



Cc:

Commissioner Dalli (SANCO)  
Commissioner Piebalgs (DEV)  
Commissioner Geoghegan-Quinn (R&D)  
INTA Committee, European Parliament  
DEVE Committee, European Parliament  
European Parliament Working Group on Innovation, Access to Medicines and Poverty-Related Diseases

**RE: ACTA and its impact on access to medicines**

29 July, 2010

Dear Commissioner De Gucht,

We are writing to you regarding the on-going negotiations of the Anti Counterfeiting Trade Agreement (ACTA) and in response to your comments on ACTA before the LIBE committee.

Our organizations have discussed with both pharmaceutical companies and governments for decades measures to improve access to safe medicines in developing countries. We are concerned that trade policies promulgated by DG Trade undermine access to affordable medicines and sustainability of treatment regimes and contradict the EU's broad commitment to improve access to health care in developing countries.

On multiple occasions, our organizations have warned DG Trade that new and unbalanced intellectual property rules, such as those included under ACTA, would condone overzealous and erroneous enforcement of intellectual property for medicines and thereby pose a danger to public health, while doing little to protect consumers from unsafe products. Despite these serious concerns the Commission still considers an impact assessment regarding access to medicines or public health irrelevant.

In recent comments before the European Parliament, you publicly affirmed that patents have been removed from the border measures chapter in ACTA, and that this collective decision would ensure that access to affordable medicines would not be hindered by the Agreement.

Despite numerous requests for transparency, the ACTA negotiating parties have decided to continue this negotiation in secret and the public has not had access to the latest version of the text. However, our organizations have had access to a recent text – dated July 1<sup>st</sup> - and strongly disagree with your assessment that ACTA will not affect public health.

We would like to share some on-going concerns that should be urgently addressed by the negotiating parties to ensure ACTA will not harm public health:

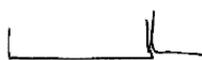
- 1) Patents remain in the Agreement. The border measures chapter still could apply to all intellectual property rights, including patents. This would raise serious concerns that border measures would be used, especially within in-transit countries, to interfere with the lawful trade in generic medicines. Furthermore, patents are still included in Article 1.X as part of the definition of 'intellectual property' and can therefore apply to several parts of the agreement. Patents

have no bearing upon whether a product is counterfeit. Including patents in ACTA will do nothing to arrest the proliferation of counterfeit products, including counterfeit medicines. Instead, it will discourage legitimate challenges to multinational pharmaceutical companies' patenting practices and will limit important flexibilities included in the TRIPS agreement.

- 2) ACTA, including in the border measures chapter, still fails to differentiate between trademark infringement and trademark counterfeiting. ACTA should only be concerned with enforcement rules that reduce or eliminate trademark counterfeiting.
- 3) ACTA still could allow for in-transit seizure of goods that infringe intellectual property in the transit country, even when it does not infringe intellectual property rules in either the exporting or importing country. As part of the EU Council Regulation 1383/2003 this provision is currently subject to a WTO case. It is not clear what it would mean if ACTA were finalized before the case concludes.
- 4) ACTA will extend intermediary liability to innocent active pharmaceutical ingredient (APIs) suppliers whose materials are used in mislabelled products without their knowledge and therefore could discourage the provision of APIs to generic producers under the risk of liability. Article 2.X.2, if enacted, would allow right holders to apply for injunctions against "[infringing] intermediaries whose services are used by a third party to infringe an intellectual property right."
- 5) ACTA will create a new entity outside of the World Trade Organization and the World Intellectual Property Organization, which will lack transparency and accountability to non-Parties and public interest organizations, and may push for ever-higher levels of intellectual property protection and enforcement around the world without adequate safeguards and evidence-based policy making.
- 6) ACTA will limit key flexibilities necessary to promote the public interest, including flexibilities included in the TRIPS Agreement on the award of injunctions as remedies. The EU should support the proposal offered by Canada and Australia in Article 2.X that would allow each Party to preserve or introduce statutory exceptions to injunctive relief in their national laws.
- 7) ACTA lacks safeguards already included under the TRIPS Agreement that ensure a proper balance in the enforcement of intellectual property rules. A lack of safeguards will delay generic competition and endanger the ability of governments to adopt innovation policies that dissociate the cost of research and development from the price of products. Our expectation is that basic safeguards and protections included under TRIPS will be introduced into the final Agreement to ensure that national governments can maintain an appropriate balance.

As the European Union looks ahead to the next round of negotiations, our organizations hope that these concerns will be taken seriously. We would be happy to further discuss these issues with you and share our ideas and expertise on safeguards for public interests.

Yours sincerely,



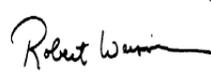
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