Key recommendations from product development partnerships on the EU Framework Programme for research and innovation

What are PDPs?
Product Development Partnerships (PDPs) are not-for-profit R&D organizations which were set up with the sole objective of researching, developing and supporting the accessibility of new health technologies that target diseases disproportionately affecting poor people in developing countries. They cover the full innovation cycle, from early discovery stages to the implementation of a product.

PDPs knit together contributions (financial, technical and in-kind) from public sector, private sector, NGOs and academia to further the development of new health technologies targeted to the needs of developing countries. Through this innovative mechanism, PDPs are able to advance global health goals by accelerating the development of products that may not otherwise have been created.

In addition, and in collaboration with a wide range of partners, including European researchers and industry, PDPs contribute to strengthening Europe’s role in finding the most efficient and effective solutions for global health challenges.

PDPs are a proven model: Prior to the creation of PDPs, the neglected disease R&D pipelines were noticeably empty; one study estimated there were only 20 development projects for neglected disease drugs between 1975 and 2000, and the historic lack of investment resulted in only 16 of the 1,393 medicines developed during this time being focused on Least Developed Country-specific diseases.

Since their establishment, PDPs have re-energized the developed of global health tools. To date PDPs have developed and licensed 12 products; in 2009, PDPs had nearly 150 biopharmaceutical, diagnostic and vector control candidates in various stages of development, including 32 in late-stage clinical trials. Paradoxically, just when many PDPs are on the cusp of achieving significant results, funding for PDPs dropped markedly according to the G-Finder survey report on 2009 global investments into R&D for new products for neglected diseases.

Currently, there are around 26 PDPs developing drugs, vaccines, microbicides and diagnostics that target a range of infectious and neglected diseases, and which will be accessible and affordable for poor and neglected populations.

**How do PDPs fit into the Europe 2020 strategy?**

**PDPs deliver life-saving, innovative new health tools.** PDPs were created from a desire to generate innovative approaches to alleviate the global burden of neglected diseases by harnessing the expertise, knowledge, and resources of both the private and public sectors. Because of their focus on the end-goal of new products, PDPs enhance cooperation between industry, NGOs and academia, by combining their strengths in the most effective manner to find the best and fastest solutions for the research challenges in the area of neglected and poverty related diseases.

**Excellence** is the guiding principle when choosing world-class partners, and PDPs have shown that they offer donors value for money.

As they cover the full innovation cycle and manage partners of excellence, PDPs also tackle the issue of fragmentation.

PDPs have significant experience in working internationally with public and private partners in the EU, in developing countries and in the rest of the world.

Global health R&D delivered by PDPs has much to contribute to the fight against poverty. Health research and development can strengthen scientific and technological capacities and, over the longer term, help diversify local economies, create jobs, stimulate economic growth and reduce poverty.

**How do PDPs contribute to the realization of the Council conclusions on the EU role in global health (May 2010)?**

In its Council Conclusions on the EU role in Global Health, it was stated that the EU and its Member States should promote effective and fair financing of research that benefits the health of all. It was also highlighted that the EU should ensure that innovations and interventions produce products and services that are accessible and affordable.

**PDPs already contribute in numerous ways to the EU’s call on global health,** as demonstrated in select examples below:

- **ad 18b of Council conclusion:** “to increase research capacities in public health and health systems in partner countries and strengthening cooperation between the EU and partner countries in this respect”.

PDPs have created various research platforms, and they strengthen health capacities in developing countries in their daily work. They collaborate with developing country partners to advance candidates in the R&D pipeline and invest significant resources in partner countries to support and expand the infrastructures in the communities in which they operate.

- **ad 18c:** “explore models that dissociate the cost of Research and Development and the prices of medicines in relation to the Global Strategy and Plan of Action on Public Health, innovation and intellectual property, including the opportunities for EU technology transfer to developing countries”

- **ad 18d:** “ensuring that EU public investments in health research secure
access to the knowledge and tools generated as a global public good and help generate socially essential medical products at affordable prices, to be used through rational use”:

• ad 18.e “strengthen and balance the complete health research process of innovation, implementation, access, monitoring and evaluation. International cooperation, common platforms of knowledge sharing and exchange of good practices are essential in this field.”

PDPs were created specifically to address the research gap present in the development of products for diseases that lack viable commercial markets. Therefore, PDPs aim to dissociate the costs of research from the price or products.

PDPs use different models of IP management and licensing arrangements in their partnerships with academic institutions and private companies. However, the common goal of all PDPs is to accelerate the development of new medical products, and to ensure that these will be made available in developing countries rapidly after licensure, at reasonable prices, and in sufficient quantities.

**Recommendations for the framework programme for research and innovation:**

The process of researching, developing and delivering life-saving health products for use in developing countries could be accelerated through specific changes in the EU Framework Programmes:

• Substantial **increase of funding** for research and development into neglected and poverty related diseases. Currently, only 4% of the overall EC contribution to health R&D under FP7, or €250 million, is dedicated to research into AIDS, TB and malaria. Even less is available for other neglected diseases.

• In order to achieve a greater impact, funding should support the **efficient management and linkage** of basic research, translational research, clinical trials, launch and implementation of a health product. The EC should ensure that funding is available to organizations with the ability to address the full innovation cycle, such as PDPs.

• Current funding mechanisms are not adapted to **fast-evolving product pipelines**, which are essential for product development, but focus on investigator-led research consortia, which only suit basic research needs. The portfolio approach constantly re prioritizes the best and most viable candidates for clinical testing in and with developing countries and succeeds when it has the flexibility to contract with partners based on needs that emerge during the product development process.

• Perseverance is essential for succeeding in scientific research. We therefore urge the EU to make available **long-term, flexible and non-project based funding** for global health product development, and to recognize the important role the public and private sectors can play in stimulating research for poverty-related and neglected diseases when market mechanisms fail.

• **Regulations, procedures, and processes of FP8 should be defined and worded as clearly as possible**, to ensure a coherent interpretation at all levels, from the EC, to the project participants, to the auditors. A lack of transparency and too much room for interpretation and discretion can lead to
uncertainty on all sides, and thus complicate participation in the Research Framework Programme as well as in the assessment of proposals.

Specific recommendations concerning EDCTP

PDPs strongly support the goal of EDCTP, and its role in facilitating clinical trials in Africa. However, the design of the EDCTP has made it difficult for some PDPs to effectively utilize this mechanism.

We therefore request the European Union to consider the following changes in the next EDCTP framework:

• Modification of the co-funding criteria, especially regarding partner requirements. Currently, the member state co-funding requirements and mechanisms favour national research institutions/universities in most countries, making many PDPs virtually ineligible partners.
• Extension of geographical area (not only Africa)
• Expansion to other neglected and tropical diseases
• Additional long-term strategic funding
• Explicit reference to Phase 1 and Phase 4 clinical activities