Elements of a global strategy and plan of action

Progress to date in the Intergovernmental Working Group

1. Progress made to date by the Intergovernmental Working Group in developing the elements of a plan of action and a global strategy is reflected in the annexes to the present document. Annex 1 contains elements of a plan of action and Annex 2 contains elements of a global strategy.

2. The text in the annexes has not been the subject of an intergovernmental negotiation process. The basis of Annex 1 was document A/PHI/IGWG/1/4, which was then subject to two rounds of comments in the Working Group. Comments have been incorporated by the Secretariat in the body of the text with the intention of being as inclusive as possible. Consequently, suggestions for deletion have generally not been incorporated. Delegations to the Working Group have not had an opportunity to comment on the text as it appears in Annex 1.

3. The text in Annex 2 was prepared by the Secretariat at the request of the Working Group on the basis of material drawn from the Constitution, Health Assembly resolutions and other relevant sources. Comments made during the debate have not been incorporated in the body of the text because of lack of time. For this reason, such comments are listed in the appendix to Annex 2, grouped under the three principal headings of the Annex. Delegations to the Working Group have not had an opportunity to comment on the text as it appears in the appendix.

4. The document is intended to serve as a basis for consultations and intersessional work, if and as required, and for further work at the next session of the Working Group.
General comment by Brazil: The elaboration of the Plan of Action and the Global Strategy should be regarded as a means to sort out the difficulties on the path to increased access to medicines. Aside from the need to set research priorities and to ensure sustainable funding for research activities, access to medicines can only be ensured if the intellectual property regulation is addressed in a balanced manner driven to “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” (TRIPS Agreement, Article 7). This is achievable if developing countries, by and large left aside in the innovation process, are given the technical conditions to take full advantage of the flexibilities provided for in the intellectual property system with a view to, among others: (i) be granted access to research that might concern their health needs and (ii) structure their national intellectual property systems in such a way that access to medicines is facilitated by a competitive environment.

Development of local capacity is a prerequisite for the use of IP-flexibilities. This assumption underlies the December 6, 2005 amendment to the TRIPS Agreement, that acknowledges the different capacities across countries in manufacturing medicines. The Plan of Action and the Global Strategy could play an important role in this context by examining and recommending concrete measures, in line with the flexibilities built in the international intellectual property system, that could be adopted by developing countries in order to better cope with their health needs.

Without addressing specific issues of intellectual property, questions relating to funding and prioritizing might prove of limited value in responding to the health problems affecting developing countries.

In view of the above remarks, it seems clear that the consideration of IP-related issues that is limited to “IP management” mistakenly assumes that problems faced by developing countries on this matter are circumscribed to administrative concerns and, therefore, risks overlooking IP areas of critical importance. For this reason, the attention of the Working Group should be drawn to IP issues that have a bearing on all aspects of access to medicines and health, such as pricing, affordability, access to data in the public domain, etc.

ANNEX 1

ELEMENTS OF A PLAN OF ACTION

1. Further to discussion at the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, the present document incorporates proposals made by delegates in respect of the elements of a plan of action:
2. **Prioritizing research and developments needs.** As a first step, the plan of action will need to set out ways to identify gaps in research on diseases that disproportionately affect developing countries. A significant improvement in the understanding of the determinants of disease is essential to drive research on new products in a sustainable fashion. This is closely linked to the need for developed and developing countries to prioritize innovation in a coordinated way. The plan of action should encourage countries to define explicit strategies for research and development, to devote a growing proportion of their budget for health research and development to research objectives in developing countries, and to provide support for establishing, implementing or strengthening the latters’ programmes for health research.

**Comments by Brazil:** The Plan of Action should also consider structural IP issues, in particular IP-related regulations that might impede increased research, with a view to overcoming possible barriers to the access of research results or research tools.

Furthermore, the Plan of Action should discuss measures to coordinate international efforts in R&D, in order to optimize resources devoted to such activities, and also the importance of building technological capacity in developing countries, with a view to allow them to take active part in the innovation process.

Areas for action:

(a) identify gaps in current coverage of research in Type II and Type III diseases\(^1\), and links to other work under way in this field

(b) expand prioritization to include very neglected diseases\(^2\), as well as HIV/AIDS, malaria and tuberculosis

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\(^1\) Type I diseases are prevalent in both rich and poor countries, with large numbers of vulnerable population in each; Type II diseases are prevalent in both rich and poor countries, but with a substantial proportion of the cases in poor countries;

\(^2\) Diseases that are overwhelmingly or exclusively prevalent in the developing countries, such as trypanosomiasis and onchocerciasis. Type III diseases are often termed “very neglected diseases”.

(c) set research priorities, including health-systems research related to delivery of products, in developing countries so as to address public health needs and implement public health policy

(d) conduct research on affordable [to be defined] and technologically appropriate products to combat Type I diseases in developing countries.³

(e) improve accessibility of compound libraries for identification of potential compounds.

Comments by Brazil: Brazil suggests the inclusion of the following item:
(f) Identify IP-related regulations that might negatively affect increased research on public health, in particular research on prioritized areas, and suggest ways to facilitate access to research results and research tools.

Elaboration of the above areas of action should consider recommendations 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, and 2.11 of the Commission on Intellectual Property Rights, Innovation and Public Health.⁴

3. **Promoting research and development.** The plan of action should also identify gaps in the discovery, development and delivery of products for diseases affecting developing countries. Product development brings together several sectors of society, so the promotion of research and development should take account of their needs and objectives.

Areas for action:

(a) devote a larger or appropriate proportion of the health research and development budget of developed countries to the health needs of developing countries

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

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

(d) set up a forum, or enhance existing ones, in order to improve the coordination and sharing of information; elaborate its role and format and cost implications; coordinate stakeholders’ research and development through WHO’s endeavours

³ Type I diseases are prevalent in both rich and poor countries, with large numbers of vulnerable population in each; Type II diseases are prevalent in both rich and poor countries, but with a substantial proportion of the cases in poor countries;

⁴ See document A/PHI/IGWG/1/2, Annex.
(e) promote discovery science in order to identify, validate and build up a sustainable portfolio of new products, whose development is facilitated through appropriate legal arrangements [to be defined] permitting unrestricted access to drug leads identified through the screening of compound libraries for diseases relevant to the public health needs of developing countries

(f) promote early-stage drug research and development in developing countries (including basic research, lead identification, lead optimization and pre-clinical trials)

(g) consider legislation relating to the form of research exemption that might be appropriate for fostering health-related research and innovation in prevailing circumstances

(h) undertake further work, taking into account existing mechanisms, to improve global coordination and financing of medical research and development in order to inform the decisions of governments and policy-makers

(i) assure that sponsors of the proposal for a medical research and development treaty develop those ideas further so that governments and policy-makers may take an informed decision

(j) incorporate methods of open source, open access and collaborative issues.

Elaboration of the above areas of action should consider recommendations 3.1, 3.2, 3.4 and 3.6 of the Commission on Intellectual Property Rights, Innovation and Public Health.5

4. **Building and improving innovative capacity.** Developing innovative capacity requires an approach that interconnects education, intellectual property and technology transfer. The innovation cycle in low-income countries is generally not self-sustaining, and they depend upon the products of innovation designed to meet needs of developed countries. Ways to overcome this difficulty could include framing of patenting and licensing policies that maximize access to innovations for development of products of relevance to the public health needs of developing countries, and support for developing countries to consider legislation containing research exemptions in order to foster health-related research and innovation.

Areas for action:

(a) provide support for development of innovative capacity through investment by developing countries in human resources and the knowledge base, especially in tertiary education

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(b) intensify North–South and South–South partnerships and networks to support capacity building

(c) strengthen human resources in research and development through appropriate training, and address issues relating to the migration of health professionals

(d) strengthen product regulatory capacity in developing countries, including improvement of ethical-review standards and clinical-trials capacity

(e) document and disseminate best practices in innovation observed in developing countries

(f) recognize, develop and promote traditional medicines

Elaboration of the above areas of action should consider recommendations 5.1, 5.2, 5.6, 5.10 of the Commission on Intellectual Property Rights, Innovation and Public Health. Some current work, such as that of the European and Developing Countries Clinical Trials Partnership and the Networking for Ethics on Biomedical Research in Africa, should be included in the plan.

5. **Transfer of technology.** The plan of action should address the inadequate capacity and skill in developing countries to adopt and develop new technologies for discovery, development, manufacturing and delivery of products.

Areas for action:

(a) provide support for transfer of technology for discovery of medicines, diagnostics and vaccines, clinical-trial capacity, manufacturing and product regulation through North–South and South–South collaboration; this includes research and development on natural products

(b) devise a mechanism, or make better use of existing ones, to promote and facilitate transfer of technology, technical support, and strengthening of innovative capacity in developing countries

(c) promote collaboration between institutions in developing countries and industry

(d) take necessary steps in developed countries to assure compliance with their obligations under Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) or encourage them to do so with a view to focusing on the transfer of health-related technologies

\[\text{\textsuperscript{a}}\] WTO documents on this matter may be accessed at http://www.wto.org/english/tratop_e/trips_e/techtransfer_e.htm.
(e) promote patent pools of upstream technologies or other mechanisms to promote innovation of products for priority diseases in developing countries [intellectual property implications of this proposal to be considered]

Comments by Brazil: The promotion of patent pools should be considered in light of the implications that such initiatives might have to the enhancement of access to research and to medicines by developing countries.

(f) promote transfer of technology and production in developing countries through action by developed countries and pharmaceutical companies

In elaborating the plan for this area of work, consideration should be given to taking advantage of work under way in universities, research institutions and public-private partnerships.

6. Management of intellectual property. The plan of action should address the development of capacities for the management of intellectual property and technologies in developing counties.

Comments by Brazil: IP-issues affecting access to medicines are not circumscribed to “management”. Rather, there is a wide array of matters within the scope of IP that deserve increased attention, if access to medicines is to be improved, such as: (a) full implementation of TRIPS Agreement flexibilities; (b) ensuring the immediate entry of generic medicines in the market following patent expiry; (c) improving the quality of patent examinations.

Areas for action:

(a) enact legislation in developed and developing countries for application of the flexibilities provided for in TRIPS and other international agreements

Comments by Brazil: Consideration should be given to mapping out the flexibilities provided for in international instruments that might be relevant to ensure access to medicines. The Plan of Action should also encompass means to ensure that countries fully implement the flexibilities that already exist in the international norms, such as by (a) examining the “research exemption” provisions with a view to recommend the widening of cases where this exemption applies; (b) discussing ways to ensure the high quality of patent examinations; (c) monitoring the implementation of the amendment to the TRIPS Agreement with the purpose of identifying possible difficulties and propose possible ways to solve these difficulties.

(b) establish or work within national and/or regional institutional frameworks to promote and manage intellectual property

Comments by Brazil: The item, as presented, is too broad and requires more clarification.
(c) explore and implement alternative incentive schemes for research and development

**Comments by Brazil:** The item, as presented, is not clear on its relations to a purported “management” of IPRs.

(d) compile and update regularly databases on patent status, and encourage WHO in cooperation with WIPO to improve dissemination of information

**Comments by Brazil:** A mapping out of patents that might be relevant to address specific public health needs has critical importance and should be coupled with the discussion of possible ways to facilitate access to the subject matter of such patents.

(c) strengthen education and training in the management of intellectual property

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

(g) encourage trade agreements to take into account the flexibilities contained in TRIPS and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health

(h) promote interrelation between national regulatory authorities for medicines and health products and intellectual property offices, and define a workplan for harmonization

**Comments by Brazil:** The interrelation between national regulatory authorities for medicines and IP offices could be seen as a positive step if its goal lies in improving the quality of patent examination. On the other hand, attempts to establish a “linkage” between the two areas should be criticized as this is not required by the TRIPs Agreement and also because it leads to postponing the entry of generic medicines in the market.

Furthermore, attempts to “harmonize” IP-related practices or standards fall beyond the scope of the TRIPS Agreement, whose Article 1.1 allows countries freedom “to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”

(i) focus on specific aspects of the intellectual property system, such as test data exclusivity, “me-too” patents, and patent linkages

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7 Resolution WHA59.24, paragraph 2(4).
Comments by Brazil: Discussion should be held with a view to identify concrete measures to ensure that countries are able to put in place measures that allow for the immediate introduction of generic medicines as the patent term expires;

The Plan of Action should also assess the impact produced by data exclusivity regulations and provisions that establish linkage between the patent system and market approval procedures over the immediate entry of generic medicines in the market after the expiration of the patent term;

The Plan of Action should also examine concrete measures that can be implemented to comply with the requirement for the protection of undisclosed test data against unfair commercial use, as set out by the TRIPS Agreement, that do not involve the granting of property rights neither the need to remunerate the party concerned;

Comments by Brazil: The following item should be included:

“(j) recommend the participation of health authorities in intellectual property negotiations in a view to reaffirm all the flexibilities and safeguards related to public health and prevent decisions that may cause damage to access”

7. Improving delivery and access. Governments need to invest appropriately if existing and new products are to be made available and accessible to those in need. Improved delivery, access and appropriate use could be addressed by encouraging governments to invest in the health-delivery infrastructure and in financing the purchase of medicines and vaccines through insurance, to institute mechanisms to regulate the quality, safety and efficacy of medicines and other products, and to adopt measures to promote competition and ensure that pricing of medicines is consistent with public-health policies.

Comments by Brazil: Along the lines of the previous comments, delivery cannot be improved if we overlook the IP-related regulations that postpone the entry of generic products in the market, such as norms that establish a “linkage” between market approval regulation and patent regulation.

Areas for action:

(a) support product introduction in developing countries through improved regulation at national and international levels

(b) accelerate regulatory approval of products with potential utility

(c) conduct operational studies to maximize the value and use of new products in high disease-burden settings with inadequate health services

(d) implement national and international disease-control policies reflecting impact-evidence of new products
(e) frame policies emphasizing essential drugs at affordable prices

(f) encourage innovations adapted to realities of health-care delivery in developing countries

(g) encourage manufacturing in developing countries that complies with good manufacturing practices

(h) devise ways to curb counterfeiting of medicines and technology

(i) take necessary legislative steps in developed countries, and other countries with manufacturing and export capacity, to allow compulsory licensing for export consistent with the flexibilities provided for in TRIPS

Comments by Brazil: Aside from legislative steps, consideration must also be accorded to possible incentives that could be put in place to induce the sustainable use of such mechanisms.

(j) provide in national legislation for measures to encourage generic entry on patent expiry, such as the “early working” exception, and more generally policies that support greater competition between generics, whether branded or not, as an effective way to enhance access by improving affordability; restrictions should not be placed on the use of generic names

Comments by Brazil: Discussion should be promoted on the impact of provisions seeking to establish a “linkage” between market approval procedures and the patent system over the full implementation of early working exceptions and recommend ways to ensure that the exception can be applied to its full extent

Furthermore, as previously stated, there are many IP-related regulations, other than the “early working exception”, that negatively affect generic entry on patent expiry that should also be addressed.

(k) assure or encourage the adoption by companies of transparent and consistent pricing policies, and work towards reducing prices on a more consistent basis for low- and lower middle-income developing countries; products, whether originator’s or generic, should be priced equitably, not only in sub-Saharan Africa and least developed countries, but also in low- and lower middle-income countries

(l) continue to consider price of treatment for communicable diseases, particularly of second-line drugs for HIV/AIDS

(m) prioritize health care in national agendas and, in view of the leverage to determine prices that patents confer, adopt measures to promote competition and
ensure that pricing of medicines is consistent with public health policies; access to

drugs cannot depend on the decisions of private companies, it is also a responsibility

government.

(n) remove tariffs and taxes on health-care products and monitor the supply and
distribution chain

Elaboration of the above areas of action should consider recommendations 2.3, 2.5, 3.1,
3.4, 3.5 of the Commission on Intellectual Property Rights, Innovation and Public Health.⁸

8. Ensuring sustainable financing mechanisms. Action is needed that generates
additional and sustainable financing for research and development in order to address the
health needs of developing countries, and engages governments in this process. A plan of
action could include steps to secure such financing for developing and making accessible
products to combat diseases that disproportionately affect developing countries, for
underpinning public-private partnerships and local research and development institutions,
and for boosting resources channeled to research organizations in developing countries in
both the public and private sectors. It is important to take account of current activities of
entities such as the International Drug Purchase Facility (UNITAID), International Finance
Facility for Immunization, Bill & Melinda Gates Foundation and other philanthropic
organizations making contributions to innovation and services in the health sector, and
advancemarket commitments. Philanthropic organizations are acknowledged as significant
new forces contributing to sustainable financing for innovation and service delivery in the
health sector.

Areas for action:

(a) estimate financing requirements of the plan of action

(b) channel more funds to research organizations in developing countries in both the
public and private sector on the basis of compliance and performance

(c) continue to support public-private partnerships and research and development
institutions in developing countries and assess their performances

(d) establish a funding mechanism, or utilize existing ones, for research and
development for neglected diseases, while avoiding duplication with existing
programmes

(e) continue to devise forms of advance-purchase schemes which may contribute to
moving later-stage vaccines, medicines and diagnostics as quickly as possible
through development to delivery.

⁸ See document A/PHI/IGWG/1/2, Annex.
9. **Establishing monitoring and reporting systems.** WHO should continue to monitor from a public-health perspective the impact of intellectual property rights and other factors on the development of new products, and on access to medicines and other health-care products in all countries, especially developing ones. Systems need to be established that can monitor the impact on innovation and on access to medicines and other health-care products of TRIPS and of the Doha Declaration on the TRIPS Agreement and Public Health; to measure performance and progress towards objectives contained in the plan of action; and to monitor and evaluate relevant programmes.

Areas for action:

(a) monitor impact on innovation and on access to medicines and other health-care products of TRIPS and of the Doha Declaration on the TRIPS Agreement and Public Health

(b) measure performance and progress towards objectives and targets of the plan of action

(c) continue to issue public health-based research and development reports, identifying from the public-health perspective gaps and needs related to pharmaceuticals, and to report on them periodically

(d) continue to monitor, from a public-health perspective, and in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the Commission’s report on development of, and access to, health care products

(e) report regularly on progress.

10. Each of the above areas for action is in itself a major challenge and requires further development, where appropriate in cooperation with WIPO, WTO and other international bodies, taking into account their mandates. The elements can be elaborated on to identify current activities and future directions, as the Intergovernmental Working Group determines the work required, sets priorities, and identifies the main actors responsible for implementation.
ANNEX 2
ELEMENTS OF A GLOBAL STRATEGY

1. The following elements have been taken from WHO’s Constitution, the report of the Commission on Intellectual Property Rights, Innovation and Public Health, resolution WHA59.24 and other recent resolutions related to this subject.

GLOBAL PRINCIPLES

2. The overarching principles of a global strategy are:

- The Universal Declaration of Human Rights provides that “Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits” and that “Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.” (resolution WHA59.24)

- WHO’s Constitution states that “Unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger.” (WHO Constitution)

- It further states: “The extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health.” (WHO Constitution)

- High-quality research, and the generation and application of knowledge are critical for achieving the internationally agreed health-related development goals, including those contained in the United Nations Millennium Declaration, improving the performance of health systems, advancing human development, and attaining equity in health. (resolution WHA58.34)

GLOBAL CHALLENGE

3. Meeting public health needs. The challenges and opportunities for achieving this objective include:

- the growing burden of diseases and conditions disproportionately affects developing countries, particularly women and children (resolution WHA59.24)

- much more needs to be done in relation to the scale of avoidable suffering and mortality (resolution WHA59.24)

- the development of safe and affordable new products needs to be continued for such communicable diseases as AIDS, malaria and tuberculosis, and

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9 Document CIPIH/2006/1.
for other diseases or illnesses disproportionately affecting developing countries (resolution WHA59.24)

- opportunities have been opened up by advances in biomedical science, and need to be harnessed more effectively in order to develop new products, and in particular to meet public health needs in developing countries (resolution WHA59.24)

- considerable progress has been made in recent years by governments, industry, charitable foundations, and nongovernmental organizations in funding initiatives to develop new products to fight diseases affecting developing countries, and to increase access to existing ones (resolution WHA59.24)

- national health-research systems should be strengthened by building relevant capacity, developing capable leadership, providing essential monitoring and evaluation tools, improving capacity for ethical review of research, and determining necessary ethical standards and regulations for population health, health care, and clinical research (resolution WHA58.34)

- appropriate, effective and safe health tools for patients living in resource-poor settings are needed (resolution WHA59.24)

- additional funding is needed for research and development for new vaccines, diagnostics and pharmaceuticals, including microbicides, for illnesses, including AIDS, that disproportionately affect developing countries (resolution WHA59.24)

- there is a need for public-private partnerships that are devoted to the development of new essential medicines and research tools, and for governments to set a needs-based priority agenda for health, and to provide political support and sustainable sources of funding for such initiatives. (resolution WHA59.24)

4. Making intellectual property work for health. The following considerations apply to work towards this objective:

- intellectual property rights are an important incentive for the development of new health-care products, but this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain (resolution WHA59.24)

Comments by Brazil: This statement is not only highly disputable but also contradicts the rest of the document, which evidences that IP is insufficient to improve research and access. It should be therefore deleted.

The term “products” hereafter should be understood to include vaccines, diagnostics and medicines.
• 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 (resolution WHA59.24)

• that Declaration, while reiterating commitment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), affirms that the Agreement can and should be interpreted and implemented in a manner supportive of the rights of WTO Members to protect public health and, in particular, to promote access to medicines for all. (resolution WHA59.24)

5. Making products affordable and accessible. The following aspects need consideration:

• high prices of medicines contribute to inequitable access to treatment (resolution WHA59.24)

• well-functioning and equitable health systems, including reliable supply systems, are key elements in any framework for expanding access to essential medicines (resolution WHA54.11)

• new thinking on mechanisms that support innovation should be promoted (resolution WHA59.24)

• it is important to strengthen capacity of local public institutions and businesses in developing countries in order to contribute to, and participate in, research and development efforts. (resolution WHA59.24)

GLOBAL RESPONSIBILITY

6. The responsibility involves the aspects set out below. (document CIPIH/2006/1)

Discovery

• All countries need to promote research to targeting the diseases that primarily affect developing countries.

• Research promotion requires gearing efforts to the discovery of new health-care products, based on clear identification of gaps relating to scientific, institutional and financial aspects of basic research and identification of lead compounds.

Comments by Brazil: Research promotion requires overcoming barriers posed by IP regulations to increased access to research outcomes and tools.

Development
• Increasing attention should be given to the drug development and regulatory process; regulatory frameworks and capacities for clinical trials need to be strengthened in all countries.

• New players need to be involved, private-public partnerships strengthened, and the range of activities broadened – from optimization of lead compounds to regulatory review of the safety, efficacy and quality of new products.

**Delivery**

• Efforts to develop new products will be of no value if they cannot be made available and accessible to those who need them.

• The factors affecting the introduction of new and existing products into developing countries need to be understood, including health-delivery systems, regulation, pricing, intellectual property and policies to promote competition.

**Fostering innovation in developing countries**

• Lessons can be learnt from those countries that have made significant progress in developing innovative capacity for health research.

• Massive indigenous resources exist in developing countries in the form of traditional medicine, the better use of which could be made through wider availability and application of knowledge in order to accelerate development of new treatments.

• Capacity building is needed in developing countries in science and technology, regulation, clinical trials, the transfer of technology, traditional medicine, and intellectual property.

**Sustainable financing**

• (Text to be developed)
Draft Global Strategy and Plan of Action to provide a medium-term framework based on the recommendations of the Commission on Intellectual Property, Innovation and Public Health, to secure, inter alia, 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.

26.02.2007

I Interpretation of the mandate of Resolution WHA59.24

1) The Global Strategy and Plan of Action shall constitute a medium-term framework of reference for needs-driven R&D, relevant to diseases that disproportionately affect developing countries. The need to redirect R&D is hereby recognized;

2) The Global Strategy and Plan of Action must ensure, among other things, an enhanced and sustainable basis for R&D. The Global Strategy and Plan of Action must, therefore, result in the creation of an innovative and stable financing mechanism. The UNITAID case may serve as an example, although with different purposes. The Global Strategy and Plan of Action must also facilitate access to research outcomes and tools by developing countries and, in this connection, measures should be envisaged with a view to ensure that intellectual property regulations do not constitute a barrier thereto.

3) The Global Strategy and Plan of Action shall also secure (according to the reading of the expression “inter alia”) that the products needed by developing countries that will result from the R&D medium-term framework of reference shall be (for developing countries): a) available in sufficient quantities; b) acceptable for users; c) effective and of good quality; d) affordable for public or individual users;

4) The Global Strategy and Plan of Action shall constitute an agreed framework of reference to ensure the complete and unobstructed implementation of the TRIPS flexibilities (use of compulsory license; use of the “Bolar” exception and of the research exemption; non-linkage between regulatory approval and granting of patents; measures to revert anti-competitive practices, such as the strict application of patentability criteria). The promotion of the full use of the TRIPS flexibilities should ensure the immediate entry of generic drugs into the market upon patent expiry, for which reason measures such as the establishment of a “linkage” between the granting of patents and the regulatory approval procedures is unwarranted. The Global Strategy and Plan of Action should also foster the use of the Doha Declaration in its entirety in light of the public health needs of developing countries and also monitor the operation of the December 6, 2005 amendment to the TRIPS Agreement with a view to point out possible difficulties that might be present in the production and/or export, export and/or import of products manufactured under the mechanism established by the said amendment. The Global Strategy and Plan of Action should also take into
consideration the fact that developing countries need technical assistance to exploit the TRIPS amendment, due to its complexity and costs;

II Background for the Global Strategy and Plan of Action

1) 4.8 billion people living in developing countries (80% of the world population);

2) Of those 4.8 billion, 2.7 billion live with less than US$ 2 a day (56.25% of the world population);

3) Communicable diseases account for 50% of the developing countries' burden of disease;

4) Non-communicable diseases have an increasing impact on the burden of disease of developing countries;

5) Poverty directly affects the acquisition of health products, especially in developing countries.

6) Growing criticism has been registered, in developed and developing countries alike, on the barriers posed by proprietary rights over the access to medicines, in particular about anticompetitive practices in the field of patent rights;

7) Although international intellectual property agreements foresee flexibilities that could facilitate increased access to medicines by developing countries, the adequate implementation of these flexibilities is hindered by the scarcity of resources and the lack of capacity of production;

III Principles of the Global Strategy and Plan of Action

1) The issues of public health rule over the issues of trade. According to the Doha Declaration on TRIPS and Public Health, “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.” A paradigm shift from a trade-centered world to a health-centered world is necessary and the WHO is adequately positioned to examine the issue of access to medicines from a public health-perspective;

2) “Only through broad and sustained efforts to create a shared future, based upon our common humanity in all its diversity, can globalization be made fully inclusive and equitable” (from the Millennium Declaration). It is only through those efforts that it will be possible to overcome the needs of developing countries and economies in transition. Also according to the Millennium Declaration, “We recognize that, in addition to our separate responsibilities to our individual societies, we have a collective responsibility to uphold the principles of human dignity, equality and equity at the global level. As leaders we have a duty therefore to all the world's people, especially the most vulnerable and, in particular, the children of the world, to whom the future belongs”;

3) a) reduce by two thirds, between 1990 and 2015, the under-five mortality rate; b) reduce by three quarters, between 1990 and 2015, the maternal mortality
ratio; c) halt by 2015 and begun to reverse the spread of HIV/AIDS; d) To have, by then, halted, and begun to reverse, the spread of HIV/AIDS, the scourge of malaria and other major diseases that afflict humanity; e) To provide special assistance to children orphaned by HIV/AIDS. The compromise of the Heads of State with the Millennium Development Goals will only be achieved, among other things, with the availability and affordability of drugs, vaccines and diagnostic kits, in sufficient quantities, of good and efficient quality and in acceptable forms;

4) To develop a global partnership for development; to develop further an open, rule-based, predictable, non-discriminatory trading and financial system; in cooperation with pharmaceutical companies, provide access to affordable, essential drugs (vaccines and diagnostic kits) in developing countries in sufficient quantities, of good and efficient quality and in acceptable forms;

5) In order to achieve the above mentioned millennium development goals with expected efficiency and efficacy it is imperative that: a) developed countries increase their official development aid (ODA); b) a coordinating mechanism among donors – countries, UN and its specialized agencies, partnerships, alliances, foundations, NGOs – be set up to increase the efficiency and efficacy of actions of aid and development, avoid duplications; c) an international effort is put in motion to help developing countries increase their capacities;

6) The intellectual property system has proved not to live up to the alleged positive effects over the increment of innovation for the development of health products necessary for diseases that disproportionately affect developing countries, a perception that pervades the IP Commission Report. Increased attention should be drawn to negative effects that intellectual-property regulations might produce over the access to medicines as well as to research in the medical area, with a view to recommend measures aimed at curbing possible distortions that might be identified in this domain.

7) Until the time the medium-term framework is adopted, the full use of the flexibilities provided for in the TRIPS Agreement shall be promoted with the support of the WHO and all the UN system, with a view to incorporate them into the national legislations of developing countries. The above mentioned flexibilities refer, *inter alia*, to the use of: a) compulsory licensing in accordance with Article 31 of the TRIPS; b) research exemption; c) early working, also known as the Bolar exception; d) measures to revert anti-competitive practices, such as the strict application of patentability criteria. The promotion of the full use of the TRIPS flexibilities should ensure the immediate entry of generic drugs into the market upon patent expiry, for which reason measures such as the establishment of a “linkage” between the granting of patents and the regulatory approval procedures is unwarranted. Also with the purpose of prompting the immediate entry of generics into the market upon patent expiry, concrete measures should be examined to protect undisclosed information in a manner that is compliant with Article 39.3 of the TRIPS Agreement (“protection against unfair commercial use”) but that does not require the granting of exclusive rights or compensation;
8) The health products, necessary for developing countries, that will result from the medium-term framework – drugs, vaccines and diagnostic kits – shall be affordable for public health or individual users; shall be available in sufficient quantities to satisfy demand; shall be acceptable to users; shall be efficient and of good quality; shall be acceptable (based on General Comment n° 14 of ECOSOC on Article 12 of the International Convention on Economic, Social and Cultural Rights relative to the meaning of the right to health). It must be pointed out that target 13 of goal 8 of the Millennium Development Goals is the same in principle;

9) Until the time the medium-term framework is adopted, the immediate entry into the market of generic producers shall be stimulated and supported by the WHO and the UN system.

IV Basis for the Global Strategy

1) Left to itself, the market and some of its incentives and mechanism, such as patent protection, are not by themselves capable of establishing enduring and stable conditions for research, development and production of health products relevant for developing countries. In that context, an innovative financial mechanism must be created to ensure that financial resources are invested in the research, development and production of health products relevant for developing countries. Besides needed structural measures in terms of intellectual property, the establishment of such an innovative financial mechanism, with financial resources coming from a specific taxing would ensure continuity and stability, both lacking in almost all the funds created in support of the Millennium Development Goals. Such a financial mechanism would have the advantage of being of a structural nature rather than wholly dependent on unknown variables. A good example might be UNITAID, although with very different purposes;

2) One of the fundamental problems in dealing with health questions in developing countries is the urgent necessity to revert the brain drainage of health professionals. It is therefore necessary in that context to support the alliance for health work with a view to strengthen the position of developing countries and promote partnerships to create an effective health working force;

3) Some developing countries have fragile health systems, making it harder for the health systems to deliver health. A strong mechanism to support the development of capacities for the optimal use of external resources must be put in place to correct that. One of the prerequisites of such a mechanism is the correct formulation of priorities that will in turn enable the coming up of effective and consistent solutions. For that purpose it is necessary to support the creation or the strengthening of schools of public health, of national institutes of public health, through which evidence based decisions will be available in those countries. The work being done by the International Alliance of National Public Health Institutes is clearly a good reference in this matter;

4) Professor Hiroko Yamane, one of the authors of the Commission Report stated that “Nowhere (in the Report) is there a clear picture of what types of medicines (old or novel) are actually needed, and which policy tools and incentives are
specifically required”. It is therefore necessary – in case this hasn’t already been done – to establish on a consensual manner among specialists what types of drugs, vaccines and diagnostic kits are needed by developing countries;

5) Other than R&D there are many issues that must be considered to support projects geared to the development of health products. Strengthening of health systems, for example, is a prerequisite. The WHO could convene in that context an ad hoc committee of specialists, with the participation of national authorities, to draw up a needs-driven agenda and the solutions that can be put in place in short, middle and long time frames. The “needs-driven agenda” would normally include the necessities of human resources in all relevant areas, making possible the build—up of a network of interrelated competences that must be put in place in a can-do public health system. Inspiration could be thought after the model of the UNAIDS “Three Ones” principle: 1) one national institution to coordinate the efforts to put in place the “needs-driven agenda”; 2) one common strategy to build the “needs-driven agenda”; 3) one authority to evaluate and monitor the work done. Nothing of this presently exists, but it must be put in place in order to achieve the possibility of governing interdependence;

6) Until the medium-term framework is adopted there will be need to establish a governance for the international health initiatives. The “Three Ones” principle could be put to work here for the purpose of having an ordered structure that will help focus and converge the different initiatives, resources flows and interests. Such a structure could be: 1) an institution to coordinate the workings of the “needs-driven agenda” that in essence would consist in bringing in focus the different initiatives, resources flows and interests. This institution could be WHO; 2) a global strategy to do 1). This would probably need the drafting of an agreed set of principles and action plan. Again it would be WHO the natural forum for this to be carried on; 3) an independent agency to evaluate and monitor the work done by WHO. In any case it is essential that the principles of the Rome Declaration act as a reference for any work on cooperation with potential donors.

7) Structural measures on intellectual property play a critical role in the development and access to drugs, vaccines and diagnostic kits. In this connection, the following aspects, inter alia, should be discussed and recommendations made: a) measures that ensure special conditions of access by research institutions in developing countries to research results or research tools of relevance to those countries; b) measures to ensure full use by developing countries of the flexibilities that exist in the IP international agreements and that facilitate the immediate entry of generic medicines into the market (e.g., the broadening of cases of research exemption); c) measures that ensure that generic drugs are available on patent expiry; d) measures that announce world-widely information on patents that are expiring (such as the creation of a data base of drug patents refused, cancelled, expired or otherwise in the public domain on a per country basis and under the Patent Cooperation Treaty - PCT) and also guarantee access to the necessary information, by disclosing the patent in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art, as well as the best mode for carrying out the invention; e) measures to improve the quality of patent examination, with a view to
preventing the granting of “broad patents”; f) monitoring the implementation of the amendment of the TRIPS Agreement, adopted on December 6, 2005, in order to identify possible difficulties that might arise in its operation, and suggest possible measures to solve such difficulties.

V The Global Strategy

1) Operative paragraph 3 of Resolution WHA59.24 establishes an Intergovernmental Working Group open to all interested Member States 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 with the aim of securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries. In that context the global strategy shall:

   i) Establish a R&D agenda that covers the health needs of developing countries, in accordance with the purpose of Resolution WHA 59.24;

   ii) Propose partnerships to carry on the above R&D agenda;

   iii) Propose innovative financial with a view to finance the activities that result from the R&D agenda;

   iv) Propose a governance system for the innovative financial mechanism;

   v) Ensure that the health products that result from the medium-term framework, necessary for developing countries – drugs, vaccines and diagnostic kits – shall be affordable for public health or individual users; shall be available in sufficient quantities to satisfy demand; shall be acceptable to users; shall be efficient and of good quality; shall be acceptable;

2) Until the medium-term framework is adopted, immediate entry of generic producers shall be stimulated and supported by the WHO and the UN system;

3) Until the medium-term framework is adopted the full use of the flexibilities provided for in the TRIPS Agreement shall be promoted with the support of the WHO and all the UN system, with a view to incorporate them into the national legislations of developing countries. The above mentioned flexibilities refer, *inter alia*, to the use of: a) compulsory licensing in accordance with Article 31 of the TRIPS; b) research exemption; c) early working, also known as the Bolar exception; d) measures to revert anti-competitive practices, such as the strict application of patentability criteria. The promotion of the full use of the TRIPS flexibilities should ensure the immediate entry of generic drugs into the market upon patent expiry, for which reason measures such as the establishment of a “linkage” between the
granting of patents and the regulatory approval procedures is unwarranted. Also with the purpose of prompting the immediate entry of generics into the market upon patent expiry, concrete measures should be examined to protect undisclosed information in a manner that is compliant with Article 39.3 of the TRIPS Agreement (“protection against unfair commercial use”) but that does not require the granting of exclusive rights or compensation;

VI The Plan of Action

1) Strengthen public health schools and the national institutes of health, with a view to generate scientific evidence and create a critical mass of specialists in health to ensure the establishment and support of all public health programs;

2) Promote the necessary training to absorb transference of technology;

3) Training of personnel and strengthening of the warehouse and distribution systems for drugs, vaccines and diagnostic kits;

4) Training of personnel and strengthening of clinical and epidemiological laboratories;

5) Propose measures to improve governance of the whole set of donnnors, with a view to optimize humanitarian actions in the area of health;

6) Ensure facilitated access to research outputs or research tools that may be of relevance to meet public health needs of developing countries, such as by putting in place measures that safeguard the public domain and the access to knowledge. Research institutions in developing countries should be afforded the possibility of taking part in research activities that might have a bearing on diseases affecting them. Therefore, measures should be devised to permit the availability of research outputs and tools for developing countries, which requires proper discussion on the adverse effects that might be posed by IP-related regulation over the access to medicines as well as discussion on measures to ensure the safeguarding of the public domain;

7) Ensure research exemption. In order to guarantee that research activity in developing countries is carried out without the risk of being forestalled or placed at risk by “patent thickets”, the issue of research exemption should be examined with a view to recommending the widening of cases where this exemption applies;

8) Ensure early working exception: Examine the impact of provisions seeking to establish a “linkage” between market approval procedures and the patent system over the full implementation of early working exceptions and recommend ways to ensure that the exception can be applied to its full extent;
9) Discuss concrete measures to ensure that countries are able to put in place measures that allow for the immediate introduction of generic medicines as the patent term expires;

10) Assess the impact produced by data exclusivity regulations and provisions that establish linkage between the patent system and market approval procedures over the immediate entry of generic medicines in the market after the expiration of the patent term;

11) Examine concrete measures that can be implemented to comply with the requirement for the protection of undisclosed test data against unfair commercial use, as set out by the TRIPS Agreement, that do not involve the granting of property rights neither the need to remunerate the party concerned;

12) Identify ways and means to fully implement the flexibilities provided for in the TRIPS Agreement with a view to ensure access to medicines;

13) Consider measures to ensure the strict application of the patentability criteria in order to obtain the best interpretation for public health in line with the stated in paragraph 4 of Doha Declaration on TRIPS and Public Health;

14) Assess the impact of lax application of the patentability criteria over possible research that could be developed by competitors and recommend measures to be taken in order to prevent such anti-competitive practices;

15) Point out possible difficulties that might be present in the export of products manufactured under compulsory licensing, pursuant to the amendment of the TRIPS Agreement and propose possible ways to solve these difficulties;

16) Recommend an effective participation of health representatives on IP negotiations in order to ensure that the results of the regulations take into consideration public health flexibilities and safeguards.