

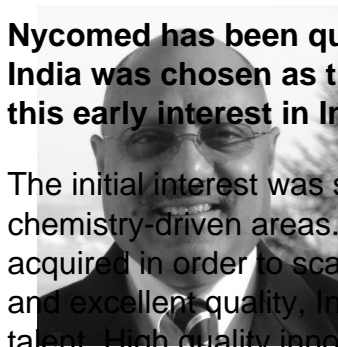
Interview with Sham S. Nikam Ph.D., Vice President, Head Global Discovery, Nycomed GmbH, Nycomed India

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ny MNCs becoming increasingly interested in India, the story of Nycomed has been quite unique. Rather than starting off with marketing and sales offices, India was chosen as the first global R&D centre outside of Europe. First of all, what sparked this early interest in Indian R&D?



The initial interest was sparked by the immense expertise India has in chemistry research and chemistry-driven areas. This was also the main focus of the Altana Pharma, which Nycomed acquired in order to scale up its chemical research capacity in India. Apart from cost-effectiveness and excellent quality, India is also renowned for having significant innovative and highly qualified talent. High quality innovation at a cost-effective rate is obviously a win-win situation. This was one of the driving forces for us to have a site here.

Yet, the lack of very good infrastructure in India makes it very hard to choose an appropriate location to set up a base. Mumbai was therefore chosen due its extensive history as the pharmaceutical industry hub of India. With R&D centers of various other Indian companies within close proximity, the Nycomed site was conveniently located at the heart of a pharmaceutical R&D hub and centrally located in Mumbai city near the international airport.

This location has been attractive to get access to the huge Indian scientific community, and talent. Site's campus like atmosphere and ecologically friendly environment is an added advantage to get the best minds to work on tough R&D issues.

At Nycomed, we have realized that the quality of work done here is at par with any of the work done in Western Europe and the USA.

In your view, why have other MNCs been less pro-active then, to set up their R&D facilities here?

There are multiple factors that come to mind. The issue, I have seen in the past, is that the Indian scientists did not have experience and full understanding of the overall pharma R&D process which limited their ability to deliver a new project idea to clinical candidate and finally to marketed product. One of the reasons for this was that their training was more aimed at doing innovative individual disciplinary (Chemistry or Biology etc.) work, rather than doing innovative multidisciplinary drug discovery projects. Rather than lack of talent and proper facilities in 80s and 90s the issue was lack of exposure and experience to the entire pharma R&D process. Several Indian scientists have done very well in pharma R&Ds in US and Western Europe with the same basic education from India. The

experience of putting all the pieces of drug discovery and development puzzle together is very important. This process is rather complicated and multidisciplinary, and landmark innovation will be limited until the process is understood very well.

The chemistry application to drug discovery was not the main focus of the Indian industry in 80s and 90s. One could engage in chemical research and synthesis, but it would not lead to drug discovery related work but rather more towards chemical process development. The connection to drug discovery with the intention to deliver development candidates has happened more within the last decade. To come up with an excellent clinical development candidate, the chemist has to understand biology, physicochemical properties, metabolic pathways and safety and many other aspects (e.g. cost of goods) of chemical synthesis.

I think India lost out in this respect. Indian chemists were labeled as not thinking beyond chemical synthesis. This, along with IP concerns, led to reluctance, in developed Western Pharma industries to prosecute important drug discovery projects in India. The change did not happen until the late 1990s. Nevertheless, it needs to be said that there were patches of excellence, even though they were never at par with the labs in the West at that time.

The patent regime in India after the 1960s was designed to protect the Indian pharmaceutical companies, and allow access to key medicines for the masses. . A "process" to make the product was given better protection than the "product" itself. As a cause per se, it of course makes a lot of sense as it provides medicines at an affordable cost to the masses. This therefore is an overarching theme in any developing country. Also, lack of proper reimbursement for medicines with patient bearing most of the cost resulted in government trying to find ways and means to make medicines available at affordable cost to the masses. However, MNCs that spend billions of dollars in pharma R&D researching a new medicine did not feel comfortable with not having the ability to patent the final product which also explains limited R&D presence in India. It surely is a fine balance in a developing country like India.

To what extent do you feel that Nycomed has had the opportunity to increase the exposure to discovery research in India?

Nycomed India is interested in both basic drug discovery and incremental innovation. These are two different aspects of our business here.

We felt that real discovery innovation could become a value added activity following the patent law changes in 2005. That is, we would have the opportunity to patent the new chemical entities generated at our Mumbai site and have full IP protection.

Our Global Discovery model is a flexible resourcing model, and is based on partnerships. This is also implemented at the Mumbai site. While we do most of the chemical research in-house, a lot of other activities, such as biology or safety, are either done at our European R&D sites or farmed out to US or W. European countries or within India itself.

We are, for example, very active in collaborating with GVK for in-vitro and in vivo biology services. Under this partnership, GVK does most of the discovery biology for some projects, while we work on identifying appropriate chemical matter. The model is thus based on doing innovative science, where Nycomed has the core scientific leaders who identify new innovative projects and manage these partnerships through deep understanding of science and process. This synergistic model allows us, to not only be flexible, but invest judiciously in areas that may be of significant interest for us in the long term.

Again, in drug discovery, the most important aspect is to get IP protection for the composition of matter and the utility or utilities of the compound that will hit the market. To get a drug patented, the chemical structure is the key and it is always preferable to have the chemical structure and the space around it under IP protection for the full patent term. This is one of the reasons why we still do

most of our chemical research in-house.

To sum up, we do feel that India now has much more experienced talent, which was not available in the 80s and 90s due to revised chemistry, biology and pharmacy curricula and return of well trained experienced scientists from US and Western Europe. There is a significant brain gain on the Indian side. Few key knowledge leaders with highly energetic bench scientists are the right mix for most drug discovery organizations in India. For example the average age at our Mumbai site is roughly in early to mid 30s with a few key leaders with postgraduate studies and experience in US and other developed economies. One can feel the high energy brought by these colleagues who want to prove themselves in global pharma R&D arena where India has still make a mark by launching a homegrown chemotherapeutic agent. This young talent has yet to experience the highs and lows of pharma R&D and are willing to take risks with "out of the box" ideas that in the more western setting may not be easy to implement. This environment is conducive to generation of high quality New Chemical Entities (NCEs) and a launched drug from Indian efforts is a distinct possibility within this decade. Obviously, the future drug that will be launched from an Indian site will be more affordable than the one that is launched from more developed economies.

While it is normal for pharmaceutical companies to be protecting their IP, the industry has also been talking increasingly about open innovation and sharing. Do you see a way out of this paradox?

In the past years, we have seen more innovation coming from small biotechs rather than large integrated pharma companies. That has fostered collaborations and partnerships.

At Nycomed, our Research and Development is based on a flexible operating model balancing a blend of external partnering and internal resources. Our in-house capabilities range from early discovery and successive phases of clinical development all the way through registration and life-cycle management. At the same time, we expect a large percentage of the compounds in our pipeline to come from in-licensing and co-development projects with our partners.

India can contribute significantly in this area. It will be good for pharma R&D companies to pool their experiences in drug discovery and development projects and improve process efficiencies to deliver affordable medicines that really matter.

In a previous interview last year, you already commented that comparing emerging markets with developed markets is comparing apples with pears. In that sense, is there really a global business model for pharma?

Nycomed has a strong presence in Europe and is expanding in emerging markets. Our experience shows that a business model based on adapting to the diverse conditions around the world works best. For example, while we do have some global products, our portfolio is very much tailored to local needs. Through that, emerging markets now account for 39% of our turnover. Nycomed already has one of the highest proportions of sales from emerging markets among major pharmaceutical companies.

While the pharmaceutical industry has the opportunity to contribute to reducing the country's healthcare costs, government's worldwide do not always seem to realize this potential. What can be done to change this image to get more support?

The pharmaceutical industry has not done a good job at selling itself, in particular, in the West. It has often been regarded as a money-hungry industry. Benefits of medicines, such as improved quality of life, have generally not been adequately conveyed to the public. The costs of hospitalization are huge, compared to the costs of purchasing medicines that indeed prevent hospitalization.

Estimating when the first NCE will come out of India is of course speculating, but once it happens, what do you think it will mean for the Indian pharmaceutical industry?

It will be great, and I am really looking forward to that day. I think it will happen in the next 5 or 10 years, because there are several compounds in late stages of clinical compounds. Other companies have done excellent work already. While Nycomed itself would also like to be part of that game, particularly in the areas of pain management, respiratory disorders and inflammation, we are anticipating having a few more preclinical candidates this year and next. The time horizon for an NCE to reach the market in India is about 7-10 years.

Is there a final message you would like to send to our readers?

India is not only a cost-effective destination, but also is a place where value is added through innovation. This is significant and on par with quality in the West. What I have noticed is that the people here do not come with a baggage like me, which stipulates a certain process that is required to take from A to Z. Because these people have not seen or experienced that, they are not afraid to do things and come up with a wide range of different ideas. If you have proper leaders to channel these innovative skills, there is significant value that India can deliver. India particularly, is attractive because of its open political system and diversity. To me, such attributes are very important for a highly innovative and productive pharma R&D.

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