HAI EUROPE Comments on ACTA stakeholder consultation

Amsterdam, 22 March 2010

This response has been prepared by Health Action International (HAI) Europe. HAI Europe is a non-profit, European network of consumers, public interest NGOs, health care providers, academics, media and individuals with over 25 years institutional experience in representing the voice of civil society, and poor and marginalised people in medicines policy debates.

Our authority rests on our integrity and independence from commercial and political party interests, our research excellence and evidence-based advocacy.

- HAI Europe promotes increased access to essential medicines, the essential medicines concept and the rational use of medicines.
- HAI advocates for greater transparency in all aspects of decision making around pharmaceuticals, for example, by reducing industry secrecy and control over important clinical data.
- HAI promotes the rational use of medicines; that all medicines marketed should meet real medical needs; have therapeutic advantages; be acceptably safe and offer value for money.
- HAI works for better controls on drug promotion and the provision of unbiased and independent information for prescribers and consumers.

Summary

HAI Europe welcomes the opportunity to share our concerns about the negotiation of a plurilateral Anti-Counterfeiting Trade Agreement (ACTA) with the Directorate General for Trade of the European Commission. Because ACTA will establish a global standard of intellectual property (IP) enforcement, this agreement will have an impact on the developing world as well as the countries currently in ACTA negotiations. This potential for global reach makes many of the proposed provisions deeply concerning.

ACTA negotiations lack legitimacy, transparency and a participatory approach

The process through which the ACTA negotiations are taking place is problematic. ACTA embodies a new model of global governance that bypasses the normal procedures of multilateral international institutions, the European Parliament and national legislatures.

The negotiations also fail to include the voices of the broader public and consumers. Given the implications of ACTA for citizens on a number of issues including access to knowledge and innovation, access to medicines, privacy, and freedom of expression; democracy and transparency should be central to this process. HAI calls on the EU and the other parties to make the negotiating texts public, hold negotiations at public venues, with an accreditation system that allows civil society to attend and observe rounds[i].

Confusion between counterfeit and generic medicines

The name of the agreement, the Anti-Counterfeiting Trade Agreement, is misleading as ACTA negotiations encompass the enforcement of all IP rights, not limited to those related to counterfeiting, such as trademark law. ACTA is pursuing stricter enforcement measures for other areas of IP, such as copyright, patent law, geographical indication, integrated circuits, designs, potentially undisclosed information, among others.[ii]

Adopting the label 'anti-counterfeiting' is misleading because it refers only to part of the substance that is under discussion, and moreover, in the field of medicines, it contributes to a damaging confusion between crucial generic medicines and counterfeit medicines. Counterfeit medicines, defined as those that are illegally and deceptively mislabelled as to source,[iii] are related to trademark law, but not necessarily to patent law. Generic medicines, on the other hand, are related to patent law, as generics have the same active ingredient as an innovator product but use a different name, appearance or package.[iv] Generics can only enter the market when there is no patent on the original product or when the patent has ended.

ACTA addresses a broad spectrum of IP rights including trademark law and patent law, and therefore, counterfeit and generic medicines. HAI is concerned that the emphasis on the threat of '*dangerous counterfeits'* is being used to advance a wider IP monopoly enforcement agenda under the pretext of public health.

ACTA or IP enforcement is not the appropriate way to address the real health concerns about medicines quality, safety and efficacy

The dominant threat to public health from pharmaceuticals in developing countries are the problems of sub-standard, adulterated, and contaminated medicines that affect both branded or generic medicines.[v] Substandard medicines are a very serious health problem, predominantly in developing countries, and medicines may contain insufficient or excessive active ingredient, no active ingredient, or contaminated or substituted ingredients.[vi]

Halting the trade in unsafe medicines requires better regulation of the pharmaceutical supply chain from producer to end user, particularly by strengthening medicines regulatory authorities in developing countries.[vii] About 20% countries around the world have a robust and functional drug regulatory system. The systems are obsolete, invalid or inoperable in another third of the world. The remaining systems fall somewhere between the two marks.[viii] Clearly, adequate resources are needed in these agencies to monitor, regulate and ultimately ensure a safe supply of effective medicines of high quality at the national level.

Counterfeiting is just one aspect of broader public health concerns regarding medicines quality, safety and efficacy. Addressing the problem of counterfeiting will not eliminate the remaining public health concerns. Improving medicines regulation frameworks to facilitate access to quality assured medicines is a more cost effective solution than policies that are excessively focused on patent enforcement measures.

ACTA could chill generic competition and threaten the generics industry

Under ACTA, the position of the IP right-holder would be strengthened to the detriment of generic competitors, effectively reinforcing market exclusivity for IP right holders. Enforcement measures could eliminate the flexibility currently available to countries under the WTO Agreement on Trade Related Aspects of Intellectual Property (TRIPS) to protect consumers through policies that embrace the national, regional or international exhaustion of intellectual property rights.

The Pharmaceutical Sector Inquiry by DG Competition has shown that abuse of the patent system by rights holders is a very real threat to generic competition. These practices are to be feared even more when strengthening the position of the right holder in environments without strong competition law, as ACTA will do.

HAI is concerned that the EU will export its far reaching and controversial regulations on enforcement of IP rights through ACTA and that this will have a negative effect on access to medicines, especially in the South.[ix] Injunctions, storage fees and information requirements that would be imposed on alleged infringers could harm generic competition, particularly where adequate safeguards or anti-abuse provisions are lacking. The same holds true for criminal and financial penalties for patent violations that hold manufacturers of active pharmaceutical ingredients (APIs) liable.

The application of border measures[x] poses a particular threat to generic competition where patent rights are enforced on shipments of generic medicines while in transit. Border measures in the EU have resulted in numerous seizures of medicines in transit through Member States' borders in the last year.[xi] These cases include the detention of a UNITAID/Clinton Foundation shipment of anti-retroviral medicines passing through the Netherlands, destined for HIV positive Nigerians,[xii] and the seizure of the antibiotic Amoxicillin in transit through Germany, intended for the Republic of Vanuatu.[xiii] In these cases, the private rights of patent holders effectively superseded the right to access medicines for citizens in developing countries.

ACTA will impose the burden of enforcing private monopolies at public expense

The implementation of enforcement measures represents significant costs. The TRIPS Agreements recognize this and therefore state "*nothing in this part creates any obligation with respect to the distribution of resources as between enforcement of IP rights and the enforcement of law in general*."[xiv] Implementation of ACTA will have significant opportunity costs and therefore could undermine efforts to identify and remove dangerous medicines in developing countries. The implementation of these measures could force countries to channel government resources into protecting the trademarks and patents of multinational companies. Private rights are transformed into public responsibilities, where the burden of enforcing these private rights falls on the public authorities. Enforcing private rights can pose a significant financial burden on developing countries and can supplant more pressing public priorities. Customs officials, policy makers and lawyers need to be trained to create the necessary national expertise. A more pressing health priority is ensuring the quality, safety and efficacy of medicines through proper regulation.[xv] Resources should be focused on medicines regulatory agencies, but the current focus on IP enforcement might actually drain capacities and resources from these agencies.

[i] Trans-Atlantic Consumer Dialogue. The broad threats of ACTA. [blog post] Accessed at: http://www.tacd-ip.org/blog/ 22 March 2010

[ii] Knowledge Ecology Institute. ACTA to cover seven categories of intellectual property [blog post] Accessed at: http://keionline.org/node/812 22 March 2010.

[iii] The WHO states that 'counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.', see www.who.int/impact

[iv] European Medicines Agency. (2007) Questions and answers on generic medicines. Accessed at: http://www.ema.europa.eu/pdfs/human/pcwp/39390506en.pdf on 19 March 2010.

[v] World Health Organization, World Medicines Situation, Chapter 9, 2004

[vi] World Health Organisation, What are substandard medicines? Accessed at: http://www.who.int/medicines/services/counterfeit/faqs/06/en/ 22 March 2010.

[vii] Xavier Seuba — Border Measures Concerning Goods Allegedly Infringing Intellectual Property Rights, 2009, See also: Carlos Correa, The Push for Stronger Enforcement Rules: Implications for Developing Countries, ICTSD, Intellectual Property and Sustainable Development Series, February 2009

[viii] World Health Organisation, Effective medicines regulation: Ensuring safety, efficacy and quality, 2003. Accessed at: http://apps.who.int/medicinedocs/pdf/s4921e/s4921e.pdf 22 March 2010.

[ix] Including: Regulation on border measures (2003), Directive on civil enforcement (2004), IPRED2, and Strategy on IP enforcement in third countries

[x] EC 1383/2003

[xi] See HAI answer by Dutch government to HAI 'Freedom of Information' request on seizures. http://www.haiweb.org/19062009/7%20May%202009%20Dutch%20government%20response%20to%20Freedom%20of%20Information%20request%20(EN).pdf

[xii] Press Release from Health Action International (HAI), Oxfam International and Knowledge Ecology International (2009) Seizure of UNITAID/Clinton Foundation antiretroviral medicines by Dutch customs authorities 'unacceptable'. Accessed at: http://www.haiweb.org/06032009/6%20Mar%202009%20Press%20release%20More%20generic%20medicines%20intercepted%20in%20the%20Netherlands%20(English).pdf 19 March 2010

[xiii] Press Release from Health Action International (HAI), Oxfam International, BUKO-pharma, Medico International and Third World Network (2009) Another seizure of generic medicines destined for a developing country, this time in Frankfurt. Accessed at: http://www.haiweb.org/19062009/5%20Jun%202009%20Press%20release%20Seizure%20of%20generic%20medicines%20in%20Frankfurt.pdf 19 March 2010

[xiv] TRIPS Agreement, article 41.5

[xv] Carsten Fink, Enforcing Intellectual Property Rights: An Economic Perspective, ICTSD, Intellectual Property and Sustainable Development Series, February 2009