MEETING REPORT

International Workshop: Building (Bio) Pharmaceutical Systems in Developing Countries, United Nations University Institute for New Technologies (INTECH), Maastricht: 26-27 February 2003

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In recent years inequalities between North and South have widened, and this shocking fact is particularly evident in recent conflicts over access to and availability of AIDS drugs in the developing world. The new pharma with its intense knowledge base, huge capital and protective global laws, oblige us to study the processes by which new drugs are created, diffused and protected, in order to generate policies and recommendations that assist developing countries. In this context, INTECH, an Institute belonging to the United Nations University system whose mandate is to conduct research and policy-oriented analyses and undertake capacity building in the area of new technologies, organized this seminar to examine experiences in (bio) pharma in different developing countries to assess the state of the art, cultural practices, innovation capabilities, legal systems on the drug industry, and derive conclusions on their chances to adapt or survive in the new globalized world.

The seminar program included an introductory framework analysis, followed by research presentations on emerging (bio) pharmaceutical innovation systems in five developing countries, namely, India, Cuba, Taiwan, Egypt and Ghana emphasizing their strengths and weaknesses, then followed by a discussion on policies, and finally a closing paper on pathways and policies.

Before any further comments, (bio) pharma name was purposely bracketed in parenthesis because it is used in a wider context which includes traditional therapies using local plants and biological ingredients, bioprospecting, modern pharmaceutical industry base on organic chemistry synthesis and recombinant DNA (rDNA), and hybridoma technologies. Case studies ranged from modern biopharmaceutical industry in India, biotechnology in Cuba, to traditional medicine of Ghana. The term innovation also was used in wider context as well ranging from the generation of new ideas, processes or products, to the capacity to copy, adapt and improve standard pharmaceutical procedures, in other words, managing knowledge and translating it into development, relevant applications, and wealth.

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In the introductory paper INTECH Director Professor Mylteka provided a historical background of the (bio) pharmaceutical industry, analyzed the innovation processes, and called attention to the need to approach the problem of developing countries (bio) pharma from a "systems" perspective. Particularly insightful was her analysis of the innovation processes where cultural, political, market and other considerations determine the existence of innovation system. The lack of a systemic integration of all components of the creative act with market forces and intellectual property, preclude the development of a healthy innovation system. Process of catching up is different in new wave technologies, such as biotechnology that are more science-based, patent intensive, and systemically embedded, than in earlier mechanically based industrial technologies and in particular, the greater importance of tertiary education and local research capabilities as the basis for understanding the technology, the industry, and making policy for it. This provides a rational for building (bio) pharmaceutical innovation systems in developing countries. Innovation systems are more than an agglomeration of organizations, universities, firms and research institutions the concept draws attention to the competences of these organizations and the interactions between them.

Dr Prasada Reddy from University of Lund provided an historical account explaining the origins and current success of the Indian pharmaceutical industry. Drug manufacture in India started in 1901 and for many years the market was characterized by high prices and a monopoly of transnational companies, in those days few had access to drugs. After independence in 1947 the Indian government democratized access to drugs establishing several state owned pharmaceutical companies. After a period of learning and adaptation, drugs were massively produced without much quality control. In latter times, spin-offs of these companies that went to private hands reached high quality standards and established modern managing practices. These companies were successful because they mastered reverse engineering, and special laws protected their activities. In addition price control and production of cheap basic raw chemicals necessary for the industry, gave them a competitive edge over transnational companies. Today, India exports good quality generics to other underdeveloped countries. An interesting aspect of Dr Reddy's paper was the description of the millenarian tra-

ditional Indian medicine whose products and practices have a promising future in the world market.

The third component of Indian Biopharma has to do with the new biotechnology based drug industry, which has been mostly advanced by private laboratories. These biotech industries are copying or imitating products that are protected by international IP laws and these abilities demonstrate a sophisticated knowledge-base and research capabilities.

What is the future of Indian Biopharma? The Achilles' heel of Indian pharmaceutical industry is innovation, the reduced investment in R&D, and the absence of an effective connection with the academic world. The absence of a robust innovation system and the compliance with WTO regulations by 2005 threatens the prosperous Indian generics market, local industries will be forced to pay royalties to International pharma causing prices increases and affecting the access of poor citizens to cheap drugs.

To try to circumvent this handicap some pharmaceutical companies are looking for strategic alliances with International companies and research centers located at developed countries.

Halla Thorsteinsdóttir from University of Toronto presented the case of Cuba (bio) pharma from an entirely biotechnological point of view. It is assumed that a more traditional pharmaceutical industry also exists, since Cuba sells anti-HIV generic drugs. Cuban biopharma development was marked by a political decision to address local health problems, and the strong Government conviction that biotechnology could provide a niche for the development of its scientific and technological system, and eventualy alleviate the country's economy from its dependence on sugar cane and cigars exports. In a more colloquial way, put many (if not all) eggs in one basket.

Cuban biotechnology started with intensive training of young researchers at centers of excellence abroad, that once back into the country, adapted products and processes. In more recent times Cuban researchers have learned to innovate within reverse engineering, and on their own, developing new products such as a meningitis vaccine which is being widely used abroad. Dr Thorsteinsdóttir's analysis revealed several interesting features of the Cuban scientific system such as: low productivity of scientific papers; research is done mainly at government institutes, whereas it is rare at universities; intensive collaboration among research centers; and scientists enjoy a high political profile. After a period of not abiding by international IP laws, Cuba is starting to patent abroad, and is getting ready to joint the WTO. From an economic point of view, it was difficult to assess how well Cuban Biotech industry is fairing since market figures were not provided. Overall, the relative success of Cuban biotechnology can be attributed to the very early start in this activity, and it looks unlikely that the Cuban example can be repeated elsewhere in the underdeveloped world, as Tirso Saez put it, "nowadays, embracing biotechnology as a mean to strenghten a country technological system and harness it to achieve development, can be regarded as an anachronysm".

Dr Reddy also presented the Taiwan case, this is a small country which has been quite succesful in electronics. Through clear market oriented government politics, Taiwan, a country of only 22 million people, has amassed the third largest cash reserves in the world. When in the early 1980's Taiwan started the Development Centre for Biotechnology, the idea was to generate spin offs in biotechnology, the Government perhaps imagined that this was a case similar to electronics, however reality of advance (bio) pharma is that it requires huge investments, a solid technological base, links with academia and long term goals, rightly or not, Taiwnese opted for cutting corners by purchasing or licesing technology generated in other countries using the knowledege and connections of young researchers trained abroad. The idea was to appropiate products or technology to generate profitable mid-size companies. An important aspect of Dr Reddy's paper was its historical account of the pharmaceutical industry and the traditional Chinese medicine. Taiwan has a weak generic market consisting mostly of drug repackging, but traditonal chinese medicine has been firmily developed. An interesting experience is the area of clinical trials where Taiwanese have combined a well establish clinical system to test drugs with exclusive market deals with transnational companies.

Dr Basma I Abdelgafar from Carleton University presented the case of Egypt; her paper was a long document detailing the development of Egyptian pharma as a reaction to nationalistic movements sprouting through the continuous years of wars in the Middle East.

As in the case of India, the industry originally governmental, lacked good quality controls, but after passing to private hands it produced quality generic drugs that under the protection of special laws, prospered and were able to compete against transnational companies. In the last three decades, Egyptian pharma remains largely dependent on formulation and packaging of generic drugs however, within the country it remains as one of the most competitive and profitable. A difference between the India and Egypt is the absence in the later of basic chemical industries necessary to produce raw materials for drug production. With the imminent implementation of the WTO-Trade Related Aspects of Intellectual Property Agreement (TRIPS), and a weak (or non existent) innovation system, local companies mostly family owned, have opted for selling out to the big pharma. Biotechnology based pharma never caught up in Egypt, despite having good labs and facilities and well trained scientists, low motivation for innovation and lack of articulation with the academic world, thwarted its development. The case of Egypt has a striking resemblance with many Latin American countries, where protectionist military regimes of the 50's and 60's applied self reliant economical practices that ended up in cautive markets with no need for improvement or innovation, and eventually to the obsolescence and disappearance of industries.

Ghana case presented by Dr George Owusu Essegbey from Ghana's Council for Scientific and Industrial Research (CSIR) was very interesting this country is likely to be a paradigm of many other countries in the African conti-

nent. Local pharma is very small in capital terms, and herbal medicine plays an important role on people's life. Government has made a good effort to regularize and control the drugs, and has stimulated the implementation of good manufacture practices for herbal medicine. The discussion of Dr Essegbey was strengthened by the contributions of Dr Maurice Iwu, executive director of Bioresources (and researcher at the Walter Reed Hospital, USA) a successful company in the production and marketing of Nigerian herbal medicine. These approaches highlight the importance of biodiversity and cultural practices in the development of alternative drugs for the needed. However, efforts should be made to show curative equivalence of herbal drugs, and once this is demonstrated, implement policies for its adoption by local practitioners.

Padmashree Gehl-Sampath from UNU/INTECH presented a paper analyzing the possible components of a flexible intellectual property system to be applied in developing countries. Current WTO-TRIPs regulations if adopted by developing countries will reduce the possibilities for generic drugs production, preclude the learning through reverse engineering, and block any the possibility to develop an innovation system. In countries with small markets pharma industry will disappear, and the poor population access to drugs will be compromised by prices fixed by transnational companies.

Professor Mylteka in a comparative fashion summarized all papers and the interesting discussions that took place after each presentation. Other participants were: Professors Norman Clark, University of Strahclyde; Tirso Saenz, CNPq Brazil; Anthony Arundel, MERIT, University of Maastricht and Drs Banji Oyeyinka, UNU/INTECH; Rohini Acharya, WTO. All documents discussed are still on their development phase, but they will soon lead to a new book to be published by INTECH (http://www.intech.unu.edu/).