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"A huge slew of chemical drugs and biotech products is in the pipeline"

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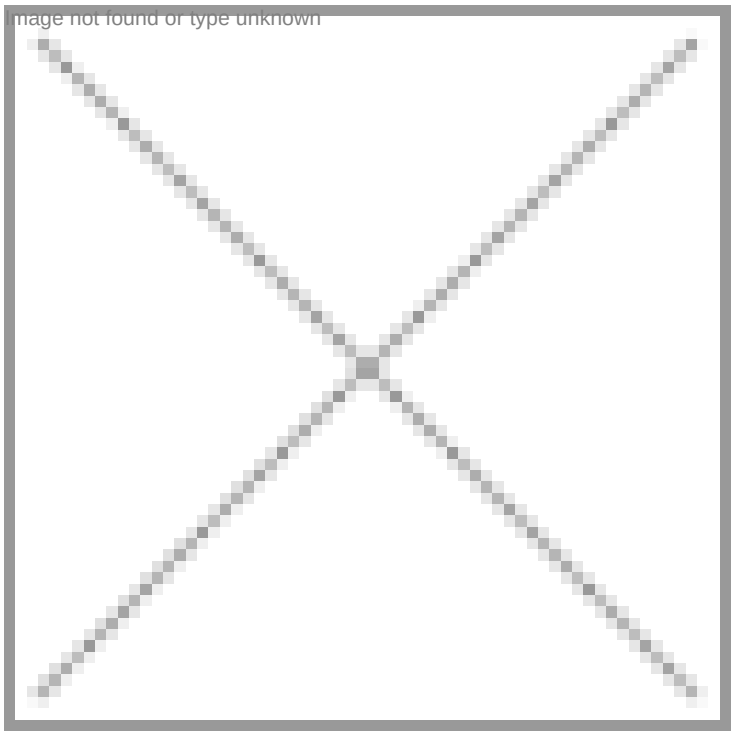

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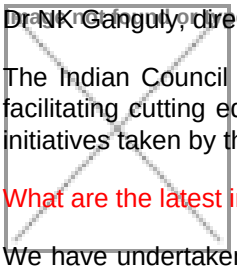

Dr NK Ganguly, director general, ICMR.

The Indian Council of Medical Research (ICMR) is spearheading the development of new drugs and policy guidelines for facilitating cutting edge research. In an exclusive interview, Dr NK Ganguly, director general, ICMR, elaborates on the new initiatives taken by the Council.

What are the latest initiatives taken by ICMR in the area of biopharma/biotech drugs?

We have undertaken a number of promotional activities in the area of biotech/biopharma research. One of the activities has been in the area of drugs for neglected diseases. We have been making efforts to make these drugs available, which are badly needed for some of the diseases and for which there is in adequate funding. One of ICMR's success has been an oral drug for Kala Azar. Though this drug, Miltefosin was known earlier, it was mainly used as an anti-cancer drug. Its introduction and trial in leishmania was formulated and carried out through our team of investigators at the Rajendra Memorial Research Institute of Medical Sciences (RMRI) in Patna. The clinical trials were done in Bihar and the trial sites were 15 GCP labs in the state. The trials have been completed successfully and we have now partnered with the WHO.

Then, in association with the Bill and Melinda Gates Foundation, we are conducting the clinical trials for Paramomycin drug. This is also an earlier known drug but is not in use for leishmaniasis.

Within the country, we have partnered with the Council of Scientific and Industrial Research (CSIR) for two anti-malarial drugs. The clinical trials for these drugs are over and now both are in the market. At the moment we are also conducting trials of a combination drug for Malaria. For combination drugs we are trying to bring in different combinations and trying to reach out to sites which are very tricky like the Indo-Nepal border and Orissa. So these are some of our efforts in the area of neglected diseases.

Then, with Lupin we are trying to develop a new anti-tubercular drug. This will bring down the existing time of treatment to three months. At the same time we have already done a trial with a combination drug which reduces the time of treatment for tuberculosis to four months.

We have also developed a new treatment regime for leprosy and this is backed by a very good diagnostic test. Its clinical trials have already been successfully completed.

We have also introduced a biotech drug, Thrombin - a clot buster, which is going to Phase I trials. This drug is aimed at early stroke victims.

In the area of HIV, we have at the moment, one phase I clinical trial going on for HIV vaccine, and the trials of the second HIV vaccine will start in the first week of September in Chennai. For this, all the clearances have been obtained, the volunteers are in place and the recruitment has started. We have also started a recombinant Cholera vaccine trial at NICD (National Institute of Cholera and Enteric Diseases), Kolkata and we are doing a trial for salmonella vaccine, which will be comparatively a cheaper vaccine.

Then with GAVI funding (Global Alliance for Vaccine and Immunization), funding from the US and the Bill and Melinda Gates Foundation we are doing a major trial for Hib vaccine (Haemophilus influenzae vaccine). A Joint ICMR and Johns Hopkins University Hib vaccine probe study is on the cards to improve the information base regarding the use of Hib vaccine in the region.

The Council is working on a Phase I trial for providing the second dose of measles vaccine and we have started an aerosol measles vaccine trial with funding from GAVI. To tackle the Human Papiloma virus, which causes cervical cancer, we are holding talks with Merck to conduct a papilomavirus vaccine study. Now a MoU is on the anvil. Another major trial, spanning over ten centers, on Hepatitis B and C is going on. So there is a huge slew of chemical drugs, biotech products in the pipeline. We help in launching them in India on the condition that the drug will be available in India at an affordable price and that the government of India will be a partner so that they know that how these products are coming in. Another notable feature is that most of these initiatives are examples of public-private partnerships.

Biomedical research is evolving very rapidly. How is ICMR facilitating research in this scenario?

Taking note of the fast changing developments in biomedical research, we have constituted a few committees here within ICMR, to provide guidelines like a committee on toxicology, a committee on drug trials and a committee on ethics, which will be known as the National Ethics Committee. This will look into ethics-related issues in the trials. We are setting up a large number of clinical trial centers in the country. We are also trying to set up a Clinical Trial Registry Council, so that anyone who is registering in this field will ultimately have accreditation from the Council.

We have also tried to help and promote drug companies in India. We have set up a set of toxicology units in the country. One such unit in Hyderabad did the toxicology studies of DNA rabies vaccine for dogs and of the interferon alpha, which has been developed by Shantha Biotech. So we have set the way of doing toxicology studies for biotech products/drugs.

We also look after the clearances of the IND molecules. Earlier, this used to take a lot of time and now we have been able to shorten the time to less than two months. Leveraging the expertise of the Council, we have now set up a system for clearances.

We have put up the ethical guidelines, which are a part of the GCP guidelines; have helped in modifying the Schedule Y and the GCP guidelines of the Drug Controller General of India. And we have created a module for adverse drug reaction monitoring. We are formulating a guideline for stem cell therapies and biologicals. We have also developed guidelines for

medical devices which did not exist till date.

In addition, we are setting up a National Drug Authority, an autonomous body, on the lines of the Federal Drug Agency and the land required for this has been purchased. ICMR is working towards setting up a pharmacovigilance network. We had started such a network about seven years back on some selected drugs and now we have to look at it in the modern day perspective.

To provide infrastructure support, we are setting up a primate breeding facility at Sasunavgarh, Mumbai and a large animal facility on a corporate model in Hyderabad to promote drug development and pharmacological development of products. The land has been acquired for this purpose.

We have set up a microbial containment facility in Pune, which I think is the largest in the country for the viral infections. This will help us in tackling any viral infection and we have put up a depository of viruses so that researchers can develop products which can be utilized to tackle outbreaks.

From the medical research perspective, we have funded over 1000 research efforts and also help in patenting the products that come out of this research. We fund our own institutes for newer areas of research. We have funded some projects on drug development in malaria and tuberculosis, vaccines, new molecule and drug targets.

ICMR has initiated an annual event called "Medical Development Congress". Can you elaborate on this?

The Medical Development Council will essentially bring together all stakeholders who are interested in developing products for improving health and find out what we have been able to put in place and what is further needed. So it is a kind of introspection as well as looking towards the future. We would take cognizance of new developments and would discuss strategies to develop products that will be of use for us as well as for the developing world, as a whole.

The Council will provide a forum where interactive dialogue, knowledge-sharing and brainstorming sessions for joint strategy development will be undertaken on a regular basis.

The event would address specific issues pertaining to medical development every year and provide a platform where industry leaders, R&D institutions, government agencies, interested ministries and select management experts will share their experiences, raise questions, suggest measures to improve the quality of medical care, increase its international competition and make it more affordable and accessible to the common man.

The very first Medical Development Congress will be held in November 2005 in Delhi with the broad topic of "Drugs & Pharmaceuticals" as its central theme. Since this area is vast, the meeting will focus on infectious diseases. The event will cover therapeutics related to the development of new molecules, new herbal formulations, relevant delivery systems, diagnostics and new devices.

Rolly Dureha

"Imperial Is Creating an India Foundation"

Dr Colin Wyatt, director of Business Development, Imperial College, London

With the mutual business in India and the UK growing, what are Imperial's plans for India?

The Indian business investing in the UK went up 47 percent in 2003-04. Almost 28 new companies from India invested in the UK, with the total now touching 480 (338 from ICT). While the UK is the second largest investor into India, India is the eight largest investor into the UK. Clearly, the mutual Indiaâ€“UK investment has been growing rapidly. Besides, the Indian R&D funding is growing too. The Science & Technology research currently is about 0.6 percent of GDP and it is touted to increase to 2 percent
by 2007.

We recognize the potential and are looking at a number of things. As an academic institution, we are looking to build academic relationships with India. Towards this, Imperial is creating an India Foundation to promote higher education, research collaboration and the funding of Indian post graduate students at Imperial College. The Foundation will focus on

education and collaborative research to promote higher education at post doctoral level. It would identify and promote collaborative research projects in India as well as in the UK at the university/institution levels.

In the commercial context, we are looking at building more relationships with the Indian commercial organizations, both in the life sciences and non life sciences sectors. These could be biotech or healthcare or devices companies. We are already in discussions with some of the major companies in India.

Could you elaborate on the India fund that you plan to create?

What we are looking at is creating and managing a fund that will help students to do a higher research. This is the first time such a fund is being planned to be created. This is to raise money in India to fund postgraduate (MSc, MBA and PhD) scholarships for talented Indian students to study at Imperial College, and to assist in creating an enhanced awareness of the benefits of higher education, promotion of the College's overall objectives in India and to raise the profile of Imperial College in India as a preferred destination for aspiring Indian students. We are in the process of identifying possible sources of funding.

What do Imperial's subsidiary companies do?

Imperial Innovations, is a partially owned subsidiary with external investors, and commercializes existing intellectual property and is focused in the area of technology transfer. The goal is to protect and market technologies to realize value from the intellectual property, typically through licensing and spin-out formation. Besides Imperial Innovations also supports early stage companies by providing access to networks of investors, management teams and incubation space, supports portfolio and asset management, and manages the spin-out portfolio and spin-out investments. Imperial Consultants, a wholly owned subsidiary company, provides consultancy. It offers technology-related services for industry, gives the link to a network of highly specialized academic experts from Imperial, and facilitates direct access to some of the best research facilities, analytical and testing equipment in Europe.

How does your model work in a coordinated way?

The University has three groups - consulting, technology transfer, and business development. We are all part of the same platform of Imperial's corporate affairs. We have formal communication processes. The heads of each unit meet every month on a formal basis. But over and above that what we do with the business development group is try and be some glue to hold all the units together. So we have joint team meetings once in a month. We are all co-located and talk to each other every day. We have recently put in place a common CRM system and database, which we all use to log on the activities of what we are doing, the people that we are talking to, the projects that we are working on, and many more. So there is an informal and formal communication and coordination with the other two groups.

The business development group spans both groups because the relationships are built between the industry and academia. Academia has a strong intellectual property component, so Imperial Innovation has to be involved in the dialogues. Similarly, where there is a consulting component and Imperial Consultants may be involved. However, they can do things independently too.

What has been the outcome of this model?

The commercialization activities are returning substantial value to the College. Research funding from industry per year is nearly £30 million now. About 10-12 inventions get recorded per month and close to 50 patents are being filed per year. While the licence income collected is now around £7.1 million, there are over 60 spin-out companies in the portfolio. Over £150 million of spin-out finance has been raised and the overall valuation of the portfolio is in excess of £300 million. The valuation of Imperial Innovations is about £60 million. And over £25 million of funds have been returned to the host institution.

What are some of the key trends that you foresee in the next few years?

We need to get better at integrating all the aspects of commercialization. We need to improve the links between the academic

communities and the business development communities, in terms of awareness and perception of working together. In the UK context, there are certain inbuilt tensions between academics and commercialization. The primary drivers of motivation for academics are to develop research excellence. In the UK, this is determined by the research assessment exercise. Such exercise determines the funding that the university gets.

Historically, one of the parameters of research excellence assessment was the number of publications in quality peer review journals and number of post-docs, etc. being supervised and managed. Industrial research revenue was never an important consideration. Because of this, there is a degree of misalignment between the two requirements--industry sponsored research versus public-funded research.

This can create problems in reducing the motivation in working on a industry-sponsored research, particularly around now, as we are in the run up to the next research assessment. The next two years are important to the universities and academics. The government is aware of this problem and it is likely that the matrix of the research assessment exercise will be modified. It is not yet entirely clear. Looking forward, we would like to see those conflicts taken away.

The business development process should be seen as a fundamental part of the way universities run themselves, just as any other function. Over the next five years, business development will be seen emerging as a core function.