Introduction

Oxfam is an international development and humanitarian organization working in more than 90 countries to reduce poverty and promote social justice. There is no development possible without good health and no health without access to quality medicines. This is why we have been working for decades to promote access to quality medicines in developing countries.

Oxfam recognises that the cost of medicines is not the only obstacle to access to quality medicines, nevertheless, high price is a key factor impeding patients in developing countries to get the medicines they need. Health is a human right and therefore medicines are not simple commodities. The development, production and sale of medicines shouldn’t be driven by commercial interest and the ability to pay but by public health needs. It is not right that every year a 100 million people are pushed into poverty because of health expenditure – mainly the cost of medicines. According to the latest World medicines situation report from WHO, 1/3 of the world population hasn’t regular access to the medicines they need.

Stringent intellectual property rules (IPR) is a key factor that keeps medicines’ price high by restricting and delaying generic competition. Since 2000, Oxfam has been involved in a global movement for patients to be considered before patent.

Oxfam believes that the EU can play a key role in enhancing human development through adopting policies and strategies that ensure access to quality medicinal products in developing countries. Currently Oxfam is concerned about a number of policies prompted by the EC which will work against the development objective. We are particularly concerned about:

1. Concerns related to FTA negotiations with India and Thailand

In the last few years, we have campaigned to avoid harmful impact of FTA provisions and strict IPR on access to affordable and quality generic medicines as proved by previous FTA negotiated by the US. We fear that FTA negotiations have the potential to reverse progress made by many governments, such as India and Thailand, towards achieving better access to medical products. We are also concerned by the lack of transparency that characterizes the negotiation of FTA. Civil society organisations should be placed on equal footing with industry groups, which often have a privileged access to negotiating texts and to negotiators. This is critical to building public trust and to ensuring that negotiating objectives match the demands, needs and realities of the public.

India is often called “the pharmacy of the developing world” because generics companies in India, due to progressive intellectual property legislation enacted by India in 1970, have thrived and acquired a special position in providing medicines in India and around the world. At present, Indian generics firms produce more than two-thirds of all of the generic medicines used in low and middle-income countries, including over 80% of anti-HIV medicines.
Since the start of the FTA negotiations with India in 2007, DG Trade has been trying to include a range of TRIPS-plus provisions that would have had tremendous negative consequences for the access to medicines and the health of millions of patients around the world. These provisions included: eleven years of patent term extension through supplementary protection certificates (SPC), five years of data exclusivity protection and far-reaching IPR enforcement measures potentially obstructing the import, transit, and export of legitimate generic medicines. These provisions generated an outcry throughout the world, which pushed negotiators to step back and exclude data exclusivity and patent term extension from the negotiations. Nevertheless, as I will explain later, great concerns remain regarding the investment chapter.

Negotiations of a FTA between the EU and Thailand started in March 2013, with both parties expressing their desire to conclude these negotiations in 18 months. The EU will host the 3\textsuperscript{rd} round of negotiation in Brussels from the 9\textsuperscript{th} to the 13\textsuperscript{th} of December this year. The FTA will include among other IPR, IP enforcement measures, border measures and an investment chapter. We fear that the concerns we have flagged above on EU-India FTA will arise again with the Thai FTA.

The Thai government has established a system of universal health coverage (universal coverage scheme, UCS) since 2002, resulting in an impressive coverage of about 99\% of the population by a comprehensive health care package. The production and availability of affordable quality generic medicines is a key element of the health package. We fear that should a TRIPS+ IPR be included in the Thai-EU FTA, the ability of the Thai government to keep on running the current health system and to provide its citizens with the medicines they need will be hampered.

2. Concerns with Investment chapters in FTAs

It is paramount that the protection of investors is not made at the expense of government freedom to take measures to ensure access to healthcare for its citizens. Oxfam is concerned that the investment chapter in the EU-India FTA, whose definition of investment includes IP, would allocate tremendous powers to investors, via an investor-to-state dispute settlement mechanism, which will interfere with future efforts of the Indian government to ensure access to quality medicines. In particular, measures taken by the Indian government, whether through law, policy or court decision, that curtail, override or strike down patents and other forms of IP protection, even if legal under WTO rules and Indian law, could be challenged as ‘expropriation’ by pharmaceutical companies. Such charges are usually performed at secretive arbitration panels that have a strong tendency to rule in favour of commercial plaintiffs.

Similar provisions in other trade and investment treaties have been shown to enable multinational companies, including drug companies, to challenge governments’ abilities to regulate intellectual property in the public interest. Two noteworthy examples illustrate this danger:

1. In February 2010, the tobacco company Philip Morris sued the Uruguayan government under the investor-state dispute mechanism contained in a bilateral investment treaty (BIT) with Switzerland. Philip Morris challenged public health measures undertaken by Uruguay against smoking that required large warnings on cigarette packets and partially removed branding from cigarette packets. The legal challenge was justified by the “expropriation” of Philip Morris’ trademarks, the abuse of its investments rights and a breach of BIT as well as the TRIPS Agreement.
2. The US pharmaceutical company Eli Lilly & Co. challenged the Canadian government under Chapter 11 of the North American free trade agreement (NAFTA) following a Canadian court decision to revoke the company's patent for the drug Strattera, which is used to treat attention-deficit disorder. The drug company is now seeking $500 million in compensation.

The European Parliament (EP) has echoed Oxfam's concerns with regards to investment provisions. An EP resolution dating from 6th April 2011 insists that any investment provisions negotiated by the Commission should not negatively impact the production of generic medicines and should "respect the TRIPS exceptions for public health". An additional EP resolution regarding the EU-India FTA, adopted on 11 May 2011, also called on the Commission "to ensure that provisions on investment protection do not lessen the parties' ability to issue compulsory licenses or undermine other public health policies."

Investment provisions could have similar detrimental consequences for Thailand. Since 2007, Thailand has issued compulsory licenses on medicines to treat HIV, cancer and heart diseases. This legal and legitimate action put Thailand in the orbit of big pharmaceutical groups that felt threatened and placed Thailand under tremendous pressure from the US and the EU. In 2007, the then trade Commissioner Peter Mandelson wrote a letter to the Thai minister of Commerce regretting the use of compulsory license. We recall that compulsory license is legal under TRIPS agreement. It is a legitimate tool that allows countries to cut the price of life saving medicines that governments could not otherwise provide for their population.

In 2006, The World Bank estimated that if Thailand used compulsory licensing to reduce the cost of second-line antiretroviral therapy to treat people living with HIV by 90%, the government would reduce its future budgetary obligations by US $3.2 billion discounted to 2025.1 It is therefore key that the future FTA will not impede Thailand from using compulsory licenses to respond to health needs when necessary.

3. Concerns with data exclusivity and supplementary protection certificates (SPC)

Oxfam was assured by several members of the Commission that the negotiators would not push for controversial TRIPS+ provisions in the Thai-EU FTA. However, we have been disappointed to be told by well-informed sources that the draft negotiating text leaves the door open to supplementary protection certificates and data exclusivity.

Data exclusivity prohibits a medicines' regulatory authority from registering generic medicines on the basis of existing clinical data. Data exclusivity acts as a powerful form of monopoly protection that enables pharmaceutical companies to prevent generic competition, whether or not the medicine is patented.

The impact of data exclusivity – imposed via FTAs – is illustrated in previous FTAs. In 2001, the US and Jordan signed a FTA that included data exclusivity. A study conducted by Oxfam found that data exclusivity for medicines resulted in significant delays to introducing generic competition for 79 per cent of medicines examined in the study. This led to between two- and ten-fold price increases in the price of key medicines to treat cardiovascular disease and cancer, which are the main drivers of morbidity and mortality in Jordan. The availability of generic equivalents would have reduced expenditures on medicines by at least an estimated $6.3–$22.05m during the study period from mid-2002 through 2006.

Supplementary protection certificates extend the monopoly on medicines which delays the entry of cheaper generic medicines and therefore keeps the prices of medicines high. The European Commission has previously justified the inclusion of patent term extension to compensate for delays in processing patent applications by the competent authorities. Such considerations have been specifically raised in the Thai case. Oxfam thinks that providing technical assistance to improve its system of patent examination would be a more effective and efficient way to address the delays than extending monopoly and hence high price of medicines.

4. Other concerns linked to EC position at TRIPS Council negotiations

Oxfam regrets deeply the hard position taken by the EU and the US during the June 2013 negotiations to renew the waiver to apply TRIPS that was granted to LDCs in recognition of their special needs and requirements and their economic, financial and administrative constraints. Both powers put LDCs under enormous pressure to accept a short new transition period (between 5 and 7 years) accompanied by conditions that went against the development interests and international rights of LDCs. The EU prioritized accelerated TRIPS compliance over the LDCs development needs and it persistently viewed the transition period as merely giving LDCs a little more time to become TRIPS compliant, irrespective of whether the basic conditions exists in LDCs to benefit from high levels of intellectual property protection and enforcement. We supported LDCs’ request to have a longer term extension because they need the space to implement intellectual property systems appropriate to their development needs, to their policy priorities and to their level of economic development. LDCs are the most vulnerable part of the international community and more than half of their population live on less than $1.25 per day. An early implementation of the TRIPS agreement would have a grave impact on access to medical technologies, educational resources, seeds and climate change adaptation technologies. While getting 8 more years is better than nothing, short time extension does not allow LDCs to build up their own technological and knowledge base, and the laws and regulations necessary for implementation of the TRIPS agreement – let alone to benefit from such implementation.

We hope that the EU will take a more flexible stance in the next negotiations to renew LDC extension that will occur in 2021 and will avoid putting any pressure on LDCs to implement policies that would go against their own development interests.

In 2002, the TRIPS Council decided to exempt LDCs from applying TRIPS provisions on patents and on undisclosed information, to pharmaceutical products, until 2016, without prejudice to the right of LDCs to seek further extensions thereof. Hard negotiations will probably start from 2015 on to extend this waiver. This extension will be very critical for LDC countries since it will impact on their access to affordable generic medicines. For instance, if LDCs were obliged to apply 20 years patents on branded medicines, this would delay the availability of affordable generic medicines to a mostly impoverished population.

It is therefore of the utmost importance that the EC grants a new long-term extension on pharmaceuticals products to LDCs countries, without any conditions attached to it.
Recommendations

The EU plays a major role in supporting developing countries to improve the health of their citizens as illustrated by the financial and technical support of departments such as DG Development and DG research. DG Trade needs to make its contribution via ensuring that trade policies and agreements support and not hinder access to quality medicines. In particular:

- The Investment chapter in the FTAs must include safeguards that enable developing countries to take measures to ensure access to medicines and protection of health of citizens especially if investment is meant to cover IP. Adequate safeguards should ensure that investors cannot sue the government for any measures it takes on IPR to promote public health that respects the TRIPS agreement. The freedom to use compulsory licenses as foreseen in the TRIPS agreement should be explicitly mentioned as safeguard.

- The EC must respect third country’s (non-EU countries) policy space and refrain from exerting any pressure on Thailand or India regarding their use of TRIPS flexibilities (e.g. Compulsory licenses). As regards Thailand, the EC must not use the end in 2014 of the generalized system of preferences (GSP) Thailand is currently benefiting from, to push the Thai government to accept IPR or investment provisions that would be detrimental to its ability to improve its health system.

- Taking into consideration article 208 of the Lisbon Treaty on policy coherence, it is crucial that DG Trade ensure its trade policies are in line with development objectives, including enhancing access to health care and medicines. Furthermore, the Doha Declaration makes explicit that IPR protection shouldn’t undermine public health and that countries should be able to fully use TRIPS flexibilities to protect the health of their citizens. We welcome the reference to Doha declaration made in FTAs negotiating texts. However, the EC must avoid the inclusion of provisions that could potentially undermine the Doha declaration, such as supplementary protection certificates or several years of data exclusivity.

- Oxfam would welcome the inclusion of mechanisms and dialogue fora that would include health expert from civil society to monitor the health effect of FTA.

- We hope the EC will adopt a flexible approach towards LDCs’ demands during upcoming TRIPS negotiations, be it for the general waiver’s extension negotiations foreseen for 2021 or be it during the pharmaceutical products waiver’s extension foreseen for 2016.