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January 2014

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PUBLIC-PRIVATE PARTNERSHIPS IN GLOBAL HEALTH: PUTTING BUSINESS BEFORE HEALTH?

Germán Velásquez



RESEARCH PAPERS

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PUBLIC-PRIVATE PARTNERSHIPS IN GLOBAL HEALTH: PUTTING BUSINESS BEFORE HEALTH?¹

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JANUARY 2014

¹ This paper is a part of the research project funded by SNIS (Swiss Network for International Studies) grant (Millennium Development Goal 8 – target 8-E, 2001 – 2013), undertaken by the EPFL (Ecole Polytechnique Fédérale de Lausanne, Lausanne, Switzerland and the South Centre, Geneva, Switzerland. The author thanks Carlos Correa, Dominique Foray, Viviana Muñoz, Fabiana Visentin, Jean-François Alesandrini, and Vicente Yu for their valuable comments and inputs; however, the author is the sole responsible for the ideas expressed herein.

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ABBREVIATIONS AND ACRONYMS

| | |
|--------|--|
| AIDS | Acquired Immunodeficiency Syndrome |
| BMGF | Bill and Melinda Gates Foundation |
| DNDi | Drugs for Neglected Diseases Initiative |
| GSK | GlaxoSmithKline |
| HIV | Human Immunodeficiency Virus |
| PDPs | Product Development Partnerships |
| PPPs | Public-private Partnerships |
| R&D | Research and development |
| TDR | WHO Special Programme for Research and Training in Tropical Diseases |
| UN | United Nations |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| UNDP | United Nations Development Programme |
| UNEP | United Nations Development Programme |
| UNICEF | United Nations Children's Fund |
| WHA | World Health Assembly |
| WHO | World Health Organization |
| WIPO | World Intellectual Property Organization |
| WTO | World Trade Organization |

INTRODUCTION

Public and private sector interaction in health has always existed at the national level; in the United Nations (UN) system, public-private partnerships (PPPs) started at the end of the 1990s with the reform of the UN system launched by Kofi Annan. In response to Resolution 55/215 “Towards global partnerships”² the United Nations General Assembly asked the Secretary General “to seek the views of all Members States on ways and means to enhance cooperation between the United Nations and all relevant partners, in particular the private sector, on how to enhance cooperation with the United Nations”. The introduction of the report of the Secretary General states that “[o]ver the past decade (...) there has been an increase in the number of non-state actors interacting with the United Nations (...) such as through consultative status with governing bodies, procurement contracts, and philanthropic-based fund raising activities”³ and reiterates later on that “[t]he number, diversity and influence of non-state actors has grown dramatically over the past 10 years” and concludes that “[s]pecial efforts are needed to ensure that cooperation with business community and other non-state actors adequately reflects the Organization’s membership and pays particular attention to the needs and priorities of developing countries.”⁴

Until 1998 the World Health Organization (WHO) remained relatively unaffected by the influence of the private sector. Member States insisted that the regular, multilateral public budget should be at least 51 per cent of the Organization’s budget and that all the normative programmes should be completely financed by the regular budget coming from regular contributions by Member States.

In her first address to the World Health Assembly (WHA), Gro Harlem Brundtland, Director General of the WHO from 1998 to 2003, stated that in order to achieve the mandate entrusted to her: “We must reach out to the private sector (...) The private sector has an important role to play both in technology development and the provision of services. We need open and constructive relations with private sector (...) I invite industry to join in a dialogue on the key issues facing us”.⁵

During the five years of the Brundtland administration at the WHO, PPPs and PDPs (Product Development Partnerships) increased in many of the areas of work of the WHO and in other public health initiatives conducted at the international level. Partnerships mostly related to innovation and access to medicines in many cases created their own “advisory bodies”. These “advisory bodies” may interfere in some cases with the governing bodies of the Organization: the Executive Board and the World Health Assembly.

In the context of WHO, the Special Programme for Research and Training in Tropical Diseases (TDR) can be considered as a precursor of the PDPs. The TDR was created by WHO

² UN General Assembly, Fifty-fifth session Agenda item 173, doc. A/res/55/215, 6 March 2001.

³ UN General Assembly, Fifty-fifth session Item 50 of the provisional agenda: Cooperation between the United Nations and all relevant partners, in particular the private sector, Report of the Secretary General, 28 August 2001.

⁴ Richter, J., “Public-private Partnerships for Health: A trend with no alternatives?” *Development* (2004) 47(2), 43-48. doi:10.1057/palgrave.development.1100043.

⁵ Gro Harlem Brundtland speech to the Fifty-first World Health Assembly, doc. A51/DIV/6, 13 May 1998, pp. 4-5.

in 1975, co-sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP) and the World Bank. The aim of the programme was to promote and intensify research on tropical diseases, taking into consideration that such activities should be carried out mainly in endemic countries, define the research priorities, extend cooperation with national institutions and other governmental and non-governmental organizations in regard to the coordination of research in this field, and mobilize extra-budgetary resources for scaling up these objectives.⁶ The TDR was set up mainly as a partnership between public donors, co-sponsors and endemic country governments represented in an independent board-type structure. Its research priorities were defined by a scientific committee of experts which oversaw the selection of research projects for funding and evaluated progress of various scientific working groups and technical staff, with representation of endemic countries.⁷

A study suggested that: "TDR-supported research contributed to the development of a number of important new products, including demonstrating the effectiveness in humans of Merck's veterinary drug ivermectin for the treatment of onchocerciasis (river blindness)."⁸

The relationship of the TDR with the pharmaceutical industry has been referred to as friendly: "TDR has seen it useful to develop friendly relations with the pharmaceutical industry, and to avoid taking positions that would alienate companies and undermine collaborations. This has, in some cases, extended to views on intellectual property right issues; and TDR has often aligned itself with conventional industry views."⁹

Some of TDR's practices during the 1970-80s established a precedent that the PDPs would later follow; for example, TDR set up an international network of academic centres to screen compounds from pharmaceutical companies for usefulness against its target tropical diseases. TDR was certainly a precursor to PDPs, and perhaps a precursor of the problems and lack of transparency that we are seeing today.

I. SOME CONCEPTS, DEFINITIONS AND VISION

I.1 PPPs

As Judith Richter observed, a global definition of PPPs does not exist, neither is there a shared vision of the new partnerships. "The first question that arises in this debate, is what is understood by the term public-private partnership. Even though many UN leaders have been promoting closer interactions with the commercial sector and wealthy business figures under the partnership label for years, there is in fact no single agreed-upon definition within the UN system."¹⁰

⁶ WHA 27.52. In May 1974, The WHA adopted Resolution WHA 27.52, a brief document that called for intensification of research on Tropical Diseases.

⁷ See UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases, *Making a Difference – 30 Years of Research and Capacity Building in Tropical Diseases* (2007).

⁸ S. Moon, "Medicines as Global Public Goods: The Governance of Technological Innovation in the New Era of Global Health", *GHG*, V. II, N. 2 (F2008/S2009).

⁹ J. Love, Implementation of the Workplan for the Period of 2008-2010 Endorsed by the Human Rights Council in Resolution 9/3, A/HRC/12/WG.2/TF/CRP.4/Rev.1, 18 June 2009, <http://keionline.org/sites/default/files/A-HRC-12-WG2-TF-CRP4-Rev1.pdf>.

¹⁰ J. Richter, op. cit., pages 42 and 43.

It should be noted that the report of the UN Secretary General on “Enhanced cooperation between the United Nations and all relevant partners, in particular the private sector” (August 2003) makes the following definition: “Partnerships are commonly defined as voluntary and collaborative relationships between various parties, both State and non-State, in which all participants agree to work together to achieve a common purpose or undertake a specific task and to share risks, responsibilities, resources, competencies and benefits.”¹¹

I.2 Views of the UN Global Compact

The UN Global Compact is a strategic policy initiative with private sector corporations that are committed to aligning their operations and strategies with universally accepted principles in the areas of human rights, labour, environment and anti-corruption. “The Global Compact asks companies to embrace universal principles and to partner with the United Nations. It has grown to become a critical platform for the UN to engage effectively with enlightened global business.”^{12,13}

According to a report commissioned by the UN Global Compact “there has been a tendency, within the United Nations system and elsewhere, to use the concept of partnership very loosely to refer to almost any kind of relationship.”¹⁴

The UN Global Compact Initiative asks companies to embrace, support and enact, within their sphere of influence, 10 principles in the areas of human rights, labour standards, the environment and anti-corruption (see Box 1). The WHO however, does not participate in the UN Global Compact.

As one of the UN agencies with the largest number of PPPs, it is paradoxical that the WHO is not one of the agencies that signed into this initiative and none of the 10 principles on which the “core values” of the initiative are based refers to Public Health or to the right to access to health care.

I.3 PPPs in Public Health

The most cited definition of PPPs in the area of public health comes from Kent Buse and Gill Walt¹⁵: “a collaborative relationship which transcends national boundaries and brings together at least three parties, among them a corporation (and/or industry association) and an

¹¹ Quoted by Richter, J., “Public-Private Partnerships and International Health Policy-making”, ISBN 951-724-464-9. Available from <http://formin.finland.fi/public/download.aspx?ID=12360&GUID=%7B3556FE5F-6CBC-4000-86F3-99EBFD2778FC%7D>, page 6.

¹² UN Secretary-General Ban Ki-moon, www.unglobalcompact.org.

¹³ The UN Global Compact is participated in by the following core UN agencies:

Office of the High Commissioner for Human Rights

United Nations Environment Programme

International Labour Organization

United Nations Development Programme

United Nations Industrial Development Organization

United Nations Office on Drugs and Crime

United Nations Entity for Gender Equality and the Empowerment of Women

See: <http://www.unglobalcompact.org/AboutTheGC/>.

¹⁴ Quoted by Richter, J., *op. cit.*, p. 44.

¹⁵ WHO does not have an official definition of Health PPPs.

intergovernmental organization, so as to achieve a shared health-creating goal on the basis of a mutually agreed division of labour”¹⁶.

Box 1

Principles of the UN Global Compact Initiative¹⁷

Human Rights

- Principle 1: Businesses should support and respect the protection of internationally proclaimed human rights; and
- Principle 2: make sure that they are not complicit in human rights abuses.

Labour

- Principle 3: Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining;
- Principle 4: the elimination of all forms of forced and compulsory labour;
- Principle 5: the effective abolition of child labour; and
- Principle 6: the elimination of discrimination in respect of employment and occupation.

Environment

- Principle 7: Businesses should support a precautionary approach to environmental challenges;
- Principle 8: undertake initiatives to promote greater environmental responsibility; and
- Principle 9: encourage the development and diffusion of environmentally friendly technologies.

Anti-Corruption

- Principle 10: Businesses should work against corruption in all its forms, including extortion and bribery.

For Buse and Walt the collaboration should be between “at least three parties”, because many of the PPPs involved in public health, such as the Global Alliance for Vaccines and Immunizations (GAVI), the Global Alliance for Improved Nutrition (GAIN) and the Global Fund to Fight AIDS, Tuberculosis and Malaria, include representatives of nongovernmental organizations (NGOs). This “at least three parties” definition was always defended by the WHO Director General Gro Harlem Brundtland: “In a world filled with complex health problems, WHO cannot solve them alone. Governments cannot solve them alone. Nongovernmental organizations, the private sector and Foundations cannot solve them alone (...) Whether we like it or not, we are dependent on the partners (...) to bridge the gap and achieve health for all.”¹⁸

¹⁶ Buse, K. and G. Walt, “Global Public Private Partnerships for Health: Part I- a new development in health?” (January 2000), p. 4. Available from http://www.scielosp.org/scielo.php?pid=S0042-9686200000400019&script=sci_arttext.

¹⁷ <http://www.unglobalcompact.org/AboutTheGC/TheTenPrinciples/index.html>.

¹⁸ Brundtland, G.H., “Address by Dr Gro Harlem Brundtland, Director-General, to the Fifty-fifth World Health Assembly, Geneva, Monday, 13 May 2002”.

According to J. Richter¹⁹ partnerships in public health include interaction such as:

- fundraising – requesting, accepting or channelling corporate donations in cash or in kind;
- negotiations or public tenders for lower product prices (for example, of pharmaceuticals and vaccines);
- research collaborations;
- negotiations, consultations and discussions with corporations and their business associations about public health matters;
- co-regulatory arrangements to agree and implement ‘voluntary’ (that is, legally non-binding) codes of conduct;
- corporate social responsibility projects (many of which are, in fact, cause-related marketing - or other strategic sponsorship projects); and
- contracting out of public services, such as water supplies.

Brundtland’s invitation to the private sector was greatly influenced by what Buse and Walt called “the growing disillusionment with UN and its agencies. Concerns about the effectiveness of UN, including increasing evidence of overlapping mandates and interagency competition, led directly towards the establishment of partnerships to deal with specific and limited issues.”²⁰

The WHO’s lack of credibility during the final years of the administration of WHO Director-General Nakajima (1988 to 1998) and its financial problems due to the developed countries’ refusal to increase the Organization’s regular budget led to the Brundtland administration’s call for the private sector to help in solving these two problems. This included bringing into the WHO Senior people who had worked for transnational pharmaceutical companies.

Brundtland’s call to the private sector was very “productive”; upon her arrival the 1998-1999 WHO Programme Budget was US\$ 1.8 billion and in 2003, by the end of her term, the WHO Programme Budget went up to US\$ 2.8 billion, all from voluntary (public and private) contributions. This trend continued and increased during successive WHO administrations. By 2012-2013, the WHO Programme Budget has more than 80 per cent—US\$ 3.9 billion—coming from voluntary contributions and not from regular quotas from Member States. PPPs in health have been promoted in such a way that the WHO itself has become a big public/private partnership. The WHO, in this sense, has become a public multilateral agency that is primarily funded by the private sector and/or voluntary specified contributions.

Thus, in the view of Buse and Walt there has been an “honest recognition by the public sector of the unique, unrivalled monopoly of the pharmaceutical industry in drug and vaccine development: They own the ball. If you want to play, you must play with them”.²¹ However according to G-Finder 2012 the public sector is still first in terms of research and

¹⁹ Richter, J., “Public-Private Partnerships and International Health Policy-making”, ISBN 951-724-464-9. Available from <http://formin.finland.fi/public/download.aspx?ID=12360&GUID=%7B3556FE5F-6CBC-4000-86F3-99EBFD2778FC%7D>, page 7.

²⁰ Buse, K. and G. Walt, “Global Public Private Partnerships for Health: Part I- a new development in health?” (January 2000), p. 4. Available from http://www.scielosp.org/scielo.php?pid=S0042-96862000000400019&script=sci_arttext.

²¹ Ibid, p. 5.

development (R&D) for neglected diseases and 64 per cent of PDP funding comes from the public sector. But, if the industry “owns the ball” it would be important to ensure that there is a referee to supervise the game.

According to Cattai, economic globalization may also have provided impetus to the private sector to enter into partnerships with the UN: “Business believes that the rules of the game for the market economy, previously laid down almost exclusively by national governments, must be applied globally if they are to be effective. For that global framework of rules, business looks to the United Nations and its agencies”²². The problem with this type of analysis is what would be the role of national governments. A key aspect of the debate over the WHO reform launched by the current Director-General Margaret Chan is what the role of the private pharmaceutical industry will be, as major shareholders. Most of the voluntary contributions to the WHO budget are specified and in this sense donors are fixing the priorities of the Organization.

The Global Forum for Health Research²³ defines a partnership as “... a group of allies sharing the goals, efforts and rewards of a joint undertaking”. The allies, however, may have different levels of knowledge, different interests, and different levels of influence in terms of health policies. And not only different points of view but at times contradictory points of view. Commercial interests do not necessarily coincide with public interests and combining these two sometimes contradictory or incompatible interests is not always easy. Which comes first, business or health?

As Buse and Walt state “Allies may use different terms to describe themselves: as partners in a partnership to one audience and as donors to another. The International AIDS Vaccine Initiative describes itself as having just five partners, but has an additional 17 organizational donors (not including many individuals). The role of any one partner may change over time, from active to passive. Partners may be defined by organization or individual, and might also be involved at different levels within the partnership. For example, although the corporate sector might not be involved in the governing bodies it may act as an integral partner at a task force, expert committee or other level”²⁴.

This is where the debate on WHO reform has come over the last two years: what will be the role of new funders in the WHO governing bodies? Since the Brundtland administration, many private partners are part of task forces, expert committees and advisory groups; what is now at stake is what will be their role in the Executive Board and the World Health Assembly as they now provide 80 per cent of the Organization’s budget.

²² Cattai, M. S., “Business and the UN: common ground”, *ICC Business World* (Paris, 3 August 1998).

²³ Global Forum for Health Research, “The 10/90 Report on Health Research 2000” (Geneva, The Global Forum for Health Research, 2000, ISBN 2-940286-01-9).

²⁴ Buse, K. and G. Walt, op. cit., p. 3.

I.4 Different Types of PPPs²⁵

The following types of PPPs may be distinguished:

- Product-based PPPs consist primarily of drug donation programmes, for example, AIDS (acquired immunodeficiency syndrome) medicines. Drug donation programmes are generally established after the discovery that an existing drug (for animals or humans) is found to be effective in the treatment of some condition for which there is limited effective demand, due to lack of willingness and ability to pay, as was seen with AmBisome for the treatment of leishmaniasis. These types of partnerships are usually initiated by the private sector and the objective is to market their ethical concerns and social responsibility. This objective is not always guaranteed, as medicines donation partnerships have been subject to controversy, and seen sometimes as a market entry strategy or a mechanism for dependency-creation.
- Product-development PPPs differ from product-donation partnerships in a number of respects. They are not limited to specific countries and they are generally initiated by the public sector. Product-development PPPs usually require the public sector to assume a number of risks associated with product discovery, development and/or commercialization for which usually the government provides some subsidies. Pharmaceutical Companies may engage in product-development partnerships to obtain a subsidy for research or to pursue their own longer-term interests, in the emerging economies, for instance.
- The issues-based PPPs are a more diverse group. Some have arisen to overcome market failures, such as the Malaria Vaccine Initiative, the Roll Back Malaria Global Partnership or the Stop TB Initiative.

Trying to classify the different types of PPPs is not very helpful if one takes into account that, as with PDPs, within each category the PPPs themselves can be completely different. Common standards do not exist.

For example, in many cases agreements entered into with PPPs are confidential, or as it is the case with the TDR in the WHO, there is no clear and transparent policy on how the intellectual property aspect of the products will be dealt with once developed by the PPP. Should they be patented or not? And if they should be patented, by whom? Should the PPP seek a patent? Or should a private partner of the PPP be allowed to apply for patents as sometimes happens in the case of TDR at the WHO.

All of the foregoing brings us to ask whether the vision and the objectives of PPPs in the health sector are clear and if they are the most appropriate way to address the current challenges of the health sector.

²⁵ Buse, K. and G. Walt, "Global Public Private Partnerships for Health: Part II - What are the health issues for global governance?", *WHO Bulletin* 78 (5), 2000. Available from http://www.scielosp.org/scielo.php?pid=S0042-96862000000500015&script=sci_arttext.

I.5 PDPs

“Product Development Partnerships (PDPs) are one variant of public private partnerships focused on improving health in developing countries. PDPs are focused on product discovery and development, as opposed to partnerships focused exclusively on delivery of existing technologies (so called “access partnerships”) or health service delivery.”²⁶

Over the last decade the number of PDPs increased significantly in the area of medicines and diagnostics. From a research project funded by the Swiss Network for International Studies (SNIS) implemented by the École Polytechnique Fédérale de Lausanne (EPFL) and the South Centre, 23 PDPs have been identified.²⁷

The figures presented by G-FINDER 2012 indicate that there is a relatively important investment dedicated to PDPs in the order of US\$3,000 million (2011). However, these figures should be taken with caution as they are usually taken from pharmaceutical industry reports which are known for the lack of transparency in relation to the cost of R&D and there are difficulties for verifying the figures reported.

In relation to the cost of R&D reported by industry an article in the journal *BioSocieties* (Feb. 2011), a publication of the London School of Economics (LSE), argued that the real cost of R&D is, in fact, a fraction of the commonly cited estimates. According to the authors, the average cost of R&D for developing a medicine varies between US\$13 million and US\$ 204 million depending on the type of product. The authors estimated an average cost of US\$43.4 million for the R&D of every new drug. They concluded that: “this is very far from the US\$802 million or US\$1.3 billion claimed by the industry”.²⁸

According to DNDi²⁹ the cost of R&D for a new product ranges between US\$40 to 50 million.³⁰

If the figures claimed by the “research based industry”, can be up to 20 times more than the real cost, as Donald W. Light and Rebecca Warburton have pointed out, it is evident then that the 2012 G-FINDER figures must be considered with care, although they may be used as an indicator, since unfortunately, it is practically the only consolidated information on the current PDPs.

²⁶ Cheri Grace, “Product Development Partnerships (PDPs): Lessons from PDPs established to develop new health technologies for neglected diseases” (London, HDRC DFID, 2010).

²⁷ The list of PDPs includes, in alphabetical order: AERAS, Consortium for Parasitic Drug Development (CPDD), Contraceptive Research and Development (CONRAD), Dengue Vaccine Initiative (DVI), Drugs for Neglected Diseases (DNDi), European Vaccine Initiative (EVI), Foundation for Innovative New Diagnostics (FIND), Global Alliance for TB Drug Development (TB Alliance), HIV Vaccine Trials Network (HVTN), Infectious Disease Research Institute (IDRI), Innovative Vector Control Consortium (IVCC), International AIDS Vaccine Initiative (IAVI), International Partnership for Microbicides (IPM), International Vaccine Institute (IVI), Malaria Vaccine Initiative (MVI), Medicines for Malaria Venture (MMV), Meningitis Vaccine Project (MVP), Microbicides Development Programme (MDP), One World Health (iOWH), Pediatric Dengue Vaccine Initiative (PDVI), Sabin PDP, South African AIDS Vaccine Initiative (SAAVI), and Tuberculosis Vaccine Initiative (TVI).

²⁸ Donald W. Light, and Rebecca Warburton, “Demythologizing the high costs of pharmaceutical research”, *BioSocieties*, a publication of the LSE (Feb. 2011). *BioSocieties* advance online publication, 7 February 2011; doi:10.1057/biosoc.2010.40.

²⁹ Drugs for Neglected Diseases Initiative.

³⁰ Pecoul, Bernard, « The DNDi Cost Model », communication at the International Seminar 2013 Building a Global Health Social Contract for the 21st Century, Barcelona, November 2013.

“In 2011, total Industry or PDP’s reported funding for neglected disease R&D was \$3,045m. (...) The three ‘top tier’ diseases – HIV/AIDS, malaria and tuberculosis (TB) – again received approximately one-third to one-fifth of total global neglected disease R&D funding each, with HIV/AIDS receiving 33.8 per cent, malaria 18.4 per cent and TB 17.3 per cent.”³¹

According to information from G-FINDER 2012, investment in R&D for neglected diseases covers:

- 31 neglected diseases
- 134 product areas for these diseases, including drugs, vaccines, diagnostics, microbicides and vector control products
- Platform technologies (e.g. adjuvants, delivery technologies, diagnostic platforms)
- All types of product-related R&D, including basic research, discovery and preclinical, clinical development, Phase IV and pharmacovigilance studies, and baseline epidemiological studies

Most of the PDPs present themselves as not-for-profit institutions. Their objective is product development of medicines, vaccines and diagnostics for neglected diseases. The majority are based on a “virtual R&D facility”: very little or no in-house R&D activities. They work with different partners from the public and private sector such as government institutions, academia, research organizations, UN agencies such as WHO, the pharmaceutical industry. The majority of their “new” products are only incremental innovations. In general they have a relatively small core staff, a board and advisory committees. 50 per cent of current PDPs receive funds from the Bill & Melinda Gates Foundation (BMGF)³². And the BMGF as a private donor is part of the majority of the PDPs’ boards and advisory committees.

According to G-FINDER 2012, the public sector continued to play a key role in the PDP for neglected disease R&D, providing almost two-thirds (64.0 per cent) of global funding, predominantly from the public sector of the developed country governments. The philanthropic sector contributions (18.7 per cent) were closely matched by investments from industry (17.2 per cent). 15 PDPs out of 23 are funded by the BMGF.

In the PDP of Malaria Vaccine Initiative (MVI) by PATH,³³ the Gates Foundation gave GlaxoSmithKline (GSK) US\$200 million. The RTS,S AS01 candidate malaria vaccine is already in clinical trials phase III and the Glaxo Chief Executive Officer (CEO), Andrew Witty, announced that if clinical trials are successful, the vaccine will be patented and the price will be the cost plus a “modest” 5 per cent of the cost. Although the results of clinical trials were disappointing (only 31 per cent of efficacy against clinical malaria and 37 per cent of efficacy against severe malaria in the group of infants, 6 to 12 weeks of age at the date of vaccination), three remarks should be made regarding Witty’s announcement: Firstly, is it acceptable from ethical and public health perspectives that a vaccine be patented? When Jonas

³¹ G-FINDER 2012, Executive Summary.

³² R&D Financing and Incentives at the Product Development Partnership (PDP) Forum, 24-26 May 2011, Washington. Available from <http://healthresearchpolicy.org/blog/2011/jun/17/rd-financing-and-incentives-pdp-forum>.

³³ The PATH Malaria Vaccine Initiative (MVI) is a global programme established at PATH through an initial grant from the Bill & Melinda Gates Foundation.

Salk, inventor of the poliomyelitis vaccine and winner of the Nobel Prize in medicine was asked in a televised interview who owned the patent to the vaccine, Salk replied: “There is no patent. Could you patent the sun?”³⁴. As a second comment, the 5 per cent of the mentioned benefits means that all the PDPs are not really “not-for-profit” as they are generally characterized. Finally, regarding the “the cost plus 5 per cent of benefit”, it is not clear whether we are going to know one day what the real cost of production is.

In connection with the same Gate Foundation/Glaxo partnership, when Dr. Pierre Druilhe, former chief of the Parasitology Laboratory of the Institut Pasteur, was asked if he considered the vaccine against malaria, the RTS,S AS01 vaccine candidate, a failure because of such low coverage in clinical trials, he stated that Glaxo would be in any case happy for the adjuvants that it developed as an outcome of the project and patented which can be used for other products GSK may commercialize.³⁵ Therefore, during research paid for by public-private partnerships, a partner of the PDP can innovate and patent products that are not for neglected diseases and later commercialize them. In contracts (which are usually confidential) regarding the PDPs, for the use of some of the pharmaceutical companies’ compounds, it is always stipulated that of what is found, whatever is not used for neglected diseases will remain the intellectual property of the drug company that has licensed or ceded its compounds. Therefore PDPs (in principle not-for-profit) can use public-private funding to identify substances that can then be commercially exploited by the industry.

With regard to PDPs, if we consider their limited scale (concentrated in neglected diseases), the majority of them dealing with minor innovations, the diversity in the way they function and their objectives not necessarily being public health oriented³⁶, one cannot really speak of a new model, but rather as an experiment. The operation of PDPs shows that:

- The current R&D model based on the patent system is not the only option, nor the most efficient,
- the cost of R&D is only a fraction of what is currently claimed by the industry, and
- the way that intellectual property rights are being used is causing more impediment than incentive to innovate.³⁷

A recent IP Watch study concluded that: “It could be summarised that the efficiency results of PDPs are mixed. On the one hand, PDPs do provide results, there are more and more used and demonstrated qualitative achievements. On the other hand, it is striking to see that PDPs attract most of the resources but the money invested is not proportionate with the results they lead to...The PDP mechanism then appears like an interesting step forward but one may

³⁴ « See It Now », CBS, 12 avril 1955: interview du Dr. Jonas Salk inventeur du premier vaccin contre la poliomyélite, par le journaliste Edward R. Murrow. In “The vaccine according to Bill Gates”, Documentary film 52’ by Frédéric Castaignède, a ZED production for ARTE French and German TV, 2013.

³⁵ See “The vaccine according to Bill Gates”, Documentary film 52’ by Frédéric Castaignède, a ZED production for ARTE French and German TV, 2013.

³⁶ Representatives of private companies who are members of PDPs boards participate on the definition of priorities, policies and strategies.

³⁷ An investigation by the EU on the pharmaceutical sector (2009) found that in 2000-2007, a single medicine may be protected by up to 1,300 patents or pending patent applications. Available from <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>.

wonder if in itself, this tool is enough to achieve the public health needs of most developing countries.”³⁸

Box 2

How PDPs can be a Laboratory of a “New Model”. DNDi Case

The Drugs for Neglected Diseases initiative (DNDi) is as an independent, international not-for-profit R&D organization working to deliver new treatments for the certain neglected diseases, in particular sleeping sickness (human African trypanosomiasis), Chagas disease, leishmaniasis, filarial and malaria. DNDi is also carrying out research for a paediatric HIV/AIDS medicine.

DNDi was founded by Médecins Sans Frontières/Doctors Without Borders (MSF), Indian Council of Medical Research, Kenya Medical Research Institute, Brazil’s Oswaldo Cruz Foundation, Ministry of Health of Malaysia, and Institut Pasteur in France, with the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) as a permanent observer.

DNDi does not have its own laboratories or manufacturing facilities. Consequently DNDi leverages partners’ specific assets, capacities, and expertise to implement projects at all stages of the R&D process, integrating capabilities from academia, public-sector research institutions, particularly in neglected disease-endemic countries, pharmaceutical and biotechnology companies, as well as non-governmental organizations including other PDPs, and governments worldwide. While investing in drug discovery for entirely new drugs, the imperative to respond to urgent patient needs guided a short-term strategy, implemented immediately upon the start of activities, and focused on improving existing treatments. The latter, as part of the core mission of the organization, aimed to deliver innovations to neglected populations as quickly as possible, notably opportunities that others were unable or unwilling to seize.

Within 10 years and with a budget of approximately EUR 210 million, the initiative has established a solid drug development pipeline, including 12 new chemical entities (NCEs), either in pre-clinical or clinical development and delivered six new treatments for neglected diseases (two fixed-dose antimalarials (ASAQ and ASMQ); nifurtimox-eflornithine combination therapy (NECT) for late-stage sleeping sickness; sodium stibogluconate and paromomycin (SSG&PM) combination therapy for visceral leishmaniasis in Africa; a set of combination therapies for visceral leishmaniasis in Asia; and a paediatric dosage form of benznidazole for Chagas disease.

According to DNDi’s funding policy established in 2003, it seeks to diversify funding sources, maintain a balance of public and private support, minimize as much as possible earmarked donations, and ensure that no one donor contributes more than 25 per cent of the overall budget.

³⁸ Tiphaine Nunzia Caulier for Intellectual Property Watch, *Special Feature: A Look At Product Development Partnerships And Innovation For Neglected Diseases*, Published on 3 July 2013. Available from <http://www.ip-watch.org/2013/07/03/special-feature-a-look-at-product-development-partnerships-and-innovation-for-neglected-diseases/>.

Since 2003, DNDi has received support from a wide range of donors, including: governments, such as those of the United Kingdom, the Netherlands, Germany, France, Switzerland, and Spain; MSF as a founding partner; private philanthropic organizations, including the Bill & Melinda Gates Foundation and Wellcome Trust; and also through innovative financing mechanisms such as UNITAID.

II. CONTRIBUTION VERSUS RISKS OF PPPs AND PDPs IN HEALTH

The PPPs in health were initiated based on the assumption that they create a “win-win” situation. However, Gro Harlem Brundtland in her second round table with the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) on 15 November 2000 stated that: “I recognize that the differences in the objectives and accountability of the research based pharmaceutical industry and WHO mean that joint working is not easy.”³⁹

This assumption of a “win-win” situation contributed to the rapid increase in the number of health PPPs without clear mechanisms for evaluation. If everyone wins there should not be too much danger, however, if in these alliances there are “winners” and “losers” one must evaluate who wins and loses what.

According to Richter, PPPs lead to certain “trade-offs” that make it necessary to see what the risks are in terms of public policies and interests. These risks include:

- commercial actors using the interaction with UN agencies to gain political and market intelligence information in order to gain political influence and/or a competitive edge;
- business actors using the interaction to set the global public agenda for commercial interest;
- business actors using the interaction to ‘capture’ and/or sideline intergovernmental public agencies; as was, for example, the purchase of massive amounts of vaccines for the H1N1 flu;
- weakening of UN agencies efforts to hold transnational corporations publicly accountable to society for their practices and actions.

II.1 Guidelines on Interaction with Commercial Enterprises

The private sector and the WHO have tried to develop codes of conduct and guidelines that some have called: “The development of safeguards within the WHO”.⁴⁰

In 1999 the WHO developed “WHO Guidelines on interaction with Commercial Enterprises”. This document, criticised by some NGOs, was presented in 2000 to the WHO Executive Board which did not approve it. However the WHO Director-General “decided that formal approval of the Guidelines by the Member States was not needed. She adopted the

³⁹ Brundtland, Director General of WHO, Opening remarks, IFPMA roundtable, Geneva, 15 November 2000.

⁴⁰ Richter, J., “Public-Private Partnerships and International Health Policy-making”, *op. cit.*, pages 11 to 17.

revised November 2000 Guidelines as a ‘managerial tool’ for WHO without change”⁴¹. Comments and concerns from developing countries and NGOs were simply ignored.

The entire process of development and approval of the WHO Guidelines on interaction with Commercial Enterprises and all the documents on conflict of interest in WHO relations with the private sector has been a slow process that has gone on for over 10 years now and is still not concluded. Furthermore “Not enough information is available to evaluate whether the situation has fundamentally changed in 2011-2012, when Member States are again being urged to approve a path towards closer interactions with the private sector.”⁴²

During the management of the A (H1N1) pandemic outbreak in 2009-2010, as well as in the debate on the reform of the WHO launched by the current Director General, a recurring issue was the possible conflicts of interest. “As reported by Deborah Cohen and Philip Carter, in the *BMJ*, some of the experts advising the WHO on the pandemic had declarable financial ties with drug companies that were producing antivirals and influenza vaccines. According to Cohen and Carter, the WHO’s guidance on the use of antivirals in a pandemic was authored by an influenza expert who, at the same time, was receiving payments from Roche, the manufacturer of Oseltamivir (Tamiflu), for consultancy work and lecturing.”⁴³ Another recent example was Dr. Chan’s defence of the presence of a Novartis representative on the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, which discussed new mechanisms on how to finance pharmaceutical R&D.⁴⁴

Dr. Chan dismissed concerns over conflicts of interest and undue industry influence on several occasions. She argued that she is ‘transparent’ about industry representatives on particular advisory committees and “told NGOs who criticized multi-stakeholder approaches (...) that ‘her’ Member States have told her to do this.”⁴⁵

In November 2000, a seminar in Rome, co-sponsored by WHO, entitled "Global Public-Private Partnerships (GPPP) for Health and Equity", concluded that before moving forward there should be a broad analysis and justification for GPPP and it encouraged the WHO to: "examine the evidence for the pros and cons of GPPP, when they are appropriate and when not, and to define an open process about how to decide for or against partnerships...Furthermore the WHO should encourage the broadest possible range of inputs to this inquiry."⁴⁶

Ten years after at the Executive Board meetings in 2011 and 2012 there was a lively discussion on the Guidelines for Public Private Interactions (PPIs). Many members of the board expressed serious concerns about the potential of the for-profit sector to distort public health priorities and programmes.

In the financial crisis that the WHO is experiencing, the proliferation of PPPs and PDPs creates a situation where the WHO Secretariat’s ability to safeguard its multilateral, independent and public character will be compromised.

⁴¹ Ibid., page 14.

⁴² Richter, J., “WHO Reform and Public Interest Safeguards: An Historical Perspective”, *Social Medicine* (www.socialmedicine.info), page 141, Volume 6, Number 3 (March 2012).

⁴³ Velasquez, G., “The management of A (H1N1) Pandemic: An alternative view”, *Journal of Health Law*, Vol. 13, No. 2 (July August 2012), pages 123 to 136.

⁴⁴ See Beigbeder, Y., *L’OMS en péril* (Paris, Editions de Santé, 2011), page 36.

⁴⁵ Richter, J., “WHO Reform and Public Interest Safeguards: An Historical Perspective”, op. cit., page 144.

⁴⁶ Buse, K. and Waxman, A., “Public-private health partnerships: a strategy for WHO”, *Bull World Health Organ.* 2001, 79(8):748-54. Epub 2001 Oct 24.

III. MULTILATERALISM, PPPS AND WHO REFORM

For 50 years, the means of funding United Nations specialized agencies, including the WHO, was mainly public contributions by Member States. This permitted a sense of ownership of the organization on the part of Member States and the fixing of priorities, policies and strategies by the Member States.

In 1998, the WHO had a budget made of a little over 50 per cent of contributions coming from regular Member States. At present, ongoing regular and public contributions do not even cover 20 per cent of the organization's funding, leading the WHO to depend on public and private voluntary contributions coming from foundations, some states and the private sector or industry. The loss of control on funding diminishes the Organization's capacity to fix priorities and to make decisions.

At the Sixty-fourth World Health Assembly and at the Executive Board's 129th session (2011), three objectives were defined for WHO reform:

- “1. Improved health outcomes, with WHO meeting the expectations of its Member States and partners in addressing agreed global health priorities, focused on the actions and areas where the Organization has a unique function or comparative advantage, and financed in a way that facilitates this focus.
2. Greater coherence in global health, with **WHO playing a leading role**⁴⁷ in enabling the many different actors to play an active and effective role in contributing to the health of all peoples.
3. An Organization that pursues excellence; one that is effective, efficient, responsive, objective, transparent and accountable.”⁴⁸

Since the special meeting in November 2011 regarding WHO reform many documents have been produced by the Secretariat upon countries' request but many developing countries and a large majority of NGOs (not-for-profit organizations working in the health sector) have expressed their dissatisfaction with the direction that the said reform has taken. Many stakeholders insist that the WHO should play a leading role among the many different actors, but it is not clear how.

The recovery of the WHO public mission and its multilateral character and therefore its independence should be the starting point of any reform.

In the reform process in the last two years including the discussions at the 66th World Health Assembly (20-28 May 2013), WHO's priority setting process dominated the discussion.

The current real problem of the WHO is the increasing dependence on discretionary donors; and the inability to align the available resources with priorities and outputs agreed by

⁴⁷ Emphasis added.

⁴⁸ WHO Special session on WHO reform doc. (EBSS/2/2), 7 November 2011.

Member States. The WHO has lost implementation capacity, and coherence between priorities and the actual activities.

The switch in power from the WHA of Member States to donors seems inevitable based on the way that the debate on reform is taking place. Numerous PPPs are originated at the initiative of the donors and not necessarily arising from the priorities fixed by governing bodies. Donors in many cases act as “owners” of their own initiatives.

Various NGOs expressed their concerns again, before the Executive Board and the WHA in 2013. In its statement to the WHA, *Medicus Mundi* said: “Under the proposed arrangements, the Assembly will adopt a budget and the DG will try to persuade the donors to fund the budget. It seems unlikely that, just because of these new arrangements, the donors will suddenly reorient their perspectives and support the programs they have frozen until now. And once the gaps become evident, how will the DG fill in these gaps?”⁴⁹

With regards to the Financing Dialogue proposed as a form of financing the WHO (an annual meeting where all current funders, private and public, would give their pledges), the concern of NGOs is clear: “The proposed financing dialogue will not prevent the distortions of resource allocation arising from donor interests. Important areas of WHO’s work which do not attract donor funding will continue to be starved of funds.”⁵⁰

The Democratising Global Health Coalition on the WHO Reform (DGH)⁵¹ goes much further, questioning the role that the private sector may play in global health policy setting:

“We are concerned that the reform may undermine, rather than reinforce, WHO’s constitutional task. It may jeopardize the ability of the organisation to work for its mandate of the universal right to health by opening the door to corporate and private for-profit entities to take part into policy setting in global health. This runs counter to basic democratic principles. We advocate for clear regulations to be set in place to protect the WHO from undue private sector influence through the development of a comprehensive conflicts of interest policy.”⁵²

IBFAN⁵³ comments on WHO’s “engagement with non-state actors” (EB 133/16) on the 30th of May 2013, expressing their worries regarding the reform of WHO concerning PPPs: “The report does not define how will WHO principles applying to the agency’s

⁴⁹ Statement by *Medicus Mundi* International to the 66th session of the World Health Assembly on agenda item 11: WHO Reform delivered by Alice Fabbri, 2013.

⁵⁰ Statement by *Medicus Mundi* International and the People’s Health Movement to the 66th session of the World Health Assembly on agenda item 12.2: General Programme of Work delivered by Marianna Parisotto, May 2013.

⁵¹ Democratising Global Health Coalition on the WHO Reform (DGH) is a group of 8 NGOs:

Health Innovation in Practice (HIP)

International Baby Food Action Network (IBFAN)

Medico International

People’s Health Movement (PHM)

Third World Network (TWN)

WEMOS/*Medicus Mundi* International Network (MMI)

World Council of Churches (WCC)

World Social Forum on Health and Social Security

⁵² Democratising Global Health Coalition on the WHO Reform (DGH) CORE STATEMENT.

⁵³ The International Baby Food Action Network.

relations to non-state actors, as discussed in part 1, be carried over and implemented also in the global health governance, i.e. application of the same rules in e.g. partnerships hosted by WHO, International Health Partnership (IHP+) and other health alliances to ensure greater coherence in global health.”⁵⁴

The loss of the public and multilateral character of the WHO, may compromise the norms and standards set in of the Organization. How can WHO effectively and independently regulate and control for instance, the pharmaceutical or the food industries if these industries are the funders of the Organization?

In recent years a common “agenda” is being developed between the WHO, WIPO (World Intellectual Property Organization) and the WTO (World Trade Organization) although the objectives and mandate of the three organizations are different and, in some cases, contradictory. The promotion of patents (WIPO) can go against access in the case of medicines (WHO).

One would expect that the multilateral agency for health would set rules and priorities for PPPs and PDPs but unfortunately this does not seem to be the case. Moreover, the multiplication of these PPPs and PDPs without clear rules and without control or coherence risks aggravating instead of solving the problem.

IV. ARE PPPs AND PDPs THE ONLY SOLUTION?

Gro Harlem Brundtland’s statement “Whether we like it or not, we are dependent on the partners”⁵⁵ sends the message that there are no alternatives to the shift towards PPPs and PDPs. Until the partnerships came into fashion it was recognized that some interactions in the health sector with the private sector were useful, others harmful and best avoided, and we realize today that all interactions with business actors need to be carefully assessed and monitored.⁵⁶

PPPs and PDPs in health are voluntary exercises started by donors from developed countries. They are the new form of aid to the countries of the global South. The North decides what the South needs... More than financial, the problem is how the global health relations are structured.

PPPs and PDPs are still a kind of humanitarian aid that emerged after the colonial period; the only difference is that they give more power to control the implementation avoiding, as before, to question the philosophy of the North-South cooperation. It is not intended at any time to end these partnerships, but it would be important to think of some measures which can help to better ensure that public-private partnerships are guided by public interest such as:

⁵⁴ IBFAN brief comments on WHO’s engagement with non-state actors (EB 133/16), Agenda item 5 to be discussed at the 133th EB (29-30th May 2013).

⁵⁵ Brundtland, G.H., “Address by Dr Gro Harlem Brundtland, Director-General, to the Fifty-fifth World Health Assembly, Geneva, Monday, 13 May 2002”.

⁵⁶ Richter, J., “Public-private Partnerships for Health: A trend with no alternatives?”, *op. cit.*

- Formulate general rules, criteria and objectives that are clearly public health oriented
- Define a clear understanding of what are PPPs and PDPs
- Assuring that PPPs and PDPs are initiated on the basis of developing countries' needs and not, for instance, to show "social responsibility of the private sector" as a marketing strategy
- Intellectual Property (IP) issues related to final products developed should be transparently defined in advance
- Health Innovation alternatives must be always clearly linked to ACCESS to the new needed products
- Overlap and competition between "not-for-profit" entities in the health sector should be avoided

Some elements of the PDP's can be interesting and useful for the estimation of the real R&D cost, for instance, but if the search is for a "new model", PDPs are far from being that model; they are an experiment that can help to find new alternatives. One of the complexities of PDPs which still not clear is the treatment of intellectual property, the dilemma between innovation and access.

In May 2012, the WHA adopted a resolution that may change the rules of the game. The Resolution requested the Director General to organize a meeting of Member States "that will thoroughly analyse the report and the feasibility of the recommendations proposed by the CEWG"⁵⁷. This experts' report proposes to re-examine the funding and coordination of pharmaceutical R&D to meet the health needs of developing countries. Its main recommendation is the negotiation of an international convention committing all countries to promote R&D, which the market alone is not enough to stimulate.

Article 19 of the WHO Constitution provides for "two-thirds of the World Health Assembly" for the adoption of such a treaty. The later could set up a public international fund, whose sustainability would derive from a compulsory contribution, adapted – and this is a major innovation – to the level of economic development of each country. The products of the research thus supported (transparently) by the fund would be considered as common goods of benefit to all.

Noting the failure of current incentives – patents – to generate sufficient R&D in the private and public sectors, the expert panel also suggested experimenting with innovation systems that are "open", not based on intellectual property. It mentions a number of "innovations based on open access knowledge": this expression defines the research activities which produce knowledge that can be reused freely without legal or contractual restriction or exclusivity.

In the first place, we find platforms for pre-competitive research, combined with open source instruments and free access. All teams from universities, government institutions and private laboratories benefiting from public funding could share their discoveries. Today, this is far from being the case: many research outputs of institutions are sold to private industry, which sometimes gets the patents on these products developed with public funds. Accordingly, the community pays twice for these products!

⁵⁷ 65th World Health Assembly, resolution WHA65.22 (p.37), Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, 26 May 2012.

The industry, whose set of new molecules at its disposal continues to dwindle, could also benefit from a revival of research. In addition, the open publication of results would facilitate the transfer of technology to developing countries. India offers an example of the "open source model for drug discovery" developed by the Council for Scientific and Industrial Research, which focuses on new therapies against malaria, tuberculosis and leishmaniasis.

V. CONCLUSIONS

PPPs like PDPs are far from truly being a new model to solve the problem of access to health, particularly in developing countries. The PDPs are more an experiment than a model. They may have some common characteristics like interaction between the public and private sectors, product development as an objective, virtual R&D⁵⁸ but their common principles and rules are not transparent.

The first and most important conclusion resulting from this brief analysis is the need to put a global moratorium on the creation of new PPPs and PDPs until WHO is able to use its authority to set clear rules and principles for the creation of new partnerships on global health.

In the health sector, PPPs are threatening the democratic, multilateral functioning on which the United Nations system and its specialized agencies such as the WHO are based. There are some concerns with the PDPs:

- Most of the products so far developed by PDPs are incremental innovations - "low-hanging fruit". There is no evidence yet that PDPs can deliver breakthrough innovations. There is the risk of "evergreening".
- Their capacity is quite modest.
- They are, in some cases, competing between themselves. This may result in overlapping and waste of resources. Duplication it is not necessarily bad in terms of promotion of competition, but in the case of not for profit initiatives, some collaboration would be important.
- Potential conflict of interest as the private sector is part of their boards and advisory committees.
- Based 100 per cent on donations. PPPs and PDPs are not sustainable on a long term basis.
- In the majority of PDPs it is not known what treatment will be given to intellectual property. Will the product be patented or not? What are the consequences that this can have on access?
- The "not for profit" character of PDPs is not completely clear; in some cases PDPs may just be a profitable investment in marketing the social responsibility of some companies.
- Patenting intermediate steps for non-neglected diseases, for commercial purposes, as is the case for PDP adjuvants for the malaria vaccine.
- They are all started by donors from the North who decide what the problems and the priorities of the South are.

⁵⁸ Not all of them.

- Some PDPs are only between two partners, like for instance the BMGF and GSK malaria vaccine. Other PDPs chose to have multiple private and public partners, as is the case of DNDi. It is clear that in terms of transparency and above all sustainability, the latter is preferable.⁵⁹ As mentioned before, 50 per cent of current PDPs receive funds from the Bill & Melinda Gates Foundation (BMGF). And the BMGF as a private donor is part of the majority of the PDPs' boards and advisory committees.⁶⁰

Talking about conflict of interest and filling out forms by individuals and/or private companies is not enough. One must ask whether PPPs and PDPs are the most appropriate route, whether their contribution is more significant than their risks, whether their growth is not complicating the problem and squandering funds due to overlap, and finally, whether there are no other, more coherent and efficient options to explore, such as a binding international treaty to finance R&D or an open source model of drug discovery.

⁵⁹ DNDi, is funded by more than 15 partners, most of them government, public entities or not for profit foundations.

⁶⁰ Op. cit. R&D Financing and Incentives at the Product Development Partnership (PDP) Forum, 24-26 May 2011, Washington. Available from <http://healthresearchpolicy.org/blog/2011/jun/17/rd-financing-and-incentives-pdp-forum>.



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ISSN 1819-6926