Overtoom 60/II
1054HK Amsterdam
The Netherlands
Tel: +31 20 683 3684
Fax: +31 20 685 5002
Email: info@haieurope.org
www.haieurope.org

Prime Minister Yingluck Shinawatra
Government House
Pitsanulok Road, Dusit
Bangkok 10300
Thailand
Fax number:+662288 4016

CC: Pradit Sintavanarong
Public Health Minister
Ministry of Public Health,
Tivanond Road, Nonthaburi 11000, Thailand
Fax number:+662 590 2021

Amsterdam, 28 January 2013,

Excellency,

I am writing you on behalf of Health Action International (HAI) Europe. HAI Europe is part of the HAI independent, global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy.[i]
All eyes are now on the European Union (EU)-Thailand free trade agreement,and we understand that Thailand is developing the framework for the upcoming negotiations for this FTA. Based on our experience with earlier EU FTA negotiations, we have serious concerns over the repercussions this FTA will have on access to medicines in Thailand and the region.

The EU's position on intellectual property (IP) in previous free trade agreements, including the earlier EU-ASEAN negotiations suggests that we can expect that the EU will push for similarly stringent IP standards that affect the right to health. Thailand's resistance to EU IP demands is crucial for the protection of health and development in Thailand and beyond. The Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS) already contains strong IP protection. IP provisions that go beyond what is required from WTO members under TRIPS - TRIPS-*plus* standards - disturb the already precarious balance that exists in TRIPS between public interests and the interests of IP holders.

TRIPS-plus provisions in earlier negotiated EU and US FTAs have been demonstrated to reduce the availability of generic medicines, thus raising medicines prices.[ii] Public health NGOs, the European Parliament, the European Council, UNAIDS, the UN Development Programme, the UK Commission on Intellectual Property Rights and Development Policy, the UN Commission on HIV/AIDS and the law, respected international IP academics, and even the World Health Organization (WHO) all recognise the link between TRIPS-plus IP provisions that disproportionately favour rights-holders, and poor access to medicines.[iii]

Therefore, we urge you to exclude from the framework for the FTA negotiations between Thailand and the EU, the possibility of including any IP provisions that are in excess of the TRIPS Agreement. We also urge you to reject the inclusion of an investment chapter and any investor-to-state dispute settlement system in the said bilateral treaty. Below, we will further explain the reasons for this caution.

1. TRIPS-plus provisions and their impact on access to medicines.

TRIPS already contains strong IP protection. However, TRIPS did allow some policy space for countries to protect public health (through the so-called „TRIPS flexibilities"). IP provisions that are TRIPS *plus* disturb the already precarious balance that exists in TRIPS between public interests and the interests of IP holders. TRIPS-plus provisions in earlier negotiated EU and US FTAs have been demonstrated to reduce the availability of generic medicines, thus raising medicines prices.[iv]

Moreover, the Thai Government recently issued compulsory licenses for three types of medicines and the World Bank has estimated that if Thailand uses compulsory licensing to reduce the cost of second-line antiretroviral therapy to treat people living with HIV/AIDS by 90%, the government would reduce its future budgetary obligations by US$3.2 billion discounted to 2025.[v] However, a number of TRIPS-plus IP provisions that are likely to be proposed by the EU in the upcoming FTA negotiations could prevent the effective use of compulsory licenses and also otherwise restrict the room for the Thai government to use IP in their public (health) interest.

Examples of TRIPS-plus provisions that the EU is likely to propose are:

- provisions on **data exclusivity** and **supplementary protection certificates** would significantly extend the length of the market monopoly for brand pharmaceutical products beyond the 20 years of patent protection. These provisions inhibit generic production and competition; maintaining high prices and impeding access to affordable medicines. A study on the impact of these same IP provisions during the EU negotiations with the Andean region show that there are good reasons to be concerned. The forecast for the 'extension of patents' proposals revealed a dramatic increase in medicines' spending in Peru and Colombia due to the lack of generic competition, resulting in an increase in spending of 250 million USD in Peru. In addition, the extension of protection of trial data (data exclusivity) would trigger an increase in medicines' spending of 217 million USD in Colombia and 136 million USD in Peru by 2025.[vi] As ever, the victims of the rising cost of healthcare are the poorest families and those without healthcare insurance.
- Measures on **IP enforcement** that go beyond current TRIPS obligations would generate additional implementation costs and could put a chill on generic competition. For instance, the EU is likely to push for measures that would grant draconian powers to customs officials through so-called **border measures**. This would give companies the right to lodge requests with Thai customs authorities to detain, suspend the release, or destroy shipments of generic medicines on the basis of allegations of IP infringement (whether trademarks or patents) without judicial review or even notification of the patent holder.

In addition, the investment chapter of the envisaged FTA can also pose a direct threat to health-related regulation by including IP—related provisions that would compromise, in particular, the ability of the Thai government to take action to promote the production, registration, supply, import, and export of generic medicines.

- the most problematic provision the EU is likely to introduce in the investment chapter is an **investor-state dispute provision** that gives foreign investors the right to sue governments for damages, if laws, policies, or other actions interfere with the enjoyment of their investments - even if the laws are in the public interest. Pharmaceutical companies could allege that health regulations undermine enjoyment of their IP-related "investments," and therefore constitute indirect expropriation or unfair and inequitable treatment. This could lead to challenges of governments seeking to promote access to medicines, for example through compulsory licenses, by pharmaceutical companies claiming their IP have been affected. A "chilling effect" could be created, diminishing the willingness of governments to use IP flexibilities or to interpret TRIPS in a manner that protects health and access to medicines.

2. Global and EU positions caution against TRIPS-plus provisions in FTAs

A number of public health NGOs, the European Parliament, the European Council, UNAIDS, the UN Development Programme, the UK Commission on Intellectual Property Rights and Development Policy, the UN Commission of HIV/AIDS and the law, respected international IP academics, and even the World Health Organization (WHO) all recognise the link between TRIPS-plus IP provisions that disproportionately favour rights-holders, and poor access to medicines.[vii] Further, both the EU and Thailand are committed to the Global Strategy & Plan of Action on Public Health, Innovation and Intellectual Property (GSPA), adopted by the World Health Assembly in May 2008. The GSPA enshrines the principle of placing public health protection over commercial interests, and devotes considerable attention to the impact of IP rights on public health, singling out the practice of overreaching IP protection clauses in bilateral trade agreements.

Further, both the European Parliament and the European Council have, explicitly and on several occasions, called upon the EU *not* to negotiate TRIPS-plus provisions as part of their bilateral trade agreements, especially with emerging and developing countries:

- The European Parliament resolution of July 2007 urges the European Commission not to demand TRIPS *plus* provisions in bilateral agreements.[viii] In 2008, the European Parliament passed a resolution on the EU-ASEAN FTA which said that *"nothing in the agreement should create legal or practical obstacles to the maximum use of TRIPS flexibilities […] and calls on the Commission negotiators […] to do nothing that could undermine the Thai government's efforts to ensure access to medicines for all its residents"*[ix]
- EU Member States in the EU Council have in their May 2010 Council Conclusions on Global Health states that the EU should: "support third countries, in particular LDCs, in the effective implementation of flexibilities for the protection of public health provided for in TRIPS agreements, in order to promote access to medicines for all, and ensure that EU bilateral trade agreements are fully supportive of this objective".[x]
- The EU Parliament has in July 2012 rejected TRIPS-plus IP enforcement provisions in the envisaged Anti-Counterfeiting Trade Agreement (ACTA) in an overwhelming vote. ACTA would have hindered generic competition, which is crucial for access to affordable medicines in Europe and developing countries.[xi]

Key Conclusions

We are concerned that despite the clear obligation of the EU Commission negotiators to respect both the letter and the spirit of the commitments entered into by the EU Member States, the EU Commission will insist on TRIPS-Plus provisions that can affect access to affordable medicines in Thailand.

If Thailand already accepts TRIPS-plus IP provisions in a free trade agreement with EU, it will threaten its own ability to make use of established IP flexibilities that have important socioeconomic benefits, including public health, including the use of compulsory licensing. Stronger IP protection and ever tighter restrictions on access to knowledge and information can weaken innovation, as well as severely limiting the ability of Thailand to develop new technologies and industries, such as pharmaceuticals, which would ultimately contribute to a more sustainable access to medicines.

Therefore, we urge you to exclude from the framework for the FTA negotiations between Thailand and the EU, the possibility of including any IP provisions that are in excess of the TRIPS Agreement.We also urge you to reject the inclusion of an investment chapter and any investor-to-state dispute settlement system in the said bilateral treaty.

Yours sincerely,

Tessel Mellema
Health Action International Europe: tessel@haieurope.org

Endnotes

i For more information, see www.haieurope.org.

ii All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines, Oxfam International (2007), http://www.oxfam.org.uk/resources/issues/health/downloads/bp102_trips.pdf. UN Human Rights Council, *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health,* Anand Grover, 31 March 2009, A/HRC/11/12, available at: http://www.unhcr.org/refworld/docid/49faf7652.html [accessed 11May 2011]. A Trade Agreement's Impact on Access to Drugs' (2010), Ellen R. Shaffer and Joseph E. Brenner, CPATH, www.healthaffairs.org [accessed 12 May 2011].

iiiIFARMA. Impact of the EU-Andean Trade Agreements on Access to Medicines in Peru. November 2009. HAI Europe.

[iv] All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines, Oxfam International (2007), http://www.oxfam.org.uk/resources/issues/health/downloads/bp102_trips.pdf. UN Human Rights Council, *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health,* Anand Grover, 31 March 2009, A/HRC/11/12, available at: http://www.unhcr.org/refworld/docid/49faf7652.html [accessed 11May 2011]. A Trade Agreement's Impact on Access to Drugs' (2010), Ellen R. Shaffer and Joseph E. Brenner, CPATH, www.healthaffairs.org [accessed 12 May 2011].

v http://www.bangkokpost.net/breaking_news/breakingnews.php?id=116803; p169, 'The Economics of Effective AIDS Treatment', Conference Edition, World Bank, Washington, 2006.

vi World Health Organization Briefing Note: Data Exclusivity and Other TRIPS plus Measures (2006), Global Commission on HIV/AIDS and the law, Chapter 6, available at: http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf; Report of the Commission on IPRs, Innovation and public health, http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf; Resolution WHA61.21 (GSPoA) on public health innovation and intellectual property http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf.

vii IFARMA. Impact of the EU-Andean Trade Agreements on Access to Medicines in Peru. November 2009. http://haieurope.org/wp-content/uploads/2010/12/11-Nov-2009-Report-IFARMA-Impact-Study-on-EU-Andean-Trade-Agreement-in-Peru-EN.pdf.

viii European Parliament resolution of July 12, 2007 on the TRIPS Agreement and access to medicines (P6_TA(2007)0353).

ix P6_TA(2008)0195.

x Council Conclusions on the EU role in Global Health, Brussels 10May 2010, available at: http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/EN/foraff/114352.pdf.

xi HAI Europe Press Release 16 July 2012, ACTA is dead, long live ACTA: http://haieurope.org/wp-content/uploads/2012/07/16-July-2012-HAI-Europe-Press-Release-ACTA-is-dead-long-live-ACTA.pdf.