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Putting public health at risk:

US proposals under the Trans Pacific Partnership Agreement (TPPA) to exacerbate Vietnam's access to medicines crisis

Background

As negotiations for the next round of the Trans Pacific Partnership Agreement (TPPA) get underway in Singapore, the United States is expected to renew its insistence that other negotiating countries, including Vietnam, adopt new intellectual property (IP) and pharmaceutical pricing rules as a part of a '21st century trade agreement'.

Yet even as the United States pushes for trade rules to address what it sees as 21st century challenges, Vietnam and other low income countries negotiating the TPPA are struggling with a problem from the 20th century that continues to plague health care systems – unaffordable medicine prices.

Today, Vietnam is suffering from an access to medicines crisis. Both the government and households already pay very high prices for medicines, and thus both the government and families are spending enormous amounts of money to pay for needed medicines. Patients pay out of pocket for 72 percent of all medicine costs. Still, medicines for many life-threatening diseases - such as cancer, Hepatitis C and heart disease - are not purchased because they simply cost too much.

Strict levels of IP protection and pharmaceutical pricing provisions in the TPPA will drastically undermine Vietnam's efforts to manage medicine prices and to promote access to low-cost generic medicines. These rules will also compromise fledgling efforts in Vietnam to ensure the quality and safety of medicines.

This coming week, the US has an opportunity to reconsider its approach to medicines in the TPPA. Instead of defending narrow interests of a few big pharmaceutical companies while punishing men and women in low-income countries with high medicine prices, the US could – and should-- return to a negotiating approach that truly seeks to balance public health with protection of intellectual property.

Vietnam's access to medicines crisis

Every day in Vietnam and around the world, millions of men and women make extraordinary sacrifices to pay for health care and medicines for themselves and their families. Worldwide, the World Health Organization has estimated that over 2 billion people – most of whom live in low- and middle-income countries - lack access to medicines.

Vietnam has taken important new steps to improve access to health care over the last decade, including developing a national health insurance system. Yet coverage is still lacking for many – less than 60 percent of Vietnamese are currently covered under the national health insurance system. While there are many barriers to achieving universal health care, the management of medicine prices is a key concern.

Today, the price of medicines in Vietnam is already unaffordable and priced out of reach. According to the WHO, medicines are less affordable in Vietnam compared to neighboring countries. Patented (new) medicines in Vietnam are up to 50 times as expensive as the international reference price (lowest international price for the therapeutic equivalent of a medicine), while generic (copies) medicines are over ten times the price of the lowest price generic available worldwide.

For many life-threatening diseases, this means medicines are already out of reach for most people in Vietnam. Today, treatment costs for diseases such as Hepatitis B, Hepatitis C and cancer are too expensive; and are not covered via the national health insurance system. Households that cannot afford to pay high prices often go without the medicines they need.

- Cancer: Treatment costs for branded and generic cancer medicines are unaffordable, as the average cost of treatment exceeds the annual income of all but the wealthiest. Even though cancer is one of the five leading health problems facing the country, medicines for cancer account for only 3 percent of the pharmaceutical market. Thus, many patients are going without treatment.
- Hepatitis B: Up to 20 percent of the population in Vietnam suffers from Hepatitis B. Yet treatment costs are high. In 2008, treatment for and complications from Hepatitis B would have cost 4.4 billion USD if fully paid for by the government – a sum it cannot afford. Paying for anti-infection medicines is 450 USD per year, while treatment for carcinoma (a form of cancer) – a common side effect - costs 1,880 USD per year. These prices are out of reach of the government and households. In one study, only 1 percent of all patients diagnosed with Hepatitis B at a major hospital could afford treatment. Without treatment for Hepatitis B, patients eventually develop cirrhosis and liver cancer, which often leads to death.
- Hepatitis C: Hepatitis C afflicts up to 4 percent of the population in Vietnam. An optimal, full course of treatment for Hepatitis C (over a 48 week period) can cost up to 10,000 USD – unaffordable to all but the wealthiest Vietnamese. While some expensive medicines are covered by the country's national health insurance plan, the Ministry of Health has not yet issued a treatment standard for Hepatitis C, which precludes coverage via national health insurance.

Medicine expenditures are consuming the government's health care budget and imposing a serious burden upon patients.

High prices for medicines pose a serious challenge to the Vietnamese government and a heavy burden upon households. The government already spends over 9 percent of its budget (as of 2010) on health care. As of 2010, 60 percent of the national health insurance fun is allocated to pay for medicines. By comparison, Thailand spends 11.3 percent of its budget on health care; India spends 3.4 percent of its budget, and Indonesia spends 6.2 percent. According to officials at the national health insurance fund, there is little additional funding available to pay for increased medicine expenditures in the future.

Yet even with so much government funding now dedicated to pay for medicines, most medicine purchases still rely on partial or full out-of-pocket payments by patients. Today, approximately half of all health-care costs are paid for out-of-pocket by patients. And medicines are the single largest expense for patients, accounting for 72 percent of all out-of-pocket costs for health care. Thus, high medicine prices have serious direct impacts upon patients, many of whom have to go without or find themselves and their families forced to make impossible sacrifices to pay for treatment.

Medicine expenditures are already set to double over the next five years without a clear source of new funding.

Medicine expenditures in Vietnam are set to double in the next five years, in part due to a growing population. While a larger volume of medicine purchases could translate into lower prices, the lack of centralized procurement of medicines and the existence of patent monopolies are key barriers that prevent prices from falling.

The country will have one of the fastest growing pharmaceutical markets in the world, and many industry analysts include Vietnam in a group of countries referred to as 'pharmemerging' markets, due to their anticipated higher demand for medicines. Yet this sunny optimism masks the reality that Vietnam remains a lower-middle income country, with an average per capita income that is expected to increase only slowly beyond its current level of 1,300 USD over the next decade.

At the same time, overseas development assistance, including funds to pay for health care and medicines – such as to treat HIV and AIDS – may be curtailed completely by 2015. Thus, even though there are expectations that medicine consumption will increase dramatically over the next five years, there will be scarce new funds to pay for health care. In order to pay for medicines, it is more likely that spending dedicated to other needs – whether to improve health care facilities, train health care workers, or to invest in education or agricultural productivity – will need to be sacrificed in order to pay for medicines.

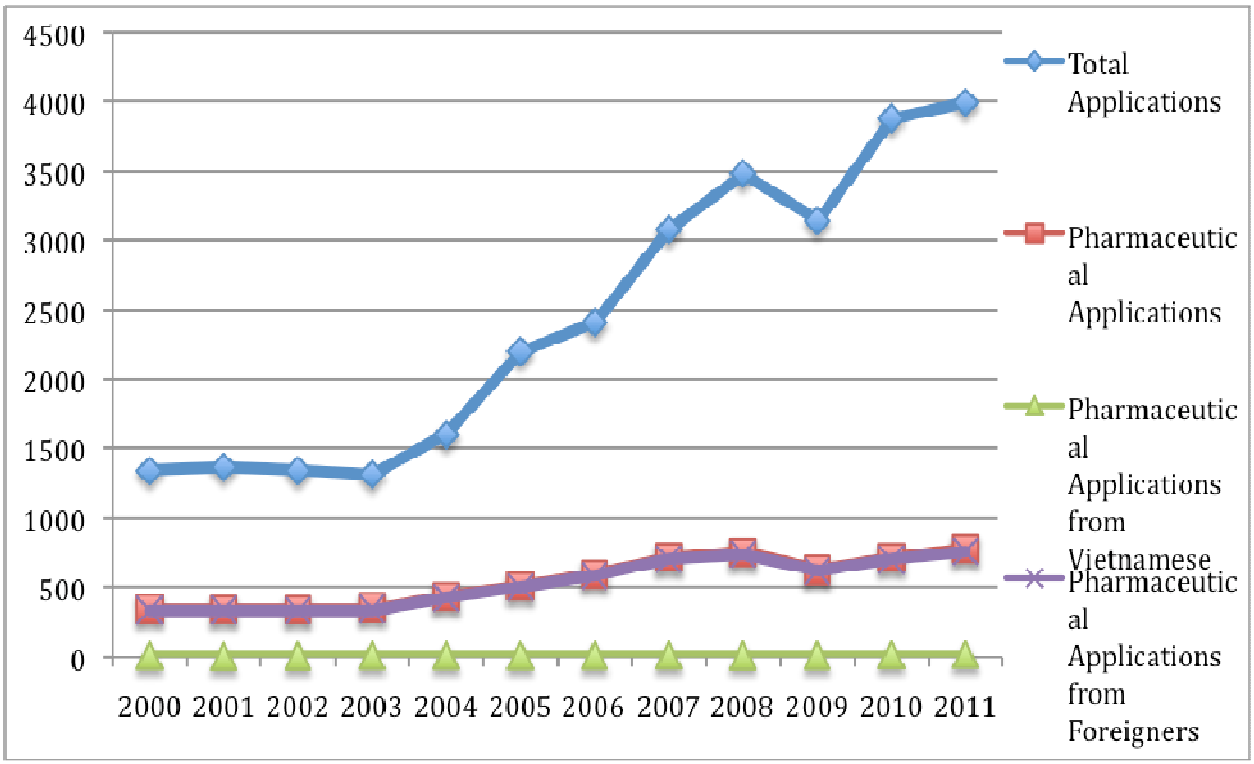
Intellectual property rules have not yet had a major impact on medicine prices.

Medicine prices are already too high in Vietnam, and yet intellectual property rules, which restrict access to low-cost generic medicines while enabling multinational drug companies to charge high prices, are not yet a major reason for the high prices of medicines. Recent studies, including one conducted by the UN Special Rapporteur on the Right to Health, indicate that ineffective and decentralized procurement of medicines, for example, has been a key driver of high medicine prices.

Patents for pharmaceuticals are still fairly new in Vietnam – the country only joined the World Trade Organization in 2007. Furthermore, other forms of monopoly protection not required under global trade rules and yet present in Vietnam, such as monopoly protection for clinical trial data, have yet to be granted in most situations. In some cases where patents have been issued, the companies who own them have not previously sought their enforcement due to the fact that Vietnam was not perceived to be a profitable market.

Yet now that Vietnam is seen as a 'pharmemerging' market by the multinational pharmaceutical industry, the situation has changed. Patent applications for all fields of technology are increasing, and companies are enforcing their patents and other forms of IP. The figure below illustrates the rapid increase in patent applications.

Figure 1: Patent applications in Vietnam (2000 – 2011)



The advent of the Trans-Pacific Partnership Agreement (TPPA) would enable multinational drug companies to use new IP and other monopoly rules to demand higher medicine prices. Just as increasing numbers of patent applications are being filed, new IP rules that abet enforcement of IP and zealous oversight and enforcement by the multinational drug industry and US government could be a devastating blow for a government that is already struggling to keep up with high prices.

US negotiating proposals under the TPPA: prioritizing drug industry interests above public health

Over the last decade, the US has negotiated a range of bilateral and regional free trade agreements with poor countries. These agreements have consistently demanded that poor countries introduce measures that will increase medicine prices. In particular, the US has demanded that low- and middle-income countries introduce a range of strict intellectual property rules that exceed minimum obligations under the TRIPS Agreement. These rules either interfere with the ability of countries to use basic, WTO-sanctioned public health safeguards to override patent monopolies when necessary to protect public health, or extend the monopoly term for a medicine beyond twenty years, thereby delaying generic competition and keeping medicine prices high for a longer period of time.

In recent years, studies have emerged that document some of the impacts of previous US trade agreements upon access to medicines in low-income countries. In 2007, Oxfam released a study of the impacts of a 2001 US free trade agreement with Jordan. Oxfam's research found that strict IP rules introduced under the FTA were a critical factor causing medicine prices to increase 20 percent between 2002 and mid-2006. In some cases, the prices of key medicines to treat cancer and heart disease were 2 to 10 times more expensive due solely to the new rules introduced under the trade agreement.

Yet compared to the TPPA, the US-Jordan agreement is far less harmful. The TPPA represents an unprecedented effort by the US Trade Representative (USTR) to deliver a trade agreement that satisfies the commercial interests of multinational pharmaceutical

companies. To date, the USTR has proposed a series of new intellectual property and pharmaceutical pricing rules that will provide the drug industry with numerous new powers to maintain high medicine prices, while crippling Vietnamese (and other countries') efforts to manage medicine prices going forward.

US TPPA proposals will exacerbate the access to medicines crisis in Vietnam

Intellectual property rules have not yet played a major role in driving up the prices of medicines in Vietnam. Yet the new rules proposed under the TPPA will seriously constrain the ability of Vietnam to manage medicine prices in the future, and will increase the burden on the government and households to pay for medicines. In Vietnam, government officials, experts and civil society groups have all expressed serious concerns with the future impact of the TPPA upon the affordability of medicines.

Data exclusivity

Under the TPPA, Vietnam would be required to maintain data exclusivity, a TRIPS-plus obligation. Data exclusivity creates a new form of monopoly protection, separate from patents, which prevents the onset of generic competition.

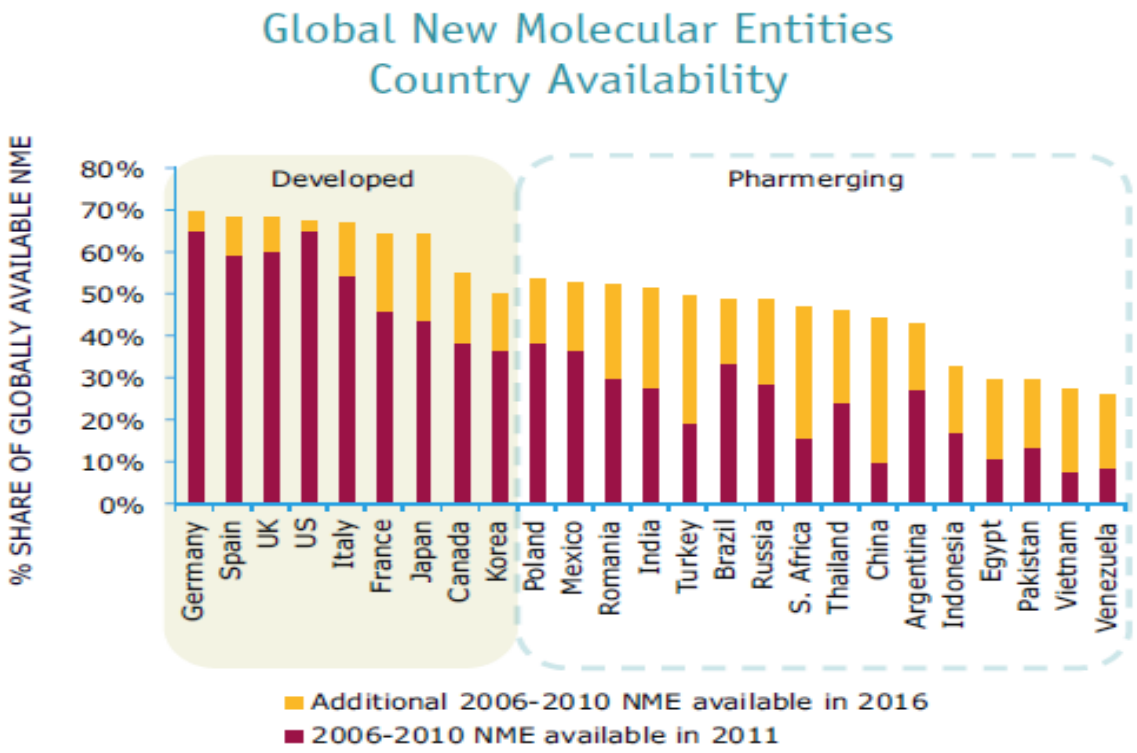
Normally, generic companies rely upon clinical trial data generated by multinational companies, who hold patents for the original medicines, to certify their medicine copies are safe and effective. By demonstrating a generic medicine is biochemically identical to a branded medicine, the generic can be declared safe and effective on the basis of the pre-existing clinical trial data.

Data exclusivity requires that drug regulatory authorities not refer to clinical trial data generated by an originator company to approve a generic version of a medicine until a term of exclusivity expires. Data exclusivity only commences when the original medicine is actually registered in the country.

Vietnam already has introduced a form of data exclusivity. However, Oxfam's research indicates that no term of data exclusivity has yet been granted in Vietnam as there have been few applicants, and those applicants have not satisfied the obligations of Vietnam's data exclusivity regime. In part due to these procedures, which are consistent with the WTO TRIPS Agreement, no company has successfully obtained data exclusivity. Under the TPPA however, these procedures would have to be abolished to comply with new obligations under the TPPA.

In practical terms, data exclusivity would result in monopoly terms for medicines that extend beyond 20 years. In many cases, drug companies only launch a medicine in Vietnam many years after the first global launch. See Figure 2.

Figure 2: Delayed launch time in Vietnam for new medicines



Source: IMS Institute for Healthcare Informatics, May 2012

In part due to such delays, an actual term of data exclusivity may not begin until late in a twenty year patent term for a medicine. Since the term of data exclusivity is at least five years, it will often result in the data exclusivity term extending beyond the actual patent term of the medicine.

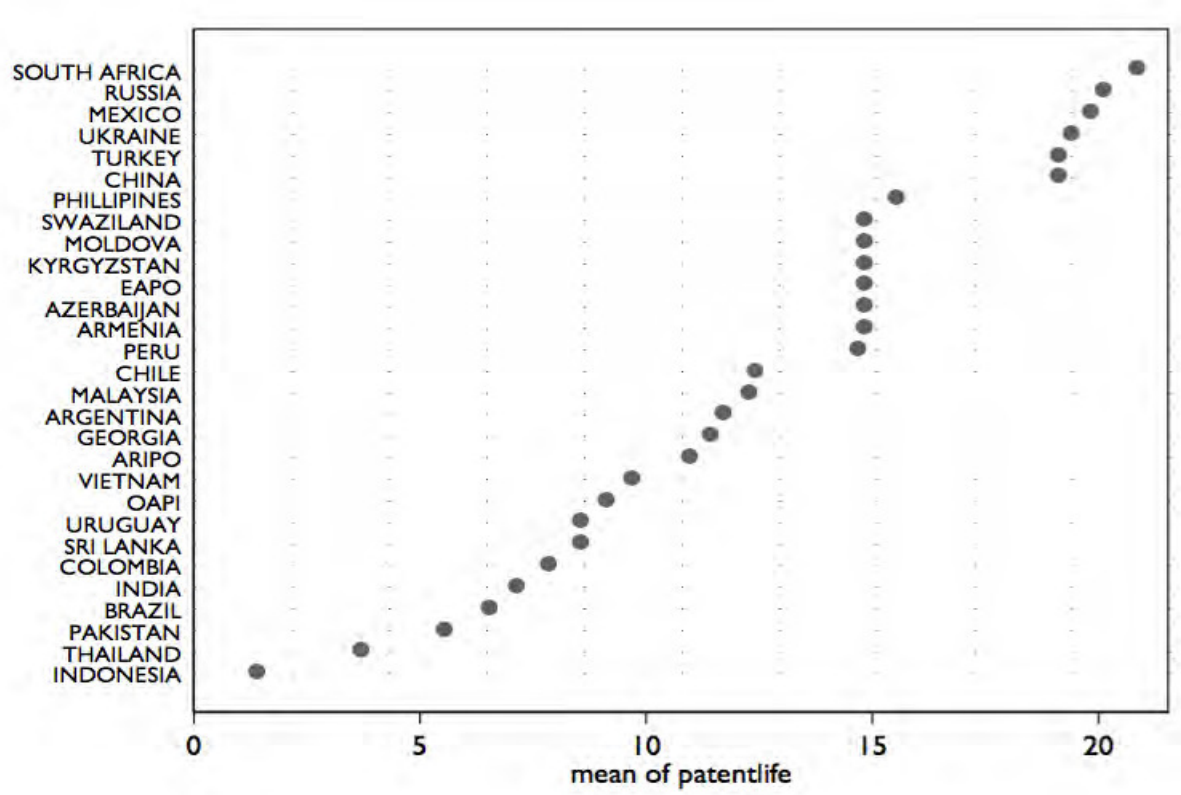
Management of intellectual property

Multinational pharmaceutical companies are always seeking to extend their monopoly power. One way they do so is by obtaining additional patents for slight, even trivial variations of medicines that already have received patent protection. This can extend monopoly control over a medicine far beyond 20 years, despite the lack of any significant additional innovation. The practice – known as 'ever-greening' – has been judged to be anti-competitive even in the US and European Union. Since ever-greening delays generic competition, it results in higher medicine prices.

In Vietnam, high medicine prices have not yet been due to ever-greening. While there is room for improvement in its system of reviewing and granting patents, Vietnam has not issued many trivial patents for medicines compared with other emerging or developed countries. This is due in part to the existence of laws that restrict what types of patents can be granted, and to the fact that the government allows for the use of pre-grant oppositions, which enable any third party to challenge a patent application it deems to be invalid, or for an invention which is not new, lacks an inventive step or is obvious.

Figure 3 illustrates that the average patent term in Vietnam for a medicine to treat HIV and AIDS at present is considerably less than the average patent term in South Africa. As such, medicines at present currently remain under monopoly in South Africa for a much longer time than in Vietnam. This is due in part to the lack of strict rules in South Africa to discourage trivial patents.

Figure 3: Average patent term for anti-retroviral medicines (through 2011)



Under the TPPA, the US, in lieu of considering the successful practices of Vietnam and other countries to discourage trivial patents, instead is proposing a series of measures to ensure drug companies can obtain large numbers of trivial patents that will undermine access to medicines and subvert the original purpose of IP protection to promote innovation. In particular, the US is demanding that countries change their patent rules to make it far easier for drug companies to obtain additional patents, and at the same time, the US is demanding that all countries eliminate the use of pre-grant oppositions. With such modifications to Vietnam's IP law, the average patent term for a medicine will soon reach the patent term for medicines in South Africa, which will limit access to medicines.

Pharmaceutical pricing

In Vietnam, one key reason the government pays high prices for medicines is the lack of effective implementation of existing policies to purchase medicines at low prices. At present, there is no central authority that purchases all medicines for use across the public health care system. Instead, each hospital or region is responsible for its own medicine purchases, which can result in higher medicine prices.

The TPPA would make matters worse. The US is demanding that all countries permanently disable their ability to effectively negotiate medicine prices. US proposals under the TPPA would allow pharmaceutical companies to interfere with reimbursement decisions that should be established independently by governments; in addition, the TPPA would interfere with the use of 'reference pricing' to set reasonable prices (reimbursement based on the least expensive therapeutic equivalent) for medicines reimbursed through the health care system.

These and other changes will lead to ever-higher medicine prices – at a time when the government and households already cannot afford to pay for medicines. For some diseases, such as Hepatitis C, Hepatitis B and cancer, treatment coverage is almost non-existent at present. Yet for other diseases, and especially HIV and AIDS, recent gains to increase treatment could be lost, due in part to higher medicine prices and also to a loss of overseas assistance to pay for medicines. See Box 1.

Box 1: Treatment for HIV and AIDS: Why US trade and aid policies could derail universal access to treatment in Vietnam

Vietnam has made important strides in addressing HIV and AIDS. With over 250,000 people living with HIV and AIDS (PLHIV), Vietnam is a high-risk country. However, thanks to low costs for first-line anti-retroviral medicines, and generous financial assistance from the United States via the President's Emergency Plan for AIDS Relief (PEPFAR), Vietnam now has over 60,000 people on anti-retroviral treatment.

Today, first-line medicines to treat HIV and AIDS are approximately 365 USD per patient per year, with most of the costs covered by PEPFAR. Since Vietnam launched its national AIDS program much later than other countries with a high prevalence of HIV and AIDS (such as Brazil and Thailand), most patients still remain on first-line treatments. Today, only 2.7% of Vietnam's HIV and AIDS patients rely on new, on-patent second- and third-line medicines. This is important since costs for second-line HIV and AIDS medicines are much higher, so when more people require them, it creates economic stress on the national AIDS treatment program.

However, the warning signs are there. The cost of new HIV and AIDS medicines in Vietnam, which are under patent, are anywhere from 5 to 10 times more expensive than first-line medicines. As the disease progresses and patients have to switch to second-line medicines, there are concerns that the high cost of these medicines will make it difficult to pay for new treatments while also initiating coverage for existing and newly infected patients in the country.

The TPPA will only make matters worse. By introducing stricter IP rules for medicines that limit the use of public health safeguards and cripple the ability of the government to negotiate medicine prices, the financial burden of higher medicine prices will increase dramatically. In addition, the additional IP rules will encourage ever-greening and other measures that will extend the patent term beyond 20 years, granting multinational drug companies additional months or even years to charge unaffordable prices.

At the same time, the US, which is responsible for pushing these stricter IP rules under the TPPA, is likely to withdraw funding for treating HIV and AIDS in Vietnam by 2015 due to Vietnam's improved economic situation. In fact, many donors are planning to withdraw foreign assistance to the country in 2015. And while treatment for HIV and AIDS is meant to be paid for through the national health insurance fund, most local experts, according to research conducted by Oxfam, cannot point to where new funding will emerge to pay for old and new anti-retroviral medicines.

The TPPA, and the intellectual property and pharmaceutical pricing demands the US has tied to the trade agreement, could not have come at a worse time for Vietnam and its citizens.

US TPPA proposals will undermine quality and safety of medicines in Vietnam

The US approach to the TPPA will also undermine the quality and safety of medicines in Vietnam.

The obligation for Vietnam to introduce patent linkage presents a particular threat. Patent linkage, a TRIPS-plus obligation, requires drug regulatory authorities to delay ascertaining the quality of a medicine until it is certain that no relevant patents are in effect in the country. Requiring drug regulatory authorities to study the patent status of a medicine transforms the drug regulatory authority from a technical agency that reviews medicine quality into a 'patent police' that is required to enforce the private rights of multinational drug companies. In doing so, it shifts the burden of enforcing IP rules from the private right holder, which can enforce its rights through the court system, to a key public health agency.

Vietnam already has a serious shortage of resources to review the quality and safety of medicines. A patent linkage system will require Vietnam to divert precious existing and future resources towards examining the patent status of medicines.

Secondly, TPPA provisions may force Vietnam to eliminate a regulation that seeks to ensure medicines are safe and effective. At present, Vietnam requires all medicines first launched overseas to have been registered for five years elsewhere in order to qualify for registration (without domestic clinical trial data) in Vietnam. Otherwise, a company must undertake

domestic clinical trials in Vietnam to demonstrate the safety and efficacy of the medicine. While such a measure benefits patients by providing further assurance of a medicine's safety and effectiveness, it delays the actual launch date of the medicine in Vietnam.

Vietnam's obligation to introduce data exclusivity (see above) will require the government to consider a difficult trade-off between quality and affordability of medicines. Data exclusivity does not begin until a medicine is first registered. If Vietnam continues to require medicines to have been on the market for five years prior to launch in Vietnam, it will automatically result in longer monopoly terms in Vietnam for new medicines.

Such a delay in launch in Vietnam could lead to the monopoly provided under data exclusivity to last beyond the patent term for the medicine, resulting in an unnecessary delay to use a generic. Over time, as health care costs continue to rise, obligations to promote safety of medicines may be compromised in order to ensure access. No government should be forced to make trade-offs between ensuring their citizens can afford to get the medicines they need and making sure those medicines are safe.

US trade agreements do not have to undermine public health

Oxfam believes that trade can be an engine for development and poverty reduction, provided the rules are crafted fairly in order to benefit developing as well as developed countries. Well-managed trade has the potential to lift millions of people out of poverty.

But to do that, trade rules must help to improve livelihoods and reduce poverty in developing countries, considering the disparities among trading partners. For instance, the differences in the economic and social development between the US and its lower-income trading partners must be fully taken into account when trade rules are negotiated between them.

Trade rules have direct and profound impacts upon public health, particularly through intellectual property rules. The same IP rules developed for rich countries may impede rather than stimulate innovation and access to new products for emerging countries. To date, IP rules promoted by the US have been harmful to poor countries needing to ensure their populations can access affordable medicines. Time and again, US trade negotiators have insisted on far-reaching IP rules that work to keep the prices of new medicines high, benefiting narrow industry interests rather than promoting true innovation in the public interest. As well as harming patients and undermining the sustainability of public healthcare programs, this approach has discredited trade itself as a tool for poverty reduction.

The US did at one time take a somewhat different, more positive approach. In 2007, it seemed that US trade policy on IP and medicines was shifting. The US Congress and Bush Administration signed the "May 10th Agreement" that modified IP rules in certain trade agreements with developing countries, having recognized the potential harmful impact of TRIPS-plus rules on public health. Under this agreement, patent linkage and patent term extensions became optional, while data exclusivity was made more responsive to public health concerns and provisions were never included to enable ever-greening or restrict governments' ability to negotiate pharmaceutical pricing. Although in Oxfam's view the agreement did not go far enough, it was a step in the right direction, particularly if applied in future trade negotiations with other developing countries.

The May 10th, 2007 agreement between the Bush Administration and Congress must, at a minimum, be upheld in the TPPA. In particular, the IP chapter of the TPPA should include more flexible provisions, in line with public health concerns, with regard to patent term extensions, data exclusivity and patent-registration linkage. Other strict IP provisions should also be eliminated. Finally, there should be no pharmaceuticals chapter in the TPPA. The US should not be negotiating programs that curb the ability of developing countries to

manage the cost of drug procurement and reimbursement, or to enact international best practices in health and medicines policy.

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