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â€œInnovation and legislation have to go hand in handâ€?

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BioSpectrum spoke to Dr Carlo Incerti, senior vice president-global market access of Genzyme Corporation which is known to be a pioneer in the area. Read on for details:

Q: Given the possibility of lesser returns, why did Genzyme decide to choose rare diseases as its focus area at the time of its inception?

When I joined Genzyme about twenty five years ago, it was a small company. In those days, the vast majority of companies such as Amgen, Genetic and others were focussed on discovery of blockbuster drugs. Focus obviously was on volume. When the founders of Genzyme took up the challenge of finding solutions for rare diseases, big pharma companies showed disinterest in the idea as the number of patients was less and thus meant lesser return on investments. However, the founders were fascinated by the elegant science. The intracellular replacement of enzyme within an organ was an interesting phenomenon. They were convinced that it was a mathematical need. It was good science that aimed at changing lives of people successfully and creates platforms for others to follow. That was the cause behind Genzyme's inception.

Also, legislation passed later in the US about rare diseases providing exclusivity to orphan drugs also helped in securing the return on investments. That led to increase in the number of companies. There was an academia, industry and legislative framework. It was a great alchemy. In fact, I feel that the real personalized medicine is here where you cater to individual requirements by developing medicines through identification of his genotype. The affected population thus gets benefitted by such interventions.

Q: What kind of operations is Genzyme running in India? What are the needs here?

In India, we started in 1990 when there was only an individual first and then the entrepreneurial spirit took over. Slowly it gained momentum and we have made our presence felt. We believe that India with its huge population needs attention. It takes years here to diagnose diseases. The pain of a family is aggravated because the local practitioner is not educated enough to diagnose. The dissemination of information is important here. We as a company are looking at two therapeutic

areas. We have developed two therapeutics for Multiple Sclerosis (MS). One oral and another intravenous monoclonal antoibody that is promising. Practically, a new modulation for relapsing MS.

Q: What is the revenue model you follow?

We have generated initial revenue from the market but now we have a sustainable market. We now have big hopes that a new stable government is opening up to the industry, not just for education, employment and commercialization but also important from the point of innovation. That should be the aim of every developing nation as imparting innovation in various spheres, will create new paradigms.

Q: How do you look at the other countries in Asia-Pacific?

I have met scientists from Sri Lanka, Bangladesh, and Pakistan. India remains central so far. China too has our presence. We are doing research there but in case of rare diseases, we might not be advanced as in the case of other countries because of complexities in its regulations.

Q: As an academician who joined industry, how do you look at the disconnect between research papers and the failure to convert it into products?

I grew up in Italy where there was a big dichotomy between medical profession, academia and industry. What I learnt in US is that there is a connect between all of them. Research is not just about producing papers but changing lives of the people. If an academician has an idea that can be translated into product and where returns are immense, he or she needs the right environment. There is a cultural shift. In Europe, there are many but not enough because of reluctance. While in US, there is more because of the vibrant atmosphere and openness. Genzyme in the early stage was almost bankrupt. The brilliant idea was to sell on Wall Street. We not only created stocks but attracted investors. It is much more difficult in Europe and just not possible in India. That is why you need to create a culture of entrepreneurship and innovation that goes hand in hand with intellectual property rights and legislation.

Q: India is still graduating to that level. What are the challenges?

It is important that everybody gives in. There is a perception that MNCs would walk away with all the goodies. But things have to change. For example, South Korean government wants to see itself as a biotech driven economy by 2020. Others must follow too.
The regulations must be clear. The rules must be set. For the environment too, there is a regulatory need but dialogue should be constructive. From a scientific standpoint, India has a great capacity and I have myself seen during my visits to prominent institutes. Foundation is right and you need to build upon the basic research in small molecular technology, new advanced therapies, stem cells, cell therapy and gene therapy. Risk is that if India doesn't chip in, the gap will expand.

Q: Whare are the technologies to be relied upon for advanced research?

The recombinant DNA technology is excellent. The possibility to reproduce the protein biosynthetically and to get it to wherever required is exceptional. Looking at the future, gene therapy is important. Inserting the mutated gene to create a cure for diseases is simply great.
In ten years, the possibility of stopping pills or incision will occur, thereby increasing the rate of survival. We as a company are looking at various new platforms. For instance, recently we have tied up with a Boston-based company for RNAi technology. The technology affects the translation mechanism so that we can shut off. This is very important. We have always followed new technologies to create platforms.

Q: Do we have enough technologies to diagnose rare diseases?

The problem with them is that these diseases are progressive. There is a moment when we don't know when you can reach the point of no return. Even if you treat them, we don't know if the results will be there. A typical case is that of Pompe disease where glycogen gets accumulated due to defective enzymes. Babies die at one year. If you detect it early they live to some extent but for others, they eventually succumb. So early diagnosis is very important. Ancillary treatment too is important in case there is an early detection.

Q: How do you look at the future?

I am an optimist. I expect our generation to work for the future. I feel that we are going through a process of change, be it political or technological. Providing hope in terms of employment, patient welfare and better solutions, we at Genzyme, are always open to new ideas.