Fourth Convocation Address
National Institute of Pharmaceutical Education and Research
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"Giving the future: Which path will you take?"

"Tomorrow's challenge is to develop new medicines that can prevent or cure currently incurable diseases.
Today's challenge is to get to tomorrow."

I am indeed delighted to participate at the Fourth Convocation of National Institute of Pharmaceutical Education and Research at Hyderabad. NIPER Hyderabad is a Pharmacy research institute, mentored by Indian Institute of Chemical Technology, Hyderabad. As an Institute of national importance it plays an important role in the Human Resource Development for the ever growing Indian Pharmaceutical industry, which has been in the forefront of India's science based industries with wide ranging capabilities in this important field of drug manufacture.

Globally, the pharmaceutical industry is at a critical juncture. The tools to develop remarkable new medicines are materializing, demand for its products is increasing and the barriers to free trade are falling. But the pharmaceutical industry also faces major economic and operational challenges to capitalize on these opportunities and create more value for healthcare payers, providers and patients. Many of the conditions that will determine what happens in 2020 are already in place.

Most of the products that will be launched are already in the pipeline; the processes being used to develop them are similar to those used for the past 10 years; the prevailing management culture remains that of the late 20th century; and a demanding technological and commercial environment look set to continue. There is widespread awareness and realization that all patients must receive the medicines they need at an affordable price, timely and where they live. More than 450 drug formulation packs are now under the price control mechanism of the National Pharmaceutical Pricing Authority (NPPA). So, Friends, I would like to speak today, on the topic ***"Giving the future: Which path will you take?"***

From Laboratory to the Market-place

The Indian pharmaceutical industry, the most respected amongst the emerging nations, is one of the most sought after sectors from a global collaboration point of view. Having a strong macro and socio economic foundation, the "driving" factors are intrinsically deep-rooted in the Indian pharmaceutical sector have not been deterred by recent speed breakers like quality issues faced by a few Indian companies. The Indian pharma sector offers a lot to be optimistic about. The sector which was only $ six billion in 2005, has zoomed to $18 billion market in 2012, clocking a CAGR of 17 per cent. The sector is expected to grow to $45 billion by 2020. Even in the most pessimistic scenario, the sector is expected to be the sixth largest in the world in terms of absolute size by 2020.

One of the key characteristics of the Indian pharma industry is the fact that it is very fragmented. The largest domestic market shareholders hold about seven per cent of the

Indian markets, while the top 10 companies command about 40 per cent of the market share. On the other hand, India has the highest generic penetration of over 99 per cent and provides equal access to both large and small players. Supply chain, the link between the laboratory and the marketplace, needs a thorough revision. Most pharmaceutical companies have complex supply chains that are under-utilized; inefficient and even ill equipped to cope with the sort of products coming down the pipeline. In order to meet the demands of a fast evolving marketplace and the shift from patient to outcome, the pharmaceutical supply chain will need to undergo a radical revolution of management procedures.

Numerous forces are reshaping the environment in which the industry operates and dictating the need for a different sort of supply chain. By 2020, the more diverse product types and therapies with shorter product lifecycles will emanate. The new ways for assessing, approving and monitoring medicines will be available. Increasing emphasis on outcomes; new modes of delivering healthcare where the care is pushed into the community and where access to information on patients, will become as important as the products themselves. The growing importance of emerging markets; a greater public scrutiny impacting the ability to manage risk and compliance; and, tougher environmental controls and regulations will demand companies to strategically reassess their supply chain approach.

Timely access to various emerging technologies will increase the efficiency of the manufacturing and distribution functions. New technologies are emerging to help pharmaceutical companies

and to manufacture a wider and more complex range of medicines and distribute them. It is also essential to accelerate the interface with the patient and getting closer than ever. In 2014, India's share of the US generic market is 24 per cent in terms of volume and 40 per cent of the new product approvals granted by the US FDA has been to Indian companies. It has established a strong reputation in the global space for being a high quality supplier of affordable generics. In order to promote the sector, the regulatory authorities must assist encouraging the results at various phases, so that inflow of funds will take place. By 2020 the pharmaceutical market is anticipated to more than double to US$1.3 trillion, with the E7 countries — Brazil, China, India, Indonesia, Mexico, Russia and Turkey — accounting around for one fifth of global pharmaceutical sales. Further, incidence of chronic conditions in the developing world will increasingly resemble those of the developed world.

International Competitiveness

To be internationally competitive, we should incorporate courses in regulatory jurisprudence so that newer legislations, domestic as well as international, are understood and implemented with utmost care and speed. Our courses must include exposure to guidelines issued by International Conference on Harmonization (ICH), Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Clinical Practices (GCP) and Generic Clearance Procedures for pharmaceutical products. Also, for submissions of technical dossiers for exports, we must familiarize students with regulatory specifications of international agencies and with our national book of standards for drugs, the Indian Pharmacopoeia, and

other similar international compendia. As you may be aware, the Government has decided to share India's traditional knowledge in medicine with other countries in a digitally documented form, so that they can reject any patent application in their countries which use India's centuries old wisdom. This is an essential step for protecting our intellectual property rights. We should be alert to monitor the world progress in drugs evolutions.

Collaboration between the institutions involved in the healthcare provision will contribute to make the industry more efficient. The supply chains for designing, manufacturing and distributing pharmaceuticals and medical devices plus those providing healthcare services will integrate so that all partners can see the full picture and assist them to plan ahead more accurately and cost-effective. For India to continue to be a force in the international markets, the industry needs to continuously invest in development of global R&D capabilities and develop its strong and well-established Contract Research and Manufacturing Services (CRAMS segment). India will have to imbibe the technical capabilities and knowledge of the experienced in other countries in the areas of research and development of manufacturing and new drug delivery systems. Strong international collaborations and partnership will insure that India continues to reinvent itself by delivering on more value added products to the global markets, thus protecting its global market position.

Upgradation of the pharmacy education system

For enabling pharmacists in India to offer world-class professional service, we must create continuing education as a

pre-requisite for all pharmacists. The education system must train him or her to become lifelong learner. Pharmacy colleges can have a collaborative program with Pharma industries and hospitals for designing an appropriate continuing education course.

I understand that the Pharmacy Council of India has decided to make a degree in pharmacy as the minimum qualification for registration of pharmacists. Also, education-wise, we have three categories of pharmacists who are registered with the State Pharmacy Councils: those registered before the enforcement of the Pharmacy Act with only experience as the criteria for enrolment; those registered with 10+2 or intermediate plus one diploma qualification; and, those registered with 10+2+2 diploma qualification. For all those who are currently practicing pharmacy, we must provide opportunities to upgrade their knowledge by carefully drafted condensed course of education and training. Every effort should be made to upgrade the existing persons to the level required for the degree program proposed by the World Health Organization (WHO) in their report entitled "The Role of Pharmacists in the Healthcare System".

Now, I would like to discuss about the need for inculcating entrepreneurship amongst pharma students.

Entrepreneurship

The aptitude for entrepreneurship should be cultivated right from the beginning and in the college environment. We must teach our students to take calculated risks for the sake of larger gain, but within the ethos of good business. They should also

cultivate a disposition to do things right. This capacity will enable them to take up challenging tasks later and create small and medium pharma industries. The next important requirement of education system is the inculcation of moral leadership.

Moral leadership

Moral leadership involves two aspects. First, it requires the ability to have compelling and powerful dreams or vision of human betterment. Moral leadership requires a disposition to do the right thing and influence others also to do the right things. There is a perception that a certain number of pharmaceutical products sold in India are counterfeit or of substandard quality. These drugs are generally made by unscrupulous elements and supplied secretly to chemist shops through illegal channels. The pharmacy education has an important role to play in equipping the students with the knowledge and ability to detect the entry of unauthorized drugs into circulation and also not to join such institutions. Also, every effort should be made to check the manufacture, sale and distribution of spurious drugs. The Central and State governments have to ensure that the Drugs and Cosmetics Act is properly enforced to check this evil practice. Pharmacists must ensure that their sources of supply of drugs are reliable to check the menace of spurious drugs. The pharmaceutical curriculum must include subjects, which will enable detection of spurious pharmaceutical products by all pharmacists.

Two Roads

There are two options for institutions focusing on specialist therapies and treatments for rare diseases and two options for

companies focusing on mass-market medicines. Most companies will fall into one of those options although large players may cover both ends of the spectrum. The current pharmaceutical industry business model is both economically unsustainable and operationally incapable of acting quickly enough to produce the types of innovative treatments demanded by global markets. In order to make the most of these future growth opportunities, the industry must fundamentally change the way it operates.

The pharmaceutical marketplace is undergoing a big change. Chronic diseases are soaring. Healthcare policy makers and payers are increasingly mandating the type of solutions needed for a particular disease. Pay-for-performance is on the rise. The boundaries between different forms of healthcare are blurring. The markets of the developing world, where demand for medicines is likely to grow most rapidly over the next 10 years, are highly varied. Governments are beginning to focus on prevention rather than treatment. Regulators are becoming more risk-averse.

Some of the major changes the Pharma Industry would face are:

- Health care will shift in focus from treatment to prevention.
- Pharmaceutical companies will have to provide total health care packages.
- The current linear phase research & development process will give way to in-life testing and live licensing, in collaboration with regulators and health care providers.
- The traditional blockbuster sales model will disappear.

- The supply chain function will become revenue generating as it becomes integral to the health care package and enables access to new channels.
- More sophisticated direct-to-consumer distribution channels will diminish the role of wholesalers.
- New drugs will emerge from molecules exclusively from native medicinal plants or combination of native and conventional.

Conclusion

Major scientific and technological advances, coupled with socio-demographic changes, increasing demand for medicines and trade liberalisation, will revive pharma's fortunes in another 10 years and deliver dramatic improvements in patient care. I believe the industry faces three fundamental challenges:

Rising customer expectations - The commercial environment is getting harsher. Healthcare payers are imposing new cost constraints on providers and are scrutinising the value of medicines more carefully. They want new therapies that are clinically and economically better than the existing alternatives, together with hard, real-world outcomes data to back any claims about a medicine's superiority.

Scientific productivity - Pharma's output has flat lined for the past decade. Yet the processes it uses to discover and develop new products remain much the same. So there's little reason to think its productivity will suddenly soar.

Cultural hardening - The prevailing management culture, mental models and strategies on which the industry relies are the same ones it is traditionally relied on, even though they have been eclipsed by new ways of doing business.

Every patient's experience now generates rivers of data which, if pooled intelligently, can trace a detailed portrait of a patient's health and, when aggregated with other patient data streams, can become deep reservoirs of knowledge about entire disease status and patient population. Pervasive monitoring and 'anywhere interface' technologies that turn a rigid surface into an interface with an electronic device will make it easier still to collect huge quantities of data on how patients respond to different treatments. Combine that with ever-present gene sequencing and the why will begin to emerge.

I am sure, as young Pharma post-graduates, you will embrace information technology and research culture in Pharma in a big way and develop necessary expertise.

My best wishes to you all. May God bless you.

Dear friends, now I would like to administer a five-point oath for the Pharma students. Are you ready?

Oath for the Pharma students

1. I realize Pharma is a noble profession to remove the pain.
2. I will always apply science and technology in pharmaceutical work.
3. I realize that pharmacy can provide cost effective pure drugs and medicines to the people.
4. While I am working in Pharmacy from design to formulation development, testing, quality control and marketing, I

realize any flaw knowingly or unknowingly will result in loss of human life. Hence, I consider every action of mine will be transparent and true.

5. I love my Pharmacy profession and I consider it as an honor to work as a Pharmacist.