



Brian Tempest

Chemistry in BRIC Countries

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Chairman of Hale & Tempest Co Ltd.

ABSTRACT: The R&D investment model of the Western Discovery Pharmaceutical Companies is starting to fall apart. The 7 emerging markets of Brazil, China, India, Mexico, Russia, South Korea and Turkey are estimated to have contributed an unprecedented 51 percent of global pharmaceutical growth in 2009. The \$ spent per ounce of innovation is said to make a dramatic difference when different R&D facilities are compared. This has had an impact on British and European R&D facilities.

The R&D investment model of the Western Discovery Pharmaceutical Companies is starting to fall apart with the well publicised reduction of NCE productivity. Surprisingly global R&D expenditures haven't changed that much in spite of all the comments on downsizing by Discovery Pharma. However there has been a rebalancing within the R&D numbers through outsourcing to Asia of R&D. At the same time regulatory hurdles have risen with more questions being raised by Regulatory Authorities on submitted clinical data during the regulatory process on potential blockbusters as identified by the financial analysts. The hurdles for gaining reimbursement in the European marketplace have also risen. Altogether this has also put more pressure on the New Chemical Entity (NCE) pipeline.

Whilst BRICS, Generics and Developing Countries are well known terms in the economic development of the global markets, IMS has now generated a new name for this Pharma sector called PHARMERGING. The 7 emerging markets of Brazil, China, India, Mexico, Russia, South Korea and Turkey are estimated to have contributed an unprecedented 51 percent of global pharmaceutical growth in 2009 (1). On the other hand the conventional mature markets of North America, Western Europe and Japan accounted for just 16 percent of the global growth. This is in sharp contrast to 2001 when these so called pharmerging markets accounted for only 7 percent of global growth compared to 71 percent share from mature markets (2). This growing sector has attracted the eyes of Global CEOs and Chairman of the Discovery Pharma companies. This high level of interest has yet to percolate down through the middle ranks of these Discovery Pharma companies and is generating interesting management issues within these companies. For example Pfizer calls its generic division "Established Products Unit" because it probably has to deal with five decades of anti generic PR. Government authorities have also become more and more invasive. The European Union has organised four separate but related Anti Trust raids on Pharma Companies in 2008/2009. In the USA the antitrust pendulum has swung both for and against Discovery Pharma-Generic Pharma deals but today it is probably resisting such deals in spite of the legal uncertainty. Corporate

HQs are looking to retain in house the added value roles like Regulatory, Clinical Trial design, price negotiators and sales/marketing teams. The outsourcing to Asia continues with Manufacturing, Clinical Trial and Development leading to an active Contract Research & Manufacturing Services (CRAMS) segment. At the same time the generic industry has become more and more skilful at finding its way around imperfect patents and this has led to most Discovery Pharma companies staring in the face of major patent erosion with some as high as 70 percent. New generic companies are appearing in the International Markets every month from India and China. This has led to restructuring of 15 of the top 18 Big Pharma Companies in recent years and the consequent loss of jobs. Additionally some companies have gone for big M&A mergers to camouflage all these problems.

Economically the West has started 2010 hoping for a better year. In Asia and India in particular the GDP growths of 8 or 9 or 10 percent are being forecasted. Where there used to be areas of jungle there are now new shopping malls with Versace and Chanel being shouted from their shop windows. Corporate offices in downtown Delhi are sporting rooftop waterfalls and lawns for the first time ever. The rise of China was the most read news story of the last decade surpassing even 9/11 and the Iraq war. On the macroeconomic front the Chinese non performing loans are now a quarter of 2002 and the Reserve Bank of India has become a model central bank owing to its careful historical management of Indian debt. In the past the China and India share of the world population has stood at around 37 percent although representing only 14 percent of the global world wealth. By contrast the USA and EU hold only 17 percent of global population but with a massive 55 percent of global wealth. Today a part of the world has substantial historical wealth and the other has dynamic GDP economic growth which is building a new era of middle classes. Investment bankers see a great opportunity here for synergising this wealth and this growth through alliances and M&A. McKinsey has forecast that with a consistent 7 percent GDP growth in India the middle class population in 2015 will become 281m middle class and in 2025 will rise to 600m³. These numbers overshadow the current size of the USA middle class, a fact which has not gone unnoticed. One of the driving forces of all this growth is the Asian high regard for education and science. India has increased its Science & Technology budget from \$4b in 2004/5 to \$6b in 2008/9. This contrasts with the recent announcement in the UK of the Chancellor's decision in December 2009 to cut a \$1b from the countries science and technology base. Although it follows the recent French plan to increase spending on Science and Technology by Euros35b. It is generally accepted that India is particularly strong in chemistry and maths with China seen as much stronger in Biology. There are now a dozen

internationally ranked Business Schools (Including Duke) setting up Business Schools in the Delhi area. The Lancaster University Management School already has 1000 students at the Goenka World Institute in Gurgaon. However China has quietly become the second source of scientific knowledge surpassed only by the USA. In 2006 China's research output was 83,000 articles per year overtaking Germany, UK and Japan at 80,000. In 2009 China reached 120,000 articles pa compared to the USA at 350,000 p.a. China now produces 20 percent of the new scientific knowledge in material sciences. Whilst quantity is not the same as quality 9 percent of Chinese papers do have a US based co-author.

The failure of the old R&D model in the Discovery Pharma space has led many Companies to reconsider their strategy and widen their vision. Discovery Pharma have become intrigued by the fact that 88 percent of the world's pharmaceuticals are shared between only 18 percent of the world's population. More significantly 82 percent of the world's population shares 12 percent of the world's pharmaceuticals. Here lies a business opportunity. This is strategically reflected in many ways. Some Big Pharma companies have a generic strategy, some have a developing world strategy, some have an outsourcing strategy and some have all three. In addition some have a parallel strategy of expanding in Vaccines, Consumer /OTC and Healthcare Venture Capital investments. The Chinese domestic vaccine market is said to be worth \$1b in 2012 growing at 25 percent pa with 40 domestic companies. Ultimately Discovery Pharma will expand strongly in the BRIC countries and the Developing World and present a Pharmedging face to the world alongside their mature markets face. With the new generation of global CEOs with young open minds in my view a new global deal on Intellectual Property will be cut with two different levels of IP protection for the mature markets and for the Pharmedging markets. The first signs are already there with the dual pricing policy which some Discovery Pharma companies are now following in Africa and South East Asia. The Global Centre of Gravity is now moving towards Asia.



In the generic space Indian DMFs continue to represent 50 percent of USA filings (3) compared to only 10 percent for Chinese sourced DMFs. In addition Indian sourced ANDAs have now reached 50 percent (4). China labour costs continue to be lower than India - although in Taiwan there are pressures from rising salaries. Chinese energy costs are also competitive and will attract investment in fermentation type facilities. The ready availability of inexpensive nuclear power in India will be an important step in competing with China on this aspect. The vibrant economic strength of China and India is pulling along the South East Asian and Oceanic economies as their supply chains are integrated into adjacent countries with a particular focus on Taiwan, Japan, Australia and South Korea. More than 200 international companies have R&D innovation centres in India with 40 percent of them located around Bangalore. The \$ spent per ounce of innovation is said to make a dramatic difference when different R&D facilities are compared. This has had an impact on British and European R&D facilities. The CRAMS market is forecast to become \$76b in 2010. What is surprising is that both India and China represent only a small percentage of this marketplace. Asia

only has a 10 percent share whilst India itself only has a 4 percent share. The potential for expanding this share is huge and explains why the investment community sees this sector as a vibrant one in the Indian situation. Indeed Pfizer is forecasting to have 30 percent of manufacturing outsourced by the end of 2010

In this BRIC dialogue what has happened to date will probably be overshadowed by what is yet to happen in the light of the many alliances being discussed today around the world.

REFERENCES AND NOTES

1. IMS
2. McKinsey Global Institute
3. JMFinancials, US FDA
4. Deutsche Bank, US FDA