RESEARCH AND DEVELOPMENT for POVERTY-RELATED and NEGLECTED DISEASES

A PRIORITY in the NEXT EU RESEARCH FRAMEWORK PROGRAMME "HORIZON 2020"

The burden and lack of research for Poverty-Related and Neglected Diseases

During the last decade, higher investments in research addressing the health needs of poor and marginalized populations have resulted in scientific advances that have provided unprecedented opportunities to develop effective and affordable tools to tackle the world's most pressing global health problems. Nevertheless, there is still a huge need for new tools to diagnose, prevent, and treat poverty-related and neglected diseases (PRNDs). The discovery of, for example, a vaccine for HIV/AIDS or malaria, more effective diagnostics for tuberculosis, and better treatments for leishmaniasis or sleeping sickness would greatly improve health in the developing world.

Millions of people still die every year from poverty-related diseases, including HIV/AIDS, tuberculosis, malaria, measles, and pneumonia, but also from diarrheal and neglected tropical diseases such as sleeping sickness. These diseases are termed "poverty-related" or "neglected" because they persist in the poorest and most marginalized settings. As a result, research and development for appropriate preventive, diagnostic, and treatment tools are lacking. More than a third of all deaths in low income countries occur among children under the age of fifteen. **Every year, malaria, tuberculosis, and AIDS together kill nearly 4 million people**.

Why should the European Union engage?

Though people in developing countries bear 90 percent of the global disease burden, only 10 percent of worldwide expenditure on health is used to address these diseases.[1] From 1975 to 2000, there was little investment in PRND research and development, and of 1,393 medicines developed during that time, only 16 were for diseases that predominately affect populations in developing countries.[2]

Financial incentives are extremely limited for pharmaceutical companies seeking to invest in research for PRNDs, because the burden is found primarily in poorer countries. Companies can expect minimal profits for developing products for these markets. Also, daunting logistical obstacles often make it more challenging to conduct research in regions where disease is endemic. Indeed, **market forces alone will not lead to the development of sufficient, affordable, and appropriate new technologies and goods for these diseases**.

Public support and public financing are required when public goods are under-supplied by the market.

Horizon 2020 presents an opportunity for the European Union (EU) to step in as a leader in addressing this market failure and stimulate innovation.

The European Union accounts for approximately 31 percent of the world's gross domestic product and is the world's biggest donor of international aid. However, it is the United States which contributes nearly 70 percent of the global public funding for poverty-related and neglected diseases. The total sums disbursed by the EU are still negligible compared to the EU's real income and allocations that are being made in other areas of health research**.** In addition, "a fresh round of funding cuts from rich nations in the wake of the global financial crisis threatens the development of a new generation of lifesaving medicines and vaccines just as they are on the verge of reaching patients in the developing world. **Public funding from the world's richest nations for research and development (R&D) of new neglected disease products fell by US$125 million-down 6%-in 2010.**"

The *Council Conclusions on the EU role in Global Health* stated that the EU and its member states should promote effective and fair financing of research that benefits the health of all. It also highlighted that the EU should ensure that innovations and interventions produce products and services that are accessible and affordable*. **Hence, Horizon 2020 should tackle global challenges consistent with the European commitments mentioned above.**

*ad 18b of Council conclusions: "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."
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 "strengthening and balancing 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."

What can be done to fill the research gap?

The Communication on the EU Role in Global Health expresses a series of commitments to a strengthened and coherent effort of the EU in global health research, including through:

- Better EU coordination of global health research.
- Effective and fair financing of research that benefits the health of all people.
- Priority to actions to address global health challenges.
- Strengthening the complete health research process of innovation, implementation, access, monitoring, and evaluation.

Through mechanisms such as the European and Developing Countries Clinical Trials Partnership (EDCPT) and the African Network for Drugs and Diagnostics Innovation, the EU is providing essential support to strengthen the national research capacity of developing countries. These efforts address the needs of low- and middle-income countries and they also make an indispensable contribution to the development of global public goods in health, which are of high relevance to EU citizens.

Innovative financing mechanisms such as prize funds or state guarantees for investment in discovery and translation of discoveries into usable and accessible new tools should also be envisaged. At this time of budget austerity and pressure on public finance there is an urgent need for new approaches to generate more resources, make funding stable, and create incentives for further engagement from the private sector. Several new financing mechanisms have been launched recently, and others are being developed. For instance the Advanced Market Commitment (AMC) initiative has created incentives to develop pneumococcal vaccines and made them affordable for developing countries.

Suggestions concerning the EU Research Framework Programme HORIZON 2020

While we recognize and appreciate the important role that Framework Programmes 6 and 7 have played in funding European research for PRNDs, we believe much more can be done to ensure that EU investments lead to accessible and affordable technologies. The draft of the Horizon 2020 presented by the European Commission proposes an €80 billion investment in research and innovation, which represents an increase of 46 percent compared with the period from 2007 to 2013. We recommend that there should be a commensurate increase in EU resources dedicated to R&D for poverty related diseases.

We are grateful for the European Commission's willingness to address the whole research cycle and the crucial need to fill the translational research gap from bench to patient. Indeed, while research funding has increased over the last few years, the allocation of funds to R&D for products has decreased, having a negative impact on the development of drugs, vaccines, and prevention tools to fight PRNDs. Basic research remains key in the fight against global diseases, but the next Research Framework Programme **should also take into account the important long term benefits of product development for patients in low-income countries**, and match its funding accordingly. Product development through innovation can translate into concrete outcomes, with palpable results for society and poverty reduction.

The European Union should strengthen its efforts by supporting innovative models of product development, such as internationally operating product development partnerships (PDPs) which focusing on results and filling specific research gaps while covering the full innovation cycle from basic science.

Funding for these innovative partnerships would ideally be provided in addition to the current call mechanisms which are oriented towards classic European consortia building and project thinking.

New mechanisms with sustainable sources of funding should complement existing efforts such as the **European and Developing Countries Clinical Trials Partnership**, which funds successful clinical trials in Africa for HIV/AIDS, malaria, and tuberculosis.

In addition, we believe that industry, especially small and medium enterprises can play an important role within the research project. However, it will depend upon the nature of the work to be done, how the roles are divided, and which entity takes on a leading role. Health calls in this area should therefore be more flexible and admit partners of associated countries and third countries states as results-oriented research for neglected diseases requires the inclusion of global excellent expertise.

We therefore urge the European Union:

1. To strongly **support the research necessary to develop affordable and accessible products for poverty-related and neglected diseases** adapted to the needs of the targeted populations.

2. To prominently **feature global health research in Horizon 2020**.

3. To substantially **increase funding for R&D into PRNDs in Horizon 2020** through a specific budget line and ensure increased funding in comparison with the previous framework programmes for R&D to tackle poverty related diseases.

4. To **promote partnerships that allow various types of and flexible collaborations between private and public partners** with sustainable and flexible funding and that are in line with research and patient's needs;

5. To **ensure sufficient and predictable funding towards EDCTP II** and consider the following changes in its structure:
    - Expansion of geographical scope of clinical trials beyond Africa.
    - Inclusion of other neglected and tropical diseases.
    - Modification of the co-funding criteria (partner requirements).
    - Inclusion of Phase 1 and Phase 4 clinical trials.
    - A more flexible funding framework than current call mechanisms.

References
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2.- Chirac P, Torreele E. Global framework on essential health R&D. The Lancet. 2006;367(9522):1560–1561.

Position paper endorsed by:

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