Generic Industry Opportunities and Challenges for Emerging Markets: an Overview

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The global economy is going through an interesting and challenging transformation. This transformation is manifesting in different ways such as commoditization of public services, mobilization of workforces, shifting of market control from suppliers to consumers, interlinked rises in product demand and customer expectations. As Asia is home to half of the world’s population, and offers both a large relatively low-cost workforce in some countries and a potentially huge retail market, this region could be central to the future of the global economy. With this dynamic situation in place, various emerging countries especially China are experiencing a rapid development and change.

Now coming to pharma world, the global situation is not different but rather more interesting and challenging. Even though on another front in this domain we are seeing and experiencing that patient demand for pharmaceuticals is and will remain robust, despite the ongoing effects of the economic downturn being felt in many parts of the world. The IMS Health reported that the size of the global market for pharmaceuticals is expected to grow nearly $300 billion over the next three years, reaching $1.1 trillion in 2014. The 5–8 percent compound annual growth rate during this period reflects the impact of leading products losing patent protection in developed markets, as well as strong overall growth in the world’s emerging countries. So overall net growth over the next five years is expected to be strong — even as the industry faces the peak years of patent expiries for innovative drugs introduced 10–15 years ago and subsequent entry of lower-cost generic alternatives."

If we have a close look over the landscape it is quite clear that so called...
“innovator drought” is almost approaching in 2015 onwards at least for a period of 5 years. This means new drugs pipeline by the innovators and multinationals is almost depleted or getting closer to that critical point and there will be very few to none exclusivity expiring during the year 2015-2020.

As a result of new drugs depletion from the market the pressure is on global generic drug industry for cost reduction, quality improvement strategies and suitable program implementation. We will be noticing a peak shift of major therapies to generic dominance due to the peak in patent expiries. Over the next five years, products with sales of more than $142 billion are expected to face generic competition in major developed markets. Collectively, the impact of patients shifting to lower-cost generics in major therapy areas such as cholesterol regulators, antipsychotics and anti-ulcerants will reduce total drug spending by about $80 - $100 billion worldwide through 2014. This impact will be felt particularly in the U.S., where nearly two-thirds of the total value of patent expiries will occur. Patent expiries in the U.S. will peak in 2011 and 2012 when six of today’s ten largest products are expected to face generic competition.

This tough and “difficult to manage” generic industry challenge is worldwide rather than “local” and the situation is getting towards worst rather than improving and stabilizing in spite all possible efforts of the industry groups and health care leaders and advocates. If we compare, the US generic industry is more prone to challenges to survive and remain in business that can continue to generate profits. Now with this situation in hand, the only option available is to move off shore to emerging markets wherein there is still a huge potential to uncover and grab the opportunity. Having said this, it is not easy for the foreign companies to just tap into this hidden opportunity but at the same time it is not impossible for them to take our share and go away.

At the same time another aspect that is getting important and coming in our way is getting funding and both ability and acceptability of the end customer to pay the demanded cost of medicine and treatment plan. Again we can very well blame the global economy health but at the end it is a fact that we are seeing that globally publicly funded health plans are under increased pressure by payers to curb drug spending growth budgets. In addition, following the global economic downturn the pressure will only intensify further especially in developed countries. Countries such as Turkey, Spain, Germany and France already have announced plans to apply across-the-board restrictions on access or reductions in reimbursements to reduce drug spending growth. Governments in other countries are also seeking to restore fiscal balance and therefore may take similar actions, or shift more costs to patients.

Like other industries, the pharmaceutical industry faces a new array of Asia-specific opportunities and challenges. Success in meeting these challenges will go to those pharmaceutical companies that best understand the unique strengths and constraints of Asia’s diverse cultures, talents and markets. The important point here is to understand as to what the emerging markets can provide and how can we be ready to embrace and take advantage before it is too late.

In this challenging and opportunity hunt arena geographic balance of the pharmaceutical market continues to shift towards pharma emerging countries. Pharma emerging markets are expected to grow at a 14 - 17 percent pace through 2014, while major developed markets will grow 3 - 6 percent. As a result, the aggregate growth through 2014 from Pharma emerging markets will be similar to the growth experienced in developed markets — about $120 - $140 billion. This compares to aggregate growth over the past five years of $69 billion in Pharma emerging markets and $126 billion in developed markets.

While here in China, we are not unaffected with this global financial health crisis either and there are no short of challenges. With China’s new 12th Five Year Plan unfolding it is quite possible that health authorities and national leaders will be unable to accommodate the price points required by Novel and innovative drugs and patented therapies. Therefore, the message is clear and loud enough that making a strong case for innovations in drug policies should be a critical element in any short-term strategy for international and foreign based organizations. The challenge here is to create the traction by demonstrating superior cost effectiveness by
pharmacoeconomic strategies and leveraging potential opportunities in a parallel for-profit private health care system to support the basic public service.

It is truly said that “China is a large country with a huge domestic potential for growth especially due to government spending policies on health care of the country citizens.” Having said this, it is also equally important to understand that the earlier golden days of making easy money off a predictable stable high priced branded generics are over.

Emerging markets especially China and India, offer a unique growth opportunity for the next twenty years at least. However, the difficulty is how and what strategy to apply and when? A quick and easier approach is to apply the western business model in the emerging markets but unfortunately this is not at all the best solution. This is because the culture is very unique here and it is very difficult and time consuming process for any outsider to understand and adapt to the existing prevailing culture. Even though the challenge of culture understanding and adaptability is unique and tough but the environment is no short of other equally tough challenges. These additional challenges are speed of action, regulatory landscape, government policies, and the client competition that changes both momentum and direction in a quite amazing and fast manner. Another difference here is that the Asia is not homogeneous markets such as even China and India have quite different environments and need tailored made policies and action plans to succeed.

In addition, to be successful in emerging markets pharma companies must carefully understand the gaps while capitalizing on their strengths. The gaps must be filled in by “local” indigenized strategies with various skilled and unskilled forces. It is important to recognize that the local markets and regulatory environments will be easier to understand and manage by the local forces rather than by “imported” work forces. Once the foot prints are established the strategy can be fine-tuned to meet the target objectives and established goals. Having achieved these goals and objectives initially, one must also not assume and take it as a guarantee that the time span and the output as the staff turnover rate is different in developed than in western companies abroad.

An important principle underlying best management policy is that understanding of the customer is equally important and critical as the implication and its relationship with the entire chain of services and/or product. Partnership both internal and external to the organization also plays a significant role in the overall success. More than ever, one should not forget to challenge old and established assumptions and explore frugal innovations as a route to real breakthroughs. Last but not least, even though cost is very important and critical to any success and profitability but it is not everything. We must aim to get it right the first time at the right cost with customer satisfaction as both quality and time are very critical and key for sustainable growth and expansion.

These are just a few of the considerations and thoughts that every potential entrepreneur should take into account when entering these markets.

About the Author

Dr. Jack Aurora is Ph.D. in pharmaceutical sciences with over 19 years of Quality and Compliance driven research and management experience to his credit. Dr. Aurora’s research experience is in all the dosage forms including but not limiting to solids, semi-solids, liquids and sterile with special emphasis for Novel Drug Delivery Systems including Controlled-Release and Nasal development and mfg. operations. At present Dr. Aurora is working in the capacity of Chief Scientific Officer, Generic Drugs for Hisun Pharma Co., Ltd. based in China. In this role, Dr. Aurora is responsible for the set-up and implementation of the newly constructed facility for US FDA and EU submission, approval and commercialization aspects of generic drug development. Prior to this he has worked as VP Formulations Operations with Azopharma Product Development Group, and with Perrigo Company, Pharmascience, Labopharm, Pathon and Ranbaxy (from where he started his professional career) in various management and technical capacities. Dr. Aurora is also a consultant with GLG Healthcare and Biomedical Council and Guidepoint Global, associations of leading physicians, scientists, and other healthcare professionals. He is also acting as adjacent faculty member and Prestige Appointment with School of Pharmacy; University of Toledo, Seneca College and Toronto Institute of Pharmaceutical Technology (TIPT) based in Toronto. Dr. Aurora is also member of visiting scientist program sponsored by AAPPS. Dr. Aurora is also editorial advisory board member of various scientific publications such as Drug Delivery Technology, Contract Pharma and Business Briefing scientific and business focused publications from US and Europe.

Dr. Aurora research focuses and wealth of experience include development of Controlled-Release Systems, Pelletization Technology, and NDA 505(b)(2) and ANDA developmental and regulatory approval pathways. In the field of controlled-release development, he has 3 US and EU patents to his credit and another four are in process. He has also successfully managed global research teams operating from different parts of world (with different work culture and practices) under one umbrella for cost and efficiencies management.

With the additional teaching assignments and speaker opportunities, Dr. Aurora has grown to a seasoned and matured professional with in depth technical and management strengths and excellence to contribute for the success and growth of an organization.