SUBMISSION
This submission is being made in response to a call for submissions on the
Global Strategy and Plan of Action by the WHO Intergovernmental Working

INTRODUCTION
It is commonplace to regard sickness, malnutrition, famine, health crises and
the collapse of natural resources as overwhelming problems of our world, and
typically associate them with poverty. These are however symptoms of a more
fundamental failing in how we deal with different societies in the world, and to
whom we give the tools to engage these failings. Four billion people are not just
a problem; they are the world’s greatest resource for problem solving. What we
currently lack are the norms, the tools and the mechanisms to harness and
empower their commitment, their drive, their local knowledge and their
creativity. We aver that this is within our grasp as a global community and we
must seize the opportunity to address these problems.

The great revolutions we have experienced in informatics, communication and
life sciences can and must be matched by a process of democratization of
scientific problem solving. We must inculcate this culture into business and
the creation of wealth – not just the accumulation of wealth.

The World Health Assembly Resolution 59.24 tasked the IGWG with drawing
up of a Global Strategy and Plan of Action in order to provide a medium-term
framework for all stakeholders based on the recommendations in the report by
the Commission on Intellectual Property Rights, Innovation and Public Health
(CIPIH). This would, inter alia, secure an enhanced and sustainable basis for
needs-driven, essential health research and development especially those
relevant to diseases that disproportionately affect developing countries. The
IGWG was asked to propose clear objectives and priorities for research and
development, and estimate funding needs in this area.

The Commission examined various issues along the broad themes of
“Discovery”, “Development”, “Delivery” and “Fostering Innovation in
Developing Countries” and produced more than 60 recommendations. In
doing so, it has linked the debate on the lack of adequate research and
development (R&D) into medical products needed in developing countries to the
problems of access to medicines. The Report notes that “innovation is pointless
in the absence of favourable conditions for poor people in developing countries
to access existing as well as new products”¹.

¹ CIPIH Report p. 9

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The report of the Commission notes that while there is “an innovation cycle in developed countries, which broadly works to provide the health care required by their inhabitants, this is far from being the case in developing countries to meet the needs of their people, in particular poor people.”

It further states that “In spite of the progress made in the last decade, exemplified by the formation of numerous new public–private partnerships and greatly enhanced funding from foundations and governments, the basis for continued progress in the development of new products needed by developing countries remains fragile.”

The Commission unequivocally calls for “additional efforts” to be made to assure the “sustainability” of new essential medicines both in terms of suitability of products in use in poor settings and of their affordability and accessibility to governments of developing countries, so as to guarantee “that medicines, vaccines and diagnostics produced reach the people” and promote “synergy among the efforts of the different partners.”

While the Report deals with complex and diverse, though inter-related issues, the apparent emphasis is on the need to establish a sustainable framework for supporting R&D in diseases that affect the poor, based on the needs that have been identified and prioritized. This is the crux of the problem. It is emphasized in the WHA Resolution 59.24 and the IGWG needs to credibly deal with this issue, if it is to succeed in its mandate.

We propose below the form and content of the Global Strategy and Plan of Action, with two specific aims:

균 focus on the problem and propose solutions and mechanisms to dealing with the problem.
균 operationalise the key recommendations of the CIPIH, which would, if implemented correctly, assist in achieving the suitable solutions.

GLOBAL STRATEGY
The term “strategy” generally refers to the devising of a careful plan or method to achieve a certain goal. While the mandate given to the IGWG leans towards providing more of a “medium term framework”, the term does indicate an approach that identifies a broad agenda, including long-term goals.

The Global Strategy as provided in Annex 2 of document A/PHI/IGWG/1/5 comprises mostly of reiteration of principles noted in WHA Resolution 59.24 and previous resolutions. In light of this, we submit that the Global Strategy document as it is currently prepared is inadequate and needs to be substantially revised. The Global Strategy should provide Member States with a

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2 CIPIH Report, p. 10
3 CIPIH Report, p.10
4 CIPIH Report, p.10-11
5 See paragraphs 2 (1), (2) and (3).
range of global policy options to address the crisis in R&D and access for needs-driven health tools.

**Vision**

To design a sustainable global mechanism for essential health innovation (research and development) aimed at the production of new, adapted, safe and effective tools to respond to global medical needs, particularly for diseases that disproportionately affect developing countries. Such new and good quality health tools need to reach those who need them, and have to be affordable and available in sufficient quantities for those in need.

**Goals**

- To ensure the leading responsibility and commitment of governments, regional and international organizations in determining priorities for R&D according to public health needs, especially those of poor patients
- To increase overall R&D efforts on diseases that predominantly affect developing countries, leading to development of good quality products that are adapted to needs of patients of all ages, simple (in terms of using, prescription and storage), and accessible (in terms of availability & affordability);
- To devise and set up sustainable sources of funding for needs-driven R&D according to criteria of equitable participation and access, adequacy and affordability of health technologies for those who need them in low income countries
- Develop the capacity for health research and development in developing countries as well as capacity for local production through measures that promote access to tools and technology necessary for innovation, better-coordinated and effective networks, appropriate financing, training of human resources and other support necessary to build the appropriate regulatory capacity in developing countries.

**Principles of the global strategy and action plan**

1. The innovation process has to be seen as a cycle consisting of three major phases that feed into each other: discovery, development and delivery. This is in contrast to conceiving of innovation as a linear process culminating in the launch of a new product. Within the innovation cycle, public health needs create a demand for product of a particular kind, suited for the particular medical, practical or social context of the group in question, and feeds into efforts to develop new and improved health tools. This concept is of particular relevance when tackling Type II and Type III diseases.

2. Redirecting today’s knowledge and scientific expertise to address health needs of people in poor countries will require a paradigm shift in the way

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6 CIPIH Report
life-saving and other essential health products are valued, and how efforts are organised globally to ensure their development and widespread availability. To do this, government leadership and commitment are essential conditions. Health and medicine must be a strategic sector, requiring large and sustainable investments, as it happens today for other industrial sectors.

3. Issues of public health prevail over trade arguments, in the context of this Global Strategy and Action Plan. The IGWG therefore marks a unique opportunity for a genuine cultural and political leap.

4. Essential innovation and access are closely linked, and cannot be considered in isolation. Innovation for the sake of technological advancement is pointless in the absence of favourable conditions for poor people in developing countries to get access to existing, as well as new, health tools.

5. In the interest of hastening the application of new health technologies for human health (especially for patients affected by Type II and Type III diseases), novel approaches of scientific cooperation should prevail over the basic logic of competition. The spirit of collaboration thoroughly inspires this proposed Action Plan.

6. No single policy instrument is likely to provide comprehensive solutions to the current crisis in R&D and access to needs-driven health tools. A wide range of policy options should be explored, and a virtuous competition among all these options should be considered, in the interest of public health, for the different needs tackled.

7. The creation and adoption of new policy tools to provide genuine, priority needs-based innovation in health require an approach that inevitably goes beyond patents, and intellectual property rights management issues. However, such an effort must rely upon the complete and unobstructed implementation of all flexibilities provided in the WTO Trade-Related Agreement on Intellectual Property Rights (TRIPs).

**PLAN OF ACTION**

In its final Chapter, the CIPIH Report\(^7\) recognized that the agenda is large, issues complex and views diverse, with many partners involved and thus “further progress will require a collective effort”. It adds that the purpose of a Plan of Action would be “to aid forward-planning and collaborative action” requiring rigorous examination of the activities, resources and institutional mechanisms needed to ensure that we meet the vision and goal.

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\(^7\) CIPIH Report, p.206

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Such a Plan would also provide an important basis for measuring progress towards the achievement of these goals. Indeed in proposing such an action, the Report highlights the problem it is trying to resolve i.e.

“Viewed across the field, there are 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.”

“.....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.

**Content of the Plan of Action (POA)**
Consistent with the WHA Resolution as well as the findings and recommendations of the Commission’s report, Kenya is of the view that the POA document should concretize an architecture that will work towards delivering 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”. If it does not address this squarely, it will not have responded to the original problem.

To achieve the Vision and Goals set out in the Strategy document the **Architecture of the Plan of Action is based on the principle of collaboration and cooperation** among Member States, pharmaceutical industries (including generic industries), medical research councils, academia, public private partnerships, donors, intergovernmental organizations, civil society organizations and other relevant stakeholders. This is on the understanding that it is in the interest of all countries to promote health research that addresses the health of developing countries8.

**Kenya therefore proposes the following as elements of the final architecture.**

### Phase 1: Needs Assessment

In order to propose clear objectives and priorities for research and development, a **needs assessment** exercise should to be conducted at different levels – national, regional, international – to identify the most urgent patients’

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8 CIPIH report, p.63

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necessities. This will enable the correct detection of existing gaps in R&D for health products that will diagnose and treat diseases that disproportionately affect the poor and in particular developing countries.

Needs Assessment is therefore the first essential phase in the architecture. It is our view that the principal actors in this early stage of health research, for developed and developing countries, should be government as funders and medical research institutes (or equivalents) as the entities in charge of carrying out the research programmes. Currently, there do exist a few heterogeneous initiatives to identify needs and these are being conducted by academics, small and large companies in pharmaceuticals or biotechnology, governments in the form of aid donors or medical research councils, foundations and civil society groups. These do not appear to be coherent and need to be aligned according to shared and set criteria of public health. Promoting a more organized information sharing principle on current activities is a key step forward. For this reason, the Needs Assessment effort should include:

- **For Member States**: immediate work to identify medical needs at the country level, with the involvement of health experts and researchers, health NGOs, and any other relevant stakeholder. This process may be more useful if pursued at the regional level in Africa and similarly poor countries, for the purpose of better utilization of local capacities and resources.

- **For WHO**: Soliciting and receiving submissions on needs from Member States, the relevant regional intergovernmental organizations, experts and other relevant stakeholders.

- **For WHO**: Convening an intergovernmental meeting with participation of accredited NGOs and experts to comment on the submissions received, to share other information that may be available as well as to make substantive inputs. This exercise would be useful for purposes of exploring the type of R&D that is taking place (if any) on the needs that will be identified, and intercepting medical R&D opportunities that can respond to those needs.
  - This convened meeting would also determine criteria for the selection of diseases in the ensuing phase of “priority setting”. For example the criteria would include morbidity, prevalence, and other national or regional specific indicators or considerations.
  - In preparation for the intergovernmental meeting, the WHO Secretariat should prepare the necessary background documents that would assist the meeting in fulfilling its tasks. Noting its expertise on health matters, it should also provide its own input on R&D needs. Public hearings should also be held, prior to the intergovernmental meeting.

- Following the conclusion of the meeting, WHO should prepare a report on the broad list of needs identified, including the discussions that took place during the meeting.

- The broad list of needs will be especially useful in guiding other actors in
R&D nationally, regionally as well as internationally as to what are the needs in countries and promoting more R&D on these areas, especially diseases that are not identified as “priority” for purposes of this framework.

### Phase 2: Priority Setting

Based on the information generated in the Needs Assessment phase and the criteria developed, an initial report of “Priority Needs” should be produced and published by WHO. This upstream interface is extremely important in translating promising science – potential targets, lead compounds, etc. – into adapted and accessible health tools.

Priority setting is important in order to better use financial and human resources, as well as to focus efforts where needs are most demanding. A series of key elements have to be considered in the process, namely the values used (equity considerations vs. cost of interventions), the openness of the process and the involvement of all diverse stakeholders, the methodologies adopted.

Criteria for the definition of a needs-driven R&D agenda should include the magnitude of the disease burden and the determinants around its persistence, the knowledge available about interventions and the opportunity to create new products, the cost effectiveness of individual interventions, and the available funding for research.

It needs to be clear that, in each disease, there are different approaches to prevention, treatment or diagnosis. This stage will therefore make very general points about priorities without considering the landscape for each disease, indication and intervention. Even then, there will inevitably be different but equally legitimate views about priorities in each diseases area.

The process of narrowing the broad list of needs into a relevant R&D agenda should be transparent and inclusive, and governments should take responsibilities for setting research priorities. Even on an agreed upon list of needs, priorities may vary according to regions, or even countries.

Developing countries’ leadership and commitment is critical to successful outcomes, just as it is the open dialogue and the exchange of information among and within WHO’s Regional Committees. On the other hand, governments of developed countries should reflect adequately on the goal of an R&D agenda for international health into their research priorities. The definition of such an agenda, which will need to be assessed on a regular basis, is essential to implement and empower national and regional platforms for health research, including the best practices for execution and management of research, with appropriate political support, and long-term funding.
Phase 3: Identification of R&D gaps & opportunities

Phase 1 and 2 should have generated significant information on the R&D gaps, and opportunities. The knowledge anticipated at this phase would be for example whether a body of baseline research exists; whether lead compounds have been identified that could potentially serve the purpose against a disease; and the R&D actors that may be interested in collaborating with WHO, and other relevant stakeholders (PDPs, the private sector, medical research councils) in the development of suitable products.

It will be necessary for Member States, through the WHO, to engage at this stage in further collation of information on the R&D gaps and opportunities specifically for the list prioritized in Phase 2. The information collated would also reveal what additional essential health R&D needs to be conducted to produce a suitable response to priority needs, to fill the identified gaps and to allow for a more accurate estimation of the funding requirements that should also be made at this stage.

This is a critical phase of the Plan of Action, as there are several complex issues at stake. Policy options adopted at this stage will need to strike a balance between some degree of visionary risk taking and the need for some success stories to be determined in a comparatively short time. We should bear in mind that science is never lost in this process and money is never wasted, even when upstream research does not bear immediate fruit initially. At this upstream stage of the innovation cycle, collaborative efforts in engaging the dormant science that exists already, and the sharing of knowledge which all parties involved will require to make use of, is in the interest of hastening the application of new technologies to human health. It is important to reach the minimum combination of feasible changes that could make innovation, incentive and access mutually reinforcing.

Following the collation of information, an appropriate, transparent and inclusive process would need to be identified to further prioritize areas where R&D would take place under this architecture. These would be areas where financing would be immediately made available for purposes of R&D (hereinafter known as “Priority List A”).

For priority research areas that are not initially selected for financial support, the information collated will be a useful guide to other actors involved in R&D at national, regional as well as international level. It will however show what the R&D gaps are on the needs prioritized which could also result in promotion of R&D in these areas. (hereinafter known as “Priority List B”).
Phase 4: Innovation in future essential medicines: a menu of strategies and policy options

This phase would require R&D to be facilitated based on the gaps identified and prioritised. There are many stages in the R&D of a drug, 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). At each of these stages, suitable partnerships with different R&D actors would need to be established to assure the emergence of a product that would satisfy the prioritised needs. In order to respond to such needs, it is necessary for the IGWG to move its discourse and policy creation beyond the mere implementation of the TRIPs flexibilities, both in the upstream and downstream interface of research.

Depending on the R&D gap that has been identified, incentives that motivate the different actors to partner in the R&D of a product will have to be explored. In some cases for instance, where basic or discovery research is involved, a public grant may need to be given for R&D to take place, and non traditional deals should be explored (such as research exemptions, socially responsible licensing initiatives, progressive technology transfers) with a critical role of universities in developed and developing countries. In other cases, institutions or companies may offer to conduct certain stages of R&D, without any financial support, in collaboration with product development partnerships (PDPs). Reward systems such as “prize funds”, should also be considered and used where appropriate.

International support for a mobilization of local resources in developing countries, with the aim of strengthening local absorptive capacity for knowledge and technology transfer, is central to policy interventions that seek viable, sustainable and long term solutions. Technology transfer frameworks could include special licensing agreements for developing countries, or affirmative commitments of allocation of research funds for collaborative projects with developing countries.

Striking the best possible balance between stimulating and rewarding investment in R&D will be a critical challenge of the IGWG’s performance, i.e. the innovative and effective use of push and pull mechanisms to grant life-saving medical innovation. In this respect, another key component of the IGWG mandate includes the proposal of a new set of legally binding obligations on member states to design accountable incentive mechanisms to boost the private sector’s involvement into health R&D for ailments that disproportionately affect people in poor countries (such as tax-deductible, in-kind contributions to R&D, higher tax breaks for industries that open their compound libraries, etc.). The IGWG will also have to consider that incentive

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mechanisms, no matter how innovatively tailored, may not work for the most neglected diseases and the riskiest areas of health research. This means that the public sector (or the non-profit sector) may have to fund these projects up front.

For this phase, an independent R&D Portfolio Committee would have to be created, fulfilling stringent professional criteria, to evaluate submitted projects and fund the selected ones. Suitable partnerships would be forged either by providing the necessary financing assistance or offering appropriate incentives for R&D of a vaccine, diagnostic or medicine that is safe, effective and adapted to the needs of patients of all ages, simple (in terms of compliance), accessible (in terms of availability & affordability) and of quality.

The R&D Committee could forge such partnerships by inviting applications for R&D on the gaps identified including an estimate of costs or by pro-actively seeking out partners that would be interested in collaborating or both. It would also have to verify the costs, assess and approve research proposals subject to conditions that are to be established. The Committee would also follow up regularly on the activities and progress of the successful applicants/partners in R&D.

For the success of this phase, access to research tools, platform technologies and compound libraries is crucial, yet often impossible. Entities that possess compound libraries should be encouraged to make such libraries accessible and countries, in particular developed countries, should provide incentives to these entities to make such libraries available. WHO should also find ways to make compound libraries more accessible to identify the potential compounds to address diseases affecting developing countries. Countries should also resolve to adopt broad research exemptions, set up patent pools or issue compulsory licences where necessary to facilitate innovations for the needs of developing countries.

Challenges during this stage include regulatory process and the related subject of clinical trials as such capacity remains weak in developing countries. Activities under this phase should aim to strengthen the clinical trials and regulatory capacity including the improvement of ethical review standards in developing countries, in particular in sub-Saharan Africa.

**For the purpose of the Plan of Action, Kenya would like to draw attention on the following policy options:**

Open source for poverty-related diseases research. The term “open source” describes a paradigm for software development associated with a set of innovation practices. Several features together qualify a project as “open source”. These include full disclosure of enabling information including source

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10 See example in CIPIH report, p.57
code, and the use of legal instruments such as copyright licences to confer both permissive rights and responsibilities; they bind contribution into a commons that is accessible to all who agree to share alike.

With biology increasingly becoming an information-oriented science, an interdependent technology requiring multiple key components to function to the point of delivery, what worked for software might be part of the answer to the spiralling cost of drug R&D. The “open source” approach to drug development can be envisaged as a decentralised, community wide effort where scientists from laboratories, universities, institutes, and the private pharmaceutical industry can work together for a common cause.

We note that thanks to the vastly greater size and variety of chemical, biological and medical databases, as well as new software and more powerful computers, researchers can now identify promising protein targets and small sets of chemicals, including good lead compounds, using computation alone (cfr. the SARS protein). Such open source upstream research would play a crucial role into feeding the R&D pipeline of medical research, and favourably connect those who have interest and biological expertise with those who have pharmaceutical tools. Just as they do today, pharmaceutical companies (including the producers of generics) would choose the best candidates. Yet importantly, this approach would greatly boost efforts by the pharmaceutical sector, because it would help contain the costs of discovering, developing and manufacturing drugs. In a sense, it would provide a way to leverage big pharma’s capabilities in order to tackle challenges that the blockbuster model cannot address economically, such as poverty related diseases. Open source initiatives funded by users and governments could institutionalise and improve the best features of creativity and flexibility of PDPs, in the sense that it would help replenish their portfolios while fostering cost containment.

As an alternative model to patents, open source R&D would restore competition by making drug candidates available to anyone who wanted to develop them, with a logic of competitive bidding which is a powerful tool to contain costs. The absence of patents would continue to keep prices low once essential medicines reached the market.

Drawing talents from all around the world, open source research appears instrumental to the involvement of scientists dispersed in disease endemic countries, to use and improve technology and add their contribution to medical innovation after agreeing to conditions that help prevent formation of patent thickets that block affordable delivery. Such policy initiatives are key to increase fairness in access to the tools of innovation as a fundamental human right.
Public funding for clinical trials\textsuperscript{11}

According to the spirit of the Helsinki Declaration, human experimentation can and must be seen as one of the most powerful tools to promote and assure the right to health to populations and individuals. The almost exclusive focus on drugs development as dependent on the constraints of intellectual property rights and patents (especially in the absence of investments by public health actors) favours a misdirected concept of human experimentation as an area of research and regulations which has little or nothing to do with unmet public health needs and human rights.

Economic principles make it very clear that privately-supplied public goods will inevitably be underprovided, and in the context of health, this can cost a great deal in terms of life or death if, for example, a head-to-head comparison between therapeutically equivalent drugs is never studied; an adverse drug reaction is never explored (such is the case of the toxic arsenical Melarsoprol against Human African Trypanosomiasis); or the possibility of a drug’s use for another disease is never investigated.

Building upon the momentum of debate and action promoted by IGWG’s work, it would seem appropriate to recommend exploring the opportunity, and feasibility, for clinical trials (from Phase I through IV) to be treated as public goods. This means public funding and public administration. One avenue could be the creation of one independent testing agency, to conduct trials at a national testing facility, under specified conditions of transparency. The merit of this proposal is the rediscovery of the philosophical and methodological roots of clinical experimentation within a context that adopts public health needs, rather than competitive drug registration policies, as guiding criteria.

Firstly, the direct link between the clinical trial sponsor, and the drug tester, which is at the core of a somewhat structural conflict of interest, would be removed. Secondly, this solution would ensure that all drug tests that are important to the public are conducted and results, especially unfavourable or negative results, fully disclosed. Finally, the incentives for companies to discover new drugs decline, as their costs of testing and developing drugs for the market increase; state subsidies of clinical trials, with the ensuing reduction of costs for drug development, could complement private initiatives that research and deliver beneficial health tools to patients in developing countries.

Transforming clinical trials to a \textit{non excluded} public good is an ambitious undertaking to stimulate needs-driven R&D, and one that should be implemented gradually. Government funding could be supported nationally by a specific tax or from general revenues, especially in donor countries\textsuperscript{12}. At the


\textsuperscript{12} The model operated by the Italian Medicines Agency AIFA, in relation to the European Directives on human experimentation, with the creation of an \textit{ad hoc} fund for independent public drug research, has some potentials for
multilateral level, ways to make finances available should be considered under the broader chapter of finance for R&D (see “Financing Mechanisms” below).

**Compensatory liability rules to stimulate local innovation**\(^\text{13}\)

In line with the AU Commission’s task to develop a Pharmaceutical Manufacturing Plan for Africa, looking at capacity mapping for local drug production in the continent in collaboration with the World Health Organization, Kenya recommends that the IGWG look at small scale-innovation paradigms, i.e how to enable entrepreneurs to appropriate the fruits of their investments in cumulative and sequential innovation without impending follow-on innovation and creating barriers for second comers.

The use of powerful exclusive rights to deal with the puzzle of small-scale innovation needs to be replaced with a compensatory liability rules regime within the community of small sized innovators. Within the framework of such compensatory regime, all the players in the pharmaceutical sector could add to the cumulative stock of know-how at different times, by dint of their individual business decisions, and each would be likely to operate as either lender or borrower of incremental innovation at different times and intervals.

Liability principles are interesting for the purpose of the IGWG, as they would offer those who innovate in a small-scale technology environment a way to alleviate or avoid market failures without impoverishing the public domain. Such a regime would help to solve some pressing needs of developing countries as it would provide them with new means of stimulating local innovation, and could prove especially beneficial to protect the know-how of indigenous peoples. A compensatory liability regime could be adapted to encourage traditional medicine, without denying the relevant indigenous communities the right to a fair share of the proceeds.

**The Essential Health R&D Treaty**

The need for global solutions to correct the current externalities in the R&D domain is solidly advocated for by an increasing number of health experts and well-trained economists. In this respect, Kenya acknowledges that both SEARO and EMRO officially expressed their support to the CIPIH recommendation 3.6, stating that “the sponsors of the medical R&D Treaty should undertake further work to develop these ideas so that governments and policy-makers may make an informed decision”\(^\text{14}\).

Addressing the crisis in R&D is a government responsibility which demands leadership and accountable action. While in setting off initiatives of policy change it is important to grasp the relevance of all stakeholders, and their


\(^\text{14}\) CIPIH Report, page 107.
potential to block reforms, on the other hand Kenya believes that the breakthrough opportunity created within the IGWG dialogue should conduce member states to consider a set of legally binding obligations to support a needs-driven R&D agenda for health both in terms of sustainable science, equitable access and affordability of health technologies for those who need them, and in terms of predictable and long-term financing mechanisms.

As the legally mandated inter-governmental agency responsible for global health, the World Health Organisation has full legitimacy to take on the challenge of working with its member states to consider and develop this new instrument. Any attempt to change current polarizations in health R&D by means of a head-on attack would not be long-lived. That is why, in addition to focussing on the big picture, attention needs to be devoted to the policy changes that governments are pursuing already.

This incremental strategy entails significant advantages. It can subtly shift the public/private balance by replacing poor policies with new ones aimed at recovering public goods from the private sector, thereby increasing public scrutiny over R&D performances. More importantly, it can produce a positively disrupting demonstration effect. It can operate to persuade governments that structural change is possible, and that, in fact, they can influence the direction of this change. Similar incremental approaches have patiently formed the bedrock of bilateral and multilateral negotiations for long time: building up confidence among relevant actors, so as to allow negotiators to move another step forward.

### Phase 5: Getting products to patients

Development of a necessary product is just the first step. Innovation is however, useless without access. The new products have to be made available and accessible to those who need them, thus issues of production and distribution have to be considered, as well as issues of price. The pricing regime adopted by governments has to be sensitive to the needs of poor consumers, and the need to ensure there are sufficient incentives to make drugs available to them at the best possible prices. Central to this debate is the culture of access built around the given product, as in the case of the ASAQ anti-malarial therapy created by the partnership between Drugs for Neglected Diseases Initiative (DNDi) and Sanofi-Aventis. Another factor is the competition among industrial actors, essential to bring down prices, and the political will to remove all possible obstacles that may erode the product’s impact on people’s health (be it at the national level, or at the level of the WHO

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15 The fixed dose combination of Artesunate and Amodiaquine (ASAQ) produced by Sanofi Aventis in partnership with DNDi is the result of a patent free agreement with the pharmaceutical company, which allows for the comparatively low price of the three day treatment. The product was registered in Morocco, where it is also being produced.
3X5 strategy to treat HIV patients). The full and unobstructed implementation of all TRIPs flexibilities is the minimum condition for this to happen.

Some key principles for operationalizing this phase are as follows:

- Prices of products should be set on the basis that it is affordable to patients in developing countries that need those drugs. Where such products are being made available to public organisations, international institutions, and NGOs for use in programmes promoting access, they should as far as possible be made available at a “no profits–no loss” price or at a reasonable mark-up price with a modest profit. The underlying principle is that prices must be fixed with the aim of achieving access to medicines to all that need these medicines.

- Several proprietary and legal issues may emerge during this phase for example, who owns the product; is there a patent on the product; and who has the right to licence production. While it may be best to allow these issues to be dealt with by a specific designated Committee, it should be based as far as possible on the principle of no-patent and open licensing. Where a patent or other forms of monopoly rights are granted, it should be subject to conditions that are to be agreed upon and that make access of the final product possible to those that need the health product.

- Activities in this phase should aim in the longer term to build the local production capacity in developing countries. For this purpose, effective mechanisms/measures to promote transfer of technology should be set up.

### Financing Mechanisms

Currently, the most pressing financing need is for the development of the new medicines, both small molecules and vaccines and also diagnostic products. The Development phase is significantly more expensive than the discovery phase. On the other hand, there is currently no financial incentive to invest in Development as there are no markets for neglected diseases despite the enormous number of patients and large medical need. These patients are simply too poor to turn a profit!

A number of recommendations on resource flow and coordination have been made in past years\(^\text{16}\), and reiterated as late as 2005 (Resolution WHA 58.4) for concrete implementation. Kenya believes that the IGWG should definitely reconsider such a financial dynamic to be set in place, potentially to converge into a new Global Fund for Health Research. Making money efficiently available

\(^{16}\) The 1990 Commission on Health Research for Development, recommending that governments should spend 2\% of their health budgets on what it called essential national health research, and that donor nations should invest 5\% of their aid for health in developing countries, on research and strengthening research capacity.
to entities discovering and developing medicines for neglected diseases is and will be a major challenge for the IGWG.

The CIPIH report has noted that more funding is a necessity and it has to be provided on a sustainable basis if R&D efforts are to be effectively supported. The report endorsed strongly the “need for more resources if this research effort is to be sustained and the development of new arrangements that may facilitate the flow of new funds for a greater impact” and a “new approach which involves governments on a sustainable basis in the financing of health-related research relevant to developing countries”.

Examples of such innovative financing arrangements would include UNITAID\textsuperscript{17}, which can be considered the first development tax. However, a multilateral norm or agreement that would ask governments to fund R&D would have to address a number of different questions, in terms of derivation of money allocations (should allocations be based upon income, or level of development?). One interesting proposal is being tabled by the Leading Group of governments, representatives of international institutions, experts and NGOs that continue to discuss on the merits of a currency transaction development levy (CTDL), whose intent is solely to raise revenues for development, primarily health. This form of more structural tax on transactions, set at a very low level (0.005%), aims to redistribute wealth from the most prominent beneficiaries of globalisation, to those who have been left behind by the same globalisation. Financial transaction taxes are not a rarity, and CTDL is too low to significantly alter the behaviour of market agents, while high enough to mobilize significant revenues, especially if applied on broad scale. CTDL can easily and unilaterally be implemented, though, essentially as a domestic tax. The benefits to health are immense.

It is vital for the IGWG to have a focused discussion on the innovative financing arrangements that are available and to assess the viability of these mechanisms to provide sustainable financing for the architecture described above. A taskforce (of member states, experts, NGOs and Inter-Governmental Organisations) should be set up as soon as possible (and before the November IGWG meeting) to examine the various mechanisms available to provide on a sustainable basis funds to work the architecture. Recommendations of this taskforce may then be placed before the IGWG for consideration.

For purposes of the discussion, the Secretariat should prepare a background document listing, describing and providing an analysis of the different types/forms of financial mechanisms that are available and implemented globally. Submissions from interested stakeholders should be solicited and considered in the background document.

\textsuperscript{17} http://www.unitaid.eu
Other Issues

COLLABORATION & COORDINATION

For successful implementation of the architecture above, and as noted by the CIPIH report “domestic and international networks are critical for purposes of sharing information and new knowledge and the building of capacity in developing countries”\textsuperscript{18} including North–South partnerships and South-South partnerships. The report also notes that the latter networks have often been neglected in the past. In any case, these kinds of collaborations have to be further developed and intensified as part of the architecture described above.

Equally essential throughout the architecture is the need to build a mechanism for regular consultation with the donor community, actors involved in R&D, production and distribution of medicines, to enable more organized sharing of information and greater coordination between different players. This is essential to facilitate in particular phases 4 & 5 above.

This mechanism could also monitor progress and bring greater coherence to R&D on health problems of developing countries, which would also have the potential to mobilize long-term funding in support of such research.

MONITORING AND EVALUATION

An independent mechanism to monitor and evaluate activities at each phase mentioned above is an important element of the architecture. The M & E mechanism will identify the successes and failures at every phase as well as make appropriate recommendations for purposes of taking corrective measures.

A very important component of M & E is the involvement of relevant stakeholders through public hearings to provide substantive inputs for consideration. M & E should also include regular reporting to the Member States.

PROPOSED INSTITUTIONS FOR IMPLEMENTATION OF THE ARCHITECTURE:

The Plan of Action should set up appropriate structures to work the architecture above.

It is proposed that an institution that may be called the “Health Research Council” be set up consisting of the various Committees mentioned above and other structures necessary to work the architecture.

\textsuperscript{18} CIPIH report, p. 170

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There are certain elements in the Architecture above that are voluntary in nature, but there are other commitments that are binding in nature and will require to be implemented by all countries (for example some of the principles mentioned in phase 4/5 above).

The Plan of Action should also clearly set out time frames within which the necessary structures are set up and the relevant phases completed.

CONCLUSION

The Working Group is at a critical juncture. It has a mandate to draft a plan of action that delivers a “secure, 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”.

Merely reiterating the recommendations of the Commission and framing them as areas of action in the plan of action will not be sufficient to achieve the mandate. The Plan of action has to concretize an architecture that identifies implementing structures as well as set targets and time-frames within which the phases are to be completed.

We are of the view that the meeting in November should in particular spend time discussing and finalizing the architecture that will deliver results, for it to be approved by the Executive Board in January 2008 and the World Health Assembly in May 2008.

If it is not possible to finalise discussion during the Working Group meeting, we are supportive of obtaining a reasonable extension of time during 2008 WHA.

Finally we reserve the right to make further submissions on the Global Strategy and Plan of Action or other background papers.

Ministry of Health
Nairobi, Kenya
April 2007.

Kenya Submission to IGWG-2