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## **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.



## 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:

- prioritizing 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
- establishing monitoring and reporting systems.

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 latter's programmes for health research.

Areas for action:

- (a) identify gaps in current coverage of research in Type II and Type III diseases,<sup>1</sup> and links to other work under way in this field

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<sup>1</sup> 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; Type III diseases are those overwhelmingly or exclusively prevalent in developing countries.

- (b) expand prioritization to include very neglected diseases,<sup>1</sup> as well as HIV/AIDS, malaria and tuberculosis
- (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<sup>2</sup>
- (e) improve accessibility of compound libraries for identification of potential compounds.

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.<sup>3</sup>

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
- (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)

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<sup>1</sup> 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".

<sup>2</sup> 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; Type III diseases are those overwhelmingly or exclusively prevalent in developing countries.

<sup>3</sup> See document A/PHI/IGWG/1/2, Annex.

- (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.<sup>1</sup>

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
- (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.<sup>1</sup> Some current

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<sup>1</sup> See document A/PHI/IGWG/1/2, Annex.

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)<sup>1</sup> or encourage them to do so with a view to focusing on the transfer of health-related technologies
- (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]
- (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 countries.

Areas for action:

- (a) enact legislation in developed and developing countries for application of the flexibilities provided for in TRIPS and other international agreements
- (b) establish or work within national and/or regional institutional frameworks to promote and manage intellectual property
- (c) explore and implement alternative incentive schemes for research and development

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<sup>1</sup> WTO documents on this matter may be accessed at [http://www.wto.org/english/tratop\\_e/trips\\_e/techtransfer\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/techtransfer_e.htm).

- (d) compile and update regularly databases on patent status, and encourage WHO in cooperation with WIPO to improve dissemination of information
- (e) 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<sup>1</sup>
- (h) promote interrelation between national regulatory authorities for medicines and health products and intellectual property offices, and define a workplan for harmonization
- (i) focus on specific aspects of the intellectual property system, such as test data exclusivity, “me-too” patents, and patent linkages

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.

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

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<sup>1</sup> Resolution WHA59.24, paragraph 2(4).

- (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
- (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
- (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 of 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.<sup>1</sup>

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 advance-market 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

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<sup>1</sup> See document A/PHI/IGWG/1/2, Annex.



- (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.

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,<sup>1</sup> 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*)

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<sup>1</sup> Document CIPIH/2006/1.

- the development of safe and affordable new products<sup>1</sup> needs to be continued for such communicable diseases as AIDS, malaria and tuberculosis, and 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*)
- 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

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<sup>1</sup> The term “products” hereafter should be understood to include vaccines, diagnostics and medicines.

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.

### 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)

## Appendix

**Comments and suggested additions by Member States****PREAMBLE****Libyan Arab Jamahiriya on behalf of Eastern Mediterranean Region**

The crux of this strategy document is the collective interest of the community of states as a whole, in public health.

**India on behalf of South-East Asia Region**

The World Health Assembly in May 2006 mandated the Intergovernmental Working Group to consider the report of the Commission on Intellectual Property, Innovation and Public Health and propose a global strategy and plan of action aiming at, inter alia, securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries.

**GLOBAL PRINCIPLES****Finland**

Add wording recognizing the role of other international bodies.

**Paragraph 2****India on behalf of South-East Asia Region**

Move paragraph 4, bullet 2 to paragraph 2, bullet 5.

Move paragraph 4, bullet 3 to paragraph 4, bullet 2.

**Libyan Arab Jamahiriya on behalf of Eastern Mediterranean Region**

These statements of principles remain incomplete if we do not also refer to a third principle which completes the circle, and that is that human public health considerations have precedence over rights to intellectual property protections.

## **GLOBAL CHALLENGES**

### **Paragraph 3. Meeting the public health needs**

#### **India on behalf of South-East Asia Region**

Bullet 5: add at the end of the sentence, “this progress is inadequate to meet these challenges”.

Bullet 7: rewrite as follows: “there is a gap in access to existing health products due to the reason of affordability as well as a gap in the development of new health products to meet the neglected and most neglected diseases”.

Bullet 8: add at the end of the sentence, “and that the existing research and development is market-driven which does not address the health needs of developing countries.”

### **Paragraph 4. Making intellectual property work for health**

#### **India on behalf of South-East Asia Region**

Bullet 1: rewrite as follows: “Intellectual property rights are one of the incentives for the research and development of new products, but this incentive alone does not meet the need for the research and development for new products to fight diseases disproportionately affecting the developing countries, which requires alternative mechanisms to meet the weaknesses.”

Bullet 2: move this bullet to paragraph 2 “Global principles”.

Bullet 3: move this bullet to paragraph 2 “Global principles”.

Add three more bullets for paragraph 4 as follows:

- TRIPS flexibility under the provisions of Doha Declaration has not yet been fully utilized.
- TRIPS-Plus efforts under bilateral free-trade agreements place a major limitation in access to affordable medicines for all by developing countries.
- There is a lack of human and institutional capacity, including intersectoral coordination, among developing countries to handle intellectual property rights issues.

### **Paragraph 5. Making products affordable and accessible**

#### **India on behalf of South-East Asia Region**

Bullet 1: reformulate as follows: “High prices of products is the major factor for inequitable access to treatment.”

Bullet 3: reformulate as follows: “New mechanisms to de-link the cost of research and development and the price of medicines are needed, which requires innovative financing mechanism for research and development.”

Bullet 4: reformulate as follows: “There is an inadequate capacity of local public and private research and development institutes and pharmaceutical industries to meet these challenges.”

### **Finland on behalf of the European Union**

Add references to removing bottlenecks on procurement, and creating social insurance systems, which are also aspects of the access to drugs.

### **India on behalf of South-East Asia Region**

In addition, there is a need for a clear objective statement. The Member States of the South-East Asia Region propose to insert the objectives prior to “Global responsibility” as follows:

To ensure global responsibilities of Member States, development partners, private and nongovernmental organizations, the discovery and development of health products are promoted and funded in a sustainable manner in order to address the health needs of developing countries, and the delivery of health products are accessible and affordable by the people and governments in developing countries.

- To clearly state the global responsibility of Member States, development partners, private and nongovernmental organizations
- To promote discovery and development of health products in order to address the health needs of developing countries
- To ensure access of affordable medicines in developing countries.

## **GLOBAL RESPONSIBILITY**

### **Finland on behalf of the European Union**

There is global responsibility for this issue, which requires common and joint action from all WHO Member States, international organizations and other relevant stakeholders.

### **Discovery**

### **India on behalf of South-East Asia Region**

Add a third bullet to this subparagraph as follows: “In the global pool of knowledge, areas which are relevant to diseases disproportionately affecting developing countries should be made widely accessible to foster rapid innovation.”

### **Finland on behalf of the European Union**

Add reference to diseases for which treatments are compromised.



## **Development**

### **India on behalf of South-East Asia Region**

Insert the following:

Bullet 1: “The developed countries need to comply with the Article 66.2 of TRIPS agreement regarding technology transfer to least developed countries, in particular the technologies related to health products.”

## **Delivery**

### **Finland on behalf of the European Union**

Add references to appropriate use of medicines, and to production capacity in developing countries, as well as procurement and pricing, including taxes and tariffs.

### **India on behalf of South-East Asia Region**

Bullet 2: reformulate as follows: “The barriers to the introduction of new and existing health products should be removed, through for example, adequate financing, proper functioning of national regulatory authorities, and the functioning of health delivery systems.”

Insert the following bullets:

Bullet 3: “Whenever required, TRIPS flexibility as stipulated by the Doha Declaration needs to be utilized in order to ensure the availability of affordable medicines in developing countries.”

Bullet 4: “There is a need to promote competition through early entry of generics by utilizing the Bolar provision.”

Bullet 5: “There is a need to be fully aware of the negative impact of TRIPS-Plus in bilateral free-trade agreement in limiting access to affordable medicines. Capacity strengthening is required to generate evidence on the economic impact of TRIPS-Plus, so that the policy-makers and other stakeholders are fully informed.”

## **Fostering innovation in developing countries**

### **Iran (Islamic Republic of ) on behalf of Eastern Mediterranean Region**

Add a fourth bullet point:

“The issue of brain drain of scientists, innovators, and researchers in the public health domain from developing countries to developed countries must be addressed urgently in order to foster innovation in developing countries.”

## **Sustainable financing**

### **India on behalf of South-East Asia Region**

Bullet 1: “In addition to greater funding by government and private sector to support research and development, there is a need for sustainable global and national mechanisms to support the research and development of new products addressing public health needs in developing countries. This may require a paradigm shift and innovative methods and effective management of financing upstream research and development.”

Bullet 2: “There is a need also to scale up the existing innovative public-private partnerships in research and development. There is also a need to document and disseminate the best practices in this regard.”

Bullet 3: “In order to ensure a committed demand, there is a need to scale up advance purchase schemes. This would help ensure the flow of resources into the research and development for diseases which disproportionately affect developing countries.”

### **General comments**

A number of delegations suggested additions of agreed language related to human rights and health matters.

### **Libyan Arab Jamahiriya on behalf of Eastern Mediterranean Region**

In our view, the second part of the strategy document should contain the list of eight elements, that form the basis of the action plan. These eight elements should be included in the strategy paper. This way we would also establish a strong link between strategy and action plan.

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