

**GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH,  
INNOVATION AND INTELLECTUAL PROPERTY (A/PHI/IGWG/2/2):**

**PRELIMINARY COMMENTS BY THIRD WORLD NETWORK**

**TABLE OF CONTENTS**

<b>General Comment.....</b>	<b>2</b>
<b>The Context.....</b>	<b>3</b>
<b>The Aim.....</b>	<b>6</b>
<b>The Focus.....</b>	<b>7</b>
<b>Element 1: Prioritizing Research and Development needs.....</b>	<b>8</b>
<b>Element 2: Promoting Research and Development.....</b>	<b>13</b>
<b>Element 3: Building Innovative Capacity.....</b>	<b>20</b>
<b>Element 4: Transfer of Technology.....</b>	<b>25</b>
<b>Element 5: Management of Intellectual Property.....</b>	<b>31</b>

## **General Comment**

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”.

The WHA Resolution can be read as listing the following tasks:

- (i) **General:** The global strategy and plan of action (GS/POA) should draw up a medium term framework based on the recommendations of the Commission.
- (ii) **Specific Focus:** The aim (among others) of the GS/POA is to secure an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries.
- (iii) **Specific:** The GS/POA propose clear objectives for research and development
- (iv) **Specific:** The GS/POA propose priorities for research and development
- (v) **Specific:** The GS/POA should estimate funding needs in this area.

Overall in trying fulfill the mandate of the WHA Resolution, the draft global strategy and plan of action prepared by the WHO Secretariat (hereinafter referred to as the Sect’s text) has included several points from the CIPIH report. However much more work on the document needs to be done as it reveals several shortcomings.

- (a) A number of vital recommendations of the CIPIH are either not reflected or are inadequately reflected. See for example, CIPIH recommendations 2.7, 3.1, 4.6, 4.16, 4.21.
- (b) In some cases, the specific action proposed by the Plan of Action, takes a step backward, although there is already a concrete finding/recommendation on that issue in the CIPIH report.

For example on the issue of data exclusivity, the specific action proposed is “Assess the impact of data exclusivity regulations”.

On this however, the CIPIH Report has recommended that “A public health justification should be required for data protection rules going beyond what is

required by the TRIPS agreement. There is unlikely to be such a justification in markets with a limited ability to pay and little innovative capacity. Thus, developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS. (Recommendation 4.20, p. 144 of the Report.)

- (c) **The Sect's text does not provide a coherent, well-organised and considered text intended to provide a concrete medium term framework. In fact in many places the text is vague. There is also no apparent logic in the way in which the Sect's text is organized. The text fragments many interrelated issues, without making proper cross-references. For example several areas in technology transfer would also relate to building innovative capacity and to promoting R&D. IP related issues would emerge almost under every element. Financing should be linked with prioritized diseases and other areas to be financed, but this link is not apparent.**

**This has resulted in a text that is large and unwieldy, significantly diluting the effectiveness of the text as a global strategy and plan of action that will provide a medium framework based on the recommendations of the Commission with the aim inter alia of securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries.**

- (d) **Progress Indicators in the Plan of action: Many of the indicators are quantitative in nature, even where perhaps such indicators are not suited. In some cases, the indicators are vague and/or disconnected from the specific action proposed and since there is no explanation, the intent of these indicators remains unclear. Some of the indicators are also not fully thought through.**
- (e) **There is also little clarity as to which organisation is taking the lead in implementing the actions proposed in the global strategy and plan of action**
- (f) **In relation to point (5) the text does not provide an estimation of funding needs.**

*\* A more detailed analysis of Element 1 (Prioritising R&D); Element 2 (Promoting Research and Development); Element 3 (Building Innovative Capacity); Element 4 (Transfer of Technology); Element 5 (Management of IP) is found below.*

#### *The context*

1. In resolution WHA59.24 the Health Assembly recognized the growing burden of diseases and conditions that disproportionately affect developing countries, and particularly women and children. Reducing the very high incidence of communicable diseases in those countries is an overriding priority. At the same time, it is important to ensure that the increasing prevalence of non-communicable diseases in those countries is

recognized and addressed.

2. Governments, the pharmaceutical industry, charitable foundations and nongovernmental organizations have made progress in recent years by funding initiatives to develop new products against diseases affecting developing countries and to increase access to existing products. However, these initiatives have proved inadequate to surmount the challenges. Much more must be done in relation to the scale of avoidable suffering and mortality.

3. Advances in biomedical science have provided opportunities to develop new, affordable health products, and in particular to meet public health needs in developing countries. These opportunities must be harnessed more effectively and more urgently.

**Comment:**

**The context presented in the negotiating text fails to capture many of the important issues that have been highlighted by the CIPIH report and which led to WHA 59.24.**

**Some key points from the CIPIH report and the WHA 59.24 that should be stated in the above section are as follows:**

**ON RESEARCH & DEVELOPMENT:**

- **The burden of infectious diseases that disproportionately affect developing countries continues to increase.**
- **In contrast to developed countries, developing countries are increasingly suffering from the *double* burden of disease (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)**

- **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)**
- **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 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)**
- **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, 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)**
- **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) Thus there is a need to urgently understand the needs of developing countries, undertake prioritization of R&D on the needs of developing countries and to identify a sustainable framework to respond to these diseases.**

#### **ON ACCESS**

- **IP has effect on the prices of medicines (Doha Declaration para 3) and high prices of medicines has an impact on access to treatment (WHA 59.24).**
- **Competition from generic medicines has been essential in reducing the prices of medicines and improving access to medicines to all, thus it is important to ensure a pro-competitive implementation of the TRIPS Agreement.**

- **The Doha Ministerial Declaration on the TRIPS Agreement and Public Health confirms that the Agreement does not and should not prevent Members from taking measures to protect public health (Doha Declaration).**
- **Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all (Doha Declaration).**
- **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.**

*The aim*

4. The aim of the proposed global strategy on public health, innovation and intellectual property is to provide a medium-term framework for an enhanced and sustainable basis for needs-driven, essential research and development relevant to diseases that disproportionately affect developing countries.

5. The global strategy, designed to promote innovation, build capacity and improve access, will:

- establish a research and development agenda that covers the health needs of developing countries
- propose mechanisms to carry out the above research and development agenda, including increasing worldwide capacity for research and development, particularly in developing countries, into diseases affecting those countries
- secure financing for the activities resulting from the research and development agenda, including exploring innovative financial mechanisms
- seek to increase the availability, accessibility and uptake of health products (in particular, medicines, vaccines and diagnostics) in developing countries.

**Comment**

**Paragraph 4 should be amended to include after the word framework “based on the recommendations of the CIPIH Commission. Such a strategy and plan of action aims to address the urgent need to take action to ensure access to medicines for all, and also to secure”**

**In paragraph 5, and additional para should be added i.e.**

**-- provide an understanding of the public health needs of the developing countries and identify R&D priorities, at the national, regional and global level**

*The focus*

6. The focus of the strategy will be on diseases or conditions of significant public health importance in developing countries for which an adequate treatment for use in resource-poor settings is not available – either because no treatment exists or because, where treatments exist, they are inappropriate for use in countries with poor delivery systems, or unaffordable. The Commission highlighted the need to focus on Type II and Type III diseases and the needs of developing countries in relation to Type I diseases.<sup>1</sup>

7. The eight elements agreed by the Intergovernmental Working Group at its first meeting provide the organizing principle for the plan of action.<sup>2</sup>

**Comment:**

**Sect’s text in footnote 1 pg. 4 of doc. A/PHI/IGWG/2/2 states that “the strategy will focus” on the following diseases:**

**Type I: diabetes, cardiovascular disease, cancer,**

**Type II: HIV/AIDS, Tuberculosis,**

**Type III: Chagas disease, dengue and dengue haemorrhagic fever, leishmaniasis, leprosy, lymphatic filariasis, malaria, onchocerciasis, schistosomiasis and human African trypanosomiasis.**

**However it is not clear from the footnote whether these diseases are the diseases being prioritized as required by the WHA Resolution, or whether the intention is to limit application of the GS/POA to only these diseases. The wording of the text seems to suggest the latter.**

**The IGWG is mandated by the WHA and should be guided by Resolution 59.24.**

**The focus in the WHA Resolution is on “needs driven”, “essential R& D relevant to diseases that disproportionately affect developing countries”. This is the focus of the Strategy and should be reflected as such in this part.**

**In some cases the needs of the people are well known, while in other cases the needs are not so well known.**

**Where needs may be better understood are e.g. “TB” and HIV/AIDS. For example in the case of TB, people with Extensively Drug Resistant (XDR) TB are resistant to both of the first-line antibiotics as well as to two classes of second-line drugs, making treatment with existing drugs virtually impossible. It is known that there is an urgent need for new R&D for TB as patients become more and more resistant to older drugs. The same is the case for HIV/AIDs cases, where it is known that there**

**needs to be more R&D into pediatric formulations and simpler combinations.**

**Further needs may vary from region to region and from country to country. But there is definitely the need for better understanding of the “needs” at the national, regional and global level.**

**The objective of conducting a “needs assessment” would be among others as follows:**

- (1) to compile information on diseases where there is lack of treatments, e.g. TB**
- (2) to compile information on diseases where there are existing treatments but they are not suitable or they are inadequate for e.g. due to weather conditions or simpler treatments are required.**
- (3) to compile information on diseases where there are existing treatments but the treatments are not affordable to patients in need.**

**Needs assessment should reveal the situation in relation to (1) to (3) at the country, regional and international level for all the three types of diseases. There may already be existing efforts on “needs assessment” either by WHO or by other organizations. If this is the case, then WHO should collect, collate and track all of this information and organize it so that it may inform IGWG negotiators. Where there are gaps in the “needs assessment” it should be addressed immediately.**

#### **ELEMENT 1. PRIORITIZING RESEARCH AND DEVELOPMENT NEEDS**

8. Health research and development policies in developed countries need to reflect adequately the health needs of developing countries. Gaps in research on Type II and Type III diseases and on the needs of developing countries in relation to Type I diseases need to be identified urgently. A better understanding of disease determinants is essential to drive sustainable research and development on new and existing products.

9. The actions to be taken to prioritize research and development needs are as follows:

(1.1) identifying gaps in research on diseases that disproportionately affect developing countries

(a) develop methodologies to identify gaps in research on Type II and Type III diseases and on developing countries’ needs in relation to Type I diseases

(b) provide an assessment of identified gaps.

#### **Comment on paragraph 8 & 9 (1.1) (a) & (b):**

**In the introductory paragraph of element 1 it is not clear whether the “Gaps” analysis is only limited to the 15 selected diseases, which the Secretariat has proposed, as the focus of the Strategy. This has to be clarified.**

The diseases selected by the Secretariat for Type II and Type III diseases are diseases where the gaps ought to be well documented compared to others. For example in relation to the selected Type III diseases, WHO's Special Programme for Research and Training in Tropical Diseases (TDR) has been conducting research on the 10 diseases selected since 1975. And as such they should be very familiar with the research gaps.

It is argued here that the Global Strategy and POA should take a broader approach and set the pace for an overall increase in R&D effort on diseases of developing countries.

The CIPIH report also states that one key issue to consider is "Actions that might contribute to increasing the overall R&D effort on diseases that predominantly affect the developing world, and improve priority setting. For example, recognizing the possible need for increased support for those that currently receive less attention than HIV/AIDS, TB and malaria."

According to the 10/90 Report on Health Research by the Global Forum for Health Research it is the failure in practically all countries to establish a process for priority setting based on the burden of diseases and their causes has led to a situation in which only about 10% of health research funds from public and private sources are devoted to 90% of the world's health problems. This extreme imbalance in research funding has a very high economic and social cost for individuals, countries and the world as a whole. To make matters worse, the Report says even the 10% of funds allocated to the 90% of the world's health problems are not used as effectively as they should be.

On this point the CIPIH Report also states that "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. Such a Plan would also provide an important basis for measuring progress towards the achievement of these goals. (CIPIH p. 206).

From these statements it is clear that what is really needed is to understand the needs of developing countries across the board, to prioritise research (at national, regional and international levels) and to ensure that adequate funds are allocated to the prioritized R&D (at all levels) and to regularly evaluate the impact of resources devoted to the research, treatment and delivery.

It has been said that the "List of priorities are only as good as their inputs and the process leading to the identification of these priorities".<sup>1</sup> Thus what is vital is to identify a process to set priorities for R&D (building on existing work) and to come

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<sup>1</sup> The 10/90 Report on Health Research 2003-2004, Global Forum for Health Research.

**up with results within the next one year. The Global Forum for Health Research has pointed to serious deficiencies in the availability and quality of data on health research and measurable efforts should be taken to correct them.**

(1.2) facilitating upstream research on new and existing products for diseases that disproportionately affect developing countries

(a) improve accessibility to compound libraries for identification of compounds with potential activity against the above-mentioned diseases, by means including public-private collaboration

(b) provide technical support to developing countries in order to create libraries of new compounds at both national and regional levels.

(1.3) coordinating research activities between developed and developing countries

(a) coordinate international efforts in research and development in order to optimize resources

(b) support developing countries in building technological capacity.

(c) promote the active participation of developing countries in the innovation process.

(1.4) formulating explicit prioritized strategies for research and development at country level

(a) developing countries to set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments

(b) conduct research appropriate for resource-poor settings and research on technologically appropriate products to combat diseases in developing countries (including Type I diseases)

(c) include research and development needs for traditional medicines in a prioritized strategy.

**Comment:**

**Generally there is a need for stronger focus on access to upstream technologies for developing countries. While some of the specific actions and progress indicators are useful, others need to be worked on. For example in relation to Element 1.2 (a), the progress indicator is number of accessible databases facilitating information exchange on innovation for product development. It is not clear what ‘accessible’ means. Is it accessible for a fee (how high or low is this fee) or is it accessible free of charge. Just increasing the number of databases may not be sufficient, the question is how accessible are these databases.**

Also element 1.2 (a) is about improving access to compound libraries, while progress indicator (i) is general about “facilitating information exchange on innovation of product development” (i.e. which is broad and it could include or may not include access to compounds). Thus there seems to be a disconnect between 1.2 (a) and the progress indicator (i).

On progress indicator (ii), in Element 1.2 (a) which states, “No. of agreements reported by companies or institutions, including academic institutions, to allow access to compound libraries for public interest research”. The issue here is not only measuring quantitatively but also qualitatively whether there is an increase in the number of agreements, what are the terms and conditions of these agreements, and the type of research for which compound libraries are given access to (i.e. is free access to compound libraries being given for research into R&D for diseases of developing countries.)

In addition, points (1.2) – (1.4) are rather general in nature and it is not clear whether it applies to the prioritized diseases or to all diseases,

This happens to be one of the shortcomings of the Secretariat’s text. It fails to make a distinction between specific actions for diseases that are selected for priority R&D and that require special treatment and other general actions points based on the recommendations of the CIPIH report

**Combining specific actions on diseases prioritized with general action points applicable to all diseases dilutes the purpose and effectiveness of GS/POA.**

**The POA should present a specific section on action that is to be taken once the diseases have been prioritized for R&D and a decision is taken to allocate funds to these R&D. The purpose of this section would be to identify a process and provide guidelines on how R&D will be conducted on these areas of priority (e.g. would the upstream research be patented or should the data be placed in the public domain), estimate financing that is required, provide principles on how the product will be treated (i.e. whether there it will be patented), priced and delivered to patients who need them. These areas of R&D (and the partners conducting the R&D) should also enjoy special treatment in relation to access to compound libraries or to research tools for essential research and the GS/POA should give guidance to all R&D actors on how this will be facilitated.**

On this there needs to be a major move to obtain a public commitment from every pharmaceutical company and other entities involved in research that it will grant access to its compound libraries for the purposes of conducting R&D on the prioritized diseases.

Matters and the mechanisms to facilitate R&D on the prioritized diseases should explicitly be fleshed out in the GS/POA.

Considering that the heading of the element 1 is “Prioritizing research and development needs” perhaps the matters can be fleshed out in this under this heading, with progress indicators that reflect the urgency of the matter and that provide qualitative and quantitative assessments as appropriate.

### *A proposal for prioritised R&D<sup>2</sup>*

A R&D model to consider is the DNDi R&D model for its recent malaria combination therapy artesunate (AS) and amodiaquine (AQ). It was produced through public financing, strategic alliance with different R&D actors and with no patent on the medicine. The offer price is at a “no profit no loss” for public organizations of endemic countries, international institutions, NGOs, and programs promoting access to drugs in pharmacies.

Following the DNDI R&D model, WHO should take leadership on the prioritised R&D. 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 Evaluation (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 to satisfy the needs prioritised.

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 grant may need to be given for R & D to take place, in other cases, institutions or companies may offer to conduct certain stages of R & D, without any financial support. Certain aspects of biomedical research perhaps can be conducted by mobilising scientists to address the health problems of developing countries, through open source approaches. Reward systems such as “prize funds”, could also be considered and used where appropriate. In short for R&D in disease of developing countries to happen, it will require public funding, the formation of innovative and strategic alliances<sup>3</sup>, and in some cases the offer of appropriate incentives.

Some key principles for operationalising R&D are:

- R&D should work towards developing a product that is adapted to the needs of developing countries<sup>4</sup>, and the needs of patients of all ages, simple (in terms of

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<sup>2</sup> Many aspects of this proposal are from the African Group submission

<sup>3</sup> For example between DNDi & Sanofi Aventis with the involvement of many other partners at different stages of R & D of Artesunate-Amodiaquine Winthrop, a new Artemisinin Combination Therapies (ACT) for treatment of malaria.

<sup>4</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.

using, prescription and storage), accessible (in terms of availability & affordability) and of quality.

- Since the R&D is being funded through public funds, the output should not be patented and the research data obtained through the use of funds within this framework should be treated as a public good and put in the public domain.
- Prices of products produced should be fixed on the basis that it is affordable to patients in developing countries that need the drugs. 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 profits- no loss” price while for other entities 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.
- Activities in this phase should aim to use the scientific talent in developing countries and in the longer term to build the R&D and production capacity in developing countries, thus where possible R & D and production should be undertaken in developing countries or in collaboration with institutions in developing countries.

Financing is a crucial issue for all stages of the above model, from research to delivery. Presently resources are used for purchasing costly medicines while significantly less is devoted to research. This model is based on the premise that with more public funding focused on prioritised R&D, the output medicines will be more reasonably priced, affordable and more acceptable to patients that need the medicines. Over time, with this model, less resources will be needed for the purchase of downstream products (as they cost much less), and thus more financial resources will be available for the R&D on diseases of developing countries. A better understanding of disease determinants can contribute to more efficacious use of resources as well.

## **ELEMENT 2. PROMOTING RESEARCH AND DEVELOPMENT**

10. This element covers both the discovery and development aspects of the innovation cycle. The range of measures to promote, coordinate and finance public and private research in both developed and developing countries into Type II and Type III diseases and into the needs of developing countries in relation to Type I diseases needs to be substantially enhanced. Greater investment, in both developed and developing countries, is required. In this context, developing countries should consider the appropriate level of investment necessary to strengthen research and research capacity.

11. The actions to be taken to promote research and development are as follows:

(2.1) increasing funding for research and development that focuses on the health needs of developing countries

*(a) developed countries to devote a larger proportion of their health research and development budgets to the health needs of developing countries.*

**Comment on paragraph 2.1 (a) :**

**The CIPIH report recognized that “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)**

**CIPIH further said “We endorse 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 greater impact.”**

**Although the CIPIH report placed significant emphasis on the issue of “sustainable financing”, Secretariat’s document does not propose adequate actions on how the issue of financing will be addressed, how will it be allocated, and what principles will govern the allocation (e.g. will the recipient be allowed to patent the medicine or the upstream research if it receives funding)**

**There is a need to begin discussions and investigations on innovative models for sustainable financing, besides direct contributions by member states and donors. Discussions on this matter should urgently be conducted in 2008.**

(2.2) supporting governments in improving national health research programmes and facilitating better coordination of stakeholders in this area

*(a) promote cooperation between private and public sectors on research and development*

*(b) provide support for national health research programmes in developing countries through political action and long-term funding*

*(c) develop and implement systems for supporting health-related innovation in developing countries (including intellectual property management).*

**Comment paragraph 2.2 (c):**

**Here WHO plays a crucial role. It should provide guidance to developing countries on policies that should be adopted or incentives that should be given to support health-related innovation. For example on IP what are the policies that should be adopted by a LDCs to encourage health related innovation. It is quite clear (even in**

**the TRIPS Agreement) that LDCs need maximum flexibilities (i.e. no IP protection) to develop a technological base.**

**The issue is not only about “management of IP” (this phrase needs to be defined) but also about adopting the right policy with regard to IP.**

**Thus in paragraph 2.2 (c), the phrase “including intellectual property management” should be modified to “including using IP safeguards such as compulsory licensing and intellectual property management”**

**The progress indicators to para 2.2(c) seem rather inadequate. Progress indicator (i) states: “No. of countries with appropriate management and monitoring system”. It however does not mention “management and monitoring” of what? Is it referring to the research undertaken nationally? This has to be clarified.**

**The more important issue is what are the results of the research and how can it be translated into a useful product and for this purpose what kind of support will be provided by the international community.**

**In relation to indicator (ii), where it states: No of countries with IP management capabilities to support research institutions - it is not clear what is meant by “IP management”. The term until defined remains vague. It should also be clarified how it will be assessed whether a country has IP management capabilities.**

**In any case if the progress indicator is to be retained, it should also include capabilities to use IP safeguards such as compulsory licensing.**

(2.3) promoting upstream research and product development in developing countries

*(a) promote discovery science, including through open-source methods, in order to develop a sustainable portfolio of new products*

*(b) promote access to drug leads identified through the screening of compound libraries*

*(c) promote basic and applied scientific research on Type II and Type III diseases*

*(d) promote early-stage drug research and development in developing countries*

*(e) developing countries to consider legislation that is compliant with the Agreement on Trade-Related Aspects of Intellectual Property Rights relating to research exemptions*

*(f) promote public funding for clinical trials and other mechanisms for stimulating local innovation*

### **Comment**

### **Paragraph 2.3 (a)**

The idea of promoting discovery science including through accessible open source methods is good but it is rather disconnected from the progress indicators. For example, what has the no of pharmaceutical companies involved in existing network (here there needs to be clarification on what the network is about) and partnership activities (see progress indicator (i) got to do with promoting discovery science.

### **Paragraph 2.3 (b)**

A major problem is access to compound libraries which is crucial for promoting R&D in developing country diseases. However often there is resistance in opening up the libraries.

According to the CIPIH report in p. 56-57, “Annotated proprietary compound libraries are one of the most important elements of a company's competitive strength. They may contain a million compounds, both natural and synthetic, and are repeatedly tested against newly emerging therapeutic targets. Because of their potential value for developed country markets, companies do not generally provide access to their compound libraries, even for public or non-profit researchers working on diseases of low or no commercial value. Some universities have also developed publicly available compound libraries.”

It further adds that “High-throughput screening of biological assays against the compounds in these libraries could provide essential leads for potentially efficacious compounds.”

On this however, the progress indicator (i) seems rather weak although the CIPIH report states that WHO should take “Actions” to overcome the difficulties experienced to date in accessing this resource. However in terms on “Actions”, little is found in the text.

One step for WHO could be to make a list of all institutions/universities that allow free access to its compound libraries (and other upstream technologies) and to make this information publicly available.

The next step is to strongly encourage companies to undertake to allow access to its compounds libraries where it concerns R&D on diseases that have no market value to the company. This should be reflected in the text.

Where there are inaccessible technologies or impediments faced by developing countries' entities these should be documented and a mechanism employed to facilitate access.

### **Paragraph 2.3 (c)**

**The idea of promoting basic and applied research is generally a good idea.**

**What is troubling is the progress indicator (i) i.e. “No of patents held by developing country research and academic institutions”.**

**It is not clear to what extent the holding of patents is a true indicator that basic and applied research is actually taking place. It should however be noted that there is an ongoing debate to what extent patents should be taken out on upstream research. There is evidence that patenting of early "upstream" research, could also deter downstream and follow-on innovation by successive inventors, limiting technological progress (see below).**

**Progress indicator (ii) i.e. the No. of operational collaborative North-South and South –South projects is also not an adequate indicator. Even if there is an increase in the number of collaborative projects, it does not automatically mean that there is promotion of basic and applied scientific research. The issue is not how many collaborative projects exists but really the kind of research these projects engage in (i.e. whether it is new basic and applied scientific research on diseases of developing countries) and the form of participation by developing country researchers in these projects i.e. whether it is increasingly being executed by developing countries entities.**

**A specific action point could be that WHO should provide appropriate support to translate basic research (conducted on developing country diseases) into a product, (e.g. by providing assistance to the research institute from developing country to link with other R&D partners so as to enable translation of the research into products). It is not sufficient in the indicator [see (iii)] to merely mention: how many applications are translated into products. A mechanism has to be set up through which WHO or a specified entity can act as an intermediary to find suitable partners to translate the research into a product.**

### **Paragraph 2.3 (e)**

**The language used in the specific action should be replaced along the lines of the language used in the CIPIH recommendation i.e. “Developing countries need to consider in their own legislation what form of research exemption might be appropriate in their own circumstances to foster health-related research and innovation.”**

**The language used in the Secretariat’s document is inappropriate for the following reasons (1) not all WHO members are members of the WTO and non-WTO members are not bound by the TRIPS Agreement; (2) LDCs (WTO Members) have flexibility until 2013 (and beyond that, on request) to not apply the provisions of the TRIPS Agreement. In both scenarios countries are not limited by Article 30 of the TRIPS Agreement and should be encouraged to go beyond Article 30 of the TRIPS**

Agreement.

The progress indicator should be amended appropriately.

**Some proposals for consideration**

(1) The CIPIH report raised the issue of broad IP protection hampering access to research tools and upstream technologies which is not addressed in the text. The CIPIH report says that there is very little empirical evidence about the impact of research tool patents in the biomedical field in developing countries themselves. The impact of such patents may be more significant than in developed countries as research institutions or companies in developing countries generally lack the legal and negotiating capacity to engage in complex negotiations and the organizational flexibilities and funds to pay licence fees (CIPIH p.65).

A survey conducted of 103 Indian firms 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 (CIPIH p. 65).

WHO itself when it came to SARS said that “WHO intends to monitor the effects of patents (and patent applications) on the speed with which SARS diagnostic tests, treatments, and vaccines are developed and made available for use and on the manner in which prices are set for these technologies.” This was in response to the many patents being filed on the SARS genome and the virus itself.

The same situation is happening in relation to avian flu, where there are patent applications on parts of the virus e.g. the genes and the sequences and this could further hamper R&D into avian flu vaccines, which poses an imminent threat of a global pandemic.

Thus in promoting upstream research and product development, one specific action point should be that WHO solicit, collate and document evidence on the patent practices in relation to upstream technologies and research tools particularly in the developed countries and the impact of broad IP protection on access to research tools and upstream technologies on R&D of products. It should also analyse the impact of such patenting practices on the biomedical field in developing countries.

Secondly there has to be a major push to strongly encourage the adoption of “no patent” policy on upstream technologies and research tools among stakeholders involved in research in developed countries. In this case the progress indicator could be the number of institutions and other stakeholders involved in R&D adopting such a policy.

There should also be strong encouragement to the use of TRIPS flexibilities for

**WTO Members to access patented tools and technologies. In relation to this, WHO's in-house legal experts in IP (which is proposed under the element of IP) could assist countries firstly to incorporate the right kinds of flexibilities in its legislation to promote access to upstream technologies and research tools and secondly to encourage and assist in the use of TRIPS flexibilities.**

**For Non-WTO countries and LDCs (WTO and non-WTO countries), WHO should promote flexibilities that go beyond the TRIPS Agreement as the TRIPS Agreement is not yet applicable.**

**On this issue, the CIPIH report states that "Countries should seek through patenting and licensing policies to maximize the availability of innovations, including research tools and platform technologies, for the development of products of relevance to public health, particularly to conditions prevalent in developing countries."**

**The CIPIH report also states that "An emphasis on patenting and licensing as the chief means by which technology transfer takes place, as compared to publication and open knowledge sharing, may have negative implications for research in the area of public health as well as others. Since revenue prospects will be greater for products which will have a developed country market, this may further distort the allocation of research funding way from the specific public health problems of developing countries. Therefore, care must be taken to ensure that research priorities, particularly those that could directly benefit poor people, are not distorted by the quest for larger licensing income.**

**It recommends that "Developing countries should ensure that their universities and public research organizations maintain research priorities in line with their public health needs and public policy goals, in particular the need for innovative research of benefit to the health problems of their populations. This should not exclude support of health-related research which meets their industrial or export objectives and that could contribute to improved public health in other countries."**

**This should also be reflected in the negotiating text with appropriate indicators.**

**(2) There should also be a section on exploring new incentive for R&D into developing country diseases in view of the fact that IP is not an appropriate incentive for this purpose.**

**This section on incentives for R&D is erroneously placed under the Element of IP. It should be removed and placed under this Section.**

**(2.4) improving global coordination and financing of medical research and development**

*(a) improve global coordination and financing, using systematic reviews and needs assessment*

*(b) set up a forum, or enhance existing ones, in order to improve the coordination of research and development activities and sharing of information*

*(c) support further discussion of a medical research and development treaty.*

<b>ELEMENT 3. BUILDING AND IMPROVING INNOVATIVE CAPACITY</b>
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12. *There is a need to frame and support effective policies that promote the development of capacities in developing countries related to health innovation. Key areas for investment are capacities relating to science and technology, clinical trials, regulation, intellectual property and traditional medicine.*

**Comment**

**Regarding the Element 3, Building and Improving Innovative Capacity, the CIPIH says “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.”. This comment of the Report should be added to paragraph 12.**

**Paragraph 13(3.1)**

*(3.1) building capacity of developing countries to meet research and development needs for new health products*

*(a) support investment by developing countries in human resources and knowledge bases, especially in tertiary education*

*(b) support existing and new research and development groups in developing countries.*

**Comment**

**Paragraph 3.1 (a) should be modified to reflect CIPIH recommendation 5.1 which calls on Governments to make the investments with the support of donors.**

**CIPIH Recommendation 5.1: “A prerequisite for developing innovative capacity is investment in the human resources and the knowledge base, especially the development of tertiary education. Governments must make this investment, and donors should support them.” There should also be an explicit indicator regarding donor support to governments making such investments either quantitatively or qualitatively. The indicators related to 3.1 (a) & (b) , (i) ,(ii) and (iii) i.e. on how many degree courses are provided, new R&D supported only measures opportunities, rather than the impact for**

example the number of trained R&D researchers/professionals available as a result of the support.

A specific action that WHO can undertake is to mobilize for and provide support (financial and otherwise) to generic manufacturers in developing countries especially the least developed countries to acquire new technologies, obtain WHO prequalification status etc with the aim of boosting production for domestic and export markets.

The progress indicator for this could be the increase in support, by whom, what type of support, to which manufacturers, and the results/impact of providing that support.

It should be noted that it is inadequate to speak of building innovative capacity without mentioning transfer of technology issues. Appropriate linkages have to be made.

*(3.2) framing and supporting effective policies that promote the development of capacities for health innovation*

*(a) strengthen product regulatory capacity in developing countries*

*(b) strengthen human resources in research and development in developing countries through a long-term plan for human resources*

*(c) address appropriate training and retention of researchers and health professionals, including issues relating to migration.*

#### **Comment Paragraph 3.2 (a)**

The para should include more systematic approaches to pharmaco-vigilance and rational use of medicines. Concerning clinical trials, the CIPIH provides an indicator, in quoting from a study, “efforts should be focused on the establishment and strengthening of locally controlled and managed research centers able to pursue their own priorities and R&D agenda.” There are no explicit indicators here that account for (i) support for local research centers; (ii) independence to pursue their own priorities and R&D agenda. Appropriate indicators to this effect should be included.

In relation to paragraph 3.2 (a), according to the Plan of Action the government is the lead stakeholder in strengthening regulatory capacity of developing countries. However recommendation 5.8 in the CIPIH Report states that “WHO has an important role to play” to strengthen clinical trials and regulatory infrastructure, particularly in Sub-Saharan Africa, including ethical review standards.”

WHO should play an effective role in relation to paragraph 3.2 (a) and this should be reflected in the text. There are many factors involved in strengthening regulatory capacity human, financial and political leadership and WHO should provide to the government the support needed to strengthen its regulatory capacity.

One aspect that needs to be clarified is in relation to progress indicator (i) is what is meant by “international standards” i.e. which standard is it referring to. Is there an existing criteria for assessment and does this criteria take into account the public health choices and needs of the country concerned. Perhaps the wording should be modified as follows: “No of developing countries able to undertake the minimum set of regulatory standards needed to ensure that good quality products are available for use”. This wording would be consistent with Recommendation 5.6 of the CIPIH as well.

CIPIH Recommendation 5.6 states i.e. “Developing countries need to assign a higher priority to improving the regulation of medical products. Developed countries, and their regulatory institutions, should provide greater financial and technical assistance to help attain the minimum set of regulatory standards needed to ensure that good quality products are available for use. This assistance should also support infrastructure developments within a country, to ensure that good manufacturing practice and supply chain management standards are implemented and sustained.”

There has to be an express obligation on the developed countries to provide assistance on regulatory issues. Recommendation 5.6 should be reflected adequately in the text.

The role of WHO would be to monitor the nature of collaborative projects between developed and developing country agencies, identify the shortcomings and successes of these projects while also providing guidance to developed countries and donors on the type of assistance required to help developing countries attain the minimum set of regulatory standards.

#### Comment paragraph 3.2 (b)

Indicators (b) (i) & (ii) indicators are ill suited to their objectives. They measure variables without regard for even an indication of the scale of human resources required and the appropriateness of their research R&D skills in relation to priority R&D.

For example instead of measuring the increased rate of trained researchers working in their field, the measure should be the increase in the number of researchers actually available in a country and in areas of specialisation related to diseases of developing countries. Appropriate indicators are also required to track the types of specialisation of health professionals in developing countries.

Further in relation to (i) the text takes a quantitative approach i.e. how many countries have human resources plans. Countries that have a plan will therefore be regarded as making progress. However having a plan does not indicate an increase in the quality and quantity of human resources available to a developing country.

In addition, the Sect.’s text does not or inadequately reflects the differences in needs of developing countries, based on their different levels of innovation capacity. In

particular the CIPIH adds that the determinants of that capacity are many, each country has a unique set of institutions which means “there is no single recipe for advance.” The CIPIH categorizes and describes different developing countries based on economic strength and innovative capability:

FIGURE 5.1 TYPOLOGY OF INNOVATIVE CAPABILITY

Economic strength	Low	Innovation capability	High
High		I	II
Low		III	IV

Source: CIPIH<sup>5</sup>

Developed countries rate high in both economic strength and innovative capability (II), while developing countries are rated low (III) or in different combinations (I or IV).

There should be a qualitative assessment of the human resources plan, based on the innovative capacity and needs of countries.

### Paragraph 13(3.3)

*(3.3) providing support for innovation capacity building in developing countries, including in areas such as science and technology, regulation, clinical trials, the transfer of technology, traditional medicine and intellectual property*

- (a) document and disseminate best practices in innovation*
- (b) promote successful models in developing innovative capacity*
- (c) intensify North-South and South-South partnerships and networks to support capacity building.*

### Paragraph 3.4

*(3.4) develop and implement policies that will promote innovation based on traditional medicine*

- (a) develop and promote traditional medicine within an evidence-based framework*
- (b) promote documentation of traditional knowledge and natural genetics resources*
- (c) encourage developing countries to ensure high standards of safety and efficacy for traditional medicines*
- (d) encourage research on mechanisms for action and pharmacokinetics of traditional medicines.*

<sup>5</sup> CIPIH Figure 5.1

## Comment

There are many issues involved when promoting innovation based on traditional medicines. These issues although discussed in the CIPIH report, are not reflected in paragraph 3.4.

One issue is fair and equitable benefit sharing. On this the CIPIH report states “An important ethical question is how any commercial benefits that might derive from the use of traditional knowledge should be shared with traditional knowledge holders.” (CIPIH p. 181). The issue of benefit sharing is currently being discussed at the UN Convention on Biological Diversity. The CIPIH report has expressed support for the principles contained in the Convention of Biological Diversity.

A related issue currently being discussed in WTO and WIPO, is that patent applicants should be obliged to disclose the geographical origin of the knowledge on which their claimed invention is based (disclosure in patent applications).

Both issues are major issues for developing countries, but are not mentioned at all in paragraph 3.4. These issues are being discussed in other fora so as to guard against misappropriation or biopiracy of the genetic resources and associated traditional knowledge of the developing countries.

In paragraph 3.4 (b) the nature of the database sought to be put in place is not clear. Nor is there clarity as to whether principles of prior informed consent will be abided. On this the CIPIH states in recommendation 5.10 that “Holders of the traditional knowledge should play a crucial role in deciding whether such knowledge is included in any databases and should also benefit from any commercial exploitation of the information.”

It is a principle of the CBD (which almost all countries are a party to) that countries have sovereign right over their own resources. As such it is up to each country to decide whether to establish a database documenting its genetic resources and traditional knowledge or not to establish such a database. It would seem to be improper to give this task to WHO (see 3.4 (a) above) that has no expertise on genetic resources and associated traditional knowledge.

Having such databases may also facilitate misappropriation (i.e. genetic resources and associated traditional knowledge used without prior informed consent or any benefit sharing with, the country of origin) since the appropriate international regimes on access and benefit sharing regimes as well as disclosure in patent applications are still under discussion in other fora.

It is proposed that paragraph 3.4 be modified. It currently is about promoting

innovation based on Traditional medicines. However as explained above, since the necessary regimes on access and benefit sharing and disclosure in patent applications are currently being discussed, it may not be appropriate for WHO to discuss promoting innovation based on traditional medicines without considering ways to guard against misappropriation.

It thus may be best to limit the paragraph to “ *support, develop and implement policies that will promote ~~innovation-based-on~~ traditional medicine*”. This is an important aspect. The CIPIH report recognizes that many developing countries are investing heavily on the promotion of traditional medicines and as such support from WHO will be needed in this area.

A progress indicator could be documentation by WHO on the challenges faced by developing countries and the type of assistance required in the promotion of traditional medicines. WHO could then outline what type of support/assistance it will be able to provide.

For reasons stated above, it is proposed that paragraph 3.4 (b) and the relevant progress indicators be deleted.

CIPIH also recognizes that in many developing countries especially in rural settings, 80% of people visit traditional health practitioners and use traditional medicines. Noting this fact and recognizing the positive impact traditional healers already have, the CIPIH report states that “There is a clear need to explore ways in which traditional medicine practitioners can be used more effectively to facilitate delivery of both western biomedical innovations and traditional therapies.” (CIPIH p. 183)

This is one area that WHO can do more.

#### **ELEMENT 4. TRANSFER OF TECHNOLOGY**

14. North-South and South-South development cooperation, partnerships and networks need to be supported in order to build and improve transfer of technology related to health innovation. The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

#### **Comment on paragraph 14**

The terms “technology” and “technology transfer” are used loosely and should be defined.

**According to the UNCTAD draft International Code on the Transfer of Technology (the draft TOT Code), “technology” can be defined in different ways. The draft TOT Code, in its describes “technology” as “systematic knowledge for the manufacture of a product, for the application of a process or for the rendering of a service”, and does not extend to the transactions involving the “mere sale or mere lease of goods,”. It is the knowledge that goes into the creation and provision of the product or service that constitutes “technology”, not the finished product or service as such.<sup>6</sup>**

**It includes not only “knowledge or methods that are necessary to carry on or to improve the existing production and distribution of goods and services” or to**

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<sup>6</sup> An UNCTAD study series on Technology Transfer and Trans-national corporations said countries need to consider the market for technology and the determinants of transfer.

Transfers from TNCs take place directly to foreign host countries in two ways:

- internally to affiliates under their ownership and control, and
- externalized to other firms;

Internalized transfer takes the form of direct investment that is difficult to measure. Using, as a partial indicator, royalties and license fees a substantial part of technology payments is estimated to be made intra-firm. Also strategic alliances between firms has created n technology transfer which blurs the distinction between internalized and externalized technology transfer.

Externalized modes of transfer by TNCs take a variety of forms minority joint ventures, franchising, capital goods sales, licenses, technical assistance, subcontracting or original equipment manufacturing arrangements.

TNCs are very important in high-technology areas and provide entire packages, including technology and management, marketing and other factors. “From a purely commercial perspective, it may be desirable to allow TNCs a “free choice of means”” in determining whether to transfer technology internally or externally. However, from “a development perspective there may be certain advantages and disadvantages” from the choice of transfer mode.

The disadvantages of internalized transfer include:

- The host economy must pay for the entire “package” and this may prove more expensive than externalization
- The retention of technology and skills within a TNC may hold back deeper learning processes and spill-overs into the local economy

It proposes a measure in the situation that where a choice exists between internal transfers to foreign affiliates or external transfers to local technology recipients, governments may wish to intervene to affect the terms of transfer associated with each modality, as, for example, where incentives are offered to TNCs for the transfer of advanced technical functions.

Also important is the diffusion of technology and skills within the host economy (externalities that arise involuntarily or are deliberately undertaken to overcome information problems). This occurs for instance when local firms and industries link technologies through “demonstration effects” and imitate the technology applied by TNCs to compete with TNCs.

Indicators should be considered to measure diffusion and the increase in the number of competitors to TNCs.

Adapted from : UNCTAD 2001 “Transfer of Technology” United Nations. New York and Geneva, 2001 Document number UNCTAD/ITE/IIT/28 available from <http://www.unctad.org/en/docs/psiteiitd28.en.pdf>

develop entire new products or processes, but also “entrepreneurial expertise and professional know-how.”

“Technology transfer” is the process by which commercial technology is disseminated in a technology transfer transaction, which involves the communication of relevant knowledge.<sup>7</sup>

Further there are no indicators in this section of the draft text to analyse whether technological diffusion or dissemination is taking place. Indicators to measure diffusion and dissemination need to be included.

15. *The actions to be taken in relation to this element are as follows:*

*(4.1) promoting transfer of technology and the production of health products in developing countries*

*(a) devise a mechanism, or make better use of existing ones, to facilitate transfer of technology and technical support*

*(b) promote transfer of technology and production of health products in developing countries through investment and capacity building.*

### **Comment**

#### **Paragraph 4.1 (a) and (b)**

The specific action in 4.1 (a) should contain “and/or”.

It is not just a matter of having a mechanism for transfer of technology, principles governing the transfer of technology especially for diseases of developing countries should also be worked out (e.g. preference should be given to promoting transfer of technology where the output is not patented)

In relation to (i) and (ii) it is unclear what will follow the monitoring. While a report can be compiled for the World Health Assembly for noting, what would be more effective is a more continuous and iterative monitoring, facilitation and corrective actions that can be taken to promote the objectives of the IGWG especially since countries will have dynamic and evolving needs as they implement strategies and actions.

A specific action could be the development of a list of essential and needed technologies in relation to the R&D requirements for diseases and needs of developing countries. Particular attention should be paid to technologies of general application and production related technologies. Accessible upstream technology in

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<sup>7</sup> The UNCTAD draft Code excludes non-commercial technology transfers, which is included in the recommendations of the CIPIH.

**developing countries is a good way to increase the ability of developing countries to improve their R&D capacities.**

**CIPIH recommendation 2.12 states: public health research institutions and universities in developed countries should seriously consider initiatives to ensure access to R&D outputs and products are facilitated through appropriate licensing policies.**

**Recommendation 2.1 similarly places emphasis on upstream and translational research. Recommendation 2.10 states that countries should provide legislation for compulsory licensing in accordance with the TRIPs agreement where it is useful to promote research that is directly relevant to specific problems of developing countries.**

**Recommendation 4.16 calls on companies to adopt patent and enforcement policies to facilitate greater access to medicines and this should be accompanied with technology transfer activities.**

**All of these recommendations should be reflected adequately with appropriate indicators.**

**Suitable indicators for monitoring and assessing licensing policies of public health research institutions and universities in developed countries should also be established.**

**In addition, where difficulties are experienced in accessing technologies, these entities should notify WHO for purposes problem-solving facilitation and transparency (in reporting) of such challenges. These challenges should be documented and included in the reports to the WHA.**

**Specific action/Indicators could include (i) the no of countries that use TRIPs flexibilities to access technology, (ii) monitoring best practices and to track company's and other relevant entities' patent and enforcement practices as to whether they promote access to medicines and technology transfer (as per CIPIH recommendation 4.16), (iii) establish mechanisms for access to appropriate technologies for purposes of promoting adaptive research, in a systematic way,**

**Indicator (b) (ii) could be useful if it is clarified. It measures the increase in capacity building for technology transfer. It is unclear what this means, it could be an increase in funding or a more qualitative measure like the increase in the absorptive capacity of a developing country.**

**CIPIH recommendation 5.4 states: developed countries, and pharmaceutical companies (including generic producers), should take measures to promote the transfer of technology and local production of pharmaceuticals in developing countries, wherever this makes economic sense and promotes the availability,**

**accessibility, affordability and security of supply of needed products. Economic sense at the micro-firm level is different from economic sense at the macro economic state level.**

**Indicators should be developed to assess both the macro/State and micro/firm level measures taken by developed countries and pharmaceutical companies that actually lead to technology transfer and local production.**

**Finally the Plan of Action does not identify any lead stakeholders for this action, which is a serious omission that should be addressed and must also include WHO.**

(4.2) supporting improved collaboration and coordination of technology transfer

(a) encourage North—South and South—South collaboration, and collaboration between institutions in developing countries and the pharmaceutical industry

(b) support technology transfer related to research and development on natural products

(c) facilitate local and regional networks for collaboration on research and development

(d) promote compliance with obligations under Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights.

### **Comments**

**Paragraph 4.2 (a) limits efforts at collaboration between institution in developing countries and the pharmaceutical industry. There is no reason for this limitation as there are many stakeholders that can contribute to technology transfer.**

**Para 4.2 (a) (iii) should be broadened to include the full range of partnerships, collaborations and institutional links.**

**In addition CIPIH recommendation stresses that developing countries institutions should be “increasingly involved in executing research and trials.” This statement should be the measure of “effectiveness” mentioned in 4.2 (a) (iii).**

**Paragraph 4.2 (b) relates to natural products. The term “natural products” is not defined. It appears to mean genetic resources and associated traditional knowledge. Concerns about this issue has been raised above under the element of building innovative capacity. Based on similar reasons raised above, the deletion of the specific action (b) and the progress indicators is proposed**

**In relation to paragraph (d), the text shows only a soft commitment to the WTO TRIPS agreement paragraph 66.2 although CIPIH recommendation 4.18 calls developed countries and the WTO to ensure compliance under the WTO Doha**

**Declaration on the TRIPs agreement and Public Health to operationalize transfer of technology for pharmaceutical production.**

**This obligation is also re-emphasized in CIPIH recommendation 5.5.**

**The CIPIH states that firms that own production technologies may be reluctant to transfer them, as they prefer to concentrate production in a few sites with large economies of scale... In fact, the transfer of technology to developing countries for manufacturing medicines and, particularly, active ingredients, is scant or nonexistent.**

**An indicator here should be a review of developed countries measures taken under TRIPs article 66.2 from a public health perspective since the WTO focuses primarily on trade and not on public health. In addition, WHO can provide developed countries with lists of technologies necessary for entities in developing countries which have challenges accessing technologies for research on diseases that disproportionately affect developing countries. The review should be presented to the WHA for consideration and discussion.**

(4.3) developing mechanisms to manage intellectual property in order to promote transfer of and access to key technologies

- (a) promote patent pools of upstream and downstream technologies
- (b) develop other effective and sustainable mechanisms to promote innovation of products for priority diseases in developing countries
- (c) examine best practices in areas such as competition, transparency and proper remuneration for patent holders.

**Comment**

**Meaning of the term “management of intellectual property” is unclear. (See discussion below). In addition it is unclear what is meant by the term key technologies and how these are defined. A mechanism to solicit and receive inputs from developing countries would need to be established to determine what are “key” technologies.**

**Paragraph (a)**

**The CIPIH recommendation 2.8 promotes patent pools in some circumstances where it will promote innovation in developing countries.**

**Thus paragraph 4.3(a) should be modified as follows to “ensure meaningful access to upstream, platform, translational and downstream technologies for R&D for diseases that disproportionately affect developing countries.”**

**There should also be indicators that measure the reduction in transaction costs for research and access to technology. The CIPIH cites the not-for profit Malaria Vaccine Initiative which confronted over 20 partially overlapping patents and quotes that “the economics of malaria vaccines make developers more reluctant to invest in such cumbersome technology acquisition.” Expertise centralized at WHO for this purpose could significantly reduce transaction costs.**

**Similar challenges faced in the enforcement of multilateral environmental agreements have sought to standardise terms of access with common but differentiated responsibilities for developed and developing countries.<sup>8</sup> This means that developing countries take on less obligations compared to the developed country counterparts including by receiving more favourable treatment and lesser obligations.**

### **Paragraph (c)**

**Sub paragraph 4.3(c) softens CIPIH recommendation 4.23 which calls on developing countries to adopt and implement pro-competitive measures to prevent or remedy anti-competitive practices of medicinal patents. Instead the draft text simply calls for an examination of best practices. CIPIH recommendation 4.23 should be reflected in the text.**

**Sub paragraph 4.3(c) also calls for “proper remuneration for patent holders”. Firstly, the issue of payment of “adequate remuneration” (according to Article 31 (h) and not “proper” remuneration) only arises if flexibility such as compulsory licensing is used and even then it is up to each government to determine the amount of remuneration that should be paid. Where a CL is issued on anti-competitive ground, this fact should also be taken into account, when deciding remuneration. It is not within the purview of WHO to ensure that remuneration is paid. The line “and proper remuneration for patent holders” should be deleted.**

## **ELEMENT 5. MANAGEMENT OF INTELLECTUAL PROPERTY**

16. Intellectual property is a vital concept in ensuring that development of new health products continues. However, complementary, alternative and/or additional incentive schemes for research and development, especially on Type II and Type III diseases and the special needs of developing countries in respect of Type I diseases, need to be

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<sup>8</sup> “The principle of ‘common but differentiated responsibility’ evolved from the notion of the ‘common heritage of mankind’ and is a manifestation of general principles of equity in international law. The principle recognises historical differences in the contributions of developed and developing States to global environmental problems, and differences in their respective economic and technical capacity to tackle these problems. Despite their common responsibilities, important differences exist between the stated responsibilities of developed and developing countries. (The Centre for International Sustainable Development Law 2002 available from [www.cisdl.org](http://www.cisdl.org)) .

explored and implemented. There is a crucial need to strengthen capacities in developing countries to manage intellectual property.

17. The actions to be taken in relation to this element are as follows:

(5.1) supporting information sharing and capacity building in the management of intellectual property

(a) promote national and/or regional institutional frameworks in order to build capacity and manage intellectual property

(b) compile and maintain national databases on patent status of relevant health-related products and promote exchange of information between relevant government departments

(c) WHO and WIPO to improve dissemination of relevant information and existing databases at international level

(d) WHO, in collaboration with WIPO and WTO, to strengthen education and training in the management of intellectual property.

#### **Comment on Paragraphs 16 & 17**

**The purpose of element 5 is not clear. The overriding objective of the section should be to promote a public health perspective on IP, as the WHO is obliged to do and to list actions in line with this overriding objective. It is critical that this pro-public health framework is put forward explicitly as the starting point, and that it is followed through in the action recommendations. It is in this context that we make our comments.**

**Element 5 contains actions on management of IP, IP policy (i.e. TRIPS flexibilities) and incentive models for R&D, all combined under the heading of “management of IP.**

**The phrase “management of IP” itself is not defined. According to the CIPIH report “There are diverse activities that the management of intellectual property entails, including negotiation of agreements on material transfer, confidentiality, and product development, not to mention expertise in patenting.”**

**It further quotes from a paper the following passage: “a research organization's IP management team needs to include or draw on individuals with skills in business strategy or business development, marketing, law, science and medicine, production, and finance. The utilization of these various skill sets is standard operating procedure in the private sector, while many public sector organizations do not take advantage of these resources thereby hobbling their efforts”.**

**In paragraph 5.1 (a) it is stated that the action to be taken is to “promote” institutional frameworks to manage IP, but there is no clarity as to whether these frameworks are for (i) more efficient filing of patent applications or (ii) setting up regional IP offices, or (iii) promoting the use of TRIPS flexibilities in order to improve access to medicines and tools necessary for R&D etc.**

**If the idea of 5.1 (a) is along the lines of (i) and (ii), then it is not within the mandate and expertise of the WHO.**

**The phrase “management of IP” has to be defined clearly before it is used. The phrase should not also be used in vacuum. The context here is public health and this context has to be made explicit in the text.**

**There also needs to be more specificity as to the type of capacity building that is proposed to be built under Section 5.1.**

**The issue in relation to IP is not only about management of IP but also about adopting the right kind of IP policy in order to promote public health, depending on the circumstances of the country.**

**Thus lumping management of IP and IP policy under the heading of “Management of IP” thus does not seem appropriate.**

**A proposal is to title the element simply as “Intellectual Property” and under that element to have sub-elements of (i) “Implementing Public Health Sensitive Policies in relation to IP” and (ii) “Management of IP from a Public Health Perspective”.**

#### **Paragraph (d)**

**In relation to Paragraph (d), the CIPIH recommendation states as follows:**

**“WHO, WIPO and other concerned organizations should work together to strengthen education and training on the management of intellectual property in the biomedical field, fully taking into account the needs of recipient countries and their public health policies”.**

**The recommendation does not limit provision of training in the management of IP (to be defined) to only WHO, WIPO and WTO. It also includes “other concerned organizations’ and the fact that training should fully take into account the needs of recipient countries and their public health policies.**

#### **Comment on Paragraph 5.1 (b):**

**This paragraphs speaks of “promote exchange of information between relevant government departments” while the relevant progress indicator states “Mechanisms for exchange of information between national regulatory agencies and patent offices**

**in developing countries established and/or strengthened”.**

**At present a drug’s patent status and its registration status are two separate things i.e. the patent offices assesses whether a drug is innovative and novel enough to be patented, while the national drug regulatory office assesses whether a drug is of quality, safe and effective enough to be used by the population they are responsible for.**

**By promoting the exchange of information between the patent office and the DRA, it confuses the mandate of the latter, which should (in actual fact) not be concerned whether a patent has been granted or not when registering a drug. The latter (i.e. the DRA) should only be concerned whether a drug is of quality, safe and effective.**

**The action suggested and the progress indicator seems to legitimize a practise that has been rejected by many as being TRIPS plus.**

(5.2) upon request, providing support for application of the flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights

(a) promote legislation to apply flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements, by means including the dissemination of best practices

(b) promote bilateral trade agreements that do not incorporate “TRIPS-plus” protection in ways that might reduce access to medicines in developing countries

(c) encourage trade agreements that take into account the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (as recognized by the Doha Declaration on the TRIPS Agreement and Public Health).

#### **Comment on 5.2 (a)**

**Paragraph 5.2 is very limiting. First WHO can only provide support when there is a request. Second WHO has to provide support for application of flexibilities that are consistent with the TRIPS Agreement, although for non-WTO members, the TRIPS Agreement may not be a relevant agreement.**

**For WTO Members in relation to TRIPS flexibilities WHO ‘s role should be the promotion of use of TRIPS flexibilities whether there is a request or not (e.g. advising countries on when to use TRIPS flexibilities), providing assistance to countries to fully incorporate the flexibilities in the national laws as well as providing all forms of support and encouragement to countries that wish to use or that have used the flexibilities.**

**For non-WTO members, WHO should promote measures that best promote access to affordable generic medicines and enhances local production of generic medicines.**

**For this purpose WHO should have a team of in house experts on IP and health generally and TRIPS and use/application of flexibilities specifically.**

**WHO should also document the experiences of countries in using TRIPS flexibilities and disseminated this information to other countries as best practices.**

**One very important aspect of patent law is the “patentability criteria”. The CIPIH Report (see pg 149) recognized that incremental innovation can be useful in providing therapeutic benefits; improve manufacturing efficiency, reduce the cost of production and so have an important impact on affordability and acceptability etc. However it also adds that “on the other hand, there are studies which find that many new medicines offer little or no improvement over existing medicines”. The report then refers to a recent Canadian study that concluded that in British Columbia, 80% of the increase in drug expenditure between 1996 and 2003 was explained by the use of new, patented drugs that did not offer substantial improvements over less expensive alternatives available before 1990 (a practise often known as “evergreening” of patents)**

**It also states that “such incremental innovations may or may not be patentable, depending whether or not they include an inventive step”.**

**The report proposes as a recommendation that “Governments should take action to avoid barriers to legitimate competition by considering developing guidelines for patent examiners on how properly to implement patentability criteria and, if appropriate, consider changes to national patent legislation.”**

**To assist governments in taking the appropriate action WHO could play a crucial role i.e. by providing guidelines on the patentability of pharmaceuticals. Work on this matter has already begun in WHO through the commissioning of a Working Paper by Carlos Correa titled “Guidelines for the examination of pharmaceutical patents: developing a public health perspective” and this should be further accelerated.**

#### **Comment on 5.2 (b) and (c)**

**Focus in paragraph 5.2 (b) is on “promote” trade agreements bilateral or otherwise that do not contain TRIPS plus provisions.**

**Further it also seems rather simplified to measure progress by merely counting the number of developed countries that have signed trade agreements containing TRIPS plus provision. The reality is that it takes only one developed country to insist during trade negotiations on incorporating TRIPS plus provisions, and the developing country would already have to change its national law to make it TRIPS plus. Now in such a situation it does not matter if 5 other developed countries that have signed bilateral trade deals do not insist on TRIPS plus provision from that**

**developing country as they would be able to free ride on the TRIPS plus provisions sought by the one developed country. The progress indicator should be deleted.**

**Thus here it is crucial to obtain a commitment from developed countries to not incorporate any TRIPS plus provisions (in relation to WTO members) in trade agreements and to respect the Doha Declaration on TRIPS and Public Health. In relation to non-WTO member, developed countries should not impose any IP obligations. It is also important to involve Ministries of Health in any trade negotiations (See CIPIH Recommendation 4.21).**

**On this issue, WHO also has a crucial role to play. It is suggested above that WHO should set up a team of experts. This team of experts should screen all trade agreements signed in recent years, and to provide feedback as to whether it is TRIPS plus, undermines the use of flexibilities and how it would hamper access to medicines.**

**The WHO team should also monitor all on-going trade negotiations particularly between developed and developing countries. Where there is a likelihood that TRIPS plus provisions that could potentially undermine access are being proposed, the team should provide support and assist in the building of capacity of the negotiators from developing countries to understand the implications of those provisions.**

**Finally, the part on TRIPS plus provisions should be in a separate section from the section on the use of flexibilities.**

(5.3) exploring and promoting complementary incentive schemes for research and development

(a) explore and implement complementary incentive schemes for research and development that separate the incentives for innovation from the prices of health-care products (for example, the prize fund model)

(b) expand the advance-market commitment approach

(c) assess the impact of data-exclusivity regulations

(d) examine measures to comply with the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights for the protection of undisclosed test data against unfair commercial use.

**Comment on 5.3 and 5.3 (a), (b)**

**Paragraph 5.3, 5.3 (a), (b) and (c) seems to suggest (as it states “promoting complementary incentive”) that what is needed to promote research and development is additional incentives over and above the granting of patents.**

It should be noted that the CIPIH report states clearly that “A main issue, from our point of view, is that market mechanisms and incentives, as well as allocative decisions of companies, lead to insufficient investment in R&D specifically directed to the needs of developing countries.” (See pg. 31 of the report)

“Because the market fails to induce adequate investment in products needed by developing countries, it is necessary that other measures be put in place to promote relevant innovation.” (See p.31 of CIPIH)

On the role of patents it states that the justification (as an incentive) “rests on the hypothesis that, in the absence of patent protection, inventors would be unable to appropriate the returns from their intellectual creations, with negative consequences in terms of innovation incentives for society as a whole.” However the Report continues to say that “An implicit assumption in the justification for patents is that they are applied in an economic and technological context where they can induce innovation, principally by the private sector.”

It also states that “ the assumption may be generally correct in developed countries and in a few developing countries which have the required capital and innovative capacity, but this is not the case in those developing countries which lack both a significant scientific and technological infrastructure and a private sector capable of innovation.” “It is also assumed that society at large will be able to benefit from present and future innovation.”

“But where most consumers of health products are poor, as are the great majority in developing countries, the monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices or increase funding”, the Report adds.

From these statements it is clear that IP as an incentive will not deliver the pharmaceutical products for developing countries. Thus the issue is not about management of IP and in this regard giving incentives over and above IP but about thinking of alternative incentives or measures that will deliver adequate and affordable pharmaceutical products for developing countries. As such these paragraphs should not be in the section on management of IP but under the element of “promoting research and development”

#### Comment on 5.3 (c)

Data exclusivity is a TRIPS plus obligation. On this the CIPIH report (in pg 142 – 144) states “Article 39.3, unlike the case of patents, does not require the provision of specific forms of rights. But it does oblige Members to protect undisclosed test or other data against unfair commercial use. It does not create property rights, nor a right to prevent others from relying on the data for the marketing approval of the same product by a third party, or from using the data except where unfair

**(dishonest) commercial practices are involved”.**

**The CIPIH report further states that “Thus, the TRIPS agreement does not refer to any period of data protection, nor does it refer to data exclusivity.” It adds that if the patent period has expired, or there is no patent on the product, this *sui generis* data exclusivity may act independently of patent status to delay the entry of any generic companies wishing to enter the market by preventing regulators from using the data during the period of protection to approve a product, even if the product (generic) is demonstrated to be bio-equivalent. The only alternative, for a generic company would be to repeat clinical trials, which would be costly and wasteful, and would raise ethical issues since it would involve replicating tests in humans to demonstrate what is already known to be effective.**

**It concludes that these “*sui generis* regimes, which provide for data *exclusivity* need to be clearly differentiated from the TRIPS agreement's requirement for data protection.”**

**The Report also notes that there is a dispute as to whether data exclusivity is indeed an additional incentive or would it not materially bring benefits to developing countries.**

**The CIPIH report thus recommends that:**

**Developing countries need to decide in the light of their own circumstances, what provisions, consistent with the TRIPS agreement, would benefit public health, weighing the positive effects against the negative effects. A public health justification should be required for data protection rules going beyond what is required by the TRIPS agreement. There is unlikely to be such a justification in markets with a limited ability to pay and little innovative capacity. Thus, developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS. (See Recommendation 4.20, p. 144)**

**What is clear from the above is that data exclusivity is a TRIPS plus obligation which could delay/prevent the entry of generic medicines, even where a compulsory licence is issued, resulting in high medicine prices. Its role as a R&D incentive is also widely disputed.**

**Thus any matter relating to data exclusivity should be removed from Section 5.3 and added into Section 5.2 or other relevant sections, where action points pertaining to TRIPS plus provisions are stated.**

**In addition the above paragraphs fail to reflect the definitive statement made by the CIPIH report i.e. that “A public health justification should be required for data protection rules going beyond what is required by the TRIPS agreement. There is unlikely to be such a justification in markets with a limited ability to pay and little**

**innovative capacity. Thus, developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS”.**

**Here the progress indicator should be how many developing countries do not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities. Another indicator should be how many countries with limited ability to pay and little innovative capacity have decided not to have data protection rules.**