

Not-for-Profit Approach Improves Prospect of Vaccines and Drugs for the Poor

US\$2 billion investment yields significant progress, but more funders required.

GENEVA, Switzerland; 16 September 2004 – A major consultation conducted by the Initiative on Public-Private Partnerships for Health (IPPPH) confirms that the roughly US\$2 billion so far collectively pledged to new not-for-profit ventures in the last 5 years to develop drugs and vaccines against diseases associated with poverty has had a significant impact. In just a few years the most mature of these ventures have built up sizeable portfolios of potential products for their target diseases. Dr Roy Widdus, organizer of the consultation, suggests that while it is too early to immediately expect licensed successes from these new efforts – commonly referred to as ‘public-private partnerships’ - the consultation confirmed that the envisaged collaborations are working effectively. It also noted approvingly that the ventures are assessing the progress of candidate products carefully, replacing very rapidly those that become less promising with newer, more attractive ones, which ultimately keeps down total costs.

Prior to the establishment of these ventures in the late 1990's, the lack of market incentives meant that products such as anti-malarials, new tuberculosis (TB) and tropical disease drugs, new contraceptives and microbicides, and various vaccines (e.g., to prevent HIV/AIDS, malaria, and TB in adults) were not a priority for the private sector. Pharmaceutical companies were not interested – on their own – in investing their unique expertise and hundreds of millions of dollars in developing products that were commercially unattractive.

“These ventures have the potential to help break the deadly cycle of disease and poverty in which too many people are still trapped” said Dr Lee Jong-wook, Director-General of the World Health Organization in a message accompanying the report. Likewise the approach has been embraced by Ray Gilmartin, CEO of Merck & Co., and current President of the International Federation of Pharmaceutical Manufacturers Associations, the international representative of the R&D based pharmaceutical companies, who said “These ventures facilitate the processes by which industry can utilize its unique strengths – expertise in innovative product development – to address the needs of the poor”.

“Public-private partnerships revolutionized the way drugs and vaccines were being developed for diseases disproportionately affecting the poor,” said Dr Widdus. “However, product development requires a long term commitment. It can take over ten years and hundreds of millions of dollars to develop drugs; probably even more for vaccines”

Using a portfolio approach similar to the pharmaceutical industry – to manage the risk of failures – some of the partnerships have candidates in the pipeline entering clinical testing that, if successful, could be delivered within the next five years. Other ventures are at an earlier stage. However, as more and more candidate products enter the final stages of development, the expensive phases of clinical trials including large Phase III efficacy studies, the guaranteed availability of sufficient funding becomes ever more critical. Long-term assurance of sufficient funding is essential to ensure that products will result from these initiatives.

According to the report, initial estimates of the additional financing required through 2007 for these vital drugs and vaccines that if successful will save millions of lives in developing countries, exceeds US\$ 1.0 billion. This additional amount needs to be pledged - and pledged soon - the consultation concluded

Using primarily philanthropic and public funds, these new ventures collaborate with industry, academic institutes, and disease control specialists and researchers in developing countries to

develop products specifically for the neglected poor populations. Direct funding has come from foundations such as the Bill & Melinda Gates Foundation, the Rockefeller Foundation, a pioneer in the area, and the Wellcome Trust as well as bilateral aid agencies (including those of Ireland, the Netherlands, Switzerland, the UK, and the USA). Significant 'in-kind' contributions from industry generally consist of staff, technical know-how and access to specialized equipment and testing facilities, representing support worth many millions of dollars. Additional funding, pledged well in advance, is critical to ensure industry and others stay engaged with these projects.

Current donors may be at the limit of their funding, given their other responsibilities and priorities. However, many of the traditional sources of support for developing country health improvement (such as other bilateral aid agencies, and domestic research agencies of industrialized countries) have not yet engaged in supporting these new efforts and innovative new financing approaches need to be explored. The consultation concluded that the current funding base could - and must - be significantly expanded. Every year the public and private sectors jointly spend more than US \$70 billion on health research and development. However, only about 10% of the money is used for research into 90% of the world's health burden. Support for public-private partnerships for the innovation of health products provides one significant opportunity to start to close this '10/90 gap'.

Beyond additional direct funding for these ventures, the report identifies a range of other activities that will assist their performance and enhance prospects for ultimate success in developing and introducing vital new products. These include: strengthening capacities and better harnessing the potential of the disease-endemic developing countries (which is the subject of a follow-on discussions among African researchers), increasing information exchange, developing common performance measures, and broadening industry participation.

The consultation was organized by the Initiative on Public-Private Partnerships for Health, a component of the Geneva-based Global Forum for Health Research, in collaboration with the Bill & Melinda Gates Foundation, the UK Department for International Development, the Rockefeller Foundation and the Wellcome Trust, which hosted the 100-person workshop in London.

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