

**SUBMISSION OF THIRD WORLD NETWORK**  
**Second Web-based Public Hearing**  
**The Expert Working Group on R&D Financing**

**I. Comment on High-Level Criteria**

1. The criteria presented are extremely brief and lacking in details that it is extremely difficult to provide a thorough comment on it. In any case the following criteria should be added:

(a) Ensures transparency with regard to R&D funding provided, the cost of R&D as well as management of conflict of interests.

(b) Ensure sufficient and meaningful representation and participation of public and private institutions and researchers from developing countries including providing developing countries (governments and civil society) an equal voice in decision-making processes.

(c) Strengthen and build research and local production capacity of developing countries, including ensure effective mechanisms/measures to promote transfer of technology to developing countries.

(d) Ensure that R&D efforts are focused on the development of products that are adapted to the needs of developing countries, and the needs of patients of all ages, simple (in terms of using, prescription and storage), accessible (in terms of availability & affordability) and of quality.

(e) Ensure that prices of products/technologies produced are fixed with the aim of achieving equitable access to products/technologies to all that need those products/technologies in developing countries including middle income countries.

(f) Ensure that outcomes and data generated from the R&D are not monopolised but are shared in the public domain, widely disseminated for other researchers to engage in additional or follow-on health research.

(g) Ensure that products/technologies emerging from R&D will be licensed to promote generic competition with the aim of increasing supply and reducing the price of the products/technologies. In short R&D outcomes will be managed on the basis of non-discriminatory and open licensing terms.

(h) De-links the cost of R&D from the price of the health products.

(i) Is not limited to Type 3 diseases but also addresses R&D gaps in Type 1 and 2 diseases.

(j) Promotes access to knowledge and technology relevant to meet public health needs of developing countries.

(k) Promotes a range of incentive mechanisms for R&D provided such mechanisms are based on principles in Part III.2 D below.

(l) Promotes access to compound libraries.

2. Criteria for assessing financing mechanisms should be dealt with separately from criteria for assessing incentive mechanisms.

3. Taking into account the origins of the EWG, it would seem fair to conclude that developing a comprehensive framework that delivers for the health needs of developing countries is now in the hands of the EWG and thus it should consider a more coherent and comprehensive approach to R&D.

**II. A Coherent Global Approach to R&D**

A fundamental problem thus far has been that public health needs of developing countries continue, “to rely on inadequate and insufficient ad hoc initiatives”<sup>1</sup>.

It is obvious that there is an urgent need for mechanisms for coordination, prioritization of R&D and ensuring adequate financing for R&D as well as for models that *inter alia* de-links the cost of R&D from the prices of the product; ensures availability of treatments that are suitable for developing country conditions and that are affordable; promotes generic competition as well as strengthens and builds R&D and production capacity of developing countries.

**For this to happen a systematic global approach to R&D is urgently required. Below such an approach is presented for consideration of the EWG with the following parts:**

Part I: Introduction

Part II: Key Issues Relating to R&D in Diseases of Developing Countries

Part III: Key Elements of a Global Framework for R&D

III.1: Sustainable Financing

III.2: R&D Architecture

- Needs Assessment & Priority Setting
- Funding R&D & Determining Appropriate Model including incentives for Research and Development
- Intellectual Property
- Guiding Principles for financing R&D
- Coordination, Monitoring & Evaluation
- Institutional Setup
- Medical R&D Treaty/Norms

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<sup>1</sup> Oxfam (2008), “Ending the R&D Crisis in Public Health: Promoting pro-poor medical innovation” p. 28

# GLOBAL FRAMEWORK FOR RESEARCH & DEVELOPMENT

## Submission of Third World Network

### I. INTRODUCTION

It is widely acknowledged that there is a serious crisis with regard to R&D in diseases of developing countries as well as access to appropriate and affordable treatments for people of the developing world. Since 2003 WHO has been attempting to grapple with this crisis and to find a solution.

The Report of the Commission on Intellectual Property, Innovation and Public Health (hereinafter known as the “CIPIH Report”) that was set up following the World Health Assembly of 2003 set the stage for further discussion and action on the part of the governments to resolve the R&D crisis.

It is important to note that the Report conceptualizes the cycle of innovation as “discovery”, “development” and “delivery”. This is a strong signal that issues of access must not be seen separately from issues of innovation. This is particularly important as the present system of innovation is based on an incentive system (i.e. the patent system) that depends on high prices to recoup investments, which then often results in the very innovative treatments being unaffordable to patients that need them the most. Thus any model for R&D must also consider the issue of “access” i.e. how to make available appropriate and affordable treatments to developing countries.

In 2006, an Intergovernmental Working Group (known as “IGWG”) was established to build on the recommendations of the CIPIH report. The World Health Assembly Resolution 59.24 tasked the IGWG “to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission; such strategy and plan of action would aim, inter alia, at securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area”. After 2 years of often-tense negotiation, the 2008 WHA adopted the Global Strategy and a Plan of Action (GSPOA) through WHA 61.21.

While the GSPOA has far reaching and important elements pertaining the R&D, the reform of financing and framework for R&D in diseases of developing countries is in the hands of the Expert Working Group (EWG) that was established pursuant to the Resolution 61.21.

The EWG is mandated “to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of funding to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases”. Thus the mandate of the EWG requires it to recommend new and innovative sources of funding to stimulate R&D, as well as the architecture and principles that would govern coordination of R&D and the use of the financing. The scope of diseases is not limited to Type III diseases but importantly also includes Type I and II diseases.

Following the basic introduction above this note attempts in Part II to capture some of the key issues pertaining to the R&D crisis and access made particularly in the CIPIH report.

This note also identifies key elements that should be considered by the Expert Working Group as it moves forward with its mandate.

### II. KEY ISSUES RELATING TO R&D IN DISEASES OF DEVELOPING COUNTRIES

*On Research and Development, the following has been noted:*

- The burden of infectious diseases that disproportionately affects developing countries continues to

increase. In contrast to developed countries, developing countries are increasingly suffering from the *double* burden of disease (See CIPIH p. 15). Despite rapid increase in technological and economic potential globally, innovation of medical products that are appropriate to the circumstances of developing countries has not taken place and there is a decline in the capacity of the pharmaceutical industry to innovate (See note of Prof. Carlos Correa, p. 224)

- Too few R&D resources are directed to the health needs of developing countries. In the private sector, companies do not have the incentive to devote adequate resources to develop products specifically adapted to the needs of developing countries, because profitability is mainly to be found in rich country markets. The great majority of health research funded by the public sector takes place in developed countries, and its priorities principally reflect their own disease burden, resource position and social and economic circumstances. (CIPIH p.194). Only 10% of worldwide expenditure on health research and development is devoted to the problems that primarily affect the 90 % of the world's population. (Global Forum for Health Research)
- Three diseases – HIV/AIDS, TB and malaria – received close to 80% of overall R&D funding spent on neglected diseases in 2007. The remaining neglected diseases and disease categories surveyed received less than 5% of global funding including diarrhea illness (4.4%); the helminth infections (2.0%), bacterial pneumonia and meningitis (1.3%). 5 diseases – leprosy, buruli ulcer, trachoma, rheumatic fever and typhoid and paratyphoid fever – received less than \$10 million or 0.4% of total global investment each. In many disease areas, funding was well below what is feasibly needed to create even one new product. (See G-Finder<sup>2</sup> 2008, p. 5, 48)
- There was a marked tendency among public and philanthropic funders to focus on drug and vaccine R&D. Diagnostics were largely neglected and platform technologies even more so. Global investment into vaccine adjuvants, diagnostic platform and new delivery devices was only 0.4% of total funding; well below the levels needed for success. (G-Finder 2008, p. 48).
- There are also few or no available mechanisms at present to advise on appropriate priorities for resource allocation between R&D on different diseases, the balance between resources needed for R&D and delivery for each disease or the means to monitor and evaluate the impact of resources devoted to treatment and delivery. (CIPIH p. 206)
- Patents are not a relevant factor or effective in stimulating R&D and bringing new products to market needed to address the diseases prevailing in developing countries (CIPIH, p. 34).
- In fact the monopoly costs associated with patents limits the affordability of patented health-care products required in developing countries. (CIPIH p. 196)
- Intellectual Property has also been identified to be a barrier to innovation itself. On this the CIPIH report (at pg. 64) quotes Heller "... the recent proliferation of intellectual property rights in biomedical research suggests a different tragedy, an "anticommons" in which people underuse scarce resources because too many owners can block each other....more intellectual property rights may lead paradoxically to fewer useful products for improving human health".<sup>3</sup> The report at pg. 65 provides evidence of a survey<sup>4</sup> conducted of 103 Indian firms that revealed that "among 13 variables that could determine the abandonment of R&D projects by the Indian pharmaceutical industry, restricted access to patented upstream technologies because of contractual difficulties was likely to have the biggest impact on a firm's decision to abandon such projects".

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<sup>2</sup> G-Finder (2008), "Neglected Disease Research & Development: How Much Are We Really Spending?". According to G-finder, it surveyed 134 funders in 43 countries for their 2007 R&D investment into 30 neglected diseases.

<sup>3</sup> Heller M, Eisenberg RS. Can patents deter innovation? The anticommons of biomedical research. *Science*, 1998, 280:698–701.

<sup>4</sup> Sampath, G. "Breaking the fence: can patent rights deter biomedical innovation in 'technology followers'?", Maastricht, UNU/INTECH, Discussion Paper Series No. 2005-10, 2005 (<http://www.intech.unu.edu/publications/discussion-papers/2005-10.pdf>).

Oxfam<sup>5</sup> (at pg. 6) also noted that increasingly the existing approach to R&D is failing rich countries too with few pharmaceutical companies successfully replenishing their drug pipelines.

- A particularly difficult issue is ensuring proper ethical standards in clinical trials in developing countries. Concerns have been voiced that vulnerable populations in developing countries might be exploited for benefits that will accrue to people elsewhere. Key ethical issues include: consent, standards of care, ethical review of research, what happens once research is over? (CIPIH, pg. 179)
- In recent years, developing countries have demonstrated that they have much to offer the world in promoting health research generally, and in meeting their own health-care priorities. The most scientifically and technologically advanced developing countries are becoming significant contributors to biomedical R&D. (CIPIH, pg. 161)
- There is a lack of transparency with respect to the cost of R&D and production. For example since there is no information available about the cost of producing pneumococcal vaccine, it is not clear whether donors are paying a high prices for a vaccine, resulting in inefficient use of limited resources. (See Oxfam, p. 19)

***On financing of R&D, the following has been noted:***

- A central problem remains that previous calls for governments to invest more in health research for developing countries have so far had only limited success. Yet there is a widespread recognition that more funding is a necessity, and that it needs to be provided on a sustainable basis to support what is necessarily a long-term R&D effort. (CIPIH p. 206)
- There is a need to mobilize financial resources and the scientific talent (particularly that is available in developing countries), necessary to address the diseases that predominantly affect the poor. (Note Prof. Carlos Correa, CIPIH report, p. 224).
- In the longer term, the development of innovative capacity for health research in developing countries will be the most important determinant of their ability to address their own need for appropriate health-care technologies. (CIPIH, p. 161)
- It is in the interest of all countries to promote health research that addresses the health needs of developing countries and to set specific and measurable targets in this regard. (CIPIH p. 63)

***On Issues of Access the following has been noted:***

- However successful efforts might be to develop new products to address the public health problems of developing countries, they will be of no value if they cannot be made available and accessible to those who need them (CIPIH, p. 200).
- IP has effect on the prices of medicines (Doha Declaration para 3) and high prices of medicines have an impact on access to treatment.
- Governments should work to create a pro-competitive environment for the marketing of medicines, as competition is in the last instance the key tool to drive prices down and improve access to medicines. Avoiding or dismantling unjustified barriers to the entry of generics is a major responsibility of governments. (CIPIH, p. 131)
- Concerning developments are the growing number of bilateral and free trade agreements, which include higher standards of protection that erode TRIPS flexibilities (CIPIH p. 34) and the proliferation of pharmaceutical patents on trivial developments that are used to obstruct generics competition.

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<sup>5</sup> Oxfam (2008), “Ending the R&D Crisis in Public Health: Promoting pro-poor medical innovation”

### III. KEY ELEMENTS OF A GLOBAL FRAMEWORK FOR R&D

From the points mentioned in Part II, it is apparent that public health needs of developing countries continue, “to rely on inadequate and insufficient ad hoc initiatives”<sup>6</sup>

It is also obvious that there is an urgent need for mechanisms for coordination, prioritization of R&D and ensuring adequate financing for R&D as well as for models that *inter alia* de-links the cost of R&D from the prices of the product; ensures availability of treatments that are suitable for developing country conditions and that are affordable; promotes generic competition as well as strengthens and builds R&D and production capacity of developing countries.

For this to happen a systematic global approach to R&D is urgently required under the auspices of WHO that is mandated by the constitution “to act as the directing and co-ordinating authority on international health work.”

#### **BELOW ARE SOME KEY ELEMENTS THAT SHOULD FORM THE BASIS OF SUCH A GLOBAL FRAMEWORK FOR R&D.**

##### **III.1 Sustainable Financing**

The key problems with regard to financing of R&D have been mentioned above in Part I. The CIPIH report at p. 209 concluded: “we do all agree on the urgent need for action to generate more and sustainable funding for R&D to address the health needs of developing countries, and to engage governments in this endeavor more than has been the case to date.” It is notable that the CIPIH report speaks not only of “financing” but of “sustainable financing” thus intending for sources of financing that are predictable at a certain rate or level.

The 1990 Commission on Health Research for Development recommended that governments should spend 2% of their health budgets on what it called essential national health research and that donor nations should spend 5% of their aid for health in developing countries on research and the strengthening of research capacity. Calls for more resources have been repeated on numerous occasions. As recently as 2005, WHO Member States passed a resolution in the World Health Assembly which urged Member States to “consider implementing” the (financing) recommendations of the 1990 Commission on Health Research for Development<sup>7</sup>.

However countries have simply not taken these recommendations seriously. The overall OECD average for health related R&D is about 0.1% of GDP. Oxfam has noted that in 2007, the total contribution from Germany for neglected diseases was only \$20.7 million euros or 0.12% of its overall research budget.<sup>8</sup> The low budget allocation by donor countries to diseases of developing countries led CIPIH to recommend that developed country governments should “devote a growing proportion of their total health R&D funding to the health needs of developing countries”.<sup>9</sup> In developing countries, average health-related R&D expenditure is even much lower<sup>10</sup>.

According to reports available it seems to be the case that private firms and philanthropic organizations are “now rivaling and exceeding spending” by public organizations and by governments.<sup>11</sup>

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<sup>6</sup> Oxfam (2008), p. 28

<sup>7</sup> Resolution WHA 58.4. In: Fifty-eighth World Health Assembly, Geneva, 25 May 2005. Geneva, World Health Organization, 2005 ([http://www.who.int/gb/ebwha/pdf\\_files/WHA58/WHA58\\_34-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_34-en.pdf)).

<sup>8</sup> Oxfam, (2008)

<sup>9</sup> See CIPIH recommendation 2.1 at pg. 63

<sup>10</sup> OECD STI Scoreboard. Paris, Organisation for Economic Cooperation and Development, 2001 <http://www.oecd.org/dataoecd/17/19/1900544.pdf>.

<sup>11</sup> See G-Finder (2008).

As a consequence, funding of R&D has been done on an *ad-hoc* basis, according to the values of the funder in a limited number of diseases. The CIPIH report notes in p. 199 that “in the absence of enhanced and sustainable funding”, new players such as PPPs and developing countries with innovative capacity will not be able to participate in R&D although they have an important part to play in developing new products that can potentially be delivered at prices that are affordable in developing countries.

It seems that what is needed is global solidarity for financing of R&D in the form of a “Global Fund” for R&D within a R&D architecture. This fund should be created under the auspices of the WHO and would achieve collection of a specific amount of funds from multiple sources of financing. In 2001, the Commission on Macroeconomics and Health (CMH)<sup>12</sup> proposed the creation of a new Global Health Research Fund of US\$ 1.5 billion annually but this did not materialize<sup>13</sup>. Some others have called for a bigger fund.<sup>14</sup>

The sources of financing of such a fund would include: contributions by developed and developing country governments and other donors according to specified targets set out. Governments could also use various levies to achieve their contribution to the fund. (See discussion below on the types of levies that could be imposed).

However relying mainly on governments may not materialize the funding needed for R&D. To resolve the R&D crisis, what is necessary is “sustainable” sources of financing. Thus exploring and recommending innovative sources of sustainable financing is perhaps one of the most important task of the EWG.

One such source of financing could be through some sort of a “levy”. Obtaining financing through “levies” has for a long time been promoted as a mechanism for financing development issues.

One example of such a levy working for health is the taxing of airline tickets supported by Brazil, France, Chile, Norway and the UK known as “UNITAID”. Revenues from this mechanism are then used for the purchase of ARVs, TB and malaria treatments as well as for supporting WHO pre-qualification programme.<sup>15</sup> On average UNITAID has spent 300 million USD per year on the purchase of medical goods for HIV/AIDS, TB and Malaria.<sup>16</sup> A similar proposal has also recently been made in the context of the climate change negotiations. It is claimed that a modest levy of \$6 on the annual 760 million passengers could raise up to US\$ 10 billion a year.<sup>17</sup>

Another levy that has been the subject of discussion is tax on foreign currency transactions. This was initially proposed by economist James Tobin to reduce financial instability. The original tax rate he proposed was 1%, which was subsequently lowered to between 0.1% and 0.25%. Development-oriented activists have long championed this type of a levy as a means to finance development. One study has proposed a rate of 0.005% as this micro-tax is too low to affect the structure of the market – whilst at the same time would still produce potential revenue of the order of \$33 – 60 billion a year.<sup>18</sup>

A variety of levies could be considered including, charging tourists an additional small visa fee, taxing different forms of transport e.g. the airline industry, alcohol, tobacco industry, the pharmaceutical industries etc. The latter is proposed by the Ministry of Health of Brazil in its submission wherein it states “Government of associate countries would apply to the pharmaceutical industries that undertake activities in their territories a percentage taxation on every remittance of profits to the offices in their countries of origin”.

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<sup>12</sup> Macroeconomics and health: investing in health for economic development. Report of the Commission on Macroeconomics and Health. Geneva, World Health Organization, 2001.

<sup>13</sup> See CIPIH report, p. 62

<sup>14</sup> In 2001, Oxfam called for the creation of a US\$5 billion international fund to support research into new medicines and vaccines to treat infectious diseases plaguing poor countries.

<sup>15</sup> See submission by the Ministry of Health of Brazil to EWG

<sup>16</sup> See UNITAID submission titled “Proposals for New and Innovative Sources of Funding Medicines Patent Pool”

<sup>17</sup> See <http://www.guardian.co.uk/environment/2009/apr/06/aviation-climate-change-tax>

<sup>18</sup> Schmidt R., The Currency Transaction Tax: Rate and Revenue Estimates, The North-South Institute, Ottawa, October 2007, <http://www.stampoutpoverty.org/?lid=10738>.

Some may counter argue that a mandatory universal levy would simply not be politically acceptable to governments particularly the northern governments. However if sustainable financing is to be achieved, the EWG will have to make bold recommendations on the issue including recommending levies that are possible at the international level in addition to contributions from governments and donors. Of course an alternative that is always available is that some keen governments get together to generate funds through a levy system (as done in the case of UNITAID) to supplement contributions of governments and donors to the fund. Whatever the case may be bold recommendations from the EWG are anticipated on this issue.

### **III.2. R&D ARCHITECTURE**

The R&D Architecture would guide and supervise the funding of R&D. The architecture could be headed by a “Public Health Council” that is made up of a range of stakeholders (governments, NGOs, as well as international organizations). The Public Health Council would have the overall responsibility for the governance of the architecture. The Public Health Council would be assisted by a Secretariat. Below possible key components of the R&D architecture are identified.

#### ***A. Needs Assessment & Priority Setting***

CIPIH recognizes the lack of priority setting mechanisms for resource allocation between R&D on different diseases<sup>19</sup> resulting in most financing directed at HIV/AIDS, TB and Malaria. Thus any R&D architecture should also include components on needs assessment and priority setting.

##### *(i) Needs Assessment*

Needs Assessment is the first essential phase in the architecture. Needs assessment would aim to identify at the country/regional/international levels the health problems, the determinants, severity, and availability of affordable and appropriate treatments, R&D gaps and resources available for research. The process of needs assessment should be transparent, participatory, member driven and involve all the relevant stakeholders.

##### *(ii) Priority Setting*

Priority setting is important in order to better use financial and human resources available, as well as to focus efforts where needs are most demanding and on products/technologies which if not for the funding made available would not see any R&D activity. The process of narrowing the broad list of needs (identified through needs assessment) into a relevant R&D agenda (that should be funded by the abovementioned fund) should be transparent and participatory, and based on a scientific methodology.

The R&D agenda should not be limited to diseases where no treatments exist but should also include gaps where treatments need to be further improved (e.g. where the side effects of existing treatments are problematic) or where treatments exist but need to be adapted to suit the conditions of developing countries (e.g. heat resistant treatments) or meet the special needs of those countries e.g. the need for pediatric formulation, fixed dose combinations.

#### ***B. Funding R&D & Determining Appropriate Model including incentives for Research & Development***

This phase would require R&D to be funded and facilitated based on the gaps identified and prioritised. There are many stages in the R&D of a pharmaceutical product/ technology, i.e. basic research, discovery research (synthesis, biological testing, pharmacology screening), preclinical testing, development research (clinical test, Phase I – III), registration (Phase IV), post marketing surveillance (Phase IV).

A crucial issue is what is the model of R&D (including incentives) that should be the basis of the conduct of R&D. There have been proposals on a variety of mechanisms that involve push or pull incentives or a

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<sup>19</sup> CIPIH, p. 206

combination of both. Several of these mechanisms have already been implemented by donors and are largely based on the intellectual property system. These include mechanisms such as Advance Market Commitments, Priority Review Voucher, Product development partnerships and tax credits. Several reports on these mechanisms have revealed fundamental shortcomings in the delivery of outcomes for R&D for developing countries in particular: that the emerging products may not be affordable to developing countries (especially to middle income countries), there is no sharing of knowledge generated from the R&D although it is fully funded, the mechanisms do not promote generic competition nor aim to strengthen or build capacity of entities in developing countries.

In any case the model of R&D most suited for the development of pharmaceutical product/technology very much depends on the gap that has been identified. Providing grants to conduct R&D is important particularly to ensure participation of developing country entities in the R&D. Having said this, it is also important to explore other mechanisms that could also facilitate R&D. For instance, there may be situations where a specific targeted technical challenge has been identified, “prizes” may work either as a stand alone mechanism or together with a grant. There could also be R&D gaps where collaborative research along the lines of “open source” approach<sup>20</sup> could be considered. This would for example “involve volunteers from the public or private sector working on existing databases to identify promising targets and drug candidates, which would then be tested in “real” laboratories”.<sup>21</sup> What is critical is that funding for R&D is provided to conduct R&D in accordance with certain guiding principles. These guiding principles are identified in Part D below.

For this phase, an independent R&D Portfolio Committee could be created that involves a range of expertise from developed and developing countries. The Committee would make a call for proposals based on the R&D gaps identified, evaluate applications and fund the appropriate applicants on a step-wise basis. The Committee would also monitor progress of the selected project that is funded and take the decision either to continue funding for the next step of the process or to discontinue funding of the project. The Committee could also explore as noted above other mechanisms, provided it is designed and implemented along the principles set out below.

In the submissions made during the public hearing there is emphasis on channeling money through public and private partnerships. The success of PPPs/PDPs is yet unknown as noted in the submission of the Ministry of Health of Brazil and it comes with its own shortcomings. It should not be the case that PPPs/PDPs are seen as the only way of channeling money for purposes of R&D. The fund should encourage applications from existing researchers from universities, research institutions and the private sector in developing countries and provide step-wise funding for the conduct of R&D.

### ***C. Intellectual Property***

An important issue that would need to be resolved is what is the proprietary status of the research outcomes including product, technologies and data that is generated from the R&D that has been funded. In Part I above the failures of the patent system to generate R&D for the problems of developing countries has been noted. It has also been noted that R&D mechanisms that result in monopolization of research outcomes do not adequately address public health problems of developing countries. In this regard, it is important to move away from this “business as usual” paradigm that is obsessed with monopolization of research outcomes even where the R&D is publicly funded.

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<sup>20</sup> CIPIH, p. 107: “Open source” refers to the method of innovation pursued by computer programmers all over the world who have collaborated to produce new software products. Open source software has developed a more or less proven research model, based on a general public licence which makes modifications of a software programme freely available for others to use or develop. The important aspect of this approach is that it mobilizes innovative effort from a range of developers at little cost”

<sup>21</sup> See CIPIH, p. 107. The Indian Council of Scientific and Industrial research (CSIR) set up in 2008 the open source drug discovery (OSSD). See [www.osdd.net](http://www.osdd.net)

As a general principle the following is proposed: Under the R&D fund and architecture when funding is provided, the research outcomes should not be patented/monopolised by the researcher/research entity. If a patent is filed (and such filing should as a general principle not be encouraged), the patent should be assigned to the R&D architecture, without any conditions. The R&D architecture must allow others to build on the R&D outcomes that has emerged as a result of the efforts of the R&D fund and architecture.

To address issues pertaining to intellectual property, access to other technologies needed for R&D, a Legal & Technology Committee could be established that is independent and involves a range of expertise from developed and developing countries including civil society.

#### ***D. Guiding Principles for financing R&D***

If the global fund for R&D is to work to address diseases of developing countries, then the architecture of such a fund would have to address weakness in the current system for funding R&D (noted above in Part I) and to spend the money more responsibly. Below are some key guiding principles that should be the basis for funding and architecture for R&D.

(i) High standards of governance and transparency are essential elements for the proper functioning of the R&D fund and architecture. For example there should be transparency with regard to R&D funding provided and the cost of R&D incurred.

(ii) R&D fund and architecture should ensure sufficient and meaningful representation and participation of public and private institutions and researchers from developing countries. This includes providing developing countries (governments and civil society) an equal voice in decision-making processes at global levels.<sup>22</sup>

(iii) Activities under the R&D fund and framework should also aim to strengthen and build research and local production capacity of developing countries thus where possible such research and production should be undertaken in developing countries by the locals or in collaboration with locals in developing countries. For this purpose, effective mechanisms/measures to promote transfer of technology should also be set up.

(iv) R&D efforts should be focused on the development of products that are adapted to the needs of developing countries<sup>23</sup>, and the needs of patients of all ages, simple (in terms of using, prescription and storage), accessible (in terms of availability & affordability) and of quality.

(v) Prices of products/technologies produced should be fixed on the basis that it is affordable to patients in developing countries (including middle income countries). Where such products are being made available to public organisations, international institutions, NGOs for use in programmes promoting access, they should as far as possible be made available at a “no profit- no loss” price or at a modest mark-up price. Whatever the case maybe, the underlying principle is that prices must be fixed with the aim of achieving equitable access to products/technologies to all that need those products/technologies.

(vi) R&D models including incentive mechanisms (push and pull mechanisms) for the conduct of R&D, should be designed to ensure that outcomes and data generated from the R&D are not monopolised but are shared in the public domain. R&D done under this architecture should be widely disseminated for other researchers to engage in additional or follow-on health research.

(vii) R&D models including incentive mechanisms (push and pull mechanisms) for the conduct of R&D, should be designed to ensure that as a condition of receiving funding, the products/technologies emerging from R&D will be licensed to the R&D fund to enable further licensing to promote generic competition

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<sup>22</sup> Oxfam, (2008)

<sup>23</sup> For example in low-income settings, there is often an absence of trained staff, reliable sources of electricity, adequate supplies and appropriate equipment – including for the storage and administration of medicines and other products, thus intervention have to be adapted to meet these needs, to benefit the people that needs medicines in those settings.

with the aim of increasing supply and reducing the price of the products/technologies. In short funding should be provided on the basis that the R&D outcomes will be managed on the basis of non-discriminatory and open licensing terms.

(viii) R&D models including incentive mechanisms (push and pull mechanisms) for the conduct of R&D, should be designed to de-link the cost of R&D from the price of the health products.

(ix) The R&D fund and architecture must not be limited to Type 3 diseases but should also address R&D gaps in Type 1 and 2 diseases.

(x) Where a product results from the genetic resource and/or associated knowledge of indigenous and local communities, the principles of prior informed consent and fair and equitable benefit sharing should be practised.

(xi) There must also be emphasis on strengthening the regulatory capacity regarding the quality of medicines and ethical standards of clinical trials in developing countries. An important concern is the fate of clinical trial participants from poor countries upon completion of clinical trials.

(xii) There must be full disclosure of clinical trial data.

(xiii) Conflicts of interest must be disclosed and as far as possible avoided.

#### ***E. Coordination, Monitoring & Evaluation***

There is a lack of coordination between various R&D efforts resulting in duplication of R&D efforts and an uneven allocation of resources to diseases or absence of funds for some diseases. This has been noted in Part I above.

Thus a key objective of the Global Fund and Architecture would be to develop mechanisms to coordinate R&D efforts as far as possible, facilitate periodic assessments of these efforts, provide guidance and direction to these efforts at national, regional and international level (as it would have the knowledge and expertise following the needs assessment and priority setting phase), advise on appropriate priorities for resource allocation between R&D on different diseases, the balance between resources needed for R&D and delivery for each disease.

The architecture should also develop mechanisms to monitor and evaluate R&D efforts generally and those undertaken under the fund including the impact of resources devoted to treatment and delivery.

For this purpose a third arm of the Public Health Council could be established called the “Coordination, Monitoring & Evaluation Committee”.

#### ***F. Institutional Setup***

From the above there is suggestion for the creation of “Public Health Council” that would have the overall responsibility for managing the fund and the architecture. Under this Council, there is suggestion for establishing a R&D Portfolio Committee, a Legal & Technology Committee and a “Coordination, Monitoring & Evaluation Committee”. The R&D Portfolio Committee would mainly be tasked with working out a balanced R&D agenda, designing mechanisms for the conduct of R&D according to the abovementioned principles and disbursing grants, and licensing the emerging product for widespread production.

The Legal & Technology Committee would be tasked with dealing with legal issues such as intellectual property as mentioned above and solving problems that researchers may have in accessing technologies to pursue R&D such as access to compounds. The Coordination, Monitoring & Evaluation Committee would have tasks as outlined above.

The institutional setup proposed is indeed very basic and it could be worked on to develop it further. The important issue is that the institutional setup is truly transparent, and ensures strong participation of developing country representatives and entities and civil society from north and south.

### ***G. Medical R&D Treaty/Norms***

The possibility of a “Biomedical R&D Treaty” has emerged on numerous occasions. There is also a submission by Bangladesh, Barbados, Bolivia and Suriname to the EWG on that issue that outlines the various elements of a possible Biomedical R&D Treaty. It seems that there is strong support at least from developing countries to set norms in the area of R&D for e.g. on coordination and prioritization of R&D, norms to ensure sustainable financing, norms on access to publicly funded research, norms on greater disclosure of the costs of R&D inputs such as the costs of clinical trials, disclosure of clinical trial data, mechanisms to monitor and evaluate global R&D efforts, norms on cooperation in the area of funding clinical trials etc.

The fund and architecture proposed above is consistent with the idea of setting norms in the area of R&D and could form the starting point of a broader discussion on R&D related norms.

### ***H. Difference between the above proposal and pharmaceutical industry’s concept of a Global Fund for Neglected Diseases R&D***

A submission to the EWG has been made by Novartis on a Fund for R&D neglected diseases (FRIND). Essentially the fund intends to focus on the 10 neglected diseases as a starting point; it focuses on grant funding, it focuses on evaluating existing compounds and would allocate funding only to promising compounds, the fund would own the intellectual property for the neglected disease indication for which funding is provided and the product will be made available at not for profit prices.

The global framework for R&D proposed above has as its starting point needs assessment and priority setting which means that R&D architecture would evaluate the needs and set priority on that basis and develop a R&D agenda. Moreover the 10 neglected diseases that FRIND is proposing to deal with is already being addressed by the Tropical Diseases Research (TDR) of WHO. As mentioned above the architecture should look at needs and fund R&D on that basis notwithstanding it is Type I, II or III disease.

The architecture above does indeed focus on grant funding however it does not exclude the possibility or the need for other incentive mechanisms or models for the conduct of R&D either as a complement or as an alternative to grant funding as appropriate. In fact creative ways to developing a product/technology should be explored. The architecture above does however insist that the principles mentioned above in Part D are followed.

The architecture proposed above does not limit the funding of R&D to situations where there are promising compounds. The architecture should not prejudge situations for which funding should be provided since there may be R&D gaps wherein basic research or discovery research may need to be funded.

Further the architecture proposed above stresses on strengthening and building the research capacity of institutions in developing countries. The FRIND proposal stresses more on the pharmaceutical industry presumably the multinational players (since they would possess the much needed compounds to evaluate its value for neglected diseases) and on PDPs.

The architecture proposed above also requires the recipient of funding to license all research outputs to the architecture for all uses to enable other entities to build on the outputs or to manufacture the products. The FRIND proposal only allows production for the neglected disease for which R&D funding was proposed while the IP for other uses of the same product, which may be relevant to the developing world, is not licensed. FRIND seems to propose for e.g. that product X developed for a neglected disease and fully funded by the fund would be licensed to the fund for the fund to allow production of product X for treating the neglected disease. But if product X could also treat another treatment relevant to developing country such as Hepatitis C or cancer, the patent would belong to the industry and sold exclusively by the industry.

As we have seen from numerous cases a product may have several uses. Thus the approach proposed by Novartis would prevent access to affordable treatments for Hepatitis C or cancer, although development of the product was initially funded by the global fund.