

***Stakeholder views on transfer of  
technology for the development of  
research capacity and local  
production***

Frederick M. Abbott  
Professor of Law and WHO Consultant

AFRICAN WORKSHOP ON TECHNOLOGY TRANSFER FOR LOCAL  
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# Objectives

- Element of WHO PHI Secretariat efforts to assist in implementation of Global Strategy and Plan of Action (introduced by WHO presenters)
- Two broad objectives of present study:
  - Research and report on activities currently being undertaken regarding transfer of technology
    - As necessary “baseline” to Secretariat assistant with implementation of elements on transfer of technology, important to establish “what is being done”
  - Survey and report on stakeholder views regarding present efforts and future endeavors (i.e., what is working, what is not working and what should be done)



# Methodology

- Internet-based stakeholder survey regarding current activities and perspectives
  - Substantial pool of stakeholders identified
  - Survey allows self-selection into one of four categories (recognizing distinctions not always clear)
    - Technology Producers and Holders
    - Technology Transferees
    - Technology Transfer Facilitators and Financers
    - Technology Beneficiaries
  - Standardized questions permit correlation and analysis of commonly reported data



# Standardized survey results

Discussion of standardized survey results premature as collection of data on-going



# Methodology

- Current technology transfer activities identified, in part, through Internet-based research
  - Reported by industry (including industry groups), governments, international organizations, foundations, public-private partnerships, universities, non-governmental organizations, procurement and supply chain managers and others
  - Share point under construction for public access to generally available information

# Internet research-based results

- A myriad of programs exist that may be categorized as "technology transfer" from developed to developing countries
  - Academic institution training and collaborative research programs
  - Private sector
    - Intra-enterprise skills training
    - Establishment of research facilities
    - Establishment of production facilities
  - Government-sponsored research, education and training programs
  - Foundation funded training and research programs



# Methodology

- Visits and interviews by team leaders with representative and leading stakeholders:
  - Interviews with heads of generic industry association groups and enterprises at Montréal annual conference
  - Interviews with leaders of major public-private partnerships in Geneva (e.g., DNDi and FIND)
  - Interviews and contacts with major originator company senior staff, e.g., Novartis in Basel
  - Interviews with US NIH Office of Technology Transfer and European Commission
  - Meeting with originator company representatives in Geneva hosted by Health Diplomats



# Representative Visits and Interviews

- Discussions at India Pharma Summit 2009, Mumbai, including review of National Institute of Pharmaceutical Education and Research (NIPER) program, November 30, 2009
- Discussions with Dr. Reddy's executives regarding new research and development models, Mumbai, India, December, December 2, 2009
- Site visits to Zydus and Torrent Pharmaceuticals Research and Production Facilities (Ahmedabad, India), and meetings with senior company executives, December 4, 2009
- Recent study undertaken for Latin America





Some general  
preliminary  
interview-based  
observations



# Human Resource Development

- Broad consensus that “human resource development” should be key focus of technology transfer
  - Movement up “value chain” in pharmaceutical sector is knowledge dependent
  - From enterprise standpoint, skill level of local personnel an important factor in determining location of facilities, particularly for R&D
  - Development of technical skills may require that national pharmaceutical industrial base move through various levels of development, from formulation, to basic API production, to complex API production, to capital investment in R&D
    - May be 15 to 30 year process



# Human Resource Development

- Enterprises view intra-corporate training as technology transfer
  - Such transfer routinely takes place between developed and developing countries
- Government programs are developed specifically to create next-generation pharmaceutical scientists and regulatory personnel
  - For example, National Institute of Pharmaceutical Education and Research (NIPER) program in India (includes training for foreign developing countries personnel)



# Human Resource Development

- Public-private partnerships (PPP's) such as Drugs for Neglected Diseases initiative (DNDi) and Foundation for Innovative New Diagnostics (FINN) include participation of developing country researchers and production personnel as core components of mission

# Factors Influencing Local Production

- From enterprise standpoint, decisions regarding “local production” strongly influenced by corporate strategic objectives
  - In principle, corporate efficiency maximized by centralized large-scale production under close expert supervision
    - Among other things, assists in assuring quality control
  - From enterprise standpoint, building localized smaller scale production facilities not inherently valued
  - Local production may facilitate market entry and regulatory approval of products

# Factors Influencing Local Production

- Governments seek local production as condition of market entry by major multinationals
- Governments offering access to larger markets with stronger growth potential in better position to bargain for local facilities
- Government incentives (notably tax related) may act as significant inducement for some private sector companies
- Government rationale for seeking local production varies (generate employment, improve public health security, develop human resource capability, create business opportunity, etc.)



# Research and Development

- Classical model of new drug development involves costs largely prohibitive for developing countries (outside a few emerging markets)
- Crisis in classical model leading to new paradigms, largely involving distribution of research and purchase or licensing of promising candidates by major multinationals
- Breakdown of classical model offers opportunity for developing country researchers



# Shifting Technology Transfer Paradigms

- Rapid evolution of information technologies resulting in wide proliferation of knowledge
- Virtual research centers now possible, breaking down North-South structure, allowing developing country researchers access to costly research and testing equipment
- Private R&D-based enterprises assert that research facilities constructed in developing countries not to take advantage of cost savings, but instead to take advantage of large pools of talent
  - Cost arbitrage opportunities diminishing



# Research and Development

- Substantial value-added opportunities exist for developing country pharmaceutical industries outside development of new molecules and biologics, including improvements to “legacy” substances, such as through development of “polypills” to treat coronary disease. Such development a promising avenue for South-South technical collaboration
- Traditional medicines may be developed into standardized pharmaceutical products
- Development of biosimilars a priority for some developing country enterprises
- Outsourcing of clinical trials provides opportunity for developing countries, but raises ethical and quality control risks

# Definitions

- Transfer of Technology: “Transfer of technology” may be considered the conveyance from one party to another of information, know-how and performance skills, technical materials and equipment. Transfer of technology may take place in a variety of settings and ways. Educators and educational resources (books, Internet access, and so on) transfer technology to students. Scientific journals, patents (and patent databases) and other technical information resources transfer technology among the scientific community. Enterprise investors transfer technology in the form of materials, equipment and training among institutions and employees. Public and private patent and know-how licensors transfer technical information, implementing skills and, in some circumstances, materials and equipment. Temporary movement of people, including intra-corporate transferees and exchange of trainers, researchers and students can also provide exposure as well as transfer of know-how and skills. All of these activities may take place in a variety of configurations, whether public or private, institutional or individual, formal or informal, through partnerships or joint ventures, and within or across national borders. Finally, aid and cooperation for development has been pointed to by the literature as a means to design and build an enabling policy environment for technology transfer.

# Definitions

- **Developing Country:** There is no standard definition of a "developing country", although the United Nations maintains a formal listing of countries considered "least developed". Members of the World Trade Organization "self select" their status as developed or developing countries, which selection influences the way they are treated under certain agreements. The stage of development of any given country can be defined across a matrix of indicators, including indicators relating to per capita income and gross domestic product, as well as across a matrix of social welfare indicators, such as infant mortality, average lifespan, individual sense of well-being, and so forth. Survey participants are welcome to respond in a way that differentiates among the developmental status of countries or groups of countries in such manner as they consider relevant.
- **Local Production:** the term "local production" is capable of different meanings when used in the context of manufacture of medicines, vaccines and/or diagnostics. One of the objectives of this survey is to seek views as to whether there should be a preference for the way the objective of local production is implemented, and that may well depend upon how the concept of "local production" is defined. From a geographic standpoint, the term "local" will be presumed to encompass at least the territory of a single nation-state. "Local production" might also be understood or interpreted to cover manufacturing taking place within a "region". The term "local" may also be used to imply nationality of ownership, such that "local production" would refer to control over production facilities by nationals of the host country. This would distinguish "local production" from production by subsidiaries or affiliates of multinational pharmaceutical companies.