Opportunities and Challenges of Indian Pharmaceutical Sector: An overview

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Abstract

The global pharmaceutical market size is estimated to reach USD 1.4 trillion and the Indian pharmaceutical market size is estimated as USD 55 billion by the year 2020. The Indian pharmaceutical sector is expected to grow with faster compound annual growth rate (CAGR) compared to global growth rate during the period 2015-2020. The world market will be dominated by countries like USA, EU and Japan and the contribution of Phrmerging countries is expected to be more in coming years. The future of the world pharmaceutical sector will be dominated by medicines for non communicable diseases and original branded medicines. The Indian pharmaceutical sector evolved in different phases from pre independence era to post Trade-Related Aspects of Intellectual Property Rights (TRIPS). Presently, Indian pharmaceutical sector is dominated by the generics drugs and more drugs are sold in anti-infective category. The Indian pharmaceutical industry is having opportunities in the domestic market with growing demand for quality health care. More opportunities are seen in the area of Contract Research and Manufacturing Services (CRAMS) by Mergers and Acquisitions (M&A) and Biogenic market. The government of India has taken measures to boost pharmaceutical sector, even though, the pharmaceutical sector is facing challenges in patent rights and methods used for fixing ceiling price for drugs. More challenges are expected due to immature clinical trial regulations and ethical aspects.

Key words: Indian pharmaceutical sector, drug price, patent rights, generic drugs.

Introduction

Health care is one of the important indicators of any country’s development and status of health care indicates the nature of the development of a country. Pharmaceutical companies are working consistently towards improvement of the health care among people. Pharmaceutical products or drugs are one of the important components of the health care management and its expenses. The increase in the income of the individuals and the change in lifestyle are contributing to the increase in the expenses of the health care management of an individual. The increase in the penetration of health insurance is another factor for the increase in the spending on pharmaceutical products. Research shows more than proportionate increase in the spending on pharmaceutical products compared to, increase in the expenses on total health care globally.

The pharmaceutical companies not only contribute to the health care of the people, but also contribute to the economy of the country by creating jobs, developing ancillary industries, export earnings, contributing to the Gross Domestic Product (GDP) et cetera. Hence, the growth of pharmaceutical sector of a country is important for the growth of the country’s economy.

A large portion of Indian population lives in the rural areas and a considerable portion of the Indian population are below the poverty line. It is a major challenge for the pharmaceutical companies,
government, doctors, and other stakes holders in the health care sector to pass the benefits of the outcome of Research and Development (R&D) to the really needy people.

**Global pharmaceutical industry**

The pharmaceutical industry is one of the fastest growing industries in the world and it is one of the biggest contributors to the world economy. The major sales of the pharmaceutical products come from the “Triad” (US, EU and Japan) in the world. The size of world pharmaceutical market in 2014 was around USD 1.2 Trillion and is estimated to be USD 1.4 trillion by 2020.

According to IMS health report, it is projected that, US contributes about 41 percent of total sales of medicine in the word by 2020, followed by EU5 and China which are projected to spend about 13 percent and 11 percent respectively. Brazil, Russia and India put together contribute about 6 percent of global consumption of the medicine. (Figure 1)

![Figure 1: Spending on medicine by geography in 2020 (in %)](image)

Source: IMS Health, Market Prognosis, September 2015

Pharmaceutical products can be classified as Original brands, Non original brands, Unbranded products and OTC (over the counter) products. Original brands are pharmaceutical products with brand names, marketed by the originator or companies, which have license to market by the originator and these products are prescription bound. Non original brands are marketed by the non originator with brand name, many a times these products will not have patent protection and these products are also prescription bound. Unbranded pharmaceutical products are active ingredients, also called as the generic medicine, marketed as the international nonproprietary name (INN). Whereas, OTC products are other medicine with non prescription bound and larger substance of which are the over-the-counter.
IMS Health report projected that, major spending on medicine in the world by 2020 will be on original brands, which is about 52 percent and 21 percent of spending in the world will be on non original brands. Totally, 73 percent of spending on pharmaceutical products are in the category of prescription bound branded products, hence, there is a large potential for branding of a pharmaceutical products. About 14 percent of spending is on unbranded products, which are commonly termed as generic medicine, which are sold on international non-proprietary names, whereas OTC segment will be about 13% by 2020. (Figure 2)

According to the IMS Health report on the amount to be spent on different diseases by 2020, it is estimated that, the majority of the spending will be on products treating for non communicable disease which is about 37 percent of spending of total global spending on pharmaceutical products. About 15 percent of spending on global pharmaceutical products is on communicable diseases which include drugs such as antibacterial, antiviral, vaccine, and anti parasitic. The spending on the cancer treatment (therapeutic cancer treatment) will be about 11 percent of spending on global pharmaceutical products. The spending on lifestyle oriented diseases, such as diabetic treatment (insulin, traditional and nontraditional diabetic treatment) and cardiovascular diseases (hypertension, heart diseases, cholesterol treatment) are estimated 11 percent and 7
percent respectively. The projected spending on pain treatment (musculoskeletal pain, arthritis, anesthesia, narcotic and non narcotic analgesics, migraine) and Autoimmune (Treatments for rheumatoid arthritis, Crohn’s disease, ulcerative colitis, psoriasis, psoriatic arthritis and other related diseases) is about 7 percent each. Whereas, 6 percent of global spending on pharmaceutical products will be on Respiratory related diseases (Asthma, COPD, Allergy respiratory/inhaled treatments). (Figure 3)

Indian pharmaceutical industry

Evolution of Indian pharmaceutical sector

Phase-I (Before 1970) Early stage

The history of Indian pharmaceutical companies goes back in the early stages of the twentieth century. The nationalism movement also had impact on the scientific sector, which motivated many entrepreneurs, academicians and leaders, to establish scientific oriented companies. It also led to initiate the establishment of modern pharmaceutical companies in India. In 1901, Acharya Prafulla Chandra Roy, a renowned scientist and academician, established Bengal Chemical and Pharmaceutical Works Limited (BCPW) in Kolkata and in 1907, Alembic Chemical Works Co. Ltd., was established in Vadodara by TK Grajjar, Rajmitra and BD Amin. Both the companies had scientific and modern approaches to the pharmaceutical sector. After independence, Hindustan Antibiotics Ltd (HAL) established in 1954. It was wholly owned Government Company established with assistance of with WHO / UNICEF and engaged in the Manufacturing & Marketing of Life Saving Drugs. In the year 1961, Indian Drugs & Pharmaceuticals Limited (IDPL) was incorporated as a public limited company under the Companies Act, 1956. Private players such as Cipla in 1935, also entered in the market during this phase.
Phase II (1970-1990) Government control and development phase

During the period 1970-1990, many local companies were started operating in the pharmaceutical sector. The public sector undertakings such as, Karnataka Antibiotic & Pharmaceuticals Limited (KAPL) in 1981 at Bangalore, Karnataka and Rajasthan Drugs & Pharmaceuticals Limited (RDPL) in 1978, at Jaipur, Rajasthan, were established during this period. The private companies like Sun Pharma, established in 1983 and Dr.Reddy’s Lab, established in 1984, started showing the impact in the market. This period also marked by some government control over pharmaceutical sector, through passing of Indian patent act 1970 and capping the drugs price. The government also took initiative to export the pharmaceutical products during this period.

Phase III (1990-2010) Growth phase

The pharmaceutical sector saw many developments during this period. The Major development was the liberalization of market, which led many multinational pharmaceutical companies to enter into the Indian market. Competition started to increase and many Indian pharmaceutical companies started operating in foreign countries. During this period, Patent (Amendment) Act 2005 was passed, which led to the adoption of product patent in India. VAT has been introduced on medicine and was kept at 4 percent, Pharmaceutical Research and Development Support Fund (PRDSF) was established during this period.

During this Growth Phase, the patents filed by pharmaceutical companies increased, and also, spending on R&D by leading pharmaceutical companies increased. The pharmaceutical companies started an aggressive marketing by adopting new sales modules such as Channel Management, Key Accounts Management (KAM), and Contract Sales Organization (CSO).
Phase-IV (2010-2015) Acceleration phase

This period was witnessed by many changes in the pharmaceutical sector. The major policy changes adopted during this period were The National Pharmaceutical Pricing policy 2012 (NPPP-2012) and adoption of New Drug price control order 2013, issued by director of food and drugs, intended to reduce the prices of the drugs. Other policy changes during this period were, allowing of 100% FDI in the medical device industry, National Health policy draft 2015 to increase expenditure in health care sector and Patent Act Amendment 2015, which includes amendments in Patent Act 2002.

The period also accounts with second largest number of Abbreviated New Drug Applications (ANDAs) and India is the world’s leader in Drug Master Files (DMFs) applications with the US. Leading pharmaceutical companies raised funds for acquisitions and increase their product portfolio during this period

Structure of Indian Pharmaceutical Sector

The Indian pharmaceutical sector can be divided into two major segments, namely, Active Pharmaceutical Ingredients (API) or bulk drugs and Formulations. The API can be branded or Generic and these ingredients will be part of Formulations, which will be used to treat Acute or chronic diseases.

Indian Pharmaceutical Market

According to Equity Master Report, Indian pharmaceutical industry is the third largest, in terms of volume and it is number thirteen in terms of value in the world market. The Indian pharmaceutical sector accounts for 10 percent in volume terms and 2.4 percent of in value terms, the world market. The Present market size of the Indian pharmaceutical sector is USD 20 billion and expected to reach USD 55 billion by the year 2020 with a compound annual growth rate (CAGR) of 15.92 per cent between 2015 and 2020. It is projected to grow more than the annual growth rate of the world pharmaceutical sector, which is estimated about 5 per cent between same period. (Figure 4)
The Indian pharmaceutical market is dominated by Branded generic drugs which contribute 70 percent of market share in terms of revenue. The patented drug market contribute 21 percent whereas, over the counter (OTC) drug market contribute 9 percent of total USD 20 billion revenue of the Indian pharmaceutical market. (Figure 5)

In the year 2015, anti infective category products dominated in the sales, which is about 16 percent of total sales of pharmaceutical products. The sales of cardiovascular products are about 13 percent and the contribution of the anti diabetic drugs is about 7 percent of the total sales. The growing number of cardiac cases and increase in lifestyle oriented disease in India is going to contribute more to the sales of these two categories in the coming years. Gastrointestinal drugs contributed about 11 percent of sales and vitamins and minerals, respiratory and pain/analgesic segments contributed 8 percent, 9 percent and 7 percent respectively in the sales of total pharmaceutical products. Other segments, other than mentioned above are contributing about 29 percent of total sales of the pharmaceutical products in India. (Figure 6)

In 2015, 22 percent growth was achieved in the anti infective category, followed by 23.4 per cent growth in the sale of gastrointestinal segment drugs. Whereas, ant diabetic and cardiovascular segment grew about 32.9 percent and 19.1 percent respectively. The respiratory segment registered the growth of 27.8 per cent, whereas Derma market and Urology market grew by 19.2 per cent and 29.8 per cent respectively.

**Figure 4**: Revenue of Indian pharmaceutical sector (USD billion)

**Figure 5**: Revenue share of Indian Pharmaceutical sub-segment in 2015 (in %)
India exports its pharmaceutical products to many countries in the world and key market is the US. Major export contribution comes from branded generic drugs and it accounts 20 percent of global generic drugs exports in terms of volume. The target for pharmaceutical export is about USD 18.02 billion in the year 2016. During FY12-15, export of pharmaceutical products increased at a CARG 14 per cent in terms of value. Import of pharmaceutical products grew at a CARG of 13.04 per cent in the FY12-14. (Figure 7)

**Trends in Indian Pharmaceutical sector**

**Focus on Research & Development**

Globally, investments in Research & Development (R&D) is about 15 percent of sales turnover and the Indian pharmaceutical companies invested about less than two percent of sales turnover until beginning of the new millennium. The investment was a peak in 2005-06 and showed slower rate in further years. Presently, R&D investment in India is about 8-11 percent of total turnover, which is less than a global investment in R&D and it is expected to increase further because of competition.

**Figure 8:** R&D-Sales Ratio in Pharmaceutical Industry in India (percentage)
Indian Pharmaceutical export market is thriving due to the strong presence in the generic market, which supplies about 20 percent of the global market in terms of volume. Pharmaceuticals Exports Promotion Council is estimated that, export will reach about USD 18.02 billion in 2016.

Joint venture

The focus on joint venture in pharmaceutical sector is increasing. Many foreign companies joining hands with Indian companies to develop new drugs. The advantages seen in the R&D is contributed by cost effectiveness, availability of skilled employees and government incentives and so on. Cipla signed exclusive partnership with serum institute of India to sell the vaccines in south Africa. ‘LAZOR’ an alliance of six leading pharmaceutical companies formed to share best practices and improve their efficiency and reduce operating costs.

Less time for approval

In order to compete with global market, the drug approval process has been simplified and approval time for new plant has been reduced. In the draft Patent (Amendment) Rules 2015, the time period of patent grant has been reduced from 12 months to 4 months.

Opportunities of Indian pharmaceutical industry

Multinational pharmaceutical companies are looking towards Pharmerging countries due to the change in the global pharmaceutical market and low growth in developed market like the US, Japan, and EU. The Indian pharmaceutical sector offers a wide range of opportunities for the pharmaceutical companies to establish their units and market their products in India. Supportive regulatory framework and availability of large number of scientists and professionals is an added advantage for the pharmaceutical companies in India. The huge investment in infrastructure and larger domestic market made India as one of the favorite destinations for pharmaceutical companies. Indian Pharmaceutical sector is looking towards promising future because of Low cost of production and developed R&D infrastructure.
Promising domestic market

The key growth drivers of Indian Pharmaceutical market are, increasing in per capita income, better health awareness, increase in health insurance penetration, higher government expenditure on the health care, shift in disease profile and adherence to Indian Pharmaceutical Association (IPA) norms. The growth of the domestic formulation market is driven by lifestyle related medicines like cardiovascular, anti diabetic, gastrointestinal and respiratory drugs. It is due to increase in the stress level, change in eating habits and unhealthy eating habits among people. The expected growth is much higher in chronic formulation segment than the traditional acute formulation segment. The increasing demand for quality health care and the size of the population are some of the other favorable domestic market conditions in India.

Contract Research and Manufacturing Services (CRAMS)

The global Contract Research and Manufacturing Services (CRAMS) market is estimated at USD 8 billion in 2015 compared to USD 3.8 billion in 2012. It is presently having around 1000 players. The availability of a large number of scientific and professional human resources, India is recognized as a global manufacturing hub. The cost of production will be 40 percent - 50 percent less compared to US and European countries. The availability of developed R&D infrastructure made India as a favorable nation for outsourcing. The CRAMS companies in India already showed the presence in APIs, clinical trials and low value and high volume space. In future, CRAMS companies going to focus on high potential APIs, biopharmaceutical outsourcing, finished dosage form and indictable manufacturing, which are other potential space for contract manufacturing pharmaceutical sector in India.

Biologics and Biosimilars

Biologic market is in nascent stage and only few MNCs entered in the market. The entry barriers are high in this segment, however, India pharmaceutical companies can get first mover advantages.

Mergers & Acquisitions

The domestic pharmaceutical companies looking for opportunities with the global players to expand their operations in the foreign market, for the purpose, domestic companies are looking for strategic tie-ups with the global players. The global players will have benefit of R&D facility and a distribution network of domestic players to operate in the huge Indian market. Thus, the win-win situation prevails in the Indian pharmaceutical sector. The global players are showing increasing interest in generic market and looking for acquisition opportunities, this in turn, provide financially lucrative opportunities for domestic companies which are looking for cash out. In the last three years, pharmaceutical sector in India, accounted for more than 70 percent of deals and reached worth of USD 1.7 billion deals of mergers and acquisitions in the first nine months of the year 2015.

Government Initiatives to boost the Pharmaceutical sector

The Indian government has taken many steps to accelerate the pharmaceutical sector in India. The approval time for new facility reduced and NOC for export licenses will be issued within two weeks. Signing of MoUs with USFDA, Health Canada, WHO and other bodies in the world is going to benefit the Indian pharmaceutical sector. For the technology up gradation, zero duty applicable to the pharmaceutical sector through the Export Promotion Capital Goods (EPCG) Scheme. The government is planning further
relaxation in FDI norms in the Pharmaceutical sector. Customs duties and excise duty exempted for the HIV/AIDS drugs and diagnostic kits supplied under the National AIDS Control Program funded by the Global Fund to fight AIDS, TB and Malaria (GFATM). The Department of pharmaceuticals of Indian government aims at making India as a major hub for end-to-end discovery under Pharma Vision 2020.

**Challenges of Indian pharmaceutical industry**

India pharmaceutical companies are key players in the space of generic market of global pharmaceutical sector and India is one of the important players of Pharma emerging market. The nature and diversity of the Indian pharmaceutical market, health care objectives and legal system pose unique challenges for pharmaceuticals sector in India. The diversity of the challenges are very complex, hence, Indian pharmaceutical sector have to face these challenges with more courage to emerge as one of the leading players in the world pharmaceutical market and to achieve progress in the health care.

*Intellectual property protection*

Indian patent (Amendment) act 2005 formed as per the requirements of TRIPS. According to OPPI, “the section 3 (d), impermissible hurdle has been added to this, which is a fourth substantive criterion of “enhanced efficiency” to the TRIPS requirements. This hurdle appears only for pharmaceutical products and some substance like salts, esters, ethers, and other derivatives of known substances are presumed to be the same substance of original chemical and cannot be patented unless it is proved these substances differ significantly with respect to efficiency”.

The price barriers created on account of the patent, for the medicines required for the treatment of diseases like HIV/AIDS, Cancer, TB, MDRTB, Diabetes, and Hepatitis C, are seen not as affordable by the committee appointed by the government under the ministry of health and family welfare. The government committee grants Compulsory License (CL) under special provisions of section 92 and section 66 of Indian Patent Act., which makes patent holder more difficult to defend their patents. It is the challenge for the government to justify the grants of CLs which has to be used under limited circumstances as the tool of industrial policy.

The patent application process for the pharmaceutical products in India is interpreted as targeted to create burdensome for foreign applicants. It is due to, Section 8 (1) requires patent applicants to notify the Controller and “keep the Controller informed in writing” of the “detailed particulars” of patent applications for the “same or substantially the same invention” filed outside of India. Section 8 (2) requires a patent applicant in India to furnish details to the Indian Controller about the processing of those same foreign patent applications if that information is requested.

According to TRIPS, India to provide protection of data which not yet done. India relies on test data submitted in another country, which is seen as not professional in the industry.

*Market Access barriers*

Fixing of ceiling price for the essential drugs by NPPA, under the Drug Price Control Order (DPCO) 2013, is cost based policy and it take into account simple average of all the drugs with a market share of 1percent
or more. The industry expects, it is more appropriate to adopt market based policy rather than cost based policy.

The contribution from the government in the areas of health care is not satisfactory, which is only 1.2 percent of the GDP and healthcare infrastructure development not up to the expectation in India. The pharmaceutical companies expect the government to improve the systems in the public health care administration, so as to reach the medicines to the needy people, which will improve overall health care of the country.

Reaching the rural market, which is very large in India, the pharmaceutical companies have to work with innovative marketing and sales tools to reach these markets.

Other challenges

FDI investment in Greenfield projects is easier than Brownfield, which will hinder the FDI investments in Brownfield projects.

India needs mere structured and matured regulations on clinical trial policies. More expectations are from pharmaceutical companies, as a compensation, for the person injured during clinical trials. Presently, the regulations in clinical trials are uncertain, which may hinder the clinical research environment in India and have an impact on the availability of new treatments and vaccines to Indian patients.

The ethical concern in the Indian pharmaceutical industry is not seen up to the mark. Many international agencies believe more improvement is needed in the ethical scenario of the Indian pharmaceutical sector, especially in the field of clinical trials and marketing practices.

Conclusion

The Indian pharmaceutical market is huge and compared to the world market, the contribution is less than its potential. The focus on other than generic market is the need of the time and Indian pharmaceutical companies constantly searching for new avenues in the innovation driven sector. The constant increase in the size of the Indian pharmaceutical market, due to a change in life style and high demand for quality health care, making this sector as a one of the promising contributors of the Indian economy. The regulatory policies need be improved, especially in the area of patent and price control, to boost the growth and create an impression as the destination for new generation pharmaceutical market.

Further scope of study

Research can be conducted focusing on the specific segments of the sector. The challenges in the import policies and FDI investments in Indian pharmaceutical sector can be further probed to improve the contributions. The innovative methods in marketing and sales of the drugs and the distribution, to penetrate into the rural area of India, can be studied. It improves the market share of Indian pharmaceutical companies and the availability of the needed medicines to the rural population.

* Pharmaerging countries are defined as those with >$1Bn absolute spending growth over 2014-18 and which have GDP per capita of less than $25,000 at purchasing power parity (PPP). Tier 1: China; Tier 2: Brazil, India, Russia; Tier 3: Mexico, Turkey, Venezuela, Poland, Argentina, Saudi Arabia, Indonesia, Colombia, Thailand, Ukraine, South Africa, Egypt, Romania, Algeria, Vietnam, Pakistan and Nigeria.

Source: Report by the IMS Institute for Healthcare Informatics.201 November 2014

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List of Abbreviations

UNICEF - United Nations Children’s Fund
AIDS - Acquired Immune Deficiency Syndrome
ANDA - Abbreviated New Drug Application
API - Active Pharmaceutical Ingredients
BCPW - Bengal Chemical and Pharmaceutical Works Limited
CAGR - Compound Annual Growth Rate
CL - Compulsory License
COPD - Chronic Obstructive Pulmonary Disease
CRAMS - Contract Research and Manufacturing Services
CSO - Contract Sales Organization
CVS - Cardiovascular
DMF - Drug Master File
DPCO - Drug Price Control Order
EPCG - Export Promotion Capital Goods
EU - European Union
GDP - Gross Domestic Product
GFATM - Global Fund to fight AIDS, TB and Malaria
HAL - Hindustan Antibiotics Ltd
HIV - Human Immunodeficiency Virus
IDPL - Indian Drugs & Pharmaceuticals Limited
INN - Non Proprietary Name
IPA - Indian Pharmaceutical Association
KAM - Key Accounts Management
KAPL - Karnataka Antibiotic & Pharmaceuticals Limited
Annexure-I

Investments, JVs of Indian pharmaceutical companies in last three years

<table>
<thead>
<tr>
<th>Date Announced</th>
<th>Indian Company</th>
<th>Foreign Company</th>
<th>Value (USD Million)</th>
<th>Type</th>
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<td>October 2015</td>
<td>Nitin Lifesciences</td>
<td>Recipharm</td>
<td>109.8</td>
<td>75% stakes in equity</td>
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<td>July 2015</td>
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<td>Temmler</td>
<td>Not disclosed</td>
<td>Acquisition</td>
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<td>Acquisition</td>
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<td>November, 2014</td>
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<td>JV</td>
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<td>33</td>
<td>Acquisition of manufacturing unit</td>
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</table>
| Source: BMI, TechSci Research, ICRA Research on Indian Pharmaceutical Sector, India Ratings Research Outlook on Indian Pharmaceutical, www.ibef.org
Notes: JV - Joint Venture, |

Annexure-II

Top Pharmaceutical Companies in India by Market Capitalization – BSE (As on 11th April 2016)

<table>
<thead>
<tr>
<th>SL.NO</th>
<th>Company Name</th>
<th>Market Cap (Rs. cr)</th>
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<td>1</td>
<td>Sun Pharma</td>
<td>196,557.52</td>
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<td>2</td>
<td>Lupin</td>
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<td>3</td>
<td>Dr Reddys Labs</td>
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<td>4</td>
<td>Aurobindo Pharm</td>
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<td>Cipla</td>
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