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## **Resolution on Innovation and Access to Medical Technologies**

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The question of access to medicines is of global concern. For many citizens in the South, access to essential medicines is often a question of life or death while in the European Union and in the US, the cost of medicines is creating a growing financial burden for national health systems.

Equitable access to medicines requires sustainable responses to medical needs that go far beyond the current efforts of charity or international aid. It requires policies that allow for and promote the full participation and economic development of the South. The cost of research and development of new medical technologies can be substantial and requires investment by both the public & private sectors. Innovation in medical technologies also requires access to knowledge, materials & technology. The mechanisms to finance the cost of R&D for new medical technologies should be transparent, economically efficient and avoid conflicts of interest and anti-competitive practices, and be consistent with human rights, including the right to development.

Official EU and US inquiries in to the pharmaceutical sector have revealed a number of systematic anti competitive practices that lead to the delay of market access for more affordable generic medicines with the EU and the US. This raises major concerns about the incentives in the current system of innovation.

Monopolies over medical knowledge exclude many from the benefits of the development of medical technologies, while these are considered public goods. It is imperative to find an appropriate balance between protecting the interests of IP rights holders; incentives for innovation; the right to access to knowledge; and the protection of public health. Furthermore, it is essential to explore and establish new models for biomedical innovation that promote knowledge sharing and address critical barriers to access and innovation.

The EU and the US should also prioritise policies that ensure the rational use of medicines and curb malpractice driven by commercial interests, leading to irrational use and putting patients in danger.

### **1. General Principles**

1 Consumers benefit from the development of new medicines but only when they are accessible, when they have a well established safety profile and when they have an added therapeutic value. Innovation and research should target public health and health results-driven consumers' and patients' needs.

1.2 The costs of research and development of new medical technologies can be substantial,

and require investments by both the public and private sectors. Innovation in the medical sector also requires access to knowledge, materials and technology.

1.3 The mechanisms to finance the costs of R&D for new medical technologies should be transparent, economically efficient and avoid conflicts of interest, fraud and anticompetitive practices, and be consistent with human rights and economic development.

## **2. Previous TACD Resolutions**

2.1 TACD recalls and reiterates its support for the following resolutions relating to medical technologies:

- a) Pharmaceuticals. Doc No. HEALTH-1-99 Date Issued: April, 1999
- b) Access to Medicines in Developing Countries. Doc No. HEALTH-2-00 Date Issued: February 2000
- c) Data Exclusivity and Health Registration Data. Doc No. HEALTH-3-00 Date Issued: February, 2000
- d) Early Working of Patents and Research Exceptions. Doc No. HEALTH-4-00 Date Issued: February, 2000
- e) Patents on Genetic Diagnosis. Doc No. HEALTH-5-00 Date Issued: February, 2000
- f) Transparency of Pharmaceutical Economics. Doc No. HEALTH-6-00 Date Issued: February, 2000
- g) Global Access to Health Care, Doc No. TRADE-10-01 Date Issued: May, 2001
- h) Resolution on Intellectual Property Aspects of Pandemics. Doc No. IP 07-09 Date Issued: May 2009
- i) Enforcement of Copyright, Trademarks, Patents and Other Intellectual Property Rights. Doc No. IP 09-09 Date Issued: June 18, 2009

## **3. Control of Anti-Competitive Practices.**

3.1 TACD calls upon the EU Member States and the US government to use competition legislation to address TACD concerns over barriers to generic competition, including measures such as “pay to delay” and fraudulent patent claims. In this respect TACD takes note of the results of EU Commission’s Pharmaceutical sector inquiry and calls for the strict compliance with EU competition law.

3.2 TACD calls upon the EU Member States, the EU Parliament, the EU Council, and the EU Commission and the US to take stock of competition laws to address anticompetitive uses of patents to block follow-on innovation, including restrictive licensing of biomedical patents. In this regard, TACD calls upon the EC to take legal action to follow up its pharmaceutical inquiry into anti-competitive practices that was concluded in 2009.

3.3 TACD calls upon the US and the EU to investigate the restrictive licensing of patents on ritonavir, and important NIH funded drug discovery that is used in co-formulated protease inhibitor regimes for the treatment of HIV/AIDS.

## **4. Protection of Test Data and Medical Ethics**

4.1 TACD expresses its concerns that the granting of exclusive rights in pharmaceutical test data is economically inefficient, subject to abuses and violates medical ethics.

4.2 TACD calls upon the US and EU to ensure that intellectual property rights for pharmaceutical test data are subject to safeguards against abuses, as are patents on medical inventions.

4.3 TACD notes it is economically wasteful to require generic manufacturers to replicate clinical trials on new medicines.

4.4 TACD notes that requirements for generic manufacturers to replicate clinical trials on new medicines violates Article 20 of the “Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects,” which states the following:

20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.

4.5 TACD notes that the 2008 World Health Assembly called upon governments to:

promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines.

4.6 TACD asks the EU and the US to evaluate alternatives to exclusive rights for the protection of pharmaceutical test data, such as cost sharing models. In this regard, TACD encourages the US and the EU to consider the proposed language in Article 11 of the intellectual property chapter of the proposed Canada - EU Comprehensive Economic Trade Agreement (CETA), concerning steps taken to avoid “duplicative testing on vertebrate animals,” which states:

7. Rules to avoid duplicative testing on vertebrate animals will be laid down by the Parties. Any applicant intending to perform tests and studies involving vertebrate animals shall take the necessary measures to verify that those tests and studies have not already been performed or initiated.

8. The new applicant and the holder or holders of the relevant authorisations shall make every effort to ensure that they share tests and studies involving vertebrate animals. The costs of sharing the test and study reports shall be determined in a fair, transparent and non-discriminatory way. The prospective applicant is only required to share in the costs of information he is required to submit to meet the authorisation requirements.

9. Where the new applicant and the holder or holders of the relevant authorisations of plant protection products cannot reach agreement on the sharing of test and study reports involving vertebrate animals, the new applicant shall inform the Party.

10. The failure to reach agreement shall not prevent the Party from using the test and study reports involving vertebrate animals for the purpose of the application

of the new applicant.]

10. The holder or holders of the relevant authorisation shall have a claim on the prospective applicant for a fair share of the costs incurred by him. The Party may direct the parties involved to resolve the matter by formal and binding arbitration administered under national law.

4.7 TACD opposes the inclusion of data exclusivity requirements in trade negotiations which will delay generic competition and limit access to medicines in developing countries.

## **5. Developing Country Trade Policies**

5.1 TACD condemns the seizures in EU ports of legitimate generic medicines in transit destined for developing countries and calls upon the EU to amend its customs regulation EC1383/2003 to remove the threat of further seizures.

5.2 With respect to trade agreements and medical technologies, the TACD reiterates its opposition to trade agreement obligations on developing countries that exceed obligations already contained in the WTO TRIPS agreement.

5.3 TACD notes in particular its opposition to demands that developing countries adopt exclusive rights for pharmaceutical test data, patents on new uses of existing medicines, patent extensions, or linkages between private patent rights and the government regulatory approval of medical technologies.

5.4 TACD condemns EU and the US bilateral trade pressure on developing countries for using the flexibilities in the TRIPS Agreement to expand access to medicines, pursuant to important global norms on public health, including paragraph 4 of the 2001 Doha Declaration on TRIPS and Public Health, or the 2008 WHO Global Strategy on Public Health, Innovation and Intellectual Property (WHA61.21). TACD condemns the use of “name and shame” lists such as the US “Special 301 Watchlist” to discourage countries from making use of legitimate public health safeguards to secure access to medicines for their citizens.

## **6. Research and Development**

6.1 When feasible and efficient, consumers support the de-linking of research and development costs from the price of medical technologies. In this regard, we support implementation of the following recommendation in WHA61.21, the WHO Global strategy on public health, innovation and intellectual property:

Proposals should be developed for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, addressing the de-linkage of the costs of research and development and the price of health products and methods for tailoring the optimal mix of incentives to a particular condition or product.

6.2 TACD supports exploration of alternative models for innovation and pricing, including but not limited to prize funds to reward innovations, product development partnerships for affordable new products, open source dividends to reward openness and sharing of knowledge, materials and technologies, and increased public sector funding of R&D, including clinical trials for product development and to establish comparative effectiveness.

6.3 TACD calls upon the US and the EU to support an alternative global framework of R&D, that recognizes the importance of both public and private sector investments, access to medical technologies, human rights, development, and promotes greater access to scientific knowledge. Possible elements for such a framework have been described in the 2009 submission to the WHO Expert groups on R&D Financing:

PROPOSAL by Bangladesh, Barbados, Bolivia and Suriname for WHO Discussions on a Biomedical R&D Treaty, April 15, 2009.

### **Possible Elements of a WHO Biomedical R&D Treaty**

Discussions on a biomedical R&D treaty should focus on a wide range of issues that would benefit from global coordination, collaboration and norm setting, including, but not limited to, creation of a framework for sustainable funding support for priority medical R&D. A comprehensive biomedical R&D treaty should address, at a minimum, the following elements:

1. Coordination and facilitation of periodic global priority assessments—including estimates of funding needs—for R&D to address public health needs.
2. Norms and mechanisms to ensure sustainable financing for R&D, including funding for:
  - (a) the development and delivery of health products and medical devices to address the special health needs of developing countries;
  - (b) the development of new antibiotics, vaccines, and other global priority health products and medical devices;
  - (c) funding of basic health-related science, open libraries for materials, open databases, open access medical publishing, and other initiatives to enhance and expand access to medical knowledge;
  - (d) the global sharing of costs for clinical trials associated with the development and independent evaluation of new medical products; and
  - (e) other relevant matters.
3. Measures to facilitate, encourage, and otherwise stimulate new incentive schemes for R&D (such as medical innovation inducement prizes, advanced market commitments, openness dividends, and other new innovative approaches), with special attention to measures that de-link R&D incentives from product prices, and reward innovations that improve health outcomes.
4. Possible governmental agreement to contribute to the global cost of R&D, considering each nation's level of development, size of economy and capacity to pay, in order to establish global norms for R&D contributions. Contributions should be allowed through multiple means.
5. Global norms and best practices to facilitate access to government funded

research.

6. Norms and measures regarding the transparency of global medical innovation, including but not limited to:

(a) Agreements on the required disclosures of clinical trials, including results, in publicly accessible registries;

(b) Requirements for greater disclosure of the costs of R&D inputs, such as the costs of clinical trials;

(c) Standards for reporting and sharing information on resource flows used to support R&D; and

(d) Greater transparency of the terms under which intellectual property rights are licensed, including, for government funded research, disclosures of licensing provisions regarding access to inventions.

7. Mechanisms to develop and improve innovative capacity for research and development, particularly in developing countries.

8. Measures to facilitate encourage or otherwise stimulate the transfer of technology between developed and developing countries as well as among developing countries.

9. Norms promoting the management of intellectual property rights in a manner that reconciles the public interest in access to knowledge and health-related innovation, including prioritizes the R&D needs of developing countries, and that protects public health and promotes access to medicines.

10. Relevant measures to improve the delivery of and access to health products and medical devices.

11. Mechanisms to monitor and evaluate both the performance of global R&D efforts and the implementation of the treaty, including appropriate reporting systems.

12. Measures to more effectively achieve compliance with appropriate ethical standards for medical research.

6.4 TACD calls for the EU to incorporate into its financial commitments concrete proposals to de-link R&D costs from the price of medicines through the promotion of biomedical innovation prizes and the reversion of public investments into medical research into shared public knowledge and goods within the context of the 8th Framework for Research and other EU innovation programs.

## **7. Counterfeits and Pharmaceutical Fraud**

7.1 Consumers face a number of serious risks in developed and developing countries as regards pharmaceutical fraud:

- a. Counterfeit drugs: the practice of falsely claiming to be an authorized product of another firm, including but not limited to the use of another firm's mark to deceive the public.
- b. Deliberately manufacturing and marketing falsified products that do not contain the required active ingredients or not contain the right amount of active ingredient.
- c. Packaging and labeling of drugs that make false claims regarding medical properties, including but not limited to the active medical ingredients, the date of expiration of products, or the methods of storage.
- d. Marketing of products using false claims regarding the efficacy of the product which will lead to its irrational use or deliberately failing to provide information about safety concerns of the product.
- e. Deliberate suppression of data, including evidence from clinical trials that reveal adverse secondary effects of the medicine.

7.2 Not all types of fraudulent practices concerning pharmaceutical drugs can be usefully addressed through the enforcement of intellectual property rights. For example, remedies to certain types of fraud are best addressed by improving the capacity and resources of government authorities with responsibility for the regulation of medicines manufacturing, distribution and marketing authorisation.

7.3 TACD urges the EU and the US to support a new resolution at the WHO on pharmaceutical fraud.