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This paper is based on the following working paper: “[DNDi, a Distinctive Illustration of Commons in the Area of Public Health](#)”, Abecassis et al. (2019), AFD Research Papers #2019-93. A French longer version is available at [encommuns.com](http://encommuns.com), EnCommuns website, WP17

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# Developing innovative drugs through the commons Lessons from the DNDi experience<sup>1</sup>

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In this paper we argue that DNDi, even though it belongs to the family of Product Development Partnerships (PDPs) created at the end of the 20<sup>th</sup> century, has followed a very particular trajectory, that allows us to characterize it as a distinctive commons in the field of public health. We illustrate this view by focusing on two features: DNDi's promotion of *collaborative platforms* and its innovative *intellectual property policy*.

## **From PDP to Commons: DNDi's trajectory**

### *Global Public Health at the Turn of the 20<sup>th</sup> Century*

To fully understand the significance of the DNDi project it is necessary to look back at the end of the 20<sup>th</sup> century. This period was heated with a strong international debate on the developing world's shortcomings in the offer and access to care (Abecassis and Coutinet, 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 *et al.*, 2008). 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 *et al.*, 2006).

This setting gave rise to a series of institutional innovations to transform the fight against neglected diseases. These innovations especially converged under the form of Product Development Partnerships (PDPs) (Branciard, 2012), themselves largely based on new 'open innovation' concepts. These PDPs can be described as *not-for-profit organisations dedicated to promoting the development of R&D in the field of neglected diseases*. The first PDPs 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.).

DNDi was part of this second wave of PDPs, but also showed unique characteristics (DNDi, 2013). This distinctiveness makes its analysis through the lens of commons – rather than that of PDPs – particularly insightful.

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

Before reviewing some of the main features of DNDi through the lens of commons, some insights are needed on the commons approach, especially as an alternative to the narrative on Global Public Goods (GPGs) that until recently was dominant regarding public health.

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GPGs were introduced at the end of the 20<sup>th</sup> century as a broadened understanding of public goods within the traditional neoclassical framework (Kaul *et al.*, 1999)<sup>2</sup>. Along with the archetypal GPGs – air, atmosphere, water – public health was often described as a GPG (WHO, 2003). After two to three decades, the GPGs approach has given way to a number of limitations and critiques, mainly that it perpetuates the standard economic vision based on the defence of property rights and efficiency (Leyronas, 2018; Boidin *et al.*, 2008).

The commons approach sets quite a 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 and largely self-organised entities.*

To be qualified as a commons, an organisation or institution should ideally combine three characteristics: i) they bring together, around an existing resource - and/or in view of producing a new resource - a group of self-organised actors that have committed themselves to some forms of sharing of the resource's use or creation ("shared resource"); ii) they allocate to the various actors a set of rights and obligations regarding the way in which the resource shall be treated and its benefits shared ("rules"); and iii) they establish forms of governance to promote the compliance with these rights and obligations ("governance") (Coriat, 2015). Commons that meet these criteria come in various forms based on their goals and the nature of their institutional arrangements.

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 *ecology* of the system considered 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.). It is ensured by governance in the case of commons formed from exhaustible resources and characterized 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, we argue that while DNDi does belong to the large PDP's family, *it presents several distinctive features that render its analysis through the lens of commons relevant and powerful.* Beyond its own governance and funding mechanisms that very much echo a multi-partner-based commons model, two of its characteristics will be further explored here: its promotion of collaborative platforms and intellectual property policy.

### **Collaborative Platforms conceived as commons-based innovative entities**

A good illustration of DNDi's philosophy is the collaborative clinical research platforms set up, once a candidate molecule has been identified. 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 product profile of drugs (i.e. main characteristics on efficacy, tolerance, mode of administration, dosage regimen, duration of treatment, price, etc.) with the objective to be delivered at affordable price. 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, especially the most vulnerable populations.

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<sup>2</sup> 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 spans the entire planet ("territoriality") and they concern current but also future generations ("temporality").

Primarily located in low-income countries, platform partners vary according to the goals pursued. They generally include national disease control programmes where they exist, health ministries, universities, civil society representatives, pharmaceutical companies, health professionals, patients' associations, and are open to donors. Currently, DNDi has three active platforms (DNDi, 2017 Annual Report): the Chagas Clinical Research Platform created in Brazil in 2009 (400 members; 22 countries; 100 institutions); the Human African Trypanosomiasis Platform created in 2005 in the Democratic Republic of the Congo (120 members; eight countries; 20 institutions); and the Leishmaniasis East Africa Platform created in 2003 in Sudan (60 members; four countries; 13 institutions).

One must note that, while initiated and funded by DNDi, these platforms do not belong to DNDi but to the medical and scientific community that works within them. Their fundamental objective is to consolidate new skills and introduce them into national and local programmes, thereby strengthening local infrastructures.

### **DNDi's Innovative Intellectual Property Rights Policy**

#### *Access to Treatment Overrides IP Law*

In the field of Intellectual Property Rights Policy, DNDi's distinction lies in the fact that *its 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 has given rise to an innovative IP policy designed to make it possible, if necessary, to conciliate the right of access to treatment of underprivileged and poor populations and the right that certain research partners, especially pharmaceutical companies involved in the research process, 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*, a 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*

A variety of examples with the private sector illustrate the different solutions, implemented and described above. One of them is the partnership concluded in 2008 between DNDi and Anacor, a biotech company since then acquired by Pfizer. This agreement gave DNDi access to a class of therapeutic compounds, held by Anacor, whose applications were still unknown. DNDi could conduct research for a specific indication, sleeping sickness. DNDi 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 DNDi and Sanofi (Branciard, 2012), the licenced agreement between DNDi and Presidio Pharmaceuticals on treatment for hepatitis C<sup>3</sup>, or the agreements signed with Abbvie<sup>4</sup> and Sanofi<sup>5</sup>.

Thus, IP policy is designed, through appropriate allocation of rights to the different partners to safeguard the principle of "needs driven" R&D activity and the benefits and access to treatment to a large number of people, especially the most vulnerable population (Pecoul, 2016).

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<sup>3</sup> For further details, see: <https://www.dndi.org/2016/media-centre/langues-press-releases/dndi-pharco-hepc-malaysia-thailand-fr/>

<sup>4</sup> For further details, see: <https://www.dndi.org/2012/media-centre/press-releases/dndi-abbott/>

<sup>5</sup> For further details, see: <https://www.dndi.org/2011/media-centre/press-releases/sanofi-dndi-agreement/>

## **Looking Ahead. The Shift from “Neglected Diseases” to “Neglected Patients”: Challenges and opportunities**

In 2015 DNDi has decided to take an additional step when DNDi’s mission evolved from “neglected diseases” to encompass “neglected patients”. This shift represents a major change. Indeed, the broadening of DNDi’s focus calls for some modifications of its business model. One of the challenges is to gather additional revenue to be able to face this new expanded mission. How can DNDi evolve and scale-up and remain truthful to this mission? More specifically, the question that appears is: can DNDi effectively derive additional resources from IP – since it is basically an entity dedicated to R&D activities – while keeping true to its founding principles?

Whilst this is largely hypothetical, some options are worth mentioning in order to open up future discussions.

### *Differentiated Pricing Based on Licence Policy*

One 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<sup>6</sup>. It somewhat interestingly evokes the commons-based ‘reciprocity licences’ used in many fields, especially open-source software. 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. These licences may represent an opportunity by *reducing the burden for fundraising (and the competition with other NGOs for these funds) while increasing the organisation’s autonomy to pursue its own objectives.*

### *Funding for Dual Destination Drugs*

DNDi’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, DNDi is developing a new hepatitis treatment potentially addressing markets in developed countries. DNDi could therefore become eligible for grants and/or contracts with different research organisations. DNDi’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. DNDi 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 prices, once they are included on the lists of prescribed drugs reimbursed by social healthcare systems.

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To conclude, we would argue that since pursuing its primary mission – the promotion of access to safe, effective and affordable treatments to the neediest – DNDi has succeeded in transforming public health into a common good, at least in the field of neglected diseases. Thus, DNDi already constitutes a distinctive illustration of the commons approach in the area of public health.

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<sup>6</sup> This mechanism has already been used by DNDi (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

More generally we can observe that the commons approach is not only insightful today: it also sheds light on the importance of the changes to come for DNDi, in the context of a shift from neglected diseases to neglected people. All commons, including DNDi, 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 essential for the future of our societies.

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