**International Partnership for Microbicides**  
**Submission to the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property**

**Introduction**

The International Partnership for Microbicides (IPM) welcomes the opportunity to make a submission to the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IWG).

The Commission on Intellectual Property, Innovation and Public Health (CIPIIH) underlined the importance of health technology innovation as an integral part of effective and sustainable global health strategies. However, the current health global innovation system does not effectively meet the needs of developing countries, and will not do so based on a solely on a commercial model. Government engagement and multi-sectoral partnerships are required.

The 59th World Health Assembly (WHA59.24) acknowledged the need for investment in the development of new technologies to meet developing country health needs. The WHA recognised the importance of policy environments and funding that can stimulate partnerships to increase and accelerate such research, including support for product development partnerships (PDPs), such as IPM.

The following submission briefly outlines key policy recommendations for the IWG to consider in its deliberations on improving the effectiveness of the global health innovation system in meeting developing country needs.

1) **Increase direct investment by governments in health technology R&D that meets the needs of developing countries**

   Investment in product development for developing countries has increased in recent years, but falls short of current estimates of what is required to develop, test, license and launch new technologies. In 2004, one report suggested a deficit of $400m - $700m annually up to 2007 in funding required to support the then current portfolios of PDPs dedicated to developing new technologies for use by developing countries.\(^1\)

   IPM has been successful in securing funding from 8 governments,\(^2\) the European Community and others, including the Bill and Melinda Gates Foundation and the Rockefeller Foundation. While this diversity of support for IPM is encouraging, it is estimated that investment in microbicide research needs to double from current levels to $300m per year.\(^3\) The diversity of funding secured by IPM is also not representative of investment in R&D for developing countries as whole. In general, philanthropic funding has played a major role in driving increased R&D for developing countries, with the Bill and Melinda Gates Foundation accounting for more than 60% of funding for product development partnerships.\(^4\)

   Public sector funding for health R&D for developing countries often falls between the remits of development agencies, that may have little experience in R&D funding but a focus on global public health, and health or science and technology agencies, which support R&D but have limited remits for global public health. The CIPIIH report notes that the US National Institutes of Health spends 4% on

---

\(^1\) Quoted CIPIIH Report, pp 77. While PDPs do not account for total investment in developing country focused health R&D, the deficit in funding for PDPs is illustrative of an overall shortfall in investment.

\(^2\) Canada, Denmark, Ireland, Netherlands, Norway, Sweden, UK and USA. Announcements from a further 2 governments are pending.

\(^3\) CIPIIH Report, pp 74.

diseases that primarily affect developing countries and the UK Medical Research Council 6%.

While philanthropic funding has and will continue to play a key role in driving global public health product innovation, increased support from governments is also needed to meet existing financing deficits, support sustainability and to ensure that product development is integrated effectively into broader health and development strategies.

2) Develop flexible funding instruments to support efficient R&D

In addition to increased scale, financing instruments need to be appropriate to the needs of R&D. Risk is an inherent part of the R&D process. Even with efficient portfolio management, the most promising candidate products may fail in late stage testing. This requires that funders accept some level risk when supporting R&D.

A report by the LSE notes that PDPs have been particularly cost-efficient in managing their product development portfolios, in part, through effective contracting out of activities to private sector companies and working with a wide range of partners with necessary expertise. The capacity to flexibly manage contracting and partnerships is essential to the PDP model.

Finally, financing for R&D needs to be long-term. The development process from concept to approved product can take 15 – 20 years. Even accelerated development can take a minimum of 5 – 10 years. Long-term commitments are necessary to support R&D and to build and sustain capacity in developing countries to participate effectively in the R&D process.

3) Support Product Development Partnerships

PDPs have emerged over the past 10 years with the explicit aim of developing or adapting health technologies to meet developing country needs. Importantly, PDPs adopt approaches and advocate for policies that will support developing country access to successful products. These include product design that focuses on developing country needs, clinical trial partnerships with developing countries and IP agreements that allow flexible pricing and manufacturing strategies to support sufficient and affordable supply of future products.

The LSE report notes that drug development PDPs have been as, and sometimes more, efficient than industry standards in moving products along the development pathway. The CIPIH report notes the cost-effectiveness of PDPs, which is in part due to their ability to mobilize contributions from a variety of partners, including the pharmaceutical industry.

While a comprehensive approach to improving the responsiveness of the global health innovation system to developing country needs is required, PDPs have been shown to be important vehicles to mobilize partnerships between donors,

---

5 Attrition rates can vary considerably across diseases and technologies. Products for which no existing proof of concept exists face particular challenges in prioritising candidate products for development.
7 ibid
8 CIPIH Report pp 75
9 IPM has successfully negotiated agreements with Tibotech, Bristol Myers Squibb and Merck to develop antiretroviral compounds as topical microbicides. In each case, IP agreements support flexibility in licensing, manufacturing and pricing strategies for product use by developing countries.
public sector agencies, industry and developing countries in support of increased and accelerated product development.

4) **Support developing countries to build domestic research capacity**

Developing countries must be key partners in the development of global public health technologies. Clinical testing of new technologies with populations and in environments similar to those in which they will be used can strengthen participation in the R&D process, help optimise product design and build confidence in the research process and health technologies.

Current research capacity, particularly clinical trial infrastructure, is a constraining factor for product development focused on developing country health needs. Efforts to strengthen health systems and scale-up the delivery of health services provide opportunities to create an environment that can support health R&D. Equally, investments in R&D, such as clinical infrastructure and training, can be supportive of broader health programme objectives. Partnerships among product developers, donors and developing countries are needed if capacity constraints are to be overcome and benefits from both health and R&D investments maximized.

5) **Work with communities to support effective and ethical trials**

Community participation in clinical trials is essential to the R&D process. Early engagement of communities to build understanding of and support for R&D, to inform trial conduct and to agree the benefits of participation in trials should be an integral part of the research process. Ongoing community participation during trials can help ensure ethical conduct, support trial implementation and provide important insights into the use and acceptability of trial products.

6) **Develop strategies to support the rapid introduction of new technologies by developing countries**

Historically the introduction of new health technologies has focused first on the high value, predictable market of developed countries. Introduction and adoption by developing countries has often lagged by many years, if it happens at all. Weak health systems, insufficient and unpredictable financing and lack of affordable supply of products have often meant that the global poor have not benefited from health innovation.

Support for developing country decision making and ability to introduce new products should be integrated in to broader health strategies. Appropriate regulatory pathways for developing country product introduction are needed. Improved information on disease burden, potential demand and financing requirements can assist informed decision making by governments and support investment decisions by product developers, manufacturers and donors. Strategies to support product affordability and supply, on the one hand, and commitments to sufficient and predictable funding, on the other, are key to supporting access to future products. Product introduction must also place technologies in the broader context of health systems and improvement and include attention to building community understanding and demand for appropriate products and services.

---

About IPM

IPM is a public-private partnership formed in 2002 to accelerate the discovery, development and accessibility of microbicides to prevent transmission of HIV, especially among women in low-resource settings. IPM is focused on overcoming the major challenges that stand in the way of microbicide development and distribution. IPM is working to: (1) accelerate product development by building production and formulation expertise; (2) build clinical trial capacity in developing countries; (3) establish appropriate regulatory pathways for microbicide products; and (4) plan for widespread and affordable distribution of these products.

IPM receives funding from the governments of Canada, Denmark, Ireland, Netherlands, Norway, Sweden, UK and USA and from the European Community, the World Bank, the Bill and Melinda Gates Foundation and the Rockefeller Foundation.