BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Generics challenge pharma drug pricing regime

July 4, 2012 | Opinion | By Nandita Singh

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Healthcare systems, globally, are grappling with different facets of the same problem: How to provide affordable healthcare to 100 percent of its citizens?

Almost all countries look up to US as a reference point for best of the systems and processes. Insurance, regulatory, healthcare systems, public policy... the examples of being modeled after US abound in every country. While US itself is looking for a system re-haul. The upcoming healthcare legislation in the US will decidedly focus on cost-control, as its healthcare industry has been growing at a pace at least two times faster than its GDP since many decades and has reached unmanageable proportions. And that is good news for companies in the generics drug market. Their time has come and how!

A recent study, released by UR Associates, an FDA approvals tracking agency, reported that the US FDA has given a total of 151 generic product approvals and tentative approvals (excluding labeling revisions, modified indications and manufacturing changes) during the period April-June 21, 2012. And Indian pharmaceutical companies have cornered 32 percent of these approvals. This translates into 49 ANDA approvals in all. Sun Pharma and Aurobindo Pharma top the list, followed by other heavyweights of the Indian pharma industry - Dr Reddy's, Strides Arcolab, Torrent Pharma, Hetero Labs, Glernmark, Cipla, Lupin, Alembic, Orchid, Ranbaxy, Suven Wochkardt and Jubilant Organosys.

What is significant is that these companies now have the opportunity to tap the generics market, which is easily in excess of $10 billion in the domestic space itself. Then there is US generics market that the industry analysts estimate to be over $400

billion, growing at about 12 percent every year.

Governments in most Asian countries are looking at including generics in their healthcare agenda besides resorting to compulsory licensing as and when deemed fit. The most recent case of compulsory licensing in India that of Natco bagging compulsory licensing for Bayer's Nexavar is still generating a lot of heat among the innovator drug companies.

So, given the background how are the innovator companies tackling the generics rush. For one, many of these innovator companies are diversifying with generics themselves and are scouting partners and acquisition targets.

Now, given that most of the generics drug approvals in Asia are with Indian companies India is the market that will witness high action with regard to mergers & acquisitions. Just last week, the news doing rounds was Merck is set to acquire Micro Labs, an API maker in India. Many other MNCs are scouting the market for a company that will boost its bottom line. In fact, this is the only way these MNCs can buy a couple of years of time to figure out their strategy ahead.

While all this action is happening, the real beneficiaries are patients across the globe, whose access to affordable generics drugs is improving and will improve further by leaps and bounds.

The pharmaceutical drugs pricing regime, globally, is set for a sea change.