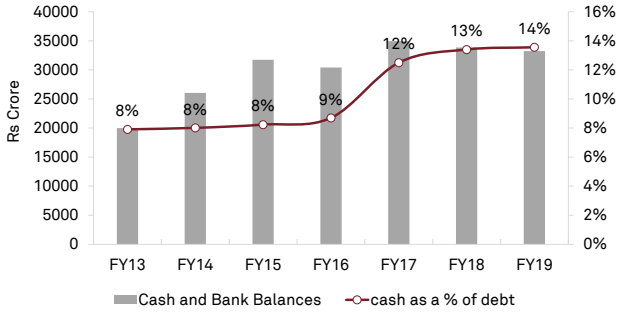
During 2016-2018, pharmaceutical companies invested in setting up facilities for complex generics such as injectables, derma products, oncology products. About 25% of the ANDA pipeline today comprises complex drugs, which would have been negligible five years ago. This investment was done to combat pricing pressures in plain generics. Complex generics are also chemical drugs but are either difficult to make or to market. Hence, returns are expected over a longer horizon. We, therefore, see operating income to gross block declining over fiscals 2020 and 2021 to 2.3 times from 2.4 times in fiscal 2019.

Pharma benefits from strong balance sheet



Source: CRISIL Ratings

Higher cash provides room for inorganic growth



Source: CRISIL Ratings

Large debt-funded acquisition, escalation of USFDA issues, adverse outcome of class action suits are key monitorables

The pharmaceutical industry is characterised by its revenue diversity, healthy profitability, positive cash flows and, hence, a healthy and stable credit risk profile. CRISIL has outstanding ratings on 350 companies with coverage across the spectrum. The sector's credit ratio, that is ratio of upgrades to downgrades, has been over 1 in most years, barring fiscal 2014. In fiscal 2014, the impact of Drug Price Control Order led to higher downgrades.

The median rating of the sector is BBB-, which is better than CRISIL's overall portfolio median rating of BB-. The pharmaceutical industry's debt-weighted median rating is AA as much of the debt is by the top-rated pharmaceutical companies. Some of the monitorables include any large debt-funded acquisition, escalation of USFDA issues or adverse outcome of class action suits on some players.

Their view

Views excerpted from a panel discussion during the CRISIL webinar on the pharmaceuticals sector. The webinar was attended by 266 external participants representing 133 organisations.

The panelists were:

Nitin Parekh
Chief Financial Officer,
Cadila Healthcare Ltd

Ajit Kumar Jain
Joint Managing Director,
IPCA Laboratories Ltd

Sundeep V. Bambolkar
Joint Managing Director
Indoco Remedies Ltd

Kedar Rajadnye
Chief Executive Officer,
Integrace Pvt Ltd

Jan Aushadhi and e-pharmacies no major threat, can co-exist with brands

Jan Aushadhi is aimed at providing affordable medicines to those at the bottom of the pyramid. These stores typically sell generic versions of products, and are more affordable compared with branded products.

However, people who can afford to pay more prefer branded generics, which offer better quality assurance, especially given that our regulatory systems are not comparable to those in developed countries. Branded products of large players, especially those exporting to regulated markets with better quality assurance systems, thus cater to a separate set of customers.

These two can co-exist, and grow.

At the other end, e-pharmacies today account for ~1% of the market. Those that survive over a longer period may attain better supply chain efficiencies.

All the same, conventional distribution is unlikely to be dispensed with entirely. Just as shopkeepers and *kirana* (local grocers) stores have survived despite Amazon and Flipkart selling products online, chemists can coexist with e-pharmacies while competing for market share.

In fact, e-pharmacies should be seen as one more channel of distribution that can become more efficient with gain in scale. Hence, the strategy for chemists should be to use it rather than compete.

Rapid growth of OTCfication to continue in India

In India, over-the-counter, or OTC, is a misnomer as virtually everything is available over the counter.

Globally, there are three success factors for OTCfication – constraints, access, and confidence or self-care ability.

Look at the doctor-patient ratio in India – we have one doctor for 1,500 patients. This is further skewed in states such as Bihar and Uttar Pradesh. This has tremendous implication for patients in terms of waiting and the consultation fee. So people start looking for surrogates in the form of chemists or quacks. This is driving self-care habit across India.

This is the reason why, in the past 5-7 years, when the pharma market grew 6-7%, the OTC and self-care markets witnessed strong double-digit growth.

We see the trend continuing. OTCfication is likely to continue growing rapidly in the next couple of years because people are becoming increasingly aware of their own needs. Knowledge, access and constraints play a role in building the OTC market in the country.

Competition in acute segment intense, but brands have an edge

Brands have been the strength of the pharma industry. Brands instill confidence in doctors about quality of medicines. Also, the regulatory systems in India are still evolving. So, pharma companies that produce branded generics have a responsibility and accountability.

In the acute segment, there is intense competition, and no single company has been able to garner a substantial portion of the market. There are some big companies in the segment, but very few of them are garnering market share, and in a few molecules at best.

Thus, even if there are disruptions in the market, brands are here to stay because of quality consciousness, accountability and responsibility of the manufacturer, and the confidence it gives to the doctors.

NLEM unlikely to take a major step going forward

The Indian pharma industry has been very resilient and defensive. Price control is not new in this space. Going ahead, the industry is unlikely to suffer much because the government is aware of the importance of healthcare. There could be minor measures, but the government is not expected to take major steps on this front.

US is intensifying scrutiny, but players have learnt from mistakes

Pharmaceutical exporters have come under heightened scrutiny from the USFDA in recent quarters.

The scrutiny factors both market and complexity of products. The FDA follows what is called a risk-based site selection model, which considers a plant's compliance history, product record history, last inspection date, nature of the products filed, inherent risks of the product or its manufacturing processes, and complexity of the product or processes. The more the complexity of the product, the more the number of inspections. In fact, there have been many product-specific inspections, too.

However, Indian players recognise what regulators such as the USFDA or the Medicines and Healthcare Products Regulatory Agency of the UK want – including their quality systems, operating procedures, and manuals – and know how they should be maintaining their plants.

These players have learnt from past mistakes and are de-risking themselves by setting up multiple sites that are inspected by the US regulator so that the impact of any adverse action is minimised. Given this, for large players, the impact of an adverse action by the USFDA today would be significantly lower compared with 10 years ago.

US the biggest market, and will remain the mainstay for Indian pharma

Pharmaceutical companies can ill afford to ignore the US market as the consumption of pharmaceuticals there is higher compared with other countries.

For Indian companies, too, the US will remain the mainstay despite the risks inherent in doing business there. They need to maintain the level of compliance through automaton, simplification, adherence to standard operating procedures, etc, in order to remain compliant with the USFDA's rising bar.

Now, as the USFDA turns increasingly cautious, it may be slightly difficult for the player in the short run to simultaneously bear the costs of compliance and of products, remain competitive, and efficiently manage the supply chain to beat competition.

Indian pharma has skillsets to operate in any emerging market

Most emerging markets require brand promotion.

Indian players already have that kind of marketing mindset, unlike their European peers. They know what kind of organisational structures are required, and already have the required skillsets needed to operate in these markets.

Indian companies will continue to do well as they have identified the opportunities and built a large portfolio of products. And the opportunity only gets bigger because some of these markets may not be very attractive for large European players.

Indian formulation players have the business models to enter Chinese market

China has been a tough market from the beginning. However, Indian companies have the business models that can work and make it easy to register products in China.

One such model many Indian companies are contemplating is setting up joint ventures with local companies initially. Later, the Indian company can bring its technology and transfer skills to the table, which will enable the Chinese company to manufacture and market products there.

The other business model involves acquiring a company there. Large Indian companies are sitting on a lot of cash, and are in a comfortable position to acquire a Chinese company and establish a firm foothold there.

Dependence on China for bulk drugs to continue

Bulk drug capacities in China have stabilised after the recent supply disruptions. However, in India, the capacities have not yet evolved and domestic sourcing is still costlier than imports. Therefore, Indian companies' negotiating power, or the ability to actually get a better pricing, won't significantly change in the next few years.

Complex generics, specialty products to boost profitability

Investments in future growth engines – complex generics and specialty products – are expected to yield handsome dividends for Indian companies in the long term.

The size of the earnings from these products and the timing of the payment, though, depend on the business models the companies follow. For instance, some expand gradually – first in India, then to emerging markets, and then to certain regulated markets. Some others take the partnership route. Some go global using their own model, while others follow an in-licensing model.

In the US market, for one, such complex generics and specialty products can boost profitability for Indian companies.

In the context of the recent regulatory clampdowns, the remedial cost may run into a few crores in rupee terms. But considering the size and scale of the US market and the opportunity, it may not be a significant amount. A far bigger cost would be the opportunity lost as product approvals are stopped once a warning letter is issued or other enforcement action is initiated.

Domestically, the decline in prices due to the National Pharmaceutical Pricing Authority regulations has stabilised and players have been maintaining and improving their EBITDA margins in the domestic business well.

Gradual consolidation has been beneficial for Indian companies

There has been a gradual and long-term trend of consolidation in the domestic pharma industry, a highly fragmented sector with a large number of players. In 2004, the top 20 players had a market share of 50-53%. Today, the top 20 have a share of around 64%.

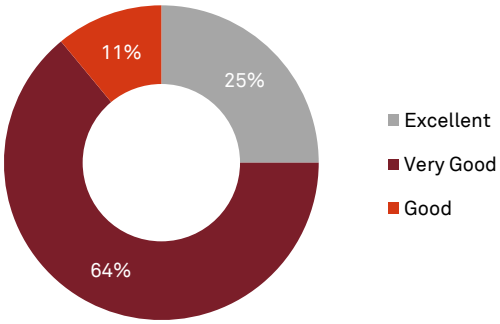
Such consolidation is good because it offers scale benefits and provides size. Increasingly, companies are also realising that it makes sense to consolidate on a few therapies and start building credible leadership.

Poll view

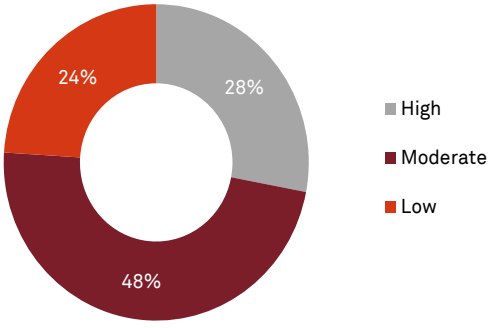
Results of the survey held during the CRISIL webinar on the pharmaceuticals sector

Based on responses from over 73 participants

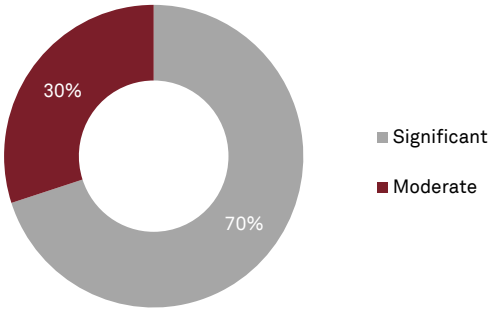
Please share your feedback on the overall session, on a scale of 1 to 5, 5 being the highest and 1 being the lowest.



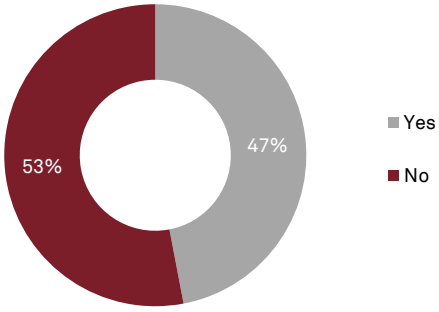
How do you see the impact of Jan Aushadi and NLEM on domestic industry growth?



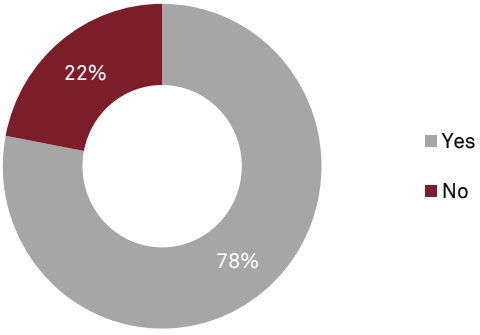
How do you see impact of US FDA's heightened scrutiny on the players future product approvals and growth?



Do you see Indian pharma companies having a meaningful presence in the recently opened up China market?



Do you believe Indian pharma companies will match the success of plain generics in complex generics as well over medium term?



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