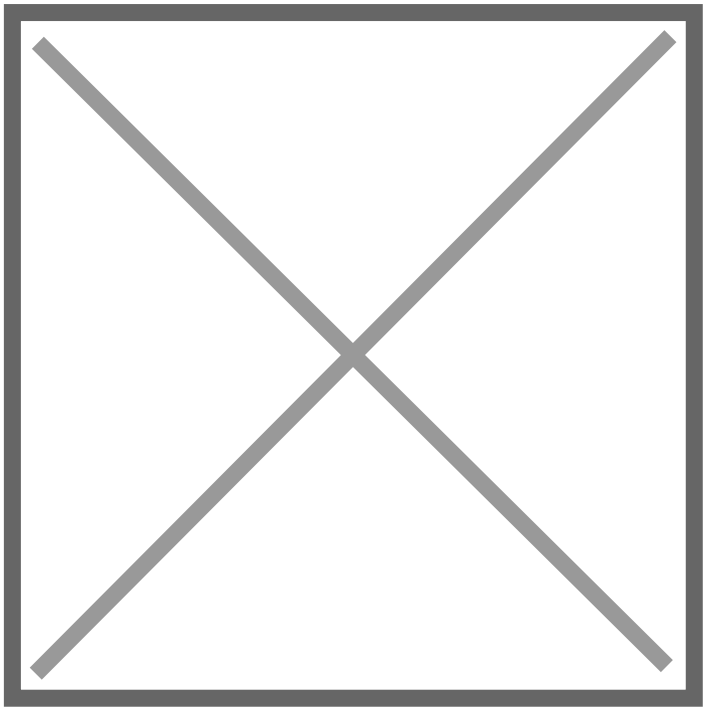
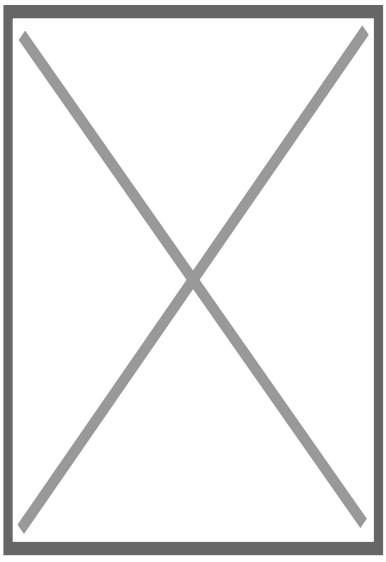
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Time to ask "Quo vadis"?

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Time to ask "Quo vadis"?



Ranjit Shahani, Vice Chairman & Managing Director, Novartis India Ltd

If Indian pharmaceutical companies are distracted with trying to reinvent the wheel, we will lose precious resources that could be focused on incremental innovation.

Often seen as an industry that is needed by all but liked by few, if at all, the pharmaceutical industry is going through testing times. It is under growing pressure to keep delivering blockbuster products so as to keep investors happy while at the same time ensure that prices are down. According to sources, $100 billion worth of drugs will be going off patent by 2010. At the same time, clinical development time has doubled since 1982 to an average high of 68 months.

With mounting pressure on all fronts, pharmaceutical companies have to rely on their innate skills to deliver products that meet today's medical needs and medical needs of the future while at the same time look at avenues to partner with others so as to deliver newer products at lower costs.

With the introduction of product patents in 2005, India took the first big step towards becoming the country of choice for research and development as well as for clinical trials. Both these areas present big opportunities for not just global pharmaceutical companies but also for national pharmaceutical companies out to make a mark for themselves. However, these opportunities will remain on the distant horizon until such time as the patent law continues in its current form and data protection remains a pipe dream.

The value of incremental innovation in contributing to medical progress must be recognized. Breakthrough innovations in all fields are few and far between. The invention of the wheel was a breakthrough innovation in transportation. The inventor of the bicycle simply combined two wheels with pedals and gears and revolutionized land travel by eliminating the need for a horse. Steam engines were added to the wheels and gears after their invention, offering an alternative power source for transportation. Once a suitable gas-powered engine was perfected, this innovation replaced the earlier steam engine, creating the first automobile and revolutionizing personal transportation. At no time, in this process of invention did an innovator return to the drawing board to reinvent the wheel. Each used prior research and experimentation as a foundation, building on existing knowledge with additional creative thinking, research and trials. One base technology, the wheel, has been continuously modified to allow transportation to become what it is today.

Not recognizing incremental innovation in the pharmaceutical industry is like asking medical researchers to reinvent the wheel. Innovation by steps is essential to pharmaceutical development of new and improved medicines and to public health "Breakthrough" innovations are rare in research and incremental innovation builds on the body of current knowledge, resulting in new, innovative medicines for patients.

Currently, it takes 8-10 years to bring a compound from an idea to a usable medicine. During that time span, pharmaceutical companies spend up to $1-1.7 billion researching, developing and testing to create a single drug. If drug discovery was forced back to the beginning each time a new medicine was needed, time and monetary investments would increase exponentially and significantly delay the delivery of medicines to patients. As a global pandemic becomes a reality, biological weapons become a threat, and preventable diseases continue to take lives, we should work to shorten the amount of time it takes to bring a product to market, not unnecessarily lengthen it.

From improving a medicine's safety and side effect profile to increasing a country's productivity, incremental innovation provides exceptional value for patients and society. Over 70 percent of medicines on the market today were developed through incremental improvements on a base compound or existing medicine.

Given the central role of incremental innovation in medical progress, the value that these types of advancements bring is exceptional. Without these building-block improvements, healthcare would not have progressed to where it is today. Allowing patents for incremental innovations is a crucial way India can improve domestic public health and bring better medicines to Indian patients.

An important piece of the research and development process is gathering data on the safety and effectiveness of medications. Protection for research-based organizations' core investment, data, is non-negotiable. Data protection is one of the incentives for companies to bring new and better medicines to market, and is necessary for medicine to progress so as to meet unmet medical needs for today and for the future.

Data protection, along with good patent laws, give the research-based pharmaceutical industry the confidence to launch innovative medicines, ensuring patients in India have access to newer therapies. Government's failure to implement these protections will reduce patient access to new medicines--now and in the future.

There is an unfounded fear that data protection will lead to higher drug prices. However, experience in other countries that have introduced data protection shows that there is no connection between data protection and drug pricing. Limitations of purchasing power and competition within therapeutic classes keep prices down.

Indian pharmaceutical companies are on the cusp of a great opportunity--the opportunity to make a positive change in global health by creating novel medicines through radical and incremental innovation. All we need to do is tap into the wealth of creative and scientific resources at our fingertips. If Indian pharmaceutical companies are distracted with trying to reinvent the wheel, we will lose precious resources that could be focused on incremental innovation--innovation that will bring real value to patients. So let us get on with the job without having to stop to ask the pharmaceutical industry "Quo vadis"?

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