

## **Introduction : Background information to the organisation/activities undertaken to prepare a response/other relevant information**

**Drugs for Neglected Diseases initiative (DNDi)** is a collaborative, patients' needs-driven, not-for-profit drug Research and Development (R&D) organisation, which develops treatments for poverty-related and neglected diseases. Our vision is to improve the quality of life and the health of people suffering from neglected diseases by using an alternative model to develop drugs for these diseases and by ensuring equitable access to these new and field-relevant health tools. DNDi was established in 2003 by six public and private founding partners from disease endemic and non-endemic countries; the Special Programme for Research and Training in Tropical Diseases (TDR) serves as permanent observer.

DNDi is a **Product Development Partnership** focusing on malaria, visceral leishmaniasis (or kala azar), human African trypanosomiasis (known as HAT or sleeping sickness), Chagas disease, specific helminth infections and more recently, paediatric HIV was added to our portfolio in the last year. Our submission draws on our experience of nine years of operations during which DNDi has developed and delivered six new treatments for neglected patients including two fixed-dose antimalarials (ASAQ and ASMQ), and established strong regional networks that help strengthen research and treatment-implementation capacity in neglected disease-endemic countries.

Millions of people still die every year from **poverty-related diseases**, including HIV/AIDS, tuberculosis and malaria; but also from neglected tropical diseases such as sleeping sickness, Chagas diseases or leishmaniasis for which no adequate treatment exist. These diseases almost exclusively affect people in developing countries who are too poor to pay for any kind of treatment and do not constitute a market that can attract investment in drug R&D.

We share the belief with Irish Aid that health is a fundamental human right and that investing in **health** is essential for reducing poverty. However, despite the fact that people in developing countries bear 90 percent of the global disease burden, only 10 percent of worldwide expenditure on health research is used to address these diseases<sup>1</sup>. In order to make a real difference in the lives of those affected, it is necessary to bring the best science to the most neglected. By addressing the **need for new or improved products** to combat poverty-related diseases, for which prevention or treatment is lacking or inadequate, Irish Aid can help to achieve the Millennium Development Goals, notably to reduce poverty and child mortality, improve maternal health and to combat malaria and other neglected diseases.

## **Progress made: Has the Government been successful in implementing the commitments contained in the White Paper on Irish Aid?**

The focus of the Irish government on the specific health needs of the poorest countries has been exemplary, not only in its approach to fund research implemented by Irish researchers and institutions, but also through global partnerships, regional bodies and country-level researchers. Through Irish Aid's support to **Global Health Partnerships (GHP)**, real progress has been made to improve interventions to tackle communicable poverty-related and neglected diseases and in the advancement for R&D of much needed health innovation.

Ireland has been at the forefront of recognising healthcare as a human right. Through Irish Aid's contribution to healthcare programmes, a direct link can be made to the significant decrease in the number of deaths related to AIDS and malaria in the world's poorest countries. We strongly believe that with these advancements, an opportunity exists for the Irish Government to expand on these

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<sup>1</sup> Lancet (Chirac P. and Torreele E.): "Global framework on essential health R&D." Lancet 367, no. 9522, 2006, page 1560–1561



programmes, such as furthering its work on **paediatric HIV projects**, as well as **increasing its scope of partners** to facilitate the development and delivery of new products for poverty-related and neglected diseases.

We applaud the approach the Government has taken with regards to GHPs, in particular its multi-annual investments in **Product Development Partnerships (PDPs)**. We believe this not only yields a high level of return from industrial partners and academia, but also facilitates Irish Aid to oversee accountability and transparency within their projects. In addition, PDPs strengthen the capacity of people and institutions involved in health research in developing countries, allowing countries to take more initiative and control of the product development and invest in a healthier future

We would therefore encourage the Irish Government to maintain their commitment to GHPs and to further invest in the PDP model, where opportunities arise.

**Changing Context: What are the implications of the changes in the global and domestic context for the Government's aid programmes in the future and how will these affect current priorities?**

We acknowledge the leading role Ireland has been playing in bringing aid effectiveness to the international agenda. The economic downturn and the global financial crisis have placed an ever higher importance on how aid is delivered as well as a greater focus on **aid efficiency and effectiveness**.

Through its foresight of investing in **PDPs**, Ireland recognised the **value** of using these partnerships to accelerate the development of innovation for the most neglected patients and the scale-up of disease control/elimination, which leads to a more productive life of many poor who then can contribute to the development of their economies. Although it is difficult to compare costs of development between different business models, preliminary data indicates that the PDP model is far more efficient than the traditional pharmaceutical business model. This may be explained by the more open, collaborative modus operandi of PDPs and the fact that they are addressing unmet medical needs and abandoned research gaps due to market failure.

DNDi's achievements during the last decade illustrates that PDPs can ensure high value for the investment in research/innovation of governments and funders as only the best and most suitable potential products are developed. Overall, as the PDP's R&D model is focused on developing products for the world's poorest population, **funders minimize the risk of supporting the delivery of inappropriate and expensive solutions that are not sustainable**.

We strongly recommend that the Irish government continues and develops further its support to the efficient new proven model which is the product development partnerships (PDPs).

**Key Issues & Ways of Working: How should the government respond to the key issues of hunger, fragility, climate change, basic needs, governance & human rights, and gender equality? Are there other issues?**

**Adapted treatments for infants and young children affected by HIV**

We commend the investment that Irish Aid has made in HIV and AIDS and acknowledge the tremendous advances which have been made in this area; notably moving towards the MDG target to achieve a two-thirds reduction in mortality rates among children under 5 by 2015 and to halt and begin to reverse the HIV/AIDS epidemic and other infectious diseases. Nonetheless, globally **some 3.4 million children are living with HIV**. Without treatment, half of all infected children are not expected to reach their second birthday. 390,000 children are newly infected each year, and 90% of these occur in Africa.

Current World Health Organization (WHO) guidelines recommend early diagnosis and immediate treatment of HIV-positive infants and children under two years. The combination of available drugs offers the most effective first-line therapy and is recommended by the WHO. However, these recommendations are not being widely implemented. Although some ARVs exist for young children, current liquid formulations have very serious limitations: extreme difficulty to administer with a high risk of dosing errors; poorly-tolerated taste and significant toxicity; drug-drug interactions that make it difficult to manage TB/HIV co-infected children; severe logistical constraints linked to short shelf-life, instability in hot climates, large volumes; and high price.

There is little incentive for the private industry to invest in expensive trials, to develop adapted treatments for this most vulnerable group. In 2011, DNDi's decided to address this public health issue. Working in close collaboration with a wide range of public and private partners DNDi plans to deliver an improved PI-based first-line fixed-dose combination that is specifically adapted for infants and young children in resource-limited settings and optimised for maximum efficacy and adherence.

Therefore, we would recommend to the Irish Government to consider the plight of young children living with HIV in their future investment programmes for the development of child and field-adapted treatments for very young children.

### **Contributing to the goals of control/elimination set by WHO (WHO 2020 NTD Roadmap)**

In January 2012, at the 'Uniting to Combat Neglected Tropical Diseases' Event organised by the Gates Foundation, the WHO and other key stakeholders and held in London, a host of other public and private partners pledged to be part of an innovative and coordinated approach to combatting 10 Neglected Tropical Diseases (NTDs) by 2020. This represents the largest coordinated effort to combat NTDs to date, with partners committing to share expertise and compounds to accelerate research and development of new drugs, and strengthen drug distribution and implementation programmes.

Since this event, pharmaceutical companies announced their commitments to provide DNDi with access to their proprietary compound libraries (in-kind contributions) to DNDi. This invaluable input for DNDi's R&D activities will strengthen DNDi's ability to translate innovation into effective, safe, adapted and affordable medicines for sleeping sickness, Chagas disease, visceral leishmaniasis and helminth infections.

By supporting DNDi's R&D strategy together with a core group of funders, Irish Aid's investment could rapidly change the history of HAT, leishmaniasis, Chagas disease, and specific helminth infections targeted for control/elimination by WHO (WHO 2020 NTD Roadmap), as well as pediatric HIV and malaria.

The deployment of an increased number of improved and the first truly innovative (oral, cost effective) treatments for poverty-related diseases will result in healthier and more productive populations, together with cost savings for health systems, which in turn will contribute to public health and poverty reduction in endemic impoverished regions across the world.

Overall, investing in PDPs will lead to a more efficient use of resources in the long-run. PDPs are striving to develop new products that will be effective and affordable. In some cases, these new products will be significant improvements that can replace older existing technologies. In others, these new products will become new and powerful weapons to be used alongside existing tools to fight these neglected diseases. Not only will costs be saved with the deployment of cheaper diagnostics, drugs and vaccines, but also

significant savings will accrue as populations grow healthier, becoming more productive and requiring less medical care.

Over the course of the next decade, in order to address questions of health and poverty with a maximum effect, we encourage Irish Aid to continue and to raise its support to PDPs.

**Other comments:**

Ireland's power of influence for a country of its size is well noted and respected on an international scale. Using the power of Ireland's leadership, and notably with Ireland holding the EU Presidency in 2013, we would encourage Ireland to yield support for the EU to take a stronger leadership in R&D for global health through Horizon 2020 and EDCTP.

