

# **Options for Sustainable Funding of a Voluntary Pooled Fund to Support Health Research and Development**

*Background document to EB140/21: “Follow-up of the report of the Consultative  
Expert Working Group on Research and Development: Financing and  
Coordination”*

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## **Acronyms & Abbreviations**

<b>AMC</b>	Advanced market commitment
<b>BMGF</b>	Bill & Melinda Gates Foundation
<b>CEWG</b>	Consultative Expert Working Group
<b>CSR</b>	Corporate social responsibility
<b>DALY</b>	Disability-adjusted life year
<b>IFFIm</b>	International Finance Facility for Immunisation
<b>GDP</b>	Gross domestic product
<b>LMICs</b>	Low- and middle-income countries
<b>MRFF</b>	Medical Research Future Fund
<b>PRV</b>	Priority review voucher
<b>SIB</b>	Social impact bond
<b>ROI</b>	Return on investment
<b>R&amp;D</b>	Research and development
<b>TDR</b>	UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases

## Executive Summary

The World Health Assembly asked the Director-General to provide options for sustainable funding of a voluntary pooled fund to support research and development for Type III and Type II diseases, and specific research and development needs of developing countries in relation to Type I diseases (Resolution WHA69.23 operative paragraph 2.9). Based upon recommendations of the study “Health Product Research and Development Fund: A Proposal for Financing and Operation,”<sup>1</sup> this background document explores options for sustainable funding of a medium-pooled fund that disburses US\$100 million per year.

If Member States decide to set up the voluntary pooled fund, it is essential that the fund is financed in a sustainable way to ensure long-term success. A financing mechanism has to guarantee that the fund can be scaled up over a ten year period to the envisaged size of US\$100 million and continues to be funded over a longer period in time.

Options discussed in this document include opportunities for governments to find new sources for contributions to the voluntary pooled fund and leveraging private sector funds through corporate social responsibility and matching funds. Further financing options that are assessed comprise debt tools (bond models and development bank loans), pull mechanisms (advanced market commitments and social impact bonds) and the sale of priority review vouchers. Overall, the fairly limited size of the fund is one reason why some of the potentially more innovative funding mechanisms are not suitable. The following two options have been identified as suitable and implementable in the short term:

Option 1: Multi-source funding model with regular contributions

Such a model could include two pillars:

a) Voluntary government payments

The required financing for the pooled fund would be partly covered by voluntary contributions from WHO Member States. In order to finance the fund, Member States could adapt existing budgets for R&D and development cooperation. However, just relying on ad-hoc voluntary contributions is likely not sustainable (see Box 2). This could be mitigated if Member States would identify new funding modalities, for example, levying a specific tax. Member States could also decide to voluntarily contribute to the fund based on the scale of their assessed contributions to WHO. This would provide a clear objective for each Member State relative to their expected contribution and thus broaden the donor base and likely increase sustainability.

b) Matching contributions from industry

Private contributions could be collected for the voluntary pooled fund in the form of a matching fund to cover the remaining 50% of the needed funding. For this to work, pharmaceutical companies would have to be willing to contribute collectively, for example, through their industry associations. The funds would have to be provided in a sustainable manner through long-term payment agreements rather than spontaneous donations. The industry would match funds provided by governments with an equal amount. In this way, the public and private sector would contribute a similar share to the voluntary pooled fund.

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<sup>1</sup> Health product research & development fund: a proposal for financing and operation. Geneva: UNICEF/UNDP/ World Bank/WHO Special Programme for Research and Training in Tropical Diseases, 2016  
[http://apps.who.int/iris/bitstream/10665/204522/1/9789241510295\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/204522/1/9789241510295_eng.pdf?ua=1)

## Option 2: Classical replenishment fund

Existing global health financing mechanisms have been successful for collecting vast amounts of money through replenishment. In this model, interested donors meet regularly, for example, every five years, and pledge funding for the following period. This is also conceivable for the voluntary pooled fund. Replenishment has the advantage that countries do not have to commit to regular payments and can periodically decide to increase or decrease their engagement. The length of replenishment cycles allows for fairly predictable funding. Due to the long-term nature of biomedical R&D, these cycles would likely have to be longer than for traditional replenishment mechanisms. For example, a ten year replenishment cycle would create security for projects to be funded through the largest part of the development pipeline.

### **Complementary options**

In principle, a R&D capital fund as described in section 2.3 could be a suitable option, but is likely not feasible in the current low interest environment. A bond programme for health R&D (section 4.1) could also be used to support the pooled fund, but does not seem to be a cost-effective instrument for a relatively small fund of only US\$100 million. The voluntary pooled fund should be open to accepting additional voluntary contributions from the public and private sector and be allowed to benefit from the priority review voucher system (section 4.5).

# 1. Introduction

## 1.1 Background

This is a background document for the 140<sup>th</sup> session of the Executive Board to agenda item 8.5: “Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination” (CEWG)<sup>2</sup> and the related EB document EB140/21. Resolution WHA69.23 requests the Director-General to present a proposal with goals and an operational plan for a voluntary pooled fund, including options for sustainable funding.

This paper addresses the last part of this request and presents options for sustainable financing of a voluntary pooled fund of US\$100 million in annual disbursements to reduce the gaps in research and development for Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases. It discusses options that are outlined in Annex 2 to EB140/21 “A Voluntary Pooled Fund: Operational Plan and Goals”. As the proposed fund tries to address the problem of underinvestment into these diseases, this paper will refer to them in short as neglected diseases.

A pooled fund as an innovative financing mechanism for health R&D has a number of benefits, as it:

- allows a collective effort to fund projects which eliminates the overlaps and duplications that are often seen with uncoordinated allocation of resources;
- forms, in conjunction with the WHO Global Observatory and the WHO Expert Committee on Health Research and Development, an integrated mechanism covering data analysis, priority setting and implementation;
- allows for the high risks of failure and possible benefits to be shared;
- accommodates different sizes of contributions opening the door for smaller economies and low- and middle-income countries (LMICs) to support global efforts in health R&D; and
- is cost-effective, in particular if it utilizes existing structures and mechanisms.

## 1.2 Aim and structure

This background document aims to assist WHO Member States in their discussions to identify the best approach for sustainable funding of a voluntary pooled fund. The document assesses various options regarding how Member States may harness new funding sources (section 2), explores the role of contributions by industry and other private donors (section 3) and discusses alternative tools to leverage money from capital markets and industry investment (section 4). The various funding options are not mutually exclusive and can be combined in order to accommodate the requirements of different donors.

## 1.3 Guiding principles for selecting and evaluating funding options

The selection and assessment of funding options in this document was guided by the principles outlined below. Each option assessed fulfils one or several of these principles.

- Ability to provide a sustainable and predictable source of funding
  - This principle indicates the ability of the funding option to provide a sustainable and predictable flow of funds.

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<sup>2</sup> Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination [http://www.who.int/phi/cewg\\_report/en/](http://www.who.int/phi/cewg_report/en/)

- Guided by the core principles of the CEWG
  - This principle indicates that the funding option is guided by the core principles of affordability, effectiveness, efficiency and equity; and the objective of delinkage.
- Flexibility in the allocation of resources
  - This principle indicates flexibility of the funding option to ensure that resources provided are not earmarked for specific projects.
- Optimal acceptability and political will
  - This principle indicates the ability of the funding option to mobilize optimal acceptability and political will for efficient and timely implementation.
- Accommodates a broad donor base
  - This principle indicates the ability of the funding option to accept and encourage contributions from a broad donor base.
- Ability to leverage additional/new sources funding
  - This principle indicates the ability of the funding option to attract new donors.

## 2. Contributions from Member States

WHO Member State governments may opt to meet the financing requirements of the pooled fund by means of regular contributions or a replenishment mechanism. Member States could identify new funding modalities or reconfigure existing funding modalities in order to augment the existing budget for global health R&D. Some of these funding modalities are outlined below.

### 2.1 Adaptation of existing budget

Currently, most public funding for neglected disease R&D (around US\$2 billion) comes from budgets for science and technology and, at a smaller scale, from development agencies (US\$184 million).<sup>3</sup> Health departments traditionally have no or very small budgets that can be allocated to research and development activities.

At the moment, most countries fall short of the funding target suggested in the CEWG report which recommended allocating 0.01% of Gross domestic product (GDP) to R&D for neglected diseases.<sup>2</sup> Member States have different options for raising the necessary contributions. For high-income countries, increasing the share coming from development cooperation could be an option as interventions to combat neglected diseases have been shown to be highly cost-effective<sup>4</sup>, and the development of new treatments would facilitate the control of these diseases. Another option for all countries would be to further orient public R&D spending towards the global burden of disease and, hence, the diseases covered by the voluntary pooled fund.

### Advantages and challenges for the voluntary pooled fund

Direct contributions by government would be a straightforward way to fund the pooled fund. However, budget constraints may pose challenges. While the principle of the fund is voluntary contributions, Member States might want to use the scale of assessed contributions as an indication of how much each Member State should contribute to reach the target of US\$100 million in annual

<sup>3</sup> G-Finder Report - Neglected Disease Research and Development: The Ebola Effect. Policy Cures, 2015.

<http://policycures.org/downloads/Y8%20GFINDER%20full%20report%20web.pdf>

<sup>4</sup> Molyneux, P. (2004). "Neglected" diseases but unrecognised successes - Challenges and opportunities for infectious disease control. The Lancet 364, 380-3.

disbursements. This could contribute to enlarge the donor base beyond the usual voluntary contributors.

## **2.2 National taxes dedicated to financing the voluntary pooled fund**

Taxes are sustainable and highly predictive sources of funding, suiting well the long-term needs of R&D programmes. There are a number of national taxes in WHO Member States that are especially dedicated to health purposes or linked with health objectives. For example, consumption taxes on tobacco, alcohol or sugary drinks discourage unhealthy behaviour. Some countries have also introduced specific taxes on some activities of the pharmaceutical industry. Italy levies a tax on pharmaceutical marketing to fund independent clinical trials (see Box 1) and France taxes sales, sales increases and promotion activities within the pharmaceutical industry.

### **Box 1: Pharmaceutical promotion tax in Italy**

Since 2005, Italy has levied a 5% tax on yearly promotional expenditures of all international and national pharmaceutical companies that target Italian health professionals. The tax amounts to approximately €35-45 million per annum. Half of this money is dedicated to a specific research programme that funds independent research. In the past, the programme was confined to supporting clinical trials and observational studies in areas having limited commercial interest.<sup>5</sup> An independent scientific committee coordinates different aspects of the programme.

### **Advantages and challenges for the voluntary pooled fund**

Specific tax levies to finance contributions to the voluntary pooled fund would ensure sustainable funding. For example, the amount raised by the Italian tax (Box 1) by far exceeds the contribution that Italy would pay to a voluntary pooled fund (US\$4.4 million)<sup>6</sup>. The introduction of a universally raised international tax was not considered a realistic option in this context. Besides the challenge of reaching a global agreement, it would not be cost-effective to introduce a global tax to raise the relatively small amount of US\$100 million.

### **Box 2: How to donate – regular voluntary contributions and replenishment**

There are different ways to organize the payment of contributions by Member States and the private sector to the voluntary pooled fund. An earlier assessment by the WHO Secretariat describes in more detail how different existing mechanisms are financed.<sup>7</sup>

a) Some organizations rely on ad hoc voluntary contributions, including the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR), as well as most product development partnerships. The disadvantage of such a mechanism is that funding is difficult to predict.

<sup>5</sup> Traversa, G., Masiero, L., Saggiocca, L., & Trotta, F. (2016). Italian program for independent research on drugs: 10 year follow-up of funded studies in the area of rare diseases. *Orphanet Journal of Rare Diseases*, 11(1), 36.

<sup>6</sup> Italy pays 4.4% of WHO assessed contributions. This would translate to US\$ 4.4 million for a voluntary pooled fund of US\$ 100 million, if all Member States pay according to their assessed contributions to WHO. Resolution WHA69.14: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA69/A69\\_R14-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R14-en.pdf)

<sup>7</sup> A68.34: Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination. [http://apps.who.int/gb/ebwha/pdf\\_files/WHA68/A68\\_34-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_34-en.pdf) and the related fact sheet on funding and research mechanisms [http://www.who.int/phi/2-funding\\_mechanism\\_factsheets\\_6nov12.pdf](http://www.who.int/phi/2-funding_mechanism_factsheets_6nov12.pdf)

b) The WHO Framework Convention on Tobacco Control (FCTC) is financed by voluntary assessed contributions. Membership to the FCTC is voluntary and independent from WHO membership, and parties to the convention contribute based on the WHO scale of assessment. This way of funding is more predictable, as members to the convention commit to long-term support.

c) Other organizations use a replenishment model, in which each donor independently fixes its contribution in the form of a pledge. Pledges are public, legally non-binding statements on planned contributions. Contributions are voluntary as donors themselves fix the amount of pledges, but such a mechanism provides for some planning security as pledges span a certain time period. Examples of this model are the Global Fund to Fight AIDS, Tuberculosis and Malaria and Gavi, the vaccine alliance. The latter also uses additional innovative financing mechanisms.

### **2.3 Research and development capital fund**

A capital fund dedicated to R&D generates interest which can be used for research projects on neglected diseases, while the capital stock is preserved. To illustrate how such a mechanism could work to finance the voluntary pooled fund, the Medical Research Future Fund (MRFF) of Australia is used as an example. Launched in 2014, the MRFF is currently filled, until it reaches a capital stock of A\$20 billion (US\$15.3 billion). Every year, 5% of this sum is drawn and used to double the medical research budget of Australia. According to this example, a fund of US\$2 billion would suffice to yield US\$100 million for the voluntary pooled fund.

To adapt this model to the voluntary pooled fund, Member States could open a special investment fund hosted, for example, by one of the international or regional development banks. The investments of such a capital fund would not be related to the products it aims to develop. Instead, money is invested in areas where the highest revenues are expected, with exceptions for potentially harmful investments, such as in the tobacco industry. There should be a minimum period of investment to ensure sustainability, for example, 10 years. After this period, investors would get back their capital plus interest earned with a deduction of 5% annually. An R&D capital fund as a financing instrument could also be open to private capital.

#### **Advantages and challenges for the voluntary pooled fund**

The advantage of this model is that it could mobilize sizable capital stocks that are invested through sovereign wealth funds. The total investment sum of such funds amounts to US\$7.4 trillion,<sup>8</sup> around 3700 times what would be needed for an R&D capital fund to finance the voluntary pooled fund. Some of the countries that have sovereign wealth funds are affected by the diseases covered by the voluntary pooled fund and could consider investing parts of their funds in an R&D capital fund.

On the other hand, most countries do not have wealth funds or capital to invest which means that they would have to “save” money from their budget or introduce special taxes to fill a capital fund. While, in the past, large funds yielded a higher return on investment than 5%,<sup>9</sup> interest is currently

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<sup>8</sup> Sovereign Wealth Fund Rankings [website]. Sovereign Wealth Fund Institute. <http://www.swfinstitute.org/sovereign-wealth-fund-rankings/>

<sup>9</sup> Piketty, T. Capital in the 21<sup>st</sup> century. Harvard University Press, 2014.

lower.<sup>10</sup> This means that the capital stock would be gradually eroded, or less money would have to be drawn.

### **3. Contributions by the private sector**

The options described in this section aim at leveraging donations from private foundations and industry. These are philanthropic contributions that do not expect return on investment. Investment mechanisms are discussed in section 4.

#### **3.1 Corporate social responsibility**

One possibility of obtaining contributions from the private sector is corporate social responsibility (CSR). This is different from classic “checkbook philanthropy” in that it tries to improve the business environment of a company, for example, by lowering harmful social or ecological externalities. While CSR does not play a very important role in some regions, certain countries do even have mandatory CSR contributions. In India, for example, more than US\$3 billion are invested annually by domestic and international companies.<sup>11</sup> The current market driven pharmaceutical R&D system neglects urgent health needs that do not provide sufficient market potential. By investing part of their CSR funds into R&D in these neglected areas, companies could counter the shortcomings of the current R&D system. Companies could pool CSR money through pharmaceutical industry associations to contribute to the pooled fund.

There is also a potential source for private contributions from Islamic countries. Banks and other financial institutions in these countries are subject to special rules, which are often referred to as Islamic Financing. In particular, there are two elements of Islamic Financing that are of special interest to the voluntary pooled fund. First, investors sometimes receive “unintended” income that has to be compensated for by paying a certain fraction as cleansing money which could go into socially advantageous projects. Second, the corporate sector in Islamic countries sometimes has to pay “Waqf” contributions, an alms-giving obligation that is one of the “five pillars of Islam.”

#### **Advantages and challenges for the voluntary pooled fund**

CSR plays a considerable role in some regions that are also affected by neglected diseases. For the multinational pharmaceutical companies, which are mostly based in Europe, the United States of America and Japan, this kind of contribution might also be attractive as it addresses the long-standing public criticism of not investing enough into the development of products that address neglected diseases. CSR funds do not seek a return and could be well suited to delink R&D costs from the final product price and as base funding for early-stage projects of the voluntary pooled fund. However, a specific mechanism would have to ensure predictable and sustainable funding that does not rely on spontaneous donations and goodwill. Companies could be motivated to give money to this purpose by the provision of matching funds (section 3.2).

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<sup>10</sup> College and University Endowments: Overview and Tax Policy Options. Congressional Research Service, 2015. <https://www.fas.org/sgp/crs/misc/R44293.pdf>

<sup>11</sup> India’s Mandatory CSR, Process of Compliance and Channels of Spending. Indian Institute of Management, 2015. <http://www.iimahd.ernet.in/faculty-and-research/research-and-publication.html&rnpid=13654>

### **3.2 Matching funds**

Matching funds are set to be paid in equal amount to money available from other sources and have been provided for several development issues. Matching funds are an attractive tool for actors that have a high interest in R&D for neglected diseases (for example, private foundations) and want to leverage contributions from other players. For example, the Gavi Matching Fund is a three-way philanthropic matching programme: companies ask their employees and business partners for donations which they top up with an equal amount. These funds are then matched again by the Bill & Melinda Gates Foundation (BMGF). The CSR funds described in section 3.1 could also be used in such a manner if the pharmaceutical industry would be ready to match contributions by public funders.

The model is also applicable to country contributions: high-income countries could, for example, consider matching funds contributed by developing countries. This has been done before in the CEWG process with Switzerland and Norway pledging money on the basis of half a dollar for each dollar contributed by developing countries. Governments could also try to leverage private sector contributions by providing matching funds through a mechanism similar to the Gavi Matching Fund.

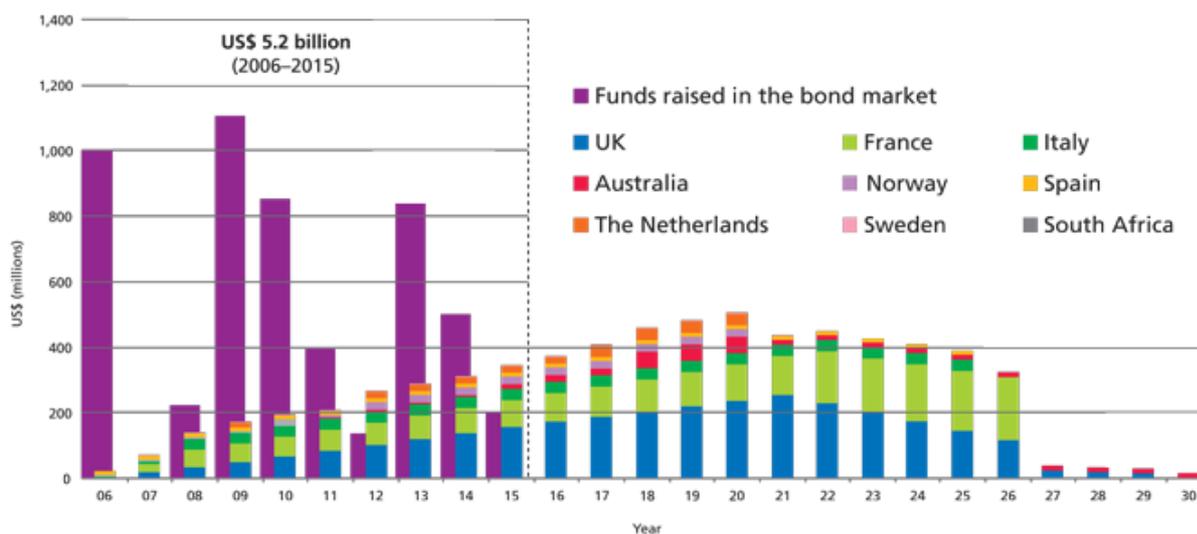
#### **Advantages and challenges for the voluntary pooled fund**

Matching funds can encourage and ensure broad participation and funding solidarity. They have a great potential to leverage new donors and harness a variety of stakeholders by creating funding equity. A matching fund should also be based on a predictable money flow. Spontaneous private donations as in the Gavi Matching Fund are hence not optimal as base funding to be matched. A more sustainable option such as a CSR fund may work for this purpose.

## **4. Alternative financing options**

### **4.1 Bond programmes – The International Finance Facility for Immunization**

Bond programmes allow direct access to capital markets in order to prefinance an intervention. The International Finance Facility for Immunisation (IFFIm) is a good example that illustrates how such a mechanism can be used in the health sector. Established as a complementary financing mechanism to support vaccination programmes by Gavi, the IFFIm augments and accelerates the availability and predictability of funds. The IFFIm uses legally binding commitments from donor governments to issue “vaccine bonds” in the capital markets, making immediately available large sums of funds. The bonds are securitized and paid back gradually by participating countries over a long period of up to 23 years. At present, Gavi’s programmes benefit from a frontloaded cash flow amounting to US\$6.5 billion from nine donor governments (Figure 1).



**Figure 1: Flow of IFFIm funds since its launch in 2006.** Violet bars are vaccine bonds issued by IFFIm, which provide money for Gavi. The bonds are paid back gradually by participating countries (multicolour bars).<sup>12</sup>

### Advantages and challenges for the voluntary pooled fund

In times of increased budget pressure, bond programmes like IFFIm allow governments to scale up effective interventions immediately, but donate in the future. While this is a similar effect to a traditional bank loan, bonds often provide more freedom to the creditor and profit from lower interest rates. Bond programmes ensure the predictability of funds with known cash flows for several years to come. This suits well the long-term nature of biomedical research and development. In addition, there is demand for such bonds as an increasing number of actors are looking for social investments, which could reduce interest rates.

However, some countries cannot enter into such long term financing commitments as it would bind future governments. Interest on bonds depends on a country's credit rating – including countries with a low rating might lead to higher interest rates. Furthermore, implementation of such a bond programme is only likely to be cost-effective beyond a certain size as it has relatively high set up and operating costs. These factors could be bypassed by appending the bond programme to an existing structure such as the IFFIm, but this would require legal adaption which, from past experience, is a long and complicated process. As the proposed voluntary pooled fund likely has capital needs that are several times smaller than those of Gavi, a bond programme as a standalone option is not a good fit.

### 4.2 Loans from development banks

Research and development on neglected disease products potentially has a high impact on development in LMICs. It could be an attractive investment target for multilateral and national development banks. The advantages of loans taken from these institutions are usually low interest rates and long time periods until redemption compared to loans from the private sector. Assuming that products developed with money from the voluntary pooled fund do not create profits, one model would be that R&D projects are financed by a development bank, and the principal plus interest is paid back by governments or other donors.

<sup>12</sup> <http://www.iffim.org/donors/>

## Advantages and challenges for the voluntary pooled fund

This model provides similar advantages as the IFFIm as it creates funding security and allows governments to make payments from future aid budgets. The number of multilateral banking institutions has risen considerably in the last years and there has been an increased focus on public health. Development bank loans could provide debt borrowings at low cost with guarantees by states for seed investments and small grants. This money could be used to build a track record for the voluntary pooled fund which could then allow making use of other innovative financing mechanisms. Given that this model is based on loans, governments or other funders would still have to step in to pay back those loans.

### 4.3 Social impact bonds

Social impact bonds (SIBs) are a type of public-private partnership that drive government resources toward social programmes that deliver proven results to those in need. SIBs are a pay-for-performance model in which a private investor pays for a service initially and gets back the money invested plus interest only if certain objectives are achieved. Thus, SIBs direct funding to more efficient service providers while the risk of a failed intervention is borne by the investor and the service provider (depending on the agreement), not the government. The investor can obtain a return on investment and at the same time create a positive social impact. SIBs have grown more popular in recent years with around 25 SIBs now commissioned by seven different countries or public entities tackling diverse social problems, for example, prisoner recidivism (Box 3).

#### Box 3: Prisoner reform bonds

Famous examples of SIBs are prisoner reform bonds. In the United Kingdom, a bond was launched in 2010 to carry out comprehensive interventions in Peterborough prison and communities. The goal was to reduce recidivism among 3000 short-term prisoners by 7.5% compared to previous programmes. If this number was not reached, the private investors that financed the intervention initially would have lost their money. A 2014 status report showed recidivism among the cohort was reduced by 8.4% entitling the investors to recoup their investment. A similar bond was issued in 2012 in New York. As an independent evaluation found that the goal of a 10% reduced reoffending rate was not met, the investor was not paid back the US\$9.6 million it invested.

The SIB model is very flexible and can leverage contributions from different stakeholders. However, it requires governments or another sponsor to pay down the principal and interest if the intervention is successful.

In the case of the voluntary pooled fund, what might an SIB look like? The principal questions are how to measure success and how to determine the appropriate amount of payment to attract investors to take the risk. A possible goal and trigger for payment could be the entry of drug candidates into a certain clinical phase or the registration of one drug or vaccine within a certain time frame. This would then be very similar to milestone prizes or end prices that have been proposed as pull mechanisms in various reports. One could even go further and connect success to access to developed interventions, linking the repayment to affordability and efficient service delivery. This would be very much along the lines of the Health Impact Fund<sup>13</sup> which proposes to reimburse medical innovations according to their health impact.

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<sup>13</sup> <http://healthimpactfund.org/>

## **Advantages and challenges for the voluntary pooled fund**

Depending on the metric for success, SIBs in the case of the voluntary pooled fund would most likely be similar to milestone prizes. As for loans and normal bonds, a private investor would prefinance R&D, but it would have to be paid back later by donors such as governments. SIBs differ from a normal bond model, such as IFFIm, in that the risk of an unsatisfying intervention is borne by the investor and not the issuer of the bond.

However, SIBs have several limitations that make them hard to adapt for the voluntary pooled fund. As investors would want to increase their chances of success and have a reasonable time horizon, they would rather fit for later-stage projects that have a high probability of success. It is unlikely that investors would be ready to invest without earmarking investment to specific R&D projects while the objective of the fund is to build up a mixed portfolio and thus needs flexible funding.

### **4.4 Advanced market commitments**

An advanced market commitment (AMC) is a guarantee by certain donors to purchase a predetermined amount (“target demand”) of a product once the product is registered. There has been one notable AMC in vaccine development, the “Pneumo AMC” financed by five governments and the Bill & Melinda Gates Foundation to speed up development and boost the launch of a vaccine for pneumococcal disease. Payment of the US\$1.5 billion granted would only be effected if the vaccine was completely developed and delivered. Participating manufacturers had to make a ten year commitment and would be awarded with a share of the AMC according to the fraction of the 200 million dose target demand they deliver. For instance, if a firm makes an offer to supply 50 million doses per year, it is entitled to receive US\$375 million, 25% of the total US\$1.5 billion AMC funds. The amount is paid out in addition to the agreed price of US\$3.50 per dose.

## **Advantages and challenges for the voluntary pooled fund**

AMCs have been proposed as pull mechanisms to incentivize private sector R&D and derisk the product development process for governments. R&D activities would be prefinanced by the drug developers, but have to be paid back through the AMC by governments.

Several factors make the use of AMCs unlikely a good fit for the voluntary pooled fund. An AMC is usually product-specific, clearly demarcating desired product characteristics through a Target Product Profile. This, in general, does not fit well the diverse product portfolio envisioned for the voluntary pooled fund. An AMC may be applicable with respect to specific products in individual cases only.

The “Pneumo AMC” has worked only in that it accelerated the rollout of vaccines, but not their development. The two successful vaccines that received AMC money were already advanced in development and candidates of additional manufacturers are not registered to this date.<sup>14</sup> AMCs could have the potential to incentivize R&D, but only for later stage development projects. This suggests that they could only be used at a later phase for the voluntary pooled fund when there are drug candidates in advanced clinical testing. Finally, an AMC is based on large volumes and requires a “buyer” (Gavi, in the case of the “Pneumo AMC”), which currently is missing for most neglected diseases. Without these, it would be very difficult to determine the target demand of a product.

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<sup>14</sup> The Advance Market Commitment Pilot for Pneumococcal Vaccines: Outcomes and impact evaluation. The Boston Consulting Group, 2015. <http://www.gavi.org/library/gavi-documents/evaluations/pneumococcal-amc-outcomes-and-impact-evaluation/>.

#### **4.5 Priority review vouchers**

Priority review vouchers (PRVs) have been in place in the United States of America since 2007 and are awarded to manufacturers that successfully register a drug or vaccine that offers major advances in treatment for rare paediatric diseases or neglected diseases specified on a list by the US Food and Drug Administration. The PRV can then be used to get priority review of an unrelated, potentially more lucrative drug, which has been done in one case for a treatment of hepatitis C virus infection. The pathway cuts down the time for the review from the standard ten months to just six. This allows the registering manufacturer to market a potential blockbuster earlier. To date, there have been four PRVs awarded for registered neglected disease products.

PRVs do not have to be used by the company that has developed the neglected disease product, but can be sold on the market. This has happened several times in the past and selling prices ranged from US\$6.75 million to US\$350 million.<sup>15</sup> PRVs are a pull incentive and do not require upfront payments by public donors. Products that are developed anyway through the voluntary pooled fund could be used to obtain and sell PRVs yielding significant cash infusion if approved on the US market.

#### **Advantages and challenges for the voluntary pooled fund**

The sale of PRVs would be a truly new source of funding that does not have to be paid back by governments. The additional money raised is paid by patients or insurers in high-income countries that do, in return, get earlier access to potentially beneficial therapies. The extra money would only be available once a product has successfully been developed and approved through the voluntary pooled fund. PRVs can generate revenue, but not for the initial phase of the fund.

There are, however, some challenges that could limit the suitability of this approach for the voluntary pooled fund. PRVs depend on the successful registration of a medicine or vaccine in the USA, while most products targeting neglected diseases are not developed for the US market. In this context, the system has been criticized for rewarding products that are not novel.<sup>16</sup> The fact that registration in the USA is required can also add costs to the development process. PRVs also do not generate sustainable and predictable income as they are only granted for specific diseases and under the conditions laid down in the US PRV programme. So far, none of the product development partnerships developing drugs for neglected diseases has obtained a PRV.

#### **4.6 Summary of assessed alternative financing options**

The various options discussed in section 4 have very different characteristics and suit the voluntary pooled fund to varying degrees. While some of the tools provide new funding, others leverage the private sector to prefinance product development (options 4.1 - 4.4), allowing governments to delay expenditures. Priority review vouchers (4.5) could provide funding through a special reward where patients in high-income countries pay for the additional money raised.

Three of the options assessed (social impact bonds, advanced market commitments and priority review vouchers; 4.3 - 4.5) are pull mechanisms that try to create incentives to private developers which

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<sup>15</sup> Regulatory Explainer: Everything You Need to Know About FDA's Priority Review Vouches. Regulatory Affairs Professionals Society [website]. <http://www.raps.org/Regulatory-Focus/News/2015/07/02/21722/Regulatory-Explainer-Everything-You-Need-to-Know-About-FDA%E2%80%99s-Priority-Review-Vouchers/>

<sup>16</sup> Doshi, P. (2014). US incentive scheme for neglected diseases: a good idea gone wrong? *BMJ*, 349. <http://www.bmj.com/content/349/bmj.g4665>

also bear the risk. SIBs and AMCs are rather means of disbursing funds than an income source for the voluntary pooled fund. The PRV system is already in place and could be used to obtain additional funds.

Finally, in terms of time-scale, the tools presented fit different stages of the product development process. While credit models (4.1 - 4.2) would yield money that is immediately available to fund research projects from the beginning, tools that put a certain risk on the investor or developer are confined to later stage R&D projects which are more likely to succeed in a reasonable time frame. Since the voluntary pooled fund will not have such advanced stage products in its portfolio in the beginning, these will only become relevant at a later stage when the fund has been running for some years. Table 1 summarizes the characteristics of the discussed options.

**Table 1: Characteristics of options discussed in section 4**

	<b>Does the mechanism provide new funding or only delay government payments?</b>	<b>Who bears the risk of failure in R&amp;D projects?</b>	<b>Can the mechanism provide funds in the early phase of the voluntary pooled fund or only for late stage projects?</b>
<b>Bond programmes - IFFIm</b>	Private prefinancing, governments pay back with interest	Governments	Immediately available, long-term borrowing matches R&D needs
<b>Development bank loans</b>	Prefinancing by development bank, governments pay back	Governments	Immediately available, long-term borrowing
<b>Social impact bonds (SIB)</b>	Private prefinancing, governments pay reward	Investor and Developer	Immediately available, depends on success measure if applicable to early stage projects
<b>Advanced market commitments (AMC)</b>	Prefinancing by industry, governments have to disburse AMC once product is marketed	Developer	Only for specific products in later stage of development, not for early funding
<b>Priority review vouchers (PRV)</b>	New funding, patients in high-income countries pay	Developer	Requires successful development of a product, not for early funding

## 5. Conclusion

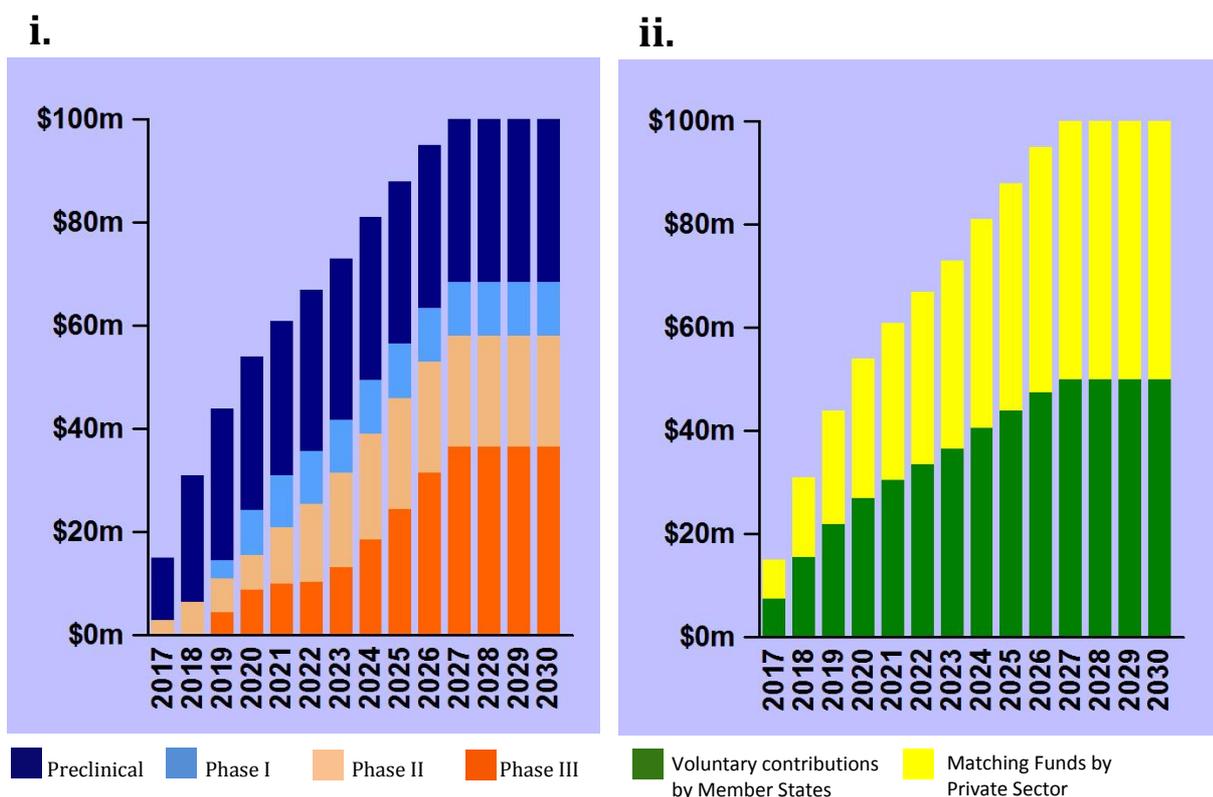
The alternative mechanisms assessed in section 4 are mostly tools to prefinance R&D, but still require a donor to commit funds. Only PRVs would provide a new source of funding and could be considered for complementary financing at a later stage. Overall, the fairly limited size of the fund is one reason why these potentially more innovative funding mechanisms are not suitable.

Therefore, we present two options for sustainable financing of the voluntary pooled fund which are based on direct contributions by Member States and the private sector. The first option is a mixed model with regular voluntary contributions by WHO Member States that leverage matching contributions from the private sector. The second option is a replenishment fund, with prolonged replenishment cycles to provide for more predictable funding.

### 5.1 Multi-source funding model with regular contributions

A multi-source funding model (Figure 2) could be suitable to achieve the funding levels needed for the voluntary pooled fund and to meet the diverse requirements of research projects in different stages. Such a model could include two pillars:

- a) Voluntary government payments
- b) Matching contributions from private actors



**Figure 2 : Funding needs for the voluntary pooled fund (i) and possible mixed model for its financing (ii).** i: The voluntary pooled fund as proposed by TDR<sup>1</sup> would scale up R&D activities gradually. It reaches its final size (US\$ 100 million/year) only when several products have advanced into late development. Funding needs are lower initially. ii: Governments provide base funding which is matched by equal contributions from industry.

### a) Voluntary government payments

The required financing for the pooled fund would be partly covered by voluntary contributions from WHO Member States. In order to finance the fund, Member States could adapt existing budgets for R&D and development cooperation. However, just relying on ad hoc voluntary contributions is likely not sustainable (see Box 2). This could be mitigated if Member States would identify new funding modalities, for example, levying a specific tax or setting up an R&D capital fund. Member States could also decide to voluntarily contribute to the fund based on the scale of their assessed contributions to WHO. Such voluntary assessed contributions would provide a clear objective for each Member State relative to their expected contribution and thus broaden the donor base and likely increase sustainability.

Box 4 explains how WHO assessed contributions are calculated and shows how much money this would translate to in a mixed funding model where Member State contributions make up 50% of the fund at its final size.

#### Box 4: How WHO assessed contributions are calculated<sup>17</sup>

Member States pay a certain amount to WHO's budget according to a formula that takes into account a country's nominal GDP, as well as its per-capita GDP. This lowers the funding burden on LMICs. There are some exceptions to the amounts calculated this way. The numbers in brackets translate this into possible contributions for the voluntary pooled fund at a fund size of US\$ 100 million, assuming that Member State contributions make up 50% of funds:

<sup>17</sup> Resolution WHA69.14: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA69/A69\\_R14-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R14-en.pdf)

- The maximum share a country has to pay is 22% (US\$ 11 million for the fund)
- The minimum contribution share is 0.001% (US\$500 for the fund)
- Least developed country contributions are capped at 0.01% (US\$5000 for the fund)

#### **b) Matching contributions from private actors**

Private contributions could be collected for the voluntary pooled fund in the form of a matching fund to cover the remaining 50% of the needed funding. For this to work, pharmaceutical companies would have to be willing to contribute collectively, for example, through their industry associations. The funds would have to be provided in a sustainable manner through long-term payment agreements rather than spontaneous donations. The industry would match funds provided by governments with an equal amount. In this way, private and public sectors would contribute a similar share to the voluntary pooled fund.

### **5.2 Classical replenishment fund**

Existing global health financing mechanisms have been successful for collecting vast amounts of money through replenishment where interested donors meet regularly (for example, every five years) and pledge funding for the following period. This is also conceivable for the voluntary pooled fund. As for option Member States as well as the private sector could contribute to such a mechanism.

Replenishment has the advantage in that donors do not have to commit to regular payments and can periodically decide to increase or decrease their engagement. Depending on the length of replenishment cycles, this model allows for fairly predictable funding. Due to the long-term nature of biomedical R&D, cycles would likely have to be longer than for traditional replenishment mechanisms. For example, a ten year replenishment cycle would create security for projects to be funded through the largest part of the development pipeline. Replenishment conferences would be held several years before a cycle ends to ensure predictability. This would allow long-term planning of research projects.