

Innovation and Technology Transfer for Global Health

'Bridging the Gap in Global Health Innovation – From Needs to Access'

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SESSION SUMMARIES – STRATEGIES FOR SECURING PRODUCT AVAILABILITY AND ACCESS¹

Gill Samuels (Global Forum for Health Research) and Dianna Derhak (DNA International Consultancy) explored a range of private sector and partnership initiatives working to improve access to medicines and the development of indigenous capacity to support near-term product supply and future innovation.

Pharmaceutical industry case studies demonstrated that there is an attempt to work with developing countries in a number of partnership formats. Industry approaches including clinical trials and scientific research capacity building, tiered pricing, IP licensing, donation programmes among other initiatives were presented and discussed. Better reporting of adverse reactions, more trust and harmonisation at multiple levels (including regulatory requirements) and common goals for different agencies are among industry's priorities. More consolidation, demand and centralisation of procurement would improve the ease and efficiency of supply.

Product development partnerships (PDPs) are making the impossible possible and making risk manageable. As products begin to come through to registration stages, concerted efforts are being made by PDPs to address downstream access issues, particularly in relation to securing supply chains for safe delivery of medicines and vaccines. However, different cultural perceptions and mistrust skew many of the activities that firms and PDPs are attempting, including clinical trials. A policy environment that provides proper incentives for firms and non-profit organizations to fill the needs in the healthcare sector is needed.

The development of Paromomycin IM for visceral leishmaniasis: Ms. Katherine Woo, Institute for One World Health

The Institute for One World Health (IOWH) is paying increased attention to delivery and supply chain issues and has signed supply agreements with a local manufacturing company to deliver Paromomycin to treat Visceral Leishmaniasis (VL). The approach places emphasis on the need for behavioural research to inform the baseline for training and the need for a basis for evaluating the economic impact of providing this treatment to communities. A tiered approach to health systems has been developed. The programme has also built partnerships with governments, NGOs, social enterprises, and companies for-profit or non-profit in manufacturing and supply chain leadership to ensure that there will be local uptake and to facilitate long-term commitment both by local and federal government.

¹ Prepared by Rachele Harris and Sarah Miller. Please address any comments or queries regarding this session summary to andrew.farlow@economics.ox.ac.uk.

On-the-horizon Developments in Biotech and Nanotechnology: Ms. Dianna Derhak, DNA International Consultancy

The Bio Ventures for Global Health (BVGH) partnering meeting (at the Biotechnology Industry Organisation annual conference) is a means to institutionalise a marketplace for neglected disease drug development. It is a means to build networks and new connections, essential to drug development.

Pharmaceutical Industry Initiatives: Dr Richard Barker, Association of the British Pharmaceutical Industry

The pharmaceuticals industry is committed to working with developing countries to influence improvements in healthcare delivery. Traditionally, industry has a very important role to play in global health as the only proven “nursery of innovation”. Despite constraints that industry faces, including weak intellectual property (IP) regimes and complex and unregulated ethical approval processes that may exist in developing countries, there is an opportunity for industry to take its role further. Industry has skills in managing risks and understanding markets, portfolio management and a range of technical expertise.

However for industry to realise its position and take its role further, it requires a facilitating environment – allowing it to contribute more through PDPs, through working with governments and the donor community, through investing in manufacturing capacity in developing countries and through working to build economic, sustainable and secure pharmaceutical supply chains in developing countries. The pharmaceuticals industry is also focusing efforts on skills development to increase knowledge transfer.

The Case of Merck: Dr. Diana Lanchoney, Merck

Merck is engaged in a number of projects to improve access to medicines. Merck has, for example, been eliminating any profit intent around novel vaccine products in GAVI eligible countries. Approaches also include facilitating tiered pricing for early-stage products to amortise the risk for the public sector and focusing efforts on developing successful partnerships with a wide range of stakeholders. Tension exists for firms in deciding between institution-building projects versus results-focused projects. The need for enhanced collaboration is clear. Timeliness, trust and excellence are needed to frame an elevated level of partnership.

The Case of Ranbaxy and ARVs: Dr. Arun Purohit, Ranbaxy

The generics industry has a substantial network worldwide and is able to support delivery of medicines for all the major diseases. It is important however to consider the need for incentives for generics firms to remain in the neglected disease area. Rising costs are among the challenges the industry faces, due to the high costs of re-registering products in different national systems. There are also additional demands to deal with, such as the WHO requirement to produce generic drugs in combinations and innovative forms and to develop co-packaging.

There is ongoing funding pressure for companies to produce the cheapest product possible within international safety and quality standards despite variations that exist in regulatory requirements across countries, which can cause delays to access. Fragmentation and unpredictability of demand also pose challenges which might be addressed through centralisation of procurement.

The Case of Eli Lilly MDR: Dr. Gill Samuels², Eli Lilly

Eli Lilly is involved in a variety of initiatives to address multi-drug resistant (MDR) Tuberculosis (TB). One initiative is based on a not-for-profit partnership in technology transfer with the Global Alliance for TB (GATB) for early-stage drug discovery. Another is a partnership in technology transfer to share both specific and general manufacturing technologies to create self-sustaining centres of manufacturing excellence, to support reliable producers to ensure expanded supply of new drugs. Lilly has provided financial support to the partners and is also making over 500,000 compounds available for screening.

The characteristics of these kinds of partnerships are technology transfer in countries with the highest disease burden; drug supplies and concessionary prices; training tools for healthcare professionals; and training of trainers.

The Case of Pfizer – Dr. Robert Mallett

Pfizer's focus is on building capacity in health systems, especially where there are challenges in running clinical trials in developing countries and funding shortages. A project with the WHO's Tropical Diseases Research (TDR) programme is underway, with Pfizer collaborating in research, development of quality manufacturing and personnel exchange in order to improve malaria management. Pfizer was involved in the establishment of the International Trachoma Initiative, where it committed to supply one of its medicines free of charge for trachoma until the disease is eliminated. Its Global Health Fellows programme of secondments has helped develop infrastructure in government ministries. The building and continued funding of the Infectious Disease Institute (IDI) at Makerere University in Kampala, Uganda is providing training around a number of infectious diseases, particularly HIV, TB and Malaria.

Discussion

Government support for neglected diseases may often be uncertain in the long term, so industry involvement and ongoing support for PDPs is essential. Partnerships are incredibly important, but managing the incentives that stem from different stakeholders requires a nuanced and informed approach. PDPs can help to make risk more manageable across partners.

Further work is needed to shed light on what other competencies industry might be able to share with the non-profit sector, particularly around embedding new health products and technologies. Although firms have found challenges relating to a lack of developing-country technical capabilities and resources, there is evidence to suggest that perceptions around the extent of these challenges are negatively biased. Rather than develop new initiatives, investment needs to be targeted at existing centres of excellence to strengthen capacity. Further research and policy adjustments are needed to support industry and other partnerships to invest appropriately, addressing challenges posed by issues such as fragmented product demand and regulatory systems and broken and insecure supply chains.

Difficulties in pharmacovigilance were discussed, particularly in reference to counterfeits, which undermine technological solutions producing high-quality products. Behavioural research is also needed to support a greater emphasis on disease prevention and integration of modern medicines into traditional practice.

² Dr Gail Cassell was the listed speaker but could not attend the conference. Dr Gill Samuels presented Dr Cassell's slides

A distrust of industry still exists in many developing country contexts and it is important for firms to work more closely both at local level and with international organizations to mitigate this reputation. Also, intensive knowledge transfer is needed to support contract high standard contract manufacturing.