

# **Expanding Funding for the Development and Distribution of Essential Medicines to Developing Countries**

Proposals for the Long Term Funding and Management of a Pipeline of  
Essential Medicines from Development to Utilisation

September 2007

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## List of Terms and Abbreviations used:

ACT Artemisinin-based combination therapy (for malaria treatment)  
AMC Advanced Market Commitment  
ARV Antiretroviral (for HIV treatment)

BRICS Brazil, Russia, India, China and South Africa

CBO Community-based organization  
CCM Country Coordinating Mechanism  
CDC Centers for Disease Control (U.S.)  
CSS Community systems strengthening

DFID Department for International Development (UK)  
DOTS Directly Observed Treatment, Short course (referring to the internationally-approved tuberculosis control strategy)  
DQA Data Quality Audit

EARS Early Alert and Response System  
EDCTP European & Developing Countries Clinical Trials Partnership  
EFA-FTI Education For All — Fast Track Initiative

FBO Faith-based organization  
FPM Fund Portfolio Manager

GAVI Global Alliance Vaccines and Immunisation  
GEF Global Environment Facility  
GBC Global Business Coalition  
GFATM Global Fund for AIDS, TB and Malaria  
GNI Gross National Income  
GNNTDC - Global Network for Neglected Tropical Diseases Control

HBC High-burden country (for tuberculosis)

IFC International Finance Corporation (Division of the World Bank)  
IFF International Finance Facility  
IFFIm IFF for immunisation programmes  
IFFnd IFF for neglected diseases  
IP Intellectual Property  
IPM International Partnership for Microbicides - <http://www.ipm-microbicides.org/index.htm>  
IRS Indoor residual spraying (of insecticides to prevent malaria)  
IRR Internal Rate of Return  
IT Information Technology  
ITN Insecticide-treated (bed) net

LFA Local Fund Agent  
LLIN Long-lasting insecticidal (bed) net

M&E Monitoring and evaluation  
MDGs Millennium Development Goals  
MDR-TB Multidrug-resistant tuberculosis  
MMV Medicines for Malaria Venture

NGO Nongovernmental organization

ODA Official Development Assistance

OECD Organisation for Economic Cooperation and Development

PDPPP Product Development, Public, Private Partnership

PEPFAR President's Emergency Plan for AIDS Relief (U.S.)

Pharma Pharmaceutical Organizations

PMTCT Prevention of mother-to-child transmission (of HIV)

PR Principal Recipient

RBM Roll Back Malaria

SWAp Sector-wide approach

TB Tuberculosis

TERG Technical Evaluation Reference Group

TRP Technical Review Panel

UNAIDS Joint United Nations Programme on HIV/AIDS

UNDP United Nations Development Programme

UNICEF United Nations Children's Fund

UNITAID international drug purchase facility, see:

<http://www.unaids.org/en/MediaCentre/PressMaterials/FeatureStory/20060920-unitaid.asp>

USAID United States Agency for International Development

WHO World Health Organization

(The above table was in the main copied from The Global Fund 2007 Partners in Impact Results Report , see -

<http://www.theglobalfund.org/en/files/about/replenishment/oslo/Progress%20Report.pdf>)

# DRAFT - FOR DISCUSSION

## Expanding Funding for the Development and Distribution of Essential Medicines to Developing Countries

### Proposals for the Long Term Funding and Management of a Pipeline of Essential Medicines through Development and Distribution to help meet MDG 1

*The stability of the global systems hinges on an international effort to fight disease and on the health of the poorest, most vulnerable people.<sup>2</sup>*

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#### A. INTRODUCTION

##### 1. The Public Healthcare Architecture

Achieving MDG requires the systematic formulation and delivery of large scale, long term and interdependent programmes for education, infrastructure and healthcare whose operations need sheltering within carefully conceived architectures. Over time all architectures evolve and expand to meet changing needs. This document is focused on the current healthcare architecture and makes proposals for scaling up and attracting new sources of funding to help meet MDG and build self-sufficiency.

Governments and philanthropists have been the funders, commissioning agents and facilities managers for the existing healthcare architecture. Collectively they have shaped the policy, set up and endowed new institutions and attracted NGOs and together have driven the global humanitarian efforts to alleviate suffering and reduce poverty in the developing nations. They have created a substantial architecture within which this collective of government, public and private foundations, institutions and organisations have developed, manufactured, procured and delivered medicines, vaccines and diagnostics to developing countries. The key activists have been multilateral donor governments, World Bank/IFC, UN and the large private philanthropic donors. Funding and programmes have been managed by organisations such as GFATM, UNICEF, and GAVI collaborating with WHO, UN, OECD and similar institutions, to name but a few, and involving the beneficiary developing countries in the resulting healthcare programs.

The proposals in this document are business driven and demand led. The primary objective is to ensure the efficient allocation of new capital to existing public and private organisations so they can better manage an integrated, market aligned, pipeline of essential new medicines spanning clinical development to utilisation. This is similar to the way large pharmaceutical organisations manage their global activities and is a long term dynamic process. The core proposal in this document are methods to provide a consistent source of funding, designed to reduce fragmentation of healthcare initiatives and structure partnerships between large existing institutions to achieve a continuous flow of essential new medicines.

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<sup>1</sup> See <http://www.un.org/millenniumgoals/>

<sup>2</sup> WHO - Report of the Commission on Macroeconomics and Health Chaired by Jeffrey D. Sachs (2001)

The second but no less important objective is to foster progressive self-sufficiency in developing and emerging markets and fund programmes offering the best developmental returns objectively defined by reduction in mortality, morbidity and poverty, see WHO Commission on Macroeconomics and Health<sup>3</sup>.

## **2. Fusing Public and Private Business Models**

A parallel and commercially driven architecture has satisfied the healthcare needs of developed countries and made significant contributions of skills and technologies to develop and manufacture medicines and vaccines for developing countries. Large pharmaceutical organisations fund portfolios of medicines during research and development. The portfolio approach diversifies risk to ensure there will be a target number of medicines gaining approval to market and generating revenues. A proportion of the revenue is then invested to fund development and secure continuity of the business cycle. This cycle can span up to twenty years with the highest risks but lower costs in early stage research and development and the cycle is most capital intensive in later stages of development and manufacture.

Managing a continuous pipeline of products from development to utilisation promotes efficient, integrated business operations and this overarching management is currently missing in the public healthcare architecture even through the individual operations are efficiently managed. Increasingly over the next decades the economies of currently developing and middle income countries will spawn increasing numbers of commercial undertakings with the scale and cost base to meet the healthcare needs of their populations but currently there is a significant funding gap. The funding methods proposed in this document are designed to enable the fusion of the best components of the public and private practice in order to meet a funding gap, accelerate healthcare provisions and ultimate self-sufficiency.

## **3. Sustainable Funding and Long Range Planning**

In the commercial healthcare model, large pharmaceutical organisations have established long range, market aligned planning procedures. These are backed by a treasury function to ensure that each business unit; research to delivery, involved in pipeline management will be assured funding if they meet predefined business criteria<sup>4</sup>. The benefits of this long range planning enable efficient, continuous operations by large pharmaceutical organisation in their chosen franchises, geographic and therapeutic, enabling consumers to rely on being the beneficiaries of sustainable healthcare. Predominantly the top 10 pharmaceutical organizations maintain AAA ratings. They accomplish this whilst managing the risks inherent in early and late stage development also the logistical and political risks encountered during distribution. This illustrates how a portfolio approach, integrated with consistent funding, can manage the perceived risks in development, the subsequent distribution and deliver substantial healthcare benefits.

In the public sector and now that portfolios of new medicines are near to market approval and about to enter the public healthcare pipeline it becomes important to take a longer term, and market aligned view, of funding needs. This is needed to support the co-ordination, planning and execution of predictable multi year balanced healthcare programmes fed by existing and new medicines. To do this requires no new type of organisation to be set up or significant changes to current practice rather it is proposed that

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<sup>3</sup> <http://whqlibdoc.who.int/publications/2001/924154550X.pdf>

<sup>4</sup> Instituting provisions for assured funding has enabled large pharmaceutical organisations to create autonomous business units, increase innovation and reducing administration also to licence in the creativity of small external businesses.

effective pipeline management can be instituted by integrating commercial practices with the fund management structure established for IFF<sup>5</sup>.

Section D./2 gives further details on proposals for pipeline management of medicines for neglected diseases.

#### **4. Accessing Capital Markets using Securitisation Methods**

The IFF was conceived as an expedient, a mechanism to bring forward money from governments that had not made full ODA contributions at 0.7% of GNI. It is based on securitisation methods routinely used to raise money from bondholders when there are highly rated sources of repayment. IFF bonds are raised against sovereign guarantees and in fifteen to twenty years when the bonds mature the guarantees will be called and repay the bondholders. The justification for IFF is that spending money now on public healthcare gives a high IRR<sup>6</sup> and justifies the small cost of finance. While the IFF places repayment obligations on future generations at the same time it delivers a benefit that the next generations of the electorate will inherit; a reduction in poverty, improvements in public health in the beneficiary countries, and accelerated economic growth. The securitisation methods underpinning IFF are routinely used to provide financial solutions in many business sectors, see Appendix A.

The mechanism underpinning IFF is quite simple, donor countries make legally enforceable guarantees to make ODA aid payments 15 to 20 years in the future and these highly rated obligations to pay are packaged as securities and sold to institutional bondholders. In the IFF formulation the guarantees will always be called on to repay bondholders. In the proposed IFF for neglected diseases (IFFnd) securitised formulation procedures will be undertaken to amplify the public funds supporting IFFnd by attracting private sector investor to participate and place these additional proceeds in a revolving trust fund. Section D./4 a. to h. lists the potential contributors to expanding IFFnd funding that can be summarised as:

- Commercial receipts for medicines sold in middle income and developed countries
- Differential payments from developing in developing countries paid at a future time when they receive the benefits of improved public healthcare.

Appendix G. also has background on this proposed formulation of future IFFnd to secure private investors. Essentially each beneficiary, philanthropic or commercial, will be given the opportunity to repay a slice of the debt proportionate to the benefits they receive and their ability to pay<sup>7</sup>.

#### **5. The Benefits of using Securitisation Methods**

The major benefit of using well formulated securitised funding as a financial service for the public healthcare architecture is:

- a. Large-scale, low-cost, fifteen to twenty year funding that reinforces transparent, good governance practices and a systematic approach over the entire pipeline/portfolio of medicines.

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<sup>5</sup> In November 2006 the first IFF issued \$1bn of debt to fund immunisation programmes (IFFIm). In total \$4bn will be raised from the capital markets by securitising sovereign guarantees of ODA pledged by a collective of developed and middle income countries. GAVI are undertaking the long term management of IFFIm with procedures that can be a 'blueprint' for other securitised funding initiatives.

<sup>6</sup> The IFFIm inaugural \$1bn issue was 1.7 times over subscribed and carried a coupon only 31bps (0.31%) above London base rate (LIBOR). GAVI estimates the "financial cost" of IFFIm at 3.5% against the IRR of accelerated benefits of 18%.

<sup>7</sup> It may be necessary to provide credit enhancement, by highly rated commercial organisations, banks and specialist insurers and potentially by IFC, for acceptance of pledges by governments in developing countries.

- b. Allows planning and execution of predictable multi year balanced healthcare programmes.
- c. Aligns capital with the needs of the operational units working within the public healthcare architecture and ensuring they have access to continuity of funding conditional on meeting preset criteria.
- d. Encourages alliances to be formed from organisations with similar interests who can reap the benefits of increased scale, operational efficiencies and effective advocacy for their collective cause. GAVI is a successful example.
- e. Repayment of bondholders occurs at the end of the fifteen to twenty term at the point when benefits are secured in the form of healthcare improvements or commercial receipts.

Setting up the foundations for long term consistent funding can bring a longer term benefit at some future time and amplify the initial public sector IFF funds with private sector inputs. The Capital Markets have the ability to structure and syndicate debt and equity tranches within the bond issue that can appeal to different investor appetites. Once commercial prospects emerge for medicines, initially in middle income countries, successive securitised formulation can incentivise specific classes of investors to participate. Bonds would be formulated to match investor risk/reward appetites and begin to build a new global investor community<sup>8</sup>. At some future time this will assist trade to begin to take on the role currently provided by donor based aid

By adopting the proposals set out in this document the continuity of flow of essential new medicines can be assured during development and distribution and help fill well defined funding gaps. The proposals build on existing and proven methods to enable the efficient allocation of capital to the organisations developing and distributing medicines to help meet MDG. Importantly they can help accelerate economic growth and self-sufficiency in the recipient countries that partner in these programs.

## **B. THE EXISTING PUBLIC HEALTHCARE ARCHITECTURE and POLICY DRIVERS**

### **1. The Existing Public Healthcare Architecture**

Healthcare is differentiated from infrastructure and educational aid in that the long timescale between the clinical developments of treatments and their delivery that can span up to twenty years. Each new medicine is an innovation, backed by patents, requiring different methods of manufacture, formulation and the management of long logistic chains. The principle strata of the healthcare architecture that deliver balanced healthcare programs to developing countries are:

- Research into the causes and prevention of disease: this is undertaken by public and research institutions, universities and established pharmaceutical organisations. (Absorbs high intellectual capital but lower financial capital.)
- Development of medicines, vaccines, diagnostics and microbicides: this is undertaken by not-for-profit and for profit pharmaceutical organisations and research institutions. (Late stage clinical development is high cost, the preceding stages are lower cost but more risky.)
- Manufacture of medicines can be capital intensive as can the purchase of active ingredients.

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<sup>8</sup> A substantial predictive model has been created to explore the risks and establish the costs of funding a portfolio of medicines in clinical development that can be used to test investor appetite prior to a bond issue.

- Procurement of medicines, vaccines, diagnostics and microbicides is undertaken by a range of public and private organisations enabling savings to be made and driving operational efficiencies<sup>9</sup>.
- Distribution of medicines, vaccines, diagnostics and microbicides: In the main large NGO manage the distribution logistics in collaborative programmes with governments in developing countries. Distribution absorbs a significant proportion of funding.
- Donors: Government agencies and large philanthropic organisations are the majority sources of predominantly grant funding.
- Governance: International regulatory bodies oversee good clinical practice during development. Each of the donors and institutions that disburse funds and the recipients have well-defined M&E and governance procedures.

Appendix B. has a more comprehensive overview of the sub components of this healthcare architectural framework, the major institutions and organisations and their interrelationships.

## 2. Policy Drivers

Humanitarian concerns to alleviate suffering have always driven public health policy and some of the key policies that have shaped the current architectural framework are that:

- the millennium development goals are met
- morbidity and mortality are reduced leading to an increased quality of life
- poverty is reduced leading to an acceleration of economic growth
- safe and effective treatments are being distributed
- exemplary governance for aid monies and guarantees is established
- medicines are procured at affordable prices
- dependence on Aid is progressively reduced and substituted by new financing methods
- all healthcare programmes are transparently monitored and evaluated
- collaboration with recipient governments is established in all programmes with progressive increase of local, human and intellectual capital
- environmental issues are considered in all programmes
- legal treaties are honoured, (TRIPS and others)
- replenishment funding rounds are substantiated with objective measures of past performance
- Public discontent in developing countries does not fester and challenge the security of developed countries

The global healthcare systems do more than develop and distribute immunisation programmes, medicines, diagnostics and microbicides. For example they also ensure there are supplies of the active compounds incorporated into treatments and take preventative measures to control diseases including the distribution of bed nets and insecticide spraying. All these activities are important to meet the overall objective of the public healthcare architecture in delivering balanced healthcare programs to developing countries.

## C. INCREASING the SCALE of OPERATIONS and FUNDING

### 1. Building a Diversified Pipeline of new Medicines

Increasing aid funding goes hand in hand with ensuring there is absorptive capacity in the recipient countries. The proposed IFFnd funding is designed to aid the incremental

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<sup>9</sup> UNITAID has been recently established to procure medicines for the "three diseases" and it is intended to open discussions on securing their involvement and potentially guarantees for IFFnd.

expansion of the current public healthcare model and build funding capacity. Initial funding will be applied to a portfolio of medicines in clinical development, several years before approval to market and preparations for manufacture, procurement and distribution. Accordingly there will be time to make the necessary planning provisions to ensure absorption. This follows the business model practised by established pharmaceutical organisations that build a pipeline of medicines then undertake market aligned development to ensure a smooth flow through the various stages in their pipelines.

Meeting MDG targets by 2015 will need an increase in push and pull funding to satisfy MDG humanitarian criteria, control the disease burden, reduce poverty and accelerate economic growth. Any increase in funding needs to:

- a. be selectively applied to diseases that cause the highest mortality and morbidity
- b. address funding gaps in critical areas
- c. be channelled to organisations that can scale up operations and have provisions to ensure balanced healthcare programmes are delivered where there is absorptive capacity
- d. have the potential to attract co-funding from commercial sources
- e. be structured to reinforce efficient operations and good governance

Taking a high level perspective and a portfolio/pipeline approach then the funding provisions for a public healthcare funding need to ensure:

1. New medicines, vaccines, diagnostics and microbicides are pushed through, high cost and lengthy development processes.
2. Affordable balanced public healthcare programs are pulled into developing and middle income economies.

## **2. Preparing to manage IFFnd**

The securitisation methods underpinning IFF can operate over a twenty year term and can be structured to attract co-investment by commercial and philanthropic investors. The IFFnd formulation can help institute self-sustaining pipeline management for public health similar to processes in the commercial sector. The foundations for this process are outlined below:

### **a. Disease Selection**

Aids, TB and Malaria cause the highest mortality and morbidity and collectively the parasitic diseases also inflict high morbidity so that these four disease types are self-selecting for control. Woman's health and contraception are important from humanitarian and socio-economic considerations so that there is a strong incentive to include microbicides on the list of essential medicines. Appendix C. provides a list of essential medicines that are illustrative of candidates that might be selected for funding.

Vaccines are a first choice to provide effective public healthcare, treatments can be delivered "under a tree" but this is balanced by the high cost and uncertainty inherent in their development. With the launch of the IFFIm there is less of a funding gap for immunisation programmes and a number of donors are supporting vaccine development and at some time IFFnd might swell this funding. However no vaccine is 100% effective and for many diseases there are no vaccines bringing a need for medicines and diagnostics that are marginally less difficult to develop but more costly to administer. Accordingly it is proposed that the new sources of funding outlined in this document are applied to the clinical development and distribution of medicines. As a matter of policy there will be close liaison with GAVI the leading manager of immunisation programmes, reinforced by GAVI's

partnership with GFATM and this might lead, at some time, to admitting vaccines into IFFnd funding programmes.

## **b. Gaps in Funding**

Developed countries are estimated to spend in the region of \$50bn per annum on R&D for their own needs, some of which is applicable for use in developing countries if the resulting medicines can be made affordable. This still leaves a significant unmet need comprising new medicines, new formulations and new manufacturing methods suitable for use in the tropics and by the poor.

Diseases change as organisms develop resistance, requiring continuous innovation to provide control. The current healthcare architecture has an understandable bias to delivering existing medicines and vaccines to secure the most rapid improvements in public health. Scaling up efforts to meet MDG will require additional funding to develop new medicines, diagnostics and microbicides especially those in late stage clinical development whose approval to market is forecast before the MDG target date, 2015.

Recently a number of new financing mechanisms have been proposed see Appendix F. These are welcome but individually they do not provide the continuity of funding needed by the PDPPP collaborating in licensing arrangements<sup>10</sup> with established pharmaceutical organisations that are currently the driving force behind creating new medicines, vaccines, diagnostics and microbicides. The securitisation methods underpinning IFF offer a solution and the benefits are set out in Section A./5.

Aid alone will not meet the combined funding gaps in development and distribution. Grant funding can perpetuate a culture of dependency and creating short term incentives for R&D can distort market forces and exclude otherwise valid contributors. The proposed formulation and management of IFFnd by the large public healthcare institutions can address these issues and incrementally help fill the funding gaps. G8 countries that have not met 0.7% ODA to GNI offer a first opportunity to fill this gap by supporting IFFnd. This can open new methods of structured funding based on securitisation and attract new funders, see Section D./4 a. to h.

## **c. Scaling up Supply and Absorption**

**i. Development of Medicines, Diagnostics and Microbicides:** a number of not-for-profit/not for loss organisations are involved in managing the development of medicines, diagnostics and microbicides collaborating with established pharmaceutical organisations and universities. This is generating intellectual capital reinforced by patents to create the new medicines, vaccines, diagnostics and microbicides essential to meet MDG. This community and the legally binding partnerships they enter into are funded by large philanthropic and government donor organisations. Collectively they have taken a portfolio of treatments through the risky stages of early development and now have a portfolio of medicines, diagnostics and microbicides some of which are highly likely to achieve approval to market from 2008 to 2015. There is a funding gap in late stage development, high benefits to MDG if the gap is filled and absorption can be assured through the

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<sup>10</sup> Further information on licensing arrangements can be found in: Valuing Industry Contributions to Public-Private Partnerships for Health Product Development - Hannah Kettler, Karen White, Scott Jordan, [http://www.globalforumhealth.org/filesupld/ippph\\_cd/01.PDF](http://www.globalforumhealth.org/filesupld/ippph_cd/01.PDF)

combined distribution channels of GFATM, GNNTDC and similar. Section D./6. sets out the benefits of providing consistent funding to the clinical development process and the objective measures that will be taken to manage risk. Appendix D. lists the inaugural organisations that will contribute development projects to a first pilot funding transaction.

**ii. Distribution:** GFATM has capacity to scale up distribution and has evolved the processes to ensure absorptive capacity with its partners in developing countries. GFATM's distribution programs cater for the three major diseases and thus could absorb the bulk of new funding. Complementing this is GNNTDC with proven competencies to expand its programmes for the control of parasitic diseases. In comparison to the costs of distributing medicines to control AIDS TB and Malaria the costs of parasitic control are significantly lower and bring rapid humanitarian and economic benefit <sup>11</sup>.

#### **d. Attracting Co-Funding**

The current public healthcare model is almost entirely serviced by grant funding and new funding methods are being sought. The proposed securitised bond issues backed sovereign guarantees will have a duration of up to twenty years. Accordingly during successive bond issues the economies of developing countries increasingly freed from poverty and disease will grow and commercial markets for medicines will spring up<sup>12</sup>. The proposed IFFnd funds will be backed by good governance and the flexibility to blend highly rated commercial and sovereign guarantees to repay bondholders. The commercial interests have different risk and reward appetites to the sovereign interests and the former can bring benefits to the latter. Section D. reviews how bond issues could be structured and progressively facilitate commercial participation as economies grow and is expanded in Appendix G.

#### **e. Reinforcing Efficient Operations and good Governance**

The development of medicines is highly regulated and follows well-defined, systematic development processes. There is risk in development but less so in the late stages of clinical development and by funding a sufficiently sized and well selected portfolio there is a very high probability that an economically viable number of new medicines will achieve approval to market. Securitisation requires detailed and objective assessments of risk to assure bondholders they will be repaid their principle and interest. Rating agencies provide bondholders with the assurance that the bond issue will be subject to good governance and undertake a rigorous assessment prior to issue and supervision over the duration of bonds. This means that the disciplines inherent in a securitisation issue can reinforce the regulatory and systematic operational processes that bring safe medicines into the distribution channels and up to a point of utilisation.

In November 2006 the IFFIm raised a first \$1bn in a \$4bn programme to fund the distribution of GAVI immunisation programmes. It is proposed to build on this by

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<sup>11</sup> Following the Second World War the policy of the Japanese government was to "de-worm" its population and they attribute their subsequent rapid economic growth to this low cost public health intervention.

<sup>12</sup> The International Finance Corporation (IFC), the private sector arm of the World Bank, collaborating with the Gates Foundation is in discussions to create an equity and debt fund totaling up to \$500m to finance commercial healthcare projects in Africa, with a projected launch date of 2007. Estimates released by the IFC suggested that 60 per cent of health expenditure in sub-Saharan Africa was privately funded, with a market excluding South Africa worth nearly \$19bn.

structuring a \$4bn fund for IFFnd with the lead partner being GFATM. This will expand core funding for GFATM and enable the development, procurement and distribution of medicines, diagnostics and microbicides as set out in Section D. Appendix E outlines a project plan for the formulation and issue of bonds for an IFFnd.

## **D. MANAGING AND FUNDING PIPELINES of MEDICINES through DEVELOPMENT and DISTRIBUTION**

### **1. Foundations for a Securitised Bond Issue**

As presented in Section C the current public healthcare model has recently achieved two significant milestones:

- Growing a pipeline of new medicines, vaccines, diagnostics and microbicides in late development with the first medicines targeted to get approval to market in 2008.
- Using the capital markets to raise, large scale, long-term funding for immunisation programmes using structured funding based on securitisation methods, IFFIm .

Both are important as they can lay the foundations for a self-sustaining business model conceptually similar to that of the large established pharmaceutical organisations. Large Pharma create a pipeline of new medicines, then manage the funding of the pipeline to allocate large scale funds over long time scales, see Section A./2/3.

### **2. Managing a Pipeline of New Medicines**

Collectively the PDPPP in partnership with Pharma have been highly effective in managing the development of portfolios of medicines during development but have not been required, so far, to manage the transition into distribution. The capabilities for 'through life' pipeline management are being established by some of the leading PDPPP but it has not been relevant when there was not a continuous pipeline of medicines, see Section A./3.

The proposals for an IFFnd can create a sizable pipeline, development to distribution and accordingly provisions are needed to scale up this aspect of management. Pipeline management is an integration of operational and financial planning the latter supported by a global treasury function. The development and distribution of medicines is capital intensive requiring relatively large allocations of funds to be made at key points in the operations of the organisations responsible for, development and distribution. Once a pipeline has been established to enable the scale up of essential medicines it is vital that the pipeline does not dry and that the various stages in development to distribution can be assured of getting funding if they meet predefined business criteria.

GAVI undertakes long term financial planning for the distribution of its vaccination programs so that IFFIm can issue bonds in a timely manner. Similarly it is proposed that a Global Alliance for Neglected Diseases (GAND) is established manages the issue of bonds for IFFnd and undertakes the long-range planning for funding development and distribution. In this arrangement PDPPP and established pharmaceutical organisations would submit development programmes for funding by IFFnd. On acceptance and following similar procedures to GAVI, GAND would plan to ensure continuity of funding for projects that met predefined development selection criteria and collaborate with the financial officers in the participating organisations. Distributing medicines would be undertaken by partner organisations with GFATM being responsible for the majority and requiring joint financial and operational planning to be instituted. (This would have similarities to the existing GFATM/GAVI partnership.)

The integration of these essential activities can follow the market aligned long range financial and process planning model that is integral to the pipeline management of large established pharmaceutical organisations. This will assist efficient business operations over the entire pipeline and enable a scale up of operations to meet MDG and beyond. Appendix G. gives an overview on proposals to create a self-sustaining pipeline of essential new medicines and establish the large scale, long-term financial and operational pipeline management that will be needed for IFFnd.

### **3. Structuring funding for an IFFnd**

When the IFF was first conceived the objectives was to bring forward up to \$50bn of new money. A first application, a sectional IFF, was dedicated to immunisation programmes (IFFIm), but did not include funding for development of vaccines. Building on these foundations a sectional IFF for neglected diseases (IFFnd) can bring forward funding for development, procurement and distribution of medicines and potentially vaccines<sup>13</sup>. Over time, and with replication, sectional IFF can aggregate to fulfil the original ambitions of this innovative concept.

Once GAND is established it is proposed that it will collaborate with GFATM, the PDPPPs, GAVI, WHO and EDCP to secure sovereign and other highly rated guarantee pledges that will be securitised to support a bond issue. Similar to GAVI's IFFIm funding, sovereign guarantees are being sought to raise up to \$4bn for an IFFnd, with bonds issued periodically over a period of up to fifteen years. This will fund development for GAND and working with GFATM, the proceeds will fund procurement and distribution. The governance of the proceeds of the bond issue will be assured by independent committees following the procedures established for IFFim. Appendix H. sets out the structure of GAND and is similar to GAVI but simplified.

The aid landscape is changing and gradually there is social and economic improvement in developing countries. This means that the focus of GAND will change over the life of the IFFnd fund and will be managed by the executive guided by a rolling five year business plan similar to GAVI. Currently the medicines pipeline is not flowing freely as there is a severe constriction in funding late phase clinical development; accordingly an initial focus will be on funding this gap. A second and equally important focus is to collaborate and improve the basic health of populations that will receive new medicines and fund any gaps. The GAVI and GFATM immunisation programmes, funded by IFFIm will greatly contribute to this objective as will programs of treatment for the parasitic diseases where there are funding gaps that IFFnd will address.

In the first bond issues IFFnd will depend entirely on having sovereign guarantees but over successive future issues it is proposed that policy measures are taken, to reduce the repayments that future generations will make. These will be backed by participating organisations including GFATM<sup>14</sup>, the beneficiary PDPPP<sup>15</sup> and pharmaceutical organisations. The proposed IFFnd securitisation framework will be designed to encourage private and public sector co-investment. Initially this will be a small proportion of total investment but successive successful bond issues will help grow the number of different types of informed investors. This can either reduce the extent to which the initial

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<sup>13</sup> GAND's securitisation methods could assist GAVI fund vaccine development and enable them to continue their close working relationship with GFATM for distribution of the resulting immunisation programmes.

<sup>14</sup> For example secure agreements to make differential payments for medicines from developing countries that can ultimately help repay bondholders.

<sup>15</sup> For example take measures to grow receipts, even if initially small, from distributing medicines in middle income and where possible developed countries, also at ranging marketing of medicines to meet the needs of travellers, expatriates and security service.

guarantees are called on to repay bondholders or preferably increase the total funds available for the development and distribution of treatments for neglected diseases. The constitutions of some donor organisations and governments, including the USA do not allow them to make multi year annual pledges however as is the case for IFFIm, any donations that could not be securitised would be accepted into a revolving trust fund and expand development programmes.

It is not the intention that IFF based securitised funding will substitute for the current core, grant funding to the PDPPP collaborating with Pharma and the program management organizations. Rather that it will be additional funding and provide similar financial services to the public health sector that have benefited the commercial sector:

- aligning capital with operational needs
- hedging risk
- open opportunities to tap new sources of funds
- scale up to ensure a continuity of supply of essential medicines.

Five years after the first issue of bonds it is proposed that a replenishment round will be held to secure further sovereign guarantees, see Section D./4 below. This will fund further portfolios of medicines, diagnostics and microbicides developed by PDPPP working with established pharmaceutical organisations in developed and middle income economies. Replenishment will be justified as set out in section 4. below.

#### **4. Securing new sources of funding for IFFnd**

Replenishment rounds will be justified by the extent to which arrangements have been made to introduce new sources of funding to either reduce the calls on sovereign guarantees or preferably amplify core funding for healthcare:

- a. Pooled differential payments from individual or collectives of the recipient countries who are the beneficiaries of IFFnd. Sovereign undertakings by these countries to make differential payments have the potential be pooled and underwritten by World Bank/IFC, to bring funding forward or when they accrue that they are placed in a trust fund to meet the costs of future development programs.
- b. Licensing arrangements with highly rated pharmaceutical organisations in developed countries participating in an IFFnd and whose products might achieve some commercial distribution. This could apply to prospective TB medicines and medicines for travellers, military and expatriate markets. Once there were a number of diversified licensing arrangements these might be securitised if there was a need to bring additional money forward<sup>16</sup>.
- c. Pharmaceutical organisations in middle income countries (BRICS) have the skills and the cost structures to deliver affordable new medicines in volume to satisfy their own needs and those of the poorer countries. They have a need for capital and their involvement in IFFnd can bring powerful new resources to close the healthcare gap also motivate their governments to provide sovereign guarantees.
- d. Potentially micro healthcare insurance providers who have structured products for migrant workers to make provisions for families in developing countries.
- e. Advanced market commitments from commercial healthcare delivery organisations wanting to make early entry into middle income countries and needing to guarantee supplies of medicines appropriate for each country's operations.

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<sup>16</sup> The international accounting issues that might have precluded commercial pharmaceutical organisations from participation in the proposed securitisation have been addressed and no potential barriers are foreseen.

- f. Advanced Market Commitments (AMCs) are being applied to funding the development of vaccines. If there is an expansion of scope to include medicines and an acceptance of the use of AMCs to fund, wide-based multiple technology portfolios of medicines, in whole or part. This can enable securitised funding to be raised against AMC payment obligations and reduce calls on the original IFFnd guarantors.
- g. Any medicine procurement scheme, including UNITAID, backed by highly rated public or private organisations, now or in the future, could provide the basis for payment obligations that could be structured to reduce calls on the original IFFnd guarantors. This might include the proposed IFC/Gates Foundation Healthcare Fund, see Footnote 6.
- h. Subsidies can be structured to reduce calls on the original IFFnd guarantors and providing a similar function to an equity layer in a commercial securitisation.

Progressive formulations of IFFnd can tap the benefits that approved medicines can bring and attract new sources of investor funding to meet MDG. Incrementally these can help bridge the time from now, when there is no commercial market, to fifteen years and beyond when commercial markets emerge stimulated by the economic growth that Aid has fostered.

Relative to the above potential sources of additional funding GAVI has secured interest from countries that benefit from their immunization programs to consider code funding lending support to item **a.** above. Work has been undertaken on item a. and is set out in Appendix G -

## **5. Alternative Formulations**

Structuring IFFnd using sovereign guarantees is the preferred approach but alternative formulations are theoretically possible and to fund clinical development my means of legally binding commitments to pay for medicines that are approved and meet a predefined therapeutic profile. These might include:

- Commitments from procurement funds with a high credit rating to purchasing medicines with predefined therapeutic profile. These commitments could be securitised and fund development of a portfolio of medicines in whole or part.
- UNITAID and private healthcare funds, including the proposed IFC and Gates Foundation fund for commercial healthcare projects in Africa, see Footnote 6.
- If AMC are ever formulated for development of medicines and the funding extended to include a portfolio of medicines then this could be the basis of a securitised funding bond issue.

## **6. Benefits**

Instituting a soundly based financial policy to manage pipelines of essential new medicines and feed treatment programmes can provide wider benefits:

- Attract funding to the more risky but less costly phase of research and early development to ensure that pipelines of medicines remain charged.
- Encourage the setting up of bulk procurement combined with physical distribution capabilities in order to drive down prices and streamline physical delivery.
- Encourage large enterprises operating and trading in developing countries to consider shared use of their transportation and infrastructure logistics to assist public healthcare delivery.

The timing is good to institute new methods to fund the expansion of the existing public healthcare model:

- Achieving MDG by 2015 requires additional resource

- GFATM intends to triple its funding provisions and scale up operations by 2010
- Leading PDPPP working with established pharmaceutical organisations and large donors have created a pipeline of essential new medicines with some nearing regulatory approval
- IFFIm has proved investor appetite for bonds backed by sovereign guarantees
- GAVI has established the management structures that can be replicated to disburse the funding working with GFATM (and these will be adopted by GAND)
- A number of G8 countries have not made full ODA commitments of 0.7% GNI and can secure electoral benefits by participating in a project of this scope
- IFFnd can incorporate or collaborate with any of the currently known proposals for innovative funding, including AMC <sup>17</sup>, UNITAID and subsidies

The above measures can leveraged GFATM's core funding and it is proposed that the process of securing funding for an IFFnd is assisted by GFATM and the proceeds managed by:

- GAND for clinical development operations
- GFATM for distribution of approved medicines for the "three diseases" and collaborating with GNNTDC for parasitic diseases.

## **E. CONCLUSIONS and NEXT STEPS**

### **Conclusions**

Starting now and progressively, trade needs to substitute for aid to prepare for sustainable development and economic self-sufficiency in the emerging economies. Good public healthcare is essential for sustainable development and these proposals outline how incremental improvements to the existing healthcare model can be made. The proposals do not rely on creating artificial stimulants for the public healthcare market that can unintentionally distort market mechanisms. Rather they integrate existing provisions, take a business driven approach and importantly give access to global capital markets and their proven inventiveness to formulate and execute new funding solutions and directly harness market forces. The collective action of a few leading organisations can turn these proposals into a plan of action and make a substantial impact on reducing world poverty and improving quality of life.

### **Next Steps**

Below are proposed key next steps, some to be conducted serially others in parallel for which Appendix D provides a draft timeline of activities.

- Structure the informal relationships that have guided the formation of the IFFnd/GAND project and formalise a shadow board to oversee bilateral government discussions and pledges of sovereign guarantees and associated preliminary activities. See also Appendix H.
- Estimate project costs up to point of issue of IFFnd bonds and secure initial funding to realise the project objectives.
- Exploring and formalise relationships with the PDPPP, Government agencies and the large public and private organisations that are in the footprint of the IFFnd/GAND initiative.

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<sup>17</sup> Currently AMC have only being proposed to fund the development of vaccines and not medicines.

- Identify sources of medicines in clinical development that can satisfy the admission criteria for IFFnd agree term sheets and create the first pipeline of essential medicines (see Appendix C).
- Model the pipeline and project the probability of outcomes, approvals, costs of development and the resultant benefits specified in terms of reduced mortality, morbidity and economic impact.
- Convene a high level meeting of key stakeholders to secure individual commitment on a timetable to progress an IFFnd, see Appendix D.
- Agree an operating structure for GAND, see Appendix H and draft a first five year rolling business plan.
- With reference to the operating structure and business plan identify and select candidates for the GAND executive.
- Working with business partners, WHO and other agencies estimate future demands for medicines in middle income and developing countries.
- Guided by the experience of GAVI, mandate the same advisors, confirm sovereign pledges and make preparations for the inaugural issue of bonds for IFFnd, see Appendix D.
- Ensure that the objective risk taking, collaborative, business led, demand driven ethos to save lives and make economic change that has guided this project is embedded in the GAND culture.

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## APPENDICIES

### APPENDIX A - Introduction to securitisation methods

Securitized finance is a large, well established world wide business, highly regulated and a significant numbers of bonds are issued daily on all the world's major financial exchanges.

Securitisation is primarily used to provide capital to organisations that own assets capable of providing a future stream of profits that will repay capital and interest over time. Risk is transferred to investors and the main objective is to secure funding for the original owners. Securitisations are structured so that the risks transferred to bond holders are primarily credit risks. If the portfolio of assets is well selected the risks, and rewards, can be stochastically modelled and different classes/tranches of bonds issued to attract investors with different risk appetites. Each class of bond in a transaction will be rated by one or more of the established rating agencies so that once the exacting task of modelling risk and securing a rating is complete bond totalling \$1bn or more can be issued on one day.

The UK Accounting Standards Board (ASB) has a list of the asset types that have been most commonly securitised in the UK and Europe with household mortgages, hire-purchase loans and trade debts predominating. A good working definition of 'securitisation' proposed by the ASB is:

"a means by which providers of finance fund a specific block of assets rather than the general business of a company."

A key point in the ASB approach is that the term 'asset' is defined to include "rights to future economic benefits controlled by a legal entity as a result of past transactions or events", opening a broad range of possible transactions. This definition has allowed securitisation to be established as an important method of finance. In effect a lender or investor agrees to look solely at the credit risk of the relevant portfolio or pool of assets and separate this credit risk from that of the original owner of the assets.

The vast majority of asset-backed securities involve assets, such as mortgage and credit card loans that generate relatively predictable amounts of cash at predictable times. A range of new asset classes is being constantly added as investors, rating agencies and insurance companies develop a greater familiarity with the various classes of asset-backed securities and ability to predict cash flows.

In the proposed IFFnd bondholders are exposed to the very low risks that a group of sovereign countries will default on making payments and as this is a vanishingly small risk the bonds will be highly rated and carry a low coupon. The risk that sovereign countries are exposed to is that a well selected portfolio of medicines in late stage clinical development will totally fail to get approval to market, again vanishingly small. It should be borne in mind that even if this catastrophic risk was to materialise not all the bondholders money would have been spent on development. Assuming median outcomes then the sovereign governments benefit from meeting MDG plus they will have created the foundations for a self sustaining business oriented collective supplying pipelines of affordable medicine to the poor.

## **APPENDIX B. - Overview of the current healthcare architectural framework**

T.B.A.

## APPENDIX C. - List of medicines selected as candidates for funding

There is no comprehensive index of candidate medicines in development for Tier II/III neglected diseases. The tables copied below were compiled in 2005 and provide a excellent basis to maintain and expand such an index.

The following tables are reproduced from a report – The New Landscape of Neglected Disease Drug Development. This was sponsored by the London School of Economics and the Wellcome Trust, and the report was compiled by a team led by Dr Mary Moran now at The George Institute <http://www.thegeorgeinstitute.org/iih/research/health-policy/director--mary-moran.cfm>

The full text of this comprehensive report can be found at:  
<http://www.wellcome.ac.uk/assets/wtx026592.pdf>

These tables show the public health medicine development Pipeline at the end of 2004 and illustrate the development activity in the public health sector. The tables do not include diagnostics or microbicides and it is proposed to update this list as the basis for proposals to review IFFnd funding allocation for projects in the later stages of clinical development.

### The New Landscape of Neglected Disease Drug Development. - ANNEXES Annexe 1. List of active neglected disease drug R&D projects as of end 2004 (grouped as PPPs and industry projects)

#### Annexe 1A. Neglected disease drug R&D landscape – PPPs (December 2004)

|    | Compound  | PPP | Partners  | Indication | Current stage              |
|----|---|-----|---|------------|----------------------------|
| 1  | Artemisone  | MMV | Bayer HealthCare<br>Hong Kong Uni                               | Malaria    | Clinical<br>(Phase II)     |
| 2  | DHF reductase   | MMV | BIOTEC<br>(Thailand),<br>LSHTM, Monash<br>Uni                   | Malaria    | Lead identification        |
| 3  | Peptide deformylase-<br>PDF                             | MMV | GSK   | Malaria    | Discovery                  |
| 4  | 4(1H)-pyridones   | MMV | GSK   | Malaria    | Preclinical                |
| 5  | 4(1H)-pyridones<br>back-ups-                            | MMV | GSK   | Malaria    | Lead optimisation          |
| 6  | Isoquine  | MMV | GSK, Liverpool<br>Uni   | Malaria    | Preclinical                |
| 7  | FAB 1   | MMV | GSK   | Malaria    | Discovery                  |
| 8  | Falcipains  | MMV | GSK, UCSF   | Malaria    | Lead identification        |
| 9  | Chlorproguanil<br>dapson/ Artesunate<br>(CDA)           | MMV | GSK, WHO/TDR,<br>Liverpool Uni                                  | Malaria    | Clinical (Phase II)        |
| 10 | DB-289 Malaria  | MMV | Immtech, North<br>Carolina Uni                                  | Malaria    | Clinical (Phase I –<br>II) |
| 11 | New dicationic<br>molecules                             | MMV | North Carolina<br>Uni, STI                                      | Malaria    | Lead optimisation          |
| 12 | FAS II  | MMV | Texas A&M Uni,<br>Albert Einstein<br>College of Med,<br>Jacobus | Malaria    | Lead identification        |
| 13 | Artemether-<br>lumefantrine<br>(Paediatric<br>Coartem®) | MMV | Novartis  | Malaria    | Clinical (Phase I)         |

|    |  |             |  |                |                       |
|----|--|-------------|--|----------------|-----------------------|
| 14 | Novel tetracycline                       | MMV         | Paratek  | Malaria        | Lead identification   |
| 15 | Synthetic peroxide (Oz)                  | MMV         | Ranbaxy, Nebraska Uni, Monash Uni, STI, Roche                      | Malaria        | Clinical (Phase I)    |
| 16 | Synthetic peroxide (Oz) Next Generation  | MMV         | Nebraska Uni, Monash Uni, STI                                      | Malaria        | Lead identification   |
| 17 | Pyronaridine/artesunate                  | MMV         | Uni Iowa, Shin Poong, WHO/TDR                                      | Malaria        | Clinical (Phase I)    |
| 18 | Dihydroartemisinin-piperazine (Artekin®) | MMV         | Sigma Tau, Chongqing, Holley, Holleykin Pharma, Oxford Uni         | Malaria        | Clinical(Phase I-III) |
| 19 | GAPDH                                    | MMV         | STI  | Malaria        | Discovery             |
| 20 | Manzamine A                              | MMV         | Mississippi Uni  | Malaria        | Lead optimisation     |
| 21 | 8-aminoquinolone                         | MMV         | Mississippi Uni  | Malaria        | Preclinical           |
| 22 | Pf-PFT inhibitors                        | MMV         | Washington Uni, Yale Uni   | Malaria        | Lead optimisation     |
| 23 | IV Artesunate                            | MMV         | WRAIR  | Malaria        | Preclinical           |
| 24 | Gatifloxacin                             | WHO/TDR     | Lupin, EC Consortium, Clinical, Thammasat University, TBRC (India) | Tuberculosis   | (Phase III)           |
| 25 | Eflornithine – oral                      | WHO/TDR     | MSF  | HAT*           | Clinical (Phase III)  |
| 26 | Berenil                                  | WHO/TDR     | Unknown  | HAT*           | Preclinical           |
| 27 | Posaconazole for Chagas                  | WHO/TDR     | Unknown  | Chagas disease | Preclinical           |
| 28 | Rectal artesunate                        | WHO/TDR     | Unknown  | Malaria        | Registration/Phase IV |
| 29 | Moxidectin                               | WHO/TDR     | Wyeth  | Onchocerciasis | Clinical (Phase II)   |
| 30 | Isocitrate Lyase Inhibitors              | TB Alliance | GSK  | Tuberculosis   | Lead identification   |
| 31 | Enoyl-ACP-Reductase Inhibitors           | TB Alliance | GSK  | Tuberculosis   | Lead identification   |
| 32 | Pleuromutilins                           | TB Alliance | GSK  | Tuberculosis   | Lead optimisation     |
| 33 | Focused screening                        | TB Alliance | GSK  | Tuberculosis   | Discovery             |
| 34 | Quinolones                               | TB Alliance | KRICT, Yonsei Uni  | Tuberculosis   | Lead identification   |
| 35 | Macrolides                               | TB Alliance | Illinois Uni   | Tuberculosis   | Lead identification   |
| 36 | Nitroimidazole Analogs                   | TB Alliance | Novartis, NIAID  | Tuberculosis   | Lead optimisation     |
| 37 | Nitroimidazole PA-824                    | TB Alliance | Fully subcontracted to CROs, RTI                                   | Tuberculosis   | Preclinical           |
| 38 | Carboxylates                             | TB Alliance | Wellesley College  | Tuberculosis   | Lead identification   |
| 39 | HTS on whole cell trypanosomes           | DNDi        | Harvard Uni (ICCB)   | HAT*           | Discovery             |
| 40 | Trypanothione reductase inhibitors       | DNDi        | Harvard Uni (ICCB), Dundee Uni                                     | HAT*           | Discovery             |
| 41 | Protein farnesyl-transferase inhibitors  | DNDi        | Washington Uni   | HAT*           | Discovery             |
| 42 | Paromomycin for                          | DNDi        | Leishmania East  | leishmaniasis  | Clinical (Phase III)  |

|    |   |      |   |                        |                     |
|----|---|------|---|------------------------|---------------------|
|    | VL for Africa                             |      | Africa Visceral Platform (LEAP), WHO/TDR  |                        |                     |
| 43 | Artesunate-Mefloquine FDC                 | DNDi | Far Manguinhos, Mahidol Uni, Universiti Sains (Malaysia), Oxford Uni, MSF, WHO/TDR  | Malaria                | Clinical(Phase III) |
| 44 | Artesunate-Amodiaquine FDC                | DNDi | Sanofi-Aventis, Centre Nationale de Recherche et de Formation sur le Paludisme (Burkina Faso) Tropival/Bordeaux 2 Uni (France), Universiti Sains (Malaysia), Oxford Uni, MSF, WHO/TDR | Malaria                | Clinical(Phase III) |
| 45 | New technology for artemisinin production | iOWH | Amyris Biotechnologies, UCSF Keasling lab   | Malaria                | Discovery           |
| 46 | CRA 3316/K777                             | iOWH | NIH, Celera Genomics, UCSF  | Chagas disease         | Preclinical         |
| 47 | Paromomycin for VL for India              | iOWH | WHO/TDR, IDA, Indian pharmaceutical manufacturer  | Visceral leishmaniasis | Registration        |

#### Human African Trypanosomiasis

#### Annexe 1B. Neglected disease drug R&D landscape – MNCs working alone (December 2004)

|    | MNC            | Compound                             | Indication             | Current Stage       |
|----|----------------|--------------------------------------|------------------------|---------------------|
| 1  | Sanofi-Aventis | Thiazolium                           | Malaria                | Lead optimisation   |
| 2  | Sanofi-Aventis | Choline up-take inhibitors           | Malaria                | Lead optimisation   |
| 3  | Sanofi-Aventis | Ferroquine (SSR 97193)               | Malaria                | Phase I             |
| 4  | Sanofi-Aventis | Trioxaquine                          | Malaria                | Lead optimisation   |
| 5  | Sanofi-Aventis | Intrarectal quinine                  | Malaria                | Phase III           |
| 6  | Novartis       | PDF inhibitors                       | Tuberculosis           | Lead optimisation   |
| 7  | Novartis       | NS3 helicase                         | Dengue                 | ** Discovery        |
| 8  | Novartis       | NS5 polymerase                       | Dengue**               | Discovery           |
| 9  | Novartis       | NS3 protease                         | Dengue**               | Discovery           |
| 10 | AstraZeneca    | DNA synthesis inhibitors             | Tuberculosis           | Lead identification |
| 11 | AstraZeneca    | Methyl Erythritol Pathway inhibitors | Tuberculosis           | Lead identification |
| 12 | AstraZeneca    | Unspecified development project      | Tuberculosis           | Lead optimisation   |
| 13 | Pfizer         | U 100480                             | Tuberculosis           | Preclinical?        |
| 14 | Pfizer         | Zythromicin+chloroquine              | Malaria                | Phase III           |
| 15 | J&J            | R207910 (diarylquinolone)            | Tuberculosis           | Phase I             |
| 16 | GSK            | Sitamaquine (WR6026) Oral            | Visceral Leishmaniasis | Phase III           |

\*\* There is no PPP for Dengue

**Annexe 1C. Neglected disease drug R&D landscape – MNCs partnering with PPPs (December 2004)**

|    | MNC              | Compound                                      | PPP         | Indication     | Current Stage        |
|----|------------------|---|-------------|----------------|----------------------|
| 1  | GSK              | 4 (1H) Pyridones                              | MMV         | Malaria        | Preclinical          |
| 2  | GSK              | CDA   | MMV         | Malaria        | Clinical (Phase II)  |
| 3  | GSK              | Falcipains                                    | MMV         | Malaria        | Lead identification  |
| 4  | GSK              | FAB 1   | MMV         | Malaria        | Discovery            |
| 5  | GSK              | Isoquine                                      | MMV         | Malaria        | Preclinical          |
| 6  | GSK              | Peptide deformylase-PDF                       | MMV         | Malaria        | Discovery            |
| 7  | GSK              | Pyridone back-up (GW844520)                   | MMV         | Malaria        | Lead identification  |
| 8  | GSK              | Enoyl-ACP-Reductase (inh A) Inhibitors        | TB Alliance | Tuberculosis   | Lead identification  |
| 9  | GSK              | Pleuromutilins                                | TB Alliance | Tuberculosis   | Lead optimisation    |
| 10 | GSK              | Isocitrate lyase                              | TB Alliance | Tuberculosis   | Lead identification  |
| 11 | GSK              | Focused screening                             | TB Alliance | Tuberculosis   | Discovery            |
| 12 | Novartis         | Artemether-lumefantrine (Paediatric Coartem®) | MMV         | Malaria        | Clinical (Phase I)   |
| 13 | Novartis         | Back up compounds for PA 824                  | TB Alliance | Tuberculosis   | Lead optimisation    |
| 14 | Bayer HealthCare | Artemisone                                    | MMV         | Malaria        | Clinical (Phase II)  |
| 15 | Sanofi Aventis   | Artesunate-Amodiaquine FDC                    | DNDi        | Malaria        | Clinical (Phase III) |
| 16 | Wyeth            | Moxidectin                                    | WHO/TDR     | Onchocerciasis | Clinical (Phase II)  |

**APPENDIX D. – Organisations in discussion on IFFnd and their roles**

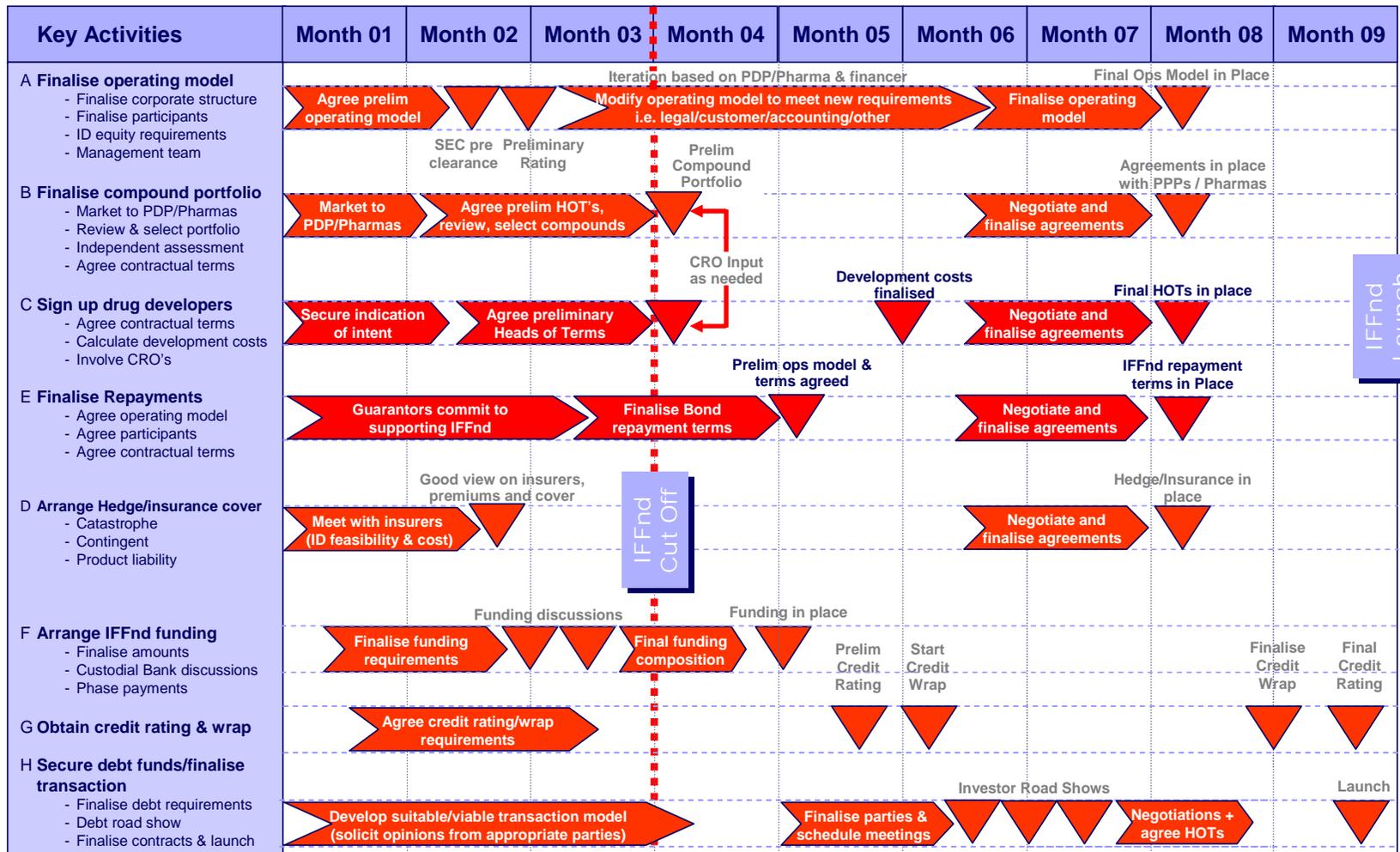
**THIS IS WORK IN PROGRESS**

| Organisations                                      | Proposals Discussed | Positive Feedback | Desire to Proceed |
|--|---------------------|-------------------|-------------------|
| Product Development PDPPP (a.)                     | YES                 | YES               | YES               |
| Established pharmaceutical organisations           | YES                 | YES               | In discussion     |
| Goldman Sachs – Formulation and Issuers for IFFIm  | YES                 | YES               | YES               |
| Linklaters – Legal advisors for IFFIm              | YES                 | YES               | YES               |
| Deloitte – Auditors to IFFIm                       | YES                 | YES               | In discussion     |
| PriceWaterhouseCoopers – Modelling, planning       | YES                 | YES               | YES               |
| Government pledges                                 | YES                 | YES               | In discussion     |
| DFID   | YES                 | In progress       |                   |
| EDCTP  | YES                 | YES               |                   |
| GAVI   | YES                 | YES               | In discussion     |
| WHO  | YES                 | In progress       |                   |
| World Bank   | YES                 | In discussion     |                   |
| Rockefeller Foundation                             | YES                 | YES               | Proposal stage    |
| Gates Foundation                                   | YES                 | In discussion     | In discussion     |
| Large Businesses Operating in developing countries | YES                 | YES               | In discussion     |
| UNDP   | Meetings planned    |                   |                   |
| UNICEF   | Meetings planned    |                   |                   |
|  |                     |                   |                   |

**Notes**

- a. Includes Medicines for Malaria Venture and WHO Tropical Disease Research and discussions are in progress with a similar leading PDPPP

## Appendix E - IFFnd : Overview of Principal Activities up to Issue of Securities



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## APPENDIX F. - Proposed new financing mechanisms for public healthcare

This review of new financing mechanisms is an extract from a report - Financing Mechanisms for Malaria that was produced for the UK All Party Parliamentary Malaria Group (APPMG) using evidence presented to the APPMG in 2006. A full copy of this report can be found at – [www.appmg-malaria.org.uk](http://www.appmg-malaria.org.uk)

### 3.11 Global initiatives to increase sustainable funding

*A major source of aid inefficiency and ineffectiveness is the lack of coherence among donors regarding objectives and requirements, and a failure to reconcile these with the needs, priorities and preferences of the countries receiving assistance. The sheer multiplicity of donors, with different outlooks, accounting systems and priorities have created a landscape of aid that, at best, can only be described as chaotic<sup>18</sup>.*

The current international aid system suffers from high transaction costs, politicisation, lack of transparency, incoherence, and unpredictability. Current requirements have stretched the administrative capacities of many recipient countries to the breaking point, undermining any pretence of local ownership of development programmes<sup>19</sup>. Additionally, while most contributions came from official development assistance (ODA) budgets of donor governments, traditional funding sources do not meet the current financial requirements.

The international community has begun turning its attention to the quality of aid. A new UN report recommends a shift to a multilateral model similar to the Marshall Plan and European Community (EC) regional funds (*see footnote 17*). Advocates, such as DFID and the Global Fund (GFATM), have proposed a number of innovative financing mechanisms to enable the reliable flow of resources necessary to ensure prevention and treatment programs are sustainable and achieve health results. Some of the more important mechanisms under debate are:

- Aid Guarantee Facility (AGF)
- International Drug Purchase Facility (IDPF/UNITAID)
- International Finance Facility (IFF)
- debt conversion (e.g. GFDC)
- Air Solidarity Levy
- Currency Transactions Tax/Stamp Duty (CTT)

#### 3.11.1 The Aid Guarantee Facility (AGF)

Unpredictability of aid (see figure 2.7) represents a major problem for recipient countries, particularly in the health sector where sustained investment is essential. The idea of an Aid Guarantee Facility has been suggested to limit the negative affects of aid fluctuations. The main aim of the AGF is to support current financing mechanisms, thus making them more

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<sup>18</sup> Spinaci, S., *WHO GMP presentation*. 2006, APPMG meeting, 6 March 2006: London.

<sup>19</sup> UNCTAD, *Doubling Aid: Making the "Big Push" work*. Economic Development in Africa. 2006, New York: United Nations.

effective. The AGF would provide developing countries with sustainable ‘bridge’ financing to continue initiatives that might otherwise fail due to delayed or halted funding.

### **3.11.2 International Drug Purchase Facility (IDPF/UNITAID)**

The French-led IDPF (or UNITAID) was launched in September 2006 at the 61st UN General Assembly. A small secretariat is hosted at WHO. Currently, five core funders (France, Norway, UK, Brazil and Chile) use the air ticket solidarity tax and long-term budget commitments to provide bulk purchasing of drugs for poor countries. This sustainable and predictable support would also serve to complement existing financing mechanisms such as the GFATM. It is envisaged that UNITAID will raise between €250-300 million in its first year, with €200 million of that coming from the French Air Solidarity Levy, and €20 million from the UK.

UNITAID aims to lower the cost of drugs for HIV/AIDS, tuberculosis and malaria, and improve the availability of these drugs. It aims to do this primarily through pooling patents and making use of the flexibilities within the TRIPS agreements to allow countries to use cheaper generic products, (see section 4.5 for more details on TRIPS and intellectual property rights) as well as through economies of scale from bulk purchasing. There has been concern that funds may be diverted from GFATM to UNITAID, which is not what is intended. France, Chile and Norway (soon to be followed by Brazil) are all dealing with this through the use of hypothecated taxes (the air solidarity levy in the case of France, Chile and Brazil, and a CO2 tax in Norway) rather than the general ODA budget. The UK’s contribution does come from the overall development budget, so can not be described as additional in the same way. It is envisaged that the hypothecated tax will mean that resources for UNITAID are more predictable and long-term than general ODA, which is important. Whilst the UK’s contribution is not hypothecated, and therefore not additional to allocated ODA, DFID have committed to funding UNITAID for 20 years, which is unprecedented for the UK’s ODA. Whilst the UNITAID board welcome the UK’s long-term commitment, it is hoped that any countries that join in the future will follow the example of France, Chile, Brazil and Norway, and hypothecate a tax to ensure additionality and increase predictability.

Large pharmaceutical companies have been nervous about UNITAID, given the mechanism’s stated aim of reducing drug prices. There may be a danger that this will affect the level of investment of the pharmaceutical industry in research and development for malaria. It is therefore important that if this is the case, additional resources and mechanisms for drug research and development need to be put in place.

If UNITAID is able to reduce drug prices and secure long term, predictable, sustainable funding, it will significantly benefit endemic countries. However, it cannot solve all the problems related to ensuring drugs reach those who need them most. Where additional drugs and LLINs have been made available without additional logistic support, national health systems have often been unable to cope. Health system capacity must be strengthened to absorb the additional resources. This includes addressing problems with forecasting, supply chain management, and lack of human resources, which continue to cause drug stock-outs or shelves full of expired materials.

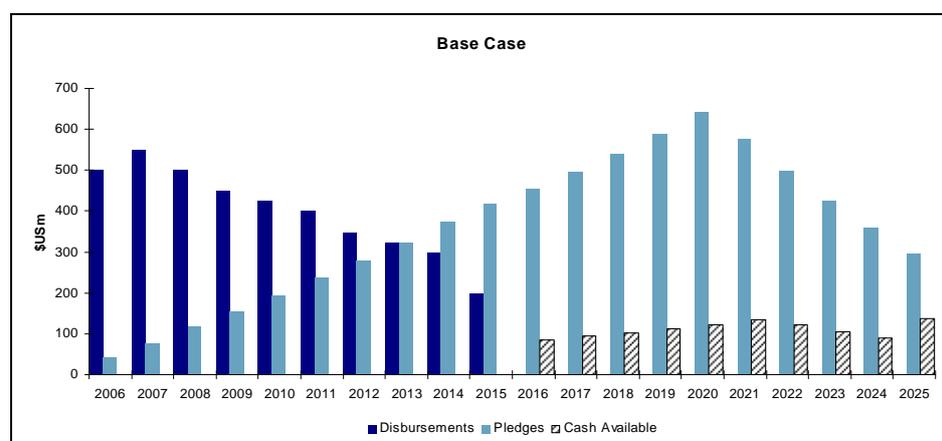
### **3.11.3 The International Finance Facility (IFF) (including IFFim)**

The IFF, as proposed by Britain and supported by France, Spain, Norway, Sweden and Italy, is a large-scale mechanism to raise up to US\$50 billion of additional annual funding necessary to achieve the Millennium Development Goals (MDGs). It would enable aid to

be 'frontloaded' by pledging future ODA expenditures to the IFF as security, against which it can issue AAA-rated bonds and thus raise cash from international capital markets. Advocates hope the IFF will allow greater predictability and play a role in anticipating disbursements of resources needed for achieving the MDGs.

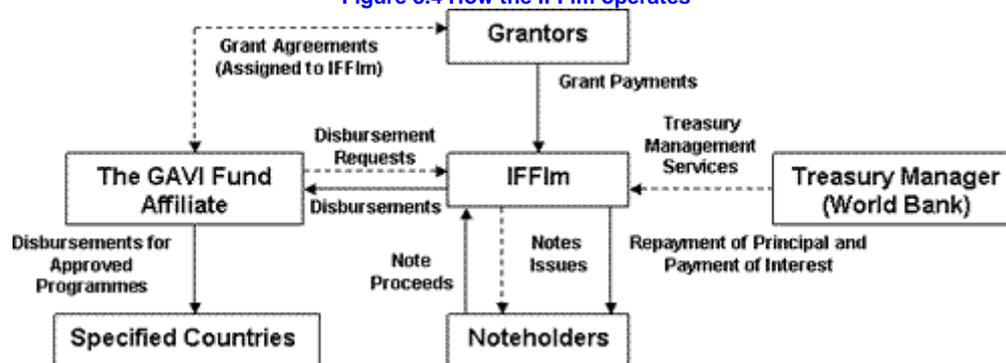
The IFF for Immunisation (IFFim), a pilot of the IFF mechanism to finance vaccinations in developing countries, was launched in November 2006. IFFim will disburse funds through the existing GAVI Alliance. Figure 3.2 shows potential pledges and disbursements, while figure 3.3 shows how it will function. Money raised from IFFim will be used to support new vaccines, strengthen immunisation services, fund measles and tetanus campaigns, and fund a polio vaccine stockpile. While these activities will not directly impact malaria, as there is currently no malaria vaccine, there may be potential for strengthened immunisation services to deliver interventions such as IPT and ITNs.

Figure 3.3 Potential IFFim donor pledges and disbursements<sup>20</sup>



Source: *IFF for Immunisation*, presented at the APPMG, 17 Oct 2006

Figure 3.4 How the IFFim operates



Source: [http://www.iff-immunisation.org/02\\_financial\\_background.html](http://www.iff-immunisation.org/02_financial_background.html)

### 3.11.4 Debt Conversion

Debt Conversion is a proposed arrangement whereby specific creditors forego future debt repayments in exchange for the debtor country converting an agreed value of the debt write-off into local currency for investment towards reaching the Millennium Development Goals (MDGs). As this would be executed directly between creditor and debtor, with Fund

<sup>20</sup> Illustrates a \$4 billion disbursement ahead of 2015. Assuming that there are no IMF defaults, the sum of additional funds released over and above the initial planned disbursement of \$4bn would be \$1.1bn. Debt will peak at \$3.03 billion in 2014

facilitation, it would not require GFATM to purchase any debt, incur significant transaction costs or alter its bylaws<sup>21</sup>.

A significant challenge in moving from concept to practice is including export credit (ECA) debt, the largest potential source of convertible funds as it has higher interest rates, in addition to ODA debt.

### **3.11.5 Air Ticket Solidarity Levy**

France has initiated a tax (solidarity contribution) on airline tickets, to finance the international drug purchase facility (IDPF/UNITAID). Seventeen other countries are considering similar steps. The solidarity levy is expected to generate over €200 million in the first year, which will be used to support UNITAID (see section 3.2.6.2). As a hypothecated tax, these funds will be additional to traditional ODA financing.

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<sup>21</sup> GFATM, *Financing the Fight Against AIDS, Tuberculosis and Malaria: Global Fund Debt Conversion (GFDC)*, in *Innovative Financing Instruments, Paper No 2*. 2005: Geneva.

## **G. Creating a self-sustaining pipeline of essential new medicines**

### **Introduction**

IFFnd replenishment requests will be supported by reportage on the progress to achieve self-sustaining funding of the pipeline of essential new medicines. Progress to meeting this goal will be incremental, managed by the GAND executive and incorporated in a rolling five year business plan. Formal support is being invited from businesses that have successfully managed pipelines spanning development to utilisation. This will include established pharmaceutical organisations and the extractive industries, especially oil and gas that also have expertise operating in developing countries.

Self sustainability for the management of any pipeline occurs when a proportion of revenues from product distribution are able to fund development of further product. For the public healthcare medicines pipeline there are two principal sources of funding that over time can help swell the current donor funding and both depend on economic growth in the middle income and developing countries:

#### **A. Pledges from middle income and developing countries:**

1. Middle income country pledges together with those of developed countries would be securitised to support the IFFnd bond issue. IFFIm has secured pledges from middle income countries and as economies grow and the benefits of IFF are substantiated the GAND executive, collaborating with GAVI would target securing a higher proportion of middle income guarantees over successive bond issues.
2. Pledges from developing countries that are the beneficiaries of IFFnd funding to make co-payments to clinical development and distribution programs. Pledges of payments would apply once the benefits had been delivered. When a pool of sovereign pledges had been secured the GAND executive and advisors would review the practicalities and benefits of securitizing these pledges to bring money forward. This would build on the securitisation processes underpinning IFFIm Alternatively when the pledges become due and are paid they could be placed in a revolving trust fund and aid self-sufficiency of funding for the medicines pipeline.
3. The countries that would be approach to make pledges would be those whose economies were demonstrably growing independent of donor government support.

#### **B. Licensing agreements with pharmaceutical organizations in developed middle income and developing countries<sup>22</sup>:**

1. In a first IFFnd bond issue the PDPPP whose medicines will be funded through clinical development will inevitably have entered into licensing agreements with established pharmaceutical organisations. Frequently some of the patents attached to the medicines will be owned by one or more pharmaceutical or research organizations and the licensing agreement will define how the costs and risks of development are shared and revenue from commercial distribution, if any is shared. IFFnd will recognise these agreements and if the PDPPP have rights to a proportion of commercial revenues, and are not for-profit organisations, then donors supporting IFFnd

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<sup>22</sup> Further information on licensing arrangements can be found in: Valuing Industry Contributions to Public-Private Partnerships for Health Product Development - Hannah Kettler, Karen White, Scott Jordan, [http://www.globalforumhealth.org/filesupld/ippph\\_cd/01.PDF](http://www.globalforumhealth.org/filesupld/ippph_cd/01.PDF)

can be assured these revenues will expand their core funding and be reinvested in clinical development programs.

2. In future IFFnd bond issues it is anticipated that medicines accepted for development and meeting strict public health selection criteria will nevertheless, and increasingly, have some commercial prospects. This could apply to pharmaceutical organizations operating in middle income countries that have a lower cost base and allowing them to secure niche revenue from developed and specific segments of markets in middle income and developing countries. Pharmaceutical organizations in developed countries may also have projects that do not meet their internal funding criteria but would meet the IFFnd public health selection criteria. Assuming medicines from these sources are acceptable for IFFnd funding then:
  - the patent owners may have the technical resources to develop the medicines or
  - may wish to enter licensing arrangements with PDPPP or other pharmaceutical organizations

In either instance appropriate licensing arrangement will be made to secure a proportion of any commercial revenues to amplify public funds an outline is set out below.

### **Licensing Arrangements for medicines with commercial prospects**

IFFnd has been specifically structured to appear to established pharmaceutical organisations as a licensing arrangement and admit their participation with provisions for co-payments and success fees. Organisations that agree to make co-payments:

- reduce the risks of adverse selection of medicines they are proposing for IFFnd funding
- allow development risk to be shared with donors
- reduce the cost of development for public sector donors
- expand the number of projects that can be admitted to the IFFnd funded pipeline.

Payment of a success fee, triggered if there is regulatory approval for a medicine and:

- captures a pre-defined slice of the commercial success
- expands donor funding

The licensing arrangements with pharmaceutical organizations will set caps on pricing in specific markets with provisions to share revenue in defined markets and there are precedents to support these arrangements. The licensing provisions will be designed to ensure affordability of approved medicines in developing countries assisted by differential pricing. Net proceeds from each licensing arrangement will be placed in a revolving trust fund whose proceeds will amplify IFFnd funds for future clinical development and distribution programs.

The GAND executive will be mandated to expand public donor funds with private sector inputs their motivation being that future replenishment rounds will be appraised on achieving predefined, objective goals. This motivation will be channeled into promoting IFFnd to PDPPP, pharmaceutical and research organizations to secure new medicines for development conditional on:

- there is a quantifiable demand and absorption capacity
- 'total' distribution channels will be open at the time of introduction
- the medicines meet public health acceptance criteria

If at some future time in the portfolio IFFnd when there are a pool of medicines with license agreements to secure commercial revenues by means of success fees then it could be possible to securitise the pooled success fees and bring money forward for development. Work has been undertaken on a model that can predict the probable outcome of successful projects resulting from a pooled approach together with the aggregate costs of developing the pool and:

- the accounting provisions to allow pharmaceutical organizations to participate in this type of pooled funding arrangement have been reviewed with generous input from PwC and Deloitte
- a large established pharmaceutical organisation has undertaken an independent verification of the accounting position
- rating agencies have reported favorably on the proposed securitisation model
- the proposed securitisation of success fee payments builds on established licensing provisions
- Indicative term sheets have been prepared

Undertaking a securitisation of the success fee pledges would bring money forward but would be implemented only if the IRR was several multiples of the finance costs.

### **Self sustaining medicine development**

The developing country pledges together with commercial licensing provisions set out in sections, A. and B. of Appendix G. above, can set the foundations for self sustaining development of essential medicines. Economies in developing countries are growing and world wide there is an insatiable demand for good health. These two fundamentals can drive progress to enable IFFnd working with other public and private sector organisations to:

- progressively catalyse the funding of a self sustaining pipeline of essential new medicines
- Ensure consistent and efficient allocation of capital to each stage of the development and distribution in the pipeline conditional on predefined operational and developmental criteria being met
- prepare for a time a decade or more away when the preponderance of new essential medicines will be predominantly sourced from the private sector

### **Attracting a new classes of investors**

The proposals for co-payments and success fees are designed to attract new investors for the development of essential medicines:

#### **Co-payments**

IFFnd will publish terms of acceptance for medicines with an offer to fund clinical development at specific stages for medicines that meet these criteria. This is designed to attract new sources of equity investment into preclinical stages of medicine development and secure public health and commercial benefits for public and private investors.

#### **Success Fees**

The proposals for securitising pooled success fees will be formulated to offer sophisticated institutional investors in global markets early exposure to the healthcare sector in the emerging markets. Various tranches of rated bonds can be formulated to attract investors guided by the syndication section in the lead issuing bank and would be issued alongside the highly rated bonds similar to those that were formulated for IFFIm. Building a base of informed investors can accelerate the path to self sufficiency.

## **APPENDIX H. - Proposed structure for GAND**

### **Initial Proposals for the Governance and Management structures of the Global Alliance for Neglected Diseases (GAND)**

**FOR DISCUSSION – This material was prepared with informal input from GAVI that has been greatly appreciated**

July 2007

#### **Alliance Objectives**

The proposed Alliance is not primarily a forum for advocacy. Its main purpose is to use innovative methods to secure, then manage, large scale, long term, funding for member programs that would not be easily accessible to its individual members. The funding secured by the Alliance will augment, and not replace, the members' existing funding from donors or other sources.

All Alliance members, public and private, will have an active professional involvement in the development and distribution of public healthcare programs. Their collective current programs address the needs of communities that are neglected by commercial markets, in whole or part, and in addition where there is inadequate donor funding.

Collectively the Alliance members will be involved in development and distribution of programs that will include, and in no particular order, malaria, TB, specific formulations for AIDS, parasitic diseases, microbicides, diagnostics and diarrhoea. All these conditions are treatable by medicines or vaccines and collectively they cause high morbidity and mortality and inhibit economic growth.

The Alliance members will retain their autonomy that brings an ability to innovate within their programmes but the Alliance offers an opportunity for shared learning and societal benefits from the integration of balanced healthcare programs from the development of essential new medicines through to their utilisation. It is at the point of patient utilisation that the benefits of the innovative funding can be measured and the benefits of linking the large scale supply logistics can be demonstrated to agencies, donors and governments.

Working with its members and partners the Alliance will oversee long-term projects and disburse large scale funding with each initiative being partnered by existing public and private organisations and institutions, in developed and developing countries, and using tested business models. The Alliance programs will incrementally help developing economies to become self sufficient in the provision of healthcare and it is envisaged that the Alliance will have a life of some 30 years.

The primary focus of the Alliance will be on the development and distribution of medicines, microbicides and diagnostics and its activities can extend to the development of vaccines in a partnership with the GAVI Alliance.

The GAVI Alliance has benefited from IFFIm funding and has instituted governance and management structures that in part are a blueprint for GAND. It is the purpose of this draft document to suggest a simplified management structure for GAND. This has been guided by informal help from the GAVI Alliance and it is based on structures routinely used to support legally based, highly rated, securitised funding transactions.

## Overview of proposed GAND Governance and Management Structures

GAND needs a separation of interests between its Board that will oversee programmes for the development and distribution of medicines and the Trustees that will give independent oversight to the management and disbursement of funds raised by successive bond issues. This is a standard structure for securitisation arrangements and this division of responsibilities is reflected in the suggested and simplified structure below.

GAND will comprise a (A.) central administration responsible for GAND programmes and (B.) a subsidiary administration responsible for GAND finances that will support (c.) an independent legal charitable entity, IFFnd that will manage the interest of bondholders:

- A. The **GAND Board**, incorporated and domiciled in Geneva – will provide administrative support to the independent committees that will accept clinical development and distribution programmes. Working with its professional accounting and actuarial advisors the board will establish GAND's long term funding needs and collaborating with partners including GFATM and World Bank the Board will initiate fund replenishment rounds to secure sovereign and other highly rated guarantees that can form the basis of a securitisation issue. The outcomes of the replenishment rounds will be communicated to:
- B. The **GAND Fund Board**, incorporated in the UK and domiciled in London – The GAND Fund Board will be a subsidiary of the GAND Board and will provide administrative support to a special purpose legal entity IFFnd and its Trustees. Working with the GAND Fund Board the IFFnd Trustees and their professional advisors will arrange for the structuring and issue of bonds, make available stage funding for approved programmes for disbursement by the GAND Board and supply statutory reports to bondholders and agreed reportage to the bond guarantors. The GAND Fund board will make provisions with custodial institutions such as the World Bank for the secure custody of funds raised by successive bond issues.

Rating agencies will not support bond issues if the bondholders interests are not protected by an independent, dedicated legal entity that will assure repayment of interest and capital to bondholders. Accordingly the GAND Fund Board will set up:

- c. A special purpose independent entity, IFFnd whose Trustees will manage bondholder interests ensuring they receive agreed reportage, interest and eventually capital repayments. They will also ensure that the bond proceeds are disbursed for the purposes, and using the procedures, agreed with the sovereign guarantors.

GAND will employ minimal staff and simplify its structure and reduce meetings by partnering with its members, leading PDPPPs and Pharmaceutical organisations, also The Global Fund, WHO, World Bank, large donor organisations, private organisations and others. GAND will enter strategic outsourcing agreements when it cannot obtain essential services from its members and partners. It may be possible to share some administrative functions with the GAVI Alliance and these have been noted in this document as a basis for eventual discussion with GAVI. An overview of the proposed GAND Governance structure is set out below.

### A. The GAND Board

GAND will be an incorporated public-private partnership and is being prepared to be instituted in 2008. It is intended that it will comprise partners, such as the Global Fund, UNICEF, WHO, OECD, the Rockefeller and Gates Foundations, the World Bank, developing country governments, donor country governments, the pharmaceutical industry, civil society groups, and research and technical health institutes. The **GAND Boards Secretariat**, see Figure 2 will comprise a small

administration will be based in Geneva and coordinate GAND activities including policy development and support to countries working with the GAND partners.

It is intended that GAND will be registered in the Geneva Register of Commerce and the Board's professional advisers will be contracted to ensure that GAND and its UK subsidiary, **The GAND Fund**, comply with Swiss law. A Geneva based host organisation will be sought for the **GAND Board's secretariat**.

**The GAND Board** will lead policy development and implementation, and will monitor and oversee all programme areas. The Board will have renewable members invited from organisations such as: The Global Fund, GAVI, WHO, the Rockefeller and Gates Foundations and the World Bank. In addition, there will be a number of rotating seats for:

- developing country governments (potentially four)
- donor country governments (potentially four)
- research & technical health institutes (potentially one)
- industrialised country pharmaceutical industry (potentially one)
- developing country pharmaceutical industry (potentially one)
- civil society groups (potentially one)

In all, potentially twelve seats and the Board will meet in principle once per year with additional board and video conference meetings convened as needed.

A core group of members on the GAND Board will form its **Executive Committee**, this will meet more frequently to ensure that key issues are properly reviewed prior to Board discussion. The Executive Committee will also be given a mandate to make critical, time-sensitive decisions that allow GAND to function between Board meetings. In the formation stages of GAND the Executive Committee will guide GAND's incorporation before handing over executive control to the GAND board and novate any agreements. Once it is formed the GAND Board will guide the incorporation of its subsidiary, the **GAND Fund Board**.

GAND will rely upon **Working Groups** for objective policy advice and the formation of these Groups will be agreed with, and led by, its members. The Working Groups will be responsible for the development and implementation of GAND's work plans, and ensuring close coordination of partner activities. The Working Group will comprise technical experts from GAND partner institutions who serve in their individual, not institutional capacity. The Working Group will meet up to six times per year, and at times with bi-weekly teleconferences. The Working Group will be chaired by the GAND Executive Secretary. Where feasible there will be a preference for the terms of reference of GAND members' existing Work Groups to be extended to include issues relating to GAND.

GAND will need **Independent Review Committee (IRC)** teams of experts to ensure that all clinical development programmes are reviewed objectively and transparently and these will be provided by member organisations. The IRC will be sub-divided into standing teams for ongoing programmes, time-limited teams recruited for specific project proposals and hosted by member organisations. The New Proposals Team will review applications for new support from eligible PDPPP and Pharmaceutical organisations to fund clinical trials and distribution programs for medicines, diagnostics and microbicides. They will do this in consultation with country members and other organisations including The Global Fund, WHO, GNNTDC to ensure there is a need and, ultimately, that absorptive capacity can be built. The monitoring teams will evaluate progress and achievements, and provide recommendations on continued support.

It is envisaged that GAND will rely upon **Regional Working Groups** to be hosted by Partner Organisations such as the Global Fund and WHO, to ensure that GAND's clinical development

programs are aligned with country needs. It is the partner organisations that will be ultimately responsible for generating distribution programmes for approved medicines, diagnostics and microbicides that emerge from GAND's clinical development programmes. Regional working groups will serve as focal points for consensus building, and advocacy, as well as a bridge for information flow between country and global levels. They will also provide essential technical support for clinical development and medicine distribution programme planning and implementation. The functions of regional working groups are crucial as GAND will have no staff presence in countries. The Regional Working Groups follow the practice established by GAVI with the potential to merge GAND and GAVI interests and avoid duplication and this might be reinforced by discussion with The Global Fund.

It is envisaged that GAND will rely upon **Time-limited task teams and groups** whose mandates will be linked to specific tasks. These might include:

- A **Roles and Responsibilities Task Team**, established to better define roles and responsibilities of partners in GAND, in the context of the five-year strategic plan;
- A **Civil Society Task Team**, formed to develop strategies for the enhanced engagement of civil society groups in GAND;

Task Teams to review issues specific to clinical development and supply logistics could bring member benefits especially with input from large private industrial partners with experience of operating in developing countries. It is intended that Task Teams will be sponsored and hosted by GAND member organisation and address issues of specific interest to GAND some of which may involve the wider public health community.

## **B. The GAND Fund Board and IFFnd Board**

The GAND Fund Board will be established as a UK incorporated, London domiciled subsidiary of the GAND Board. It will be tasked with fiduciary responsibilities including asset management and investment, financial control, auditing and accounting. The Fund Board will provide administrative support for the IFFnd trustees with whom it will liaise within defined channels of communication that will respect the essential fiduciary independence of the IFFnd Trustees. A number of the function of the GAND Fund Board might be formally shared with GAVI. There may also be benefits from sharing programs distribution with GAVI to provide balanced healthcare programs in partnership with The Global Fund.

The GAND Fund Board will:

- enter into pledge agreements with IFFnd donors and assign these pledges to the IFFnd Board of Trustees to raise bonds the proceeds of which will fund development and distribution programme. The Global Fund will be a lead partner in securing pledge agreements with IFFnd donors and a beneficiary from GAND's programme management.
- be comprised of experts in global health, investment, auditing and accounting and will review and approve programme funding requests, and make subsequent requests for release of funding to the IFFnd Board. The Board's professional advisers will be contracted to ensure that the GAND Fund complies with UK law and maintains its charitable status.
- shape the financial strategy to support implementation of GAND's Strategic Plan. In this capacity, the Fund Board will monitor GAND income received from multiple sources; validate budgets, certify availability of funding, and determines funding sources for programmes. In addition, the Board will monitor investments and asset liabilities to ensure financing is available as needed.

The GAND Fund Board will rely on four committees to better support its role as fiduciary:

- i The **Fund Executive Committee** will function between Board meetings acting with the full powers of the Board, with the exception of duties including appointment of new

Board & committee members, the CEO and officers. However, the full Board will reserve the right to ratify or nullify decisions of the Executive Committee in order to ensure that all directors have the opportunity to fulfil their Duty of Care. The Executive Committee will also act as the Nominating Committee.

- ii The **Fund Audit / Finance Committee** will assist the Board to fulfil its responsibilities in the areas of financing, corporate accounting, reporting practices of the GAND Fund, and the quality and integrity of the financial reports of the GAND Fund.*
- iii The **Fund Investment Committee** will oversee investment management in line with GAND's operating needs and overall programme goals. The committee will develop strategies for asset preservation and growth within the Fund's investment portfolio.*
- iv The **Fund Development Committee** will be tasked with the development of strategies for both public and private fundraising, in order to support GAND's programmes.*

For the Audit, Investment and Development Committees arrangements will be explored to outsource or share some administrative functions with GAVI.

### **International Finance Facility for Neglected Diseases (IFFnd) Board**

The GAND Fund Board will be responsible for setting up IFFnd as an independent, bankruptcy remote, special-purpose, charitable entity. It is envisaged that the IFFnd will be established as a charity with the Charity Commission for England and Wales and domiciled in London. The IFFnd Board will be composed of experienced independent Trustees with expertise in the areas of finance, investment, international law and global health and development.

The Trustees powers will be narrowly focused and limited to managing the bondholder interests, working with their professional advisers and supported by the GAND Fund administration. The IFFnd Board will oversee each bond issuance and develop funding, liquidity and other operating strategies to safeguard and maximise the value of IFFnd proceeds. The Board will also review and approve requests from the GAND Fund Board for IFFnd funds to be used for GAND programmes.

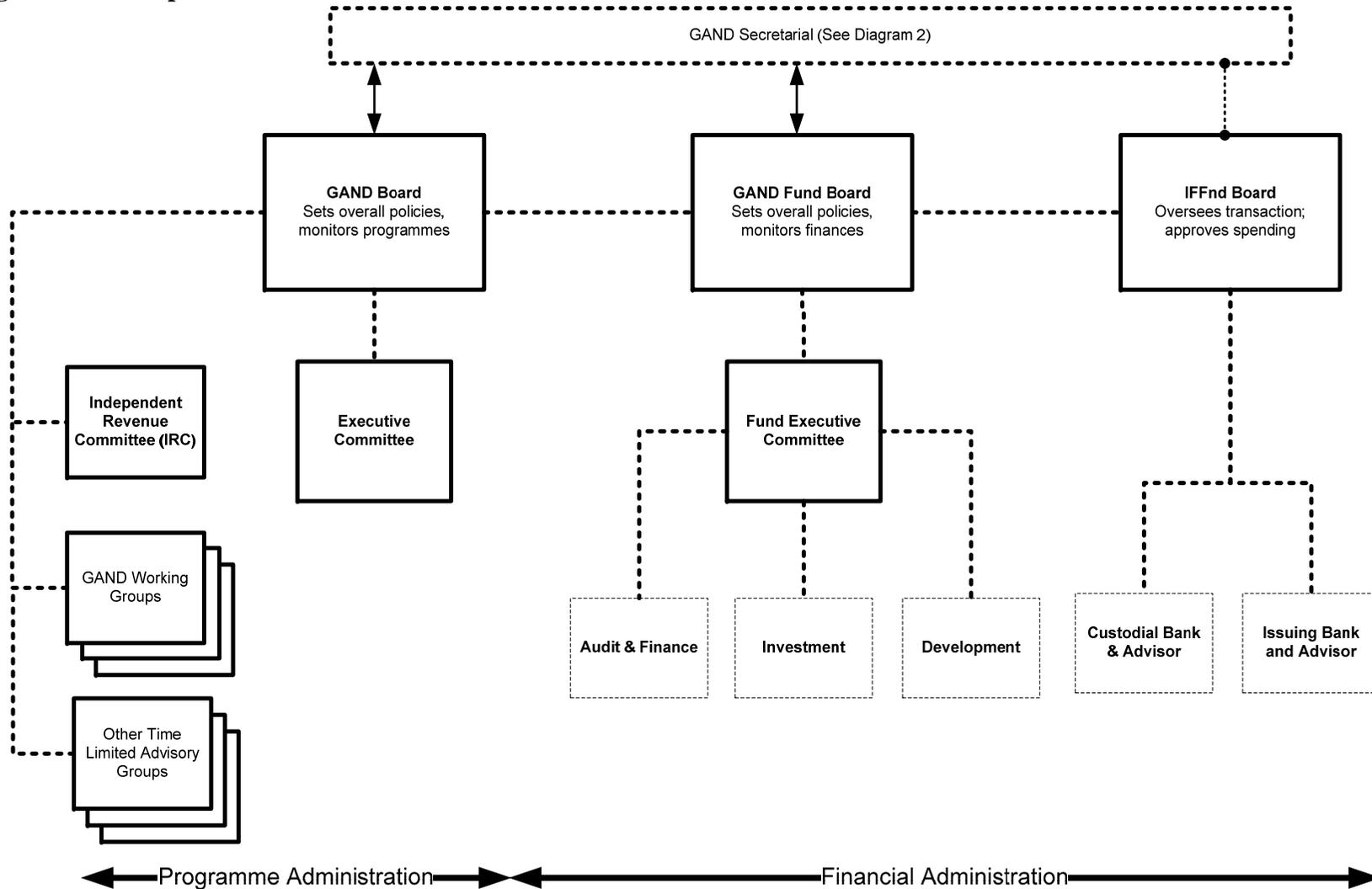
Administratively the Trustees will ensure the bondholders receive agreed reportage and their fiduciary duties will be to sanction payments of interest, less frequently capital repayments. The Trustees will be responsible for overseeing statutory reportage also ensuring that the bond proceeds are disbursed for the predefined and legally agreed purposes, and using the procedures, agreed with the sovereign guarantors. Working with the GAND Fund board and its advisors the Trustees will appoint:

- i a custodial bank who in addition to custody will provide professional services including funding, liquidity and operating strategies to maximise the proceeds of successive bond issues.
- ii an investment bank that will mandate accounting and legal advisors and provide professional services to formulate and issue tranching securities, predominantly AAA but also structured to appeal to a wide and global investment community. These securities will be backed by sovereign and other highly rated guarantees.

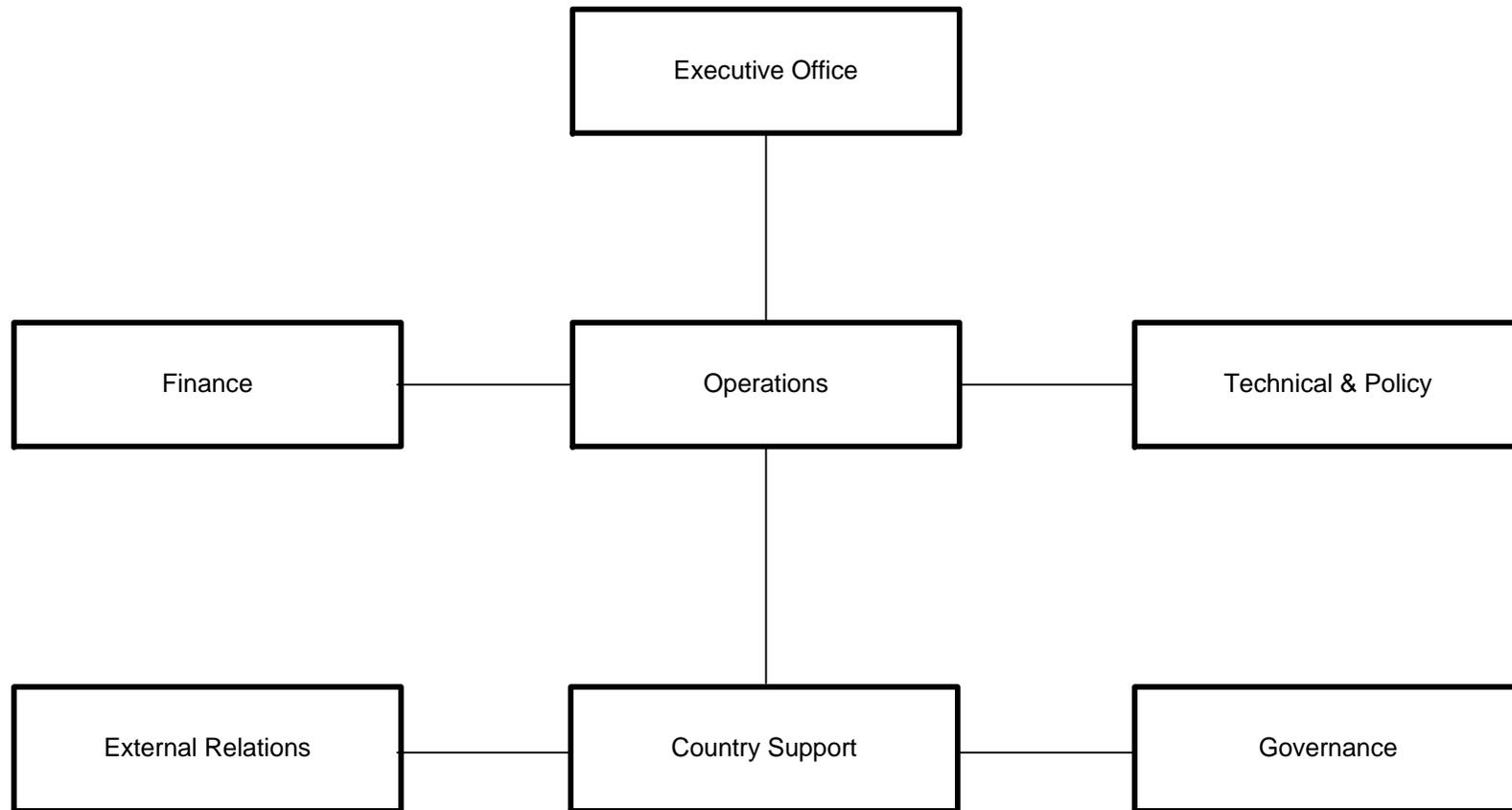
Essentially IFFnd will be constituted to follow established practices for special purpose entities associated with a securitisation transaction. The policy of strategic contracting of services from established professional organisations will ensure access to current practice in the securitisation and capital markets.

Figure 1 shows the proposed Governance structure for GAND and Figure 2 the organisation chart for the proposed GAND Secretariat.

**Figure 1 The Proposed GAND Governance Structure – For Discussion**



**Figure 2 Organisation Chart for the Proposed GAND Secretariat**



## APPENDIX I - Millennium Development Goals (MDG)

See the following link to the UN web site for a full description of the eight MDG:

<http://www.undp.org/mdg/goal1.shtml>

### OVERVIEW

The Millennium Development Goals (MDGs) are eight goals to be achieved by 2015 that respond to the world's main development challenges. The MDGs are drawn from the actions and targets contained in the **Millennium Declaration** that was adopted by 189 nations-and signed by 147 heads of state and governments during the **UN Millennium Summit** in September 2000.

The 8 MDGs break down into **18 quantifiable targets** that are measured by **48 indicators**. [Click here for a full list of Goals, Targets and Indicators](#)

Goal 1: Eradicate extreme poverty and hunger

Goal 2: Achieve universal primary education

Goal 3: Promote gender equality and empower women

Goal 4: Reduce child mortality

Goal 5: Improve maternal health

Goal 6: Combat HIV/AIDS, malaria and other diseases

Goal 7: Ensure environmental sustainability

Goal 8: Develop a Global Partnership for Development

### The MDGs:

Synthesise, in a single package, many of the most important commitments made separately at the international conferences and summits of the 1990s;

- recognise explicitly the interdependence between growth, poverty reduction and sustainable development;
- acknowledge that development rests on the foundations of democratic governance, the rule of law, respect for human rights and peace and security;
- are based on time-bound and measurable targets accompanied by indicators for monitoring progress; and
- bring together, in the eighth Goal, the responsibilities of developing countries with those of developed countries, founded on a global partnership endorsed at the International Conference on Financing for Development in Monterrey, Mexico in March 2002, and again at the Johannesburg World Summit on Sustainable Development in August 2002.