Will compulsory licences improve treatment for patients?

The case of Thailand

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Introduction

In late 2006 and early 2007, the interim military government of Thailand issued compulsory licences for three Western-owned pharmaceuticals. In each of its applications, the government claimed that the price of these drugs undermined its commitment to provide universal healthcare to its citizens. This paper is an attempt to contextualise the issuing of these compulsory licences, and to assess their impact on the future health of both Thai and foreign patients.

Thailand's health landscape

While Thailand has for many years been fêted by health activists for the scope and scale of its HIV/AIDS treatment programme, the interim military government has cited a lack of funds as the primary justification for the recent compulsory licences it has issued for HIV/AIDS medicines. On announcing in November 2006 the compulsory licence on the Merck-owned second-line ARV Stocrin (whose generic name is Efavirenz) the Ministry of Health stated that the high price of the patented drug meant that "the budget allocated from the Thai government can only cover some patients with Efavirenz, whereas the others have to use other non-patented more toxic antiretrovirals."[1]

This was followed in January by a compulsory licence for Abbott Laboratories' Kaletra, an HIV protease inhibitor. In the text of its compulsory licence, the Thai Government again cited budgetary constraints as justification: "With this high price [caused by patent monopoly] the budget allocated from the Thai Government can only cover some patients with [Kaletra], whereas the rest has to face fatal opportunistic infections. If this ARV's formula could be produced or imported, the lower price would help more accessible [sic]."[2]

This compulsory licence for Kaletra was issued almost simultaneously with a further licence for a heart drug (Plavix) patented by Sanofi-Aventis and Bristol Myers Squibb. Again, the government claimed that the allegedly high price of the drug was hindering patient uptake of the medicine.[3] The government has also threatened to issue compulsory licences for 11 more drugs.

The reasoning behind these compulsory licences is clear. Patent monopolies on drugs inflate their price to the extent that they are undermining access to medicines. The only way for patients to get these vital medicines at affordable prices is to circumvent the rights of the patent holder and manufacture copies of the drug domestically, or import them from countries that have the capacity to make copies. In April 2007, the Thai government again cited budgetary constraints as justification for compulsory licences: "Our health system is in danger of going bankrupt," Health Minister Mongkol na Songkhla told BBC News, "and one of the biggest expenses we face is the cost of drugs."[4]

Thailand has certainly been achieving solid progress in its overall healthcare in recent years. According to the World Bank, infant mortality in 2002 was 23 per 1,000 live births, a significant improvement from 84 in 1964. Life expectancy for women is projected to reach 76.5 years by 2020, compared to 55.9 years in 1963. The UN Development Programme has praised the country's AIDS programme, and the WHO has been complimentary about its efforts to control tuberculosis. Vaccination coverage is high.

The previous prime minister, Thaksin Shinawatra, also achieved some degree of popular support amongst

Thailand's poor for the "30 Baht scheme" which aimed to provide universal healthcare coverage. However, this scheme has proved fiscally difficult for many healthcare providers, leading to budget deficits and the closure of many hospitals and clinics: 265 of the 819 hospitals run by the Ministry of Health had a total debt of 1.365 billion baht at the end of 2004. [5] Thailand also suffers from an acute shortage of healthcare workers – the latest available data indicates that Thailand has only 0.37 doctors per 1,000 people, compared to 1.2 in the Philippines, and 0.7 in Malaysia.[6] These problems are only likely to get worse as the military government, keen to build popularity, decided in November 2006 to abolish even the nominal 30 baht fee.

While not in a state of emergency, the healthcare situation in Thailand could be much better. Many of these problems stem from the historic lack of prioritisation of healthcare spending by successive governments. Under the previous prime minister, Thaksin Shinawatra, only 3.3 per cent of Thailand's GDP was spent on health, lagging well behind regional neighbours such as China with 5.6 per cent, Cambodia with 10.9 per cent, and Vietnam with 5.4 per cent.[7] These problems will be compounded by the military government's decision to cut health spending by some $12 million per annum – while at the same time increasing defence spending and salaries for the regime.[8]

The GPO and Thailand's industrial interests

Inconsistencies about budgetary priorities aside, the government's claim that its use of compulsory licences is solely about safeguarding public health deserves scrutiny, not least because of the operations of the main beneficiary of the compulsory licences – the state-owned Government Pharmaceutical Organisation (GPO).

The GPO will be granted the sole licence to manufacture the three drugs in question. According to Achara Akesangsri, the GPO's deputy chief of research and development, Thailand plans to begin building an Efavirenz factory that meets international Good Manufacturing Practices in late 2007,[9] meaning that the earliest a bio-equivalent drug could be produced would be in 2009. In the meantime, it is likely production will start imminently in existing facilities that have yet to meet GMP. At the time of writing, it is unclear when domestic production of Kaletra and Plavix will begin, but in the meantime, Thailand is expected to import copies of Kaletra from India.[10]

Thai government officials are on record describing their ambitions for the GPO, which appear to revolve around making Thailand a regional hub for the manufacture and export of copy medicines. The current government has stated that it wishes to significantly bolster the manufacturing capacity of the GPO, with the ambition to double current revenue to 10 billion baht by 2010.[11] The government has also signalled its intention "to improve the potential, capacity and competitiveness of the local industry."[12]

Supporters of the Thai government's licensing policy, such as the NGO Médecins sans Frontières, argue that domestic production will lead to a more reliable supply of the drug, as well as reducing costs.[13] As we have seen, the Thai government is also keen to present the expansion of the GPO's capacity as being driven entirely by concern for Thai patients. But there are several facts which undermine this interpretation.

- The Thai government has consistently undermined access to imported ARVs and other classes of medicine. It has inflated the price of imported Efavirenz with onerous taxes, duties and tariffs. The WHO has stated that "taxes and duties levied on medicines, as well as the mark-ups applied, frequently contribute more to the final price than the actual manufacturers' price." Thailand is no exception, placing an average tariff of over 11 per cent on imported manufactured pharmaceutical products, and the compounds used in their manufacture.[14] Furthermore, these taxes raise little revenue, but simply act as a regressive tax on sick people. [15] Why would Thailand actively discourage access to medicines in this way, if the need for these drugs is so pressing as to warrant multiple compulsory licences?

- The GPO is not being run on a non-profit basis. In 2003, the GPO made a profit of 642 million baht, with that figure rising to 1 billion baht in 2005. The

GPO plans to double its 2005 revenue to 10 billion baht by 2010, widening the scope for profit still further. Making profits out of pharmaceuticals is no bad thing in itself, as it provides revenue to reinvest in research and development and thereby furthers medical progress. What is also clear, however, is that the GPO has shown itself to be unwilling to participate in this process – it invested less than 0.5 per cent of its sales revenue in research and development in 2005,[16] compared to the pharmaceutical industry average of 17.5 per cent of sales revenue re-invested in R&D.[17]

- Politicians and bureaucrats connected with the GPO have used its profitability to engage in rent-seeking behaviour. The Thai Auditor General reported in 2002 that the GPO had stolen around $13m from the government over the previous four years. That same report revealed that in 2002 "the GPO sold about 60 per cent of its medical products to government agencies above market prices. In some cases products were marked up 1,000 per cent".[18]

- The Global Fund for AIDS, Tuberculosis and Malaria has said that it will pay for Efavirenz copies from India that are already on the WHO's pre-qualification list. This means Thai patients would immediately get WHO-endorsed medicines at no cost to themselves. However, the government has turned down this offer and is persisting with its course of issuing compulsory licences for eventual domestic manufacture. The government is thus asking Thai taxpayers to foot the bill for producing the drugs locally, instead of taking advantage of the international community's philanthropy via the Global Fund. Similarly, Thailand expressed its determination to go ahead with the compulsory licence for Kaletra, despite Abbott's announcement that it would reduce the drug's price in Thailand below any copy version currently in production.[19] Why is it necessary to go to the effort and expense of developing public sector manufacturing capacity when private industry will provide medicines at such a cheap price?

- The Thai government has exclude other private Thai manufacturers from procurement contracts, despite claiming that health needs can only be met with multiple compulsory licenses. The implication is that concerns other than public health were on the mind of the government.

The GPO and drug resistance

Once ARV treatment begins, experience points toward two certainties: firstly, drug resistance will inevitably set in among a certain percentage of patients each year – even in the best of medical environments – and, secondly, medical care costs increase over time. However, if a copy ARV is not exactly bioequivalent to the original branded product, then the emergence of drug resistance can accelerate rapidly.

At this point, it is worth pointing out the difference between a true "generic" and a "copy" drug. A true generic must demonstrate pharmaceutical equivalence and bioequivalence in a series of stringent tests administered by the Food and Drugs Administration (FDA)[20] or some other reputable regulatory agency. A "copy" (also known as an "investigative") drug, however, has undergone no such tests, and may work on the body in subtly different ways than a demonstrably bioequivalent generic.

These tests are vital to ensure that generics do not have adverse effects on patients. In the case of ARVs, a drug that contains incorrect amounts of active ingredient may result in the multiplication and spread of resistant strains of the virus.[21] Terrence Blaschke, professor of molecular pharmacology at Stanford Medical School, has noted: "successful treatment of infectious diseases is the result of complex interactions between the patient, the drug and the infectious agent. Drug concentrations that are too low can cause the therapy to fail, and equally important, promote the emergence of resistant forms of the infectious agent."[22]

Much confusion has arisen as result of misuse of the term "generic." Despite widespread use of the word, the reality is that many drugs used by Thailand in its HIV/AIDS programme are not true generics but untested copies. The original triple fixed-dose combination ARV

manufactured by the GPO, GPO-Vir, is one such example. Back in 2002 the Global Fund for HIV/Aids awarded Thailand $133 million to test and manufacture this drug but the grant carried two conditions: Thailand had in the interim to purchase drugs from companies pre-qualified by the World Health Organisation, and the GPO's facilities had to meet international standards in two years' time. With no reliable data on GPO-Vir's bioequivalency, Thailand was therefore gambling with prospect of rising drug resistance in order to make short-term cost savings with its copy drug.

In August 2006, the Global Fund finally withdrew funding for GPO-Vir because the GPO still had not brought its facilities up to standard, nor had the WHO pre-qualified this experimental drug.[23] But it was too little too late: Dr Wasun Chantrtita from Mahidol University's faculty of medicine at Ramathibodi Hospital revealed at the 10th National AIDS seminar in Bangkok that GPO-Vir was causing a rise in drug resistant AIDS cases among Thai patients[24]: 49 per cent of the patients in his study had developed resistance to lamivudine, 39.6 per cent to stavudine, and 58 per cent to nevarapine. GPO-Vir remained unlisted on the WHO's prequalification programme at the time of writing.[25]

Although the WHO considers GPO-Vir inadequate for sale outside Thailand, this drug continues to be used on Thai patients. This untested drug would never be approved for use on Western patients, but MSF distributes GPO-Vir in Myanmar and Cambodia as well as Thailand. The effect of using experimental GPO-Vir in Thailand was to force patients onto "second-line" therapies – increasing the drug price from $24 per person per month to $239, according to figures calculated by Médecins Sans Frontières.[26] Therefore, the increased drug costs faced by Thailand are to a large degree self-inflicted.

The price of therapies – both 1st and 2nd line – are only a small part of the AIDS treatment cost equation, however. Even 2nd line drug costs are comparatively minor compared to the cost of running the extra medical infrastructure required to administer these complicated medicines, such as specialist physicians, the costs of monitoring, and extra in-patient care, sometimes requiring hospitalisation.

These extra medical costs (separately from the cost of drugs) could potentially drive Thailand's AIDS treatment costs up far beyond its current HIV/AIDS budget, dwarfing current concerns about the prices of branded therapies. In order to salvage the situation, Thailand would inevitably have to turn to other nations for financial assistance, but substantial sums of foreign aid would in turn wreak all kinds of macroeconomic damage. In 2004, the IMF warned of the dangers of increasing aid flows for HIV/AIDS:[27] large inflows of foreign currency raise local exchange rates, hitting exports; increase inflation when aid funds are spent locally on "non-tradable goods"; and push up domestic interest rates that can squeeze social spending by raising public debt service payments. These all hurt the poor the most.

In essence, Thailand's decision to manufacture and distribute experimental AIDS therapies has undermined patient health by rapidly accelerating drug resistance. This is set to have long-term macro-economic consequences, the symptoms of which are only now becoming visible. Judging by the GPO's track record, these problems will only be worsened by fresh compulsory licences.

How will Thailand's compulsory licensing affect drug prices in Africa?

The need for second-line therapies as a result of using sub-standard ARVs would be less damaging if Thailand could be assured a limitless supply of cheap new drugs to replace drugs that have been rendered obsolete by resistance. However, Thailand's compulsory licences disrupt the delicate pricing strategies that both facilitate access to expensive drugs by the world's poorest countries and provide funds for developing new therapies.

ARV therapies are exceptionally time-consuming and expensive to develop, test and bring to the market, costing upwards of $500m each.[28] Pharmaceutical companies normally sell these products at different prices to different kinds of consumers to ensure that they reach as many consumers as possible while still maximising revenue. If a company is able to segment markets precisely according to each individual's

willingness to pay, then every consumer willing to pay at least the marginal cost of production for the product should be able to purchase that product. This would maximise both the number of people who benefit from the product and the company's revenue, which in principle would enable more to be spent on R&D. So, for example, drug prices in South Africa are far lower than in Europe and the USA.[29]

This means that market segmentation can be particularly beneficial for patients in poorer countries. Where the overall market for a drug is very large and where that market is readily segmented, companies may set the lowest price close to the marginal cost of production. In the context of a disease such as HIV/AIDS, where the total market for medicines is massive and the humanitarian case for widespread distribution is great, companies may even choose to sell below marginal cost in some markets, provided that sufficient profit is recuperated in others.[30] This means that the poorest countries with the highest HIV/AIDS prevalence, such as those in sub-Saharan Africa, are able to obtain branded drugs at an extremely low price, while middle-income countries like Thailand pay slightly more. Further up the chain, wealthy countries such as the USA pay very high prices, in effect subsidising the high costs of R&D that poor countries are unable to bear themselves.

Market segmentation is underpinned by intellectual property – especially patents and trademarks – and contracts. If intellectual property rights and contracts are respected, firms can operate freely within the marketplace without running the risk of having separate national or international markets compromised by the resale of the lowest priced medicines into markets where prices are relatively higher. However, infringements upon intellectual property rights – such as compulsory licences – mean that firms cannot control their own pricing schemes, with serious consequences.

While issuing compulsory licences can prove to be a politically popular move in the short term, it undermines the ability of innovator companies effectively to price-differentiate, placing strain on pricing strategies aimed at offering the cheapest medicines to patients in extremely poor countries. It also acts as a disincentive for firms to develop new and improved medicines for the diseases unique to less-developed countries.[31] It may also discourage companies from registering their products in markets where they are unsure of the safety of their intellectual property, as happened with Abbott Laboratories in Thailand in March 2007.

Perhaps the most serious unintended consequence of compulsory licences issued by middle-income countries such as Thailand is the effect they will have on the prices paid by considerably poorer countries for the same product. So, while Thailand may enjoy the short-term benefits of cheaper drug prices, companies will be forced to adjust their pricing strategies in order to recoup foregone revenue. In practice, this may mean poorer countries being forced to shoulder higher prices. If more middle-income countries, such as Brazil, follow Thailand's examples, this will only put pressure on companies' ability to sell to African countries at the marginal cost of production.

While this is currently only a hypothesis, some lessons can be drawn from the "parallel trading" of pharmaceuticals in the European Union, in which third parties take advantage of price differentials between countries in order to import drugs from countries enjoying cheaper prices to countries that have more expensive prices. While this may theoretically drive down prices in certain markets, in practice this lead to a significant reduction in price dispersion across the EU in the 1990s. Companies were forced to increase their prices in the "cheaper" countries to take account of losses in revenue from foregone sales in the "more expensive" countries – resulting in the poorer countries paying more for their medicines, while richer countries paid less. Swedish research from 10 EU countries shows that pharmaceutical price dispersion decreased from 30 to 10 per cent between 1986 and 2001,[32] with the countries with a lower GNI per capita experiencing the highest price rises.

This somewhat perverse outcome meant that the wealthy patients of northern Europe benefited at the expense of poorer patients of eastern and southern Europe, who suffered reduced access to medicines as a result of higher drug prices. The same is likely to repeat itself on a global scale if more middle-income countries follow Thailand's example and issue compulsory licences. If large middle-income countries such as Brazil,

China, India or Mexico undermine commercial price discrimination strategies through issuing compulsory licences, companies may be forced to raise prices in poorer countries in order to make their products commercially sustainable. Drugs that are popular targets for compulsory licences are likely to develop a "global" price which may prove unaffordable to the poorest countries. As such, compulsory licences are not an equitable way of improving access to medicines.

At any rate, companies may in future decide that those classes of drugs which are most likely to be appropriated present too much of a political risk to warrant the huge investments required to bring a drug to market. Companies would then be more likely to focus their attentions on drugs that present far lower political risk, such as those for "lifestyle" diseases, or for diseases that are mainly found in the richest countries. The result will be fewer new ARVs, just at the time when new therapies are most needed due to rising drug-resistance.

Does intellectual property hinder access to medicines?

The rationale behind compulsory licensing is that patents create a barrier to access to medicines by increasing prices. While this is theoretically plausible, the reality is that intellectual property and the price of medicines are largely irrelevant in the face of the other major factors that affect a nation's health.

Take the example of India. In 1981 Indira Ghandi called for an end to "profiteering from life or death", and India weakened intellectual property laws in the belief that it would drive down the price of medicines. It certainly did that for some drugs, but did it make the Indian people any healthier?

Access to even basic medicines in India remains unacceptably low – most of the 620 million rural Indians lack access to basic health care facilities.[33] Children go without routine vaccinations. Simple off-patent anti-infectives are out of reach of the majority of the rural poor. Despite pumping out cheap copy AIDS drugs for years, Indian patients see little benefit: only 12,000 of India's five million AIDS sufferers were receiving the drugs at the end of 2005.[34]

For the Indian poor, intellectual property is not the issue. The real issue is the state of their healthcare infrastructure. The government-run system is a shambles, riddled with inefficiency and corruption and beset by a lack of resources. The transport network is so bad that rural people struggle to get to a clinic, even if one exists within 100km of their home. Doctors frequently abandon their practice in rural clinics in favour of towns.[35] Meanwhile, dirty water, indoor air pollution and poor sanitation exact a terrible toll of disease on the poor.

So, when the Indian government decided in 2005 to strengthen its intellectual property laws in order to accelerate India's economic development, it was able to do so because the people did not see a connection between arcane patent laws and the reality of their lives. What they require are hospitals, clinics, doctors and nurses – without these things, you can give drugs away for free and they still won't get to the most needy.

There are similarities with many other countries. In the Philippines, 40 per cent of people will never see a doctor in their entire lives. Clinics and hospitals are rare. PhilHealth, the government-run social insurance scheme, provides very basic cover for only around half of the population.[36] The exodus of healthcare workers to better opportunities overseas is acknowledged to be a major problem in the majority of less-developed countries, and has reached such high levels in the Philippines that in 2005 the Filipino Alliance of Healthcare Workers warned that the healthcare system faces "imminent collapse."[37] This is compounded by counterproductive policies, such as VAT on doctors' visits and other government-imposed mark-ups on healthcare. Many of these factors apply to Thailand as well.

This situation is repeated throughout much of the developing world. Most countries in Africa, and many in Asia and Latin America have dysfunctional health systems, a lack of health insurance and regressive taxes on medical goods and services. As a result of these failures of governance, less than 50 per cent of people have regular access to essential medicines in some parts of Africa and Asia.[38]

In July 2006, Kevin de Cock, the head of the WHO's AIDS division told Reuters: "It is very obvious … that

the elephant in the room is not the current price of drugs. The real obstacle is the fragility of the health systems. You have health infrastructure that is dilapidated, a health workforce that is demoralized, labs that don't work, supply chains that don't exist and diagnostics that are missing."[39]

In the end, it is the patients who suffer from the current fixation on patents and prices. It is taking energy and discussion away from the things that really matter, such as infrastructure, doctors and nurses. Unless these things are made more widely available, people will go on dying from easily preventable or treatable diseases.

Conclusion

To return to the question posed at the beginning of this paper, will Thailand's use of compulsory licences improve healthcare? Given GPO's track record with GPO-Vir, it is more than likely that, for AIDS patents at least, their health status will deteriorate. But there are ramifications beyond the individual tragedies of those who have been or will be treated with experimental copy drugs. From the perspective of national health policy over the long term, can the ministries of finance, trade and development afford the minister of health's short-termist use of compulsory licences? This policy will benefit a few patients in the immediate future but will cause great health and financial problems a few years hence. The minister of health is in effect taking out a short-term mortgage via this compulsory licence, leaving a balloon payment of unknown fiscal dimensions for the ministers of finance, trade and development to cope with in the future.

Moreover, African patients stand to lose if compulsory licences become *de rigueur* amongst middle-income countries, because of the pressure this will put on price discrimination strategies. Furthermore, the effects may blow across into other classes of medicines as companies seek to recoup revenue elsewhere, leading to higher prices across the board.

In the end, the flexibilities outlined in Article 31 of the TRIPS agreement should not be used to further industrial and personal interests, especially if the will or resources do not exist to make the large investments necessary to manufacture and test bioequivalent generics. The long-term health and economic risks of relying on investigative copy drugs are too great. Moreover, compulsory licences, while politically popular in the short-term, detract attention from those factors that can genuinely improve health: sufficient health infrastructure such as clinics, hospitals and well-trained doctors and nurses. These things require investment – something Thailand has proven unwilling to undertake.

Thailand's licensing policy has stirred a great deal of sometimes heated debate amongst defenders and opponents of intellectual property. In one sense, this is a good thing, because it has drawn international attention to the genuine health needs of people in developing countries. One must hope that this attention will result in a greater awareness of the real determinants of successful healthcare, such as a functioning health system. But proponents of compulsory licences must accept that they will have little bearing on these crucial elements, and could indeed undermine them by driving up the costs of treatment in the long term.

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Will compulsory licences improve treatment for patients?

In late 2006 and early 2007, the interim military government of Thailand issued compulsory licenses for three Western-owned medicines, citing the pressures on its health budget as justification. But will these licenses actually improve patient health?

Notwithstanding Thailand's historic under-funding of its health sector, there is evidence that the government's decision to hand manufacturing contracts to the state-owned General Pharmaceutical Organisation (GPO) was motivated by economic, political and personal interests – rather than public health.

Unfortunately, the GPO's track-record does not inspire confidence in the safety of the drugs it is about to manufacture under the compulsory licenses. Its current experimental and untested AIDS therapy – GPO-Vir – has been implicated in rapidly accelerating drug resistance amongst large numbers of Thai AIDS patients. This drug resistance is set to have all manner of negative health and economic consequences.

Moreover, the decision to override the patents of these drugs will put extreme pressure on the delicate commercial pricing strategies that allow quality AIDS therapies to be sold at marginal cost or even donated to African countries.

In the end, intellectual property is of marginal relevance to providing good healthcare. By politicising the issue through compulsory licensing, the Thai government is courting short-term popularity while deflecting attention from the broader shortcomings of its health system. Indeed, the experimental copy drugs that are likely to be used on Thai patients as a result of these licenses could undermine the health system still further by risking patient safety.