Management Discussion and Analysis

Economic review

Global economy

The global economy posted a strong growth in 2017. According to the International Monetary Fund (IMF), the upward trend has been the biggest growth upsurge witnessed ever since 2010. Improved investments and manufacturing output contributed to the growth of developed economies. Similarly, key emerging markets and developing economies, including China and India, posted strong momentum.

The US economy expanded at a strong rate in Q1, led by robust export and investment growth. Subsequently, from the next quarter onwards, the upsurge was further fortified by recovery in household spending, healthy labour market and tax cuts. Given the strong recovery in 2017, the IMF has revised its growth forecast for the US. The US economy is expected to gain from higher external demand and the macroeconomic impact of the tax reform.

The UK has experienced some weakening due to lower-than-expected growth in the first two quarters. The same is reflected in its growth projections; IMF estimated 1.8% decline in 2017. The slowdown is driven by softer growth in private consumption, currency depreciation and the looming uncertainty over its new economic relationship with the European Union (EU).

China, meanwhile, continues to defy any sign of an economic slowdown, as household spending remains strong and factories benefit from robust global demand. China is steadily progressing and transitioning towards a more sustainable economic model, with services and private consumption taking the helm of economic growth.

The growth forecast for advanced economies in 2018 and 2019 has also been revised by the IMF. The US growth forecast has been raised from 2.3% to 2.7% in 2018 and from 1.9% to 2.5% in 2019. In emerging and developing Europe, activity in 2018 and 2019 is projected to remain stronger than previously anticipated. Moreover, the advanced Asian economies are particularly expected to deliver stronger. Emerging and developing Asia is expected to grow at around 6.5% in 2018–19, broadly at the same pace as in 2017.

Global growth pattern (%)

	2017	2018 (P)	2019 (P)
World Output	3.8	3.9	3.9
Advanced Economies	2.3	2.5	2.5
United States	2.3	2.9	2.7
Euro Area	2.3	2.4	2.0
Japan	1.7	1.2	0.9
United Kingdom	1.8	1.6	1.5
Other Advanced Economies*	2.7	2.7	2.6
Emerging and Developing Economies	4.8	4.9	5.1
China	6.9	6.6	6.4
Brazil	1.0	2.3	2.5

P: Projections *(Excludes the G7 – Canada, France, Germany, Italy, Japan, United Kingdom, United States and euro area countries)
(Source: International Monetary Fund)

Indian economy

India's economy picked up pace in FY 2017-18 and the gross domestic product growth stood at 6.7%. Transformational policies like Goods and Services Tax (GST) and structural decisions like demonetisation have improved investments and supported economic growth.

With an improving business ecosystem, stable macro-economic indicators and liberal FDI regime, foreign capital inflow has provided impetus to the domestic economy. According to World Bank's Global Economic Prospects Report, India's GDP is expected to rise to 7.4% in 2018-19 and 7.8% in 2019-20.

Key contributors to India's growth story

Long-term growth through structural changes

The Government has undertaken several reforms for promoting inclusive growth, improving business climate, widening the tax base and addressing indigenous challenges for the Indian economy.

Ease of doing business

India undertook more than 7,000 steps at the Centre and State-level, to simplify business regime and attract foreign investments. India jumped a record 30 places in World Bank's Ease of Doing Business Report, 2018 to achieve the 100th rank. The country was one of the top performers in the report for the year 2017 and was credited with registering the highest ever jump.

Growing impetus to manufacturing

With a vision to increase manufacturing output's share in GDP to 25% by 2025, the 'Make in India' programme was launched by the Indian Government. Under the programme, 25 sectors have been identified, which could help in propelling India's manufacturing industry.

Opening avenues for foreign investments

In 2016, the Indian Government liberalised FDI policies across defence, pharmaceuticals, civil aviation, food trading, broadcasting services, etc. In addition, in the 2017 Union Budget, the Government announced plans to abolish the Foreign Investment Promotion Board (FIPB), to further simplify the bureaucratic processes for foreign investors.

Global pharmaceutical industry

Global healthcare spending is projected to increase at an annual rate of 4.1% in 2017-2021, up from just 1.3% in 2012-2016.

Combined healthcare spending in the world's major regions is expected to reach $8.7 trillion by 2020, up from $7 trillion in 2015. Ageing and increasing populations, developing market expansion, advances in medical treatments and rising labour costs will drive spending growth. (Source: 2018 Global health care outlook: The evolution of smart health care by Deloitte)

Global market review

US

The US pharma market reported pharmaceutical sales of about $453 billion. In other words, the industry witnessed a slight growth of 2.2% over the last year, despite continuing public scrutiny of drug pricing.

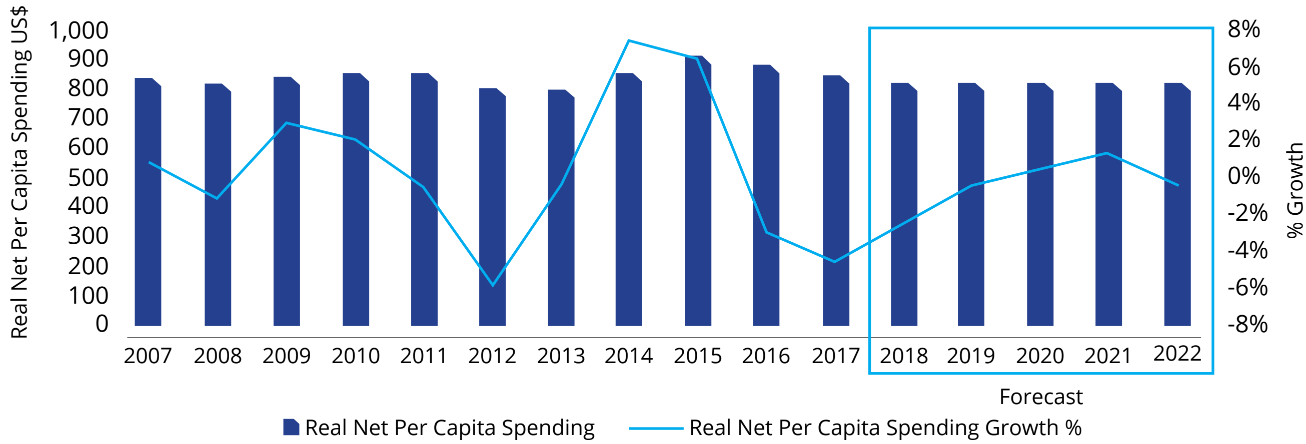
In the US, there is significant pricing pressure driven by payer consolidation, restrictive reimbursement policies and cost control tools such as exclusionary formularies and price protection clauses. In addition, patients are seeing changes in the design of their health plan benefits and may experience variation, including increases, in both premiums and out-of-pocket payments for their branded medications.

Outlook

According to IQVIA Market Prognosis, real net per capita spending on medicines in the US will decline in 2018 and continue almost unchanged at almost $800 per person through 2022.

The combination of rising off-invoice discounts and rebates, slowing overall medicine spending growth and a strong economy resulted in the aggregate adjustment of normalised medicine spending to decline in three successive years following the peak in 2015 and this is estimated to continue unchanged upto 2022.

US real net per capita drug spending and growth



Note: Real medicine spending reflected in 2009 US$.
Source: IQVIA Market Prognosis Sep 2017; US Census Bureau; US Bureau of Economic Analysis (BEA), Dec 2017; IQVIA Institute, Feb 2018

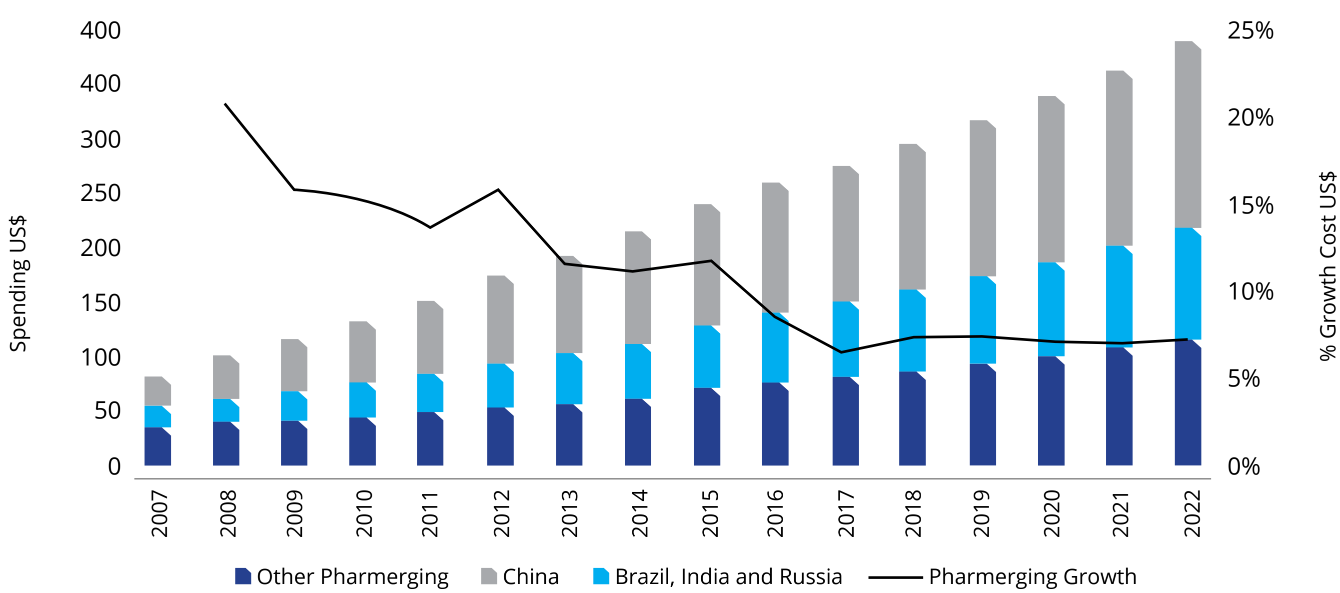
Pharmerging markets

Pharmerging markets' contribution to the share of global medicine spending has risen from 13% in 2007 to 24% in 2017. In other words, it has increased from $81 billion in 2007 to $270 billion in 2017, with an average rate of 12.8%, more than twice the rate of global growth.

This growth has been driven both by governments' efforts to expand access to healthcare for their people and by the investments of multinational manufacturers who expanded operations, acquired or partnered with local companies and significantly expanded their revenues from these countries.

The majority of medicine use and spending in these countries continues to be for generic medicines and payment continues to be predominately out of pocket for consumers, ultimately tying medicine spending growth to economic growth of their overall economies.

Pharmerging spending and growth



Source: IQVIA Market Prognosis, Sep 2017

Outlook

Pharmerging markets will be driven by volume changes and the use of generics and will grow by 7-8% in 2018, down from the 9.7% CAGR over the prior five years and marking the third year that growth will be less than 10%.

The pharmerging markets are projected to grow by 6-9% to $345-375 billion by 2022. China is the largest pharmerging country but will grow by only 5-8% over the next five years to reach $145-175 billion in 2022.

India

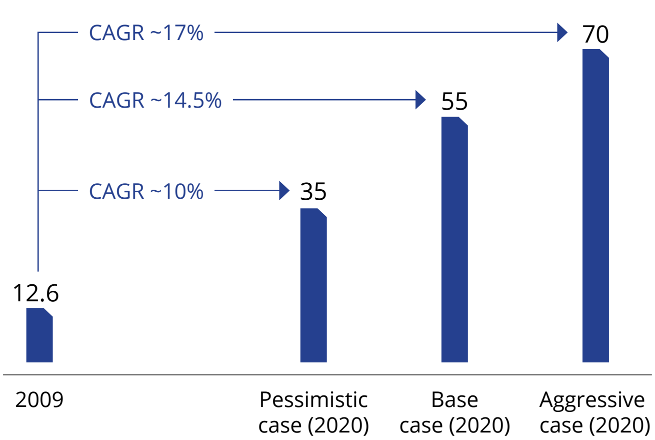
During the year, India saw a record FDI of $747 million in the healthcare sector. However, new drugs under Drug Price Control Order (DPCO), a price cap on stents and implants, and the procedure and cases of licenses being cancelled adversely affected the sector.

Moreover, India continues to face the challenge of a low spend on healthcare (around 4.5% of the country's GDP vis-a-vis the world average of around 9%), around 62% of which is still funded out of pocket.

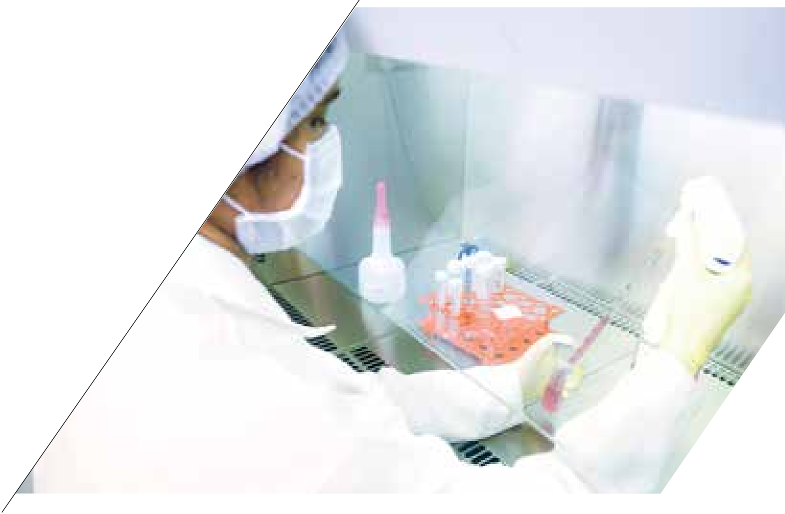
According to IQVIA Institute, medicine spending in India is expected to grow by 9-12% in the next five years compared to China's 5-8%. Spending in India will continue to grow enough to have it rise into the top 10 countries in 2018 and to the ninth largest in 2019 through 2022.

The domestic industry contributes to 20% of global generics exports, making India the largest provider of generic medicines, globally. By 2020, the overall industry revenue is expected to reach $55 billion.

Projected size of the Indian pharma market ($ in billion)



Source: India Pharma 2020: Propelling access and acceptance by McKinsey



The Government has been actively focusing on policies to provide impetus to the sector. In the Budget 2018-19, the Finance Minister announced the launch of a flagship National Health Protection Scheme (NHPS) to cover over 10 crore poor and vulnerable families. The centre intends to provide coverage of upto ₹5 lakh per family per year for secondary and tertiary care hospitalisation.

Business overview

NATCO Pharma (NATCO) is an India-based vertically integrated pharmaceutical company with a presence in multiple specialty therapeutic segments. Over the years, NATCO has developed an innate ability to deliver molecules, mostly with limited competition when launched. The Company manufactures specialty medicines and niche pharmaceutical products.

In the pharmaceutical value chain, our business operations are classified into two categories: Formulations and API. Our formulations business is categorised into a) domestic business; and b) export business, primarily to the US, Canada and RoW. We manufacture and use own APIs at our facilities as well as sell APIs to domestic and international markets.

According to IQVIA Institute, medicine spending in India is expected to grow by 9-12% in the next five years and will continue to grow to become the ninth largest spending country in the world.

Domestic formulations

India is a key market and we derived ₹7,202 million in FY 2017-18 from our domestic formulations business. In India, our products are primarily focused on the oncology and gastro hepatology therapeutic areas. We also develop, market and sell products in areas such as orthopaedics, gastroenterology, critical care, central nervous system and Cardiology and Diabetology therapeutic areas.

Oncology

We are one of the major pharmaceutical companies in the domestic oncology segment. As of 31 March, 2018, we had a portfolio of 30 products catering to various oncology diseases, including breast, brain, bone, lung and ovarian cancer. Our oncology product portfolio in India has six key brands, i.e. Veenat, Lenalid, Erlonat, Geftinat, Sorafenat and Bortenat, each of which has annual sales value of more than ₹100 million for FY 2017-18. We have increased our product range, starting from six products in 2004 to 30 active products as of 31 March, 2018.

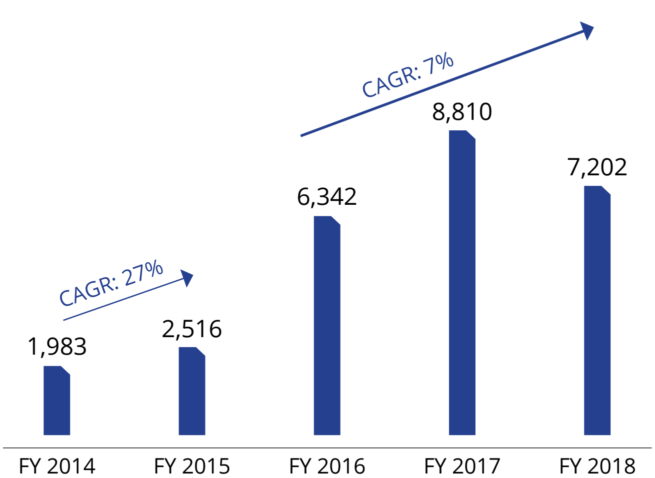
Pharma specialties

Our pharma specialties division deals with products related to gastroenterology, orthopaedics and critical care. The orthopaedics range covers all the important bisphosphonates, including the oral and injectable drugs. In gastro hepatology therapeutic area, we have the leading market share in Hepatitis C drugs in India.

Cardiology and Diabetology

We have diversified our product portfolio by launching products in cardiology and diabetology (CnD) therapeutic areas in 2017. In this division, our focus is to launch niche products with high entry barriers. We recently launched generic Argatroban and Dabigatran to cater to patients with thrombosis syndrome.

Domestic formulation sales* (₹ in million)



*Includes third-party sales

International formulations

We manufacture generic formulation products for sale outside India as well. This comprises exports plus formulation sales generated out of our subsidiaries. Our primary markets are (a) the US; (b) RoW, including Asia and Europe. Our focus is primarily on niche therapeutic areas and complex products in these markets. Our core strength lies in developing and manufacturing pharmaceutical products in-house, which we primarily commercialise either through our relationships with multi-national pharmaceutical companies or through our distribution network.

US formulation exports business

We aim to handle differentiated products and focus our pipeline on molecules with complex chemistry, which would have fewer players to compete against. We seek to leverage our experience and R&D capabilities to assist in regulatory filings and approvals. As of 31 March, 2018,

we had 29 approved ANDAs and 16 Para IVs yet to be approved and launched. During FY 2017-18, we launched some high-value products such as Glatiramer Acetate, Liposomal Doxorubicin and Lanthanum Carbonate. Some of the key products in our pipeline as of March 31, 2018 are:

	Key Brand	Molecule	Therapeutic Segment/ Indication	Para IV
To Be Launched	Gilenya	Fingolimod	Multiple Sclerosis	✓
	Treanda	Bendamustine	Cancer, CLL	✓
	Nexavar	Sorafenib	Liver, Kidney Cancer	✓
	Tracleer	Bosentan	Hypertension	Para III
	Revlimid[1]	Lenalidomide	Multiple Myeloma	✓
	Afinitor	Everolimus (higher strength)	Kidney Cancer	✓
	Zytiga	Abiraterone	Prostate Cancer	✓
	Tarceva	Erlotinib	NSCLC, Pancreatic Cancer	✓
	Kyprolis	Carfilzomib	Multiple Myeloma	✓
	Aubagio	Teriflunomide	Multiple Sclerosis	✓
	Eliquis	Apixaban	Anticoagulant	✓
	Pomalyst	Pomalidomide	Multiple Myeloma	✓
	Sovaldi	Sofosbuvir	Anti-Viral / Hep C	✓

RoW exports

We are focused on growing the reach of our Hepatitis C generic in the Asia-Pacific region by leveraging our existing relationships. Our agreement with Gilead Sciences Inc., Medicines Patent Pool and Bristol Myers Squibb allows us to expand access of our Hepatitis portfolio in 112 developing countries. We also intend to expand into the oncology segment by selling certain products that we develop for India, the US and other regulated markets.

Business in our subsidiaries has grown well in the past fiscal year and we intend to establish our subsidiaries as cornerstones for the Company. We have subsidiaries in:

Canada

We market and distribute our products in Canada through our subsidiary, Natco Pharma Canada Inc. Our facility at Kothur, Telangana has been approved by Health Canada regulator. We have obtained approval for 13 products in Canada from Health Canada and marketing these products.

Brazil

We distribute our products in Brazil through our subsidiary, NATCO farma do Brazil. Our facility at Kothur, Telangana has been approved by ANVISA regulator, Brazil. We are in the process of registering some of our existing products, particularly in the oncology therapeutic area to grow our Brazilian operations. We have also received our first product approval for Letrozole in Brazil.

Singapore and Australia

We are in the process of marketing and distributing our products in Singapore and Australia through our subsidiaries, NATCO Pharma Asia Pte. Ltd. & NATCO Pharma Australia Pty. Ltd. which are in the initial stages of growth. We have obtained eight approvals for our products from Health Sciences Authority in Singapore.

PAT

₹6,962 million

43.2% growth

International formulation sales: Geography-wise (₹ in million)

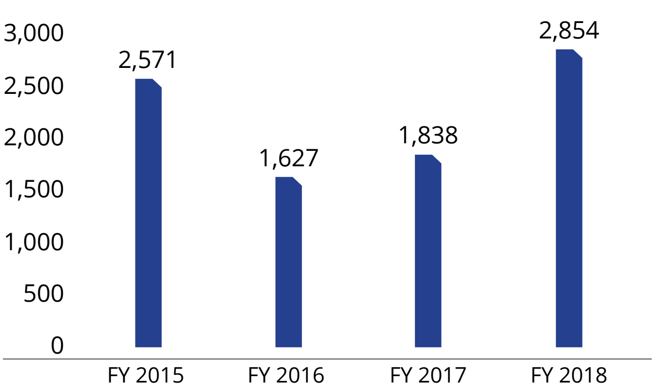
Year	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Export sales to US, including profit share	1,103.6	922.5	1,125.6	7,696.8	10,031.4
Export sales to RoW (all non-US)	829.8	846.3	1,168.2	673.2	386.5
Sales from subsidiaries (net)	1,175.6	1,115.8	1,194.4	630.0	945.5

Active pharmaceutical ingredients (API)

Our API business is strategically important since it allows us to backward integrate our operations. We manufacture API products that are primarily used for captive consumption and are also sold to customers for various international markets such as Canada, Europe and certain countries in the Middle East. In the API area, we have capabilities to develop and manufacture products with multi-step synthesis, semi-synthetic fusion technologies, high-potency APIs and peptides. As of 31 March, 2018, we have filed 42 active DMFs with the USFDA for our API products in therapeutic areas such as oncology, central nervous system, anti-asthmatic, anti-depressant and gastrointestinal disorders.

Our backward integration of the formulations business ensures steady supply of APIs at an equitable cost, minimising any market fluctuations. In the US formulations portfolio, a majority of our products are backward integrated. Our vertical integration model of business helps us reduce cost and increase revenue margin and timely delivery of raw materials of the desired quality and quantity. It further protects us from relying on external sources for our raw materials, thereby reducing risk of unfavourable terms of supply such as high pricing and long timeline for delivery.

Gross API revenue (₹ in million)



Financial overview

In FY 2017-18, NATCO's revenue from operations on a consolidated basis amounted to ₹22,424 million vis à-vis ₹20,789 million in FY 2016-17, recording a 44% CAGR over the last three years.

The PAT was recorded as ₹6,962 million compared to ₹4,860 million in the previous year. It has grown at a CAGR of 110% in the last three years.

EBITDA has grown at a CAGR of 85% over the last three years and was recorded at ₹9,688 million vis-à-vis ₹6,973 million in FY 2016-17.

Average return on equity was 22.6% in the current year compared to 29.5% in the previous year.

The Company's market capitalisation as on 31 March, 2018 stood at ₹138 billion.

No material changes and commitments occurred after the close of the year, till the date of this Report, which could affect the financial position of the Company.

Threats, risks and concerns

Adverse assessment of a manufacturing facility by any key regulatory body has the potential to significantly change the business prospects of any pharmaceutical company.

Environment, health & safety

NATCO has always been committed to environmental care across the value chain. Thus, the Company integrates energy and environmental considerations across all its facilities by reducing carbon footprint and increasing renewable energy measures. NATCO – Mekaguda facility is accredited with ISO 14001- 2015 Environment Management Systems (EMS) and OHSAS 18001-2007 Occupational Health and Safety Management Systems.

Besides, NATCO has also won the prestigious Golden Peacock award for Occupational Health and Safety in 2017 and 2014 and for Environmental Management in 2016.