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South America, an important market of the future

, **Thursday, August 01, 2013, 08:00 Hrs [IST]**

South America, especially Brazil and Argentina are very important markets for India in the future. Despite the mammoth presence of the multinational companies, Indian pharmaceutical and biotechnology companies can make a big difference in Brazil in particular and South American markets in general. India's cost advantages with the right partnering or acquisition can help companies make a promising headway in the region, says **Ajay Bharadwaj**, CEO, Anthem Biosciences in an email interaction with **Nandita Vijay**. *Excerpts:*

How would you describe the importance of BRCS and s pecially Brazil for bio pharma companies of India?
Brazil, Russia, China and South Africa (BRCS) are very important countries as they are the emerging economies of the world. Of course the registration rules and requirements are very different for each. Brazil in particular is among the most important, because it has transparent rules and a higher health spend per person than most of the other BRCS countries. Biological therapeutic products are among the most expensive treatment options for patients but are highly recommended because they are often potent, specific and have relatively little side effects. Brazil, like all other emerging countries, is keen to lower its cost of therapy and bring these treatments within the reach of its larger population, without compromising safety or quality. Indian biosimilars which have been extensively tested clinically and have gone through due process of registration are likely to win big in BRCS countries.

How do you think the Indian bio pharma companies in cluding Anthem can leverage the opportunities in Br azil and South America?
Luckily, many biopharma companies have had good exposure to Latin America and many of them have already established a beach head with their products. This does make life easier for others to follow. Anthem has also got its own representation and registrations are underway.

What is under-explored is the biopharma services po tential in these markets. That could present an opp ortunity. Going forward as business expands we woul d also be keen to look at a manufacturing site in Brazil or Argentina as that would allow us to be close to the markets. It is imperative that companies like ours have a global manufacturing footprint if we are to truly unlock our potential.

Could you list some of the initiatives taken by Ant hem to tap Brazil and the other markets of South Am erica?
Selection of the right product, where Anthem has strengths and technologically superior product opportunity is the key. After identification of the right product, the right type of documentation has to be filed. Having a local representative to assist in filing and collating the right data is important. Brazil is an open country and they are looking for the same portfolio of drugs like insulin, GCSF(granulocyte-c olony stimulating factor), vaccines etc that are in creasingly being made by Indian companies.

As the world gains wider experience with biosimilars and the patient population on these products grows even more significant, the last vestiges of resistance would crumble and policies and guidelines would be made friendlier for biosimilars. Let us not forget that a couple of decades ago, there was tremendous resistance to Indian generics or small molecules and today we are the pharmaceutical facto ry of the world. So in the not very distant future, Brazil and other South American companies would adapt even more complex biosimilars like monoclonal antibodies etc. Anthem is putting in place regulatory compliance which allows us to benefit from these changes.

Would there be opportunities for the unique Anthem DRAP (Discovery Research Alliance Partner) model in this region?
Hard to say and this is because there are not enough discovery-based companies in the region. However, there are other services where this market is underserved. We are exploring those markets. Having said that, it is again a matter of time when the region will boast of its own drug discovery companies. Brazil has some world beating companies in other high-tech areas like for instance Emberaer in aviation, Petrobras in oil exploration. I am confident that as the scientific talent pool gets built, drug discovery would also be pursued. Our DRAP model would be useful for such co mpanies.

Could you comment on the competition you are facing in this region?
Since ours is a diversified portfolio from services to products, we do not have a single identified co mpetitor in the region. Since we supply enzymes, p robiotics, nutritional products, dietary supplement, we have a number of competitors from all over the world in each of those categories. And the competition would only get fiercer but believe we have the scientific differentiators to create an impact abov e and beyond our competitors.

How tough is the regulatory environment here and th e kind of technical documentation required for Indi an bio-pharma to make a presence?
Anvisa registration is more and more in line with current guidelines from USFDA, EMA etc with some small differences. So one must have the same level of regulatory compliance and data as advanced countries which included clin ical data. Now in order to have a presence in thes e markets, one has to be prepared completely.

Having a huge presence of multinational companies h ere, how are the Indian bio- pharma companies positioned to garner a share of the opportunity?
Even though multinational companies are present in full force, with our cost arbitrage and with the right partnering or acquisition, Indian companies can make a dent in these markets. As I have said earlier the cost of therapy including for biosimilars is the key decision parameter, if all the safety and clinical data is positive. I believe we will be able to provide the right data for the users to decide, whe ther they want to pay horrendously high prices or u se cheaper, yet equally safe alternatives.

Going forward what is Anthem's action plan in India and globally?
We are investing in a bigger facility which would also be fully approved by the likes of USFDA, EMEA etc. Our labs are getting GLP(good laboratory practice) accreditation this year. We have invested a lot of money in research and will continue to do so in the coming years. Our new manufacturing facility should be ready by 2015. We are already present in all the main markets with our research services and in the last couple of years have started export ing our actives in South Asia, South East Asia, Middle East and Latin America. We will be expanding this to developed economies by next year.

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