

# MANAGEMENT DISCUSSION AND ANALYSIS

## INDUSTRY OVERVIEW

### World

Overall, global use of medicine has accelerated in the last decade, in areas of high priority, including the treatment of non-communicable diseases, which were responsible for 71% of deaths worldwide in 2016. This indicated the value placed on medicines in addressing the needs of patients, prescribers and health systems the world over.

The rate of increase in medicine use is currently outpacing population and economic growth, implying more patients are receiving treatment. This expansion has largely occurred in pharmerging markets (countries

with per capita income below US\$ 30,000 per year and pharmaceutical spending growth above US\$ 1 billion over five years). However, in many pharmerging countries, such as India, China and Mexico, greater access and/or availability is still needed to reach more patients.

Success in closing the gap in per capita use of medicines will differ by country; increased use will primarily be in pharmerging markets, while developed markets' volumes will remain more stable. Developed markets will continue to use more original branded and specialty medicines per capita while pharmerging markets will use more non-original brands, generics and over the counter products.

## GLOBAL MEDICINE USE 2009-19

Exhibit 1: Global Medicine Defined Daily Doses in Billions 2009-2019

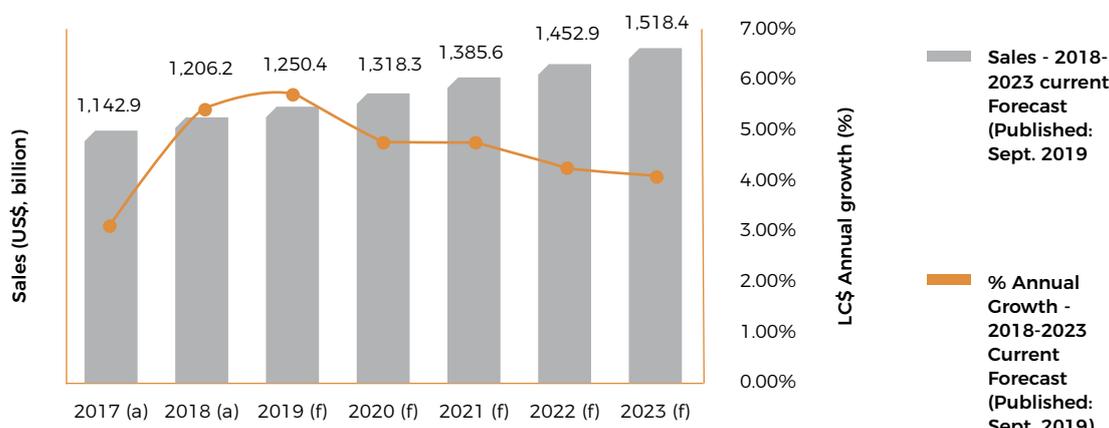


Source: IQVIA Market Prognosis Global, Sept. 2019

Notes: Chart represents IQVIA Institute estimates of global defined daily doses (DDD). These estimates are based on IQVIA audited data and application of WHO-DDD factors in IQVIA MIDAS as well as additional DDD calculation assumptions developed by the IQVIA Institute (see Methodology).

## GLOBAL MEDICINE SPENDING AND GROWTH 2017-24

Pharmaceutical Market Forecast - Overview



Source: IQVIA™ Market Prognosis Global, September 2019

**KEY EMERGING TRENDS**

- In 2019, patients globally received an estimated 1.8 trillion days of therapy, an average of 234 per person. This is a 16% rise over 2014 and corresponds to a 3% CAGR, slowing from a 4% rate seen during 2009-2014.
- Most of the medicine use is in pharmerging markets, which have large populations, but have per capita rates of use still markedly lower than in higher income countries.
- In terms of invoice spending on medicines, the global pharmaceutical market size in 2019 was pegged at US\$ 1.25 trillion. Spending is expected to exceed US\$ 1.57 trillion by 2024, growing at a CAGR of 3-6%.
- The key drivers will continue to be the US and the pharmerging markets – US for the launch of high-end specialty medicines and pharmerging markets for their volume play. That said, spending is likely to be offset by overall pricing pressure and patent expiry in the developed markets.
- Medicines in 2020 will include a vast array of treatments, ranging from those that provide symptom relief available without a prescription to lifesaving genetically personalised therapies unique to a single patient.
- The adoption of innovative specialty products is driven by oncology and autoimmune therapies. Developed markets spent a combined US\$ 354 billion on specialty products in 2019, with 30% of that on oncology products. Oncology spending is expected to remain the largest contributor to specialty spending, with a projected increase of 51% through 2024.
- New brands will contribute US\$ 165 billion in spending growth through 2024, up from US\$ 126 billion in the past five years.
- Brands' Loss of Exclusivity (LOE) is projected to have a US\$ 139 billion impact on their sales from 2020-2024, compared to the US\$ 107 billion impact seen during 2014-2019.
- Spending in the US in 2019 is estimated at US\$ 510.3 billion and will grow at 3-6% CAGR over the next five years, to reach US\$ 985-1,015 billion.
- Having crossed an estimated US\$ 141.6 billion in 2019, China spending on medicines will grow at 5-8% CAGR over the next five years to reach US\$ 165-195 billion.

Source: <https://pharmaceuticalcommerce.com/business-and-finance/global-pharma-spending-will-hit-1-5-trillion-in-2023-says-iquia/>; <https://www.iquia.com/insights/the-iquia-institute/reports/global-medicine-spending-and-usage-trends>

**IMPLICATIONS FOR THE CONTRACT RESEARCH AND MANUFACTURING INDUSTRY**

- With increasing privatisation of clinical trials, there has been an increase in the outsourcing of research processes in developing regions, such as China and India.
- Growing investments by several pharmaceutical and biopharmaceutical drugs manufacturing companies are also supporting the growth of the contract research market in the region. As part of its five-year Research, Innovation, and Enterprise 2020 plan, the Singaporean government has committed to invest nearly US\$ 2.4 billion, in advancing manufacturing and engineering in the pharmaceutical market.
- In January 2019, Lambda, headquartered in India, announced the acquisition of US-based Novum Pharmaceutical Research Services, in a move to increase its presence in the US.
- The contract manufacturing market in Japan is still in its nascent stages. However, the country witnessed incremental growth over the past few years. The Japanese CMO market witnessed a growth of about 30%, following the recognition to separate manufacturing and sales by the Pharmaceutical Affairs Act.

Source: <https://www.globenewswire.com/news-release/2020/04/14/2015926/0/en/Pharmaceutical-Contract-Manufacturing-CMO-Market-Growth-Trends-and-Forecast-2020-2025.html>

**IMPACT OF COVID-19 ON GLOBAL ECONOMY (AS OF MARCH 2020)**

- The risk of global recession in 2020 is extremely high, as nations shutdown economic activity to limit the spread of the disease. Most cases are now outside of China.
- As production is curtailed around the world, firms may not have necessary inputs and supply.
- The outbreak has disrupted supply chains around the world and curtailed energy and commodity demand.
- Governments are learning by doing, when addressing the economic risks of closing the economy and asking citizens to engage in social distancing.
- China's connectivity to the world can be analysed by its dominant place in trade, supply chain and shipping/transport linkages.
- The impact on the US economy is likely to be high due to lower consumption and weaker business investments.

**REAL GDP GROWTH RATES %**

Top 10 countries by GDP)		2017	2018	2019
1	U.S.	2.4	2.9	2.3
2	China	6.9	6.7	6.1
3	Japan	2.2	0.3	0.7
4	Germany	2.8	1.5	0.6
5	U.K.	1.9	1.3	1.4
6	France	2.4	1.7	1.3
7	India	6.5	6.7	5.3
8	Italy	1.7	0.7	0.3
9	Brazil	1.3	1.3	1.1
10	Canada	3.2	2.0	1.6

Notes: Annual growth rate y/y%

Source: Respective countries National Statistics Office, Haver Analytics, KPMG's analysis 2020 based on secondary research

Source: <https://home.kpmg/content/dam/kpmg/in/pdf/2020/04/potential-impact-of-covid-19-on-the-Indian-economy.pdf>; <https://assets.kpmg/content/dam/kpmg/cl/pdf/2020-03-kpmg-chile-advisory-coronavirus-mapping.pdf>

**IMPACT OF COVID-19 ON CHEMICAL INDUSTRIES**

- Industries which are dependent on migrant labour will face significant challenges on restart.
- Export demand continues to be strong for key players, however logistics is a challenge.
- Domestic demand continues to be low except for essentials.
- Potential restructuring of workforce due to lack of working capital.
- Capital and R&D investments are being deferred indefinitely.

Source: BCG COVID-19 discussion with ICC leadership (April 22, 2020)

**BUSINESS IN A POST-COVID WORLD**

- Consumption and purchase patterns will change dramatically, leaning towards more online deliveries than offline buying
- Companies will constantly evaluate cost structures and M&A opportunities will increase as valuations decline
- Disruptions in trade are expected, with a rise in geo-political tensions
- Data will be the new currency of business
- Companies will shift to new models of working that enable remote working and implement social distancing measures at the workplace

Source: BCG COVID-19 discussion with ICC leadership (April 22, 2020)

**INDIA**

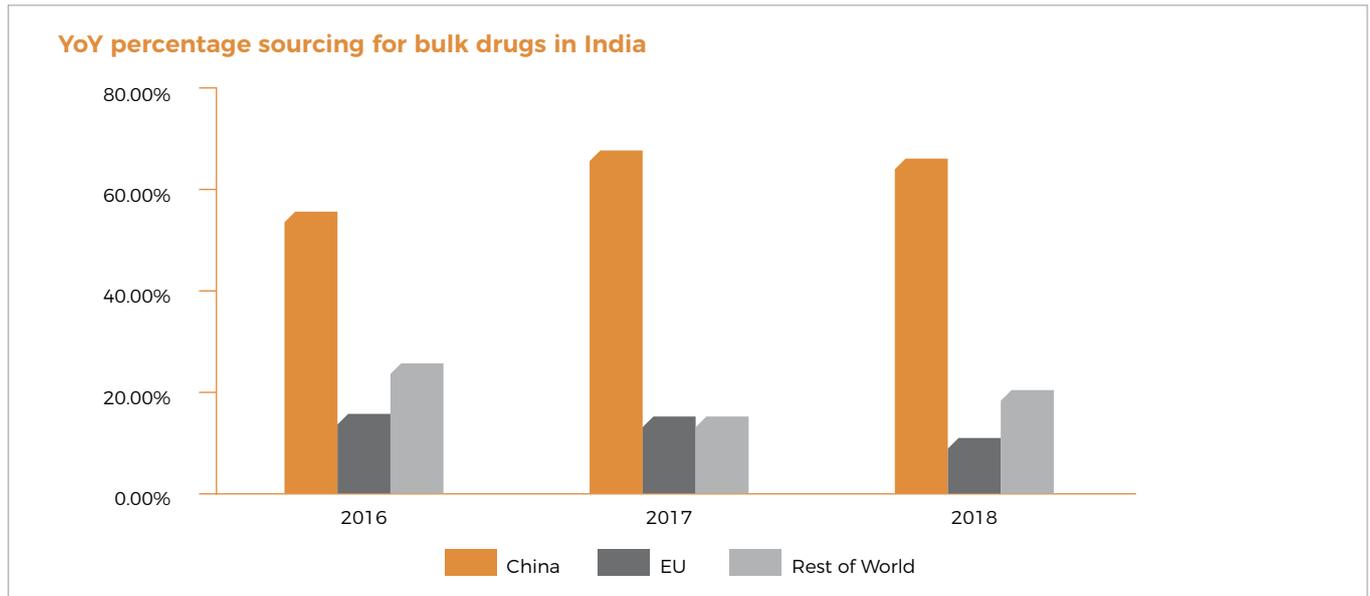
The Indian pharmaceutical industry is the third largest by volume and 14th largest by value in the world, being valued at US\$ 40 billion in FY 2018-19.

Indian companies have dependence of as low as 20% and as high as 80% on Chinese imports, which includes Active Pharmaceutical Ingredients (APIs) and key intermediates, which are converted into generics and FDF in India, for exports to more than 200 countries. This is on account of the following reasons.

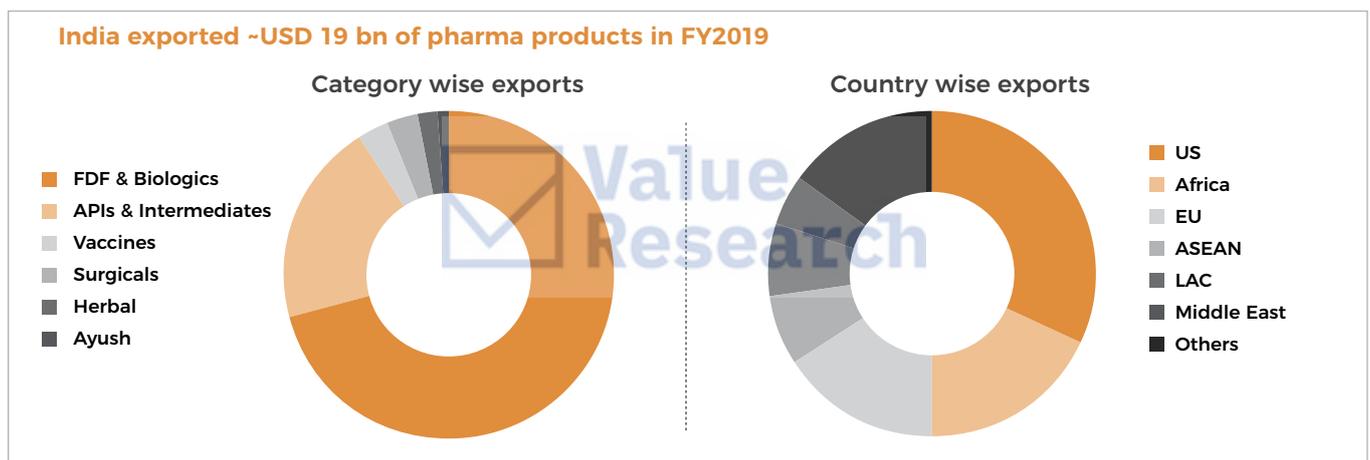
- Lower operating cost through economies of scale as well as greater availability of cheap electricity and water
- Favourable cold climate and larger capacities of fermentation boilers
- Less stringent pollution control norms (which are now changing) and developed infrastructure
- While Indian players have the requisite capabilities, they have been more focused on value-added products.

Apart from mainland China, there are other sources like the US, Italy and Singapore from which bulk drugs can be imported during contingencies.

SOURCING OF BULK DRUGS BY INDIA



INSIGHT INTO INDIA'S PHARMACEUTICAL EXPORTS



COVID-19 IMPLICATIONS FOR INDIAN PHARMACEUTICAL COMPANIES

- Indian pharmaceutical companies will enter prescheduled delivery contracts with buyers at pre-determined prices.
- Higher cost of procuring raw materials will hit profitability margins and return on capital employed (ROCE). Price of key ingredients like paracetamol and montelukast sodium (an anti-asthma drug) has almost doubled.
- With restricted or low supply, the volatility and price of raw materials will increase, and suppliers will prefer favourable payment terms like cash advances, instead of LC/credit terms – thus adding stress on the liquidity position of buyers
- Most of the small- and medium-sized pharmaceutical companies do not have sufficient working capital to address these issues, which may lead to temporary manufacturing shutdowns.
- Companies may face difficulties in servicing their working capital loans, increasing the risk of default.
- With the Government of India restricting exports of 26 drugs from India, the following issues are expected to also emerge:
  - Contracts mandate supply as per committed timelines. Non-supply of one item can lead to cancellation of entire order by the customer.
  - Non-supply can also lead to blacklisting of companies and attract huge financial penalties.
  - Given the disruption to supply, Indian manufacturers may pass on consequent price increases to the customer.
- The price differential between India and China for intermediates was ~30-40%. However, the prices have started to increase due to shortage with effect

expected to extend to the second quarter of fiscal 2020, if the crisis is not mitigated.

- Most Indian companies which depend on China for intermediates and APIs have balance inventories for 1-2 months. Their operations may be severely impacted if the situation persists
- 57 APIs of crucial antibiotics (Azithromycin and Amoxicillin), vitamins (B12, B6) and hormones (progesterone) could go out of stock. The Government has imposed export restrictions to ensure their availability in domestic market.

Source: <https://home.kpmg/content/dam/kpmg/in/pdf/2020/04/potential-impact-of-covid-19-on-the-Indian-economy.pdf>; <https://assets.kpmg/content/dam/kpmg/cl/pdf/2020-03-kpmg-chile-advisory-coronavirus-mapping.pdf>

## ACTIVE PHARMACEUTICAL INGREDIENTS

The global API market is expected to reach US\$ 232 billion in 2024, growing at 6% CAGR. Some of the key market drivers include the rising prevalence of infectious diseases, cardiovascular conditions and other chronic disorders. genetic disorders are also significantly upping the use of biologicals and biosimilars, which are low-cost options.

The API market has traditionally been dominated by anti-infectives and diabetes, cardiovascular, analgesics and pain management drugs. That said, the current R&D trends indicate that the demand is shifting toward the development of complex APIs used in novel formulations, pursuing niche therapeutic areas.

Several drugs are in the pipeline to develop treatments for cancer, autoimmune disorders and metabolic diseases. Manufacturers are venturing into the development of highly potent API and specialty APIs, to cater to the rising demand for these products.

Source: <https://www.marketwatch.com/press-release/active-pharmaceutical-ingredient-api-market-global-markets-to-2024-2020-04-23>;  
<https://www.marketwatch.com/press-release/active-pharmaceutical-ingredients-api-market-size-share-2020global-industry-analysis-with-current-trends-future-growth-competition-strategies-application-region-and-forecast-to-2024-2020-04-23>

## ABOUT SOLARA

Solara Active Pharma Sciences (Solara) is a research-centric and customer-driven API manufacturer, with a footprint across 75+ countries. We benefit from a legacy of over three decades and trace our origins to the union of the demerged API business of Strides Pharma Science Limited (formerly known as Strides Shasun Limited) and the human API business of Sequent Scientific Limited into a separate entity. Our equity shares were subsequently listed on the National Stock Exchange (NSE) and the Bombay Stock Exchange (BSE) on June 27, 2018.

We have a team of 200+ scientists working at our two dedicated R&D centres in Bangalore and Chennai, and six API manufacturing facilities in Ambarnath, Cuddalore, Mangalore, Mysore, Puducherry and Visakhapatnam with a capacity of over 2,000 kilo litres. We received recognition from Department of Scientific and Industrial Research (DSIR) for the two R&D centres, while each of our API facilities is certified with global approvals.

## GROWTH PILLARS

### API and Intermediates

We develop and produce generics and commercial APIs across niche therapeutic categories, with proven capabilities in complex products like APIs based on polymers and for injectables. Our existing portfolio includes 80+ commercial APIs and 25+ APIs under development across high-value product segments, such as anthelmintic, anti-malarials, beta blockers, muscle relaxants, novel oral anti-coagulants, anti-infective and other niche segments.

We are well positioned in the API space with its global presence and leadership position in top 10 APIs. We continue to invest in our two R&D centres for new products and support market expansion of our existing APIs along with cost improvement programmes. We have filed four new DMFs in 2019-20, taking our total new DMF count in the last two fiscals to 12, with different phases of launch over the next few years. We also extended eight APIs across 13 new markets. Enabled by this combination of launches of new products and new markets, the API business will deliver on our ambition to emerge as one of the top 10 pure-play API companies globally.

### Contract Research and Manufacturing Services (CRAMS)

We provide differentiated services for APIs, including contract development and manufacturing, analytical services, impurity synthesis and profiling to our customers. Our capabilities in contract development and manufacturing (on a full-time basis) span the entire value chain of a new chemical entity, from pre-clinical to commercial phases, from lead analogues, building blocks, reference studies and custom synthesis for pilot campaigns to clinical supply and so on.

CRAMS today accounts for 10% of our total revenue pie. The success of CRAMS depends on quality, safety compliance and supply chain reliability. We have earmarked funds, raised through equity subscription from promoters and the TPG group, for inorganic acquisition. This will enhance our growth in this segment, while we continue to build business value the organic way. During the year, we bid on new proposals, out of which we expect to win some new business in 2020-21. We expect new opportunities to arise for the Indian pharmaceutical sector operating in this space, to mitigate risk of over-dependence on China.

**Outlook**

We believe COVID-19 has opened up opportunities for the Indian pharmaceutical sector. Excess dependence on China has led to dual source qualification, while stocking of essential medicines has led to increase demand in short to medium term. Solara has initiated efforts to backward integrate the Key Starting Materials (KSMs) of its key APIs as well as collaborate with local manufacturers to reduce its dependence on China. While there are cost differences between India and China, the deciding factor in a post-COVID-19 world will be supply chain reliability.

Our overarching objective remains to bridge the industry gap by delivering value-based products that cater to customer requirements. And we are poised to grow as a leading 'global pure-play API company' with focus on highly compliant business operations and customer advocacy.

**FINANCIAL PERFORMANCE**

**Consolidated profit and loss metrics (₹ in Crores)**

Particulars	FY 2019-20	FY 2018-19	Change
Revenue	1,349.27	1,399.06	-4%
Operating EBITDA	328.04	286.24	15%
Operating EBITDA margin	24.3%	20.5%	
R&D Cost	(46.96)	(44.85)	5%
Exchange gain/(loss)	(1.74)	(9.81)	-82%
EBITDA*	279.34	231.58	21%
EBITDA margins	20.7%	16.6%	

\*Excludes interest income

**HUMAN ASSETS**

Our workforce strength numbers at 2,300+ as on March 31, 2020. An experienced senior management team helps us in effectively pursuing our growth strategies. Our teams' rich domain expertise as well as deep motivation to stay ahead of industry trends and market changes is critical to helping us translate on-ground opportunities into tangible and intangible value for stakeholders.

**RISK MITIGATION**

Business success requires both opportunities to be recognised and associated risks to be identified and evaluated. Our risk mitigation strategy is focused on ensuring the Company is profitable and sustainable in the long run. We aim to increase risk awareness and establish a value-led risk culture at all levels. Risks are therefore analysed transparently and systematically incorporated into business decisions.

Below we outline the risks that affect our business in the near term and briefly capture the measures to mitigate the same.

Principal risk	What it means	How we mitigate it
External environment risk	Volatility in India's macroeconomic indicators, adverse movement in global market forces and geopolitical events can have a material consequence on the business.	<ul style="list-style-type: none"> <li>Steady investments to enhance supply chain resilience</li> <li>Diverse segments and geographies that reduce overdependence on any one product or market</li> </ul>
Operational risk	Any manufacturing or quality control problems may damage our reputation which could adversely affect our business, results of operations and financial conditions	<ul style="list-style-type: none"> <li>Consistent track record of approvals from all leading global regulatory authorities</li> <li>Regular inspection of production facilities for compliance vis-à-vis both quality as well as environmental aspects</li> <li>Routine upgradation of audit procedures to comply with any changes in international regulatory requirements</li> <li>Regular review mechanism to enhance optimum utilisation of operational facilities</li> </ul>
Research and Development risk	Risk from the lack of timely development or commercialisation of new APIs	<ul style="list-style-type: none"> <li>R&amp;D efforts are dedicated towards developing new products and expanding product portfolio</li> <li>Product selection is based on three buckets to reduce dependence on one approach</li> </ul>
Suppliers risk	Our profitability and margins can be affected in case there is significant change in raw material prices and operational cost, among other factors	<ul style="list-style-type: none"> <li>Long-term contracts with approved vendors (domestic and global) after stringent vendor audit ensure supply of raw materials</li> <li>Local manufacturing of key intermediates</li> <li>Cost improvement programmes for key APIs to maintain margins due to increase in raw material prices</li> </ul>

Principal risk	What it means	How we mitigate it
Competition risk	The pharmaceutical industry is intensely competitive and our inability to compete in real time may adversely affect our business, results of operations and financial condition.	<ul style="list-style-type: none"> <li>Continued elevation and evaluation of business in line with global standards</li> <li>In-house teams that conduct cost improvement programmes</li> <li>Geography expansion of APIs</li> <li>Portfolio restructuring to ensure better utilisation of capacity</li> </ul>
Safety risk	Any untoward accidents may damage our reputation which could adversely affect our business, results of operations and financial conditions	<ul style="list-style-type: none"> <li>Regular inspection of facilities for compliance vis-à-vis both safety as well as environmental aspects</li> <li>Implementation of risk-based process safety management systems</li> <li>Identification of high risks and implementing precautionary measures through Risk Buckets program</li> <li>Regular review of safety performance to monitor the progress against safety improvement plans of operational facilities</li> <li>Implementation of Corrective Action Prevent Action (CAPA) of external third-party audit findings</li> </ul>

## INTERNAL CONTROLS

The Internal Auditors and Senior Management continuously evaluate the internal controls. Solara has also invested in advanced infrastructure that ensures all-round control over business processes and practices. The internal control system provides reasonable assurance about the integrity and reliability of the financial statements. Further, we have a strong in-house audit programme, which regularly encompasses various operations. The Audit Committee reviews internal audit observations on a regular basis.

