



## **What does the “London Declaration on Neglected Tropical Diseases” reveal about research and development efforts into neglected and tropical diseases?**

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Earlier this week the Gates Foundation, USAID, DfID, the WHO, DNDi, the Governments of Mozambique, Tanzania, Brazil and a host of multinational biopharmaceutical manufacturers including GlaxoSmithKline, Merck, Eisai, Johnson & Johnson, Sanofi, Novartis, Bayer and Abbott, committed to eradicate and control a number of neglected and tropical diseases (NTDs).

This brief will examine the declaration, the pledges made and the methods to be used.

### **NTDs – background and context**

Neglected and tropical diseases are those diseases for which there is no significant market in developed nations and that disproportionately affect poor and marginalized populations, often in low and middle income countries.<sup>1</sup> In its 2010 report *Working to Overcome the Global Impact of Neglected Tropical Diseases* the World Health Organization (WHO) estimated that 1 billion people were impaired by neglected tropical diseases.

Since the late 1990s there has been a growing focus in the international community on the fact that relatively smaller amounts of biopharmaceutical R&D have gone into the development of new drugs and treatments for NTDs. One of the most frequently cited studies found that out of a total of 1,393 new chemical entities marketed in the period 1975-1999 only 16 were for NTDs.<sup>2</sup>

Findings like this prompted a number of new initiatives and international programs aimed at increasing drug development and available medicines. Scholars, researchers, international organizations, drug companies and policymakers have all tried to understand how to best incentivize new R&D into NTDs and a host of new R&D models have all been put forward including patent pools, research prizes, advanced purchase commitments, R&D tax credits and product development partnerships (PDPs).

### **A new R&D model?**

Since 2000 R&D in NTDs has increased substantially. Research by the Tufts Center for the Study of Drug Development shows that between 2000 and May 2009, 26 products for neglected diseases

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<sup>1</sup> The US Food Drugs and Cosmetics Act identifies the following diseases as tropical: tuberculosis, malaria, blinding trachoma, buruli Ulcer, cholera, dengue/dengue haemorrhagic fever, dracunculiasis (guinea-worm disease), fascioliasis, human African trypanosomiasis, leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis, schistosomiasis, soil transmitted helminthiasis, and yaws. The WHO uses a similar definition.

<sup>2</sup> P Trouillier, P Olliaro, E Torreele, J Orbinski, R Laing, N Ford, “Drug development for neglected diseases: a deficient market and a public-health policy failure”, *Lancet* 2002; 359: 2188–94



were marketed with a total of 26 indications.<sup>3</sup> Out of these almost half of approvals occurred in malaria with 11 new drugs being marketed. New partnerships between industry, governments and philanthropic groups have increased the funding for neglected diseases substantially. The Global Funding of Innovation for Neglected Diseases (GFINDER) survey finds that in 2009 \$3.2 billion was allocated for research relating to neglected diseases – a stark increase from a decade or two before.

While many of these new R&D initiatives are yet unproven, there is growing evidence that many PDPs are having some success in developing new drugs and treatments for NTDs and other diseases which disproportionately affect poor populations, including HIV/AIDS, malaria and tuberculosis. For example, the percentage of approved NTD products sponsored by public-private partnerships increased from 15% in the time period 1975-1999 to 46% in the decade 2000-2009.<sup>4</sup> Significantly, one of the largest PDPs is the Drugs for Neglected Diseases initiative (DNDi), a key partner and signatory of the London Declaration.

### The London Declaration

The stated purpose of the declaration is to mobilize and coordinate the development and dissemination of drugs and treatments for a number of NTDs. Specifically, the declaration seeks to eliminate 5 NTDs (Guinea worm, Leprosy, Lymphatic filariasis, Blinding trachoma and Sleeping sickness) and control 5 others (Schistosomiasis, River blindness, Soil-Transmitted Helminthes, Chagas and Visceral Leishmaniasis) by 2020. There are 3 main measures or methods that will be used to achieve these goals:

- **Greater quantities of drugs donated by international manufacturers** – examples include Eisai's donation of 2.2 billion DEC tablets for the treatment of Lymphatic Filariasis and MSD's commitment to continue unlimited supplies of ivermectin for the treatment of river blindness for an unlimited period.
- **Research partnerships between DNDi and manufacturers** – examples include partnerships with Eisai to develop ravuconazole for the treatment of Visceral Leishmaniasis; agreement with 11 companies to allow DNDi access to their compound libraries, including data and knowledge about the compounds; and clinical and preclinical partnerships with Abbott, Johnson & Johnson and Pfizer to repurpose flubendazole as a potential macrofilaricide used in the treatment of Lymphatic Filariasis and River Blindness.
- **Technical support and implementation** – examples include the World Bank continuing to play a crucial role in funding and overseeing local health systems' efforts against NTDs; also USAID will continue to support integrated NTD programs in low and middle income countries.

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<sup>3</sup> J Cohen, M Staroselsky Dibner, Andrew Wilson, "Development of and Access to Products for Neglected Diseases", *PLoS ONE*, May 2010, Volume 5, Issue 5, e10610

<sup>4</sup> Ibid.



## **Conclusion**

The London Declaration in many ways confirms that the partnership route between industry, public sector, nonprofits and philanthropic organizations is a key component of continued R&D as well as dissemination of existing treatments targeting NTDs. Collaborative initiatives with the specific and concerted objective of bringing new products to the market seem particularly promising when it comes to expanding R&D into NTDs and other diseases which disproportionately affect poor populations.