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'Indian biotech needs stringent regulations'

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“Indian biotech needs stringent regulations”

—Gunther Winkler, senior vice-president-International, Biogen Idec

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Gunther Winkler

It is not everyday that we see bigwigs from the ‘Big Biotech’ bandwagon coming down to India. So when Gunther Winkler, senior vice-president - International, Biogen Idec made a recent visit to India, we did not miss the opportunity in pinning him down for an interaction. In a free-wheeling interview with BioSpectrum,Winkler was extremely candid about the need for the Drug Controller General of India (DCGI) to come up with a compact and stringent regulatory structure, and his apprehensions for India in terms of Biogen’s investment plans to have a huge presence in India.

In terms of large scale investments, how is Biogen looking at India as a prime destination?

India is an important place in terms of executing our Asia strategy. This includes accelerating our R&D and doing it morecost-effectively. We have been successful in the last two years since we set our base here. Indian physicians are highly educated, have good knowledge about the field, and are good in spoken English. The main strategy is to expand our product pipeline into the Indian market. At the moment, I would not like to comment on our investment numbers.

We have realized that many diseases which have been characterized and diagnosed in the West have not yet been diagnosed here. So we will be investing in education, both for doctors and patients, especially for multiple sclerosis; the numbers of which are rising in India than what is given in the official figures. By investing money in education, we will then bring our products into the market. We will also look at business deals. For the last two years, we have been looking at potential research partners, but have not found one as yet, strategic moves of investments like moving up a manufacturing facility from the West to India are also in the pipeline.

What is it that you are looking for in a business partner? How do you think that can be achieved?

I think we have not been able to find the right partners because we have been cautious. We have more than 4,200 people worldwide, and getting any significant partners would increase that number. We are looking at a partner who can help us develop our innovative pipeline because we are a company that brings out innovative products for the patients. Now, we are looking for partners who can help us create and develop new products.

Which disease portfolios are you looking at in India ?

Currently if you look closely, the incidence of heart-related diseases is showing a sharp rise, and India today has the highest percentage of heart diseases. We do have existing products for heart diseases in our portfolio. There is a strong rise in rheumatoid arthritis in India and immune-related diseases. There is no shortage of bringing value to the patients with our existing portfolio.

Are there any new products that will be launched next year in India?

We will be launching our innovator product by January 2010, but on generic pricing. Here, we will be relaunching Avonex, an interferon for multiple sclerosis treatment which is our flagship product. This time, the launch will be under our brand and sales force.

What is your opinion about India as far as R&D investment in biotech is concerned?

After several interactions with the DCGI, I have realized that India is moving in the right direction. First of all, they understand that biotech products are different from small molecule products; the former are much more difficult to reproduce and mimic for biosimilars than it is with small molecules. The DCGI is now in the process of putting some regulations.

Coming up with regulations for biosimilars is very complicated. Europe has come up with a pathway but it is not perfect. US has been in the process for biosimilars regulations for the last three years and is yet to come up with one pathway. It is difficult to configure all the nuances, because we still do not have the technology which allows us to test the product in laboratories.

In India, on one side the top companies have a good understanding of what is biomolecule, how to manufacture it, how to characterize and test it, while on the other, there are small companies who are there to make quick money and go the short-cut way. This can be dangerous because for a molecule which is a million times larger than a small molecule, many things may go wrong that it will harm patients. That is where the Indian government needs to draw the line and come up with strict regulations.

Have you raised the issue for an independent regulatory structure for the approval of biotech drugs before the government?

Yes, but I think the government is aware about this issue. It will take time. It took a long time in the US for the FDA to segregate into specialized biologics and specialized products in small molecules. I feel that the Indian government will be on a faster track if it learns some lessons from the FDA.

There are a lot of products in the Indian market like EPO, Interferon insulin which goes through the same process of approval. Will that be a comfortable point for Biogen?

In biosimilars, companies will be targeting the more complex molecule. For the next few years, I strongly believe that there will still be a vacuum in terms of regulations and understanding as to what it really takes to make an effective biosimilar product.

During this time, we will be seeing products that are harmful to patients. My message to the Indian players is to be careful. This can ruin the reputation of the Indian industry. As long as the government does not have any regulation, there needs to

be an element of self-regulation among players which unfortunately is not happening in India.

What were the concerns that you put forward before the government?

We have had informal discussions with the government. My message is clear – the technology available does not allow us to test for lab analysis of biosimilars which guarantees that the product is similar to the innovator. Therefore, a company in biosimilars needs to follow strict guidelines as to what pre-clinical and clinical tests needs to be done to issue safety efficacy.

You have emphasized on the enforcement of stringent laws in clinical trials in India. Has that held you back from working in this country?

Nothing of that sort, but there needs to be a compliance in the future. Things will happen. But if compliance is lacking and there is a fall out of IP issues then, we will see companies moving out of the country.

What is your observation with regard to the comparison between India and China? Who is going ahead?

We are present in China. It is difficult to say who is ahead but I can definitely say that the country which is ahead will have better regulatory guidelines and structure; and the country with better IP protection for companies in general will go ahead.

Of the two, which country is favorable in terms of regulatory guidelines?

In terms of clinical trials, I think India is much ahead because it is faster but China is changing; and are reforming their structure for which they will catch up quickly.

Nayantara Som in Mumbai