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Review of the Product Development Partnerships Fund 2011-2014

Final report to the Dutch Ministry of Foreign Affairs



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Table of Contents

Abbreviations	1
Executive summary	2
Introduction	3
Background, aim and scope of the review	3
The methodology	4
Structure of the report	5
1. Product Development Partnerships: background and model	6
1.1 Global burden of disease	6
1.2 Why and when Product Development Partnerships emerged?	6
1.3 Characteristics of the PDP model	7
1.4 The PDP Funders Group	8
1.5 Overall PDP funding	9
2. The PDP Fund 2011-2014	11
2.1 The main mission and objectives of the PDP Fund	11
2.2 Specifications of the 2011-2014 Grant Framework and selection	11
2.3 The seven PDPs funded	12
3. The current Dutch policy focus and other relevant policy areas	15
3.1 Current policy focus of MoFA	15
3.2 Other relevant policy areas	16
4. Review of MoFA funded PDP activities	18
4.1 Grant objectives and key achievements	18
4.2 Contribution to PDP Fund objectives	26
4.3 Contributions of the Dutch funding	27
4.4 Fit to the current policy focus	29
4.5 Sustainability	30
4.6 Collaboration	30
5. Assessment of the Grant Framework and funding mechanism	32
5.1 Financial analysis of MoFA funding	32
5.2 Added value of PDP funding	37
5.3 Effectiveness of the funding mechanism	38
5.4 Role of the private sector	38
5.5 Dutch perspective on academic, economic and societal relevance	39
5.6 Strengths and weaknesses of the funding mechanism	40
6. Conclusions and recommendations for the future	42
6.1 Limitations	42

6.2 Main conclusions	42
6.3 Recommendations	43
<hr/>	
Appendix A Terms of Reference	49
Appendix B Operationalisation of review questions	55
Appendix C Threshold criteria for funding eligibility	61
Appendix D List of interviewees	63
D.1 Representatives from the PDPs	63
D.2 Representatives of the Dutch government	64
D.3 Representatives of other PDP funders	64
D.4 Partner organisations of the PDPs	64
<hr/>	
Appendix E Interview topic guide	65

Table of Figures

Figure 1 Methodological framework of the review of the PDP Fund	4
Figure 2 Members of the PDP Funders Group (2014)	9
Figure 3 Evolution of overall PDP funding 2007-2012	10
Figure 4 General information of the seven PDPs funded.....	12
Figure 5 MoFA's priority themes, PDPs funded and associated budget.....	13
Figure 6 Overview of the focus (diseases and modalities) of the seven PDPs funded..	14
Figure 7 Relevant policies in the context of the PDP review	17
Figure 8 Overview of MoFA supported activities (proposed and implemented) of the PDPs ..	24
Figure 9 Evolution of total PDP funding (2007 – 2012, in Euro).....	32
Figure 10 Number of unique funders per PDP	33
Figure 11 PDP funding by disease (2009-2012) for 7 PDPs (all funders and MoFA) ..	33
Figure 12 Funding by type of product (all funders, 2009-2012).....	34
Figure 13 PDP funding sources, by country (2009-2012).....	35
Figure 14 PDP funding sources, by type of funder (2009-2012)	36
Figure 15 Breakdown of PDP expenditures (2012)	37
Figure 16 Dutch partner organisations for MoFA funded activities	39

Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ARV	Anti-retroviral
BMGF	Bill & Melinda Gates Foundation
DFID	United Kingdom Department for International Development
DGIS	The Netherlands Directorate General for International Co-operation
DNDi	Drugs for Neglected Diseases Initiative
EDCTP	European & Developing Countries Clinical Trials Partnership
FIND	Foundation for Innovative Diagnostics
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
HAT	Human African Trypanosomiasis (also known as sleeping sickness)
HIV	Human Immunodeficiency Virus
IAVI	International Aids Vaccine Initiative
IPM	International Partnership for Microbicides
LMIC	Low- and middle-income countries
MDG	Millennium Development Goal
MoFA	(Dutch) Ministry of Foreign Affairs
NCE	New Chemical Entity
NTD	Neglected Tropical Disease
POW PDP	Protection Options for Women Product Development Partnership
PDP	Product Development Partnership
PDP Fund	Product Development Partnership Fund 2011-2014
PFG	PDP Funders Group
R&D	Research & Development
Sabin	Sabin Vaccine Institute
SRHR	Sexual and Reproductive Health and Rights
STI	Sexually Transmitted Infection
TB	Tuberculosis
USAID	United States Agency for International Development
USFDA	United States Food and Drug Administration
WHO	World Health Organization

Executive summary

Every year, millions of people in the developing world are affected by poverty related diseases. Yet, in the absence of clear profit potential, pharmaceutical companies have been reluctant to invest in the development of new and better treatments to fight these diseases. In response to this market failure, in the mid-1990s Product Development Partnerships (PDPs) emerged. Although PDPs differ in form, they are broadly characterised as public-private collaborations that use some private sector approaches to tackle R&D challenges, target one or more poverty related diseases, have public health rather than commercial gain as their primary objective, and are focused on developing products suited for use in developing countries.

In 2010 the Dutch Ministry of Foreign Affairs (MoFA) awarded €69.6 million to seven PDPs for a period of four years (2011-2014) to stimulate the development of medicines, vaccines, diagnostics and other devices for poverty related diseases, increase access to these products, and contribute to research capacity development in developing countries. In the period July to October 2014 the Technopolis Group conducted an independent external review of MoFA's PDP Fund. The purpose was to assess the key achievements obtained with MoFA funding, and determine to what extent the fund has reached its objectives. The review will inform decision-making on continuation of the PDP Fund, and future funding priorities. The review is based on document analysis and in-depth interviews with representatives of the PDPs and other stakeholders.

MoFA awarded funding to a total of seven PDPs: Aeras, DNDi, FIND, IAVI, IPM, Sabin, and POW PDP. Collectively, these PDPs focus on improving the prevention, diagnosis and treatment of HIV/AIDS, tuberculosis and neglected tropical diseases (NTDs). With MoFA's support, they have successfully progressed a number of promising drug and vaccine candidates through their R&D pipelines. Several of these are currently in clinical trials. Other products, like the Woman's Condom and diagnostic tests for HIV/TB and visceral leishmaniasis, have reached or are about to reach the market. Additionally, by conducting some of their research activities in developing countries, the PDPs have stimulated local research capacity development. MoFA's support has also contributed to greater awareness about novel products to prevent HIV infection, such as microbicides and female condoms.

The PDP Fund is widely seen as an effective funding mechanism, and MoFA as a valued partner to the PDPs. MoFA has been credited for its forward-looking and flexible approach to R&D support. Nonetheless, it is at present not possible to state that the PDP Fund has fulfilled its objectives since many of the products are still under development. It will take many more years before these products can be expected to reach the market and the effects of the funding become visible. It is clear, however, that Dutch funding has enabled PDPs to conduct activities that otherwise would not have been possible. Dutch support for the PDPs has also been of significant importance to the PDPs because of the pioneering role the Netherlands has long played in R&D for NTDs and sexual and reproductive health and rights (SRHR). Many of the PDPs have successfully leveraged Dutch support to secure additional funding from other donors. Conversely, although not an explicit grant requirement, many Dutch universities, companies and NGOs have been vital partners in the PDP activities and have benefited from the funding.

In regards to continuation of the PDP fund and future funding priorities, several factors should be taken into account. Firstly, although in its current development policy MoFA prioritises primarily on SRHR-related activities, the work of the PDPs should equally be viewed against the broader international development agenda and the Dutch Top Sector policy Life Sciences & Health. Furthermore, the financial support for PDPs permits the Dutch government to participate in setting the global health and development agenda, and credibly advocate for increased commitment from other donors and the private sector. Lastly, in order to optimise the efficiency of its financial assistance, MoFA should carefully assess where along the R&D value chain this will have the greatest added value, and be willing to commit resources for a sufficiently long period.

Introduction

Although substantial progress has been made in reducing the burden of poverty related diseases across the world over the past decades; HIV/AIDS, tuberculosis (TB), malaria and neglected tropical diseases (NTDs) are still causing disproportionate rates of illness and death in developing countries^{1,2}. The establishment of the Millennium Development Goals (MDGs)³ in 2000 led to joint actions by the international community to increase investments in developing new treatments, diagnostics and preventive interventions addressing these major diseases⁴, because of the absence of traditional financial incentives for the private sector. This is one of many elements of the public health context of poverty-related diseases, which also includes matters such as local culture and living conditions, and local capacities and infrastructure for research, policy and health services. It is in this complex and dynamic context that several Product Development Partnerships (PDPs) have been established over the past 15 years. Through these PDPs public and private partners jointly aim to accelerate the development of new medical products and to ensure their availability in developing countries rapidly after being licensed, at affordable prices and in sufficient quantities⁵.

In 2010 the Dutch Ministry of Foreign Affairs (MoFA) awarded €69.6 million to seven PDPs for a period of four years (2011-2014), through a dedicated PDP Fund. These grants were awarded to promote research and development (R&D) on treatments, diagnostics and preventive interventions for HIV/AIDS, TB and malaria. The products and/or technologies being developed needed to be effective, safe, applicable and accessible for the poor population of developing countries.

Background, aim and scope of the review

The period of the current grant agreements between the seven PDPs and MoFA ends by December 2014. As stated in the Terms of Reference of this external review (included as Appendix A), the rationale has been defined as to feed future policy direction and decisions with evidence-based judgements on the achievements of the seven PDPs that have been funded and to provide suggestions for improvement of the current funding mechanism. A possible renewal of the Grant Framework will partially depend on the outcome of the review. Moreover, the review also provides input for the decision on funding priorities and possible changes in the funding mechanism, if the Grant Framework will continue.

The review focuses on whether the original aims of the PDP Fund have been achieved and what can be done better in the future. It also determines to what extent the PDPs and the funding instrument that has been applied (i.e. seven individual grants over a period of four years) meet their specific objectives in support of their general objective/outcomes.

¹ World Health Assembly (2010). Public Health, Innovation and Intellectual Property: global strategy and plan of action. Report of the Expert Working Group on Research and Development Financing (IGWG).

² United Nations (2013). The Millennium Development Goals Report 2013.

³ A complete overview of the Millennium Development Goals can be found at: <http://www.un.org/millenniumgoals/>.

⁴ EDCTP, RAND Europe and BAIRD's CMC (2014). Africa mapping: current state of health research on poverty-related and neglected infectious diseases in sub-Saharan Africa.

⁵ PDP Funders Group Briefing Paper 1 (2012), Product Development partnerships (PDPs): working together: collaborations between PDPs.

For the review three specific objectives are formulated, namely:

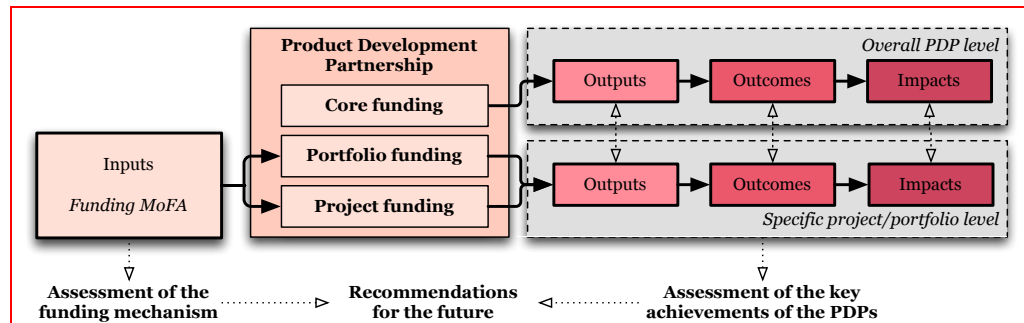
1. To assess the achievements of the PDPs in light of the policy objectives of the Dutch government funding (retrospective) and the relevance of the PDPs in light of the current policy focus (prospective);
2. To assess the extent to which the funding mechanism has been effective and efficient in reaching the (policy) goals both for the Dutch government and the PDPs;
3. To provide recommendations on possible renewal of the funding for PDPs, funding priorities and possible changes to the funding mechanism, as based on current and future (inter)national policies and funding challenges, taking into account the complex context in which PDPs operate.

It has to be mentioned that the review is mainly based on the analysis of information collected from and provided by the PDPs themselves. It is, however, not a comprehensive evaluation of the individual PDPs, nor is it meant to compare the PDPs with each other. This is consistent with the scope of the review, as agreed upon by MoFA.

The methodology

For each of the objectives listed above a number of specific review questions were formulated to guide the review. The operationalisation of these review questions is presented in Appendix B. The table shows the indicators for each question and the data sources and methods applied to answer the questions. Figure 1 below outlines the general methodological framework for the review.

Figure 1 Methodological framework of the review of the PDP Fund



Source: Technopolis Group (2014), based on Terms of Reference.

Assessment of the key achievements of the PDPs

For the assessment of the key achievements of the PDPs, all reports that were provided to MoFA during the current grant framework period have been collected and systematically analysed. These are the annual reports to the PDP Funders Group (2011 to 2013), additional financial information specifically related to the MoFA grant, and the general publicly available annual reports of the PDPs. Based on the information included in this documentation, the achievements of the PDP have been identified, focusing primarily on the following aspects:

- The composition of the product development pipeline (new treatments, vaccines, microbicides, diagnostics and devices developed or in development);
- Information on clinical trials (started, stopped, finished) on various patient groups;
- Research capacity on clinical development established/strengthened;

- Partnerships established/strengthened;
- Infrastructure developed/strengthened;
- Changes in governance structure and other processes and procedures.

This part of the review led to initial drafts of fact sheets for each PDP, summarising their key achievements in relation to the MoFA grant.

In addition to this desk research, a number of in-depth interviews were conducted with representatives from the PDPs (see Appendix D for an overview of all interviewees) in order to gather additional (qualitative) information on the following dimensions:

- The contribution and importance of the Dutch funding towards reaching the achievements set out in the report;
- The strengths and weaknesses of the Dutch funding mechanism, as compared to mechanisms operated by other funding organisations;
- The role of the Dutch funding in the overall work of the PDPs;
- The future of the PDPs, including their sustainability;
- Cooperation between the PDPs and with other (Dutch) organisations.

After the interviews were completed, the fact sheets were supplemented with insights from these interviews. The fact sheets were then shared with the PDPs for factual checking and completion of missing information. Hereafter, the finalised fact sheets informed a horizontal analysis across the seven PDPs funded, as presented in Chapter 4.

Assessment of the funding mechanism

In relation to the assessment of the PDP Fund as a funding mechanism, interviews were conducted with a number of stakeholders. These include Dutch policy makers at MoFA and representatives from the PDP Funders Group. Several representatives of Dutch PDP partner organisations (public partners receiving funding from PDPs, and private sector enterprises/entities that collaborate with PDPs) were interviewed as well. The annexes provide a list of all interviewees (Appendix D) and the interview topics (Appendix E). The results of the assessment of the funding mechanism are presented in Chapter 5.

Structure of the report

The report is structured as follows: Chapter 1 introduces the concept of Product Development Partnerships in terms of background and models in use. Chapter 2 describes the Product Development Fund 2011-2014 in terms of its mission and objectives, the specifications of the grant framework (including the selection procedure) and introduces the seven PDPs that have received funding. Chapter 3 outlines the current policy focus of the Dutch government in relation to the area in which the PDPs operate, in particular the policy of MoFA. The next two chapters form the core of the report: Chapter 4 reviews the seven PDPs on a number of aspects, including the key achievements in the period 2011-2014, the contribution to the PDP Fund objectives, the contribution of the Dutch funding to the PDPs, the fit to current policy objectives, sustainability and collaboration. Chapter 5 assesses the grant framework and funding mechanism in terms of the financial contribution of MoFA to the PDPs, the added value and effectiveness of the PDP Fund, the role of the private sector, contributions to Dutch society, and strengths and weaknesses of the Dutch funding approach. Finally, Chapter 6 presents the main findings and conclusions of the review, and formulates recommendations to MoFA for future support of the PDPs.

1. Product Development Partnerships: background and model

This chapter introduces the concept of Product Development Partnerships and provides some characteristics of the model and its varieties that are currently applied by various initiatives. It furthermore provides general information on the funding of the PDPs and the PDP Funders Group that has been established by different funding organisations around the globe supporting PDPs.

1.1 Global burden of disease

A recently published study by Murray and others provides a comprehensive estimation of the global burden of disease between 1990 and 2013, and offers an opportunity to assess whether accelerated progress has followed since the Millennium Declaration⁶. It shows that, in 2013, globally there were 1.8 million new HIV infections, 29.2 million prevalent HIV cases, and 1.3 million HIV related deaths. More optimistically, through interventions such as prevention of mother-to-child transmission (PMTCT) and antiretroviral treatment (ART), 19.1 million life-years were saved, of which around 70% in developing countries.

Including HIV-positive individuals, that same year the incidence of all-form TB was 7.5 million, with a prevalence of 11.9 million, and an estimated number of deaths reaching 1.4 million. Even in individuals who were HIV-negative alone, there were 1.3 million deaths directly attributable to tuberculosis.

Furthermore, globally, malaria cases and deaths grew rapidly from 1990, reaching a peak of 232 million cases in 2003 and 1.2 million deaths in 2004. Fortunately, some progress has been made in the fight against malaria: since 2004, child deaths from malaria in sub-Saharan Africa have decreased by 31.5%, whereas outside of Africa, malaria mortality has been steadily decreasing since 1990.

In addition to the 'big three' diseases (HIV, TB and malaria), infectious diseases like sleeping sickness, schistosomiasis, Chagas disease, or hookworm put a heavy toll on the health and socio-economic development of people in developing countries.

1.2 Why and when Product Development Partnerships emerged?

In 2004, the Initiative on Public-Private Partnerships for Health (IPPPH) published a paper that sketches the background against which public-private product development partnerships (PDPs) emerged⁷. It recounts how, at the end of the 20th century, several developments drove the establishment of these new initiatives that focus on the development of products for combatting diseases associated with poverty, through a multi-candidate/portfolio-based approach:

- A systematic analysis of the global burden of disease highlighted 'diseases associated with poverty' and deficiencies in tools to combat them;
- Pharmaceutical companies faced increasing R&D costs, consolidation, and greater competitive pressures, rendering them more averse to commercially risky or financially unattractive projects;

⁶ Murray CJ et al. (2014) Global, regional, and national incidence and mortality for HIV, tuberculosis, and malaria during 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 384(9947).

⁷ The Initiative on Public-Private Partnerships for Health, Global Forum for Health Research (2004). *Combating Diseases Associated with Poverty - Financing Strategies for Product Development and the Potential Role of Public-Private Partnerships*.

- Vaccines increasingly became ‘orphan’ products, despite their public health importance, especially in developing countries;
- The HIV/AIDS pandemic drew global attention to the need for greater action on the health needs of low- and middle-income countries (LMICs);
- Public sector and public interest organisations improved their understanding of industry motivations and product development expertise.

In the mid to late 1990s two initiatives, independent of each other, adopted the multi-candidate/portfolio approach as a means of enhancing the likely success in addressing the global health challenges through effective public-private collaboration. With support from the Rockefeller Foundation and the WHO Special Programme for Research and Training in Tropical Diseases (WHO/TRD), the International AIDS Vaccine Initiative (IAVI) and the Medicines for Malaria Venture (MMV) were established⁸. The Bill & Melinda Gates Foundation (BMGF) and the Rockefeller Foundation have been instrumental in setting up a number of other PDPs, such as the Global Alliance for Tuberculosis Drug Development (TB Alliance), the International Partnership for Microbicides (IPM) and the Paediatric Dengue Vaccine Initiative (PDVI). BMGF has also provided significant resources to existing PDPs, such as the Foundation for Innovative New Diagnostics (FIND), the Sequella Global TB Vaccine Foundation (currently Aeras), the Human Hookworm Vaccine Initiative (HHVI, which belongs to the Sabin Vaccine Institute) and the Malaria Vaccine Initiative (MVI). In addition, Médecins Sans Frontières (MSF) committed its 1999 Nobel Peace Prize fund to setting up a working group on innovation & access, which in 2003 led to the creation of DNDi with four institutions from endemic countries.

A decade on, many of the arguments that fuelled the creation of the first PDPs still apply. Research on poverty related diseases largely remains an area where, without the intervention of the public sector and philanthropic organisations, the market would fail. However, many more PDPs have since been created, or have expanded their operations, to help address these problems. Furthermore, large pharmaceutical companies like GlaxoSmithKline (GSK), Novartis, Eli Lilly, have increased their commitment to combatting NTDs and have set up their own public-private partnerships to accelerate drug discovery and development.

1.3 Characteristics of the PDP model

The IPPPH has identified a set of general characteristics that underpin PDPs such as those described previously⁹:

- They use some private sector approaches to tackle research and development (R&D) challenges;
- The majority of the partnerships work as virtual organisations;
- They target one or more ‘neglected diseases’ (i.e. HIV/AIDS, tuberculosis, malaria and neglected tropical diseases);
- They use, or intend to use, variants of the multi-candidate/portfolio management approach;
- Their primary objective is public health rather than commercial gain;
- They are focused on developing products suited for use in developing countries;

⁸ In combination with the United Nations Development Programme (UNDP) and the World Bank.

⁹ The Initiative on Public-Private Partnerships for Health, Global Forum for Health Research (2004). Combating Diseases Associated with Poverty - Financing Strategies for Product Development and the Potential Role of Public-Private Partnerships.

Stemming from these common purposes, and inherent to their nature as organisations concerned with the development of health products for the poor, PDPs also share a set of basic ‘needs’. These include:

- Engagement of industry, public/governmental agencies and civil society organisations;
- Sufficient resources to implement their chosen strategies;
- Strategies for management of intellectual property (IP) and leveraging R&D investments to assure product access for the poorest populations;
- Access to clinical trial capacity;
- Access to regulatory experience, including that relevant to LMICs;
- Access to expertise in assessing need, demand and markets for their products, particularly in LMICs.
- Access to expertise in assessing production options and their costs;
- Knowledge of the best strategies for delivering products to the poorest, including ways to work effectively with/within the existing health services infrastructure;
- Ways of measuring progress, in product development or delivery, or health status;
- Strategies for ensuring that non-contractual allies in the collective efforts to develop and improve access to health products actually fulfil their responsibilities and obligations.

Notwithstanding these commonalities, there are significant differences between PDPs in their organisational structure and their specific approach to product development. Some PDPs operate primarily as a convener of partnerships, providing a platform for collaboration between academic scientists, research and clinical trial organisations, pharmaceutical companies, product manufacturers and other stakeholders. Others more directly engage in product development, and may operate their own research and manufacturing facilities. Also the extent of private sector engagement varies. Whereas some PDPs work closely with a number of pharmaceutical and biotech companies (e.g. through licensing agreements on compounds, or joint product development), others have more limited interactions with industry partners (e.g. for product manufacturing only).

1.4 The PDP Funders Group

The PDP Funders Group (PFG)¹⁰ is an informal network, set up by several public and private organisations, to provide financial support to one or more PDPs that are developing new health technologies. The PFG also provides a forum where those responsible for managing an institution’s PDP investments can:

- Share information and experiences to make better informed funding decisions;
- Identify areas where it would be beneficial for funders to work together in a coordinated manner.

The PFG strives to increase the overall resource base for R&D funding for neglected diseases and, more specifically, to increase the funding available for PDPs. A selection of the current members of the PDP Funders Group is presented in Figure 2.

¹⁰ <http://www.pdpfundersgroup.org/>.

Figure 2 Members of the PDP Funders Group (2014)

National funding organisations in Europe	Funding organisations in the United States
<ul style="list-style-type: none"> • Denmark – Ministry of Foreign Affairs • Germany – the Federal Ministry of Education and Research (BMBF) • Ireland – Irish Aid • Netherlands – Ministry of Foreign Affairs (MoFA) • Norway – Norwegian Agency for Development Cooperation (Norad) • United Kingdom – Department for International Development (DFID) • Sweden - Swedish International Development Cooperation Agency (SIDA) • Spain: Agencia Española de Cooperación Internacional para el Desarrollo (AECID) 	<ul style="list-style-type: none"> • United States Agency for International Development (USAID) • National Institutes of Health (NIH)
European funding initiatives	Philanthropic organisations
<ul style="list-style-type: none"> • European Union: Directorate General for Research • European & Developing Countries Clinical Trials Partnership (EDCTP) 	<ul style="list-style-type: none"> • Bill & Melinda Gates Foundation (BMGF) • Wellcome Trust

Source: Website of the PDP Funders Group (2014).

1.5 Overall PDP funding

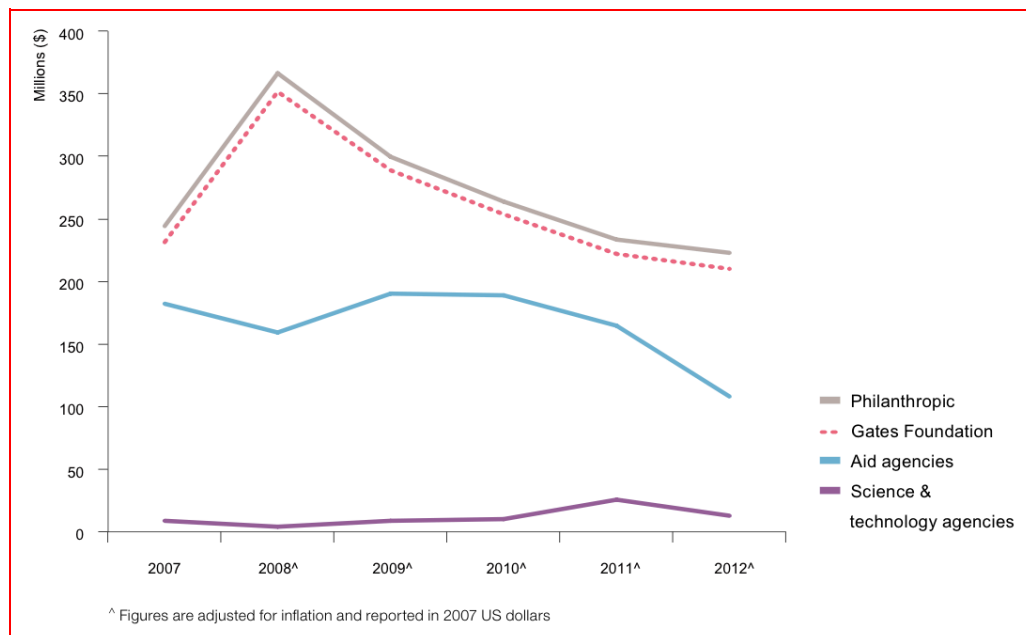
The independent research group *Policy Cures* collects all publicly available data on Global Funding in Innovation for Neglected Diseases and annually publishes this as a searchable database known as G-FINDER¹¹. According to the 2013 G-FINDER report, in 2012 sixteen PDPs jointly received €376.1 million^{12,13}. This means that for the fourth consecutive year total PDP funding has declined (see Figure 3). This decrease can be partially explained by the fact that the WHO Special Programme for Research and Training in Tropical Diseases (WHO/TRD) ceased its R&D activities, and by the decrease in funding provided by BMGF, but it also reflects a trend among high-income countries to limit their financial contribution to development assistance in general, and to neglected disease R&D in particular.

¹¹ https://g-finder.policycures.org/gfinder_report/.

¹² The sixteen PDPs that are taken into account in the 2013 G-FINDER report are the seven that are currently funded by MoFA: Aeras, DNDi, IAVI, IPM, FIND, POW PDP and Sabin, complemented by the Medicines for Malaria Venture (MMV), the Global Alliance for TB Drug Development (TB Alliance), the Infectious Disease Research Institute (IDRI), the Innovative Vector Control Consortium (IVCC), International Vaccine Institute (IVI), OneWorld Health (OWH), the TuBerculosis Vaccine Initiative (TBVI), the European Vaccine Initiative (EVI) and the WHO Special Programme for Research and Training in Tropical Diseases (WHO/TRD).

¹³ Policy Cures (2013). G-FINDER report 2013. Neglected disease research and development: the public divide.

Figure 3 Evolution of overall PDP funding 2007-2012



Source: G-FINDER data (2013). Figures are adjusted for inflation and reported in 2007 US \$.

In 2012, a total of twelve funders contributed 93% of all PDP funding (i.e. not only the seven PDPs currently funded by MoFA), with BMGF accounting for more than half (56%), and 7 aid agencies¹⁴ for an additional 31%. Within this second category, the Netherlands were the third biggest contributor (3%), after the UK (12%) and the USA (10%).

¹⁴ In order of decreasing contribution: United Kingdom, United States of America, The Netherlands, Australia, Germany, Ireland, and Switzerland

2. The PDP Fund 2011-2014

This chapter sets out the main characteristics of the current PDP Fund, in terms of its mission and objectives and specifications (including the selection procedure applied). It furthermore introduces the seven PDPs that were awarded for the current grant period (2011-2014).

2.1 The main mission and objectives of the PDP Fund

Prior to the current PDP Fund (from 2006 to 2009), MoFA contributed €80 million to cooperative partnerships (the PDPs) for the development of medicines, vaccines and diagnostics for HIV/AIDS, tuberculosis and malaria through a designated PDP Fund. It was felt that Dutch support for PDPs would bring significant added value in a number of respects¹⁵:

1. It entails multi-year contributions;
2. A range of PDPs can be supported from a relatively early stage; and
3. MoFA plays a constructive role in the PDP Funders Group.

Based on experiences gained in this first period, MoFA decided to continue funding of the PDPs for an additional period spanning from 2011 to 2014, and earmarked €70 million for this purpose. The overall aim of this second PDP Fund is *“to stimulate the development of medicines, vaccines, diagnostics and other devices for poverty related diseases (from basic research to production) where there is a clear need for government support”*¹⁶. The new grants are designed to contribute towards five main objectives:

- Increasing production of effective, safe and usable prevention methods, medicines, vaccines and diagnostics to combat poverty-related diseases;
- Enabling PDP partners to have a positive impact on innovation;
- Increasing access in developing countries to medicines to combat poverty-related diseases;
- Giving a sustainable boost to developing countries capacity for research and producing medicines, vaccines and diagnostics to combat poverty-related diseases;
- Giving developing countries greater voice in international forums in which research policy and agendas on combating poverty-related diseases are set.

The new PDP Fund furthermore aims to increase the efficiency of the funding mechanisms and different streams for R&D on this topic, for both the Dutch government as well as the PDPs and to reduce the administrative burden.

2.2 Specifications of the 2011-2014 Grant Framework and selection

In the 2011-2014 PDP Grant Framework, MoFA identified four priority themes where Dutch funding could have clear added value¹⁷:

1. Promote sexual and reproductive health, including the prevention of HIV/AIDS;
2. Prevent tuberculosis;

¹⁵ Ministry of Foreign Affairs (2010). Grants Framework for the 2011-2014 Product Development Partnerships Fund.

¹⁶ Order of the Minister of Foreign Affairs of 21 May 2010, no. DSO/GA-266-2010.

¹⁷ Ministry of Foreign Affairs (2010). Grants Framework for the 2011-2014 Product Development Partnerships Fund.

3. Prevent and treat neglected tropical diseases¹⁸; and
4. Meet local needs for diagnostics on the above themes, adapted to the local situation.

The Grant Framework stated that only applications that met specific threshold criteria would be eligible for funding, with highest priority given to those applications that best met the criteria. Criteria were formulated for both the PDP or applicant organisations, and for the applications themselves (Appendix C). The aim was to distribute the total available funding of €70 million equally across the four specified policy priorities, with a maximum of eight proposals funded, although quality of the applications was considered an overriding factor.

All submitted proposals that met the threshold criteria were subsequently assessed for technical quality, relevance and governance structure by internal and external experts. An evaluation committee organised by MoFA decided on the final recommendation for funding to the Minister of Foreign Affairs.

2.3 The seven PDPs funded

Based on the assessment of the grant proposals submitted by 13 PDPs, a total of seven were jointly awarded funding of €69.6 million. In order of decreasing amount of funding, these were:

- Drugs for Neglected Diseases Initiative (DNDi) €14.0 million
- International AIDS Vaccine Initiative (IAVI) €13.3 million
- Aeras €11.7 million
- Foundation for Innovative Diagnostics (FIND) €10.2 million
- International Partnership for Microbicides (IPM) €9.4 million
- Sabin Vaccine Institute (Sabin) €5.9 million
- Protection Options for Women Product Development Partnership (POW PDP) €5.1 million

The following table (Figure 4) provides some general information of the seven PDPs funded (i.e. the year in which the PDP was founded, the diseases and modalities targeted and their mission).

Figure 4 General information of the seven PDPs funded

PDP	Founded	Diseases targeted	Modalities targeted	Mission
Aeras	1997	Tuberculosis, including co-infection with HIV	Vaccines	To develop new tuberculosis vaccines that are affordable and accessible to all who need them.
DNDi	2003	NTDs, in particular three parasitic diseases: Human African Trypanosomiasis (sleeping sickness), visceral leishmaniasis (kala-azar) and Chagas disease	Treatments	To develop new drugs, or new formulations of existing drugs, for patients suffering from the most neglected communicable diseases

¹⁸ In general, 'NTDs' refers to a wide range of diseases caused by parasitic, viral and bacterial pathogens. These include, for example, Chagas disease, leishmaniasis, and soil-transmitted helminths (transmitted by worms). Sometimes a wider definition may be used that also encompasses HIV/AIDS, tuberculosis and malaria.

PDP	Founded	Diseases targeted	Modalities targeted	Mission
FIND	2003	HIV, tuberculosis, malaria, Human African Trypanosomiasis, leishmaniasis, Chagas disease, Buruli ulcer, hepatitis C, and trachoma (peripheral focus)	Diagnostics	To drive the development and early implementation of innovative diagnostic tests that have a high impact on patient care and disease control in low-resource settings.
IAVI	1996	HIV/AIDS	Vaccines	To ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world.
IPM	2002	HIV/AIDS	Microbicides	To prevent HIV transmission by accelerating the development and availability of safe and effective microbicides for use by women in developing countries.
POW PDP¹⁹	2011	POW PDP has focused on building supply and market introduction for the Woman's Condom – a new product that expands women's options for protection from HIV and unintended pregnancy.	Devices	To accelerate the development of new and lifesaving reproductive health technologies and to ensure their availability and accessibility in low-resource settings.
Sabin	2000	The Sabin PDP portfolio currently includes vaccine candidates for seven major neglected tropical diseases (NTDs): 1) human hookworm; 2) schistosomiasis; 3) ascariasis; 4) trichuriasis; 5) Chagas disease; 6) leishmaniasis and 7) onchocerciasis. The Sabin PDP is also pursuing development for a vaccine to protect against severe acute respiratory syndrome (SARS) and West Nile virus.	Vaccines	To develop and test safe, effective and low-cost vaccines to prevent or treat humans suffering from infectious and neglected tropical diseases.

Source: Technopolis Group analysis (2014).

The funded activities of the seven selected PDPs can be broadly allocated to each of the four priority areas defined by MoFA and shows the following results:

Figure 5 MoFA's priority themes, PDPs funded and associated budget

Priority areas identified by MoFA	PDPs funded by MoFA	Budget per priority area
1. Promote sexual and reproductive health, including the prevention of HIV/AIDS	IAVI, IPM and POW PDP	€27.8 million (39.7%)
2. Prevent tuberculosis	Aeras	€11.7 million (16.78%)
3. Prevent and treat NTDs	DNDi and Sabin	€19.9 million (28.5%)
4. Meet local needs for diagnostics on the above themes, adapted to the local situation	FIND	€10.2 million (14.6%)

Source: Technopolis Group analysis (2014), based on information provided by MoFA.

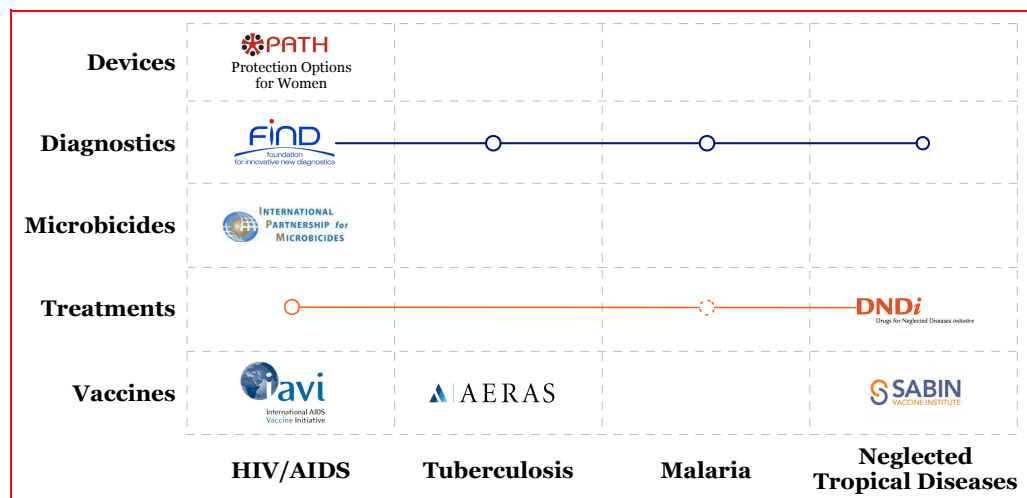
¹⁹ The MoFA supported project is conducted under the flag of the Protection Options for Women (POW) PDP, in which PATH is the implementing partner. To distinguish between PATH and the POW partnership, the name POW PDP will be used for the latter.

Nearly 40% of the total budget was allocated to the first priority area, consistent with the observation that this area involved three of the seven PDPs (Figure 5). The fourth priority area, through funding of FIND, received the smallest budget share. However, this area cuts across all other three areas and, as such, similar activities could also be covered in grants here assigned to those areas.

Figure 6 shows the focus of the seven PDPs, and their proposed activities, according to the diseases and modalities (vaccines, treatments, microbicides, diagnostics and devices) targeted:

- **IAVI, Aeras** and **Sabin** all work on development of vaccines, albeit in different disease areas (HIV, tuberculosis and hookworm, respectively).
- **IPM** is uniquely focused on preventing HIV infection using products based on microbicides, compounds that can be applied internally to protect against sexually transmitted infections (STIs) including HIV.
- The proposed activities of **DNDi** aimed primarily at the development of new drugs against Chagas disease, Human African Trypanosomiasis (HAT, also known as sleeping sickness) and leishmaniasis.
- The aim of **FIND**'s proposal was the development of novel diagnostics for a range of diseases, including tuberculosis and various NTDs.
- The **POW PDP** was created specifically to support the development of the Woman's Condom to offer women protection against HIV, STIs and unintended pregnancy.

Figure 6 Overview of the focus (diseases and modalities) of the seven PDPs funded



Source: Technopolis Group analysis (2014). Note: FIND focuses on the development of diagnostics for multiple diseases (represented by the line and circles), DNDi focuses (although to a lesser extent than its activities towards Neglected Tropical Diseases) also on HIV/AIDS and used to focus on malaria (it is transferring its activities in this area to the Medicines for Malaria Venture, represented by the dotted circle).

3. The current Dutch policy focus and other relevant policy areas

3.1 Current policy focus of MoFA

The three main aims of the current Dutch foreign policy are to improve the Netherlands' economic position in the world, to promote global stability and security, and to foster human rights and the rule of law. Based on a 2010 report from the Advisory Council for Government Policy, entitled '*Less Pretension, More Ambition. Development policy in times of globalization*', the Dutch government fundamentally redefined its development policy. The main change is a shift from the social to the economic sectors, with more focus on developing countries' self-reliance and creating more opportunities for private initiatives. Additionally, recent cuts to official development assistance have necessitated some drastic choices in the countries with which The Netherlands retains a bilateral relationship.

Against this backdrop, the Netherlands designed a new development policy based on four spearheads, each forming a bridge between global problems and Dutch expertise: Security and rule of law; Food security; Water management; and Sexual and Reproductive Health and Rights (SRHR). Policies designed around these priorities will aim to promote a healthy business climate and invest in partnerships with the business community.

For the spearhead 'Sexual and Reproductive Health and Rights', the Directorate-General for International Cooperation (DGIS) of MoFA has defined a number of priority areas²⁰. These are:

1. Increasing young people's access to information about sexuality and health;
2. Improving access to contraception and products for preventing STIs (including HIV), and access to HIV treatment and other life-saving drugs and medical technologies for sexual and reproductive health;
3. Improved access to, and utilisation of, better public and private sexual and reproductive health care;
4. Defending the sexual and reproductive rights of marginalised groups;

By supporting activities in each of these areas, the Netherlands aims to contribute to reducing global maternal mortality, and halting the spread of HIV. The latter three goals in particular are of great significance to LMICs. Support for the development of HIV prevention products like microbicides, female condoms and vaccines will be an explicit component of the SRHR agenda.

In addition to this specific policy focus, in 2013 MoFA adopted a new strategic agenda entitled '*A World to Gain: A New Agenda for Aid, Trade and Investment*'²¹. This agenda is based on recent international developments –such as the decline of poverty throughout the world, progress in achieving the Millennium Development Goals, the rise of new economies, and challenges for the Dutch economy– and has three main aims:

1. Eradicating extreme poverty ('getting to zero') in a single generation;
2. Realising sustainable, inclusive growth all over the world; and
3. Achieving success for Dutch companies abroad.

While it remains the objective of MoFA to promote global prosperity and reduce economic inequity, it will do so with a greater emphasis on Dutch interests. This incorporates strengthening the business climate for investment in developing economies

²⁰ Ministry of Foreign Affairs (2012). Policy agenda 2012. Key policy changes for 2012.

²¹ Ministry of Foreign Affairs (2013). A World to Gain: A New Agenda for Aid, Trade and Investment.

by Dutch entrepreneurs. In turn, such investments will stimulate local economies, and thereby increase the economic self-reliance of LMICs.

In the field of aid and trade, MoFA distinguishes three types of bilateral relationship: aid relationships, transitional relationships and trade relationships. The aid relationships focus on a set of countries that are unable to solve their poverty problems singlehandedly²². The transitional relationships focus mainly on low- and middle-income countries with growing economies²³. The activities include both aid and trade and can benefit both the developing country and the Netherlands. The main aim of the trade relationships is to promote trade and investment, with activities that contribute to economic growth and employment in the Netherlands²⁴.

3.2 Other relevant policy areas

In addition to the previously discussed development and foreign aid policy, several other policy areas are relevant in relation to the PDP Fund. The main areas of these are the Dutch Top Sector policy and, at an international level, the Millennium Development Goals and the post-2015 agenda.

3.2.1 Top Sector Policy

The Dutch Top Sector policy was developed in 2011 to build on a selection of sectors of unique strength to the Dutch economy. Nine so-called ‘top sectors’ were defined: Life Sciences & Health; Agro-food; Horticulture and Propagating Stock; High Tech Systems and Materials; Energy; Logistics; Creative industry; Chemicals and Water. These sectors are all characterised by strong market and export positions, a good knowledge base, public-private collaborations, and potential to contribute to innovative solutions for societal challenges.

Of the nine top sectors, the sector Life Sciences & Health is the most relevant in the context of the PDPs. Within this sector, ten roadmaps have been defined, of which one relates specifically to neglected diseases²⁵. This roadmap aims to provide solutions for poverty-associated diseases that affect more than 2 billion people in the developing world. It focuses on the formation of new public private partnerships (PPPs) and encourages the continuation, or expansion of, PPPs and the utilisation of their know-how, infrastructure, and products to provide new, sustainable solutions for emerging diseases. The goal is to alleviate the burden of emerging diseases through better, simpler, and more cost-effective detection, prevention, and treatment of these diseases and to improve the contribution of afflicted people to societal and economic activities. This includes solutions for children’s and women’s health and access to safe, clean water, all of which plays a role in management of emerging diseases. Affordable solutions should be available for the (poor) populations living in the affected areas and individuals travelling and working in developing countries.

3.2.2 Millennium Development Goals and the post-2015 agenda

In 2000, the United Nations defined eight Millennium Development Goals (MDGs) in order to address major global issues, such as reducing extreme poverty, halting the

²² Afghanistan, Burundi, Mali, the Palestinian Territories, Rwanda, South Sudan and Yemen.

²³ Bangladesh, Benin, Ethiopia, Ghana, Indonesia, Kenya, Mozambique and Uganda.

²⁴ Australia, Belgium, Brazil, Canada, China, Colombia, France, Germany, the Gulf States, India, Iraq, Japan, Malaysia, Mexico, Nigeria, Poland, Romania, Russia, Singapore, South Africa, South Korea, Turkey, UK, Ukraine, US and Vietnam.

²⁵ Roadmap Neglected Diseases (2012), available at <http://www.zonmw.nl/nl/themas/thema-detail/topsector-life-sciences-health/neglected-diseases/>. Last accessed 21 October 2014. Note that the RVO refers to this same roadmap as the ‘innovation theme’ *Global health, emerging diseases in emerging markets* (<http://www.rvo.nl/subsidies-regelingen/mit-regeling-topsector-life-sciences-health>).

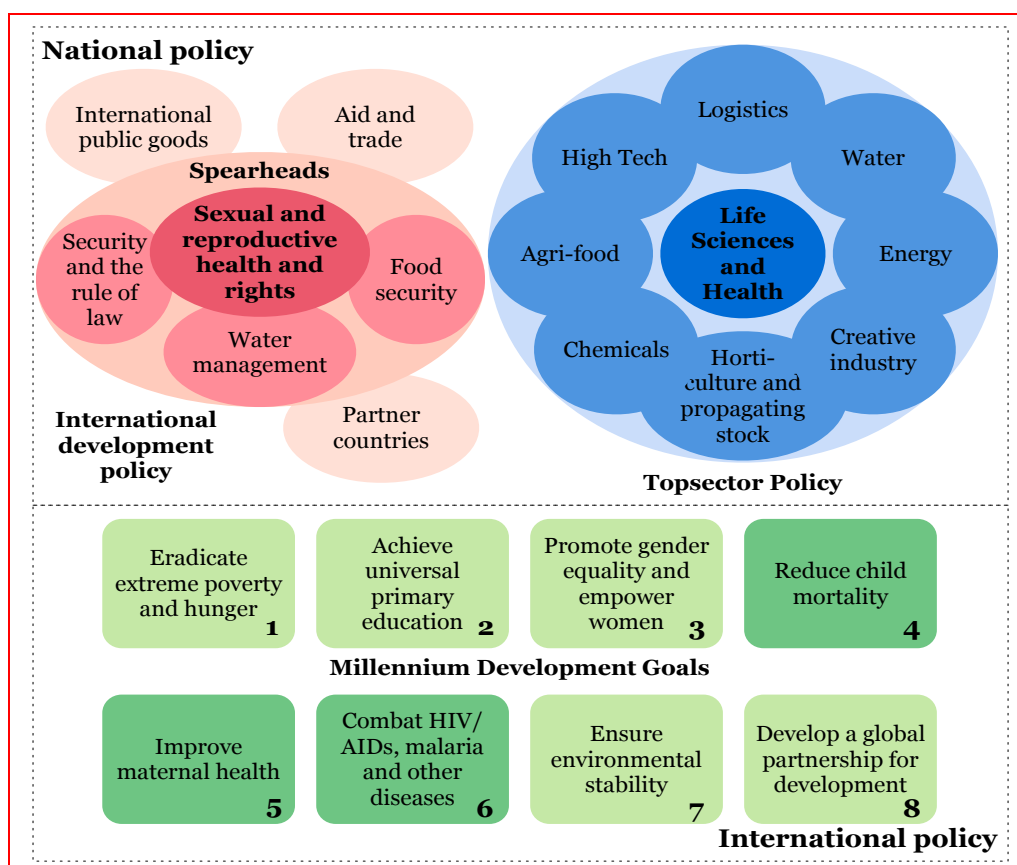
spread of HIV/AIDS and other diseases and providing universal primary education²⁶. Countries and development institutions universally agreed upon a set of ambitious targets, to be achieved by 2015. Specifically, the targets were to:

1. Halve the number of undernourished people	5. Improve maternal health
2. Achieve universal primary education	6. Combat HIV/AIDS, malaria, and other diseases
3. Promote gender equality and empower women	7. Ensure environmental sustainability
4. Reduce child mortality	8. Develop a global partnership for development

The health related goals MDG 4 (reduction of child mortality), 5 (improvement of maternal health) and 6 (combatting HIV/AIDS, malaria and other diseases) are the most relevant in the context of the PDPs.

With the deadline of the MDGs rapidly approaching, it is clear that –despite encouraging progress– several targets are unlikely to be met. For the health related MDGs in particular, insufficient progress has been made in reducing child mortality and improving maternal health. More success has been achieved in reversing the spread of HIV in sub-Saharan Africa, the part of the world with the highest incidence. It is evident that continued commitment from all countries is required beyond 2015. At a high-level summit in September 2015 world leaders are expected to announce a new sustainable development agenda with a further set of goals, building on the MDGs. These goals are currently under development.

Figure 7 Relevant policies in the context of the PDP review



Source: Technopolis Group (2014).

²⁶ <http://www.un.org/millenniumgoals/>

4. Review of MoFA funded PDP activities

This chapter reviews various aspects of the activities performed by the seven PDPs, their expected and achieved results, contributions to the PDP Fund objectives, the fit to the Dutch policy focus, and the contribution of Dutch funding (i.e. how Dutch funding made a difference to the PDPs). Furthermore, the sustainability of the PDPs and their collaboration with each other, and with other partners are presented. The main focus is on activities performed with support of the Dutch funding in the period 2011-2014.

4.1 Grant objectives and key achievements

In the following section the stated grant objectives and key achievements for each of the seven funded PDPs have been summarised. The main focus is on MoFA supported activities, although in some cases a brief overview of additional relevant achievements is provided as well.

Aeras

One of the main objectives goals of the Aeras grant was a Phase IIb clinical trial of a new tuberculosis vaccine candidate, conducted in collaboration with the Dutch biotechnology company Crucell²⁷, in multiple sites in Africa. The vaccine was intended to boost the immune response elicited by the Bacille Calmette-Guérin (BCG) vaccine, the only vaccine being used today to prevent TB in infants. However, although the product showed acceptable safety, it was not considered sufficiently effective to merit further development. Consequently, the trial was halted and a decision was made to change the composition of the vaccine. The Dutch government has been flexible and supportive in allowing the necessary changes to be made, which led to a combination vaccine that is currently in phase I of clinical development. The global TB vaccine pipeline currently has 15 candidates that are being tested in humans. Half of these candidates are being jointly developed by Aeras and its partners and the MoFA grant also supported the clinical development of a number of these promising vaccine candidates in late stages, and also supported epidemiology studies in preparation of additional trials.

Since its inception, Aeras has helped develop clinical trial sites in six countries in Africa and Asia. At these sites, Aeras helped to build state-of-the-art laboratory systems, quality control and quality assurance programmes and data management systems. Local staff is trained in clinical research through professional development programmes and active participation in clinical trials. Hundreds of individuals at Aeras' partner trial sites in South Africa, Kenya, Uganda, Senegal and Mozambique have received training that allows for technical skills development of the local workforce, as well as job creation and economic development in these countries.

Aeras' clinical research has contributed to better access to care and health status, as the local health care capacity to diagnose and treat tuberculosis in infants and adolescents has been strengthened at the clinical trial sites. The laboratories and equipment that Aeras sets up at its sites are sometimes the only TB culture and rapid diagnostic capabilities in the region. This local ability for early and sophisticated diagnosis has directly led to a lowering of TB morbidity and mortality in the field site areas. Affected communities where the trials are being conducted also benefit from increased access to medical professionals, referrals to local health clinics, and heightened awareness about tuberculosis that leads to progressively better management of the disease.

²⁷ In 2011 Crucell was acquired by the pharmaceutical company Johnson & Johnson and operates as the center for vaccines within the Johnson & Johnson pharmaceuticals group.

DNDi

DNDi's mission is to develop new drugs or new formulations for existing drugs for patients suffering from the most neglected communicable diseases and to ensure equitable access to new and field-relevant health tools. DNDi does not have any own research facilities. Instead, it follows a virtual research model, whereby most research is outsourced. The R&D projects are actively managed by DNDi personnel experienced in different aspects of pharmaceutical development.

DNDi requested support from MoFA for its project to develop improved treatments and innovative medicines to support control and elimination of NTDs (supporting the WHO Roadmap on the elimination of ten NTDs by 2020²⁸). The principal objective of the grant was to provide children and adults suffering from 3 NTDs (Human African Human African Trypanosomiasis or sleeping sickness, leishmaniasis, and Chagas disease) with improved treatments while progressing additional candidates towards clinical development.

Since the initiation of the MoFA grant in 2011, two series of compounds with activity against both leishmaniasis and Chagas disease, and two series of compounds with activity against Chagas disease alone, were entered into lead optimisation programmes to make them safer and more effective. Of the two proposed new compounds for leishmaniasis one progressed towards pre-clinical development and one towards clinical development. Furthermore, one out of two proposed improved treatments in this area was implemented in East Africa. For Chagas disease, a paediatric treatment formulation was implemented. Another new compound progressed towards clinical development, but did not progress to a Phase III trial since, although the results from a Phase II trial showed acceptable safety and effectiveness in clearing the parasite, it demonstrated little efficacy after one year.

Two new compounds for oral treatments with potential activity against sleeping sickness moved into clinical development (Phase II/III) with the objective to register them in 2016 and 2017. However, in order to focus its resources on leishmaniasis and Chagas disease, DNDi decided to reprioritise drug discovery, as the pipeline for leishmaniasis and Chagas disease is more limited than the pipeline for sleeping sickness, which currently already consists of two strong candidates.

DNDi has helped to establish three regional disease-specific platforms in disease endemic countries: The Leishmaniasis East Africa Platform (LEAP), the HAT Platform and the Chagas Clinical Research Platform (CCRP). These platforms bring together clinical researchers, ministries of health, disease control programmes, NGOs, and the WHO through regional networks that help strengthen research capacity and treatment implementation in the countries. Capacity strengthening activities include building and renovation of hospital wards, clinics and health posts; renovation and re-equipping of clinical laboratories; and training of health service personnel with emphasis on building expertise in clinical trial methodology and conduct, good clinical practice and ethics, patient treatment and evaluation. Since 2009 over 900 people have been trained through these platforms.

DNDi has played a prominent role in international and regional forums to increase the commitment to combatting neglected diseases. It has promoted a new framework for R&D at the WHO level, published over 60 scientific papers in the last four years, and has attended and organised multiple international conferences. In addition, DNDi with PATH is co-chairing a European PDP-coalition for advocacy.

²⁸ World Health Organization (2012), Accelerating work to overcome the global impact of neglected tropical diseases – A roadmap for implementation.

FIND

FIND specialises in the development and delivery of diagnostics. The proposal to MoFA therefore focused on improving diagnostic tools and expanding the repertoire of existing test platforms for poverty related diseases. Specifically, it aimed to develop or improve diagnostic tests for detecting leishmaniasis, TB (as well as drug-resistant TB) and trachoma, and on expanding the capability of a technology platform to test not only for tuberculosis but also for HIV and other STIs.

Two separate tests (based on different technologies) for leishmaniasis were successfully developed and are being evaluated in the lab and at clinical sites in Sudan, Bangladesh and Kenya. The introduction of one test is expected in 2015; an early prototype of a third, simpler and faster test for leishmaniasis is in preliminary testing and a completed product is expected for 2016.

Two activities are currently on hold: the development of tests for trachoma and one for a point-of-care TB test. FIND requested a redirection of unspent funds to include more activities under the scope of sexually transmitted infections and, since the end of 2013, has been increasing its focus in this area.

The ability to test for HIV was successfully added to a technology platform used to test for tuberculosis, and will be commercialised end 2014. Work on developing another rapid point-of-care TB test continues as do several for detection of drug resistant TB forms (including multi- and extreme drug resistance).

In addition to these activities, FIND successfully conducted a number of trials of products in various stages of development. These products include tests for HIV, (drug-resistant) TB, malaria, leishmaniasis and sleeping sickness.

In addition to offices in India and Uganda, FIND has a training centre in Bangalore for building diagnostic laboratory capacity and, until 2012 had R&D lab in Kampala for assessing sputum-processing methods. Over 4,400 laboratory staff members in developing countries have been trained through FIND programmes in the last four years. FIND co-organises, lectures and participates in training courses dedicated to developing capacity of staff in LMICs and provides an annual advanced diagnostics course in Montreal. Quality Assessment training courses are a regular activity in FIND's "downstream" work, including training of trainers. FIND has over 60 partners in developing countries that participate primarily in implementation work and also in trials. Recently, FIND has started its first R&D partnerships with Argentina and Colombia, where joint research is carried out on Chagas disease. Furthermore, a course on Operational Research was set up in Mozambique for Portuguese-speaking African countries. FIND has also contributed to upgrading of 156 TB laboratories in TB endemic developing countries.

FIND contributes to 15 international conferences a year, hosting symposia to engage the global health community in urgent issues around diseases of poverty. Between 2011 and 2014 (inclusive) FIND was presented in 134 academic articles, and in 144 media publications.

IAVI

The overall aim of IAVI's MoFA funded project was to leverage scientific advances and accelerate progress on agreed scientific priorities and milestones, with the ultimate goal of furthering global efforts in HIV vaccine development. Specifically, it set out to advance vaccine development by identification of at least one suitable compound and progress this to Phase I trials. Additionally, it aimed to advance other promising candidates to clinical trials and advance at least one vaccine candidate to Phase IIb efficacy trials.

Under the first goal of the grant, IAVI has successfully identified four new families of compounds with the potential of generating vaccines with a broad ability to block multiple HIV strains. Two clinical Phase I trials are on-going and 2 compounds are

under development. Under a separate programme, IAVI is currently undertaking a third Phase I trial, and two additional candidates are pending approval for further development.

A lead candidate for Phase II trials failed the go/no-go criteria. Following manufacturing challenges, IAVI decided to not proceed with this line of research, but rather seek partnerships with two groups (Oxford University and Crucell) who had initiated the development of alternative methods, both following a similar approach to that planned for the IAVI lead candidate and both with the potential to proceed to Phase IIb trials. To date, four Phase I trials using this new platform have been completed and the results have been incorporated into further developments.

IAVI has developed and expanded clinical trial centres capacity in African project sites, to a current network of 7 collaborating research centres and 13 laboratories in East and Southern Africa. Moreover, IAVI has advanced local scientific, clinical and laboratory capacity in East and Southern Africa and in India. IAVI has also built and supported capacity for research to better characterise the African HIV epidemic and inform HIV/AIDS vaccine development. Furthermore, IAVI helped to strengthen African partner capacity to generate their own resources such that now, for example, Kenya AIDS Vaccine Initiative (KAVI) is generating at least 40% of its own annual income from sources other than IAVI. In 2013, the Gates Foundation and IAVI jointly established the Vaccine Product Development Centre (VxPDC). The centre is directed by IAVI and aims to assist investigators with analytical methods that could speed transitions of new compounds to clinical testing.

IAVI has been involved in discussions, jointly with other PDPs, to help shape the post-2015 development agenda and the new EU framework for research and innovation Horizon 2020. IAVI has also played a leadership role in updating the UNAIDS Investment Framework to incorporate messaging on the potential impact of a vaccine.

IPM

IPM aims to contribute to the global fight against the HIV/AIDS epidemic by developing vaginal microbicides that are designed to protect women from HIV infection during sex by slowly releasing a long-acting antiretroviral drug that prevents the virus from replicating in healthy cells. With support from the MoFA funding, IPM proposed to conduct a Phase III clinical programme, consisting of two parallel trials, with a ring based on a high-priority microbicide candidate to determine efficacy against HIV infection, and to conduct additional studies on selected priority products in the pipeline.

As of 2013, a combined total of 3,409 women had been enrolled in the Phase III trials at research centres in South Africa, Uganda, Malawi, and Zimbabwe. A licensure programme for the microbicide ring has been started and IPM is focusing its efforts on obtaining WHO prequalification status for the product. It is hoped that the product will be available in the market by 2017.

IPM also continued development of its other pipeline products, including an important microbicide candidate with a mechanism of action that has yet to be used for HIV treatment or prevention, and a combination ring, containing both a microbicide and a contraceptive compound.

Five smaller safety studies were completed in preparation for preclinical and clinical evaluation and licensure, while one study is still on-going. IPM provides on-going capacity-strengthening support to 7 research centres in sub-Saharan Africa and has trained approximately 350 staff members at a total of 15 research centres to conduct clinical trials. It has also supported more than 500 community advisors with educational materials. Currently, manufacturing of IPM's products is not done in Africa, since there is insufficient technical capacity in silicone manufacturing there. However, IPM continues to look for opportunities in this area, potentially by encouraging future manufacturers to set up local subsidiaries.

IPM conducts advocacy for microbicides on African, European and US levels through collaboration with its global network of advocacy partners to help raise awareness among their constituents by disseminating information through newsletters, educational seminars, conferences, high level meetings, briefings with policymakers and social media. Findings of IPM's work have been presented at various international conferences and have been published in peer-reviewed journals.

POW PDP

The POW PDP was created with the aim of accelerating the development of new and lifesaving reproductive health technologies and to ensure their availability and accessibility in low-resource settings. With support of MoFA POW PDP proposed to enter and further expand the markets for the Woman's Condom in China and sub-Saharan Africa by extending private-sector market opportunities, exploring non-traditional private-sector distribution channels, and developing public-sector market opportunities. It also aimed to raise awareness of and demand for female condoms globally by building and sustaining advocacy initiatives.

POW PDP has provided technical assistance to its Chinese manufacturer, Dahua, to support scale-up and optimisation for the production of the Woman's Condom, as well as build regulatory and quality assurance capacity. The product is currently under review by the WHO for prequalification status. Once achieved, Dahua will be qualified to compete through the international tender process used for large-scale procurement.

The POW PDP has raised awareness among policy makers, programmers, and researchers in China about Woman's Condom. Five successful market tests of uptake and acceptability have been conducted among target groups in nine provinces in China. These findings will be used to gain support for the inclusion of the Woman's Condom in public-sector programming, both for family planning and for HIV prevention. Additionally, Dahua has explored market opportunities in the private sector.

To enter the African market POW PDP has identified a distribution partner in South Africa (rrtMedon), achieved local approval of the product, and explored market opportunities in both private- and public-sector channels. It is working with local research partners to assess uptake and acceptability among various target markets and distribution channels. The focus has been on exploring private-sector channels to expand the female condom market beyond its current reliance on distribution of free products from the public sector. The POW PDP is also evaluating whether the product can be commercially sustainable in South Africa. Market clearance approval for the product has also been achieved in Malawi and Zambia.

POW PDP's global and country-level advocacy activities focus on building awareness and interest among NGOs and civil society leaders, educating and influencing decision-makers to support programming, and leveraging traditional and social media to raise awareness and gain support among policymakers and key influencers. To this end it has, among other initiatives, organised a film contest to increase knowledge of and commitment to female condoms among policymakers, health organisations, and potential end-users and to bring the voice of country level advocates to national and global discussions. In conjunction with other global advocates, it helped initiate Global Female Condom Day, as a focus for raising awareness and advocating for expanded access to female condoms. It also continues to work with female condom coalitions to shape advocacy agendas.

Sabin

The mission of Sabin is to develop and test safe, effective and low-cost vaccines to prevent or treat human suffering from infectious and neglected tropical diseases. In the context of the MoFA grant, the project is aimed specifically at the development of a

vaccine to prevent infection with Human Hookworm. To this end, it requested funds to support two separate Phase I clinical trials in adults and children.

The manufacturing and preclinical toxicology tests for both vaccine compounds were successfully completed. One of the Phase I trials has been completed, and demonstrated that the compound was both safe and effective. The other trial is still on-going. However, the two Phase I tests in children were cancelled. Instead, a new formulation that combines both compounds will be entered into a Phase I trial, as part of a European 7th Framework Programme (FP7) project called 'HOOKVAC'. A share of the MoFA funding, originally allocated to testing a combination of both compounds, was reallocated to an additional Phase I test using one of the compounds in a different formulation.

With MoFA support, Sabin has been able to modify the vaccine manufacturing process, resulting in a five-fold increase in its production yield and consequently lowering production costs, so that the product can be manufactured at lower cost.

Dutch funding has enabled Sabin to boost the scientific capacity at its Brazilian partner institutes, and at the local clinical trial studies. Sabin has also been successful in getting additional funding from the European Commission for its FP7 HOOKVAC project.

The Sabin PDP advocacy programme includes high profile writings in leading print and electronic media, major addresses and speeches, and interface activities with US and international government agencies. It also engages with current and former world leaders to conduct high-level government advocacy.

The table on the next two pages (Figure 8) provides a summary overview of the proposed and implemented activities of the PDPs that are supported by MoFA. A distinction is made between activities directly related to research and development and other activities including capacity development and advocacy.

Figure 8 Overview of MoFA supported activities (proposed and implemented) of the PDPs

	AERAS	DNDi	FIND	IAVI	IPM	POW PDP	Sabin
Research & Development (R&D)²⁹							
<i>Preclinical</i>	<ul style="list-style-type: none"> Development of multiple candidates; epidemiology studies completed. 	<ul style="list-style-type: none"> <u>Leishmaniasis & Chagas Disease</u>: Lead optimisation and pre-clinical development of multiple compounds. 	<ul style="list-style-type: none"> <u>TB</u>: 2 tests and 4 approaches in pre-clinical feasibility testing; <u>Malaria</u>: 1 molecular test for use in elimination programme; 1 tool for quality control. 	<ul style="list-style-type: none"> Identified 4 new series of compounds. 	<ul style="list-style-type: none"> 5 safety studies completed; 1 on-going; On-going development of new products (incl. a combination product); Preclinical development of the dapivirine ring. 	Not applicable	<ul style="list-style-type: none"> Preclinical toxicology testing of 2 compounds completed.
<i>Phase I</i>	<ul style="list-style-type: none"> 9 phase I trials with 6 vaccine candidates. 	<ul style="list-style-type: none"> <u>Leishmaniasis</u>: 1 compound progressed toward clinical development. <u>Chagas Disease</u>: 1 compound progressed toward clinical development, no progress to Phase III. 	<ul style="list-style-type: none"> <u>TB</u>: 3 clinical feasibility studies (1 paediatric; 2 adult). 	<ul style="list-style-type: none"> 3 trials on-going; 4 (new) trials completed. 	None	Not applicable	<ul style="list-style-type: none"> 1 trial completed (in adults); 1 trial (in adults) on-going; 1 (new) trial in preparation; Separate testing in children was cancelled.
<i>Phase II</i>	<ul style="list-style-type: none"> 7 phase II trials with 3 vaccine candidates. 3 phase IIb trials with 2 vaccine candidates. 	<ul style="list-style-type: none"> <u>Sleeping sickness</u>: 2 compounds entering Phase II/III trials. 	<ul style="list-style-type: none"> <u>TB</u>: 1 molecular detection, 1DR TB, 1 MDR TB evaluation trials; <u>Malaria</u>: molecular test evaluation. 	<ul style="list-style-type: none"> 1 proposed trial cancelled. 	None	Not applicable	None
<i>Phase III & IV</i>	None	None	<ul style="list-style-type: none"> <u>TB</u>: 2 molecular test demonstration; <u>Malaria</u>: demonstration of RDTs in pregnancy, demonstration of molecular testing in low transmission settings 	None	<ul style="list-style-type: none"> 2 parallel trials on-going 	Not applicable	None

²⁹ The categorisation into preclinical and clinical development (Phase I-IV) stages applies only to development of health products such as drugs or vaccines, but is not used in development of diagnostics. Therefore, these categories are considered not applicable to the activities of FIND. The POW PDP focuses on production and marketing of an existing product, and thus is also not involved in preclinical and clinical testing.

	AERAS	DNDi	FIND	IAVI	IPM	POW PDP	Sabin
<i>Implementation</i>	None	<ul style="list-style-type: none"> • 1 improved treatment for leishmaniasis; • 1 paediatric treatment for Chagas. 	<ul style="list-style-type: none"> • Integrated TB and HIV test in commercialisation; • <u>TB</u>: 3 TB and MDR TB tests, 1 TB speciation; • <u>Sleeping sickness</u>: 1 rapid test. 	Not applicable	Not applicable	<ul style="list-style-type: none"> • Obtained product approval in China South Africa; pending WHO pre-qualification; • Market studies completed in China and South Africa. 	Not applicable
<i>Technology development</i>	Not applicable	Not applicable	<ul style="list-style-type: none"> • 2 tests for leishmaniasis under evaluation; • Development of trachoma and TB tests discontinued. 	Not applicable	Not applicable	Not applicable	Not applicable
Other							
<i>Capacity development</i>	<ul style="list-style-type: none"> • Identified and developed clinical trial sites in 6 countries in Africa and Asia. (e.g. through building laboratories, and staff training). 	<ul style="list-style-type: none"> • Strengthened research capacity in disease endemic countries through 3 regional disease-specific platforms (e.g. infrastructure renovation, staff training). 	<ul style="list-style-type: none"> • Strengthened TB, malaria and HIV diagnostic capacity in endemic countries through lab staff training, training and QA material development, job aid development and dissemination. 	<ul style="list-style-type: none"> • Strengthened research capacity in Africa and India (e.g. staff training, development of training materials, supporting local research centres). 	<ul style="list-style-type: none"> • Strengthened research capacity in sub-Saharan Africa (research centre support, staff training, community advisor support). 	<ul style="list-style-type: none"> • Strengthened production and marketing capacity of local manufacturer in China. 	<ul style="list-style-type: none"> • Strengthened clinical trial capacity at Brazilian partner institutes.
<i>Advocacy</i>	<ul style="list-style-type: none"> • TB Vaccine R&D business case developed together with the TuBerculosis Vaccine Initiative (TBVI), European Commission and European Investment Bank. 	<ul style="list-style-type: none"> • Prominent role in international forums to increase the commitment to global health R&D for neglected diseases. 	<ul style="list-style-type: none"> • Awareness raising through campaigns, on importance of testing children for TB in Indian slums; HAT testing and elimination in endemic countries. 	<ul style="list-style-type: none"> • Contributed to, among others, development of post-2015 development agenda and Horizon 2020 framework to ensure commitment to HIV vaccine R&D. 	<ul style="list-style-type: none"> • On-going advocacy and education efforts to promote awareness about microbicides and inform future commercialisation and access strategies. 	<ul style="list-style-type: none"> • On-going efforts to create awareness of the Woman's Condom, and advocate for female condoms in general. 	<ul style="list-style-type: none"> • High profile writings in leading print and electronic media; • Major addresses and speeches; • interface activities with US and international government agencies; • High-level government advocacy.

Source: Technopolis Group analysis, based on information provided by PDPs (2014). Note: this table summarises only those activities that were explicitly listed in the grant proposals and that were (at least partially) funded by MoFA. Additional activities conducted by the PDPs may therefore not be shown here, but may have contributed to progress in all categories.

4.2 Contribution to PDP Fund objectives

As discussed in section 2.1, the overall aim of the PDP Fund is “to stimulate the development of medicines, vaccines, diagnostics and other devices for poverty related diseases (from basic research to production) where there is a clear need for government support”. It, furthermore, identified five main objectives.

The primary first objective was to increase production of effective, safe and usable prevention methods, medicines, vaccines and diagnostics to combat poverty-related diseases. It is clear that this was also at the core of the proposals of all seven PDPs. Although most products are still in various stages of development, in general the PDPs have made encouraging progress in identifying and developing candidates for new vaccines (Aeras, IAVI, Sabin), treatments (DNDi), diagnostics (FIND), or infection prevention methods (IPM, POW PDP) against a range of poverty related diseases.

The second objective of the PDP Fund was to enable PDP partners to have a positive impact on innovation. It is considerably harder to assess if, and how, PDPs have been successful in this area and whether this was in fact a realistic expectation. Not only do the PDPs vary greatly in the type and stage of activities they conduct along the R&D value chain, different PDPs engage with partners in different ways. For instance, as compared to many drug discovery programmes, research on microbicide-based products (IPM) and HIV vaccines (IAVI) can be considered innovative, as currently no such products are on the market. Both IPM and IAVI also work in partnership with other organisations on development of these products, but it is insufficiently defined if this constitutes true impact. In addition, DNDi included 12 new chemical entities (NCEs) for its portfolio including 3 in clinical development for leishmaniasis and sleeping sickness.

Increasing access to medicines (and other health products) to combat poverty related diseases, the third objective of the PDP fund, is an integral part of the strategy of several PDPs. To ensure affordable prices for their products in developing countries, PDPs like Aeras, DNDi, IAVI, and IPM negotiate licensing agreements with their industry partners or, for as FIND does for diagnostics, pricing agreements. Inclusion of products in the WHO Essential Medicine List (e.g. DNDi) or ensuring that products are endorsed by WHO disease programmes (e.g. FIND) also serves to safeguard their availability and affordability, and correct use in countries. More generally, PDPs like POW PDP work to promote greater access to their products through advocacy and awareness raising among policy makers.

Even where capacity development activities were not a clear component of the MoFA supported activities, all PDPs have contributed to some extent to building greater research capacity and infrastructure in the countries in which they conduct their trials or activities. For Aeras, DNDi and IAVI, this was explicitly included in the activity plan in the MoFA proposals, whereas for POW PDP and Sabin it was more a natural consequence of the implementation of the MoFA supported activities. Although not directly linked to the MoFA grant, FIND and IPM also have contributed in various ways to local capacity development.

The final objective of the PDP fund was to give developing countries greater voice in international forums in which research policy and agendas on combating poverty related diseases are set. Although the PDPs engage in many different forms of advocacy, the involvement of stakeholders from developing countries in these processes has been relatively limited; most advocacy efforts are conducted top-down, rather than bottom-up. This is perhaps not surprising given that much of the advocacy is directed at high-level policy makers and opinion leaders, with the intent of obtaining financial and political commitment. However, DNDi has organised three scientific/advocacy meetings with its founding partners in endemic countries in Brazil (2011), Malaysia (2012) and Kenya (2012). In addition, Aeras supports the participation of developing country researchers in the Global TB Vaccine Forum by providing travel stipends to them. This provides professional development and networking opportunities as well as facilitates the inclusion of their voices and perspectives. Furthermore, PDPs whose activities fall

more at the downstream end of the R&D value chain, such as IPM and POW PDP, do engage with local communities to obtain information about product acceptability and market needs.

4.3 Contributions of the Dutch funding

Much of the work conducted by the PDPs has benefited from contributions by multiple donors. It is therefore often not possible to unambiguously attribute specific results to individual funders. Nonetheless, from our interviews with representatives of the seven MoFA supported PDPs, it is clear that the Dutch funding has been instrumental to the PDP's achievements in several important ways, as outlined in the following sections.

4.3.1 Continuation and completion of R&D activities

Compared to the total funding for PDPs (see also section 1.5), the Dutch contribution is relatively modest (the financial information is presented in the next chapter). For a number of PDPs, however, Dutch funds have been indispensable for the continuation of particular activities. For instance, POW PDP reported that prior to 2011 their work on the development and marketing of female condoms had been severely threatened by lack of funds. The Dutch grant enabled POW PDP to move the project forward, resulting in the development of a new product that is slated to receive WHO prequalification status, and is set for market entry in China and South Africa. Similarly, without the Dutch contribution, IPM would not have been able to initiate their Phase III microbicide ring trial. For FIND Dutch support has been essential not only for specific project activities, but for the survival of the organisation as a whole when it went through a period of organisational difficulty. The Dutch funding also allowed Aeras to continue and finish activities that otherwise would have been stopped or slowed down. For example, the Crucell trial in infants was finished as a result of support from the Dutch government, as there was not that much interest in these trials by other funders.

4.3.2 Catalysing research and attracting funding

The Netherlands has long been an important actor in the fields of development assistance, sexual and reproductive health programming, and research on poverty related diseases. Because of this, the contribution of the Dutch government to the PDPs extends beyond its financial value alone. Many representatives from PDPs, as well as those from MoFA and other organisations, expressed a conviction that Dutch support for a particular scientific direction or technology engenders confidence in other potential funders about the viability and relevance of the research. A clear example of this has been the support for the work of POW PDP on the Woman's Condom. It was felt that the donor community had become somewhat fatigued with the product. Dutch readiness to back the product has had an important signalling function and has helped to reinvigorate funding for the field. A similar situation applies to the microbicide research performed by IPM. This area had previously not received much attention from the private sector and had been largely ignored by researchers. The creation of IPM, with Dutch support, has been vital in putting microbicides research on the global agenda. Other areas where the Dutch have played a catalytic role include the development of (paediatric) TB vaccines (Aeras), HIV vaccines (IAVI) and diagnostics (FIND). In addition the Netherlands has been an early adopter to fund neglected tropical diseases (DNDi, Sabin).

More generally, Dutch funding has been used to attract further resources from other donors by offering the possibility of financial risk sharing. DNDi, Aeras, FIND and Sabin, for instance, have indicated that the MoFA grant directly contributed to their procurement of additional funding from the British, German, French and Australian governments, and from the European Commission. Additionally, according to some stakeholders, there are signs that Dutch PDP support has raised interest of the Irish, Norwegian and German governments for the PDP model. Nonetheless, additional funding can seldom be attributed solely to pre-existing funding commitments. The PDP

Funders Group, for example, also plays an important role in showing countries' commitment.

Unavoidably, the important signalling role attributed to the Dutch funding entails that the reverse effect also applies: that is, a reduction or cessation, of Dutch funding may be interpreted by other donors as a loss of faith in the particular line of research, in the PDP, or even in the PDP model, thus triggering these donors to follow suit and withdraw their own funding as well. Several stakeholders have expressed concerns to this effect.

4.3.3 Portfolio development and pipeline stocking

Compared to many other donors, in particular BMGF, MoFA provides its grantees a significant amount of flexibility. For many of the PDPs, the Dutch funding has supported the development of the product portfolio as a whole, rather than individual projects. This comprehensive approach enables PDPs to switch more rapidly between lines of investigation: terminating less promising candidates, if necessary, and focusing instead on those with the most potential. Consequently, PDPs can pursue more innovative strategies that typically have a higher risk of failure, but –if successful– may yield ground-breaking impacts.

Portfolio funding also helps to stock the R&D pipeline with suitable alternatives to products that are currently on the market, or under development. The growing risk of drug resistance to existing HIV treatments (which is a major challenge for TB treatment and control as well), for example, necessitates the development of new technologies to combat HIV. These can include microbicides (both oral and topical) and vaccines. As the HIV prevention field and end beneficiaries will benefit from the existence of alternative choices of HIV prevention technologies, it is appreciated by the interviewees that financial support from MoFA enables them to simultaneously advance both vaccine-based and microbicide-based solutions. Because of its holistic approach to product development, and its willingness to support high-risk projects, MoFA is viewed by many interviewees as more forward looking than some other large donors.

4.3.4 Focus on capacity development

In its threshold criteria for the 2011-2014 Grant Framework, MoFA stated that, in order to be eligible for funding, PDPs must “*aim to improve capacity for research into, and production of, medicines to treat such diseases in developing countries*”. For several of the seven PDPs, whose primary focus has traditionally been squarely on R&D, capacity development in developing countries was not previously an explicit component of their activities. MoFA has thus contributed to PDPs placing greater emphasis on local capacity development, through encouraging investments in local research capacity (e.g. training of local researchers, outfitting of laboratories, and creation of clinical trial sites) and manufacturing. Most other funders are primarily concerned with supporting R&D, so there are few other funding options available to support these types of activities.

4.3.5 Improving efficiency and transparency

In 2009, at the end of the first funding period, MoFA commissioned an external review of its PDP Grant Framework³⁰. For some PDPs the outcomes of this review inspired changes to their organisational structures, with the aims of streamlining operations and improving efficiency. IAVI, for instance, indicated that at the instigation of its donors –including MoFA– it took significant measures to demonstrate greater transparency and efficiencies, which subsequently contributed to its ability to attract further resources from other donors. Nonetheless, several of the PDPs acknowledge there remains room for improvement in their financial reporting processes.

³⁰ HLSP (2009). External Review of Product Development Partnership Grant Framework.

Also for some PDPs that did not previously receive funding from MoFA, Dutch funding has impacted the organisational structure. Prior to 2011 POW PDP had largely been operating as an ‘informal’ PDP through loosely defined partnerships; in order to be able to respond to the MoFA call for proposals, it had to formalise these relationships, fostering greater commitment from all parties.

4.4 Fit to the current policy focus

Since the beginning of the Grant Framework in 2011, the focus of the Dutch policy on development and aid has shifted in various ways (see also Chapter 3). Whilst the decision to fund the current seven PDPs should be understood in the context of then prevailing policies, in moving forward it is relevant to also assess the alignment of their activities to current policy priorities.

At present, Dutch development policy prioritises activities related to Sexual and Reproductive Health and Rights (SRHR). This spearhead clearly aligns well with the work programmes of IAVI (HIV vaccines), IPM (microbicide rings, offering dual protection against HIV and unwanted pregnancy), POW PDP (Woman’s Condoms offering protection against HIV, sexually transmitted infections and unwanted pregnancy) and partly –because of its broader focus– FIND (HIV diagnostics HIV).

Although at first sight the SRHR spearhead may not directly align with the work of PDPs like DNDi, Sabin or Aeras, several linkages do exist. Firstly, there are important unwelcome interactions between HIV/AIDS and the infectious diseases that are the focus of these PDPs. For instance, infection with schistosomiasis, hookworm or visceral leishmaniasis severely weakens the immune system of afflicted patients, making them significantly more susceptible to infection with HIV and other sexually transmitted infections. In patients who already are HIV positive, co-infection with NTDs may also worsen their response to treatment, whilst hookworm infections have been shown to increase the risk of mother-to-child transmission of HIV³¹. Particularly problematic is that the geographic areas where these NTDs are most likely to occur often overlap with areas where there is high HIV prevalence, so that the risk of co-infection is substantial. Conversely, infection with HIV can open the door to other so-called ‘opportunistic’ infections, which increases rates of HIV-related morbidity and mortality. In particular, TB is the largest killer of people with HIV and the rising incidence of co-infection with TB and HIV in sub-Saharan Africa severely threatens the advances that have been made over the last decade in combatting HIV/AIDS. Furthermore, it is important to highlight the fact that many of the diseases targeted by these PDPs disproportionately affect women and children. For instance, some existing treatments are not recommended during pregnancy due to safety concerns and infected pregnant women have higher risks of dying in childbirth. It is therefore not coincidental that all three aforementioned PDPs are working on the development and testing of paediatric formulations of their products.

The Dutch government also clearly recognises the importance of addressing poverty related diseases, as underlined by its decision to formulate a roadmap “*Global health, emerging diseases in emerging markets*” within the Top Sector Life Sciences & Health (see section 3.2.1). Many interviewees, from the PDPs as well as from other organisations, therefore stressed the significance of maintaining support for these programmes and urged MoFA to not interpret SRHR too narrowly in its future policy development and decision-making processes.

Aside from their focus on SRHR and combatting poverty related diseases, all PDPs align well with the stated aim of the Dutch government to involve the private sector in its development agenda. Although in practice the extent of private sector involvement varies across the funded PDPs, the PDP model likely represents one of the most viable

³¹ Noblick J, Skolnik R, Hotez PJ (2011) Linking Global HIV/AIDS Treatments with National Programs for the Control and Elimination of the Neglected Tropical Diseases. *PLoS Negl Trop Dis* 5(7).

ways to engage for-profit companies and other private organisations in responding to challenges of the developing world.

4.5 Sustainability

Drug development is a lengthy and costly process, with uncertain outcomes. The sustainability of the PDP model therefore hinges on the willingness of all parties, funders and implementers alike, to commit resources for the long-term, and on the PDPs' ability to build a sufficient base of support. PDPs that rely on a small number of relatively large donors are especially vulnerable. Not only does this situation directly endanger the PDPs' survival in case funding is terminated, but it also jeopardises their flexibility and scientific independence by effectively wedding the PDP to the priorities of the donor. In recognition of these risks, DNDi has capped its relative funding contributions at 25% per donor. All PDPs continually aim to broaden their funding base, but do so with various degrees of success (see section 5.1.1), as global financial pressures and shifting political priorities have caused a general decline in budget allocations for development assistance.

As various PDPs are beginning to move their products further into stages of clinical development (e.g. IAVI, Aeras, Sabin, and DNDi), or as they explore new chemical entities (e.g. DNDi) –processes that are considerably more costly than early stage R&D or progressing existing candidates–, it becomes imperative for these PDPs to secure additional funding.

4.6 Collaboration

Most of the seven funded PDPs frequently interact with each other in several ways, such as through:

- Joint product development and research coordination;
- Sharing of resources: e.g. (laboratory) facilities and clinical trial sites;
- Sharing of experiences on crosscutting issues: e.g. regulatory issues or advocacy.

Not surprisingly, many of the interactions are found between PDPs that share a focus on specific diseases (e.g. IAVI, IPM and POW PDP on HIV; DNDi and Sabin on NTDs), or technologies (e.g. IAVI, Aeras and Sabin on vaccines). Opportunities for joint development or coordination of research activities also arise in areas where complementarities between PDPs exist, as exemplified by the collaboration between FIND, which has broad expertise in developing diagnostics, and the more disease focused PDPs Aeras (TB) and DNDi (NTDs), to jointly develop products across the spectrum of care: from diagnosis to treatment.

Another important way in which PDPs work together, and promote the efficient use of resources, is by sharing research facilities and clinical trial sites in developing countries. Research collaboration centres and capacity in Africa have been shared by, among others, IAVI, IPM and Aeras. IAVI has furthermore shared laboratory facilities with PATH–Malaria Vaccine Initiative (MVI), a separate programme not currently supported by MoFA. Similarly, PDPs like Aeras, Sabin and FIND have shared some manufacturing facilities.

In terms of exchange of information and experiences, both informal interactions between individual PDPs and more formalised networks exist. IAVI, in particular, has played a key role in coordinating its advocacy activities with other PDPs, such as IPM, FIND and Sabin. Recently IAVI and Aeras jointly organised a briefing in the Dutch

Parliament³². Furthermore, a European PDP-coalition has been set up in 2009, first led first by IAVI and DNDi to develop joint advocacy for resource mobilisation and policy towards European Union's Seventh Framework Programme (FP7). This PDP-coalition is currently chaired by PATH, DNDi and EVI and decided in 2013 to expand its activities beyond EU to other targeted European countries. Most of the PDPs are members of the Global Health Technologies Coalition (GHTC), a group of organisations advocating for increased resources and improved policies to accelerate the development of and access to new global health technologies. Several other coalitions and working groups exist for the coordination of specific advocacy initiatives.

Many of the PDPs also have an active relationship with the European & Developing Countries Clinical Trials Partnership (EDCTP), which similarly aims to contribute to reducing poverty related diseases.

³² Committee on Foreign Trade and Development Cooperation meeting on the Product Development Fund 5 November 2014 <http://www.tweedekamer.nl/vergaderingen/commissievergaderingen/details?id=2014A03977>

5. Assessment of the Grant Framework and funding mechanism

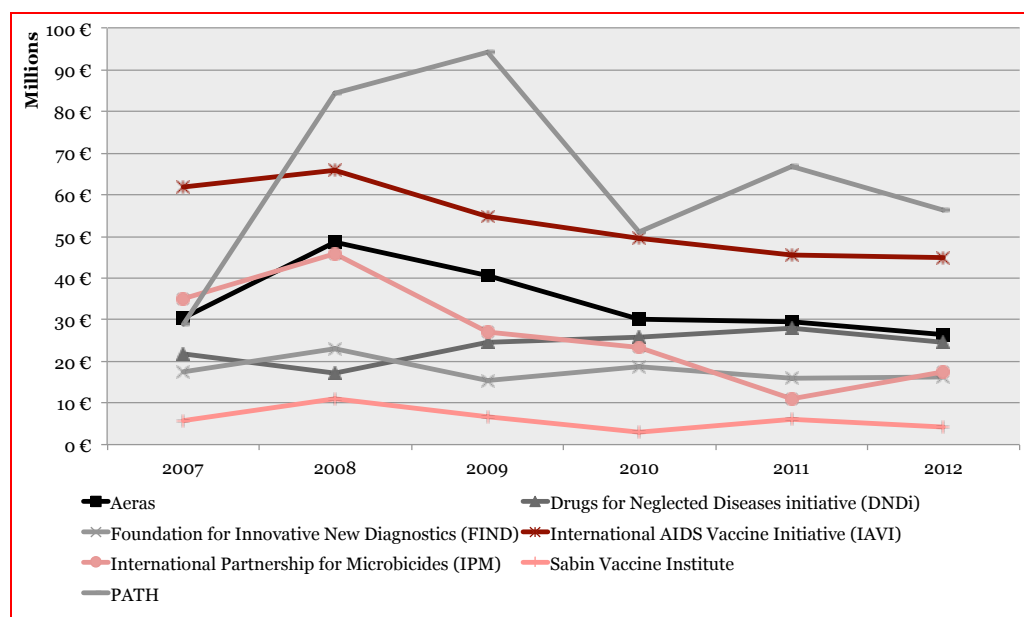
In this chapter we summarise our findings from the assessment of the grant framework and funding mechanism.

5.1 Financial analysis of MoFA funding

5.1.1 Overall PDP funding and number of funders

Figure 9 shows the overall development of total PDP funding between 2007 and 2012 for each of the seven PDPs supported by MoFA³³. Total yearly budgets range from around €3 million (Sabin, 2010) to €94 million (PATH, 2009).

Figure 9 Evolution of total PDP funding (2007 – 2012, in Euro)



Source: G-FINDER data (2013).

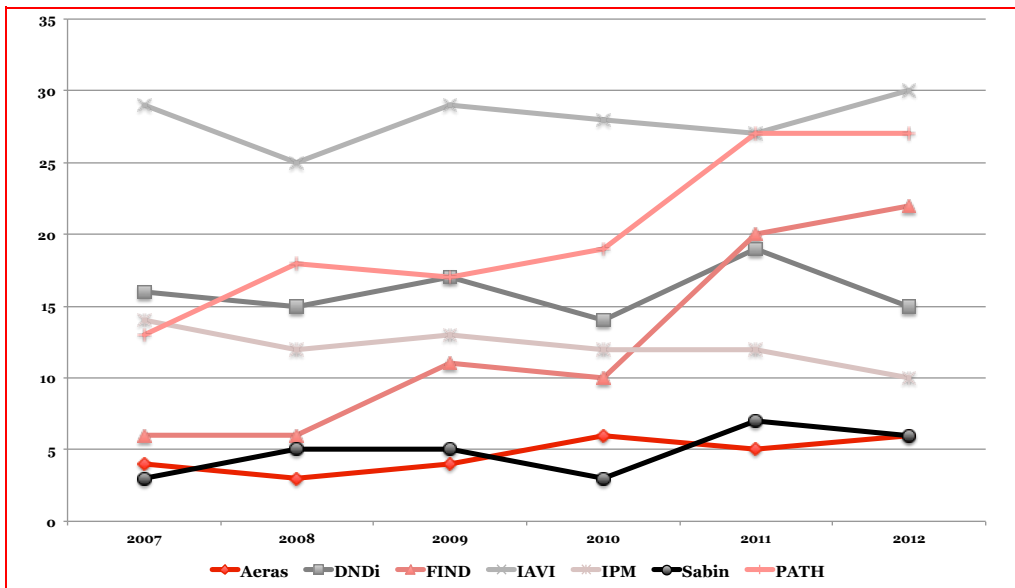
The total budget for the seven PDPs evolved from €201 million in 2007 to €296 million in 2008, and then slowly declined to €189 million in 2012. This trend is relatively consistent when reviewing all PDPs covered by the G-FINDER report: total funding first increases from €357 million euro in 2007 to €440 million in 2008, then slowly decreases each year to €285 million in 2012 (see also section 1.5). The last five years show a consistent decrease of between €20 million - €60 million a year.

Over time, the overall number of unique funders for the seven PDPs has increased from 85 in 2007 to 116 in 2012 (Figure 10)³⁴. Aeras and Sabin both depend on a very small number of funders, while IAVI has consistently garnered between 25 and 30 supporters. In recent years, PATH and FIND have also successfully broadened their funding base, while for others this has been relatively stable or even showed a slight decline.

³³ Data for 2013 was not yet available during the review period.

³⁴ Note that G-Finder records only cash, but not in-kind, contributions.

Figure 10 Number of unique funders per PDP

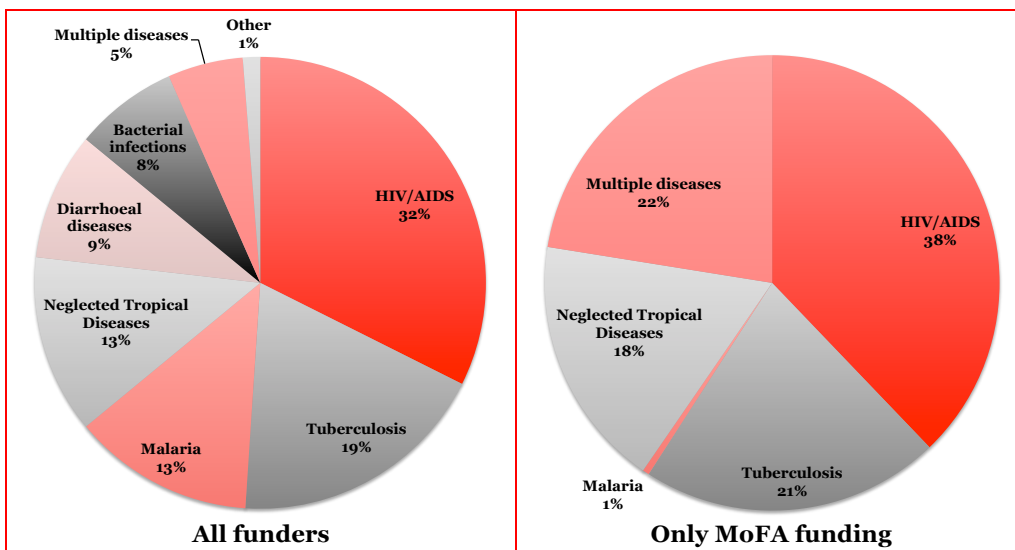


Source: G-FINDER data (2013).

5.1.2 Funding characteristics

The contributions by funders have been analysed in terms of their focus on distinct types of disease and products. Figure 11 shows the funding by diseases of all funders for the seven PDPs included in this review (the left chart) and only MoFA funding (right chart). Together, malaria (13%), tuberculosis (19%) and HIV/AIDS (32%) account for two-thirds of all funding (Figure 11: left). Compared to these global averages, the Netherlands have contributed significantly less to malaria (1%), but somewhat more to HIV/AIDS (38%) and NTDs (18%)(Figure 11: right). The Netherlands have also invested a comparatively large amount in multi-disease programmes (22%).

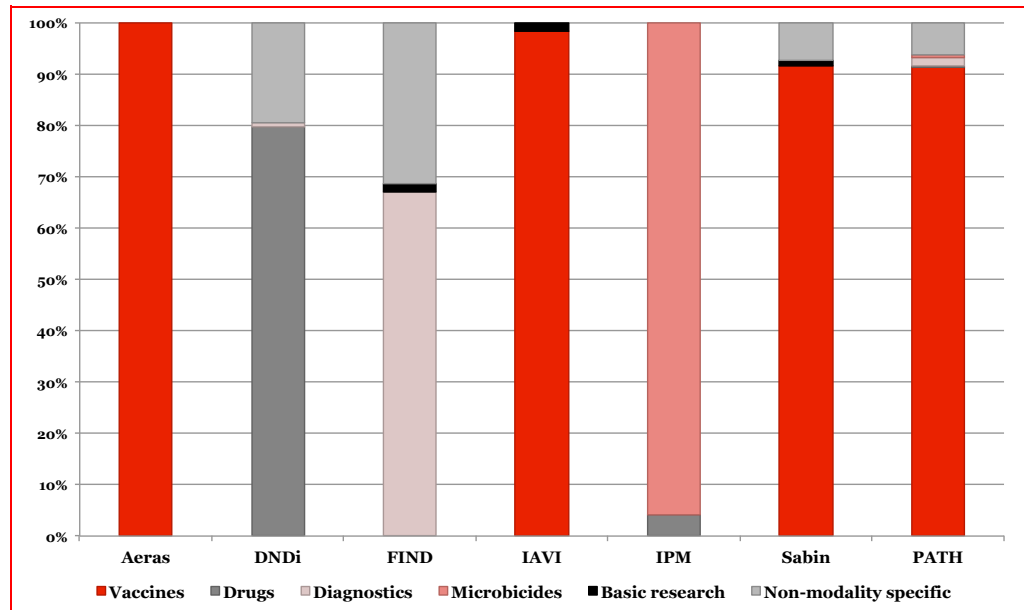
Figure 11 PDP funding by disease (2009-2012) for 7 PDPs (all funders and MoFA)



Source: G-FINDER data (2013). Note: the group ‘Neglected Tropical Diseases’ comprises dengue, kinetoplastids, helminths (worms and flukes) and leprosy. ‘Bacterial diseases’ here refers to bacterial pneumonia & meningitis, and salmonella. ‘Other’ encompasses the categories adjuvants & immunomodulators, delivery technologies and devices, and general diagnostic platforms.

Significant variation can be observed across the seven funded PDPs in how funding has been allocated to different types of products (Figure 12). Most of this variation, however, can be directly attributed to the different focal areas of the individual PDPs. For instance, Aeras, IAVI, Sabin and PATH focus almost exclusively on vaccines. DNDi works exclusively on drugs, FIND on diagnostics and IPM on microbicides, although all three also have a significant share of non-product specific funding (e.g. platform technologies).

Figure 12 Funding by type of product (all funders, 2009-2012)



Source: G-FINDER data (2013).

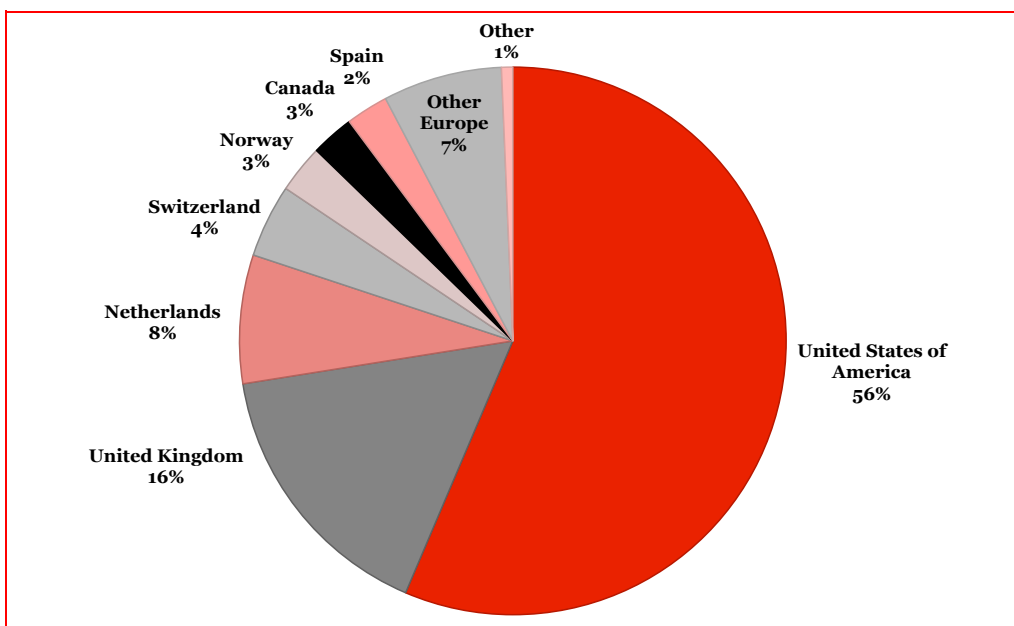
The above two charts show the diversity of the PDP funding provided by MoFA, both in terms of diseases and modalities (vaccines, drugs, microbicides) targeted.

5.1.3 Funding sources

Between 2009 and 2012, over half (56%) of all funding for the seven PDPs originated from the United States³⁵, followed by the United Kingdom (16%) (Figure 13). The Netherlands was the third largest donor (8%), followed by Switzerland, Norway, Canada and Spain, with contributions between 4% and 2%.

³⁵ Note that these numbers include contributions from governmental aid agencies, as well as from charitable foundations and other science & technology agencies.

Figure 13 PDP funding sources, by country (2009-2012)



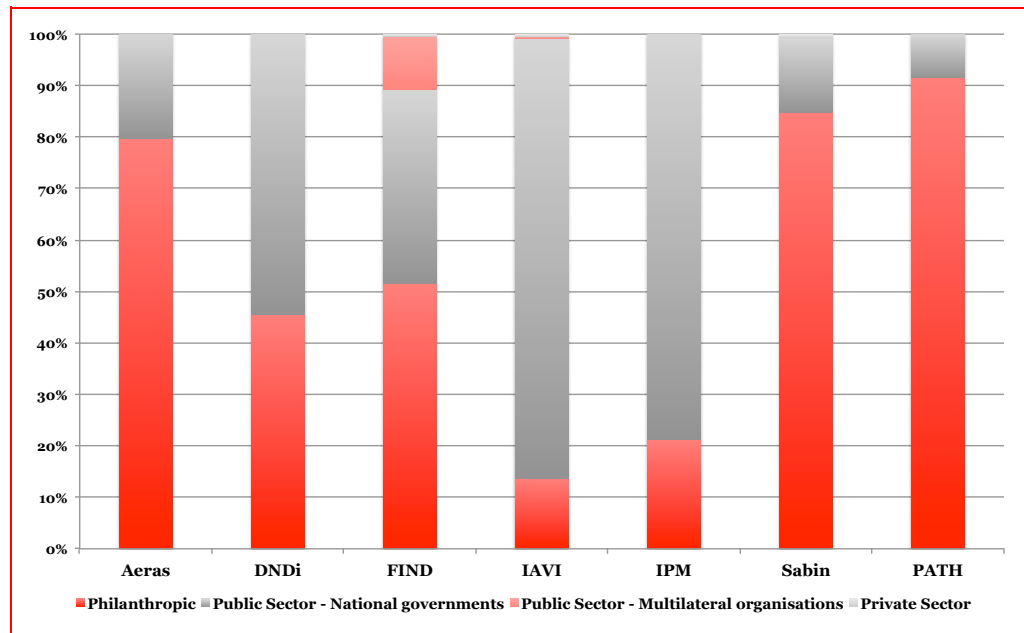
Source: G-FINDER data (2013).

Together, national governments and philanthropic organisations were responsible for virtually all PDP funding, although the distribution between the two varies significantly across PDPs (Figure 14). IAVI and IPM are largely government-funded, whereas Aeras, PATH and Sabin are mostly funded by philanthropic organisations (with the Bill & Melinda Gates Foundation as the major funder). FIND receives around 10% of its funding from the World Health Organization.

Overall, direct private sector contributions are negligible. This may in part be due to the fact that many private sector contributions are provided in-kind and do not register in the G-FINDER data set. For example, the (bio)pharmaceutical companies Crucell and GlaxoSmithKline (GSK) have contributed substantial in-kind resources to Aeras' and IAVI's immunology, vaccine manufacturing and distribution activities (i.e. shipping of samples). This contribution is not captured in financial reports, but is estimated by the PDPs themselves to be in the order of magnitude of millions of dollars.

Some PDPs (amongst which DNDi and FIND) have started to capture in their annual financial reports the in-kind contribution coming from their partners but further analysis should be conducted to better estimate the magnitude of in-kind contribution, particularly from the private sector. The PDP Funders Group could support the development of joint methodology to capture in-kind contributions by the PDPs.

Figure 14 PDP funding sources, by type of funder (2009-2012)



Source: G-FINDER data (2013).

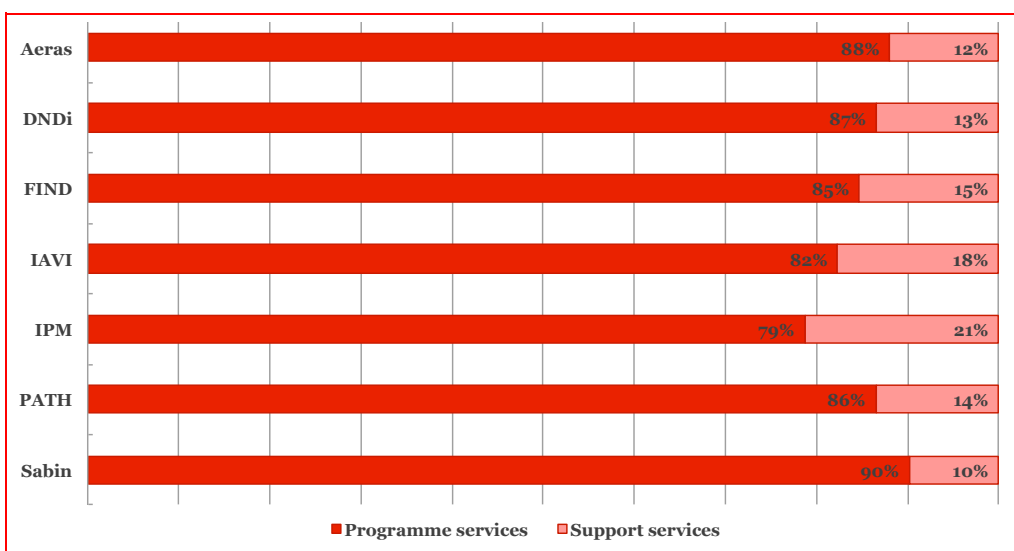
5.1.4 PDP expenditures

It is somewhat challenging to meaningfully compare expenditure data between the PDPs based on data provided in the annual reports alone, as differences exist in how each PDP classifies specific types of expenses. Nonetheless, in order to provide an impression of how PDPs compare to each other in terms of their expenditures, two broad categories can be distinguished: those directly related to core programme services (including R&D, capacity development and advocacy), and those allocated to support services. The latter includes management and administrative costs, and costs for fundraising. The year 2012 was chosen as the benchmarking year, since –at the time of writing– this is the year for which the most complete and up-to-date data were available. As Figure 15 shows, the share of expenditures for support services ranges from 10% (Sabin) to 21% (IPM), with an average of 15%.

It is worth noting that, even when fundraising costs are excluded, the support service expenditures for all PDPs, except for DNDi (8%) and Sabin (10%) (data not shown), exceed the 10% cap that some donors, including MoFA, have set for allowable overhead³⁶. Indeed, various PDPs have expressed frustration with this cap, as it is considered unrealistic given the complex organisational structures of some of the partnerships. On the other hand, various interviewees from outside the PDPs observed that, over time, some PDPs appear to have evolved into quasi-biotech companies with large overheads, and urged a return to leaner management structures.

³⁶ These figures are calculated at the level of the PDP, not on the level of the MoFA grant.

Figure 15 Breakdown of PDP expenditures (2012)



Source: PDP 2012 Annual Reports. Note: for PATH, data from the PATH annual report were used. These reflect expenditures of the whole organisation, rather than those specific to the POW PDP. For Aeras, expenditures relating to fundraising are included under programme service costs, as these were captured as a separate line item under support services in the annual report. At Aeras, fundraising costs also include several other activities (policy, advocacy, and communications). These are all lumped together under one category.

5.2 Added value of PDP funding

The activities performed by the seven funded PDPs span much of the R&D value chain, extending from basic research to market implementation of new drugs and technologies. It is therefore relevant to consider where PDPs can provide the most added value, and whether this is consistent with the MoFA supported activities.

Overall, interviewees agree that the principal value of the PDPs lies in their ability to support the transition from basic (‘upstream’) research, as performed in academic and research institutes, to the more ‘downstream’ stages of clinical research and development. Most academic scientists lack the resources and the know-how to directly engage in translational research. PDPs, on the other hand, are able to take research findings forward and push products down the R&D pipeline. By operating on a portfolio model, they are also better positioned than organisations that focus all their efforts on single products or technologies to identify the most promising candidates, and to make fast go/no-go decisions about which products to progress.

Despite a broad recognition that PDPs are uniquely positioned to bridge the gap between basic and translational research, PDPs are increasingly becoming involved in upstream research activities as well. Some interviewees have questioned whether this evolution is desirable, regardless of the scientific merit of these efforts. This development presents funders with a challenge, as separate funding mechanisms already exist for supporting basic academic research. The mission creep of some PDPs risks blurring the lines between research funding and development assistance. At the same time, some interviewees have cautioned against funding only activities at the far end of the value chain, recognising that *“you must sow before you can reap”*. Consistent with these considerations, the MoFA PDP funding has been targeted mainly at clinical research and product development activities at the middle and downstream end of the value chain.

Additionally, because of their research activities in developing countries, PDPs are extremely well positioned to help increase local R&D capacity. There are currently few other mechanisms to efficiently achieve this, aside from some partnerships between

universities in developed countries (primarily the US and Europe) and institutes in the developing world. The financial support that MoFA provides for these capacity-building activities is therefore considered of great value to the development of a local research infrastructure.

5.3 Effectiveness of the funding mechanism

Determining whether the PDP Fund has been effective in achieving its stated objectives remains difficult. It is clear that many PDPs have made significant progress in advancing products through the R&D pipeline, but in most cases it is still too early to tell whether these advances will eventually result in marketable products, and how these will then translate into improvements in the health status of target populations. This long time horizon is inherent to the process of drug development: the US Food and Drug Administration (FDA) estimates that, on average, it takes around 14 years from first testing to regulatory approval of a drug³⁷. As many of the products are currently still in clinical trial phases, it will likely take many more years before these products can be expected to reach the market and the effects of the funding become visible. However, since their creation, PDPs have developed more than 30 products that generated global health impact for some diseases. DNDi has contributed with treatments for malaria, visceral leishmaniasis, Chagas disease and sleeping sickness; FIND has delivered on diagnostics and PATH has developed several products. Currently, some of the projects have advanced significantly during the recent funding programme.

Aside from effectiveness as defined in terms of achieved impacts, the effectiveness of the PDP fund as a funding mechanism itself requires consideration. Interviewees have indicated that the current way of organising the PDP Fund has been rather time consuming for the MoFA policy officers involved. As the direct point of contact for the PDPs, the policy officer is responsible for a variety of grant related activities (e.g. progress follow-up, approving annual reports, requests for adjustments due to project results, and advocacy activities), as well as for future policy preparation. At the moment, MoFA is internally exploring an alternative model to separate the execution of a grant framework (i.e. the direct follow-up of grant progress) from content and policy related issues.

The PDPs expressed general satisfaction about their interaction with MoFA. Particularly the flexibility in allowing for changes to the original proposal (when necessitated by project results) and for no-cost extensions, and a relatively light administrative burden were much appreciated. MoFA was seen as a responsive partner in a relationship based on mutual trust. However, for many of the PDPs, frequent changes in the position of the MoFA policy officer have caused challenges. Especially for PDPs that had not previously interacted with MoFA, this created uncertainty about MoFA's expectations. PDPs indicated that they would have welcomed clearer guidance and leadership from MoFA regarding alignment with future Dutch development policies.

5.4 Role of the private sector

The PDP model is, in part, based on the assumption that, through financial risk sharing, the private sector can be encouraged to contribute to R&D in the commercially unattractive field of poverty related diseases. To some extent this expectation has been fulfilled, though in terms of cash contributions the share of private sector involvement remains limited. Potentially more valuable, however, is the role of the private sector as an active partner in the R&D process, through sharing of knowledge and resources. As PDPs are moving their products further along the pipeline, it will become increasingly

³⁷ http://www.fda.gov/oc/ohrt/2014/10/14/20141014_01.html. Accessed 14 October 2014.

important to involve biotechnology and pharmaceutical companies in this product development process. Several interviewees have indicated that they feel the Dutch government could, and should, do more to encourage (Dutch) companies to take their responsibility, both as funders and as active partners to the PDPs.

Part of the reluctance of companies to engage with public sector partners may rest in concerns around intellectual property (IP). In order to address this barrier and attract more companies to the field, IAVI and BMGF have set up an Innovation Fund. This seed capital fund provides funds to small and medium-sized companies with new, but untested technologies to further develop their products, but allows them to receive commercial returns by negotiating ‘access agreements’. These agreements guarantee that developing countries get access to drugs at affordable prices, but enable the company to retain its IP and sell its products at more profitable prices in other markets. An example of innovative IP licensing is that DNDi has signed agreements with private companies for access to compound libraries and to advance candidates in the portfolio. These agreements helped accessing knowledge and data to avoid duplication of activities and therefore to save money and time.

5.5 Dutch perspective on academic, economic and societal relevance

The main objectives of the PDP Fund (see section 2.1) do not explicitly include contributions to Dutch society. However, this does not mean such contributions did not occur. Based on observations by interviewees, several types of impacts could be distinguished: scientific, economic and societal.

The threshold criteria for the Grant Framework did not require the involvement of a Dutch organisation. Yet, because of the Netherlands’ strong track record in research for HIV, tuberculosis and NTDs, a significant number of Dutch public and private research organisations have been involved in the PDP supported activities (Figure 16). Although in some cases MoFA has helped to forge contacts between the PDPs and Dutch institutions, the PDPs underscored that their decision to engage with Dutch partners was not motivated by considerations relating to grant eligibility, but was driven by the extent to which these organisations were felt to contribute particular solutions to specific areas of research. Further downstream also a number of Dutch biotechnology and chemical companies have participated in aspects of the work. It is widely agreed that these partnerships have been mutually beneficial and have enriched Dutch research. Despite this significant involvement from Dutch research organisations, a number of interviewees expressed disappointment that a substantial share of the Dutch funds has flowed toward research organisations abroad, whereas it is felt these already can benefit from domestic research funding and do not need to be funded by the Dutch government as well. However, Aeras has invested approximately \$21 million in the Netherlands for joint research projects with Dutch investigators.

At a relatively limited scale, the involvement of Dutch research organisations and biotech companies has also benefitted the Dutch economy. It stands to reason, however, that the potential for Dutch biotech companies to be involved will increase over the coming years, as more products move into later stages of development and production.

Figure 16 Dutch partner organisations for MoFA funded activities

PDP	Universities & research institutes	Private companies	Other
Aeras	Leiden University Medical Centre (LUMC), Netherlands Cancer Institute (NKI), Maastricht University (UM), Biomedical Primate Research Centre (BPRC).	Crucell	KNCV Tuberculosis Foundation, TB Vaccine Initiative.

PDP	Universities & research institutes	Private companies	Other
DNDi	University of Amsterdam, Academic Medical Centre (AMC), Utrecht University (UU), Royal Tropical Institute (KIT), Top Institute Pharma (TI Pharma), and Slotervaart Hospital.	Mercachem	Médicines Sans Frontières Holland, i+solutions, IDA Foundation.
FIND	Radboud University Nijmegen (RUN), KIT, University of Leiden (UL).		KNCV Tuberculosis Foundation
IAVI	AMC	Crucell, Pepscan	AIDS Fonds/Stop Aids Now
IPM		Kinesis Pharma, Pharmaceutical Research Associates Group, Analytical Biochemical Laboratory.	AIDS Fonds
POW PDP			Universal Access for Female Condoms (UAFC)
Sabin	AMC, Amsterdam Institute of Global Health and Development (AIGHD), UL		

Source: Technopolis Group analysis (2014).

Although the diseases targeted by the PDPs have been labelled ‘poverty related diseases’, they are by no means exclusive to developing countries. According to the most recent estimates, in the Netherlands every year around 1,100 people become infected with HIV³⁸. Tuberculosis, once thought to be on the verge of eradication in our part of the world, has also re-emerged as a credible threat, made worse by increasing rates of antibiotic resistance. Of the 27 MDR-TB high-burden countries, 15 are located in the European region and the economic burden of TB in the EU totals nearly six billion euros per year^{39,40}. Development of vaccines against these diseases will therefore contribute not only to the health of people in developing countries, but also of those in the Netherlands.

Lastly, at the international level the Dutch government’s support for the PDPs is viewed as enhancing its credibility with international partners in discussions around global health and development assistance, thereby increasing the country’s global standing.

5.6 Strengths and weaknesses of the funding mechanism

Based on discussions with interviewees, and as elaborated in the previous sections, several main strengths and weaknesses of the MoFA PDP Fund could be identified.

Strengths:

- By funding PDPs, MoFA is helping to bridge the gap between fundamental and translational research for poverty related diseases, thereby contributing to the development of highly important clinical products for developing countries.

³⁸ <http://www.hiv-monitoring.nl/english/patients-and-public/hiv-aids-epidemic-update/netherlands/>. Accessed 14 October 2014/

³⁹ <http://www.tbcoalition.eu/2013/12/16/health-advocates-call-for-eu-leadership-on-multi-drug-resistant-tuberculosis/>

⁴⁰ http://www.stoptb.org/news/stories/2013/ns13_051.asp

- MoFA's support for a broad coalition of partners enables PDPs to focus on development of a portfolio of products, resulting in risk sharing and increased chances of success.
- MoFA has demonstrated a good understanding of the nature of drug discovery and product development by allowing PDPs sufficient flexibility in their execution of the grants. It also respects the internal processes the PDPs have in place to make decisions to select, progress or abort activities.
- MoFA has leveraged its financial support for the PDPs to contribute to R&D capacity development in developing countries.
- MoFA is viewed by the PDPs as a transparent, responsive and constructive partner.
- MoFA has positively contributed to reducing the administrative burden placed on PDPs by harmonising its reporting requirements with other funders, through the PDP Funders Group. The separate annual work plans that MoFA requires PDPs to submit are mostly seen as a useful tool for discussing intermediate 'course corrections'.

Weaknesses:

- Although a substantial number of Dutch research organisations have been involved in the research activities of the PDPs, the involvement of the Dutch private sector has been somewhat lagging.
- Although MoFA is considered a valued partner, the communication between MoFA and PDPs has been suboptimal during the current funding period. The high turnover of PDP policy officers at MoFA has in some cases resulted in insufficient communication about mutual responsibilities, and a lack of clarity on the part of the PDPs about MoFA's expectations and requirements.
- In part because of the limited communication between MoFA and the PDPs (as perceived by some of the PDPs), the PDPs are unclear about their eligibility for future funding from MoFA. Yet, long-term commitments and timely knowledge about funding availability are vital to the PDPs for effective strategic planning.
- Among Dutch policy and decision-makers there appears to be limited awareness about the work of the PDPs and MoFA's contributions to the PDPs. By better showcasing its achievements, MoFA would be able to advocate more for the PDP model and help bring on board more partners.

6. Conclusions and recommendations for the future

This chapter first outlines some of the limitations of this study. Next, it presents the main conclusions and provides recommendations for the future.

6.1 Limitations

Whilst the authors of this review have aimed to compose a review that is both comprehensive and relevant, certain limitations apply that should be kept under consideration when interpreting the findings.

Firstly, the review was necessarily time-limited. Therefore, a limited number of information sources could be used. A decision was made to principally rely on primary data, collected through interviews with key stakeholders, supplemented by secondary data in the form of the grant proposals, annual PDP Funders Group reports, and annual PDP reports. Other secondary data sources, in particular external evaluations, were only utilised when considered necessary to triangulate observations. In this way much of the information synthesised in this report was provided by the PDPs themselves, or by those with a personal involvement with the PDPs, and thus may carry some favourable bias towards the PDP model. However, critical considerations were explicitly sought out and, whenever applicable, have been included in this report.

Secondly, although this review includes an overview of key achievements by the PDPs, it should not be taken as an evaluation or audit of the individual PDPs. An assessment of the scientific merit of the research conducted and the results obtained was outside the scope of this review.

6.2 Main conclusions

Based on a comprehensive analysis of documentation and interviews with a wide range of stakeholders, the following conclusions can be drawn:

- Overall, the seven funded PDPs (Aeras, DNDi, FIND, IAVI, IPM, POW PDP, Sabin) have made substantial progress towards their grant objectives. Because of their focus on different diseases and technologies, it is difficult to compare results between the individual PDPs: for instance, combining pre-existing treatments can lead to earlier implementation than the development of entirely new chemical entities. However, it should be kept in mind that most of the funded projects are still in early stages of clinical research and development, so that their impacts will not become fully visible for several more years.
- Aside from achievements in terms of research and product development, the PDPs have successfully contributed to strengthening the capacity of developing countries to conduct clinical trials. Through advocacy and awareness raising, they have, furthermore, helped put poverty related diseases on the international agenda.
- The MoFA funding has made important contributions to the work of the PDPs. Through its broad portfolio support and flexible approach, MoFA has helped push forward a number of research activities that otherwise might not have been possible. Dutch funding has also been instrumental in helping PDPs to attract additional resources and in catalysing further research in the field of poverty related diseases. This has been aided by the good reputation of Dutch research in this area, and the longstanding and well-known commitment of the Dutch government to development assistance. Support for local capacity development has been a distinguishing feature of Dutch PDP funding.
- Overall, despite the encouraging progress made towards the PDP Fund objectives, it is evident that the formulation of the fund objectives has been mostly aspirational,

rather than grounded in a realistic assessment of what could be achieved within the constraints of time and resources.

- Alignment between the programme of work of the funded PDPs and Dutch policy priorities should firstly be viewed against the background of prevailing priorities at the time the grants were awarded. Since then, Dutch development policy has shifted focus, with an increased emphasis on SRHR. This shift may have consequences for future funding decisions. However, the work of the PDPs fits well in the broader international development policy as included in its strategic agenda from 2013 ‘*A World to Gain: A New Agenda for Aid, Trade and Investment*’, including the focus on private sector involvement. Furthermore, the PDPs address the Dutch’s government’s roadmap on addressing global health and emerging diseases in emerging markets that has been formulated within the Top Sector Life Sciences & Health.
- The Dutch government has been a valued partner of the PDPs, having shown a good understanding of the nature of drug discovery and a willingness to engage with PDPs on a basis of mutual trust. The PDP Fund is generally viewed by the PDPs as an effective mechanism, with a relatively light administrative burden. However, there appears to be a mismatch between the hopes and expectations from the PDPs about the role of the MoFA as a partner, and the MoFA’s actual mandate. Better communication and management of mutual expectations between the MoFA and the PDPs is required.
- The sustainability of the PDP model requires continued and increased commitment from the private sector, both as funders and as active partners. This is particularly the case as products move into later stages of clinical research and development. Although the private sector is already making significant contributions to the PDP model, primarily through in-kind support, more action is needed to bring private companies into the space.

6.3 Recommendations

Based on the review findings, a number of recommendations have been formulated. We have distinguished between recommendations specific to MoFA (and potentially other donors), those more broadly applicable at the level of the PDP Funders Group, and those most relevant directly to the PDPs.

Recommendations for the Ministry of Foreign Affairs

- In its decision making process about possible continuation of the PDP Fund, MoFA should take the following into consideration:
 - Alignment with the current policy focus. In this context MoFA should consider not only direct linkages to the spearhead SRHR, but also connections to the broader international development agenda and to the Dutch Top Sector policy (in particular the Top Sector Life Sciences & Health).
 - Added value of PDP support. In order for MoFA to optimise the effectiveness of its investments in the PDPs, it should have a clear vision of what type of activities it wants to support (without becoming overly prescriptive), where along the R&D value chain its funding is most needed, and what other financing instruments exist to support (part of) these activities. This can be used in defining clear objectives for a potential future PDP Fund.
 - The Dutch pioneering role. The Netherlands has long been a principal European player in the fight against poverty related disease and a champion of sexual and reproductive health care. As such, it has a guiding role as advocate for these

fields. As a funder, the Dutch government has also shown a readiness to support innovative research in areas where other funders are more reluctant to venture.

- The position in the PDP Funders Group. Jointly, the European funders represented in the PFG are able to provide direction to the PDPs and offer a counterweight to other influential funders. A decrease in the number of countries represented in the PFG can affect the PFG's ability to make a mark on the international development agenda.
- Risk sharing with the private sector. Research in the field of poverty related diseases has been characterised by market failure. To incentivise the private sector to take on a much-needed role in the process, mechanisms for financial risk sharing between the public and private sectors are indispensable. If donor support is ceased, private partners are unlikely to remain involved in the product development.
- Relationship with the PDPs. Through its two consecutive PDP funding cycles, MoFA has invested significant time and resources in building a relationship with the PDPs. Because of this, MoFA is now able to engage in constructive dialogue with the PDPs about ways to increase efficiency and transparency.
- Support for PDPs requires sufficiently long-term commitment, as PDPs typically perform activities that do not yield results in the short-term. Ceasing financial support in the middle of a development process reduces the chances for impact and decreases the effectiveness of the funding already provided. It is therefore preferable to commit resources for an extended period of time. Ideally, commitments should cover a period of 7 to 10 years, though this may prove unrealistic because of political pressures and shifting policy agendas. A minimum funding period of 5 years should be considered. However, in the context of a static or reduced funding envelope for PDP support, longer funding periods may entail a reduction in the total number of PDPs supported.
- At the moment, the gap between consecutive funding cycles is perceived as too big, creating uncertainty for the PDPs about continuation of projects and difficulty with forecasting their funding needs. MoFA should consider planning for new financial periods earlier, and more clearly communicating future funding opportunities to the PDPs.
- Greater stability in staffing at the side of MoFA would be desirable to ensure the PDPs can reliably engage with a contact person who is sufficiently informed about the activities of the PDPs and whom the PDPs can regularly communicate with. In principle, it is MoFA policy to rotate policy officers every 4 years, but over the duration of the current PDP fund more frequent changes have occurred. This has somewhat hampered the communication between MoFA and the PDPs. Although such changes are sometimes unavoidable, MoFA should strive to limit its staff rotations and optimise the changeover process between subsequent policy officers.
- In the context of the current exploration of MoFA to create a clearer division between policy formulation on the one hand, and policy implementation and execution on the other, it could be explored whether the administrative execution of a future PDP Fund could be transferred to another entity, while MoFA continues to provide the PDPs with all content related guidance.
- Currently, there is insufficient knowledge amongst Dutch policy makers about the work of the PDPs and the contribution of MoFA. MoFA should focus on better showcasing its contributions to the activities of the PDPs, both internally within the ministry and to other policy makers. It could do this in the form of regular engagement with a wide range of stakeholders, with support from the PDPs, and becoming an ambassador for the PDP model. This could also serve to attract additional resources and interest new partners. The Dutch government could play a greater role in brokering relationships between PDPs and Dutch companies and research organisations. The Top Sector Life Sciences & Health could be a

mechanism to increase this. Attention should also be paid to the role that Dutch companies with a presence in developing countries could play in supporting local activities.

Recommendations for the PDP Funders Group

The PDP Funders Group provides a useful platform for communication and coordination between different donors. Nonetheless, room for improvement exists in a number of areas.

- We propose improvements in the current structure of the Annual PDP Funders Group Report to reduce duplication, and provide stronger guidance on specific aspects (including financial reporting) to obtain clearer and more comparable results. The reports could focus less on technical information, instead using language that invites dissemination to a wide audience to better communicate the achievements of the PDPs and their funders.
- At present, only a selection of funders (i.e. MoFA, DFID, IrishAid and the Danish Ministry of Foreign Affairs) accept the Annual PDP Funders Group Report ‘as is’. Other members of the PFG require additional reporting. Financial audits are all done individually. These requirements create duplication of efforts and increase overhead costs. The different funders represented in the PFG should strive for better coordination of their activities and harmonisation of requirements.
- Although in terms of reporting requirements better harmonisation between funders is warranted, for continuity of funding it is preferable if funders operate on overlapping, rather than synchronised, funding periods. This way the risk of major funding gaps, potentially necessitating discontinuation of activities, can be mitigated.
- Much of the support for PDPs so far has been directed at early stage (Phase I and II) clinical trials. As products advance into later trial stages (Phase III), costs exponentially increase. In order to ensure funding for these costly trials, different funders may need to pool resources and collaborate more closely. It is important for the PFG members to timely prepare for these developments.
- By definition, PDPs are organisations based on a partnership structure. Although the number and nature of partners involved varies significantly between the different PDPs examined, the management of these partnerships is often complex and challenging. This means that adequate funding for organisational support functions is required. Currently, many of the major funders do not allow their funds to be used for general management costs. The PFG members should recognise the legitimate need of the PDPs for inclusion of a share of management costs into programme proposals. At the same time, the PFG should maintain pressure on the PDPs to reduce unnecessary overhead, by better sharing of resources and streamlining of operations.
- Currently, a number of European initiatives exist to support research and development in the field of poverty related diseases. Aside from the direct PDP support, there are the EU Framework Programme Horizon 2020, which provides funding for research and innovation⁴¹, and the European & Developing Countries Clinical Trials Partnership (EDCTP), which in its second phase⁴² supports all stages of clinical trials (from phase I to IV) for the development of drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis, malaria and

⁴¹ http://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/main/h2020-wp1415-health_en.pdf. Accessed 15 October 2014.

⁴² In 2014 the European Commission and Parliament approved a second ten-year period of EDCTP.

neglected tropical diseases⁴³. European PDP funders should assess how best to optimise the complementarity between these initiatives, without creating too much overlap. It should however be kept in mind that PDPs might have difficulties to apply for funding through these initiatives as a result of strict requirements for building consortia with European partners for specific research projects and stages. This does not necessarily align with PDPs way of selecting partners for its operations.

- The international research agenda for poverty related diseases has been largely set by US and European institutions, and has been imposed top-down. Greater voice should be given to researchers from developing countries to help formulate research objectives, as they are best placed to understand the local needs and context in which these diseases occur. Because of their in-country presence and engagement with local researchers, PDPs could play an important networking role.

Recommendations for PDPs

The main purpose of this review was to assess the performance of the PDP Fund as an instrument for supporting R&D for poverty related diseases. As such, this review has not focused in detail on the performance of the individual PDPs. Nonetheless, based on our observations some general recommendations could be formulated.

- Between different PDPs many informal networks for collaboration and information exchange, particularly in relation to R&D, already exist. However, it was felt that more formal structures would be helpful to promote information sharing and mutual learning on overarching themes such as advocacy and capacity building. The PFG has previously assisted in this process through creation of thematic working groups, but these initiatives could be taken forward more by the PDPs themselves.
- Many of the PDPs appear to spend a significant share of resources on non-core activities and support services. Some of these costs could be reduced by greater sharing of resources (e.g. clinical trial sites, manufacturing facilities, logistics) and streamlining of operations.
- The PDPs could develop a clearer communication and advocacy strategy that is specifically targeted at policy and decision-makers, to highlight their achievements to date, raise awareness about poverty related diseases, and advocate for additional resources. This should be done in language that is accessible to a lay audience. MoFA, as well as other funders in the PFG, could provide the PDPs necessary input. It is similarly important for PDPs to routinely engage in information dissemination and relationship building with their current and potential future funders, and not only do so around the time of completion of a funding cycle.

⁴³ Website of EDCTP (<http://www.edctp.org/>). Accessed 15 October 2014.

Appendices

Appendix A Terms of Reference	49
Appendix B Operationalisation of review questions	55
Appendix C Threshold criteria for funding eligibility	61
Appendix D List of interviewees	63
Appendix E Interview topic guide	65

Appendix A Terms of Reference

TOR PDP external review 2014

Terms of Reference External Review DGIS PDP Grant Framework

1. Background

In 2010, the Ministry of Foreign Affairs (MoFA) awarded grants to seven (7) Product Development Partnerships (PDPs) e.g. public-private partnerships for research & development of medicines, vaccines and diagnostics in the domain of Aids, TB and malaria. A total amount of maximally € 69.6 million was awarded for a period of four years (2011-2014). PDPs can be seen as one variant of public private partnerships focused on improving health in developing countries.

PDP	Budget (EURO)
Drugs for Neglected Diseases Initiative (DNDi)	14.000.000
International Aids Vaccine Initiative (IAVI)	13.300.000
International Partnership for Microbicides (IPM)	9.400.000
AERAS (Global TB Vaccine Foundation)	11.700.000
Foundation for Innovative Diagnostics (FIND)	10.200.000
Sabin Vaccine Institute (Sabin)	5.900.000
PATH	5.100.000
Total	69.600.000

These grants were awarded to promote research and development (R&D) on medicines, vaccines and diagnostics for HIV/Aids, tuberculosis and malaria. The products and/or technologies being developed needed to be effective, safe, applicable and accessible for the poor population (a.k.a. the Bottom of the Pyramid – BoP) of developing countries.

Thus, the PDPs were to provide accelerated access to safe & affordable medicines, diagnostics and vaccines in developing countries, with a specific focus on capabilities in terms of governance and cooperation with the industry, clinical trial management and readiness for change.

The Dutch Government funded a group of PDPs with the aim to:

- i) Stimulate the development of medicines, vaccines, diagnostics and other devices for poverty related diseases (from basic research to production) where there is a clear need for government support
- ii) Increase the efficiency of the funding mechanisms and different streams for R&D on this topic, for both the Dutch government as well as the PDPs and to reduce the administrative burden.

2. Purpose, scope and objectives of the review

Purpose

The current grant period (2011 – 2014) with MoFA ends in December 2014. MoFA seeks to contract a consultant to review the current Dutch PDP funding 2011-2014. A renewal of these grant agreements will depend partially on the outcome of this review. Moreover, this review should provide input for the decision on funding priorities and possible changes in the funding mechanism, if the grant agreement will continue.

Scope

This external review should focus on whether the original aims have been achieved and what can be done better in the future. It should determine to what extent the PDPs and the used funding instrument (7 individual grants over 4 years) meet their specific objectives in support of their general objective/outcomes.

Thus, this review should look into the achievements of the PDPs, AND it should assess the effectiveness, efficiency of the funding mechanism (7 grants for 4 years). The review will have to take into account the dynamic context within which the PDPs operate.

It is beyond the scope of this review to provide a detailed analysis with which to judge the relative merit of investing in the individual PDPs or in alternatives to the relevant PDPs. The focus will therefore be on the effectiveness of systematic ways in which PDPs and the government's funding instrument track the external environment and respond appropriately to it. It should also measure how well PDPs govern their activities and how they engage with key external players and stakeholders, whether they are institutions, organizations, networks, programmes, governments or individuals.

Specific objectives of the review

1. To assess the achievements of the PDPs in the light of the policy objectives of the Dutch government funding (retrospective) and the relevance of the PDPs in the light of the current policy focus (prospective).
2. To assess the extent to which the funding mechanism was effective and efficient in reaching the (policy) goals for both the Dutch government and the PDPs.
3. To provide recommendations on possible renewal of the funding for PDPs, funding priorities and possible changes in the funding mechanism based on current and future (inter)national policy- and funding challenges.

3. Key review questions

The following sections provide guiding questions for each of the objectives. The consultants is however encouraged to propose alterations or additional questions if needed.

- 1) Assess the achievements of the PDPs

Achievements may be 'hard' and 'soft', tangible and perceived, intended and expected. It will be helpful to collect opinions of key external stakeholders regarding the relevant PDPs contributions to the product development and to the entire field.

- What have been the **key achievements** of the specific PDPs in this period in terms of new products and pipeline development?
 - How do these main achievements compare with the ambitions set out in the original grant proposals to the Dutch Government?
 - How do these relate to issues of *increased access* for the poor and *accelerating delivery* of effective products to people most in need?
- What has been the **contribution and importance of the Dutch funding** towards reaching these achievements? What has happened if there had not been Dutch funding?
- What role has the Dutch funding played in the overall work of the individual PDPs? (E.g. leveraging, towards strategy and priority setting, governance) and how does this relate to other funding sources?
- How well do the individual **PDPs learn from their past experiences** and how well do they respond to a changing context and environment?
 - How well do PDPs deal with 'failures' and risk in the innovation process?
 - How well do PDPs keep abreast of developments and players in the field?
 - How well are PDPs planning for the future?
- How **sustainable** are the individual PDPs? (both in terms of finance, governance, IP management, programming, monitoring and evaluation)
 - Have the PDPs secured adequate financial commitments to confidently implement their strategy? If not, what are the implications and options?
 - Are the estimates of resource requirements for the future reasonable?
 - What will happen if funding from the Netherlands will be increased/reduced/stopped
- To what extent do the PDPs **co-operate** with each other and with other organisations outside the 'partnership'? What are the results of this cooperation, and what are challenges and risks?

2) Assess the funding mechanism

- How have the recommendations from the evaluation of the previous PDP grant been followed up and implemented? To what extent has this influenced the funding mechanism and funding management?
- What is the impact of the current Dutch government funding on the group of PDPs, in relation to the constraints of different models of donor funding (core- vs. portfolio- vs. project-funding);
 - On finance (% of total funding; does the Dutch grant make a difference, is it earmarked or mainstreamed?),
 - On strategy (does the Dutch grant attract other funding sources / partners), management (is the Dutch grant manageable, incl. reports requested).
 - on outputs and outcomes (specifically in terms of safety and accessibility of new products)
- Has the funding mechanism provided leverage for Dutch policy priorities in international fora?
- What are the strengths and weaknesses of the funding mechanism in terms of manageability, administrative burden and transparency – both from the perspective of the Dutch Government and the specific PDPs?

3) Recommendations for the future

- What are the strengths and weaknesses of the current funding mechanism? What are threats and opportunities?
- Which specific needs should be addressed in case a new grant framework is being established? What should be key priorities?
- What can be done to improve the relevance, efficiency and effectiveness of such a new framework compared to the current one taking into account the current policy focus of the Dutch Ministry of Foreign Affairs, in specific the policies related to sexual and reproductive health and rights and the balance between aid and trade?

4. Approach

4.1 Methods

The Social Development Department / Health and Aids Division of the Ministry of Foreign Affairs, will provide overall leadership and direction of the review. Responsible managers of the 7 PDP's will be actively involved in the process and will provide their support.

The assignment will entail a thorough desk review and stakeholder interviews. Optionally, a validation workshop could be organised with participation of among others senior representatives of the 7 PDP's and representatives of the Dutch government, the PDP Funders group, et cetera.

1) Desk review of documents

- a) Context analysis
- b) Analysis of the seven (7) PDPs

Key documents will include:

- Key policy documents of the Dutch government and the PDP funding policy framework, such as for instance: "A world to gain, a new agenda for aid, trade and investment", "Letter to the House of Representatives on policy on sexual and reproductive health and rights, including HIV/AIDS", and

“Report on key issues affecting access to sexual and reproductive health commodities and options for future DGIS engagement”.

- Strategic documents on the work of the PDPs in the context of global health developments
- If available, reports of recently conducted external reviews
- Strategic documents provided by PDPs (strategic plans, performance frameworks, donor progress and annual reports)
- (external) Evaluation reports

2) Interviews

The interviews are considered supplemental to the desk review and shall be carried out predominantly by telephone.

Suggestions for respondents:

- PDP key staff, board members / scientific review panels
- Staff at relevant global (health) organizations (WHO & WHO special programmes like TDR, RBM, StopTB; UNAIDS; Gates Foundation)
- Dutch government policy makers involved in PDP or related funding and funding instruments
- Representative(s) of the PDP funders group
- Public partners receiving funding from PDPs (staff from academic institutions, including African scientific representatives)
- Staff from private sector enterprises / entities that collaborate with PDPs
- CSOs / (I)NGOs working in close collaboration with PDPs

4.2 Composition of the review team

The review Team will comprise one subject matter specialist (likely to be the team leader) and one institutional (i.e. organisational) management specialist, possibly supported by a small number of support staff.

The evaluators should possess a good understanding of:

- the international (health research) agenda
- the concept of PDPs (public-private-partnerships for product development)
- evaluating partnership programmes and initiatives, including private sector, NGOs and international and multilateral organisations
- innovation policy and public private partner funding mechanisms

In addition, the evaluators would need to:

- Be familiar with the basic principles of early stage research and product development in the pharmaceutical and diagnostics sector
- Understand the basic concepts of policy development at the MoFA vis-à-vis the role of research for health development
- Have good knowledge of the major stakeholders that are active in the international health research field (UN, EU, regional and national bodies and (I)NGOs).
- Understand field issues associated with translation of evidence into policy and practice.

The proposal should provide a detailed insight into the CVs and the relevant experience of the experts that will be part of the review team, as well as their proposed tasks and role in the review.

4.3 Process

- a) Prepare review design
 - a) Take note of key documents, made available by the PDPs

- b) Formulate or adapt specific review questions and testable goals and identify means of verification, in consultation with MoFA and the PDP Funders Group (PDP-FG). Relevant stakeholders will be asked to make suggestions.
- c) Design for data collection, including the identification and selection of individuals to be interviewed.

b) Collect and analyse data

c) Prepare and present draft and final report.

5. Contact and Reporting

The review is commissioned by the Social Development Department / Health and Aids Division of the Ministry of Foreign Affairs. Contact persons will be Ms. Wieneke Vullings and Mr. Lander van Ommen.

The review team will deliver a concise report in the English language. The main report will contain a maximum of 30 pages including an executive summary but excluding annexes. The report will contain conclusions and recommendations, and be (partly) presented to the PDPs interviewed to make the necessary & factual corrections. The final report will be submitted to MoFA.

All relevant information sources used to accomplish the assignment are to be mentioned in this report. All documents are to be treated in a confidential manner; publishing review results or outputs without explicit permission from MoFA is not allowed.

Please note: Presenting the results to a wider group of interested and like-minded organisations, in particular the PDP funders group (tentatively in September 2014), might be requested.

6. Planning

Planning of the preparation, implementation, reporting and completion of the review is as follows:

TOR published	June 2014
Deadline submissions proposals	June 23
Selection evaluator	June 30
Inception report	15 days after contract signed
Inception meeting to discuss evaluation design	Within 2 weeks after inception report
Draft report with conclusions and recommendations, distribute to PDPs for correction	End of September
Final report	October 2014

The budgetary ceiling is EUR 50.000, exclusive of VAT but including travel and subsistence costs.

7. Assessment of the offer

The offer should be concise and no longer than 6 pages, excluding annexes if needed. It should include:

- Your understanding of the assignment
- The proposed approach and methodology. This should be in line with internationally accepted standards on evaluations
- A detailed planning

TOR PDP external review 2014

- Overview of the team, CVs (may be delivered in annexes), roles and functions of the reviewers proposed
- A detailed budget per person in days, with day rates specified.

The offer will be evaluated based on quality (80%) and price (20%).

Tenders must be written in English and signed. Remuneration cannot be granted for drafting tenders. They should be delivered by Monday June 23, 17.00 hrs and send to: DSO-GA@minbuza.nl with reference "PDP REVIEW 2014".

Appendix B Operationalisation of review questions

Review question	Indicators and expected results	Data sources
Assessment of the achievements of the PDPs		
<ul style="list-style-type: none"> • What have been the key achievements of the specific PDPs in this period in terms of new products and pipeline development? <ul style="list-style-type: none"> - How do these main achievements compare with the ambitions set out in the original grant proposals to the Dutch Government? - How do these relate to issues of <i>increased access</i> for the poor and <i>accelerating delivery</i> of effective products to people most in need? 	<ul style="list-style-type: none"> • An investigation of the outputs, outcomes and impacts achieved by the PDPs between 2011 and 2014, with a distinction between: <ul style="list-style-type: none"> - Scientific progress and performance - Infrastructure development - Capacity strengthening - Regulatory and ethics issues • The extent to which the outputs, outcomes and impacts achieved by the PDPs are (un)intended when related to the objectives and expectations set out in the original grant proposals • To extent to which the outputs, outcomes and impacts address the issues of increased access for the poor and accelerating delivery of effective products to people most in need <p>Potential relevant indicators on each of these result levels could be:</p> <ul style="list-style-type: none"> • <i>Outputs</i> <ul style="list-style-type: none"> - Regulatory approval/permission for starting clinical trials - Number of clinical trials initiated - Composition of the product pipeline (with a focus on both incremental and breakthrough technologies) - New drug delivery models and analytical systems developed - Candidate treatments, vaccines and microbicides submitted for pre-qualification procedures by WHO - Clinical research partnerships and clinical trial capacity built - Local field sites developed/strengthened in endemic countries - Partnerships built (agreements) with biotechnology firms, multi-national pharmaceutical companies, universities and research centers (also in developing countries) and contract manufacturers - Meetings arranged with representatives of regulatory and ethics committees • <i>Outcomes</i> <ul style="list-style-type: none"> - Scientific breakthroughs (high-impact publications and sharing of results at international conferences) - Number of clinical trials successfully completed (per phase) - Number of treatments, diagnostics, vaccines, microbicides developed and delivered - Treatments, vaccines and microbicides approved by regulatory authorities - Clinical research infrastructure developed in developing countries to prepare for clinical trials (GCP) - Manufacturing facilities established for production purposes (GMP) - Progress in developing/improving an adequate and professional management and governance structure 	<ul style="list-style-type: none"> • Desk research: <ul style="list-style-type: none"> - The original grant proposals to the Dutch government - PDP Annual Funders Reports - PDP annual reports - PDP websites - Existing evaluation/reviews of PDPs • Provision of information by the representatives of the individual PDPs on the agreed list of indicators. • Interviews: <ul style="list-style-type: none"> - PDP representatives - Dutch government policy makers involved in PDP funding - Public and private sector organisations that collaborate with PDPs

Review question	Indicators and expected results	Data sources
	<ul style="list-style-type: none"> • Impacts <ul style="list-style-type: none"> - Advancements in earlier diagnosis of diseases, reduced duration of treatment and higher immunisation - Health systems capacity strengthened (ethical trial design and management, treatment and care delivery and laboratory capability) - Contributions to policy formulation and adoption in guidelines and protocols 	
<ul style="list-style-type: none"> • What has been the contribution and importance of the Dutch funding towards reaching these achievements? <ul style="list-style-type: none"> - What would have happened if there had not been Dutch funding? 	<ul style="list-style-type: none"> • The percentage of the funding from the Ministry of Foreign Affairs as share of the total PDP budget • The percentage of the funding from the Ministry of Foreign Affairs as share of the budget for the specific granted project • The availability of co-funding (matching) funds for the specific granted project, divided by: <ul style="list-style-type: none"> - Charitable organisations - National governments - European Commission - WHO, FDA, etc. • Qualitative judgement on the likeliness of the initiation/continuation of the project in case no funding from the Ministry of Foreign Affairs had been available. What would have been the effect on the area that has been supported by MoFA? 	<ul style="list-style-type: none"> • Desk research: <ul style="list-style-type: none"> - The original grant proposals to the Dutch government - PDP Annual Funders Reports - PDP annual reports - PDP websites - Existing evaluation/reviews of PDPs • Interviews: <ul style="list-style-type: none"> - PDP representatives
<ul style="list-style-type: none"> • What role has the Dutch funding played in the overall work of the individual PDPs? (E.g. leveraging, towards strategy and priority setting, governance) and how does this relate to other funding sources? 	<ul style="list-style-type: none"> • The overall availability of co-funding provided by other organisations, divided by: <ul style="list-style-type: none"> - Charitable organisations - National governments - European Commission - WHO, FDA, etc. • Qualitative judgement on the influence of Dutch funding on the overall strategy of the PDP especially related to the topics of the specific grant. • What has been the added value of the Dutch funding over other sources of funding (better, faster, easier, et cetera)? • What changes (no complete description) have occurred in the governance and organisational structure of the PDP in terms of: <ul style="list-style-type: none"> - Professionalism of internal processes - Monitoring and evaluation - Quality assurance procedures - Project management 	<ul style="list-style-type: none"> • Interviews: <ul style="list-style-type: none"> - PDP representatives - Dutch government policy makers involved in PDP funding
<ul style="list-style-type: none"> • How well do the individual PDPs learn from their past experiences and how well do they respond to a changing context and environment? <ul style="list-style-type: none"> - How well do PDPs deal with ‘failures’ and risk in the innovation process? - How well do PDPs keep abreast of developments and players in the field? - How well are PDPs planning for the future? 	<ul style="list-style-type: none"> • Qualitative judgement on the learning ability and responsiveness of the PDPs, illustrated by identifying concrete examples: <ul style="list-style-type: none"> - The identification of future challenges - The identification of potential areas for future funding - The actions taken to deal with failures and risks when applicable and the level of satisfaction - Identification of the methods/systems in place to keep abreast of developments and players in the field (concrete examples of activities) and judgement about success of the PDP in this perspective? - Strategic approach and activities in place to ensure that the PDP is able to respond flexibly to a changing environment - Judgement of the adequacy of the future planning process of the PDP and identification of room for improvement 	<ul style="list-style-type: none"> • Desk research: <ul style="list-style-type: none"> - Strategic documents on the work of the PDPs in the context of global health developments • Interviews: <ul style="list-style-type: none"> - PDP representatives - Dutch government policy makers involved in PDP funding - Representative(s) of the PDP Funders Group - Public and private sector organisations that collaborate with PDPs

Review question	Indicators and expected results	Data sources
<ul style="list-style-type: none"> • How sustainable are the individual PDPs? (both in terms of finance, governance, IP management, programming, monitoring and evaluation) <ul style="list-style-type: none"> - Have the PDPs secured adequate financial commitments to confidently implement their strategy? If not, what are the implications and options? - Are the estimates of resource requirements for the future reasonable? - What will happen if funding from the Netherlands will be increased/reduced/stopped? 	<ul style="list-style-type: none"> • An overview of the already secured and expected financial commitments to implement its strategy and judgement on the adequacy of these commitments in the context of the strategy • Estimation of the effects that might occur in the hypothetical situation in which the funding from the Netherlands will be <ul style="list-style-type: none"> - Substantially increased (> 25% increase) - Marginally increased (<10% increase) - Marginally reduced (< 10% reduction) - Significantly reduced (> 25% reduction) - Stopped 	<ul style="list-style-type: none"> • Desk research: <ul style="list-style-type: none"> - PDP Annual Funders Reports - PDP annual reports - PDP websites - Existing evaluation/reviews of PDPs • Interviews: <ul style="list-style-type: none"> - PDP representatives - Public and private sector organisations that collaborate with PDPs
<ul style="list-style-type: none"> • To what extent do the PDPs co-operate with each other and with other organisations outside the partnership? <ul style="list-style-type: none"> - What are the results of this cooperation, and what are challenges and risks? 	<ul style="list-style-type: none"> • Overview of all formal and informal collaborations of the PDPs: <ul style="list-style-type: none"> - Formal partnerships between the PDPs - Formal (new and prolonging) partnerships with other organisations - Formal partnerships with Dutch organisations (public and private sector) • Identification of the achievements of the collaboration activities, e.g.: <ul style="list-style-type: none"> - Joint projects (clinical trials, manufacturing and delivery of results) - Joint capacity development initiatives • Qualitative judgement of the challenges and risk associated with collaboration • Qualitative judgement of the degree of collaboration between the PDP, the perceived importance and the room for improvement/strengthening of the collaboration 	<ul style="list-style-type: none"> • Desk research: <ul style="list-style-type: none"> - PDP Annual Funders Reports - PDP annual reports - PDP websites - Existing evaluation/reviews of PDPs • Interviews: <ul style="list-style-type: none"> - PDP representatives - Representative(s) of the PDP Funders Group - Public and private sector organisations that collaborate with PDPs
Assessment of the funding mechanism		
<ul style="list-style-type: none"> • How have the recommendations from the evaluation of the previous PDP grant been followed up and implemented? 	<ul style="list-style-type: none"> • Implemented changes in funding mechanism since evaluation <ul style="list-style-type: none"> - Attribution of changes to evaluation 	<ul style="list-style-type: none"> • Desk research: <ul style="list-style-type: none"> - MoFA PDP grant framework 2011-2014 - Existing evaluation/reviews of PDPs - Other (internal) Dutch policy documents related to PDP grant framework • Interviewees: <ul style="list-style-type: none"> - Dutch government policy makers involved in PDP funding

Review question	Indicators and expected results	Data sources
<ul style="list-style-type: none"> • What is the impact of the current Dutch government funding on the group of PDPs, in relation to the constraints of different models of donor funding? 	<ul style="list-style-type: none"> • Impact on finance <ul style="list-style-type: none"> - Dutch grant as percentage of total PDP funding - Fitting of Dutch type of funding within other funding for PDP <ul style="list-style-type: none"> o Core- vs. portfolio- vs. project-funding (earmarked vs. non-earmarked) o Fitting of the Dutch grant requirements within existing management structures in PDP (reporting and planning within existing budget cycles) o Overview of current models of donor funding applied by MoFA in the 7 PDPs o Pros and cons of different models of donor funding of PDPs - Fitting of the Dutch type of funding within the project dynamics <ul style="list-style-type: none"> o Flexibility in grant employment o Strictly earmarking of funding o Non-earmarked funding o Possibility for relabeling other committed funds • Impact on strategy <ul style="list-style-type: none"> - Contribution of Dutch grant to attracting other funding sources or partners <ul style="list-style-type: none"> o Advocacy of the Dutch MoFA with other donors - Impact on PDP's flexibility <ul style="list-style-type: none"> o Flexibility to adjust strategy of PDP to changes in context o Flexibility to adjust project to changes in context • Impact on outputs and outcomes <ul style="list-style-type: none"> - Effect of Dutch grant on delivery of new products <ul style="list-style-type: none"> o Speed-ups or delays due to increased or decreased Dutch funding - Effect of Dutch grant on safety of new products - Effect of Dutch grant on accessibility of new products for local population 	<ul style="list-style-type: none"> • Desk research: <ul style="list-style-type: none"> - The original grant proposals to the Dutch government - PDP Annual Funders Reports - PDP annual reports - PDP websites - Existing evaluation/reviews of PDPs • Interviews: <ul style="list-style-type: none"> - PDP representatives - Dutch government policy makers involved in PDP funding - Representative(s) of the PDP Funders Group
<ul style="list-style-type: none"> • Has the funding mechanism provided leverage for Dutch policy priorities in international fora? 	<ul style="list-style-type: none"> • Contributions of Dutch funding mechanism to increased awareness and funding in international fora for: <ul style="list-style-type: none"> - Promoting sexual and reproductive health, including the prevention of HIV/AIDS - Prevention of tuberculosis - Prevention and treatment of Neglected Tropical Diseases (NTDs) - Meeting local needs for diagnostics on the above themes, adapted to the local situation 	<ul style="list-style-type: none"> • Key expert desk research: <ul style="list-style-type: none"> - Literature on changes in global health research agenda • Interviews: <ul style="list-style-type: none"> - Dutch government policy makers involved in PDP funding - Representative(s) of the PDP Funders Group - Public and private sector organisations that collaborate with PDPs • Validation workshop
<ul style="list-style-type: none"> • What are the strengths and weaknesses of the funding mechanism in terms of manageability, administrative burden and transparency – both from the perspective of the Dutch Government and the specific PDPs? 	<ul style="list-style-type: none"> • Strengths and weaknesses of Dutch funding mechanism for Dutch government and PDPs <ul style="list-style-type: none"> - Manageability - Administrative burden - Transparency 	<ul style="list-style-type: none"> • Interviews: <ul style="list-style-type: none"> - PDP representatives - Dutch government policy makers involved in PDP funding • Validation workshop

Review question	Indicators and expected results	Data sources
Recommendations for the future		
<ul style="list-style-type: none"> • What lessons can be learned for potential future grant frameworks? 	<ul style="list-style-type: none"> • Inventory of strengths and weaknesses (internal factors) of the current funding mechanism • Inventory of opportunities and threats (external factors) of the current funding mechanism • Specific needs and key priorities that should be addressed in case a new grant framework is established <ul style="list-style-type: none"> - Needs and priorities that result from complexity of global health context 	<ul style="list-style-type: none"> • Interviews: <ul style="list-style-type: none"> - PDP representatives - Dutch government policy makers involved in PDP funding • Validation workshop
<ul style="list-style-type: none"> • What can be done to improve the relevance, efficiency and effectiveness of such a new framework compared to the current one 	<ul style="list-style-type: none"> • Integration of the different needs and priorities <ul style="list-style-type: none"> - Needs and priorities of PDPs - Needs and priorities of MoFA <ul style="list-style-type: none"> ○ Policy focus on sexual and reproductive health and rights ○ Policy focus on the balance between aid and trade 	<ul style="list-style-type: none"> • Interviews: <ul style="list-style-type: none"> - PDP representatives - Dutch government policy makers involved in PDP funding • Validation workshop

Appendix C Threshold criteria for funding eligibility

Threshold criteria for the PDP or applicant organisation⁴⁴

- The PDP must be a partnership of public and private organisations, pooling their knowledge and expertise to manage a portfolio of new and/or improved products for combating poverty-related diseases.
- The PDP's primary objective must be to develop new and/or improved products for developing countries to combat poverty-related diseases and thus improve public health. It must also aim to improve capacity for research into, and production of, medicines to treat such diseases in developing countries.
- The costs and risks must be jointly borne by all partners.
- The applicant or lead party must have legal personality.
- The applicant or lead party must be non-profit-making.
- The PDP must include, or work with, at least one private partner.
- A PDP can be based in any country (not necessarily a developing country).

Threshold criteria for the applications

- The activities for which grant funding is sought must relate to one of the four priority themes;
- Applications for PDP Fund grants must relate to activities that will take place between 1 January 2011 and 31 December 2014.
- The duration of the activities for which grant funding is sought does not exceed four years.
- The minimum grant application is €1 million per year, and the maximum €4 million per year.
- At least 50% of the funding of activities for which grant funding is being sought must be guaranteed by partners in the PDP and/or by other donors and/or other parties.
- The goal of the activities for which grant funding is sought must relate to development cooperation.
- The activities for which grant funding is sought must not previously have been awarded a grant from a Ministry of Foreign Affairs budget.
- The products that will be developed must be specifically suitable for use in low-income countries.

If an application does not comply with one or more of these threshold criteria, it will be refused. Furthermore, there can only be one applicant/grant recipient per partnership. The product development must relate to products where there is market failure and which demonstrably require public investment. Funding is intended for new activities. However, the Netherlands can also fund new areas within broader packages of activities. Grants will not be awarded for activities that have already started before the date of the grant application.

⁴⁴ Grants Framework for the 2011-2014 PDP Fund (2010), MoFA.

Appendix D List of interviewees

D.1 Representatives from the PDPs

PDP	Interviewee	Position
Aeras	Thomas Evans	Chief Executive Officer
	Ann Ginsberg	Chief Medical Officer
	Salma Samad	Senior Director Donor Relations
DNDi	Bernard Pecoul	Executive Director
	Graeme Bilbe	Research & Development Director
	Jean-François Alesandrini	Fundraising & Advocacy Director
	Thomas Saignac	Director of Operations
	Laurence Vielfaure	Director of Finance and Planning
	Julia Fahrman	Fundraising Coordinator
FIND	Catharina Boehme	Chief Executive Officer
	Sharon Saacks	Head of Operations
	Jérôme St-Denis	Senior Advocacy & Resource Mobilization Officer
IAVI	Jane Waterman	Vice President for External Relations
	Hester Kuipers	Director Advocacy and Communication
	Fiona Barr	Senior Director Resource Mobilisation
IPM	Zeda Rosenberg	Chief Executive Officer
	Karen McCord	Senior Director of Strategic Planning
	Lauren Dolak	Director of Resource Development
POW PDP	Eirin Peterfreund	Project Administrator
	Patricia Coffey	Senior Programme Officer
Sabin	Tara Hayward	Director Resource Development
	Peter Hotez	Director of the Sabin PDP and President of the Sabin Vaccine Institute
	Maria Elena Bottazzi	Deputy Director, Sabin PDP; Director, Product Development, Sabin Vaccine Institute

D.2 Representatives of the Dutch government

Organisation	Interviewee	Position
Dutch Ministry of Foreign Affairs	Lander van Ommen	Health and Gender Adviser, Health and AIDS Division, Social Development Department
	Lambert Grijns	Director, Social Development Department
	Reina Buijs	Deputy Director General for International Cooperation
	Anno Galema	Coordinator Public Private Partnerships, Environment, Water, Climate and Energy Department
Dutch Ministry of Health, Welfare and Sport	Marja Esveld	Senior Advisor International Research and Innovation

D.3 Representatives of other PDP funders

Organisation	Interviewee	Position
Bill & Melinda Gates Foundation	Samia Saad	Senior Program Officer
Department for International Development UK (DFID) and PDP Funders Group	Sue Kinn	Chair of the PDP Funders Group
European and Developing Countries Clinical Trials Partnership (EDCTP)	Gabrielle Breugelmans	North-North Networking Manager
PDP Funders Group	Alex Fullem	Coordinator PDP Funders Group
USAID	Margaret McCluskey	Senior Technical Advisor for HIV Vaccines

D.4 Partner organisations of the PDPs

Organisation	Interviewee	Position
Crucell	Hanneke Schuitemaker	Head Viral Vaccine Discovery and Translational Medicine
Amsterdam Institute of Global Health and Development (AIGHD)	Remko van Leeuwen	Director of Acquisitions
	Frank Cobelens	Professor of Epidemiology and Control of Poverty-related Infectious Diseases
Maastricht University	Peter Peters	Professor of Nanobiology
Royal Tropical Institute (KIT)	Paul Klatser	Head of biomedical research

Appendix E Interview topic guide

Interview guides for representatives from the PDPs

Achievements of the PDPs

A specific template with more detailed indicators capturing the outputs, outcomes and impacts of the PDPs will be used for the review of the achievements, based on annual reporting documents. A factual check on the completed templates will be performed by the PDPs before finalising the review. The questions below are meant to provide more qualitative information on the achievements and further information that is not included in the annual reporting documents.

- In the Annual PDP Funders Group reports the achievements of the last couple of years have been listed, what do you consider the key achievements in the period 2011 – 2014?
- To what extent are these achievements linked to the objectives and expectations set out in the original grant proposals?
 - If applicable: what was the reason to deviate from the original grant proposal? And how did this process go?
 - What have been (un)intended effects?
- To what extent do the achievements address the issues of increased access for the poor and accelerating delivery of effective products to people most in need?
 - Could you give any examples to illustrate this?
- In addition to the key achievements, what were other results (i.e. results that lead to outcomes on an earlier basis)?
 - Could you give any examples to illustrate this?
- Did you miss opportunities that could potentially have had a high impact?
 - If so, what was the reason these opportunities were missed (e.g. lack of funds, lack of internal procedures, etc.)?

Objectives of the PDP Fund

- In the PDP Grant Framework MoFA identified a couple of objectives for the PDP Fund. To what extent did the PDP address these objectives and could you give some examples to illustrate?
 - Increasing production of effective, safe and usable prevention methods, medicines, vaccines and diagnostics to combat poverty-related diseases;
 - Enabling PDP partners to have a positive impact on innovation;

- Increasing access in developing countries to medicines to combat poverty-related diseases;
- Giving a sustainable boost to developing countries capacity for research and producing medicines, vaccines and diagnostics to combat poverty-related diseases;
- Giving developing countries greater voice in international forums in which research policy and agendas on combating poverty-related diseases are set.

Contribution of Dutch funding

- How did the Dutch funding make a difference?
 - Could you give any examples to illustrate this?
- What is/has been the advantage of Dutch funding over funding provided by other organisations?
 - Could you give any examples to illustrate this?
- What would have happened (in terms of initiation or continuation of the project) in case no funding from the Dutch government had been available?
- How would you assess the focus of the Dutch funding in terms of innovative character (incremental improvements versus higher risk/higher reward technological developments)?
- Did the support from the Dutch government lead to attract additional resources?
 - If so, please report on the origin of these resources (which donors, countries).
- What has been the influence of the Dutch funding on the overall strategy of the PDP especially related to the area of the grant awarded?
 - Could you give any examples to illustrate this influence?

Internal processes and procedures

- What have you done with the results from the external review that has been conducted in 2009 or other PDP reviews that have taken place?
- What mechanisms are in place to identify future challenges and potential areas of future funding?
 - Could you provide some examples to illustrate this?
- What mechanisms are in place to deal with 'failures' and risks in the product development process?
 - How do you identify these risks?
 - What are the main risks that you identified?

- What criteria are in place to decide on dropping projects?
 - Do you have examples of projects that have been dropped?
 - What are the lessons learned?
- Do you see any changes in the governance and organisational structure of the PDP as a result of the Dutch contribution?
 - Could you give any examples to illustrate this?
- Do you see room for improvement when it comes to future planning processes?
- How do you balance between the role of product developer and convenors/coordinator (without the risk of conflict of interest)?

Sustainability

- How would you estimate the effect in the hypothetical situation in which Dutch funding will be:
 - Substantially increased (> 25% increase)
 - More or less continued
 - Significantly reduced (> 25% reduction)
 - Stopped
- How does this potential effect influence the overall strategy, activities, outputs and outcomes?

Cooperation

- To what extent do you cooperate with other Product Development Partnerships?
 - What is shared in these partnerships (e.g. manufacturing facilities, laboratory facilities, field sites, et cetera)?
- How important are Dutch organisations (both public and private) as partners to the PDP?
 - Could you provide some concrete examples to illustrate this?
- How would the partnership structure look like in 5 years from now?
 - In what organisations/countries do they see opportunities?
 - In what areas?

Funding mechanism

- What are the strengths and weaknesses of the funding mechanism applied by the Dutch government in terms of:
 - Manageability
 - Administrative burden
 - Transparency

- What are the pros and cons of the different other models of donor funding?

- What are your PDP funding needs for the next 5 years?

- What is the biggest challenge for which you would need support from the Dutch government?

- Do you see some room for other improvements in the way Dutch funding is provided?
 - What are the lessons learned?
 - What are specific needs and key priorities?

Concluding remarks

- Do you have any other remarks that you think are relevant and add value to this review?

Interview guides for Dutch government policy makers

Achievements of the PDPs

- In the Annual PDP Funders Group reports the achievements of the last couple of years have been listed, what do you consider the key achievements in the period 2011 – 2014?
- To what extent do the PDPs address the issues of increased access for the poor and accelerating delivery of effective products to people most in need?

Objectives of the PDP Fund

- In the PDP Grant Framework MoFA identified a couple of objectives for the PDP Fund. To what extent was the funding mechanisms effective and efficient in reaching the following objectives:
 - Increasing production of effective, safe and usable prevention methods, medicines, vaccines and diagnostics to combat poverty-related diseases;
 - Enabling PDP partners to have a positive impact on innovation;
 - Increasing access in developing countries to medicines to combat poverty-related diseases;
 - Giving a sustainable boost to developing countries capacity for research and producing medicines, vaccines and diagnostics to combat poverty-related diseases;
 - Giving developing countries greater voice in international forums in which research policy and agendas on combating poverty-related diseases are set.
- What do you think the main aim of a potential future PDP Fund should be?
- What do you consider to be the importance of Dutch funding towards reaching the achievements of the PDPs?
- What is your general impression of the Dutch government contribution to the PDPs in relation to the total funding budget of the PDPs?
- What has changed in the funding mechanism/support to the PDPs as a result of the previous external review of the PDPs funded by MoFA?

Current policy focus

- How do you assess the relevance of a Product Development Partnerships Fund in the current policy focus of MoFA?
- How do you assess the relevance of a Product Development Partnerships Fund taking into account the broader policy of the Dutch government (e.g. Ministry of Economic Affairs (Top Sector Policy), et cetera)?

- What is the added value of funding PDPs for the Dutch government?
 - Could you give some examples to illustrate this?
- Has the funding mechanism provided leverage for Dutch policy priorities in international fora?

Funding mechanism

- Compared to other sources of funding to the PDP, what do you consider the added value of the Dutch funding?
- What are the strengths and weaknesses of the funding mechanism applied by the Dutch government in terms of:
 - Manageability
 - Administrative burden
 - Transparency
- Do you see some room for improvement in the way Dutch funding is provided?
 - What are the lessons learned?
 - What are specific needs and key priorities?
- What would be good potential alternative funding mechanisms for the PDPs?
 - Could you give examples of other mechanisms that have been used in the past and present that might be useful to take into consideration when funding the PDPs?
- What can be done to improve the relevance, efficiency and effectiveness of a new Grant Framework compared to the current one?

Concluding remarks

- Could you provide two arguments in favour of keeping a PDP Fund?
- Could you provide two arguments against keeping a PDP Fund?
- Do you have any other remarks that you think are relevant and add value to this review?

Interview guides for representatives of the PDP Funders Group

Funding of PDPs

- What are your main reasons for funding PDPs?
 - Has your reasons/motivation changed over the years? If so, in what way?
- What in your view makes a PDP more effective than other product development activities?
- Did you consider increasing, decreasing or stopping the amount funding provided to the PDPs?
 - If so, what were the arguments in favour and against funding of PDPs?
- What do you consider the added value of funding PDPs?
 - Could you give some examples to illustrate this?

Achievements of the PDPs

- In the Annual PDP Funders Group Reports the achievements of the last couple of years have been listed, what do you consider the key achievements in the period 2011 – 2014?
- To what extent do the achievements address the issues of increased access for the poor and accelerating delivery of effective products to people most in need?
 - Could you give any examples that illustrate this?
- How sustainable are the individual PDPs in your opinion?

Funding mechanism

- Which criteria are in place to make the funding decision for the PDPs?
 - What is the balance between scientific versus political considerations?
- In making funding decisions, do you look at the PDP portfolio as a whole or evaluate each PDP individually?
- Does the funding provided to PDPs follow the same funding time frame/cycle?
- What is the length of the time frame?
- Do you earmark funding for specific projects or provide core funding to the PDP?
- What is your projected PDP support for the next 5 years?

- Did you already secure budget for future support of the PDPs?
- What are the pros and cons of the different models used of donor funding?
 - In terms of number of PDPs supported?
 - In terms of continued support over a longer period of time?
 - In terms of duration of the grants?
 - In terms of available budget?
 - In terms of competitive bidding?
 - In terms of funding agreements?
- Do you see some room for improvement in the way funding is provided to the PDPs based on previous experiences?
 - What are the lessons learned?
 - What are specific needs and key priorities?

Concluding remarks

- Do you have any other remarks that you think are relevant and add value to this review?

Interview guides for representatives from public and private organisations that collaborate with the PDPs

Achievements of the PDPs

- In the Annual PDP Funders Group reports the achievements of the last couple of years have been listed, what do you consider the key achievements in the period 2011 – 2014 in terms of:
 - New product and pipeline development
 - Scientific progress and performance
 - Infrastructure development
 - Capacity strengthening
 - Regulatory and ethics issues
- To what extent do the achievements address the issues of increased access for the poor and accelerating delivery of effective products to people most in need?

Contribution of Dutch funding

- What would have happened (in terms of initiation or continuation of the project) in case no funding from the Dutch government had been available?
- What has been the effect of the Dutch PDP funding on your research area?
- What can be improved in the way Dutch funding is provided to the PDPs?

Cooperation

- To what extent do you cooperate with the Product Development Partnerships?
 - What is the focus of these partnerships?
 - What is the added value of the collaborations?
 - What are the results of these partnerships?
- How important are the PDPs for you as a partner organisation?
 - Could you provide some concrete examples to illustrate this?
- Do you see some room for increasing the cooperation with the PDPs?
 - If so, in what way?

Concluding remarks

- Do you have any other remarks that you think are relevant and add value to this review?

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