Geneva Pharma Forum

# forum highlights

9 March 2011

IFPMA International Federation of Pharmaceutical Manufacturers & Associations

# Technology Transfer: a collaborative approach to improve global health



The IFPMA Geneva Pharma Forum on 9th March 2011 highlighted the importance of transferring technologies for medicines in developing countries.[1] Mr. Eduardo Pisani, Director General of the IFPMA, underscored the central role played by technology transfer in the economic and societal transformation of countries. He stressed the benefits for countries in terms of living standards, generation of new knowledge, productivity and exports, explaining that *"Technology transfer of medicines and vaccines shares many of the challenges of other high-technology industries… but in addition, the research-based pharmaceutical industry strives to factor into the mix its commitment to global health."*

To play its part in the WHO Global Strategy and Plan of Action, the research-based pharmaceutical industry launched a new publication that brings together over 50 examples of technology transfer. The IFPMA publication identifies the risk of a "technology transfer gap": while middle income economies are involved in a growing number of pharmaceutical technology transfer partnerships, low income countries may not be so attractive as partners, as they may lack many of the enabling conditions for successful technology transfer. The publication shows that companies see technology transfer as a practical, sustainable approach to making their products available in a particular country, providing the necessary enabling conditions are in place. These include a viable and accessible local market, political stability and good governance, clear local development priorities, effective regulation, availability of skilled workers, adequate capital markets, intellectual property rights and enforcement, and a good relationship between government and industry. IFPMA companies will continue to support technology transfer to both middle and low income countries, but governments can facilitate this process by building these enabling conditions.

1 WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property Rights.

## IFPMA members' experience suggests…

- Low income countries should focus on attracting technology where there is already demand from local companies and consider using mutual recognition of regulatory decisions within regions to increase the market;
- High income countries can help by low and middle income country experts access to international standard setting bodies.

**Publication is downloadable at:**
http://www.ifpma.org/fileadmin/webnews/2011/pdf/IFPMA_Technology_Transfer_Booklet_2011.pdf

# WHO on the technology transfer for health

Dr. Zafar Mirza, Coordinator, Department of Public Health, Innovation and Intellectual Property at the World Health Organization, provided an overview of the WHO's current work in the area of technology transfer and observations drawn from this work. He underscored how transfer of technology relating to global health was an emotive area for developing countries. The question of inability of countries to make available the essential products of innovation have been termed as a "moral imperative" by the Commission on Intellectual Property Rights, Innovation and Public Health.

The bigger picture perspective for technology transfer and global health has been shaped by the important declarations of intent by developing countries to serve their public health needs. These views have been prominent both in the trade and public health arenas, and have been reflected in many international agreements and statements from international governmental organizations.

The WHO has undertaken two projects to promote technology transfer: one in the area of medicines, another in the area of vaccines. For the former, the WHO has also commissioned research and case studies, the most important of which is a global trend analysis report (available in May 2011). The WHO project focusing on vaccines began in the wake of the pandemic influenza preparedness (PIP) discussions, and involves the WHO promoting vaccine production in developing countries, with two centers that provide support to 11 countries and facilitate technology transfer and licensing arrangements between providers and users in vaccine production.

"The WHO has undertaken two projects to promote technology transfer: one in the area of medicines, another in the area of vaccines."

Dr. Mirza

Dr. Mirza made the following observations on transfer of technology:

- Local production of medicines and vaccines in emerging countries has its own momentum today and many countries are taking notable initiatives in this area to address their public health needs.
- As identified by the IFPMA in its publication, certain conditions must prevail in developing countries for effective use of technology. An important prevailing condition that is often missing is the need for policy coherence in recipient countries, with a national vision, where technology transfer and public health development are part of the same strategy and "in sync" with each other.
- One size does not fit all and different approaches are needed for the different kinds of health products and level of development of countries.
- There are ethical questions where a country is successfully exporting medicinal products yet the country has unmet medical needs among its own population.
- There is a need for development organisations to consider the public health framework to promote and support local production and related transfer of technology.
- Dr. Mirza concluded: "The development agenda's role involves looking at how to contribute to capacity building, infrastructure and policy coherance. There is a strong case to look at stimulus to contribute to build capacity of countries that aspire to achieve local production".

**Dr. Victor Konde,**
**Scientific Affairs Officer, ICT, Science and Technology, UN Economic Commission for Africa**

Technology Transfer in Africa is growing faster than in other areas, although its global share remains small. The region needs to work to reduce cost and risks. Countries in Africa need to:

**1.** Promote industry alliances between Africa and other emerging and developing countries;

**2.** Encourage PPPs with industry, universities and governments;

**3.** Support R&D agreements between countries;

**4.** Governments need to use their contractual agreements strategically; development partners both public and private can play an important role in supporting this.

# Provider experience of technology transfer
# The Lilly MDR-TB Partnership

The Partnership was set up with a pledge of USD 135 million in cash, medicines and technology to increase access to treatment and focus global resources on prevention, diagnosis and treatment of patients with MDR-TB. This public-private partnership has transferred the technology, expertise, formulas and trademarks to manufacture two Lilly-developed antibiotics for MDR-TB to manufacturers in China, India, Russia and South Africa — some of the world's highest-burden countries.

As Lilly developed medicines to treat MDR-TB, it was asked by Medecins Sans Frontiers (MSF) and the World Health Organization (WHO) to provide the drugs at concessionary prices. This led to Lilly deciding to make MDR-TB medicines available more widely through the creation of the MDR-TB partnership, whose aims are to combat the growing MDR-TB pandemic and support the Global Plan to Stop TB. The first steps were not promising: Lilly approached several generic companies to see if they wanted to accept Lilly's TB knowhow for free but none of them expressed an interest. With widely unpredictable rates of MDR-TB, the generic companies felt that the business was too risky. As a result Lilly decided to share not only the dossier but also provide financial support. It identified companies in China, India, Russia and South Africa who were willing to receive Lilly's manufacturing-knowledge and support in creating manufacturing centres of excellence. The two anti-TB drugs required the companies to develop expertise and capabilities in two very different technologies and knowhow: oral formulations (capsules) and injectables. In order to overcome the barrier of a small market such as the one of MDR-TB market, and to identify additional use of the technology received it is critical for generic companies to offer their manufacturing new skills and capacities to other multinational companies like Lilly. As production quantities of MDR-TB medicines are very small it is important these companies are able to export without unnecessary regulatory burdens, especially if drugs are already approved by stringent drug authorities. The WHO and other organisations are key to ensuring ways to have mutual recognition between countries. In conclusion, Dr. Carlevaro underlined the need for patience as it can take six to seven years to transfer the technology successfully. Even when the technology transfer provider's approach is mainly toward corporate social responsibility, the recipients will not be interested if it is not set up to be sustainable.


"It can take six to seven years to transfer the technology successfully." Dr. Carlevaro

**Presentation available:**
http://www.ifpma.org/iipt/index.php?id=4365

### How technology transfer helped Aspen Pharmacare South Africa

- New product / capacity – production of injectable sterile formulation and capsules;
- Revenue stream – sales allowed profit to sustain ongoing re-investment in local staff and facilities;
- Employees skills-building.

### Lilly's contribution

- Provided technical staff and know-how, and financial support for facility upgrades;
- Program supports South Africa's Industrial Policy of retaining and developing critical skills and unique technology;
- Reducing the dependency on imported products and providing export opportunities for the pharmaceutical sector.

# Provider experience of technology transfer Fiocruz/BioManguinhos: a technology transfer WIN-WIN model

Brazil's longstanding experience in technology transfer (started in 1985), is an integral part of the Brazilian government's vaccination program for polio, Haemophilus influenzae type b (Hib), measles, mumps, rubella, rotavirus and pneumococcal disease. A technology transfer program has been initiated to provide a vaccine to protect over 17 million children from rotaviruses. Fiocruz is also part of a joint R&D initiative to develop a vaccine for dengue fever.

Mr. Antonio de Padua Barbosa, Director of Production at Fiocruz/Bio-Manguinhos (BM) explained that his organization is part of the Brazilian Ministry of Health. Today, BM develops and produces vaccines, diagnostics kits and biopharmaceuticals, and has a staff of 1,300. Its mission is to contribute to the improvement of Brazilian Public Health Standards through technological research and production of immunobiologicals, thereby helping to meet the demands of the country's 190 million citizens and the 3.2 million children that are born each year. Today the company has a healthy pipeline, which in part is the result of an innovation strategy that uses technology transfer.

Mr. Barbosa illustrated how the expertise and capacity is shared in the partnership Hib vaccine technology transfer agreement BM has with GlaxoSmithKline. BM has the technological and production capabilities, including a large freeze-drying facility. It also has the structure, organization and budget to ensure it has a team ready to receive the technology. GlaxoSmithKline brings scientific and technological knowledge, a team dedicated to technology transfer, and most importantly a company-wide commitment to ensuring full technology transfer. This win-win model shows how the provider of technology increases its market and benefits from revenue assurances including royalties, while also demonstrating the company's social awareness and enhancing its international recognition. For BM, the advantages are that it is able to quickly incorporate technology for production, guarantee vaccine supply and have access to modern technology platforms. The benefit of this technology transfer for Brazil is a lowering of the cost per dose. The Hib technology transfer made it possible for the Brazilian government to roll out a mass vaccination programme from 1999 onwards and already by 2001, it was able to reduce incidence of Hib meningitis from 26 % to 3.3 % [1].

1 Kmetzsch CI, [et al]. J Pediatr (Rio J), 2003; 76(6):530-6.

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**About the IFPMA**

The International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO representing the research-based pharmaceutical industry, including the biotech and vaccine sectors. Its members comprise 26 leading international companies and 44 national and regional industry associations covering low, middle and high income countries. The industry's R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal (www.ifpma.org/ClinicalTrials), the IFPMA's Ethical Promotion online resource (www.ifpma.org/EthicalPromotion) and its Developing World Health Partnerships Directory (www.ifpma.org/HealthPartnerships) help make the industry's activities more transparent. The IFPMA supports a wide range of WHO technical activities, notably those relating to medicine efficacy, quality and safety. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

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