SESSION SUMMARIES – PARTNERSHIPS IN PROMOTING INNOVATION AND MANAGING RISK (1)

This part of the conference was broken down into two sessions so that the topic could be fully explored both through presentations on overall strategies and suggestions for best practice, and also through case studies on different initiatives and partnerships. Dr K Satyanarayana and Andrew Farlow addressed partnerships for the development of products and the challenges related to product development and, increasingly, access and delivery.

The session explored the need for policy and funding to be adapted to reflect the changing nature of research and development (R&D) for neglected diseases, the work of international initiatives through collaboration with public and private sector partners to create health technologies and new intervention solutions; and the different approaches used by product development partnerships (PDPs) and other public-private partnerships to bring low value products to the market by reducing and mitigating market risk. Several case studies were presented, describing different PDPs and other initiatives’ approaches to research and product development including community based approaches.

With regards to fostering innovation, the session highlighted many deterrents to engagement in this area, particularly for academia and small start-ups in developed and developing countries. These exist in the form of procedural and policy deterrents and include a lack of special tax incentives, and the fact that the majority of patents are transferred before they are granted. Models are needed to inform partnerships in order to both share the benefits of product innovation and to provide access to markets to enable product innovation.

Strategies for Product Innovation: the PDPs: Dr. Mary Moran, The George Institute

It is important to consider the different costs and risks that exist through the product development process. There are different modules in vaccine development – the main ones being discovery and innovation, commercial application or commercialisation, large scale clinical development and large scale manufacture and distribution. These processes involve different interim markets and stakeholders with different incentives. It is necessary to move on from the old “John Wayne” policy model which does not effectively consider these differences and which does not meet different incentives well. Companies should focus on their area of comparative advantage and collaborate efficiently for other aspects. PDPs can play a strong role

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in presenting smart and flexible ways of dealing with strategies for product innovation.

**The Aeras Foundation: Achieving Access: Dr. Jerald Sadoff, Aeras Global TB Vaccine Foundation**

Aeras operates as a not-for-profit pharmaceutical company, conducting research, development and manufacturing activities. It works to shape the TB vaccine market as a developer, manufacturer and distributor through various partnership arrangements with industry, academic groups, philanthropic groups and governments. These partnerships enable Aeras to work towards widespread availability of vaccines and affordable vaccines.

Through working in partnerships it is possible to alleviate the difficulties of predicting the investment required for manufacturing, the costs of testing and validating a product; the prices which people are willing to pay and the demand for the vaccine. Therefore the risks that exist in the vaccine development process can be borne more easily, although challenges do exist in mixing intellectual property (IP) from different sources. Where it is possible to collaborate efficiently and to control IP consistently, there will be better ultimate control of price and distribution.

**Potential New Approaches to Scientific and Financial Innovation in PDPs - the example of AIDS vaccines: Mr. Labeeb M. Abboud, IAVI**

IAVI is a fully integrated product development partnership. Its focus is where the disease burden is greatest, in the developing world, where over 95% of new HIV/AIDS infections occur. It works in partnership across developing countries, with scientists, academics, community and political leaders and industry. These partnerships enable IAVI to promote innovative financing mechanisms to stimulate investment in R&D and to support the R&D process to create an HIV/AIDS vaccine, to absorb some of the early stage risk in vaccine development, and to create appropriate performance indicators through ‘test of concept’ trials. Through a combination of IP management, license rights and technology transfer IAVI is able to strengthen industry involvement. IAVI also works to strengthen community capacity building and to generate political support and advocacy for the vaccine.

**PDVI – What is the End Game?: Dr. Harold Margolis, PDVI**

The Paediatric Dengue Vaccine Initiative (PDVI)’s mission involves accelerating vaccine evaluation as well as introduction of vaccines. Vaccine discovery has not been part of the PDVI mission. PDVI’s programmes on access involve working with a developing country vaccine regulators network, developing a series of dengue prevention boards for Asia and the Americas, and developing a public health network (engaged in activities such as surveillance and diagnostics). Its measure of success will be to introduce dengue vaccines into the national immunisation programmes of at least one developing country in each dengue endemic region.

**The PATH Strategy: Dr. Michael Free, PATH**

The Program for Appropriate Technology in Health (PATH) has had over a hundred partnerships with commercial companies to advance over sixty technologies, many of them currently in use and many in the current pipeline. PATH works to build the
evidence base for informed decision-making by different stakeholders across the overlapping areas of innovation, introduction and integration, through engaging with many commercial partners, and targeting country decision-makers and international agencies. It is important to understand the needs of at risk populations, to target public investment appropriately and to engage the right organisations to develop sustainable technologies. Through partnership it is possible to develop capital and to harness innovation capacity.

**The South African Malaria Initiative: Jane Morris, African Centre for Gene Technologies**

The South African Malaria Initiative (SAMI) is a nascent PDP. It is unusual in its location in the developing world and is developing a comprehensive local and global research network, enabling a strong research base and a focus on accelerating developments in discovery and diagnostics for malaria technologies. SAMI has developed innovative IP policies to support structured collaboration across a consortium, but is limited by regulatory issues. In evolving as a PDP it will need to rely on partners to undertake activities including developing regulatory capacity and the production of new compounds.

**Discussion**

*Please continue to the second part of the session of Partnership in Promoting Innovation and Managing Risk to read the summaries of the other speakers and the points that were made in discussion of all the issues raised.*