After the Ebola crisis, the need for greater mobilization

In the wake of the Ebola crisis, global opinion has shifted and voices have converged on the need for greater mobilization by governments and global health stakeholders to secure the political and financial commitments required to address public health priorities in a sustainable way, with public leadership at the helm. A recurring theme throughout all these global health concerns is the dearth of innovation for new health tools – for example diagnostics, drugs, and vaccines – to respond to clearly-identified and well-documented patient needs.

The current R&D landscape has several distinctive shortcomings: R&D priorities do not adequately address patients’ needs and do not sufficiently emanate from low- and middle-income countries; medical innovation is not linked to equitable access; and market-based incentives aligned with the intellectual property system generally fail to address the health needs of poor people.

WHO/CEWG process toward new incentive mechanisms for R&D

It is with a view to addressing these shortcomings that the WHO-mandated Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) process selected several ‘demonstration projects’ that aim to employ collaborative approaches, including open knowledge approaches to R&D; promote the de-linkage of the cost of R&D...
from product price; propose and foster financing mechanisms including innovative, sustainable, and pooled funding; and provide evidence in support of long-term, sustainable solutions to financing and coordination of R&D for neglected diseases.

One of the demonstration projects, the DNDi ‘Leishmaniasis Global R&D and Access Initiative’ aims to fill certain critical R&D gaps and provide health tools in support of the WHO control and elimination goals for visceral leishmaniasis (VL). The initiative’s objective is to demonstrate that health R&D can be incentivized and optimized through innovative mechanisms, such as the NTD Drug Discovery Booster (see p. 17). Ultimately, these demonstration projects will examine the possibility of financing R&D, notably through pooled funding, increasing knowledge and decreasing the risk of failure, raising the resources needed while capitalizing on existing resources, and developing affordable health tools while applying the principle of de-linkage.

The follow up to the CEWG process received strong support and there was a consensus on the establishment of a pooled fund for R&D programmes, with concrete funding commitments. DNDi published a paper in 2014 entitled ‘Considerations for the New International Fund for R&D’, which examined the potential parameters of such an R&D fund to meet the public health needs of developing countries.

While there are encouraging signs of improvement, there is still a need to ensure that a framework is put into place to enable an adequate global response to the current crises in innovation and access, notably with the following key principles:

- Patient needs-driven priority setting;
- De-linkage of the cost of R&D from the price of products delivered;
- Integration of global health R&D monitoring, coordination, and financing;
- Creation of a more enabling regulatory environment to expedite approval of essential medicines; and
- Setting up of sustainable financing mechanisms, including through a global health pooled fund for long-term innovation.

A push to reform the US Priority Review Voucher programme

DNDi has long advocated for new incentive mechanisms to stimulate R&D for neglected patients. One such mechanism, the US Food and Drug Administration (FDA) Priority Review Voucher (PRV), holds promise, but requires reform in order to represent a true ‘win-win’ for both companies and neglected patients. Created in 2007, the PRV programme awards a voucher to companies that receive FDA approval for a drug against one of a list of neglected diseases, unfortunately not including Chagas disease. PRVs can be used to fast track a drug application of the company’s choice or can be sold to other companies.

In July 2014, DNDi North America, MSF USA, and the TB Alliance wrote a joint letter to the US Congress expressing concern about the design of the PRV and recommending a number of ways to improve it. Among them: PRVs must be granted only in return for new investments in R&D, patient access must be guaranteed, and PRVs granted must meet real public health needs. MSF and DNDi also spelt out their concerns in a joint blog in PLOS Speaking of Medicine,1 in which they advocated for changes to the design of the PRV to ensure it both stimulates new R&D and guarantees affordable access to the medicines for which it is granted.

1 http://blogs.plos.org/speakingofmedicine/2015/01/20/fda-voucher-leishmaniasis-treatment-can-patients-companies-win/
Launch of the Paediatric HIV Treatment Initiative (PHTI) in 2014

To scale-up treatment for children with HIV, DNDi, UNITAID, the Medicines Patent Pool (MPP), and the Clinton Health Access Initiative launched the Paediatric HIV Treatment Initiative (PHTI). The PHTI focuses on overcoming the barriers to developing and delivering specific paediatric formulations and combinations appropriate for children, by working to accelerate development of priority paediatric ARVs within the next three years. The initiative does this through working with drug manufacturers to develop and supply ARVs, and aims to increase access by facilitating regulatory approval, adoption, and rapid uptake in hard-hit countries as soon as drugs are available. A launch event took place on the eve of the 67th World Health Assembly, in the presence of ministers of health from over fifteen countries, including Brazil, Chile, Mauritius, and South Africa; industry and global public health leaders; as well as senior representatives from the HIV/AIDS community.

ICOPA XIII, Mexico City: test and treat Chagas disease patients

In August 2014, over 1,300 participants from 81 countries gathered for the first time in a Latin American country for the 13th International Congress of Parasitology (ICOPA). DNDi participated in nine symposia and satellite meetings, and Dr Bernard Pécoul, DNDi Executive Director, delivered a plenary presentation on ‘R&D for Neglected Patients: Evolution over a Decade and Future Perspectives on Access & Innovation’ in which he addressed the significant changes in the neglected disease R&D approach in recent years, examined progress made in Chagas disease, and surveyed the remaining gaps and challenges for innovation and access.

During the congress, the Global Chagas Disease Coalition hosted an event for key Chagas disease stakeholders, entitled ‘Let’s Raise Our Voice’. The gathering was aimed at mobilizing the Chagas community to urgently address the need to test and treat Chagas disease patients and rapidly improve the current treatment rate, which is only one percent. The event gathered 200 participants from governments, civil society, the healthcare sector, research groups, and patients to discuss simple actions, such as following WHO treatment recommendations for both acute and chronic phases of Chagas disease, and raising awareness of the disease within primary healthcare to boost patient access to diagnosis and treatment.

‘Of the 3.3 million children with HIV in the world, there is a great burden in South Africa. Current treatment options are insufficient and there is little to no incentive for drug development. The most commonly used regimens used today for children with HIV have toxicity and formulation concerns. New adapted treatments are an emergency, and a dream that must be made reality.’
H.E. Aaron Motsoaledi, South African Minister of Health


(1) http://blogs.plos.org/speakingofmedicine/2015/01/20/fda-voucher-leishmaniasis-treatment-can-patients-companies-win/
Nearly EUR 65 million additional funding secured in 2014

The year 2014 marked a cornerstone for DNDi’s regional offices in their involvement in raising new funds.

DNDi North America received its first major public grant of USD 10 million provided by USAID. With this first-ever grant for R&D for neglected tropical diseases from USAID, DNDi will target the development of new oral drugs for onchocerciasis and lymphatic filariasis.

DNDi Latin America signed an unprecedented agreement with the public organization Ruta-N for the development of innovative health tools targeting leishmaniasis, with a shared investment of USD 647,500 over a period of two years in Colombia. In Brazil, a partnership with the Brazilian Development Bank (BNDES) was agreed and a special ‘Award for Innovation in Social Technology’ of EUR 67,000 was granted to DNDi Latin America by the public Science and Technology Innovation Agency (FINEP). Private donors also continued to provide large donations for activities in the region.

DNDi Japan continued to strengthen its involvement in fundraising activities in the country with the provision of a second grant of EUR 2.8 from the Global Health Innovative Technology Fund (GHIT) to develop new oral treatments for Chagas disease in partnership with Eisai.

Another critical advancement was the provision of a new form of support from the Bill and Melinda Gates Foundation. Until this year, the Foundation financially supported earmarked projects, but with USD 60 million in ‘portfolio funding’, investments can be now used across three disease areas. Greater R&D flexibility and leveraging vital funding from other engaged donors are notable benefits. The Foundation also allocated a supplemental investment of USD 4.3 for fexinidazole for sleeping sickness and awarded DNDi an ‘Innovative Fund Award’ of USD 1 million. In addition, a number of donors reiterated their commitments to DNDi such as DFID (UK) with a supplemental grant of GBP 3 million. Private foundations such as ARPE and Starr International also continued to support DNDi.

DNDi has raised EUR 353 million since its inception in 2003, with 51% from public institutional donors.

Key contributions received in 2014

Bill & Melinda Gates Foundation / USA
USD 60 million (2015 – 2019)
Building upon the long-term partnership between DNDi and the Bill and Melinda Gates Foundation that began with a first grant in 2007, the Foundation granted USD 60 million through a new form of support called ‘portfolio funding’ that allows DNDi to use the grant across three disease areas (sleeping sickness, visceral leishmaniasis, and filarial diseases).

USD 1 million (Innovative Fund Award, 2014 – 2015)
The Foundation awarded DNDi a special grant of USD 1 million over a period of two years. This ‘Innovative Fund’ was awarded to six product development partnerships to commend their efforts to date and to stimulate exploration and innovation to identify, develop, and deliver new health tools.

USD 4.3 million for HAT
The Foundation provided a supplemental grant of USD 4.3 million to support the fexinidazole project for sleeping sickness, bringing the total of this grant to USD 19.4 million.

United States Agency for International Development (USAID) / USA
USD 10 million (2014 – 2019)
USAID awarded USD 10 million to DNDi to develop new treatments for onchocerciasis and lymphatic filariasis over five years. This is the first-ever USAID grant for R&D for neglected tropical diseases. The Bill and Melinda Gates Foundation is providing the mandatory matching of this project, included in the portfolio funding listed above.

Department for International Development (DFID) / UK
GBP 3 million (2014)
DFID provided DNDi with supplemental funding of GBP 3 million for the year 2014 to be used as core funding (excluding paediatric HIV activities). DFID’s total contribution to DNDi has reached GBP 64.4 million since 2006.

Global Health Innovative Technology Fund (GHIT) / JAPAN
EUR 2.8 million (2014 – 2015)
The Japan-driven Global Health Innovative Technology Fund (GHIT), which celebrated its one-year anniversary in 2014, awarded a second grant of EUR 2.8 million to DNDi to support a Phase II, proof-of-concept study of the E1224-fexinidazole combination over a two-year period, in collaboration with the Japanese pharmaceutical company Eisai.

Ruta-N / City of Medellín / COLOMBIA
USD 317,500 (2015 – 2016)
Ruta-N and DNDi/Latin America signed an unprecedented agreement for the development of health innovation with a shared investment of USD 647,500 for a period of two years in Latin America. The collaboration begins with a programme dedicated to leishmaniasis. Ruta-N is based in Medellin, Department of Antioquia, Colombia, and focuses on knowledge as a primary source for R&D.

Science and Technology Innovation Agency (FINEP) / BRAZIL
Brazilian Real 67,000 (2015)
DNDi/Latin America received the FINEP Award for Innovation in Social Technology in recognition of its innovative R&D model that delivered a new antimarial drug (ASMO FDC) developed in Brazil.

IN MEMORIAM

On 13 June 2014, Dr Richard Rockefeller – a family physician who was instrumental to the creation of DNDi in 2003, as part of his long-standing commitment to Médecins Sans Frontières (MSF) – died tragically in a plane crash. DNDi deeply admired Richard and his dedication to the alleviation of human suffering, including his strong support for urgently needed R&D for neglected patients. He was a wonderful friend and advocate and is terribly missed. In December 2014, the Rockefeller Brothers Fund provided DNDi a one-time, one-year, general operating grant of USD 25,000 via the Staff Grantmaking Program to honour Dr Richard Rockefeller.
2014 KEY FINANCIAL PERFORMANCE INDICATORS

Maintaining balanced and diversified funding is essential to DNDi's vision and independence

To develop its activities and meet its objectives, DNDi seeks diversified sources of funding from public and private sources, which include financial contributions from governments, public institutions, private individuals, foundations, founding partners, and innovative funding mechanisms. The diversification of donors increased in 2014 with four new donors. DNDi welcomed: USAID, Ruta' N, FINEP, and the Rockefeller Brother Foundation. Among these new donors, two are from endemic countries.

Concerted efforts were made to ensure that no one donor contributes more than approximately 25% toward DNDi’s business plan and, that at maturity half of DNDi’s budget is covered by public funds and half by private funds.

In 2013, public funding (projected to 2018) was at 57%, with 43% private support. In 2014 with secured funds until 2019, the split is much more balanced with public funding at 51% and 49% for private support. This is mainly due to the fact that one of the major private donors (Bill & Melinda Gates Foundation) renewed its long-term commitment until 2019 with broader portfolio support, which amounts to EUR 49.2 M (14% of total income committed).

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A successful shift toward unrestricted funding

Over the last five years, DNDi managed to maintain a balance between restricted and unrestricted grants. While the ratio is relatively balanced, this requires substantial effort. Unrestricted funding has been part of DNDi’s success to date as it allows the organization to respond quickly to research opportunities and also terminate projects that do not meet targeted goals set forth in the business plan. In 2014 DNDi received significant portfolio funding from the Bill & Melinda Gates Foundation which allows a certain degree of risk mitigation within restricted grants because this is supporting three diseases and various projects within each diseases. Portfolio grants were estimated at 18% in 2011, 22% in 2012, 29% in 2013 and 33% of the 2014 total income.

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