Oxfam is an international development and humanitarian organization working in more than 90 countries to reduce poverty and promote social justice. We have been working on access to quality medicines in developing countries for decades. This work includes assessing the harmful impact that FTA provisions and strict IPR on access to affordable and quality generic medicines.

Influential countries like the UK are in a favourable position to influence the EC position and decision-making. This is the reason why we are taking part in this call for evidence to urge the UK to continue to take all opportunity to defend access to medicines and affordable health care for developing countries' citizens.

Call for Evidence: Review of the Internal Market: Free Movement of Goods including the EU Customs Union and Intellectual Property Rights

1. To what extent has EU action on the free movement of goods brought additional costs and /or benefits to you when trading with countries inside and outside the EU? To what extent has EU action on the free movement of goods brought additional costs and /or benefits to you as a consumer of goods?

2. Do you think that the EU strikes the right balance between regulating imports and exports and facilitating international trade?

Customs enforcement of intellectual property rights

Oxfam has been following this issue very closely because of its direct impact on access to medicines. Therefore, we have followed the revision of the EU Regulation concerning customs enforcement of intellectual property rights' (EU Customs Regulation 1383/2003).

The previous regulation led to several illegitimate seizures of generic medicines in transit through the EU on its way from India and Brazil to other developing countries. These generic medicines were wrongfully mistaken as counterfeiting medicines. The problem was so acute that both export countries challenged the EU regulation for hampering lawful trade in generic medicines at the World Trade Organization (WTO). In December 2011, the European Commission issued a proposal to review this regulation and tackle the flaws it contained. While we have welcomed that move, we are worried that the new text adopted on 11th June 2013 during the EP plenary session still presents some features that could lead to wrongful seizure of generic medicines by customs authorities.

We have 3 main concerns related to this new regulation:

1 Impact of in-transit IPR enforcement at the border on trade in generic medicines

Border actions targeting medicines passing in transit can interrupt the global supply of quality, legitimate generic medicines. They may do so directly, through detentions and even destruction, or indirectly, by forcing producers to tranship via more expensive routes, or by creating a "chill" for the global generics industry. The Dutch & German seizure cases (2009) have demonstrated that this risk is not hypothetical[1] .

[1] *Dutch seizure puts pressure on access to medicines in developing countries* 6th February 2009 http://haieurope.org/wp-content/uploads/2010/11/6-Feb-2009-Press-release-Dutch-seizure-of-generic-medicines.pdf;http://www.msfaccess.org/content/letters-ec-netherlands-customs-seizure and http://www.msfaccess.org/content/letters-ec-netherlands-customs-seizure; *Another seizure of generic medicines destined for a developing country, this time in Frankfurt.*5June2009 http://haieurope.org/wp-content/uploads/2010/11/5-Jun-2009-Press-release-Seizure-of-generic-medicines-in-Frankfurt.pdf.

In June 2009, customs officials in Frankfurt, Germany seized a shipment of the generic medicine amoxicillin, whose commercially branded name was “amoxillin”. Thus, the medicine’s branded name was based on the international non-proprietary name (INN) for the medicine. The generics were seized because its name was similar to that of the GSK originator product, “Amoxil”, which had also been named on the basis of the INN. The interruption of medicines supply chains, even temporarily, has grave consequences for patients, especially in developing countries. This is only one example among more than 20 seizures that occurred between 2008 and 2009.

The European Court of Justice (ECJ) in its recent (2011) case law, has now provided explicit and clear rules on the scope of enforcement of EU IPRs on goods passing in transit by customs authorities in EU Member States: this is not allowed without a preliminary finding based on “clear and convincing evidence of a substantial risk of diversion” of the goods onto the EU market[2]. The ECJ emphasised that “it is essential that those goods be able to pass in transit, via the EU, without that operation being hindered, even by a temporary detention, by Member States’ customs authorities’[3]. Unfortunately, in the new regulation, the recital on the scope of in transit IPR enforcement is not sufficiently clear, which could lead to new wrongful seizures of generic medicines.

2 Impact of lack of procedural safeguards

Oxfam does not oppose IPR enforcement in general. Nevertheless, enforcement of IPRs at the border is a specific form of law enforcement that is carried out by non-judicial authorities - customs officials - who are not properly trained and equipped to perform complex legal assessments on inspection of alleged IPR infringement of goods. Determining counterfeit trademark and pirated copyright infringements at the border involves a relatively straightforward assessment. But establishing other types of IPR infringements - especially patents, supplementary protection certificates and confusingly-similar branding disputes - involves a complex legal assessment. The Dutch & German seizure cases (2009) have demonstrated the risk that customs authorities can make mistakes when assessing patent and civil trademark infringements of in-transit medicines at the border.

Border enforcement should be applied with full caution and due consideration of defendant’s rights. When it comes to IPRs related to medicines. It is only fraudulent trademark counterfeits involving the use of an *identical* trademark or brand, which can be - even arguably - linked to trade in dangerous counterfeit medicines. In contrast, patent infringements and confusingly similar branding disputes have in principle nothing to do with trademark counterfeiting or unsafe medicines. Moreover, the main public health concern lies with the *quality* of the medicines, which has nothing to do with IPR enforcement, but should be addressed by better health regulations through quality standards.

IPR infringements other than counterfeit trademark infringement and copyright piracy constitute merely commercial disputes between private parties occurring in the course of legitimate trade. These kinds of disputes should therefore be handled and reviewed by competent judicial authorities rather than customs officials.

The new regulation contains a simplified procedure which is applicable to all IP rights, and includes the right to destroy the goods in cases of an alleged IPR infringement and tacit consent of the

[2] ECJ (2011), C-446/09 and C-495/09. The ECJ also clarified that the so-called manufacturing fiction – the premise that goods in transit may be considered to have been manufactured in an EU Member State, applied by inter alia the Netherlands – can no longer apply to products in transit.
[3] ECJ (2011) C-446/09 and C-495/09, paragraph 63.

holder/declarant of the goods. Oxfam fears that this could facilitate the illegitimate seizure or destruction of generic medicines and multiply the number of mistakes**.**

3 Impact of broad liability intermediaries on trade in generics

Vague and broad wording of provisions that provide for liability of third party intermediaries involved in trade of goods, puts a broad group of third parties at risk of enforcement measures at the border. In the trade in generics this group of third parties can potentially include suppliers of active ingredients for medicines, or NGOs procuring and distributing legitimate generics for treatment. In many instances such intermediaries might not be aware of the challenged IPR status of the goods in question and it imposes an undue and costly burden on them to try to ascertain the same. This liability could act as a significant deterrent to anyone involved in the production, sale and distribution of affordable generic medicines.

How could the UK government make sure that the new regulation will not lead to illegitimate seizure of generic medicine?

→ The ECJ case law established that in transit IPR enforcements by customs authorities should only occur when there is a clear risk of diversion of the goods in the EU market. We exhort the UK to make sure that the ECJ case law is well respected in the implementation of this regulation and that the free movement of generic medicines passing through the EU is not obstructed.

→ The UK government should use its power of influence to call out the EC in case procedural safeguards are infringed and third intermediaries are wrongfully embedded in legal battle, especially in the case of the movement of generic medicines.

Article 37 of the new regulation allows the EC to submit a report by 31 December 2016 on the implementation of the regulation, and specifically on the medicines on transit, to be accompanied by recommendations. That report shall refer to any relevant incidents concerning medicines in transit including an assessment of its potential impact on the Union commitments on access to medicines under the "Declaration on the TRIPS Agreement and Public Health" adopted by the Doha WTO Ministerial Conference on 14 November 2001, and the measures taken to address any situation creating adverse effects in that regard.

→ We urge the UK government to seize this opportunity and push the CE to issue such report should any incident involving wrongful seizure of generic medicines occur.

Call for evidence: Trade and investment

1. What are the advantages and disadvantages of the EU's competence over trade and investment, particularly in relation to international trade and investment negotiations?

Oxfam is submitting a call for evidence that focuses most specifically on:

- FTAs the EU is negotiating on behalf of the 27 Member states with third countries and its potential harmful impact on access to medicines for developing countries
- The flexibility LDCs countries need as regards to TRIPS agreement

Analysis of prior FTA negotiated by the US and EU with several developing countries have clearly demonstrated the negative impact of these agreements on public health and access to medicines in developing countries .

Over the last decade, Oxfam has followed closely EU trade policies and has witnessed in disappointment the movement towards proposals that undermine development. The Directorate General (DG) for trade is demanding a range of aggressive IP measures that support the commercial interests of the multinational pharmaceutical industry, while undermining both innovation and access to affordable medicines in developing countries. In particular, the EU has included numerous TRIPS-plus rules that exceed minimum WTO obligations and which create new barriers impeding access to medicines. We fear that FTA negotiations have the potential to reverse progress made by many governments, including in India, towards achieving better access to medical products in developing countries.

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. This is critical to building public trust and ensuring that negotiating objectives match the demands, needs and realities of the public

Specific concerns on the EU/India FTA negotiations

India is 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 all medicines used to treat HIV and AIDS. IP and investment provisions that exceed minimum obligations under TRIPS, and which are allegedly included in an FTA with the EU, are harmful and could have tremendous negative consequences for the access to medicines and the health of millions of patients around the world.

Thus, Oxfam urges the UK to prevent the EC from including IPR provisions that go beyond minimum obligations included in the TRIPS Agreement.

The range of TRIPS-plus provisions the EU has attempted to implement in previous trade agreements include:

- Data exclusivity provision: significantly enhancing protection for clinical trial data by providing up to 11 years of exclusive use of such data to obtain marketing approval, effectively prolonging monopoly protection for medicines;
- Patent term extension: extending patent monopolies through supplementary protection certificates (SPC);
- IPR enforcement measures which potentially obstruct the import, transit, or export of legitimate generic medicines.

Given that flexible intellectual property rules have played a critical role supporting India's role as 'pharmacy of the developing world', we would like to highlight three areas in which we urge the EU not to push India to insert provisions that will harm access to medicines:

1. Investment chapter

We are concerned that the investment chapter included in the EU/India FTA would vest tremendous powers, via an investor-to-state dispute settlement mechanism that is included in the investment chapter, to interfere with future efforts of the Indian government to manage intellectual property and ensure access to medicines. In particular, measures taken by the Indian government, whether through law, policy or court decision, that curtails, overrides or strikes 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 at secretive arbitration panels that have a strong tendency to rule in favour of commercial plaintiffs. This would constrain India's national policy and legislation in the domain of public health.

Oxfam suspects that challenges based on the Indian government's management of intellectual property are possible because intellectual property has been included within the definition of "investment".

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, as these two noteworthy examples indicate:

- 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.
- The US pharmaceutical company Eli Lilly & Co. challenges 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 $100 million in compensation.

The European Parliament (EP) has echoed our 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."

While there have been indications that safeguards will be included in the investment chapter, Oxfam is concerned that these will not be strong enough to override all the threats to legitimate public health measures.

→ We therefore urge the UK to put pressure on the EC to exclude IP from the definition of "investment" as well as exclude the "investor-to-state" arbitration mechanism from the investment chapter. If the investor-to-state arbitration mechanism remains, robust safeguards should be put in place to ensure that companies cannot interfere with the Indian government's right to introduce and enforce measures that protect and promote public health.

2. IP enforcement measures

IP enforcement measures can have a direct negative impact on the production and trade of generic medicines. Branded companies are provided with the power to accuse generic competitors of infringing their IP without providing evidence. Enforcement of border measures at the behest of multinational pharmaceutical companies can lead to the seizure and even the destruction of legitimate generic. Some companies could also use these powers as a commercial tactic to create a "chilling effect" that interferes with the production and export of generic medicines.

Vague, broad or imprecise wording of provisions that provide for liability of third party intermediaries involved in the trade of goods places a broad group of third parties at risk of enforcement measures at the border. In the trade in generics, this group of third parties can potentially include suppliers of active ingredients for medicines, or non-governmental organizations that procure and distribute legitimate generic medicines for treatment in developing countries. In many instances such intermediaries might not be aware of the challenged IPR status of the goods in question and it imposes an undue and costly burden on them to try to ascertain the same. This liability could act as a significant deterrent to anyone involved in the production, sale and distribution of affordable generic medicines. Indeed all the parties concerned run the risk of facing injunctions, provisional measures and being placed under constraints that generate economic losses.

This concern is not hypothetical as such measures have produced harmful impacts within the European Union itself. The EU Customs Regulation 1383/2003, which enforces IPR at the EU border, and which is under challenge by both the Indian and Brazilian governments, resulted in several seizures of shipments of generic medicines on the grounds of mistaken assessments of patent infringement and trademark infringement. The seizures that occurred in EU Member States, including the Netherlands and Germany, drew broad public attention and demonstrated some of the risks with such measures, including the fact that they are often carried out without adequate analysis, guidance, understanding, or expertise of IP rights by border officials.

For instance, in June 2009, customs officials in Frankfurt, Germany seized a shipment of the generic medicine amoxicillin, whose commercially branded name was "amoxillin". Thus, the medicine's branded name was based on the international non-proprietary name (INN) for the medicine. The generics were seized because its name was similar to that of the GSK originator product, "Amoxil", which had also been named on the basis of the INN. Such confusion, if applied at the borders of India, could result in the delays and destruction of generic medicines intended across the developing world, with economic impacts in India and public health impacts in other developing countries.

More broadly, Oxfam is concerned that such provisions, if included in the EU-India FTA, would have a tremendous 'chilling' effect upon the Indian generics industry, and result in the destruction and detention of multiple shipments of essential generic medicines.

→ We urge UK officials to make sure that IPR enforcement provision do not go beyond existing obligations under TRIPS, while also avoiding inclusion of provisions that are too broad or vague and which enable pharmaceutical companies to demand border measures that abridges the legitimate movement of generic medicines.

3. Data exclusivity and patent term extension

Previous leaked drafts of the negotiating text have revealed the inclusion of 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 multinational pharmaceutical companies to prevent generic competition, whether or not there is a patent on the medicine (or if a patent had even been issued in the first place).

The impacts of data exclusivity – imposed via free trade agreements – are demonstrating the negative public health impacts. In 2001, the US and Jordan signed a FTA that included data exclusivity. A study conducted in 2007 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 for 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.

Implementation of data exclusivity would mean that generic companies would have to repeat the clinical trials that are already done by the originator companies. This will add unnecessary cost to the price of generic medicines. Moreover it is unethical to repeat trials on people when the outcomes are already known.

In addition, earlier leaked versions of the EU-India FTA have indicated demands from the EU to introduce patent term extensions in India, or extensions of the patent term of the medicine beyond twenty years due to delays in processing patent applications.

Due in part to concerns expressed by public health and development organizations; it appears that patent term extensions and data exclusivity provisions have been withdrawn from the FTA. Nevertheless, Oxfam wants to reiterate that these provisions are not included in the EU-India FTA or any other FTA that the EU may negotiate in the future, especially with developing countries.

→ We urge the UK to use all its influence to oppose any TRIPS plus measures during FTA negotiations, including data exclusivity and patent term extensions.

Concerns as regards to EU/Thailand FTA:

Negotiations between both parties have started in March 2013. Since negotiations are still recent (the first round of negotiations was concluded in May), we haven't had the opportunity yet to access a draft negotiating text. But we already know that this FTA will include IPR, IP enforcement measures, border measures and an investment chapter (which will consider IPR as an investment). Both parties have declared that they aim to conclude these negotiations in 18 months, thus the pace of negotiations will be quick.

We fear that all the concerns we have flagged above on the EU/India FTA will arise again with this FTA. It is almost certain, considering the previous failed negotiations between the EU and ASEAN countries that the EC will try to push for very stringent IPR and IPR enforcement rules and try to have an investment chapter that could open the door to excessive legal challenges from industries.

The Thai government has established a system of universal health coverage (universal coverage scheme, UCS) since 2002. Different groups of citizens are covered by different types of schemes which means that 99% of the population is covered by a comprehensive health care package. The production and availability of affordable and quality generic medicines is a key element to sustain the public health care. 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 might be hampered.

Since 2007, Thailand has issues several compulsory licenses on HIV/AIDS, cancer and heart disease medicines. This move put Thailand in the orbit of big pharmaceutical groups that felt threatened by that sort of practices. We recall that compulsory licenses are legal under TRIPS agreement's safeguards and are practices that allow countries to drastically slash down the price of live saving drugs that they could not otherwise provide to their populations. The World Bank had estimated in 2006 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.[4] It is therefore key that the future FTA will not impede Thailand to issue compulsory licenses to respond to health needs when necessary.

→ We urge the UK government to influence the EU/Thai FTA negotiations in order to ensure that TRIPS+ provision and harmful investment chapter are not included in the negotiating text. The UK should consider the Thai public health system value for Thai people before big pharmaceutical monopolies.

LDC extension to apply TRIPS agreement

A further concern we have is related to the recent WTO decision to grant 8 more years transition to LDC to apply the TRIPS agreement.

Article 66.1 of TRIPS explicitly permits LDCs not to apply TRIPS provisions in recognition of their special needs and requirements, their economic, financial and administrative constraints and their need for flexibility to develop a viable technological base. The current waiver that was granted to LDCs was bound to expire in the end of June 2013.

On November 2012, Haiti issued a "duly motivated request" on behalf of the LDC group to extend the transition period and allow LDC countries not to implement TRIPS as long as they remain in the LDC category and without conditions. After months of harsh and tense negotiations, the WTO TRIPS Council took a decision (IP/C/64) on June 11th to extend for a further 8 years, the flexibility of LDC Members under Article 66.1 to not apply the provisions of the TRIPS Agreement except for Articles 3, 4 and 5 (which concern national treatment and most-favoured nation treatment).

In coalitions with other civil society organizations, Oxfam has followed the negotiations that have precluded this decision very closely. We deplore the very radical and obstructive stance the EC and USA adopted during these negotiations. Both powers put LDCs under enormous pressure to accept a shorter new transition period (between 5 and 7 years) accompanied by conditions that went against the development interests and international rights of LDCs. Both powers wanted to include a binding "no-rollback clause" in the decision, prohibiting LDCs to modify a national TRIPS compliant legislation once it has been adopted. Throughout months of behind-the-scenes negotiations, the EU consistently sought to undermine both the requested length of the transition period and LDCs' freedom to determine the level of IP protection, if any, that was optimal in light of their special circumstances. 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.

During these negotiations, we have had several contacts with UK civil servants and diplomats in charge of this dossier to urge them to let LDCs the flexibilities and the time they need to become TRIPS compliant. We received positive response from the UK authorities to our concerns. While getting 8 more years is better than nothing, the compromise deal falls short of the LDCs' request for extension until a country ceases to be an LDC. The 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 supported LDCs' request 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

[4] 'The Economics of Effective AIDS Treatment', Conference Edition, World Bank, Washington, 2006

have a grave impact on access to medical technologies, educational resources, seeds and climate change adaptation technologies.

→ We therefore urge the UK government to take a bold pro-development stance in the next negotiations to renew LDC extension that will occur in 2021 and to avoid putting any pressure on LDCs to implement policies that would go against their own development interests.

Right after the TRIPS council announced its decision to grants LDCs countries 8 more years transition, the EC issued a press release misinterpreting the decision. The EC inaccurately and wrongfully stated that LDCs "have committed themselves not to reduce or withdraw the current protection that they give" (no-rollback). This is a disingenuous reading of the decision adopted and of the negotiating history, where the EU clearly lost its efforts to secure a no-rollback clause.

The no-rollback clause, included in the previous extension decision adopted in 2005, is not included in the current extension. The LDC Group rightly objected to its inclusion in the new decision, though the developed countries particularly the US and the EU continued to demand it. As a compromise, the new decision replaces the obligatory no-rollback clause with a sentence whereby LDCs only "express their determination to preserve and continue the progress towards implementation of the TRIPS Agreement". To remove any doubt, the decision further clarifies, that "Nothing in this decision shall prevent least developed country Members from making full use of the flexibilities provided by the Agreement to address their Needs".

Clearly, the new extension decision does not prevent LDCs from rolling back existing IP protections. Therefore, the EU's interpretation of the new extension decision is fundamentally flawed and purposefully misleading, and is just another attempt to undermine rights of the poorest nations granted under Article 66.1 of TRIPS.

→ We urge the UK to clarify the issue and prevent the EC from putting LDCs under pressure to apply illegitimate conditions that have not been agreed during the 11th of June TRIPS Council.

In 2002, the TRIPS Council Decision of 27 June 2002 (IP/C/25) specifically exempted 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. 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, pushed by the UK government, grants a new long-term extension on pharmaceuticals products to LDCs countries, without any conditions attached to it.