A NEW FORMULA

After years of anaemic growth, pharma multinationals in India seem poised for a steroid-led growth. And it's not all M&A-led.

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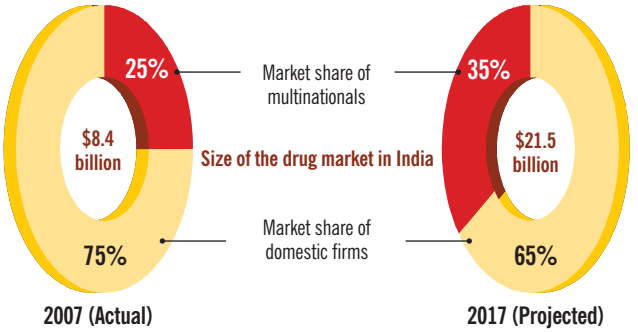
RISE AND SHINE: India is among the fastest growing emerging markets for pharma and healthcare.

ANDREW WITTY, THE 46-year-old Chief Executive Officer of GlaxoSmithKline (GSK), has visited India twice during his two-year stint at the helm of the world's third-largest drug maker by sales. His predecessors were far less enthusiastic about the country—no one in GSK's India head-quarters can remember when they played host to a travelling CEO prior to Witty.

This new fondness for India isn't restricted to GSK. At Sanofi-Aventis, a $40-billion drug

SPREADING THEIR WINGS

MNCs are looking at a 40% rise in market share over 10 years.



Source: Yes Bank

firm headquartered in France, this has led to a change in its reporting structure—India is now a direct reportee to corporate headquarters in Paris. "This signifies the importance the company attaches to the future of our business in India," says Shailesh Ayyangar, Managing Director (India) & Vice-President (South Asia), Sanofi-Aventis.

This India fascination—despite a relatively small domestic drug market size of $11 billion vis-à-vis the $289 billion US market and $130 billion European market—is understandable. Big Pharma's traditional business model with its focus on developed markets and patented products is undergoing a dramatic transformation. Why? Well, for one, pharma majors are facing a patent cliff—drugs with sales of more than $120 billion are expected to go off patent in the next three years, leading to increased competition from generics, i.e., therapeutic equivalents of patented or innovative drugs.

Second, there's the problem of declining R&D productivity. Put simply, this means the number of new innovative drugs getting commercially launched is on the wane. In 2010, for example, 26 such drugs were launched, compared to 50 in 1997. The combined effect of the patent cliff and fewer innovative drug launches is impacting Big Pharma's growth numbers. There's more bad news—spiralling healthcare budgets across the world are forcing governments and reimbursement authorities to contain costs through policies that push cheaper generic drugs. That's a double whammy.

> **"Big Pharma is only just beginning to put serious money in India. You will see the outcome of these investments in the next few years.**
>
> **—Hasit Joshipura**
> **MD, GlaxoSmithKline India**

Strategic Shift

As easy pickings in their traditional battleground (US and Europe) come to an end, the focus of global pharma companies has shifted to the emerging markets. At $55 billion, this market is small compared to Europe or US but is expected to grow more than seven times its current size to $400 billion by 2020. The developed markets, on the other hand, are expected to grow by 30% during the same period. It was an easy choice and emerging markets, including India, became the new battleground for Big Pharma. Speaking at the earnings call for the fourth-quarter of 2008-09, Sanofi-Aventis Chief Executive Office Christopher Viehbacher remarked, "We're seeing markets in China, India and Latin America as the real growth drivers… I sometimes think we in the healthcare industry still haven't really appreciated the kind of economic revolution that is going on in some of those markets."

Within emerging markets India is not the biggest—China ($16.2 billion) and Turkey ($11.2 billion) rank higher than India. But it is among the fastest growing. Rising disposable incomes, increased awareness, growing insurance penetration, greater life expectancy and a shift in disease profile towards chronic life-style illnesses make India an attractive destination despite nagging concerns over the new patent regime *(see: Government Price Controls Are Unnecessary)*.

Interestingly, when Big Pharma turned its focus to emerging markets in 2007, the first preference was China and Brazil. Hasit Joshipura, Managing Director (India) & Vice-President (South Asia), GSK, explains, "Brazil was familiar territory because of its proximity to the US. China has a more conducive intellectual property environment and there's hardly any domestic competition. Besides, both are payor or reimbursement markets unlike India where health insurance coverage is minuscule." This is why all investments in the early days went to China and Brazil—India came into focus only in the last one year. "Big Pharma companies are only beginning to put serious money

into the commercial side of their operations in India—in the next few years we will see the outcome of these investments," notes Joshipura.

Anaemic Growth

Pharma MNCs are not new to India—they have been around for decades. But barring GSK (and to a lesser extent Pfizer and Aventis), most multinationals had a small footprint in India.

Lack of focus from the parent and a small product basket covering only a few therapy areas put them at a disadvantage vis-à-vis domestic Indian drug makers like Cipla, Ranbaxy, Nicholas Piramal, Zydus Cadila, Dr Reddy's Laboratories and Sun Pharma. While the Indians managed to keep pace with market growth numbers (often even exceeding it), pharma MNCs were the underperformers.

The reasons are simple. India is almost entirely a generic drug market unlike the US or Europe where generics account for less than 15% of the total drug market. Growth here is contingent upon the number of new product launches. In the absence of a generic portfolio and the lax patent regime preventing the launch of innovative products from their global portfolio, MNCs had little option but to flog their old horses. They did a good job of it—MNC products make up over half the list of the top 10 drugs in India—but it wasn't enough to bolster their growth rates beyond low single digits. GSK, the largest pharma MNC in India until Abbott catapulted to the numero uno slot post its M&A deal with Piramal Healthcare in 2010, grew by 3-5% per annum during 2000-06. It was a similar story at Pfizer—up until now.

> **"Incremental innovation is vital in R&D. Over 70% of all drugs have been developed via incremental innovations.**
>
> **—Ranjit Shahani**
> **MD, Novartis India**

A New Avatar

In the last one or two years a new era has dawned for pharma MNCs, one where growth is no longer a pipe-dream. They are not only keeping pace with the growth in the market, a few of them are even seeing industry-leading growth. This is a first for pharma MNCs. Abbott is growing at 15-16% per annum; so is Pfizer. The days of low single-digit growth are over for GSK and Sanofi-Aventis, while relatively smaller players like MSD (the India subsidiary of the $27 billion Merck & Co) and Merck (the India subsidiary of the $10 billion Germany-headquartered Merck KGaA) are growing in excess of 20-25% per annum.

KG Ananthakrishnan, Managing Director of MSD India, says, "By 2013-14 we expect to earn 25% of our global revenue from emerging markets, up from 18% currently. We also want to be among the top two players in priority markets like China, India, Brazil, Mexico, Turkey and Russia. We have a product basket that can meet the unmet medical needs of all these markets, including India." It's a tall order as MSD India currently has a market share of less than 3%. But Ananthakrishnan remains undaunted. "We are firing on all cylinders," he offers by way of an explanation. And to be fair, the company is growing at 33% per annum.

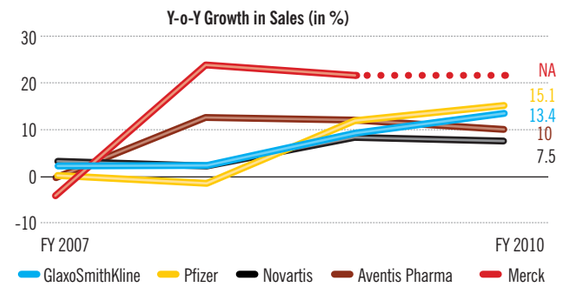
K Shivkumar, Director, Pharmaceuticals, Merck, admits that years of neglecting the India market has seen pharma MNCs playing second fiddle to their domestic peers. (GSK is an exception—even though India was not a priority market within the group, investments weren't put on hold.) "Big Pharma has now realised that it's possible to grow in India provided they adopt an India-specific strategy. It's no longer a one size fits all," notes Shivkumar. The India-specific strategy meant having a broad-based generics portfolio including an exposure to anti-infectives (the largest therapy segment in India valued at $2 billion) and coming to grips with the price sensitivity of the Indian market.

A re-think of the business models has led to a flurry of investments in the India subsidiaries (and that of the other emerging markets). According to Ajit Mahadevan, Partner, Business Advisory Services, Ernst & Young, these investments are going into ramping up headcount (primarily sales but also line functions like IT and HR), broad-basing the product basket and brand-building initiatives. Manufacturing capabilities are not a priority as local sourcing is expected to take care of it. "The one area where investments are not coming into India is research and development. China has taken the lead in attracting R&D investments," adds Mahadevan.

MNCs ARE NOW KEEPING PACE WITH THE MARKET; A FEW ARE EVEN SEEING INDUSTRY-LEADING GROWTH.

UPPING THE MOMENTUM IN INDIA

Three out of the top five companies in the domestic pharma market are MNCs.



Source: Companies

While statistics for individual countries are not available, GSK's annual results reveal an uptrend in fund-flow to emerging markets. SG&A (or selling, general & administrative) cost as a percentage of sales for emerging markets has increased from 42% in 2007 to 53% in 2009, while that of the developed markets has dropped from 58% to 47%. And contrary to popular perception, not all of this fund-flow is M&A-led. As Witty mentioned during GSK's earnings call, "For the very first time we employed more sales representatives outside of America and Europe than we did inside of America and Europe. This will give you a sense of the reality of the shift of resources in the organisation."

Generics Play

Pharma MNC has a three-pronged strategy for growth in India—aggressively build (or buy) a branded generics product basket; launch patented drugs from the parent's portfolio at India-specific pricing; and get a rural exposure. All three mark a significant departure from tradition. Take, for example, pharma MNCs' entry into the branded generics segment. The typical modus operandi is partnerships with local players. While Big Pharma has inked tie-ups in the past with Indian drug manufacturers, these were contract manufacturing deals covering proprietary products.

Now, for the first time, pharma MNCs are inking sourcing deals with Indian firms to launch generic versions of their global competitor's molecules. Unthinkable a few years ago, these tie-ups are necessary for pharma MNCs to quickly operationalise their generic strategies without going through the lengthy process of developing a broad range of products and sinking significant capex for manufacturing capabilities.

Pfizer has been the most aggressive global player in this space—in 2009 it announced sourcing deals with Aurobindo Pharma and Claris Lifesciences, followed by Strides Arcolab and Biocon a year later. Pharma analysts say Pfizer has a very ambitious generics plan, not just in emerging markets like India but also the developed markets. GSK, on the other hand, is building a generics portfolio only for the emerging markets. The company has a sourcing tie up with Strides Arcolab and Dr Reddy's Laboratories.

To build a strong and broad-based branded generics portfolio, pharma MNCs have not only stepped up new product launches but are also upping their field-force and promotional spend. A look at the financial statements of these companies reveal a spurt in personnel and selling expenses. Take Merck, for example. Personnel cost as a percentage of sales has gone up from 7% in 2006 to 11% in 2009. Selling expenses have doubled to 10%. GSK's field-force addition has resulted in personnel cost as a percentage of sales inching up from 9% to 11% in the last three years. The company has added more than 200 people, taking the total field-force headcount to around 2,500. Pfizer added 500 sales staff last year, taking its total field-force strength to around 2,300.

Ernst & Young's Mahadevan says pharma MNCs have many more products to sell today than they did a few years ago and, hence, they have to significantly enhance their sales-force numbers. And the MNCs still have a lot of catching up to do vis-à-vis the large domestic drug makers. Dr Reddy's Laboratories, for instance, launched 11 new products in FY09 and boasted a

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MNCs WITH A SMALL INDIA FOOTPRINT ARE BUYING GROWTH; THE REST ARE INKING LOCAL TIE-UPS.

field-force of 3,500. In comparison, GSK India launched only four new drugs and Pfizer India two.

Drugs And More

In an effort to distinguish themselves from the crowd—the Indian drug market is fragmented with 300 large and 18,000 small units—pharma MNCs are going beyond just selling drugs to offering what they call 'healthcare solutions'. Sanofi-Aventis' Ayyangar explains, "The patient is at the centre of our activities. Instead of just pushing pills we are thinking of everything that a patient may need. Things like support, creating awareness and even disease prevention."

MSD's strategy, too, goes beyond launching new products (both branded generics and innovative drugs) to offering a healthcare solution. A case in point, MSD's Ananthakrishnan says, is the diabetic patient support programme Sparsh. "Run with the help of doctors, nutritionists and counsellors, it's a diabetes management programme where patients can dial into a call centre (located in Hyderabad) and learn how to manage the disease. They can get any information they need—from diet and nutrition to exercise and weight control to diabetes-related complications and even medicine compliance," he explains.

Sanofi-Aventis recently unveiled the 'I am a Champ' initiative, a first-of-its kind diabetes award programme. The company invited entries from patients on how they manage their diabetes—some 5,000 people participated. This was narrowed down to 42, who were then vetted by a panel of doctors, nutritionists and fitness experts. Seven winning entries were felicitated at a public ceremony in Mumbai.

These initiatives entail money outgos but both MSD and Sanofi-Aventis view it as an investment. As Ayyangar puts it, "In diabetes, the treatment regime has to be complemented by a more comprehensive approach to disease management for the health and well-being of a patient." What he leaves unsaid is the benefits of this investment—diabetes is a very lucrative market. "If a company can create a strong brand recall, not just with doctors but also with patients, it's going to yield them big money in the long-term," says Vishal Gandhi, Vice-President (Life Sciences & Technology) at Yes Bank.

Better lifecycle management of drugs in their portfolio is another way pharma MNCs are looking to shore up growth numbers. Take, for example, Sanofi Aventis' anti-hypertensive drug Cardace. It's an old drug that competes with more than 100 similar products in the market. The company has been able to retain its number one position in this category and grow at 17% per year by launching new combinations (like Cardace and Amlodipine meant for patients with high blood pressure who need to be protected from cardiovascular risk factors).

"By launching newer combinations we are able to drive further usage of our old drugs," says Ayyangar. Combination drugs are not new to India—domestic Indian companies have been walking this path for a number of years now. But pharma MNC executives say the difference is launching combination drugs that are relevant to a patient's needs.

The M&A Route

Big Pharma has been on the prowl to buy generic capabilities, both in India and elsewhere. But it wasn't until Daiichi Sankyo's acquisition of Ranbaxy in 2008 that the M&A appetite in India was fuelled. "We are very open to looking at acquisitions to grow our generics business so long as it complements our portfolio. But we won't buy something just because it is available in the market," says MSD's Ananthakrishnan.

"Big Pharma has realised that it's possible to grow here provided they adopt an India-specific strategy. It's no longer a one size fits all.

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Director (Pharma), Merck

He can afford to take it slow as the merger of Schering Plough India with MSD (it was a global acquisition) has resulted in a broad-based product basket covering a number of therapy areas. But for players like Abbott Laboratories, an acquisition is perhaps the only choice to play catch up. While Abbott India's portfolio had a few strong brands like pain-killer Brufen, laxative Cremaffin and antacid Digene, it was limited to a few therapy areas like gastroenterology, pain management and metabolic disorders. The $3.72-billion acquisition of Piramal Healthcare's domestic formulations business in June 2010 not only catapulted Abbott India to the number one position in terms of market sales but also broad-

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based its portfolio to include therapy areas like anti-infectives, respiratory diseases, cardiovascular diseases and neuroscience. In addition, it gained a field-force of about 5,000 and a product basket of 350 drugs.

In 2009, Sanofi-Aventis bought Indian biotech's poster child Shantha Biotech for $783 million. This was in sync with the French drug maker's strategy of adding to its vaccines portfolio—a high growth market globally.

Sanofi-Aventis's M&A activity has not been restricted to the Indian shores. It's made three acquisitions around the world to shore its generics capabilities—Czech firm Zentiva ($2.6 billion buyout), Brazilian drug maker Medley ($664 million) and Mexico-based Kendrick (amount not disclosed). Similarly, GSK acquired Bristol Meyers Squibb's branded generics business (which gives it access to markets in the Middle East) and South-Africa-based Aspen (16% stake) to feed the African markets. GSK's Joshipura is often asked why the company has shied away from big-ticket acquisitions in India and he is always quick to retort, "Our story is different. We already have a broad footprint in India." He, however, is equally quick to add that GSK is not averse to inorganic growth but the high valuations make M&As in India expensive. Pharma analysts say the choice is clear—big-ticket acquisitions for those who lack a footprint in India and small, targeted acquisitions or partnerships for those looking to plug gaps in their product portfolio.

India-Specific Pricing

Pharma multinationals are now more comfortable with India-specific pricing than they were a few years ago. So much so that they are launching patented products from their parents' portfolio at a fraction of their global prices. While opinions may vary on whether these drugs continue to be unaffordable to a vast majority of patients despite the steep discount to global prices, the fact is that tiered pricing is now the norm in India rather than an exception. Novartis has launched Diovan, an in-patent drug to manage blood-pressure, at an 80% discount to its prevailing global market price. The company is also selling Galvus, another in-patent drug used in the treatment of diabetes, in the India market.

Interestingly, Novartis' prolonged legal battle over its cancer drug Glivec (the patent office in India has nixed the company's demand for a patent citing lack of innovation and affordability) has not deterred the company from launching innovative products from its parent's portfolio. Ranjit Shahani, Vice Chairman & Managing Director, Novartis India, says, "It is preposterous to think we will not launch innovative drugs in India just because of what's happening with Glivec. The two issues are unrelated."

He, however, says it is unfortunate that India does not recognise incremental innovation. "Incremental innovation is the life-blood of research. Over 70% of all medicines available in the market today have been developed through incremental improvements to the base compound or existing drug."

MSD also has its share of India-priced products. In-patent cervical cancer drug Gardasil is being sold in India at a 75-80% discount to global prices. Similarly, pharma analysts point out that Januvia, a new age under-patent diabetes drug, is available locally at one-tenth the global price. Ananthakrishnan says the company plans to launch more innovative products from the parent's portfolio and as early as possible.

Patented products currently account for less than 0.25% of the India drug market, but this is expected to rise to 5-7% over the next five years. Will this impact drug prices? The answer depends on who you speak to in the industry—it's an emotive issue that has split the industry down the middle. While domestic players can't stop talking about the impending price inflation, MNCs say this is not borne out by facts. They have a point—drug prices in India have risen by less than 1% in the last one to two years while the market is growing at more than 15%. At the same time, it must be said that innovative drugs currently account for a minuscule portion of the market.

MNCs ARE TODAY LAUNCHING INNOVATIVE DRUGS IN INDIA AT STEEP DISCOUNTS TO GLOBAL PRICES.

Q&A

'Government price controls are unnecessary'

Ranga Iyer is an influential pharma voice—he was ranked among the 40 most influential pharma people by World Pharmaceutical Frontiers. Currently advisor to PhRMA (the global industry body representing Big Pharma), Iyer talks about some of the contentious issues in the Indian pharma market.

ACCESSIBILITY OF DRUGS: 65% of Indians don't have access to medicines, but this unmet medical need cannot be met by only providing medicines. You have to look at the larger picture—where are the doctors, the nurses, the pharmacies, the hospitals? You cannot spend 1.2% of GDP on healthcare and expect to take care of 1.2 billion people. This has to go up.

PRICE CONTROL: Take the top 100 companies, which account for 92-93% of the market—all of them have a very wide product range with a few hundred brands each. This has given rise to intense competition, which keeps prices in check. With market forces keeping prices in check, government price controls are unnecessary. How many of the 74 drugs under price control are actually available in the market today? My guess would be none—companies have stopped production because it doesn't make economic sense.

PATENTED PRODUCTS: There are an enormous number of generics—including first-generation anti-infectives like penicillin and tetracycline—in the market and they will continue to be there. The product lifecycle in India doesn't follow the usual bell-curve—instead it goes up, plateaus and stays there. The first-line therapy drugs are all generics—there are enough and more generic alternatives available in the market to take care of our basic drug needs. Concerns that patented products will flood the market are unfounded.

NEW PATENT REGIME: The first problematic issue is incremental innovation—the law discourages it. Incremental research is not the same as ever-greening (extending the life of a patent). Most medicines in the market today are a result of incremental innovation—because it costs less than basic research, it helps companies recoup investment in R&D. The second issue is data protection. You need to submit data to a drug regulator for clinical trials conducted for a drug on the basis of which you seek marketing approval. In the absence of data protection, people can rely on another's data instead of conducting their own trials. This can have dangerous repercussions, especially in case of an adverse event. Then there's pre-grant opposition (before the grant of the patent)—it's being misused as a delaying tactic to prevent grant of a patent.

The Hinterland Beckons

While pharma MNCs are stepping up their rural initiatives, most of them still are community activities and outreach programmes. And they deny this is a precursor to a commercial launch in the years to come. GSK has set up the Gramin Aarogya Vikas Sanstha to provide healthcare facilities to the tribal population in Peth, a remote area in Nashik district, through mobile health clinics equipped with doctors and healthcare workers. The firm has also tied up with the Institute for Indian Mother & Child, a non-governmental organisation committed to promoting child and maternal health, to support the medical needs of the rural poor in West Bengal.

Sanofi-Aventis's Prayas initiative seeks to improve the quality of healthcare practices in rural India by bridging the diagnosis-treatment gap through a structured education programme for doctors in remote areas. The idea is to share the latest medical knowledge and clinical experience and thereby equip doctors in rural areas to treat patients more holistically.

Life seems to be coming full circle for pharma MNCs. Until 1970 (when the Patent Act allowed reverse engineering of globally patented medicines) the India drug market was dominated by multinationals. Between 1970 and 2005, however, the market share of the domestic drug firms soared from 20% to 85%. Currently, MNCs enjoy a 25% market share—thanks to a few big-ticket acquisitions, aggressive expansion of India operations and entry of new global players. Yes Bank believes this will go up further to 35% by 2015. "MNCs are better placed than their Indian counterparts because they have access to global pipelines. The latter will slowly lose their flexibility to launch copies of newer global molecules because of the new patent regime in India. And the resultant slowdown in product-based growth will impede their growth going forward," says Gandhi. Will this mean game, set and match to pharma MNCs? Only time will tell. ■

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