2019-93

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DND*i*, a Distinctive Illustration of Commons in the Area of Public Health

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February 2019

Please cite this paper as: ABECASSIS, P., J.-F. ALESANDRINI, B. CORIAT, N. COUTINET and S. LEYRONAS (2019), "DND*i*, a Distinctive Illustration of Commons in the Area of Public Health", *AFD Research Papers Series*, No. 2019-93, February.

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ISSN 2492-2846

DND*i*, a Distinctive Illustration of Commons in the Area of Public Health

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Abstract

Following many years of structural adjustment programmes, the last decades of the 20th century saw drastic reductions in the public health resources of developing countries. The failures of the liberal policies then promoted, alongside the emergence of the AIDS pandemic, gave rise to new public health practices and instruments under the "Global Health Initiative". Among these, Product Development Partnerships (PDPs) dedicated for developing and delivering new health technologies for neglected diseases, emerged in association with the Millennium Development Goals adopted by the United Nations in 2000 to meet the needs of the world's poorest populations. Along with these practices came novel conceptualisations. The description of public health as a Global Public Good (GPG) and then as a common good captures the trends in the narrative that fed and justified health practices especially regarding low resource setting countries. At the crossroad between operational and conceptual considerations, the aim of this article is to demonstrate how a distinctive PDP – the not-for-profit development organisation Drugs for Neglected Diseases *initiative* (DND*i*) – can illustrate what can be presented as a "commons" within the area of public health. After setting the stage of PDPs' emergence and the relevance of the commons approach 1), three features of DND*i*, indicative of commons, will be more thoroughly developed: 2) its promotion of collaborative platforms and open innovation, 3) its innovative intellectual property policy, and 4) its governance, partnership and funding mechanisms. The document will then open up 5) on the implications of DNDi's shift from neglected diseases to neglected people, especially regarding its nature as a chain of nested commons.

Key words: Public health, DND*i*, neglected diseases, commons, development

JEL Classification: I14, I15, I16 O19, O34, O35

Special Thanks

The authors would like to thank the following DNDi staff for their availability and valuable contribution to this report in 2017 and 2018 (by alphabetical order): Pascale Boulet, Thi-Hanh Cao, Spring Gombe-Gotz, Bernard Pécoul, Benjamin Perry, Serge Sagodira, Thomas Saugnac, Nathalie Strub-Wourgaft, and Rachel Tisseuil. A special thanks as well to Nadège Legroux (AFD) for her contribution in editing this report.

Original Version: English

Accepted: January 2019

I. Setting the Stage: the Emergence of Product Development Partnerships and the Relevance of the Commons Approach

Global Public Health[4] *at the Turn of the 20th Century*

The end of the 20th century was heated with a strong international debate on the developing world's shortcomings in the offer and access to care (Abecassis & Coutinet, 2015, 2018). A distressing imbalance in the offer of drugs became clear: 90% of research and development (R&D) was conducted for the benefit of the 10% most wealthy and creditworthy patients (Malpani & al., 2008). This left vast amounts of the world's population in total misery and in the most precarious health conditions. This concern was fuelled by the sudden tightening of Intellectual Property (IP) standards following the signature of the Trade-Related Aspects of the Intellectual Property Rights (TRIPS) Agreement in 1994 (Coriat, 2008). The changes set up by the TRIPS Agreement included the compulsory patenting of therapeutic molecules in all signatory countries, thus creating a unified global market for patented drugs regardless of countries' levels of development (Coriat & al., 2006). As a consequence, in approximately fifty developing countries that did not authorise the patentability of therapeutic molecules, production and imports of generics were prohibited. The world's premium medicine market became homogeneously globalised with patentability standards similar to those prevailing in developed countries. This unprecedented extension of IP gave rise to criticisms all the more heated by the dramatic context of the AIDS pandemic (Médecins sans Frontières, 2001; Correa, 2000, 2004), whose impacts were most disastrous in limited-resource countries especially on the African continent. In addition, awareness rose on a number of neglected diseases for which the absence of a solvent market led de facto to the withdrawal of private research. These diseases prevail in the global South and are associated with very high morbidity and mortality rates. The WHO has listed 20 of such diseases, including HIV/AIDS, malaria and tuberculosis (WHO, 2006). Here again, they primarily concern developing countries that generally lack the skills and financial resources to overcome the disengagement of the private sector (Abecassis & Coutinet, 2017).

The Rise of Product Development Partnerships and "Open Innovation"

This setting gave rise to two series of institutional innovations which mutually fed on each other to transform the fight against neglected diseases: Product Development Partnerships (PDPs) (Branciard, 2012), itself largely based on new "open innovation" concepts. PDPs, were novel and innovative entities designed to initiate or revive research on compounds against the major pandemics of the South. PDPs can be described *as not-for-profit organisations dedicated to promoting the development of R&D in the field of neglected diseases*. Their purpose is to fill R&D gaps by creating public/private partnerships to conduct projects, meanwhile ensuring that the resulting goods will be made available at affordable prices to the most vulnerable populations. Although they engage with multiple partners that adhere to the spirit of open innovation, as described below, in general PDPs

[4] **Global Health Initiatives** (**GHIs**) are initiatives conceived for raising funds and allocating them in additional ways for the fight against infectious diseases or for immunization and the strengthening of health systems, mostly in developing countries.

operate within existing IP legal frameworks without questioning them. PDPs' costs of research and development risks are borne primarily by public funding or donations from charitable foundations, yet overall they are largely dominated by private actors both in terms of funding, partnership and governance. The first PDPs[5] created for R&D in neglected diseases were the International Aids Vaccine Initiative (IAVI) and Medicines for Malaria Venture (MMV). They were followed by PDPs that mostly focused on medical products (vaccines, diagnostics, drugs, microbicides, etc.) or on neglected diseases.[6]

DND*i* was part of this second wave of PDPs. It was created as a foundation under Swiss law in 2003 by five public research institutions from India, Brazil, Kenya, Malaysia and France, and Médecins sans Frontières with the participation of the WHO. Initially designed as an experiment, its objective was to explore new ways of promoting innovation in access to treat neglected diseases for which drugs were lacking, not adapted or highly toxic, with significant side effects. While following the momentum of PDPs, DND*i* has since its emergence presented unique characteristics (DND*i*, 2013). This distinctiveness makes its analysis through the lens of commons – rather than that of PDPs – particularly insightful.

The "open innovation" concept (Chesbrough, 2003, 2006) soon became a core feature of most of the PDPs practices and proved to be an effective research instrument. In this R&D model, companies bring together a variety of external partners (universities, research institutes, biotech companies, etc.) on a digital platform in order to work on a research project. While practices vary widely, this model's distinctiveness is that despite its adherence to convention IP rules, it allows companies to involve multiple contributors throughout the project's lifetime. Innovation no longer stems from a single company but from the collaborative work and networks that stretch far beyond it. These practices, which emerged in developed capitalist countries often initiated by leading companies, quickly became a characteristic of some PDPs. They allowed PDPs, which generally lacked sufficient resources or their own laboratories or their own libraries of compounds, to heavily rely on external partners for work in open innovation. They placed PDPs in strong R&D positions for diseases in developing countries. Despite many successes, PDPs cannot however satisfy the huge R&D needs for pandemics of the South – including neglected diseases – due to persisting inadequate funding in the field.

The Shift from Global Public Goods to Commons and its Relevance in Understanding DNDi

While DND*i* unquestionably belongs to the wide PDP family, the characteristics of its institutional model and the arrangements it promotes clearly set it apart from conventional PDPs (DND*i*, 2013). In this context, the analytical framework provided by the commons concept – increasingly referred to by public health actors – interestingly sheds light on the DND*i* and its action. Before reviewing

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5 Historically, PDPs followed the creation of the Special Programme for Research and Training in Tropical Diseases (TDR), created in 1975 by the UNDP (United Nations Development Programme), UNICEF, the World Bank and the WHO. The TDR programme heralds the shift to an internationalisation of public health issues associated with tropical diseases.

6 The first PDPs created for R&D in neglected diseases were MMV, Medicines Malaria Venture and IAVI (International Aids Vaccine Initiative followed by FIND (Foundation for Innovative Diagnostics), TB Alliance (the Global Alliance for Tuberculosis Drug Development) and IOWH (Institute for One World Health).

some of the main features of DND*i* through the lens of commons, some insights are needed on the commons approach, especially as a necessary alternative to the narrative on Global Public Goods (GPGs). Our question is whether the commons may, in the area of public health, help overcome the limitations encountered with the GPGs approach, and help characterise an innovative entity such as the DND*i*.

GPGs were introduced at the end of the 20th century as a broadened understanding of public goods within the traditional neoclassical framework (Kaul & al., 1999). They share the attributes of non-rivalry in use and non-exclusion in access that traditionally define public goods (Samuelson, 1954) while presenting two additional characteristics. The scale of GPGs spams the entire planet ("territoriality") and they concern current but also future generations ("temporality"). Along with the archetypal GPGs – air, atmosphere, water – public health is often described as a GPG (WHO, 2003). After two to three decades, the GPGs approach has given way to a number of limitations. The major criticism towards GPGs is that their effectiveness relies on their recognition by international controls and regulations. They suppose that a worldwide governance exists and is capable of applying regulatory and economic tools to all actors. In line with the traditional neoclassical vision of the market, GPGs consider the economic rationale of actors as the basis for the performance of organised systems (Leyronas, 2018). They thus purport the standard economic approach based on efficiency, as opposed to a concept based on fundamental human rights and ethical considerations (Leyronas, 2018; Boidin & al., 2008). However, no such governance has been put in place. The example of the TRIPS Agreement in the area of patentability illustrates, *a contrario*, the tremendous setback in rules and regulation on access to care in developing countries spurred by an intergovernmental governance instrument.

The commons approach sets a very different perspective. It questions the very roots of the GPGs approach, which focuses almost exclusively on regulations in a world seen as governed by agents in pursuit of private interests. While it does not exclude at all the need for appropriate regulations, the commons approach attaches at least equal importance to the establishment of local, decentralised, often largely self-organised entities. It requires the formation of local entities, i.e. actors which, to be qualified as a commons, should ideally combine three characteristics: i) bring together, around an existing resource and/or in view of producing a new resource, a group of self-organised actors that have set out the rules under which they intend to operate ("resource"); ii) they allocate to the various actors a set of rights and obligations regarding the way in which the pooled resource shall be treated and the benefits that may be derived and shared ("rules"); and iii) they establish forms of governance to promote the compliance with these rights and obligations ("governance") (Coriat, 2015; Cornu & al., 2017). The commons that meet these three criteria constitute both organisational and institutional innovations with precise set-up rules. They come in varied forms based on their goals and the nature of their arrangements. A common good refers to a system comprising an open-access local or global resource for which, as opposed to a commons, a governance structure is not in place (Coriat, 2017).

In addition to these formal characteristics of commons, two moral and political considerations conceived from the outset as an intrinsic part of their identity ought to be highlighted. First, the overall *ecology* of the system is at the very core of the construction of a commons: the rules implemented by commoners must therefore target the reproduction or joint enrichment of the resource and the community around it (Ostrom, 1990). Second, equity is key (Ostrom, 1990; Cornu

& al., 2017): it is ensured by governance in the case of commons formed from exhaustible resources, and characterised by universal access in the case of commons that are not rival and not exhaustible such as intangible goods or knowledge.

Based on these definitions, this article argues that while DND*i* does belong to the large PDP family, it presents several distinctive features that render its analysis through the lens of commons relevant and powerful. The following sections analyse three features according to this light: 1) DND*i*'s promotion of collaborative platforms and open innovation, 2) its innovative intellectual property policy, and 3) its governance, partnership and funding mechanisms.

II. DNDi's Promotion of Collaborative Platforms and Open Innovation

Throughout its initiatives and practices, DND*i* facilitates the deployment of an array of commons and thereby contributes to turning certain aspects of public health into public goods, at least when it comes to the treatment of neglected diseases. These are tangible in a first characteristic of the initiative: its promotion of collaborative platforms for clinical research to achieve its objective and to open innovation initiatives in order to identify potential new drug candidates. The open innovation concept for upstream research is, along with the clinical research platforms' philosophy and operating principles, a relevant illustration of commons.

Collaborative Platforms: Clinical Research Commons Focusing on the Consolidation of Local Skills

A first example of such a framework is the collaborative clinical research platforms set up by DND*i* once a candidate molecule have been identified, at a cost deemed affordable for patients. The platforms provide a network of medical and scientific skills to promote a common approach for health authorities in endemic countries, as well as to define R&D priorities and the target product profile (i.e. type of drug, efficacy, tolerance, mode of administration, dosage regimen, duration of treatment, price, etc.). Their goal is first to support clinical research (Phase 2 and Phase 3 clinical trials) and then to facilitate the access of treatment for the greatest number of people, first and foremost of the most vulnerable populations. These platforms bring together a variety of national and regional actors involved in a disease and its treatment to share experiences, skills and technical knowledge.

Primarily located in low-income countries, partners vary according to the diseases and the environment. They generally include national disease control programmes where they exist, health ministries, universities (health sciences and other fields, such as anthropology), civil society representatives, pharmaceutical companies, health professionals, clinicians, patients' associations, diseases experts, and are open to donors. While their primary purpose is to support the development of new treatments, platforms are also designed from the outset to strengthen local skills and to prepare access to treatment for the greatest number of people. Currently, DND*i* has three active platforms (DND*i*, 2017): the Chagas Clinical Research Platform (CCRP) created in Brazil in 2009, comprising almost 400 members from 22 countries and 100 institutions; the Human African Trypanosomiasis (HAT) Platform, created in 2005 in the Democratic Republic of the

Congo, comprising 120 members from eight countries and 20 institutions; and the Leishmaniasis East Africa Platform (LEAP), created in 2003 in Sudan, comprising 60 members from four countries and 13 institutions. Their common threefold objective is to create or rehabilitate clinical trial centres, to train clinical trial personnel, and to ensure the transfer of knowledge and technology in regions affected by the endemic diseases in order to promote a wide local distribution of treatments.

The decision taken by DND*i* to create a platform is based on the review of an existing - or potential - ecosystem of actors involved in a given disease. There are no standard platforms and their format varies according to the disease, the location and nature of their partners. These latter contribute widely to the definition of the rules by which they intend to operate. In terms of governance, some platforms are ruled by a Board, while others depend on a scientific advisory committee or on principal investigators. All platforms have a "coordinator" reporting to DND*i*. A number of local researchers working on these platforms are remunerated by DND*i* (roughly fifty for all combined platforms). The rules and obligations are variable and not highly formalised. Based on information-sharing, their objective is to promote access to care. Their operating principles are based on common times and places, with regular meetings organised once or twice a year, funded by the DND*i*, to discuss the work progress, future of the platform, and organise training sessions. Their purpose is to build networks fed by a strong sense of belonging, a challenge which may be circumvented by such operating methods when platform members are geographically dispersed.

Platforms, built around a disease, are not intended to last. The HAT (Human African Trypanosomiasis) platform will probably be the first one to shut down in its current form in 2023, once DND*i* will have launched its second drug to treat sleeping sickness and secured its deployment in endemic countries. While initiated and funded by DND*i*, these platforms do not belong to DND*i* but to the medical and scientific community that works within them. Their fundamental objective is therefore to consolidate new skills and introduce them into national and local programmes, thereby strengthening local infrastructures.

Upstream Research and Screening: Open Innovation

The networks for upstream research are designed to identify lead compounds to bring the selected molecule to the final stage of an effective treatment. They involve important preliminary research and resources. In order to have access to such knowledge as a virtual R&D organisation without its own compound libraries, DND*i* has initiated original mechanisms with companies based on the open innovation concept and practices. Different protocols currently exist. As an illustration, the NTD Drug Discover Booster, a global consortium launched by DND*i* in 2015, brings together eight pharmaceutical companies[7]. Initially focusing on leishmaniasis and Chagas disease, the NTD Drug Discovery Booster gives DND*i* access to the proprietary chemical library of the consortium's members, less than 40% of which are patented compounds. This opens the access to the chemical libraries of pharmaceutical companies, generally not accessible. Any progress or new treatment for

[7] Eisai Co. Ltd., Shionogi & Co. Ltd., Takeda Pharmaceutical Company Ltd., AstraZeneca UK Ltd., Celgene Corporation, Merck KGaA, AbbVie Inc. and Astellas Pharma Inc. This platform is supported by the Japanese GHIT fund, cf. infra.

both diseases resulting from the Drug Discovery Booster shall be attributed to the collective effort of all partners, who agree to waive all intellectual property positions on resulting treatments[8].

DND*i*'s promotion of collaborative platforms and open innovation arrangements for upstream research both present characteristics of commons (Carballa & Coriat, 2017). They instigate forms of cooperation and knowledge-sharing, rights and obligations of partners defined by largely emergent rules, and non-exclusivity of research results, which are at the very least free from the constraints of patents when used for the benefit of disadvantaged populations. All of these aspects are strong markers of collaboration. These collaborative principles, a characteristic of commons, do not exclude the involvement of the private sector and in our setting, of pharmaceutical companies. They are part of the frameworks set by DND*i* in ways that allow to safeguard the commons nature of the platforms. When private pharmaceutical companies are involved in the drug development process, they are generally only present at the earliest and latest stages. They are not true stakeholders of the platforms and are not always involved in discussions. This gives rise to flexible sharing of expertise from these actors without jeopardizing the platforms' collaborative nature.

III. DND*i*'s Innovative Intellectual Property Rights Policy

The various forms of inclusion of pharmaceutical companies in DND*i*'s collective research processes described above illustrate the sensitivity of IP issues. Indeed, scientific information is a non-rival good whose production cost can be very high despite a very low reproduction cost. As a consequence, incentivising research through the attribution of exclusive rights and monopolies to the inventors has been at the heart of pharmaceutical innovation policy in developed countries. This vision, imposed to the world by the TRIPS Agreement, sets IP as an exclusive and private right, the impetus for innovation policies. Since its inception, DND*i* distinguishes itself from these practices by placing access to treatment above IP law and conceiving IP as a set of shared rights. Both of these features are relevant attributes of DND*i* in the context of an analysis through the commons' approach.

Access to Treatment Overrides IP Law

DND*i*'s distinction lies in the fact that without questioning the existence of IP, its own IP policy set up at its inception differs from the principles prevailing in most research and development entities. DND*i* policy relies first and foremost on the primacy of access to treatment, as set by its founding documents which state that *"the mission of DNDi is to develop safe, effective and affordable new treatments for patients suffering from neglected diseases, and to ensure equitable access to these treatments"*. This commitment to initiate affordable treatments for which access is equitable is a first founding principle of DND*i*. A second strong principle is its will to develop new drugs that constitute public goods "when possible" and to commit itself: *"…to contribute to the thinking and development of IP approaches in health R&D that are aimed at serving the public good"*. This highlights the singularity of DND*i*'s IP policy, designed to foster alternative approaches in health R&D to produce drugs considered as public

[8] Other examples of protocols are the *Open Synthesis Network*, the *Pathogen Box* and the *MycetOs – Open Source Mycetoma.*

goods, i.e. free of exclusive rights, and make them available to those in need. This vision is in line with the joint concepts of commons and common goods, as:

- the rules implied by DND*i*'s IP policy serve a resource – neglected diseases treatments – that is seen as shared;
- furthermore, DND*i*'s approach is innovative because it offers a way to escape from the all-or-nothing dichotomy which has dominated all IP issues: private and exclusive IP law versus a total absence of rights;
- in line with the commons' approach, DND*i*'s vision is that IP can and must be conceived as a set of shared rights. For example, DND*i* conciliates the right of access to treatment of underprivileged and poor populations and the right that certain research partners, especially pharmaceutical companies, can retain to exploit under given limits the molecules shared in the platforms on which they hold patents.

In this way, *DNDi is fully committed to a concept of ownership seen as a bundle of rights*, characteristic of the commons' approach, whereby different attributes of property rights are distributed and allocated to different types of partners (Orsi, 2015).

Multiple Forms of the Bundles of Rights

The IP policy applied by DND*i* varies according to a case-by-case basis and offers the advantage of flexible implementation. Indeed, it takes on a different form if the molecule used as a basis for clinical research already belongs to the public domain, or if it is the property of a third party. In the first case, the treatment(s) that derive(s) from it shall not be subject to any property rights and shall be released into the public domain. In the second scenario, a negotiation process must be triggered with the pharmaceutical company who owns the rights. The motivations of a company to agree to waive some of its IP rights will very much depend on its nature, the circumstances and characteristics of the diseases. For companies, setting an IP agreement with DND*i* can carry different advantages. Besides the benefits borne out of a positive Corporate Social Responsibility image, it allows them to transfer the risk of research investment to DND*i* and take advantage of their research results in other areas. Such agreements also provide companies with vectors to penetrate new markets especially in the South, thereby acting as access busters. A variety of examples illustrate these different solutions, one of which is the partnership concluded in 2008 between DND*i* and Anacor. This agreement gave DND*i* access to a class of therapeutic compounds held by Anacor but whose applications were still unknown. DND*i* could conduct research for a specific indication, sleeping sickness. It was granted non-exclusive rights to the molecule(s) for all applications that may result from its research in this field, while Anacor retained their rights for any other indication. Other examples include the development of the antimalarial ASAQ Winthrop by DND*i* and Sanofi (Branciard, 2012), the licenced agreement between DND*i* and the Californian company Presidio Pharmaceuticals on treatment for hepatitis C[9], and the

[9] For further details, see: https://www.dndi.org/2016/media-centre/langues-press-releases/dndi-pharco-hepc-malaysia-thailand-fr/

agreements signed with Abbvie[10] and Sanofi[11]. Agreements are also established with research universities. Although this is often time-consuming due to the universities' desire to file patents in order to obtain scientific recognition for their work, DND*i* has generally succeeded in convincing these institutions to forgo patents. This constitutes a prerequisite for them to benefit from DND*i* knowledge and network and feeds on DND*i*'s primary objective, the access to treatment and research data.

Three aspects of DND*i*'s innovative IP policy particularly enhance its relevance with the commons' approach.

First, it grants IP attributes according to varying terms, in opposition with the monolithic block of private and exclusive rights. Innovation can thus spark from this differentiated IP approach. This is a particularly effective way to instigate research on new drugs, especially in the field of neglected diseases where available resources are notoriously lacking. Second, this IP policy generates a new manner of conducting research, one that is "needs-driven" rather than one where priorities are set according to expected IP returns. Through this shift in objective, IP becomes a property with shared usage, where the aim is to safeguard the benefits and access to treatment to a large number of people, especially the most vulnerable populations. Third, when IP rights are fully waived, combined with a distribution of medication free-of-charge or at drastically reduced price, with collaborative clinical research, public health becomes a common resource. Its access is guaranteed to treatment for those in need thanks to the system set up by DND*i*.

IV. DND*i*'s Governance, Partnership and Funding Mechanisms

DND*i*'s distinctive research implementation and IP policy are strengthened by governance methods in line with its mission. Although DND*i*'s current business model and institutional format are being questioned and may be transformed in the future, the approach chosen today by DND*i* for its partnerships and funding further characterises it as a commons.

A Public Sector-Led Governance with Multiple Partnerships

A very distinctive feature of DND*i* is its affiliation to the public sector. As DND*i* considers that meeting the needs of populations is a public responsibility, its governance originates predominantly from the public sector, with a large representation from developing countries. DND*i* is the first and the only PDP whose founding partners include medical research institutes from the public sector of developing countries[12]. The Board of Directors, which did not include any active member of the pharmaceutical industry to safeguard its independence, is constituted predominantly of public health experts from the public sector.

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10 For further details, see: https://www.dndi.org/2012/media-centre/press-releases/dndi-abbott/

11 For further details, see: https://www.dndi.org/2011/media-centre/press-releases/sanofi-dndi-agreement/

12 These founding partners are the Indian Council for Medical Research (ICMR), the Kenyan Medical Research Institute (KEMRI), the Oswaldo Cruz Foundation Brazil (Fiocruz), and the Malaysian Ministry of Health, two private organisations, Médecins Sans Frontières (MSF) and Institut Pasteur and the WHO Special Programme for Research and Training in Tropical Diseases (TDR) acting as observer.

Another key feature of the DND*i* model is its creation of a large number and variety of partnerships with a heterogeneous cast of actors[13]. The choice of these actors and their ability to commit to a shared vision and mission is what fundamentally brings them together in a partnership. Their aim is to build a general ecosystem that includes and facilitates not only the development and production of drugs, but also their access for neglected populations. For this reason, partnerships must include specific actors (public health programme managers, international donors, etc.) in charge of drug distribution and access to care. The variety of set-ups launched by DND*i* underline the need to design governance methods based on hybrid commons. These succeed in mobilizing spaces and resources with various legal statuses. Thus, the solutions provided by DND*i* are often nested in a multitude of institutions within the overarching ecosystem of drug development and distribution. Many DND*i* partners, such as foundations or NGOs involved in access to care for vulnerable populations, can be considered as commons themselves. Their association with DND*i* produces "commons of commons" with chains of nested commons that feed into each other.

Funding Mechanisms

Since its creation, DND*i*'s funding policy is based on the following principles: at least 50% of the budget must be from publicly funded system; no one donor can contribute over 25% of all donations[14]. To guarantee its independence from donors, DND*i* seeks diversified sources of funding – cash contributions, in-kind contributions, grants, sponsorships, and legacies, or any other source of funding in line with its ethics. DND*i* refuses direct grants from the pharmaceutical industry, not only to preserve its independence, but also to give priority to in-kind contributions from pharmaceutical companies such as access to chemical libraries or product registration. Even though the industry participates de facto in projects, its financial contribution is considerably lower than that of NGOs.

In 2017, 83% of public funding originated from European cooperation agencies[15], the UK-AID (previously the Department for International Development) being the leading public donor. Other sources of funding originate from European, US institutional funds and other private sources. DNDi benefits from the support of new mechanisms created over the last decade, such as UNITAID (funded by a tax on plane tickets), the GHIT fund (Global Health Innovative Technology Fund) funded by the Japanese government and pharmaceutical companies, and the Bill &Melinda Gates Foundation (BMGF). DND*i* tries to raise funds from emerging countries, but these governments have no mechanism and/or little funding capacities to contribute for innovation even for neglected diseases endemic in their own country. However, donations from local health ministries and health programmes are increasing. Private funds are mainly provided by the BMGF

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13 These range from academia and research institutions to civil society, NGOs, patients' organisations, other PDPs, national control programmes in endemic countries, international organisations and industry. For an illustrative table, see the Funding Proposal sent to DGIS/Netherlands in 2015.

14 DND*i*'s fundraising policy states also that donations cannot originate from revenues from tobacco, alcohol or weapons, nor originate from donors who encourage racism and intolerance (https://www.dndi.org/wp-content/uploads/2018/03/DNDi_Fundraising_Policy.pdf).

15 Including AFD in France, SDC in Switzerland, BMBF-KFW in Germany, DGIS in the Netherlands, UK-Aid in United Kingdom and AECID in Spain.

(20.7% of all donations), Médecins Sans Frontières (15,1%), and the UK Wellcome Trust (less than 3.5%) (DND*i*, 2017).

Overall, 71% of DND*i*'s resources originate from four donors: BMGF, MSF, UK-AID and DGIS (DND*i*, 2017). Even though its funding principle is based on an equal share between public and private donors, DND*i* seeks to prioritise public funding. Bar a few exceptions, public funding provides greater flexibility as the funds are generally spread over several years and less restricted than private funds. Unrestricted funds allow DND*i* to define its own policy and overall R&D priorities and guarantee its independence and autonomy from the pharmaceutical industry and foundations which pursue their own agenda.

Donors may choose to earmark their funding by allocating it to specific diseases, which is the case of 50% of cumulated funds from 2003. The remaining 50% provide DND*i* with the freedom to respond to research opportunities or finalise projects that have not achieved their expected objectives (DND*i*, 2017). DND*i* seeks to maintain a balance between restricted and unrestricted funds to assure its flexibility. This overall financial independence is an essential prerequisite to produce commons, as it guarantees the rights of partners and beneficiaries. DND*i*'s public-sector led governance, partnerships and funding mechanisms all contribute to safeguarding its independence and the ability to conclude agreements guaranteeing the access to and availability of affordable products. In this way, they constitute key features of DND*i*'s promotion of commons.

V. Looking Ahead: Implications of the Shift from "Neglected Diseases" to "Neglected People"

Initially created as a simple PDP, DND*i* constitutes a unique and distinctive institutional model in the area of public health. While this was not predetermined, its practice evolved over the years to include features typical of commons. Its implementation methods based on collaborative clinical research platforms and open innovation approaches, its IP policy as well as its methods of governance all secure the participation and representation of actors and partners while safeguarding their rights and needs. As DND*i* thus became a commons, it promoted other commons such as the collaborative platforms hosting multiple projects, designed to promote technology transfers and develop local skills. By pursuing its primary mission – the promotion of access to safe, effective and affordable treatments to the neediest – DND*i* truly helps transform public health into a common good, at least in the field of neglected diseases.

Two of DND*i*'s features highlighted in this analysis through the commons' approach constitute both its strength and limitation. The first one is its funding mechanism. While it guarantees its independence, it is also surrounded by the uncertainties of fundraising, for which advocacy requires a great deal of time and energy. As DND*i* is strongly based on public leadership, fundraising depends on global health policies. The emergence of new global health issues, such as epidemic preparedness, antimicrobial resistance and non-communicable diseases, may create competition in between different areas in addition to the rise of nationalism and protectionism which could affect aid and international development priorities in some countries for global health issues.

The second feature is the principle of delinking the costs of research from the final price of drugs to make them affordable for those most in need. It is based on the premise that costs and risks associated with R&D should be rewarded, and incentives for R&D provided, by means other than the price of the end-products or sales volume.

The two components of grant-based funding and delinkage are closely related. Grant-based funding makes delinking possible, and with it, policies that characterize DND*i*'s action by guaranteeing the drugs' quality and safety, equitable access and availability at reasonable prices (Pecoul, 2016). This feature, at the heart of the model, allows for needs-driven research.

However, the search for new principles and new models are now on the agenda. The question of an evolution of DND*i*'s business model is particularly relevant since DND*i*'s mission evolved from "neglected diseases" to encompass "neglected patients". This shift occurred in 2015 and represents a major change. It raises a question characteristic of the evolution of a commons. How can DND*i* evolve and change scales without losing its DNA, and remain truthful to this mission? This question must guide such a change and also benefit from the lens of commons. Indeed, the broadening of DND*i*'s focus calls for potential additional revenue and raises the question of whether the organisation could generate such revenue through its own activity. More specifically, could DND*i* effectively derive additional resources from IP – since it is basically an entity dedicated to R&D activities – while keeping true to its founding principles?

While this is not the heart of our paper, three options are worth mentioning in order to open up future discussions.

PRVs – Priority Review Vouchers

In order to generate additional revenue, a first possibility for DND*i* is to share data eligible for Priority Review Vouchers (PRVs)[16] with pharmaceutical companies. PRVs, introduced in 2007 by the US government, entitle companies to a fast track review for the registration of some of their drugs by the US regulatory authority. This opportunity depends on a specific conditionality: the company has obtained marketing approval from the Food and Drug Administration (FDA) for a new treatment for a neglected disease or a pediatric orphan disease. Thus, the PRV enables these companies to advance the marketing date by four to six months, thereby generating substantial differential revenue (Ridley & al., 2006). PRVs can also be traded, often for considerable amounts (estimated at US$ 100 to 300 million), on the PRV market. By letting its pharmaceutical partners using data generated within a legal partnership framework to register their own drug and obtain a PRV, DND*i* is creating an additional novel incentive for pharmaceutical companies to collaborate with it and potentially opens itself to a significant additional source of revenue. For DND*i*, such PRVs should however be shared at the condition that they include access components and guarantees for the most vulnerable populations. This could then effectively allow DND*i* to spur additional revenue for itself while remaining true to its mission of promoting the access to products.

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[16] For a detailed presentation of PRVs, see the WTO website: https://www.wto.org/english/tratop_e/trips_e/trilatweb_e/ch3c_trilat_web_13_e.htm

Differentiated Pricing Based on Licence Policy

Another source of additional revenue could be generated from the transfer of licences and hence of exploitation rights at prices that vary according to populations and/or territories. This mechanism has already been used by DND*i* (Branciard, 2012). It consists in compensating the low costs of drugs for the more vulnerable populations in low-income countries with a "royalty" on the sale price of the product in high-revenue countries. It somewhat interestingly reminds the commons-based reciprocity licences used in many fields, especially open-source software, and their distinction between users of licenced material. According to this practice, the "commoners" who have invested time and resources in the production of the shared material have free and unimpeded access to the licenced material produced by the commons. On the other hand, third parties who have not participated in such production may use the material in exchange for the payment of a "compensation" to the commons. Reciprocity licencing is an avenue worth exploring to safeguard the principle of needs-driven research, the primacy of access to drugs, and the generation of the additional resources necessary to further its most ambitious projects. These licences, adapted to drugs, would reduce the burden of fundraising while increasing the organisation's autonomy to pursue its own objectives. Once ownership and IP are thus no longer seen as necessarily private and exclusive, licencing possibilities broaden significantly. This opens the way to creative commons licences[17] with differentiated access based on the political and social objectives pursued by the rights-holder[18].

Funding for Dual Destination Drugs

Last but not least, DND*i*'s shift from neglected diseases to neglected people could lead to investments in diseases and drugs that target patients not only in developing but also in developed countries. For instance, DND*i* is developing a new hepatitis treatment potentially addressing huge markets in developed countries with powerful social security systems and public research institutions. It could therefore become eligible for grants and/or contracts with different research organisations (in France for example: CNRS, INSERM, etc.). DND*i*'s ability to develop molecules and bring them to the market at costs considerably lower than those dictated by pharmaceutical companies, held to huge payments to satisfy their shareholders, could generate significant savings for these countries. DND*i* could therefore receive funds in the form of grants or advances for its commitment to research projects of national interest. In return, the research results and hence the compounds would be governed by special licences allowing their use for free or at greatly reduced price, once they are included on the lists of prescribed drugs reimbursed by social security systems. This solution would not constitute in any way an infringement or derogation from the applicable competition rules, as all major national R&D systems provide direct or indirect public funding to the different actors, including pharmaceutical companies.

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[17] For creative commons licences, see Cornu & al., 2017, and the P2P Foundation website, which also gives a definition of reciprocity licencing.

[18] R. Stallman created the concept of copyleft, authorising the free duplication, reproduction and distribution of his own software, thus transforming it into a common good. See Broca, 2018, as well as Broca & Coriat, 2015.

These different opportunities can be further explored in the context of the evolution of DND*i*'s mission. If well-orchestrated, they could initiate additional revenue while maintaining DND*i*'s focus on access to treatment for those most in need. Such practices would however imply an extremely rigorous accountability, linked to a new revenue-generating business model. Such a high level of accountability would be another distinctive feature of not-for-profit and needs-driven commons, radically different from the opaque world of private for-profit pharmaceutical companies.

To conclude, DND*i* already constitutes a distinctive illustration of the commons approach in the area of public health. Its implementation methods, IP policy and governance methods are some of its main and most interesting features. The reading through commons is not only insightful today: it also sheds light on the importance of the changes to come for DND*i*, in the context of a shift from neglected diseases to neglected people. All commons, including DND*i*, cannot live off donations and grants indefinitely. Their sustainability depends on their ability to continue to diversify their funding sources and to generate their own resources more substantially. The capability of commons to create institutions and business models that satisfy essential needs while guaranteeing universal access, especially for the neediest, is without doubt a major stake for the future of our societies.

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