Trans Atlantic Consumer Dialogue

Coordinated by Consumers International

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Resolution on Access to Medicines

The question of access to medicines is of global concern. In the European Union (EU) and in the United States (U.S.) the cost of medicines is creating a growing financial burden for patients and health systems.

At present our biomedical innovation and pricing models are often hurt by anti-competitive practices, rigid Intellectual Property Rights (IPR) monopolies, lack of transparency across the board and weak social return on public research investments.

We need new, fair incentives for biomedical innovation that promote the right to access, the sharing of medical knowledge and the protection of public health. New models of biomedical innovation should support policies that de-link Research and Development (R&D) costs from the marketing price of new, useful and safe medicines.

We take note and re-affirm the positions of previous resolutions by the Transatlantic Consumer Dialogue (TACD) related to this issue, including:

- Resolution on Intellectual Property Rights in the Transatlantic Trade and Investment Partnership [1]
- Resolution on Innovation and Access to Medical Technologies [2]
- Resolution on Intellectual Property Aspects of Pandemics [3]
- Resolution on Global Access to Health Care [4]

[1] TACD (October 2013), *available at* http://test.tacd.org/wp-content/uploads/2013/09/TACD-IP-15-13-IPR-in-the-Transatlantic-Trade-and-Investment-Partnership.pdf

[2] TACD (June 2011), *available at* http://test.tacd.org/wp-content/uploads/2013/09/TACD-IP-14-11-Innovation-and-Access-to-Medical-Technologies.pdf

[3] TACD (May 2009), *available at* http://test.tacd.org/wp-content/uploads/2013/09/TACD-IP-07-09-IP-Aspects-of-Pandemics.pdf

[4] TACD (May 2001), *available at* http://test.tacd.org/wp-content/uploads/2013/09/TACD-TRADE-10-01-Global-Access-to-Healthcare.pdf

1. TACD calls upon the EU and its Member States as well as the U.S. government to use competition legislation and enforcement measures to address TACD concerns over barriers to generic competition, including measures such as “pay to delay” and non-innovative patent claims.

2. TACD supports strictly enforced norms in the U.S. and the EU (including by the U.S. Food and Drug Administration and the European Medicines Agency) to guarantee the transparency and public access to data from all clinical trials for existing and new biomedical products. TACD believes that clinical trial data should not be considered commercially confidential and public health interests should prevail over commercial considerations. TACD also opposes the extension of existing data exclusivity rules in the U.S., the EU or elsewhere in the world as a result of free trade agreements.

3. TACD asks the U.S. and the EU to reform the systems of exclusive rights in test data, to replace exclusive rights with cost sharing when duplication of trials is contrary to the ethical norms for scientific research involving human subjects, such as the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects. TACD notes that the EU and Canada have already undertaken such reforms when duplication of tests violates ethical norms for tests on non-human animals.

4. TACD calls upon the U.S. and the EU to evaluate the feasibility and benefits to the de-linkage of R&D costs from product prices, and to convene stakeholder consultations on possible implementation strategies of de-linkage in areas where high prices block universal access to medical technologies.

5. TACD supports the exploration of alternative models for innovation and pricing in the EU, the U.S. and at the World Health Organization, including but not limited to prize funds to reward innovations, public-private product development partnerships for affordable new products, open source incentives to reward openness and sharing of knowledge, materials and technologies and publicly funded clinical trials for product development in order to establish comparative effectiveness of a drug in health technology assessment.

6. TACD calls upon EU member states and the U.S. to take measures to prevent conflicts of interest in regulatory decision-making bodies including medicine evaluation agencies and health technology assessment bodies. Information disclosing the financial links between industry and prescribers (and other health professionals) should also be publicly accessible online.

7. TACD asks the EU and the U.S. to assure that publicly funded health R&D results in the creation of public goods and medical products that are effective, safe, affordable and accessible. In particular, U.S. and EU authorities should incorporate conditions and guidelines for its biomedical R&D grants that promote the highest level of sharing of knowledge (e.g., non-exclusive licensing conditions for state funded research, open access policies for research publications and research results as well as open source research incentives).

8. TACD calls upon the U.S. and the EU to modify drug registration procedures that makers of biologic drugs provide complete disclosure of know-how within five years of registering new biologic drugs, in order to facilitate the subsequent entry of safe, effective and affordable bio-similar drugs.

9. TACD calls upon the U.S. and the EU to evaluate the costs and benefits of patent buyouts of drugs to treat Hepatitis C.

10. TACD asks the U.S. and the EU to consider issuing compulsory licensing when faced with great difficulty in providing universal and affordable access to high-priced life-saving drugs with evidence of a high level of efficacy and quality.

11. TACD calls upon the U.S. and the EU to cooperate and share transparent, robust and independent health technology assessments to measure the effectiveness and added-value of new medicines and technologies.

12. TACD opposes direct advertising of prescriptions medicines as it leads to inappropriate, costly and unhealthy demands for medications.

13. TACD supports fair and equitable EU and U.S. international trade policies that facilitate universal access to affordable medicines and TACD favours strong support for EU and U.S. funding for research on “neglected” and tropical diseases that tend to affect countries of the Global South. TACD calls upon both the EU and the U.S. to refrain from pressuring countries in the Global South against legal measures that permit greater affordable access to life-saving medicines.

14. TACD calls upon the U.S. and the EU to negotiate minimum standards for the disclosure of economic data on drugs, vaccines and medical devices, including disclosures of the costs of R&D, the extent of public R&D subsidies, and revenues from products.

15. TACD asks the U.S. and the EU to end the practice of providing asymmetric access to trade negotiation texts, so that consumers have exactly the same access to information as drug and medical device companies, and the public has an opportunity to have a wide and informed debate on policies.