Draft


Cairo, 15–16 August 2007

1. Introduction

At the Fifty-sixth World Health Assembly (WHA), a Commission on Intellectual Property, Innovation and Public Health was established\(^1\) to produce an analysis of the relationship between intellectual property rights, innovation and public health.\(^2\) The Commission submitted its report to the Fifty-ninth WHA, which duly established\(^3\) an intergovernmental working group to develop a global strategy and plan of action for needs-driven essential research and development for diseases that disproportionately affect developing countries.

The Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG), at the end of its first session (Geneva, 4–8 December 2006), issued the *Draft global strategy plan of action on public health, innovation and intellectual property*\(^4\) (GS). The IGWG agreed that Member States should be given the opportunity to review the document and provide additional comments and inputs.

A Regional Consultative Meeting was held from 15–16 August 2007 in Cairo, Egypt, for representatives of Member States of the WHO Eastern Mediterranean Region to review the global strategy. The meeting was attended by representatives of the following countries: Afghanistan, Bahrain, Djibouti, Egypt, Islamic Republic of Iran, Iraq, Jordan, Lebanon, Libyan Arab Jamahiriya, Morocco, Oman, Pakistan, Palestine, Sudan, Syrian Arab Republic, Tunisia, and Yemen, as well as representatives from the Geneva Missions of Egypt, Islamic Republic of Iran, Libyan Arab Jamahiriya and Pakistan. Also attending were a CIPIH commissioner, a Vice-Chair of the Bureau representing the Eastern Mediterranean Region (EMR), and the Executive Secretary of the WHO Secretariat for the IGWG, along with other WHO staff from headquarters and the Regional Office for the Eastern Mediterranean.

The following civil society groups were represented at the meeting: Drugs for Neglected Diseases (DNDi); Knowledge Ecology International (KEI); Médecins Sans Frontières

\(^1\) In Resolution WHA56.27,
\(^2\) Document CIPIH/20061
\(^3\) In Resolution WHA59.24
\(^4\) Document A/PHI/IGWG/1/5
After few stage-setting presentations, the consultation followed the “eight elements” format of the global strategy. A presentation was given on each of the elements: prioritising research and development needs; promoting research and development; building and improving innovative capacity; transfer of technology; management of intellectual property; improving delivery and access; ensuring sustainable financing mechanisms; and establishing monitoring and reporting systems. The context, the aim and the focus of the global strategy were also reviewed. Each presentation was followed by a discussion and comments by Member States, and then by civil society. These comments were noted and are recorded in this report.

Four countries from East Mediterranean Region had already submitted their written inputs on the outcome document from first IGWG meeting: *Intergovernmental Working Group on Public Health, Innovation and Intellectual Property: Report of the first session, Geneva 4-8 December, 2006*. These countries are Egypt; Islamic Republic of Iran; Kuwait and Pakistan. For quick reference these inputs are being made available along with this report as four pdf files. Some representatives from these countries emphasized during the meeting that their comments and inputs during the meeting must be read along with their earlier inputs.

The report is divided into two main sections: *Comments by Member States*, and *Comments by Civil Society*. Each section is sub-divided by element. Within each element, both general comments and specified modifications are recorded.

### 2. Comments and edits on the draft global strategy

#### 2.1 Overall comments

The following were comments relevant to multiple elements of the global strategy and plan of action:

- The content and language of the global strategy should be more consistent with the vision of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) report. The language used in the document should be more binding, rather than suggesting a “best endeavour” approach. A number of CIPIH recommendations are not reflected, or are poorly reflected in the global strategy and plan of action.

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5 Document CIPIH/20061

6 These include Recommendations 2.3, 2.7, 2.9, 2.11, 2.12, 3.1, 3.4, 4.6, 4.7, 4.8, 4.9, 4.10, 4.16, 4.20, 4.21, 4.23, 4.25, 4.26, 4.27, 5.4, 5.8 and 6.2. Ibid, pp 175-187.
The global strategy should suggest more concrete ideas for capacity building in all aspects of R&D in developing countries, including in the promotion of R&D and collaboration between stakeholders (particularly at national level).

Participants agreed that there should be more focus within the document on how the global strategy would be implemented. Examples of best practice should be given. The language used should avoid any ambiguity, so as to avoid any confusion over implementation.

In the plan of action, a better and clearer stakeholder hierarchy should be defined and responsibilities and accountability clarified. In some parts of the action plan, no lead stakeholder is indicated. There should be more detailed indicators to measure the success of the global strategy, and these should include qualitative indicators.

2.2 Comments by Member States

The aim

*Specified changes to the text*

Paragraph 5

In bullet point 5, the language should be more binding. Substitute “ensure” for “seek to increase” in the sentence “Seek to increase the availability, accessibility and uptake of products.” [Iran].

The focus

*General comments*

- The global strategy and plan of action appears to limit the application of the strategy to only specific diseases (see page 4, footnote 1) although there is no such limitation in WHA Resolutions or in the CIPIH report. Any list provided should be non-exhaustive and indicative of immediate priorities.

Element 1: Prioritising research and development needs

*General comments*

- The global strategy should avoid the implication that developing countries do not know, set or undertake research according to their priorities. Some developing countries know their research and development needs and priorities, and are already following a strategy. The strategy could build on these examples of good practice.
Specified changes to the text

1.2 a The fact that some traditional medicines have a preventative use should be recognised. Insert “prevention of” before/after “activity against” [Palestine].

Replace “improve accessibility” with “free access” [Islamic Republic of Iran].

1.2b Add “or other” after the word “technical” [Egypt].

1.3c Specify stakeholders to be governments and the pharmaceutical industry in the plan of action [Egypt].

1.4a Add “or update” after “set”. [Egypt]

1.4c Replace “include research and development needs for traditional medicines” with “support research and development needs…” [Pakistan]

Element 2. Promoting research and development

General comments

- A number of participants requested that the requirement “At least 2% of developing country national health budgets should be allocated on research and research capacity building,” be included within the main body of the text, rather than in a footnote. The obligations of developing countries to encourage developed countries to invest in research on Type 2 and 3 diseases should also be highlighted. But there should also be more emphasis on the obligations of developed countries.

- There should be reference to the establishment of a specific fund devoted to supporting R&D activities in research institutions in developing countries, which would be supported by different sources including the pharmaceutical industry.

Specified changes

Paragraph 11

2.1a After “the health needs of developing countries” insert “as recommended by the Commission for Health Research for Development (1990) and WHA Resolution of 2005.” [Pakistan].

2.2 State that Ministries of Health should lead in promoting private-public cooperation. [Palestine].
2.2a Modify “promote cooperation” to “create a mechanism of cooperation.” [Pakistan].

2.2b Since many developing countries do not have national health research programmes, modify to “support governments in establishing or improving health-related innovation” [Afghanistan].

2.3a Modify “promote discovery science” to “undertake discovery science” [Pakistan].

2.3b Replace “promote” with “facilitate.” [Pakistan].

2.3c Replace “promote” with “support” [Pakistan].

2.3d Replace “promote” with “support” [Pakistan].

2.3e Modify to “WHO to provide technological assistance in drafting legislation that is compliant with”. [Pakistan]

2.3f Replace “promote public funding” with “establish a fund to support developing countries”. [Pakistan]

2.4c Replace “support further discussion of” with “identify elements that should be part of”. [Pakistan]

**Element 3. Building and improving innovative capacity**

**General comments**

- The document should emphasise more strongly the importance of networking within developing countries (13, 3.3c).

- It was suggested that the issue of migration by health professionals to developing countries (3.2c) was too broad to be dealt with in this document, and was being dealt with by other agreements and inter-governmental agencies (e.g. IOM). A link should be established with other global organizations and initiatives working on this issue.

**Specified changes**

**Paragraph 13**

3.1a Insert “WHO to” before “support investment” and insert “in and by” before “developing countries in human resources”. [Pakistan]
3.2a Add “efficient and adequate regulations to encourage innovation adapted to local capacities.” [Morocco]

3.2c Replace “address” with “undertake”. Remove “retention” and “including issues relating to migration”. [Pakistan]
Add in the progress indicators “loss to the government due to the migration of health professionals.” [Libya Mission to Geneva]

3.3 Add “within joint venture products”. [Morocco]

3.3a Insert “health” after “document and disseminate best practices in”. [Pakistan]

3.3b Insert “health innovation” after “promote successful”. [Pakistan]

3.4 Insert “encourage protection of traditional medicine rights” [Morocco]

3.4a Remove “within evidence-based frameworks”. [Pakistan]

3.4b Insert “protection and” before “documentation of traditional knowledge”. [Pakistan].
In the annex, stakeholders should include “research institutions”. [Jordan]

3.4c Replace “encourage developing countries to ensure high” with “ensure adequate”. [Pakistan]

**Element 4: Transfer of technology**

*General comments*

- Egypt requested that its comments on Element 4, submitted to the IGWG (26 February 2007) be incorporated.
- In the (annexed) action plan more specific about progress indicators.

*Specified changes*

**Paragraph 14**
In the phrase “in a manner conducive to social and economic welfare”, replace “welfare” with “development”. [Egypt]

**Paragraph 15**

4.1a Clarify what mechanisms there are to facilitate technology transfer. [Egypt]
“International and national research institutions”, and “WHO” to be identified as lead stakeholders. [Egypt]
4.1b Governments of developing countries and the pharmaceutical industry to be identified as lead stakeholders. [Egypt]

4.2a Replace “encourage” with “facilitate” [Pakistan] or “support” [Libya/Mission]. After “South-South collaboration, insert “for technology transfers”. [Pakistan] The language should reflect support for South-South collaboration, therefore modify to “welcome with appreciation and recognition South-South collaboration”. [Egypt] Recognise that WHO should play the role of facilitator for collaborations. [Egypt]

4.2b Insert “establish a regulatory authority network at regional level to facilitate and enhance the transfer of technology.” [Iran]

4.2d Since TRIPS is legally binding, replace “promote” with “ensure”. Also refer to Article 40 of TRIPS. [Egypt]

4.3 Refer to the flexibilities in Article 30 of TRIPS and to some of the obligations and rights set out in the DOHA Declaration. [Iraq] After “access to key technologies” insert “including sharing of patent databases.” [Pakistan]

4.3a Replace “promote” with “establish”. [Pakistan]

4.3c After “areas such as competition, transparency,” insert “use of flexibilities”. [Pakistan]. Clarify, or give examples of the “best practices” referred to. [Oman]

**Element 5: Management of intellectual property**

**General comments**

- Strengthen the capacity of developing countries to manage IP, including regulatory capacity. Establish applied and practical criteria of patent.

- Capacity building is needed in education and training on intellectual property rights. WHO should encourage academic institutions in the developing world to promote intellectual property and social development in their curricula. Some universities should be selected which could become centres of excellence.

- There was concern over the unavailability of data on patent status in developing countries. WHO should play a stronger role in this, both in raising awareness of the content and impact of TRIPS among the relevant professionals.

- "Bolar" provision should be included in national patent law.
The IP should be a tool to stimulate innovation and not a marketing tool with a negative effect on the affordability of medicines. Mechanisms like voluntary or obligatory licensing systems; international and regional exhaustion (parallel importation) should be used.

This part of the document should reflect WHO advice that Member States avoid TRIPS-plus in bilateral agreements since it has been shown to have a negative effect on public health.

WHO should establish a unit to provide legal advice to Member States on using flexibilities consistent with TRIPS.

Participants requested more information to be included on incentives for innovation, other than patency.

The role of WIPO should be clarified.

**Specified changes**

**Paragraph 16**

After “Intellectual property is” replace “a vital concept in ensuring that” with “one instrument that can be used to ensure development.” [Pakistan].

At the end of the paragraph, after “manage intellectual property” insert “including the use of flexibilities inside the TRIPS agreement.” [Pakistan].

Insert “and make it [intellectual property] conducive to innovation in the public health sphere.” [Egypt].

**Paragraph 17**

5.1b Insert “WHO, in collaboration with WIPO to” before “compile and maintain national databases”. [Pakistan, Egypt, Oman, Bahrain]

5.1d Insert “health-related” before “intellectual property” [Egypt]. After “management of intellectual property” insert “including use of flexibilities”. [Pakistan]

5.2. After “upon request” insert “WHO, in collaboration with WTO to provide” [Pakistan].

5.2b Insert “WHO and WTO to ” before “promote bilateral trade agreements”. [Pakistan]. Insert “affordable”, before “medicines” [Egypt]. Insert “encourage positive trade measures to encourage compliance, rather than negative sanctions such as “name and shame” lists [Egypt].
5.2c The provision within Doha, which allows manufacture for other countries, not just local markets, should be mentioned here.

5.3c Insert “on access to affordable medicines” [Egypt]. Insert “and data protection” after “data exclusivity” [Pakistan].

5.3d Add “devise mechanisms to comply with TRIPS Article 39”. [Egypt]

Element 6: Improving delivery and access

General comments

- Member States should form a national medicine policy, within a strong legal framework, that includes all actions and elements of this section.
- It was suggested that WHO should ensure the standard of medicine in both the country origin and country of use, including medicines donated in emergencies.
- Egypt requested that its comments on Element 6, submitted to the IGWG (26 February 2007) be incorporated.
- Member States should form a national medicine policy, within a strong legal framework, that includes all actions and elements of this section.
- There is a need for a binding code of conduct for the pharmaceutical industry to prevent improper advertisement and marketing of their products.

Specified changes

Paragraph 20

6.2 Stakeholders should include the pharmaceutical industry [Egypt]. Progress indicators should include the development of a binding code of conduct for the pharmaceutical industry [Yemen and Egypt].

6.3d Remove reference to public health emergencies in the progress indictors [Egypt and Oman].

6.4a Increased access to generic products requires increased awareness of users, doctors and pharmacists. [Morocco]
Element 7: Ensuring sustainable financing mechanisms

General comments

- The issue of ensuring sustainable financing was a major concern of Commissioners. The element should be reviewed to ensure that the concept of sustainability is emphasised.

- A number of Members States commented on the lack of awareness of funding opportunities. WHO was requested to create a database of possible sources of financing for research and development.

Specified changes

7.1 Insert “to encourage international and regional financial institutions to design new low cost financial instruments to ensure easy access to finance for R&D activities in public health in developing countries” [Egypt].

Element 8: Establishing monitoring and reporting systems

Specified changes

8.2 After “monitoring”, insert “report periodically to the WHO” [Egypt].

8.2b Clarify whether this is a separate point from 8.2. [Egypt]
   In the action plan, after (i) and (ii) insert “to be determined on a biannual basis.” [Pakistan]
Civil Society Comments

The context

General comments

- There was a concern that paragraphs 1-3 fail to capture the context set out in the CIPIH report. They imply that all that is required to face the current challenges is “a bit more of the same”. This is not a realistic representation: there are numerous obstacles to needs-driven innovation and access to essential medicines. A suitably framed contextual analysis is crucial if the global strategy, and the actions attached to it in the global plan, are to be seen in right perspective.

Specified changes to the text

Paragraph 2

Move current paragraph 2, to new paragraph 4. Replace with: “For all types of diseases, there is a need to find ways to encourage the development of medical products and technologies appropriate to the circumstances of developing countries. On the other hand, the existing incentive structures encourage drug producers to invest in the creation of products targeting those with purchasing power. The profit propelling incentives, such as patent protection, cannot by themselves address the needs of developing countries. That is why it is necessary that alternative measures be put in place to promote and ensure relevant essential innovation” [DNDi].

Then insert new paragraph 3 to read: “Drugs discovery and development is a complex, lengthy and costly activity. There is an urgent need to think very seriously about how this cost can be reduced, if new safe and adapted products are to be made available to developing countries. Governments’ leadership is key in ensuring the linkage between needs-driven innovation and access to lifesaving health products, which would contribute to fulfilling people’s right to the highest attainable standard of human health” [DNDi].

Current paragraph 2 would then become paragraph 4, with the following modifications: after “in recent years”, insert “to orient medical R&D towards social goods”. Replace last sentence of paragraph with: “Moreover, they require international governance. There is a need for a stronger political commitment towards an articulated and sustainable effort to address and overcome the research gaps throughout the innovation cycle, including the crucial issue of drug regulation procedures and clinical trials” [DNDi].
Paragraph 3

Paragraph 3 to become new paragraph 5. Begin with new sentence: “Never before have the same possibilities existed to address the problems of public health of the developing countries.” Modify the last sentence to read (new language is in italics): “These opportunities must be harnessed more efficiently and effectively by a process of ‘democratisation’ of science, through knowledge sharing and an increased cooperation and networking between developed and developing countries” [DNDi].

The aim

Specified changes to the text

Paragraph 4

Modify paragraph 4 to read, “The aim of the proposed global strategy on public health, innovation and intellectual property is to commit WHO Member States to providing a medium-term….” Add at the end of the sentence “proposing clear objectives and priorities for research and development, and estimating funding needs in this area” [DNDi].

Paragraph 5

Insert "essential" before “innovation, build capacity and improve access” [DNDi].

Modify second bullet point to read: “encourage innovative mechanisms to carry out the above essential research and development agenda….” [DNDi].

Third bullet point: insert "sustainable and predictable" before "financing" [DNDi].

Modify fourth bullet point to read: “ensure the availability, accessibility and uptake of health products (in particular, medicines, vaccines, diagnostics and other health technologies) in developing countries” [DNDi].

The focus

General comments

- Regarding the footnote 1 on page 4, which gives a list of diseases that the Global Strategy and the Plan of Action should cover: this list has not been negotiated anywhere within the previous meetings of the IGWG process. Although some government submissions do refer to an R&D priority list, this has
not been compiled in any of these submissions, and it seems to come unduly before the priority setting exercise provided by the Global Strategy has been put in place.

While primary attention is dedicated to communicable diseases for the purpose of this Global Strategy, both the CIPIH Report and later various governments’ intervention during the IGWG 1 have underlined the growing relevance of non-communicable diseases’ burden in developing countries. This sentiment should not be lost in the draft text.

Finally, the list proposed in footnote 1 excludes many serious diseases that the Global Strategy should address including; influenza, pneumonia and other respiratory diseases; maternal and perinatal diseases, Hepatitis C, and other new emerging infectious diseases.

Options for governments to define their own priorities should be left open, precisely because non communicable diseases are moving increasingly their burden towards developing countries, and potential future pandemics – like avian flu – are expected to hit the world population on a global scale.

The CIPIH report in p. 184 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….”. This sentence expresses the necessity for a “needs assessment” at national, regional and international level to be conducted. This needs assessment would then guide national, regional and international research agendas and advise on priority setting and resource allocation for these priorities.

- It should be recognized that some of the diseases of the South also affect specific groups in the north, for example sickle cell anaemia which is prevalent among some ethnic minorities.

Specified changes to the text

Paragraph 6

Modify to fit the language used in the CIPIH p13e, “for which an adequate treatment does not exist for use.” [KEI]

Element 1: Prioritising research and development needs

General comments

- The Kenyan/Afro submission to the IGWG has made some points about priority needs that could be useful for the global strategy.
The draft gives the impression that none of the strategies are yet in place. It should be clarified that for some diseases – for example, tuberculosis - priority setting has already been fixed. For those diseases the timeframe for action should be reduced.

The issue of access to compound libraries is a crucial and difficult one. Millions of molecules and compounds are locked in libraries, both in academia and in the private companies. It would demand innovative policy thinking by governments to make sure that basic research and knowledge (often funded publicly) do not remain inaccessible to scientists and follow on innovation, for new lifesaving medical applications.

As it is now, the language is too wishful and too vague. The pharmaceutical companies cannot be relied on to make sure that compound libraries are made accessible. The issue of the power balance between government and corporate, state and market, should be carefully addressed here. In this and other actions, verify more carefully the potential conflict of interest of certain stakeholders – private companies, public & private partnerships, etc. – in the implementation of some of the specific actions identified.

Currently, the only example of strategies to access libraries is public-private collaboration. Other options should be included, such as those mentioned in the CIPHI: patent pooling for upstream technology, incentives for universities, etc. The role of the government in improving access should be emphasized. Recognise that academic institutions also have compound libraries which may be difficult to access. There should also be provision for emergency access to compound libraries.

**Specified changes to the text**

**Paragraph 8**

Amend paragraph 8 to read (new language in italics): “Health research and development policies in developed countries need to reflect adequately the health needs of developing countries. Gaps in discovery, development and delivery concerning the needs of developing countries must be identified urgently, together with policy measures that are appropriate to address and overcome those gaps. A better understanding of diseases determinants is essential to drive sustainable research and development on new and existing products (medicines, vaccines, diagnostics and other essential health technologies).” [DNDi]

1.1a  Modify to read (new language in italics): “develop methodologies to identify research and development gaps in responding to the health needs of developing countries and make sure that governments use them at the
national/regional/international level through a more organised information sharing mechanism” [DNDi]

1.2 Modify “facilitating upstream research” to read “government and funder advancement of upstream research”. [KEI]

1.2a Devote a more structured paragraph to the issue of compound libraries issue under Element 2: Promoting research and development, and incorporate the reference to this issue in 1.2a there. [DNDi]

Insert a new bullet (c) (and change existing bullet c to d) based on the CIPIH Recommendation 2.4: “Assign high priority to combat the rapidly growing impact of Type I diseases on developing countries.” [KEI]

1.4 Insert a new bullet (e) reflecting CIPIH recommendation 3.1: “Governments and the appropriate national authorities and funders should assign a higher priority to research on the development of new animal models, biomarkers, surrogate endpoints and new models for assessing safety and efficacy, which would increase the efficiency of product development. They should also work with their counterparts in developing countries to formulate a mechanism to help identify research priorities in this area for Type II and Type III diseases particularly relevant to developing countries, and provide funding for this R&D.” [DNDi]

In the action plan (page 19) one indicator should read: “(iii) the number of developed and developing countries that have implemented WHA resolution on 2% and 5% devoted to health research” [DNDi]

Element 2. Promoting research and development

General comments

- Indicators in the plan of action are mainly quantitative. There should also be qualitative indicators. For example in p. 23 (e) and (f) of the plan of action, the indicator is “no. of countries with TRIPS compliant legislation in relation to research exemption” and “no. of new clinical trail sites funded and implemented in developing countries”. If the intention is to reflect Recommendation 2.9 of the CIPIH report 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” then the progress indicator would not be sufficient. The progress indicator would have to be for example, how many developing countries have adopted some form of research exemption, and how broad are the exemptions, the role of these exemptions in promoting R&D. Further whether research exemption is TRIPS compliant or not is a relatively small matter, as Article 30 rather broadly gives mandate to
countries to adopt exceptions to patent rights. Also LDCs and non-WTO members need not be TRIPS compliant.

- On clinical trials the relevant CIPIH recommendations speak about “strengthening clinical trials and regulatory infrastructure” not merely about increasing the number of clinical trials. On clinical trials, the important issue is the conditions under which clinical trials are taking place. Does the developing country have the capacity, is the capacity strengthened, what are the criteria for assessing whether capacity for clinical trial has been strengthened?

Specified changes

2.3 To be amended as follows: “implement policies and device new mechanisms at the national/regional/international level to promote accessibility to compound libraries of academia and the private sector to screen and identify compounds with potential activity against diseases that disproportionately affect developing countries.”

Current 2.3 a-f, to be replaced with:

(a) governments to maximise the availability of innovation by strongly rewarding sensible patenting approaches and positive licensing practices of academia and the private sector;

(b) WHO to promote and facilitate patent-pooling of upstream technologies to favour access to drug leads identified through the screening of biological libraries;

(c) introduce TRIPS Agreement compliant legislations to fully implement research exemptions and other such flexibilities like compulsory licences for upstream research to foster needs-driven innovation especially for developing countries;

(d) adopt a non-working clause: if a promising compound has not been developed by a drug company after a given period, then it should be put on the market for licensing to a group willing to pursue it, with appropriate remuneration for the originator company.

(e) promote discovery science through open-source approaches, in order to favour the expansion of research commons and develop a sustainable portfolio of new products (cf. the Consultative Group on International Agricultural Research); governments and the appropriate national authorities and funders should assign a higher priority to research on the development of new animal models, biomarkers, surrogate end-points and new models for assessing safety and efficacy, which would increase the efficiency of product development.” [DNDi]
Element 3. Building and improving innovative capacity

General comments

- The indicator for paragraph 13, 3.4 is “database in place to document available and new information” on traditional knowledge and “information on traditional knowledge and natural genetic resources widely disseminated”. However it should be noted that the Convention on Biological Diversity (CBD) recognises the sovereign rights of countries over its own biological resources including genetic resources and associated knowledge. Noting that countries have sovereign rights over their own resources, and 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 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), which is what developing countries are trying to prevent. In any case, discussions on this matter are already being undertaken in several fora such as the WTO, CBD and WIPO.

- Stress the role of quality tertiary education in building innovative capacity.

Specified changes

Paragraph 12

Paragraph 12 to be amended as follows (new language in italics): “There is a need to frame and support effective policies that promote the development of capacities in developing countries related to health innovation. 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 technologies. In recent years, developing countries have demonstrated that they can have much to offer in promoting health research generally and in meeting their own healthcare priorities. Key areas for investment are capacities relating to science and technology, clinical trials, drug regulatory procedures, local productions, intellectual property and traditional medicine” [DNDi]

An investment approach is not sufficient. Add “support and grant funding” [Oxfam].

Paragraph 13

3.2b In the plan of action, include a progress indicator, “collect information about the number of health professionals who migrate from home countries or who do not practice within their field in the host countries.” Also “assess the cost of migration to the developing countries.” [TWN]
3.4 Insert “taking into account developing country interests and rights in current discussions at the WIPO and the Convention on Biodiversity” [Oxfam]. Add “and ownership and benefit sharing arrangements.” Clarify that this process should not support bio-piracy. [Oxfam].

**Element 4: Transfer of Technology**

*General comments*

- If there is a desire to transfer technology, developed countries have to adopt policies national and internationally that promote transfer of technology. For example on avian flu, noting the current limited global production capacity of influenza vaccines (i.e. only about 500 million doses of vaccine are available) and the fact that production of vaccines is limited to 9 developed countries only, it is important that technology in relation influenza vaccine manufacturing be transferred royalty free to developing countries. This is equitable considering that influenza viruses for producing avian flu vaccines are biodiversity from Indonesia and other neighbouring countries.

*Specified changes*

**Paragraph 14**

Paragraph 14 to be modified to: “International support and assistance for a mobilization of local resources in developing countries, with a strengthening of local absorptive capacity for knowledge and technology transfer, is central to policy interventions that seek viable, sustainable and long term solutions to the crisis in needs-driven R&D. North-South and South-South partnerships and networks need to be supported in order to build and improve processes of technology transfer to and in between developing countries, related to essential health innovation. The success of technology transfer activities should be measured by the degree to which they facilitate access to essential health products.” [DNDi]

The plan of action should include qualitative indicators [TWN].

In the plan of action, separate studies to be carried out from concrete actions. [Oxfam].

**Paragraph 15**

4.1a/b In the plan of action, no leading stakeholder is identified. WHO is not listed as a stakeholder in (b) [DNDi]. There is a complete lack of qualitative indicators [TWN].
4.2a Modify to, “facilitate technology transfer frameworks in North-South and South-South collaborations. Technology transfer schemes could include special licensing agreements for developing countries, or affirmative commitments of allocation of research funds for collaborative projects with developing countries.” [DNDi] In the action plan, a meeting is not a progress indicator. Instead, include “the number of product development projects based on the patent pool.” [Oxfam]

4.2c Modify to, “facilitate local and regional technology sharing networks so as to increase and upgrade research and development sites in developing countries”. [DNDi]

4.2d Modify to, “international collaboration will have to ensure that capacity is increased in drug regulatory agencies of developing countries” [DNDi].

4.3b Remove as it repeats points that have already been more fully expressed in other parts of the document [DNDi].

**Element 5: Management of intellectual property**

*General comments*

- Paragraph 5.1b recommends “promote exchange of information between relevant government departments”, while the relevant progress indicator (ii) states “Mechanisms for exchange of information between national regulatory agencies and patent offices in developing countries established and/or strengthened”. This appears to legitimize a practice, known as “patent linkage” that has been rejected by prominent experts including civil society.

The duties of national regulatory agencies and patent offices differ. 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 drug regulatory authority, 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 with the safety and efficacy of a drug.

- 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. The purpose of the use of TRIPS flexibilities is to 
promote access to affordable generic medicines, build research, development and 
production capacity.

For non-WTO members WHO should promote measures that best promote access 
to affordable generic medicines and which 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 accelerate its work on patentability criteria and 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. This is 
recommended by the CIPIIH report as Recommendation 4.27 but not reflected in 
the text.

WHO should assist governments by providing guidelines to patent examiners on 
the patentability of pharmaceuticals. WHO has already started this process by 
having a working paper titled “Guidelines for the examination of pharmaceutical 
patents: developing a public health perspective” by Prof. Carlos Correa. This 
work should be further accelerated.

The progress indicator for paragraph 5.2 (b) is “number of 
developed countries not incorporating TRIPS plus protection in bilateral trade 
agreements with developing countries”. This is not adequate to measure progress. 
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. In such a 
situation it does not matter if five 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.

It is therefore crucial to obtain a commitment from countries, developed countries 
in particular, on not incorporating TRIPS plus provisions in trade agreement and 
to respect the Doha Declaration on TRIPS and public health. It is also important 
to involve Ministries of Health in any trade negotiations (See CIPIIH 
Recommendation 4.21).

The WHO should monitor all on-going trade negotiations particularly between 
developed and developing countries. Where there is 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 provision.
Paragraphs 5.3, 5.3 (a), (b) and (c) seem to suggest (by use of the term “promoting complementary incentive”) that what is needed to promote research and development is an additional incentive over and above the granting of patents. From the CIPIH report, 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 or other 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”.

**Specified changes**

**Paragraph 16**

At the end of the paragraph insert “as well as the adoption of innovative IP management schemes (such as collective management of IP, open source collaborative models, non exclusive licensing, no-patent agreements, etc) in the interest of public health.” [DNDi]

**Paragraph 17**

5.1 In the plan of action, there is a risk of conflict of interest in 5.1 (a) and (d). The pharmaceutical industry is listed as a stakeholder, while it is also the beneficiary of the incentive mechanism linked to intellectual property rights. It should be removed. [DNDi] Specificity the type of capacity building that is proposed in this section. [TWN].

5.1a Define “management of IP” [TWN].

5.1b Delete “promote exchange of information between relevant government departments, and the related progress indicator (ii). [TWN]

5.2a The text should reflect more closely Recommendation 4.27 of the CIPIH report [TWN].

5.2b Modify to read: “ensure that bilateral trade agreements do not incorporate ‘TRIPS-plus’ protection that reduces access to medicines in developing countries” [DNDi]. Move these recommendations on TRIPS plus provisions to a separate section from the section on the use of flexibilities.

5.3a Clarify what is meant by “promoting complementary incentive” [TWN]. After “implement complementary” insert “and alternative”. After “(for example,” modify to “open source avenues, patent pools, non exclusive licensing, the prize fund model, etc.)” [DNDi]
5.3b Modify to read: “Encourage and facilitate innovative and/or collective IP management schemes within the advanced-market commitments initiatives” [DNDi]

5.3c Any matter relating to data exclusivity should be removed from Section 5.3 and added into another section, where issues and action points pertaining to TRIPS plus provisions are stated. CIPIH Recommendation 4.20 should be reflected in the draft global strategy and plan of action.

One key progress indicator should be: “the number of developing countries who 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; and, the number of countries with limited ability to pay and little innovative capacity who have decided not to have data protection rules”. [TWN]

Assign a body (preferably WHO) to provide guidelines and evidence-based assistance to countries undergoing bilateral agreements. [Oxfam]

Element 6: Improving delivery and access

Specified changes

Paragraph 18

Modify paragraph to read (with additions in italics): “Support for health systems is vital for the success of the strategy, as are the stimulation of competition and the adoption of appropriate pricing and taxation policies for health products. Regulatory approval processes must be seriously considered and streamlined in order to rapidly deliver lifesaving medicines to patients. Mechanisms to regulate the safety, quality and efficacy of medicines and other health products, coupled with adherence to good manufacturing practices and effective supply chain management, are critical components of a well-functioning health system. A more structural linkage has to be promoted between unmet public needs and lifesaving health tools. The risks and benefits of each drug or vaccine must be assessed in relation to the patients’ needs, the severity of the disease and the availability of alternative preventive/therapeutic options. Regulatory authorities can play a huge role in terms of promoting access, identifying needs, eroding costs, both a priori and a posteriori of any R&D project.”[DNDi]

6.1 Include reference to international community support for “fragile states” which cannot finance their own health care. [Oxfam]
National legislation is needed to promote use of generics. [Oxfam]

6.2a After “strengthen” insert “drug regulatory authorities”. After “efficacy of health products,” insert “so as to progressively ensure that they steer research and
development activities effectively and grant expeditious registration of lifesaving preventive and treatment products.” [DNDi]

Add new 6.2b: “facilitate and support the creation of regional platforms for drug regulations, so as to strengthen the adequate implementation of clinical trials and promote appropriate registration standards for drug approval concerning diseases that affect developing countries.” [DNDi]

Add new 6.2c: “strengthen the role of the WHO prequalification programme, and promote its effectiveness in granting assessment of safety, quality and efficacy of lifesaving medicines, beyond the scope of HIV/ Aids, tuberculosis and malaria. [DNDi]

6.3c The CIPIH report qualifies its recommendation (4.12) to remove tariffs and taxes as “where it is appropriate, in the context of policies to enhance access to medicines”. This qualification should be reflected in the global strategy and plan of action [TWN].

Element 7: Ensuring sustainable financing mechanisms

Specified changes

Modify the title of the element to read: “Ensuring sustainable and predictable financing mechanisms” [MSF].

7.1 Insert “long-term” before “financing.” Be explicit about the number of years. (Precedent has been established by the UK government’s guarantee of 20 years of funding for UNITAID) [Oxfam].

7.2a Replace “expanding” with making more effective and productive”. [Oxfam]

Element 8: Establishing monitoring and reporting systems

General comments

- Systems should be in place not merely to monitor but also to evaluate and to immediately take corrective actions following the evaluation. Any monitoring and evaluation mechanisms established should involve civil society organisations.

Specified changes

8.2 An additional action point to be added: (d) “assessment of the impact of complementary and alternative incentive mechanisms on discovery, development and delivery of new essential health products.” [DNDi]