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'Converting research into policies, that are then translated into action'

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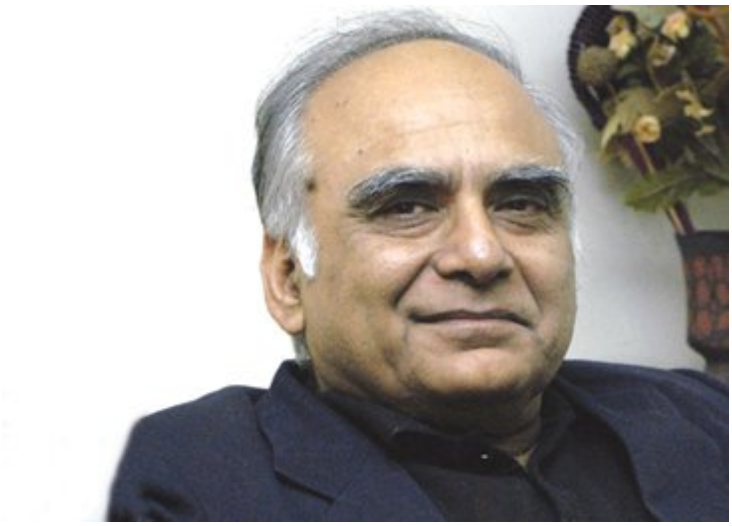

From a global perspective, it should be remembered that 3 out of 8 Millennium Development Goals (MDGs), 8 of 16 MDG targets and 18 of 48 MDG indicators are health-related. These health-related goals can be achieved by increasing the access to and effective use of biopharmaceuticals including drugs, vaccines and diagnostics. Importantly, the development of a HIV/AIDS vaccine, more effective diagnostics for tuberculosis (TB), better treatments, and possibly vaccines for leishmaniasis and malaria would greatly improve health in the developing countries. Hence, promotion of research and development in drugs and vaccines can contribute immensely to the timely achievement of the United Nations MDGs.

The biotechnology revolution has played an immense role in the development of biopharmaceuticals. India has a multitude of strengths in R&D. These include various forms of infrastructure in the form of educational and research institutes, medical colleges and hospitals, drug testing laboratories, transgenic animal facilities, clinical research organizations, bio-containment facilities, toxicology research centres, national animal resource facilities, microbial repositories, and clinical trial centres. India has also developed a number of national level ethical and regulatory guidelines to take the research agenda forward. Most importantly, new model institutes are coming up in various parts of the country. The Indian Institute of Science Education and Research (IISER), National Institute of Pharmaceutical Education and Research (NIPER), the new IITs could be cited as important examples in this regard. Moreover, of the 39 or so central universities already existing, approximately 20 are up-coming. India also has a number of public health institutes, including the Asian Institute of Public Health, the Public Health Foundation of India, Institute of Public Health, besides the three ICMR institutes of public health. Aside from the existing institutes under the various funding agencies, the newly upcoming NCR biotech cluster deserves particular mention. The newly established Translational Health Science and Technology Institute (THSTI) is a crucial component of the cluster, and its permanent structure in coming up in Faridabad. Therefore, the infrastructural strength of India in the area of biotechnology is formidable.

India has made distinct efforts in the area of drug development, including both the areas of communicable and non-communicable diseases. Currently, in India, there are over 450 biotechnology-based drugs in development, ranging from anti-

retrovirals to anti-cancer drugs. Importantly, there are a number of Investigational New Drug (IND) molecules, produced both from the public and private sectors, which are undergoing clinical trials. These include anti-hyperglycemic agents, anti-bacterials, dyslipidemic agents, anti-cancer drugs, to name a few. There are a large number of recombinant therapeutic drugs approved for marketing in India. Of the Indian drug development efforts that warrant mention include the anti-TB drugs sudoterb (Lupin) and benzothiazinone (AstraZenaca), the inhalable microparticles for pulmonary TB developed at Central Drug Research Institute and the ICMR-DNDi visceral leishmaniasis Combo trials carried out in India.

A number of new platforms have been developed recently. These include the biosimilars such as the clot-buster Elaxim (Tenecteplase), the erythropoietin biosimilars, both manufactured by Gennova and approved by USFDA; various Virus Like Particle (VLP) platforms, and the hand-held PCR developed by Bigtec Labs.

However, in spite of the huge advances that have been made, there are many challenges that still exist. There has been a slowdown in pharmaceutical innovation after the year 2000. There have been escalating costs and prolonged time taken to develop new drugs. In recent times, there has been a more stringent focus on drug safety. Importantly, a single drug development process takes over $1.2 billion investment. Other challenges include access, treatment costs, drug financing, public funding, global trade, and the spread of antimicrobial resistance. It is of paramount importance that the challenges be overcome in order to forge a way forward. Promoting manufacture and uptake of generic drugs would be an important way of reducing cost and increasing access to life-saving drugs. Promoting biosimilars could be worthwhile, considering the fact that over 60 percent of the top players in the global biosimilars market are based in South-East Asia. Some of the top companies working on biosimilars include Biocon, Bioton, Emcure (Gennova), Hospira, Intas, Bio Farma, LG Life Sciences, Novartis (Sandoz), Ranbaxy, Teva, and Wockhardt.

Promoting more clinical trails in India appears to be an ideal proposition, considering the fact that India has a genetically diverse population, the costs for the trials would be comparatively low, involving faster regulatory approvals, and high quality clinical trials set-up. More partnerships and collaborations should be promoted. Established partnerships include DNDi, Stop TB Partnership, and TB Alliance. New examples include the Open Source Drug Discovery (OSDD), spearheaded by the CSIR. In the area of Product Development Partnerships, the important concept of "Islands of Promise" should be promoted, where "islands" of various resources and expertise are joined together by "bridges" in a bid to prevent fragmentation of research. New and innovative ways of funding also needs to be evolved. There is a need for government programs to convert research into policies, which are then translated into action.

There are many health related problems in modern day society, many of which afflict the poor and downtrodden. The MDGs promote health as an overarching strategy for poverty reduction. Therefore, research should address these societal issues. In essence, if we miss the poor, we miss the point!