Pharmaceutical Sector

24 April 2019

Sector Update

Regulatory Expert's View – Evolving China Regulations On Generics

China represents the second-largest drug market in the world with US$122bn in drug sales in 2017, and is growing in high single digits. Of late, CFDA, the Chinese drug regulator, has introduced major reforms that intend to align the country's regulatory process with other advanced markets (US and EU) and thus ensure access to best quality generic and novel drugs for patients. We met a regulatory expert (Dr. Gurudatta – CEO of Estima Pharma) to understand the nature of these reforms and their impact on generic drug market in China for Indian companies. The key takeaways from our interaction are given below.

Need for regulatory reforms in China: Historically, the regulatory environment in China has witnessed major deviations in the area of comparative quality between international standards and some local products as generic drugs are approved without bioequivalence studies and are not compared to international standards. Also drug application review and approval is longer when compared with most major countries. There is insufficient capacity at the regulatory body that resulted in a backlog of applications. With an overarching intention to address the above problems, bring about a structural adjustment to align with developed markets, and also upgrade the pharmaceutical industry, the reforms have been introduced.

Impact on generic drug approval process in China: To ensure the quality problems with generics are put to rest, China has adopted the best practices and has aligned its approval process with that of developed markets (EU and US). As a result, CFDA is now a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The revised guidelines require generic companies to start drug consistency research on quality and efficacy which require comparison studies that include formulation, quality standard, crystal form, particulate size, impurities and dissolution profile, and vivo BE studies. Data from generic drug filings for approved drugs in US can be leveraged for China filings. The dossier submission process is now quite similar to European markets, while the underlying bioequivalence studies that need to be done for dossier submission are identical to US guidelines. Like the US, China would grant incremental generic drug approvals only to those companies which have demonstrated bioequivalence in both fasting and fed state. Injectables will need to demonstrate Q1/Q2 sameness.

Priority review status and exclusivity for newly launched generic drugs: To ensure that generic drugs are brought to the market at the earliest, the Chinese regulator ensures priority review for first-time generic drugs. The priority review allows approval within six months post dossier submission. The first generic drug of which the originator drug is not approved in China - if it successfully challenges the innovator's patent - will receive 18 months of exclusivity for its clinical trial data. During the period of data exclusivity, subsequent generics are not allowed to enter the market.

On-the-ground initiatives to ensure implementation: The Centre for Drug Review (CDE) has laid a target of reducing the backlog in the drug review procedure and to ensure the same is met, CDE resources have been enhanced multifold. Until 2015, CDE had only 70 reviewers, but was expanded to 600 by the end of 2016 and the expansion continues.

Certified CRO sites outside China can be used for conducting bioequivalence studies: Bioequivalence trials for generic drugs approved in the US, EU or Japan can be used for filing applications in China but CFDA would do a prior on-site inspection of clinical trial site / CRO.

How Indian generic players can benefit: India's pharmaceutical exports to China are currently less than 1% of its overall pharmaceutical exports. A number of Indian companies have been working towards building their presence in China. Dr. Reddy's Laboratories has been an early entrant, while of late Cipla, Aurobindo Pharma and Natco Pharma have also indicated that they are also looking at opportunities. According to the regulatory consultant we spoke to, oncology injectable/general injectable represents a large opportunity and can be tapped imminently by Indian players. A large portion of injectables which do not require bioequivalence studies can be filed for approval. China has waived off import duties on cancer injectables to incentivize filings. Companies can leverage on the data of their filings in the US market to get expedited approval.

In the medium term, Indian players can also look to do First To File generics of innovator drugs that are not approved in China. Around two-thirds of the drugs that have been approved in the US (post 2001 and until 2016) are not approved for marketing in China, which creates a large opportunity for Indian players. In addition, there is also scope for Indian players to leverage their skill-set in complex formulation (a major competitive advantage over Chinese players) to file for such drugs. Gaining market access in China is gradually easing owing to recent regulatory shifts which require physicians to prescribe generic names and shift to a two-invoice system (just one distributor) which lowers supply chain complexities. Around 70% of pharmaceutical sales in China are driven by hospitals which are relatively easier to access.

Vishal Manchanda
Research Analyst
vishal.manchanda@nirmalbang.com
+91 9737437148

DISCLOSURES

This Report is published by Nirmal Bang Equities Private Limited (hereinafter referred to as "NBEPL") for private circulation. NBEPL is a registered Research Analyst under SEBI (Research Analyst) Regulations, 2014 having Registration no. INH000001436. NBEPL is also a registered Stock Broker with National Stock Exchange of India Limited and BSE Limited in cash and derivatives segments.

NBEPL has other business divisions with independent research teams separated by Chinese walls, and therefore may, at times, have different or contrary views on stocks and markets.

NBEPL or its associates have not been debarred / suspended by SEBI or any other regulatory authority for accessing / dealing in securities Market. NBEPL, its associates or analyst or his relatives do not hold any financial interest in the subject company. NBEPL or its associates or Analyst do not have any conflict or material conflict of interest at the time of publication of the research report with the subject company. NBEPL or its associates or Analyst or his relatives do not hold beneficial ownership of 1% or more in the subject company at the end of the month immediately preceding the date of publication of this research report.

NBEPL or its associates / analyst has not received any compensation / managed or co-managed public offering of securities of the company covered by Analyst during the past twelve months. NBEPL or its associates have not received any compensation or other benefits from the company covered by Analyst or third party in connection with the research report. Analyst has not served as an officer, director or employee of Subject Company and NBEPL / analyst has not been engaged in market making activity of the subject company.

Analyst Certification: I, Mr. Vishal Manchanda, research analyst and the author of this report, hereby certify that the views expressed in this research report accurately reflects my personal views about the subject securities, issuers, products, sectors or industries. It is also certified that no part of the compensation of the analyst was, is, or will be directly or indirectly related to the inclusion of specific recommendations or views in this research. The analyst is principally responsible for the preparation of this research report and has taken reasonable care to achieve and maintain independence and objectivity in making any recommendations.

Disclaimer

Stock Ratings Absolute Returns

BUY > 15%

ACCUMULATE -5% to15%

SELL < -5%

This report is for the personal information of the authorized recipient and does not construe to be any investment, legal or taxation advice to you. NBEPL is not soliciting any action based upon it. Nothing in this research shall be construed as a solicitation to buy or sell any security or product, or to engage in or refrain from engaging in any such transaction. In preparing this research, we did not take into account the investment objectives, financial situation and particular needs of the reader.

This research has been prepared for the general use of the clients of NBEPL and must not be copied, either in whole or in part, or distributed or redistributed to any other person in any form. If you are not the intended recipient you must not use or disclose the information in this research in any way. Though disseminated to all the customers simultaneously, not all customers may receive this report at the same time. NBEPL will not treat recipients as customers by virtue of their receiving this report. This report is not directed or intended for distribution to or use by any person or entity resident in a state, country or any jurisdiction, where such distribution, publication, availability or use would be contrary to law, regulation or which would subject NBEPL & its group companies to registration or licensing requirements within such jurisdictions.

The report is based on the information obtained from sources believed to be reliable, but we do not make any representation or warranty that it is accurate, complete or up-to-date and it should not be relied upon as such. We accept no obligation to correct or update the information or opinions in it. NBEPL or any of its affiliates or employees shall not be in any way responsible for any loss or damage that may arise to any person from any inadvertent error in the information contained in this report. NBEPL or any of its affiliates or employees do not provide, at any time, any express or implied warranty of any kind, regarding any matter pertaining to this report, including without limitation the implied warranties of merchantability, fitness for a particular purpose, and non-infringement. The recipients of this report should rely on their own investigations.

This information is subject to change without any prior notice. NBEPL reserves its absolute discretion and right to make or refrain from making modifications and alterations to this statement from time to time. Nevertheless, NBEPL is committed to providing independent and transparent recommendations to its clients, and would be happy to provide information in response to specific client queries.

Before making an investment decision on the basis of this research, the reader needs to consider, with or without the assistance of an adviser, whether the advice is appropriate in light of their particular investment needs, objectives and financial circumstances. There are risks involved in securities trading. The price of securities can and does fluctuate, and an individual security may even become valueless. International investors are reminded of the additional risks inherent in international investments, such as currency fluctuations and international stock market or economic conditions, which may adversely affect the value of the investment. Opinions expressed are subject to change without any notice. Neither the company nor the director or the employees of NBEPL accept any liability whatsoever for any direct, indirect, consequential or other loss arising from any use of this research and/or further communication in relation to this research. Here it may be noted that neither NBEPL, nor its directors, employees, agents or representatives shall be liable for any damages whether direct or indirect, incidental, special or consequential including lost revenue or lost profit that may arise from or in connection with the use of the information contained in this report.

Our reports are also available on our website www.nirmalbang.com

Access all our reports on Bloomberg, Thomson Reuters and Factset.

Team Details:

Name		Email Id	Direct Line
Rahul Arora	CEO	rahul.arora@nirmalbang.com	-
Girish Pai	Head of Research	girish.pai@nirmalbang.com	+91 22 6273 8017 / 18
Dealing			
Ravi Jagtiani	Dealing Desk	ravi.jagtiani@nirmalbang.com	+91 22 6273 8230, +91 22 6636 8833
Pradeep Kasat	Dealing Desk	pradeep.kasat@nirmalbang.com	+91 22 6273 8100/8101, +91 22 6636 8831
Michael Pillai	Dealing Desk	michael.pillai@nirmalbang.com	+91 22 6273 8102/8103, +91 22 6636 8830

Nirmal Bang Equities Pvt. Ltd.

Correspondence Address

B-2, 301/302, Marathon Innova,

Nr. Peninsula Corporate Park,

Lower Parel (W), Mumbai-400013.

Board No. : 91 22 6273 8000/1; Fax. : 022 6273 8010