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I. INTRODUCTION

Over the past two decades there has been growing recognition that the current global system for biomedical innovation fails to deliver adapted and affordable health technologies. The lack of *innovation* of and *access* to health tools that address public health needs is well-documented. This crisis was initially understood to affect 'diseases of poverty' in developing countries but today, despite important progress, the dominant model for financing and incentivizing R&D, which relies primarily on the intellectual property system, is increasingly problematic for all countries – regardless of disease area or income classification.

The Drugs for Neglected Diseases *initiative* (DNDi), an independent, international research and development (R&D) organization, was created in 2003 as an experiment in 'innovation for access' by Doctors Without Borders/Médecins Sans Frontières (MSF) and five public research institutions from India, Brazil, Kenya, Malaysia, France, and the World Health Organization Special Programme for Research and Training in Tropical Disease Research (WHO/TDR), in response to the frustration of being faced with medicines that were ineffective, highly toxic, unavailable, or had never been developed.

This contribution provides concrete evidence of DNDi's experience implementing needs-driven, open, collaborative R&D, which has resulted in the development of seven adapted, affordable, and non-patented treatments and the most robust pipeline ever for some of the world's most neglected diseases. DNDi's model is a practical illustration of how R&D can be conducted in the public interest, if a de-linked approach is implemented, with R&D costs at a fraction of the traditional pharmaceutical business model.

It draws lessons that may be applicable to other disease areas and product types, to help inform the Canadian government's approach to biomedical innovation, particularly as relates to innovations of public health importance.

Finally, it recommends a series of progressive policy steps Canada can support to re-orient the global biomedical R&D system so that it (1) prioritizes patient and public health needs; (2) is sustainably financed; and (3) incorporates global norms that will enable the discovery, development, and delivery of and equitable access to innovations of public health importance.

II. DNDi: AN EXPERIMENT IN 'INNOVATION FOR ACCESS'

The Drugs for Neglected Diseases *initiative* (DNDi) is an international not-for-profit research and development (R&D) organization created in 2003 by Doctors Without Borders/Médecins Sans Frontières (MSF) and five public research institutions from India, Brazil, Kenya, Malaysia, France, and WHO/TDR.[1] DNDi was a response to the frustration of being faced with medicines that were ineffective, highly toxic, unavailable, or had never been developed.

In 2001, MSF and partners[2] found that of the 1,393 new drugs brought to market globally between 1975-1999, only 1.1% were for tropical diseases that represented 12% of the global disease burden.[3] This situation was a result of both market failure, as investments in R&D were guided by market considerations leaving public health needs unaddressed, and public policy failure, as governments had not corrected this situation.

Despite important progress, today the 'fatal imbalance' persists. A 2012 study by DNDi and MSF showed that of the 756 new drugs approved between 2000-2011, 3.8% were for neglected diseases, despite a corollary global disease burden of 10.5%.[4] The 2014 Ebola epidemic[5] and the global challenge of antimicrobial resistance[6] are stark reminders of the need to steer R&D to respond to global public health imperatives. Global attention has also focused on the high prices of hepatitis C (HCV) and cancer treatments, illustrating that the accessibility and affordability of new health technologies, even when they are developed, is a major concern, including in high-income countries such as Canada.[7]

DNDi is an experiment in innovation both in **what** it did – develop urgently needed treatments for neglected populations – and **how** it did it – testing an alternative R&D model based on patient needs, not profit maximization. DNDi's 13-year experience can highlight lessons for other diseases and product types, which may inform the Canadian government's reviews of innovation and science policy.

III. DNDi's MODEL

DNDi's funding model[8] delinks the costs of investments in R&D from the price of the end product, as it does not require the organization to recoup R&D investments or finance its future research through the sales of products or revenues generated by intellectual property (IP). Public and private contributions pay for the cost of R&D upfront, allowing DNDi to independently identify needs, gaps, and priorities based on patient needs; promote sharing of research knowledge and data; and price products at the 'lowest sustainable price.' As such, the DNDi model is a practical illustration of how R&D can be conducted in the public interest, if this de-linked approach is implemented.

To date, with total expenditures of CAD 375 million, DNDi has delivered seven new treatments for five diseases (malaria, sleeping sickness, visceral leishmaniasis, Chagas disease, and pediatric HIV) that are **affordable**, **adapted,** and **non-patented**. In addition, DNDi has created a robust pipeline with 40 R&D projects covering six disease areas, including 15 potential new chemical entities (NCEs).[9] An example of the six new therapies is the more than 500 million treatments of the anti-malarial artesunate-amodiaquine (ASAQ) that have been distributed. Developed in partnership with Sanofi and others in 2007, ASAQ is available for less than CAD 1.30 per treatment course for adults (just over 50 cents for children), was prequalified by WHO in 2008, and is registered in 35 African countries and elsewhere.[10] The technology was transferred to a manufacturer in Tanzania for the African market.[11]

Key pillars of DNDi's model include:[12]

1) <u>Patients' needs at the center of the R&D process</u>

Therapeutic impact is the most important driving force behind DNDi's work, and is exemplified in the following ways:

- *Governance*: DNDi's founding partners, particularly from endemic countries, MSF, and two patient representatives on the Board ensure the organization remains rooted in the reality of patients' needs.
- *Target product profiles (TPPs):* TPPs describe the ideal specifications needed for a treatment to be developed by DNDi, considering the needs of the patients and the characteristics of the related health system, and drive all R&D activities. Because they are tailored to patient needs from the start, products developed by DNDi are, by design, adapted to 'field conditions' and aim for maximum affordability.
- *Commitment to research capacity-strengthening:* Rather than 'parachuting' in expertise, DNDi helps increase sustainable endemic-country ownership in health R&D, for example by establishing three regional clinical research 'platforms'.[13]
- *Continuous assessment of needs and landscape:* In 2011,[14] DNDi added **filarial infections** and **pediatric HIV** to its portfolio. In 2015,[15] DNDi took on work on **mycetoma,**[16] for which DNDi plans to test a promising treatment in Sudan; **HCV,** for which DNDi aims to develop an affordable (< CAD 400 per treatment course), pan-genotypic combination of existing direct-acting antivirals to enable dramatic treatment scale-up in low- and middle-income countries;[17] and **antimicrobial resistance,** for which DNDi and WHO are collaborating to incubate a new initiative, the Global Antibiotic Research and Development Partnership (GARDP), to develop antibiotic treatments for neglected populations and priority public health needs, promote antibiotic stewardship, and ensure equitable and affordable access.[18]

2) Scientific access to data and knowledge and patient access to medicines

IP rights can create roadblocks throughout the innovation cycle, limiting the possibility of collaboration, follow-on R&D, production, or equitable access to end-result products. To address these barriers, DNDi's IP policy[19] is based on two guiding principles that inform all contract negotiations: the need to ensure that drugs are affordable and accessible in an equitable manner to patients who need them; and the desire to develop drugs as global public goods.[20]

DNDi negotiates research and licensing agreements to gain access to patented compound libraries and data, and secure the necessary freedom to operate. Such information jumpstarts the expensive and time-consuming discovery phase, avoids duplication, and reduces overall R&D costs.

Using its negotiating experience with pharmaceutical companies and others, DNDi has defined 'gold standard' licensing terms to ensure equitable and affordable access to treatments, including whenever possible terms such as perpetual royalty-free, non-exclusive, sub-licensable licenses to DNDi in the contractually defined target disease(s); worldwide research and manufacturing rights; commitment to make the final product available at cost, plus a minimal margin, in all endemic countries, regardless of income level; and non-exclusivity, enabling technology transfer and local production to multiply sources of production and decrease price of product.

Licenses can be more difficult to negotiate in cases of pre-existing licenses, prospects of returns on investment from sales in certain markets, and/or significant investments of a private partner in early stages of development. Where IP barriers exist (e.g. HCV), DNDi uses available IP flexibilities for research purposes (e.g. experimental use and/or research exemptions) and supports the use of TRIPS[21] flexibilities to enable production/importation of products.

In an effort to encourage open access to research knowledge and follow-on R&D, data emanating from DNDi projects including clinical trials are made available primarily in open access journals and publicly accessible databases.

Open models of innovation[22] may speed up research and reduce overall R&D costs, although they should be carefully monitored and evaluated.[23] There are encouraging signs from industry in the field of AMR for a more open, collaborative approach.[24] In addition, in 2015, DNDi launched the Neglected Tropical Diseases (NTD) Drug Discovery Booster, which aims to speed up the process and cut the cost of discovering new treatments for leishmaniasis and Chagas disease. By using a simultaneous search process across four pharmaceutical companies' compound libraries, DNDi accesses millions of unique compounds to screen, significantly condensing the time it will take to find promising treatment leads. Any progress or successful new treatment resulting from the Booster will be attributed to the collective effort of all partners, which have agreed that no IP barriers for NTD indications will be imposed.[25]

3) Decreasing R&D costs through partnerships and collaboration

DNDi does not have its own laboratories or manufacturing facilities, and consequently cannot function without the engagement of partners. Acting as a 'conductor of a virtual orchestra,' DNDi leverages partners' assets, capacities, and expertise to implement projects at all stages of the R&D process, integrating capabilities from academia; public research institutions; NGOs and other PDPs; governments; and pharmaceutical and biotechnology companies (DNDi has partnered with more than 20 companies on early stage research, clinical development, and implementation).

Not all R&D efforts should function virtually, but the important lessons are that openness and collaboration are critical to reducing the time it takes to deliver new technologies and decreasing the overall cost of R&D. In 2014, DNDi published case studies to document the actual expenditures associated with several DNDi products.[26] DNDi

estimates its direct costs to range from CAD 8.5-29 million for an improved treatment, and CAD 43-58 million for a NCE. Applying the usual attrition rate in the field of infectious diseases, the cost to develop an improved treatment would be CAD 14-58 million and CAD 144-216 million for an NCE. Deeper analysis of R&D costs should be conducted, particularly to fairly quantify in-kind contributions of partners. Although it is difficult to compare R&D costs between different business models, DNDi's experience indicates that innovative models can both deliver rapidly for patients and potentially be more efficient than the traditional pharmaceutical business model.

4) Strengthening and harmonizing regulatory mechanisms

A DNDi-commissioned report on the regulatory environment in Africa showed that new regulatory pathways are needed to expedite research, registration, and patient access to new health tools.[27] DNDi has jointly involved regulators from endemic countries – who know patients' needs best and are responsible for assessing the benefit/risks for their own populations – and regulators from developed countries – who have broader experience approving new drugs.[28] For example, the dossier for ASAQ, which was first approved in endemic countries, was reviewed for a virtual approval by participants from African countries, with support from WHO's Prequalification Programme and European Medicines Agency experts.

Ultimately, it is necessary to strengthen capacities of poorly-resourced regulatory bodies in endemic countries and stimulate support for regional initiatives and harmonization aimed at maximizing patient access to quality medicines.

IV. LESSONS LEARNED

Over the past decade, there have been positive trends in the global health R&D field, including new resources from public and private donors; new incentives and financing mechanisms; increased interest in open innovation models; and new R&D initiatives from governments, academic consortia, and the pharmaceutical industry as well as PDPs.[29]

But the patchwork of 'solutions' that have emerged to date is still *ad hoc* and highly fragmented. Scientific progress has been largely incremental and the situation for neglected patients has not fundamentally changed.[30] Private sector engagement is still being driven primarily by public relations or corporate social responsibility concerns. Funding is insufficient and unsustainable, with unhealthy dependence on a handful of donors, often driven by national interests or a charity-based approach. Many new incentive mechanisms, such as the United States Food and Drug Administration's Priority Review Voucher program, though promising, need to be amended to prevent abuse, drive genuine innovation, and ensure access and affordability. There is no global body in place for identifying needs, gaps, and priorities for all global public health needs, little effective monitoring and coordination of R&D efforts to maximize scientific collaboration and reduce wasteful duplication. And there are no globally agreed norms to encourage sharing of data and knowledge and ensure the affordability of end products.

It is time to transform individual successes into a more systematic and sustainable approach for all diseases of public health importance. DNDi's collaborative model has shown at a small scale that alternative approaches to R&D that address pressing public health needs are possible. However, individual initiatives cannot be the only solution to the problem. To fully address the scale of public health needs, public leadership is needed to redefine the 'rules of the game.' Canada can play a significant role here.

V. RECOMMENDATIONS

Canada has a critical role to play both nationally and in international and multilateral fora – including the G7, G20, World Health Assembly, and various UN policy processes – in supporting progressive innovation and access policies. Canada can also adopt into its own innovation policies, strategies, and science and innovation financing mechanisms key public health 'safeguards' that will ensure that biomedical innovation responds to patient and public health needs, and that the fruits of innovation will be more broadly and equitably shared.

Specifically, DNDi recommends that the government of Canada support both internationally and nationally the following pillars in its innovation policies:

(1) An agreed method to identify R&D needs, gaps, and priorities to ensure public health and patient needs-driven directionality, and coordination between R&D actors to reduce duplication

R&D that addresses priority public health needs must be the overarching objective. Globally, WHO may be best placed to establish an independent body to identify R&D needs and gaps, establish clear priorities, and coordinate efforts to enhance collaboration and reduce duplication will be necessary. Canada should consider both providing financial support to the WHO Global Health R&D Observatory and reinforcing the WHO's critical role in facilitating global public health R&D priority-setting, while simultaneously establishing a transparent and independent process of setting R&D priorities at the national level.

(2) Adequate, sustainable public financing based on the principle of delinkage

R&D requires adequate, sustainable funding from governments, which should be available at the national, regional, and international levels, as well as mechanisms to incentivize innovation and secure access, based on the principle of delinkage. Funding and incentive mechanisms must be sustainable, and include both upfront 'push' funding of R&D projects and appropriately designed incentives to 'pull' investment in R&D. Such financing and incentive mechanisms should promote open, collaborative approaches that aim from the start to deliver affordable products efficiently. Canada should support and implement appropriate funding and incentive mechanisms that meet these goals.

(3) Safeguards attached to any public financing of R&D that ensure innovation <u>and</u> access, accelerating the R&D process and decreasing R&D costs

Public funding from the Canadian government for global public health R&D should be tied to the adoption of safeguards to ensure a public return on public investment. These should include:

- **Delinkage,** to ensure public health focus and access, which applies across the innovation cycle and can be implemented in a number of ways (e.g. grants, prizes);
- **Accessibility**, meaning requirements that universal and equitable availability and affordability of health technologies is guaranteed for individuals and the health systems that serve them;
- **Openness, transparency, and access to knowledge**, meaning encouraging the greatest possible sharing of research knowledge to ensure efficiency and collaboration, and transparency of R&D costs;
- **Pro-public health IP management and equitable licensing** – concerning the availability, scope, and use of research tools and affordability of end products – to enable research and the fruits of innovation to be treated as public goods;
- **Scientific and technological cooperation** to harness expertise in both developed and developing countries, encourage collaboration between research centers, and facilitate technology transfer;
- **Essential regulatory standards** to expedite access for patients, while ensuring that new treatments are safe, effective and of quality, reduce R&D costs linked to regulatory approvals, and strengthen regulatory capacity.

These norms should build on **research ethics** principles[31] as well as the principles formulated in the WHO Consultative Expert Working Group (CEWG) on R&D Financing and Coordination, reiterated in multiple political declarations, and summarized in WHA 66.22,[32] namely '**affordability**, **effectiveness**, **efficiency** and **equity**, including delinking the costs of R&D from the price of end products.'

VI. IMPLEMENTATION

The Canadian government has the unprecedented opportunity to implement nationally key policies that will ensure a greater public return on public investments in R&D in Canada and that could play a critical role in a political process that will support the changes needed to re-orient the global biomedical R&D system as a whole. Thus, the Canadian government should:

- Support countries[33] to implement and use TRIPS flexibilities to allow development of and access to medical technologies;
- Strongly encourage Canadian governments agencies, industry, and academia to increase participation in and support for approaches to access medical technologies and data, e.g. disclosure of research data and R&D costs, pre-competitive research platforms, and patent pools that further develop licensing conditions to include all affected countries;
- Adopt policies ensuring that public funding for R&D from the Canadian government will be tied to implementation of safeguards in section (V)(3) above and play a progressive role in supporting the development of a Code of Principles outlining these norms;
- Implement incentive mechanisms that both induce innovation and guarantee access; and
- Pilot innovative regulatory pathways that expedite research, ensure access, and strengthen regulatory capacity where needed.

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