The Unknowns

While one view is that Trump’s aim to reduce drug prices will benefit Indian makers of affordable generic medicines, the clamour to Make in America may result in import barriers like a “border tax”

Indian pharma leaders like Sun and Dr Reddy’s have their factories under USFDA import alert

Six Indian pharma companies are under investigation by US Department of Justice over cartelisation of drug prices. If proven guilty, the fines will be a burden on the balance sheet

US Big Pharma has been putting pressure on India to amend its patent laws, which subsequent Indian governments have refused

The Way Forward

No more just generics, companies have to diversify to speciality or branded generics portfolio

Invest in innovative drug products: Sun Pharma, Dr Reddy’s and Glenmark are betting big on IP

Diversify into emerging markets, look at Eastern Europe, Latin America as back up

Clean up USFDA mess, with top management playing a direct role in quality and compliance issues

Increase focus back home, a market that continues to generate profits for Indian pharma

“Will Manufacture More in the US”

Glenmark Pharma, an Indian generics maker, is taking the innovation route by focusing on complex generics. In an exclusive interview with ET Magazine, Robert Matsu, president, North America and global API business, talks about the company plans in the US market. Excerpted excerpts:

On how generics makers in the US are looking at the current political climate

I think every political party before election was talking about pharma and price increases. We said that we are not banking on unconstrained price increases for growth; our strategy is continuous evolution of growth for our pipeline. Right now we have about 114 ANDAs (Abbreviated New Drug Applications), which contain data that does not require approval for a generic drug, another 65 waiting for approvals, so the first point is that you constantly evolve our portfolio. A year from now, we would expect to have another 10-15 ANDAs and another 15 products that have moved to development. If you think about it, whether it is to diversify or to make generics, they constantly need new products to be successful in the business.

On revamping the portfolio

We are getting into complex generics in various areas like dermatology but the biggest one is a drug device combination, another one is respiratory technology that we will licence. So we are not going to look at in-house development, we already have five. And there is more to come.

On possibilities of price increases in the Trump administration

On the branded side in the US, there is single-digit net price increases. However, on the generic side, the price increase is 7-9%. We have come out and publicly stated that our price increase is going to be 10%.

In terms of manufacturing, Glenmark, well before the existing political climate, started investing in manufacturing in the US. We started that in 2014, so we have manufacturing more in the US. Taking a broader industry perspective, approximately 40% does not happen. However, with Trump’s administration, there might be a change in the regulatory environment. We need to work through a number of things.

The bureaucracy in the US would advise that China and India cannot be antagonised, so it is unlikely that the Trump administration would be hard on India

DG Shah, secretary general of the Indian Pharmaceutical Alliance

The PBR

The PBR is a macro worries of a trade tussle over intellectual property rights (IPR) is an old sore point between the US and India. The US Trade Representative (USTR) continues to corner India over its intellectual property (IP) laws, India was once again included in Special 301 of the USTR which considers India’s IP as a barrier to American businesses. In a tennis match of sorts, both countries keep trading bars over IP, but with a new administration in the US, how this will pan out is yet another matter of uncertainty. The Indian government, meanwhile, is firmly behind its industry and laws.

“Those who are making these (allegations) are not challenging that there is no violation of trade-related intellectual property. Some countries are trying to use TRIPS to TRIPs - but that is what we are not signatory to. Our commitment is to TRIPS, and that is the position we have maintained,” Sudhamshu Pandey, joint secretary commerce ministry, told ET last week. Trade-Related Aspects of IPR, or TRIPS, lays down minimum standards for IP regulation for WTO member countries. TRIPS is a collection of higher standards of protection that some countries – not India – have agreed to.

Pandey also thinks that the brouhaha over quality issues is overplayed in the media, as he thinks Indian companies are “honest” in their approach. On the possibility of a trade war between India and the US, the Indian pharma lobby thinks if all there is it could be with countries like Mexico and China. “If the US would want a trade war with India, considering we recently bought arms worth $5 billion from the US, it would come down to the US,” points out Shah.

Even a clutch of mid-size pharma companies like Glenmark persist with their plans to build manufacturing units in the US (see “We Will Manufacture More in the US”), they’re also stepping up the pace in emerging markets. Russia, a few parts of Latin America and Japan are where these companies are moving their focus to. And, of course, there is always the domestic turf, where relatively lax regulations and an ever-increasing monopoly ensure that MNC Big Pharma has to play second fiddle.