Political Economy of Thailand Drug System: What Lessons Learned?

Vichai Chokevivat, M.D., M.P.H.*
*Institute for the Development of Human Research Protections, Thailand

Abstract The political economy, which explains the relationships between individuals and society and between markets and the state, have direct and indirect influences over the health and drug system. This article analyzed the influence of political economy on the drug system in Thailand, by reviews of relevant literature and drew a few lessons. As medicine is one of the four essential needs for human lives; in the era of absolute monarchy, medicines were used as a governing tool to gain loyalty and goodwill among the populace subjects. In the 1932 Siamese Revolution from absolute monarchy to a constitutional monarchy, medicine and public health were not one of the six policy pillars proposed by the Revolutionaries; however every government had given importance to the advancement of the public health system by expansion of public health facilities in every province, district and sub–district nation–wide. In parallel, extension of financial risk protection to the vulnerable population (such as the low income households, the disable, elderly and children under 12 years) and the formal sector public and private employees provided financial access by citizens. Until 2002 Universal Health Coverage was achieved for the whole population. In the Thai drug system; Thailand has followed western allopathic medicine since the time of major reform in the era of King Rama V (1853–1910). Thailand has been under the influence of western countries in terms of academia, business and politics. However various Thailand public health champions had boldly challenged these western influences using wisdom and courage. National List of Essential Medicines was adopted and effectively implemented following the principles recommended by the World Health Organization. Further national drug policies enforced the use of reference drug price for public procurement which contains drug expenditure and improves efficiency. The 1998 drug procurement scandal masterminded by politician was publicized by civil society organizations which led to prosecution and imprisonment. Additionally the pharmaco–vigilance was fully established to monitor adverse drug event and result in immediate withdrawal of certain medicines. Despite pharmaceutical industry filed a law suit to the Administrative Court to retract the withdrawal of Phenylpropanolamine; the court dismissed the case. Furthermore for public health emergency which requires the use of certain expensive patent drugs, with bold leadership, Thailand implemented the compulsory license through legal provisions by the Thai law in the height of political pressure from the US government and pharmaceutical giants. In contrast, the prohibition of excessive and irrational use of Glucosamine was brought to the Administrative Court by Civil Servant Association which, controversially, the Court had ruled its continued use. Drug policies emerged under
Introduction

Economics is the study which involved the distribution of finite resources so that society gains the greatest benefit. Though at the early stages, Economic was a part of Social Sciences discipline, when making decision on social resource allocation which involved politics, a sub-branch of Political Economy gradually emerged. Economic study had become more of a science by itself, which then called Economics. (1)

Political Economy is a “superstructure” of society and often times it has either direct or indirect, positive or negative consequences on health of the population and health system at large. It is crucial and important to understand the process and outcomes of Political Economy on Thailand health system.

This paper analyzes various dimensions through a number of case studies of Political Economy of the Thai drug system through review of relevant literature as a primary source; and draws a few lessons.

Political Economy in Drug System

1. Historical background of political economy in drug system

Medicine is one of the four essentials (food, shelter, clothes and medicines) for human lives. In the era of absolute monarchy, medicine was used as a means to gain loyalty among the subjects. This was applied in the Ratanakosin era during the reign of King Rama I (1737–1809) where medicine knowledge were collected, distributed and transformed into inscriptions. Later during the reign of King Rama III (1788–1851) there was another monumental effort to assemble and distribute knowledge of medicine. Eventually older inscriptions were modernized under the govern of King Rama V (1853–1910). (2) In the 1932 Revolution (B.E. 2475), although public health was not one of the six policy pillars declared by the Kana Rasadorn (Revolutionaries), it was de facto recognized as a major policy and implementation by the Kana Rasadom; where provincial hospitals were established in all provinces. Subsequently in 1977 policy towards a full geographical coverage of district hospital was initiated and accomplished in 1990, while full geographical coverage of health centre in all sub-districts was launched in 1992 and accomplished by 2001. Parallel reform towards financial risk protection expansion by targeting different population groups was launched since 1975 until Universal Health Coverage was achieved in 2002.

After the Second World War the world entered
into the Cold War era. Since the time of King Rama VI (1880–1925), Thailand chose to ally with the West including medicines, where the 1923 Medical Act (B.E. 2466) which also regulated pharmacists was adopted. The law that regulated medical products throughout its entire process was promulgated in 1967 (B.E. 2510). In 1974, the Consumer Protection Committee was established. This took place during the heroic structural reform of the Ministry of Public Health. The Thai Food and Drug Administration was established followed the United States (US) model of US Food and Drug Administration (FDA) though it was modified to fit the social norms and Thailand context.

The development of the drug system followed the same path of the West; it gave way to transnational corporations that sought to expand their influence and control over the drug system in developing country. However Thailand public health champions were able to face the challenges by using wisdom and courage. Efforts were made to develop a national essential drug list that was in line with the philosophy and principles of essential drug list proposed by the World Health Organization.

The national drug policy advocates the use of reference price for public procurement by all public health facilities throughout the country; it effectively contains medicine expenditure and improves efficiency. Furthermore the strong civil society had uncovered the drug scandal which involved politician and other high rank officials in the Ministry of Public Health, which led to prosecution and imprisonment. Once the public health emergencies which require costly medicine under patent protection; the government, with high leadership of Public Health Minister had successfully applied compulsory licensing in the height of harsh bullying and retaliation by the US government and its proxies pharmaceutical industry. Once information concerning the fatal complications of Phenylpropanolamine (PPA), a decongestant for cough and cold medications and weight loss products was revealed, the Thai FDA had swiftly withdrawn the product from the market and termination of registration. The Administrative Court had reaffirmed the legally correct action by Thai FDA of such withdrawal in the height of strong resistance by the self-interested group in the Medical Council. In contrast to the PPA case, however, the Comptroller Generals Department’s prohibition of the excessive and inappropriate use of “ineffective” glucosamine for arthritis, was brought to Administrative Court by Civil Servant Association. The judiciary decided in favor of the plaintiff; ruling the Comptroller Generals Department, as defendant to cancel its administrative order; on the ground of the principle defined in the Constitution. The Department surrendered and did not appeal. All the aforementioned case studies related to political economy are analyzed and discussed at great length below in order to draw a few lessons.

2. Drug consumer health protection system

The US has a system and organization that efficiently protects the drug consumers, namely the Food and Drug Administration or FDA which was founded in 1937; before that time however there were continuous efforts to protect the distribution of drugs but the law was not accepted by the Congress. Corporations cite the spirit of freedom that was inscribed in the declaration of independence, that the US is the land of the freedom, where every man and
woman has the rights to live, freedom and to search for happiness. Manufacturers was interpreted they have freedom in the production and distribution of medicine, and citizens were free to choose whether or not they were willing to buy; the government has no duty in creating a mechanism that may inhibit any citizens’ freedom.

This ideology last until the case of the Sulfa drug, which manufacturer used diethylene glycol as a solvent to produce Sulfa suspension, and was used by children. Elixir sulfanilamide was an improperly prepared sulfanilamide medicine that caused mass poisoning in the US in 1937 resulting in over 100 deaths of renal failure. These deaths had a strong association with the use of Sulfa and there were numerous non-fatal cases also suffered from kidney failure. It was discovered that diethylene glycol was highly toxic to kidney; this case convinced the Congress to pass the 1938 Federal Food, Drug, and Cosmetic Act, which established an organization US FDA to regulate medicines safety and quality products. It is clear that medicine is a sophisticated technology, and the general population is not educated, prepared and able to safeguard their own health, hence requires State’s interventions. In the first stage the organization’s first priority was to primarily focus on safety after which there were regulations to ensure efficacy as well, by requiring manufacturers to provide evidences from credible sources that their product was both safe and efficacious as claimed in their registration filing.

There were efforts to develop standards in both the “research” and “development” of medicine by setting the standards, for pre-clinical research i.e., laboratory and animal research. Clinical research was divided into 3 phases before they were initially registered; there was also a fourth phase for research conducted on a new population, and to closely monitor its safety.

After the outbreak of HIV/AIDS that took the lives of countless people, identified first in the US. The first medicine had been discovered i.e., Zidovudine or AZT and was accepted as safe and effective for the treatment of HIV/AIDS; when the research on human subjects were finished at only Phase II; but there was strong pressure from over one million patients all of whom urged the US FDA to shorten the procedure of registration for AZT, despite having only data from Phase II; which the experts panel who considered the issue agreed to accept, and thus the US FDA agreed to the conditions. All of this was due to HIV/AIDS being a deadly disease without medicines, and that AZT was the first ever possible safe and effective treatment. If research were to be conducted through Phase III it would result in massive losses of lives before a result can be concluded. That is why this case could be considered a major reform of the registration system, by accepting data from phase II clinical research only. This type of registration is limited to medication for illnesses that are fatal and have no other effective existing treatments. Furthermore aside from the reform that occurred to the registration system, drugs that were in this nature were allowed to be used in other countries which has yet to accept the aforementioned drug as an officially registered medication. This system was called “compassionate use,” and could be used with general patients or in human research.

All three phases of bio-medical research for the development of new medicines or vaccines which require test in human subjects need to adhere to the ethical principles of human research which has been
continuously developed and improved.

The first instance of a Thai law that regulates medicine was passed in 1909, in the Criminal Act 1908, a regulation which punished those who placed the consumer in danger by distributing adulterated food or medicine, subsequently the 1923 Medical Act which for the first time licensing physicians as well as pharmacist. (3)

The Drug Act 1967 has the most impactful to the quality medical products and the pharmaceutical system as a whole, it has been amended numerous rounds; currently the law is in its sixth version when the last amendment was made in 2019.

Initially the drug protection was left to another organization; this was until 1974 where a major reform in the Ministry of Public Health took place, by establishing the Thailand Food and Drug Administration as a department in the Ministry of Public Health; working to protect consumers of health products, which includes such as medicine, cosmetics, medical device, narcotics and psychotropic substances. The structure and philosophy of the Thai FDA is similar to the US FDA, that it is the sole agency responsible for the consumer protection of all health products, however there are a few key differences as follows:

First, the department responsible for quality of medicines through rigorous laboratory tests is Department of Medical Science, thus the Thai FDA cannot interfere with test results either positive or negative.

Second, the head of US FDA is proposed by the President and approved by the Senate similar to many other Offices. In the case of the Thai FDA however, the secretary general is a government official who holds the position equivalent to the director general, and appointed by Minister of Public Health (MOPH). The Secretary General of the Thai FDA is the secretary of various multi-sectoral committees established by relevantActs such as Drug Act, Food Act, Cosmetic Act; in many cases each decision has to be approved by the committee first, in contrast to those in the position of Director General in other MOPH Departments, they often hold complete authority within the Department.

Third, the US FDA is much larger than the Thai FDA. In 2000 the US FDA had over nine thousand employees, while the Thai FDA had only one thousand employees. On the other hand the Drug Control Division of the US FDA has more than four thousand employees; while the Thailand has only around one hundred. This is why Thai FDA often relies on and outsource expertises from qualified outside partners.

In the era of the Reagan Administration the socialist world collapsed and the US led the world in advocating the “neo-liberalism”; there were many policies that were implemented, and scholars have come to call this policy package which consisted of ten policies under the “Washington Consensus,” which encouraged free trade. One of them was “deregulation” which decreased restrictions and liberated all regulations. (4) Although Thailand did not need to follow these policies, since Thailand relied heavily on the US market, implicitly, Thailand needs to comply with it. Not only policy to limit the size of government workforce, the limited capacities of the Thai FDA is the result from policies in the “Washington Consensus”.

In line with this policies, the intention of all the existing Acts and related regulations needs reform; the philosophy of “control” has been replaced by “monitor”; such as in the case of the Food Act. However the Drug Act has kept the “control principle” in place.
In summary, it is evident that the Thailand’s drug consumer protection system was influenced by many actors such as academia, politics or western countries. Whether it is on the principles of safety and efficacy of drugs, the establishment of organizations and laws, especially after the 2nd World War where the world was plunged into the age of the Cold War, Thailand has been deeply influenced by the United States. The birth of organizations such as the FDA in Thailand for example, was made to follow the format of US FDA; but modified to fit the Thailand health systems context and social environment. When Cold War was over and came along with the neo-liberalisms, Thailand was still under the influences of the United States whether it be ideologies or actions; the trajectories and decisions was more or less influenced by scientific evidence, moral and ethical courage, blessed and by various Thai public health champions. This allows Thailand to face these influences head-on and create systems that fit the context of Thai society with success.

3. National List of Essential Medicines

Currently there are over 155 countries, both developed and developing, that applied the Essential Drug List published by the World Health Organization.

Thailand is vigilant towards the issues that arise from drug usage, including issues such as excessive spending and the lack of essential items; there have been attempts to address these problems through the mindset of the “essential drug list,” for over ten years before the model drug list created by the WHO in 1977 was published.

Thailand’s essential drug list was later developed into the “National Drug List” which has innovative ideas, and can be used as an example as both a list and a process which possesses a high standard in both academia and governance. The national drug list is the reference benefit packages for all three public health insurance schemes since the 2004 revision. The good governance emerged when all members of the sub-committees and working groups for the revision have to declare “no conflicts of interests” in conducting review of medicines to be included in the National Drug List. It is the first ever in the history in 2004 with strong resistance from various professors who had conflicts of interest with pharmaceutical industries in the previous revisions. The process of improving the National Drug List has been developed until it became good examples to committees, sub-committees and other working groups. (5)

4. Reference drug price for public procurement

While the National Drug List played an important role in ensuring essential drug that promotes health, prevent diseases and treat patients are available; the reference drug price is an important tool that controls the medical spending to be affordable and not causing financial burden to the government who subsidized public health insurance systems and the citizens. Reference price system leads to financial sustainability and system efficiency. It is noteworthy that the Social Security Scheme was the first which adopted the National Drug List as the pharmaceutical benefit package for its members since 1991 when the Social Health Insurance was launched. Later in 2002 the Universal Coverage Scheme which covers the remaining 75% of Thai citizens who are not public or private sector employees also adopted national list of essential medicines as its benefit packages.

The most important factor of the Social Health
Insurance implementing the National Drug List was to ensure that health facilities retain a standard, by ensuring that beneficiaries receive a adequate amount of essential medicine. The Social Health Insurance chose capitation as the payment system for its contractor hospitals (both public and private), however, a flaw with this particular system is that health facilities would often aim to contain its expenditures including medicine, by enforcing a minimum expenditure for medicine according to the National Drug Expenditure, is a minimum guarantee ensuring access to medicines by members.

The Minister of Public Health, Professor Dr Sem Pringpuangkaew, designed a model to contain the costs of medicine, by supporting the National Drug List as a key mechanism in controlling the use of medicine. Starting from 1981 the hospitals in the Ministry of Public Health were required to spend no less than 60% of their drug budget to procure items in the National Drug List; this was enforced through in “the Ministry of Public Health’s 1981 regulation on the purchase of medicine by health facilities in the Ministry of Public Health”. Following this, there was a Cabinet decision on the 27th August 1985 that the National Drug List’s shall be extended to cover all other government health facilities (beyond Ministry of Public Health). This was enforced through the “1986 Regulations of the Office of the Prime Minister on Procurement (issue 7)” that all public hospitals were obliged to procure medicines in National Drug List according to the proportion in the Regulation. Ministry of Public Health must purchase no less than 80% of the drug budget while health facilities owned by other ministries must use no less than 60% of drug budget to procure items in the national drug list.

Besides designating the proportions of the budget there was also a designation for the Ministry of Public Health to be responsible for producing reference price for all essential medicines for procurement purpose. All public health facilities are required to purchase medicine by generic name from the National Drug List, without exceeding the reference price. The reference prices are estimated from the median price of actual purchased items by all public health facilities in the past years; all purchased prices are downloaded on the public website of the MOPH. The reference price was regularly updated by the Ministry of Public Health. However an exception is allowed to procure medicines manufactured by the Government Pharmaceutical Organization (GPO) or the Military Pharmaceutical Factory; but not exceeding 3% of the reference price. With this, the regulations were then developed into the 1992 Procurement Regulations responsible by the Office of the Prime Minister; the Purchasing of Drugs and Medical Supplies was defined in Section 2, Clause 60–64 of the 1992 Procurement Regulations. (6)

The announcement of the reference price was later improved to be within the jurisdiction of the National Drug Development Committee; with the announcement on the 5th April 2019 consisting a total of 49 groups and 1490 listed entries. (7)

5. The 1400 million baht drug scandal in 1998: Role of civil society organizations

5.1 The triggers of scandal

The embezzlement of 1400 million Baht (US$ 46.7 million) was a key history of the political economy related to Thailand drug system.

It began with the 1997 Asian Economic Crisis
triggered by Thailand fall in financial institutions; the Ministry of Public Health was allocated an approved budget of 1400 million Baht, to be used for medicine and pharmaceuticals to mitigate the population as there are major influx of patients from private to public health facilities, hence there is a significant increased in demand for health services in public sector. The Ministry of Public Health distributed the budget into two parts; the regional and general hospitals were given 560 million Baht, and the community (district) hospitals were given 840 million Baht.

Politicians who planned to embezzle and corrupt the budget started by conspiring with high ranking officers in the Ministry of Public Health. The incident began when the Deputy Permanent Secretary of the Ministry of Public Health proposed that the reference price system should be abolished. The Minister of Public Health, using his legal authority, had approved the proposal, and announced that the reference price was to be cancelled by the 15th of December 1997, this paved the way for the purchase of drugs at expensive price; all according to the plan for corruption.

The decision opened up the opportunities for the purchase of medicine with much higher price in 3 possibilities. This included; (1) buying drugs from a designated puppet companies, the companies share the gains from high price to the politician; (2) the health facilities can purchase medicines from any sellers but these sellers must share 10% of the total sales to the politicians; (3) health facilities can purchase medicines from companies designated by the GPO; and share the gains to politicians. In this case the politician is the Minister of Public Health at that time.

The orders were announced by the Ministry of Public Health, through meetings with Executive Directors in the provinces; while the provincial Executive Directors met with “the Minister’s team” in a hotel, when the Minister’s team convinced them to cooperate using the three corruption tactics. It turns out that many government officials in central and provincial levels were willing to “cooperate” by purchasing large amounts of costly medicine; until the day they were exposed.

The director of Uthai District Hospital in Ayutthaya province was the first whistle blowers to the public, where high rank Executives in the Ministry deny any allegations. This triggered the high level government officials in the Ministry who had involved in the “rural doctors movement” to come out and expose and publicize the wrongdoings, following this there was a “concerted efforts” by various other civil societies to come out and reveal what has happened.

5.2 The establishment and role of civil society organization

The groups of civil societies mostly active citizens in the Ministry of Public Health began to establish and form a large coalitions across different disciplines such as doctors, pharmacists, dentists and nurses. After the student-led revolution took place on the 14 October 1973; the Rural Doctor Federation was formed, which after the Army cracked down the student fronts on the 6 October 1976; the Federation was renamed as “the Rural Doctor’s Society.” The pharmacist activists established “Drug Study Group” the 8 March 1975, during the auspice of International Women’s Day. In the countryside, the Rural Pharmacists Group was also created.

After the major outbreak of HIV/AIDS in Thailand
in 1990s, various groups of non-government organizations working on HIV/AIDS were established, notably the AIDS Access Foundation. There are many other groups. Dr Sanguan Nittayarumpong, advocated for MOPH budget subsidies to these NGO to support health intervention in particular in the context of HIV/AIDS epidemics. The annual budget subsidies of 49.2 million Baht has been gradually increased.

The civil societies showed up with tremendous support in publicize the corruption, furthermore with the press reported on the scandal for over a month; it pressured the government to respond by referring the case to the Committee on Prevention and Anti-Corruption (which was renamed as the National Anti-Corruption Commission following the 1997 Constitution) and the Audit General to further investigation. In addition the Ministry of Public Health had also nominated an investigation committee. Doctor Banlu Siripanich, a member of Committee on Prevention and Anti-Corruption, who was asked to be a member, requested that be the Chairman of the investigation committee, to which the Ministry of Public Health obliged to due to pressure from the civil society and press. The investigation results concluded that there was corruption involved. The Prime Minister then had to elect an investigation committee to proceed further with the probe. In conclusion of the probe, there were 2 incidents of punishment which was the Assistant to Permanent Secretary of the Ministry of Health and the Director of Provincial Health Division, both of whom were dismissed from the offices. Furthermore there were removals of Provincial Chief Medical Officers in 5 provinces which included Ayutthaya, Chacheongsao, Nakhonpathom, Pang-nga and Naratiwas.

With high level of societal pressure that the Minister and Deputy Minister of Public Health were forced to resign. The newly appointed Health Minister appointed an investigation team to examine all invoices purchased through the Government Pharmaceutical Organization (GPO). Over the 70,000 purchase orders were by trade name. Huge efforts are required to thoroughly review each of these purchasing orders; with supports from volunteer pharmacists that this monumental task was accomplished.

Investigations found that during the 1998 incident; the total purchased amount was 918,578,694 Baht, with large variation in purchased prices. The mark up ranged from 50% to 300%. If these products were purchased based on the reference price, the estimation of total losses from this scandal was 181,748,170.57 Baht. Investigation results were submitted to the National Anti-Corruption Commission; further new evidence was also received, investigated and submitted. The former Advisor to the Deputy Minister of Public Health, who had been imprisoned, confessed to receiving a cheque of 5 million Baht from drug company which involved in this scandal.

Ultimately the panel of judges of the Criminal Prosecution Department of the Supreme Court had unanimously ruled that the Minister of Public Health was guilty based on the Criminal Law section 149. Considering all the events and circumstances, given that the defendant had pledged his service to the country through seven rounds of being elected as a member of parliament; and served five rounds of Minister positions, and taking into account that the defendant had a Bachelor’s degree in law and as a lawyer practitioner; a criminal act such as this corruption deserved a 15-year imprisonment.(8)
The exercise of political power to embezzle the health budget had resulted in 181 million THB (US$6 million) loss to the society due to unjustified high price of medicines. The high rank officials who cooperated with corrupted politicians and teams were also punished and dismissed from their positions. The exposure of large scale drug scandal had empowered the active citizens and the civil society organizations. This is not a common case in the history of Thailand health systems. Such fight to clean up the society require utmost courage, endurance, selflessness and persistence by active citizen and civil society organization. One of the leaders in the fight against corruption was later sued, and had to face a lonesome and extensive battle till the charges were finally dropped by the Court, which incurred large expenditure throughout the court processes.

This story reminds us of William Shakespeare’s work on “The Merchant of Venice,” which was translated by His Majesty King Rama VI and in one of the verse which was composed into Thai, “in the course of justice none of us shall see salvation.”

6. The case of PPA: phenylpropanolamine

PPA was used to relieve stuffiness of nose for the treatment of common cold. It is commonly mixed with other anti-allergic and antipyretic. While there were announcements to withdraw PPA as a component of any medication in late 2000 till early 2001. There were more than 450 drugs registered with the Thai FDA which had PPA as a component at the time of announcement. In total there were 447 and 3 pharmacopeia in the private and public sector manufacturers respectively. In addition to PPA, there were Type 3 narcotic drugs in 16 pharmacopeia where PPA was one of the drug components. As such the medicine was announced to be withdrawn by two FDA orders; the first was released on the 14th December 2000, and the second targeted the narcotics combined with PPA formulae on the 12th January 2001.

The withdrawal of PPA has a long story in both the United States and Thailand. In Thailand not only was the incident a major media coverage, it was also a subject of debate that was asked extensively in both the media and the professional organizations, that is the Medical Council. A plastic surgeon went to Administrative Court to sue the FDA so that they may retract both notifications while the Medical Council became a witness of the plaintiff in support for retraction of the FDA order. An interesting observation however is that this plastic surgeon had a rough history with the Medical Council, and was punished several times for unethical conducts on the account of false advertisement. Later, the Medical Council proposed PPA as prescription only medicine, however the proposal conflicted with the studies conducted by Yale University; that the complication on intra-cerebral hemorrhage were from “first time use” which is used to relieve most colds and coughs. Thus the aforementioned risk is unpredictable and even doctors, as prescription medicines only, cannot ensure patients are safeguarded from stroke and intra-cerebral hemorrhage.

The Deputy Secretary General of the Medical Council who vigorously pushed for retaining PPA claimed in a meeting that “politics ordered it” and were “pushing the PPA” against scientific evidence of its fatal side effects. Such movement which was self-interest and against scientific evidence created tensions and badly destroyed the credibility of the
Medical Council.

These petitions by Medical Council against scientific evidence and put patients at risk of using PPA did not have any effects; as the Central Administrative Court decided to dismiss the case which confirmed the legitimacy of FDA orders on the ground of protecting the consumers. The Supreme Administrative Court confirmed to the decision made by the Primary Administrative Court.\(^9\)

The Food and Drug Administration gathered the information, evidence and published in two separate books. These books were the “Truths about PPA (phenylpropanolamine)” which was published in April 2001\(^{10}\) and the “Controversies on PPA” published in March 2005.\(^{11}\)

7. The drug patent and the compulsory licensing

7.1 The Drug Patent

Thailand first legislated the drug patent for the first time in 1979\(^{12}\) which only permitted process patents, later with the strong pressure from the United States and from drug companies resulted in product patents. This has always been boycotted by the civil societies as product patents always results in higher drug prices and inaccessibility by the needy patients. Higher drug prices is a burden to citizens who could not afford to purchase them. Patent results in product monopolies and unjustified high prices.

As the Thai government was pressured by the US to amend the Act, the Deputy Minister of Public Health who at the time was Professor Attasit Vejajiva saw that Thailand would lose many benefits, additionally there would be a major burden placed on the budget of the Ministry of Public Health, which at the time Thailand was facing with major HIV/AIDS epidemics; where antiviral medicines were all patented.

It was the Secretary General of the Food and Drug Administration (Dr Morakot Kornkasem) and the Secretary of the Deputy Minister of Public Health (Dr Jakradham Dhammasak) and Director of the Technical Division of the Food and Drug Administration (Dr Suwit Wibulpolprasert) all of whom explained to the Prime Minister on how much the price of drugs would increase and add strong pressure on the limited health budget, on medicines for HIV/AIDS epidemics.

However the Prime Minister insisted that it was essential to comply with the US requests as the US had used the Trade Act Section 301, in down grading Thailand from the Priority Watch List (PWL) to the Priority Foreign Country (PFC) list from the year 1991 onwards, which has a penalty measures in place that is the revocation of the Generalized Systems of Preference (GSP), which would have carried heavy repercussions on Thai exports to the US, amounting 40% of total export. The Prime Minister pledged that if the Ministry of Public Health were to receive any repercussion then he would increase the health budget, however it was “flung back” that by then he would have been out of office already.

In conclusion there were additional amendment on the patent act in 1992\(^{13}\) covering product patents 8 years prior to the schedule dates designated by the World Trade Organization in 2000. As expected, the patented drugs increased in price which led to the utilization of the seven entries of the Compulsory Licenses in the following years.

7.2 The usage of the Compulsory License (CL)

Thailand was the first country in Asia to have been severely affected by the HIV/AIDS epidemics. In 1999, DDI the second line ARV for the treatment of
HIV/AIDS was registered and issued a drug patent, which should not have been possible to register as patent as DDI did not have shown its novelty. This incident sparked a movement within HIV/AIDS patients and the civil society to call for the patent registration with Ministry of Commerce to be revoked, by protesting overnight in front of the Ministry of Public Health. Additionally there were calls for the exercise of Compulsory License in the Thailand Patent Act; however the Ministry of Public Health did not respond to these demands.

The utilization of the Compulsory License that took place for the first time in Thailand occurred in the late months of 2006 and followed into 2007, which was in the era of Dr. Mongkol Na Songkla who was the Minister of Public Health and General Surayuth Julanont as the Prime Minister. The process included two entries of anti-viral drugs and one cardiovascular medicines. Additionally the government also processed four other cancer drugs at the early of 2008. By concisely stating the reasons and necessity of public health emergencies which where the medicines are not affordable to the patient in the application of Compulsory Licensing while also adhering to the international trade regulations in the TRIPs Agreement as well as following legislative provisions in the Thai Patent Act. It allows the Thai government to use CL; this event caught high attention by the media. The Thai government purchased and supplied high quality drugs that were lower cost than patent products, save lives of the people.

When confronted with the aggressive retaliation by transnational pharmaceutical companies and the bullied United States Government, the Thai government was able to solve the issue which was external peer reviewed by both national and international experts on the legitimacy of Thailand using compulsory licensing. In recognition to their contributions, an award was bestowed to all leaders in the implementation of compulsory licensing granted by the previous Prime Minister who decided to amend the Patent Act due to pressure from the United States.\(^{14-17}\)

8. The glucosamine incident

Glucosamine was once registered with the Thai FDA as both a drug and food supplements. Later the owner of the drug registration was asked by the FDA to remove the registration from the food supplements while still keeping the registration as a drug; however, this drug was not in the Essential Drug List.

Glucosamine is a medicine that was used to treat knee osteoarthritis and has been evaluated by Thai Royal College of Orthopedic using 5 principles, which was (1) safety (2) efficacy, based on results from research data (3) effectiveness based on medical practice (4) efficiency, by comparing the outcomes with the cost of medicines and (5) benefit, meaning benefit to the population and society as a whole. Based on these five criteria, the Royal College of Orthopedists gave a final summary assessment by using a score of “+/−”, which meant that it was unclear whether or not the drug was useful for medical practice in Thailand.

Glucosamine was one of the drugs that the Comptroller Generals Department responsible for Civil Servant Medical Benefit Scheme (CSMBS) decided to suspend its reimbursement; this is in line with the research findings and scientific evidence from 134 research reports. In addition there were also public hearings from all stake holders who agree that the drug...
is not cost effective. And governments such as the United Kingdom, Scotland, Sweden and Republic of Ireland and the US Department of Defense did not allow the reimbursement of Glucosamine from the welfare scheme. The US did not categorize Glucosamine as a drug, instead it was categorized as a food supplement, and thus it wasn’t possible for hospitals to reimburse from the healthcare system for this product.

This control of the use of Glucosamine in CSMBS came from the abuse of drugs which resulted in extreme high expenditures in CSMBS as shown in 2004 that the total expenditures from this scheme increased from 26,000 million Baht to 61,000 million Baht in 2009, therefore the Ministry of Finance has proposed to the cabinet to abolish the reimbursement of Glucosamine to which the cabinet had approved.

Following this there were retired government officials who filed a law suit to the Central Administrative Court to retract the aforementioned orders by Comptroller Generals Department. The Central Administrative Court has ruled on the 26th of February 2015 on “red court” number Z502/2015 to remove the cabinet’s decision. The Comptroller Generals Department did not appeal the case, thus the Administrative Court’s decision to remove the order was a final. Finally the Central Administrative Court declared that the order was to be removed on the 19th of May 2015 and was to be published in the Royal Gazette, which was broadcasted on the 20th of May 2015.

Following this there was commentary on the verdict of this case published as a series in the newspapers, which was later reprinted into a single book. A Constitutional Court judge who wrote the prefaces in this book states that this book presents one of the most superb ruling of the court and that it is an invaluable research on administrative law and should be developed to benefit broader areas such as law, administrative justice system and good health administration.

“This book demonstrates the heart that strives for justice and the intention to give benefits to all the people of Thai society. In this book data is presented in a straightforward manner without any bias towards any party and the discussion chapter was based on clear and truthful information and theories. The suggestions were also creative and gave confidence that there were better solutions for this issue.”

Discussion

1. The role of political economy in the health system

Political economy has many roles in the health system such as:

The development of the health sector is challenging and creates much debate within society. To make decisions on results of health is thus related to politics and economics by default.

In every government there must be an evaluation on which problems amongst many are the most pressing, therefore for the government to see the importance of healthcare it is essential for them to understand and increase the desire to work on this sector, furthermore it is important for the government to see that the task is indeed possible.

In revolutionizing the health system, which includes the push for UHC it is vital to manage resources which often times leads to winners and losers that either gain or lose advantages over one another, and therefore
Political economy is a study that explains and puts heavy emphasis on issues of structural inequality within the health system, furthermore the study is also conscious of the importance of social movement in improving the quality of life for those in poverty.

The weakness of all medical partners is a major obstacle in improving health. Political economy is capable of analyzing the many factors and point out how different organizations can improve in responding to the essential health needs and the needs of the population. (19)

2. Development of health economics in Thailand

The Ministry of Public Health has given much priority to health economics for more than 4 decades, which began by cooperating with the Faculty of Commerce and Accounting of Chulalongkorn University to start training health economics within the Ministry of Public Health; this course was supported by the World Health Organization who sent Anne Mills, a health economist to be a consultant of the course, later Anne Mills had received the Prince Mahidol Award in 2009. By cooperating with the Public Health and London School of Hygiene and Tropical Medicine of University of London, and the Public Health Faculty of Prince Leopold I of Belgium resulted in Thailand increasing its adequate number of health economists, after which led to the creation of numerous research units, for example the International Health Policy Program and the Health Intervention and Technology Assessment Program, which conduct research to develop the national health policy. Their works included capitation payment in the Social Health Insurance and the Universal Health Coverage, which resulted in Thailand health systems is global role model of achieving high level of health status with low cost; so called “good health at low cost”.

The development of the public health infrastructure across the country after the revolution in 1932 including the construction of hospitals in all districts and health centers in all sub-districts, the development of the provider payment methods using capitation system, the diagnosis related groups (DRG), and the development of public health personnel by giving scholarships to local students to trained as nurses, midwives and junior sanitarians; so that they return to work in their hometowns. There was also the creation of reformists together with efforts to strengthen the public; this resulted in the major success of the health system. (20)

3. The development of the drug system

3.1 Thai Traditional medicine

Thailand has compiled Thai medical textbooks namely the Praosotpranarai in King Narai the Great Period that mentioned two traditional medicine textbooks. In the era of King Rama I, King Rama II and King Rama III, the traditional medical formularies were compiled and inscribed at Wat Po and Wat Raja-oros. In the era of King Rama V there were compilations and revisions of the medical textbooks; the textbooks were later combined into the Vejasart Royal Textbook of King Rama V which was the root of many other Thai medical textbooks. Later the Ministry of Public Health announced that there were 30,442 Thai medical formularies (21), however the formularies provided little use to the public, even though there were many efforts to revive Thai traditional medicine since the age of Professor Uay Getusingh through the forming of Ayuravej College. The National Economic and Social Development Plans...
3.2 Modern medicine

Thailand has always accepted foreign knowledge and technology throughout its history; the Praosotpra-narai included many foreign medicines from China, India and Western countries.

Since the early days of the Ratanakosin era Thailand has given much significance to the production of medicine, such as: the production of Smallpox vaccine in the era of King Rama III, the creation of the Otsapa pharmaceutical factory in the era of King Rama V, the production of rabies vaccines in the era of King Rama VI, and finally the training for freeze-dried smallpox vaccine production for countries in Asia. Yet Thailand’s pharmaceutical industry did not develop as expected; manufacturers in Thailand were neither able to research nor develop new drugs, moreover fully reliance on imported pharmaceutical active ingredients for local production of generic finished products. On top of that the drugs produced did not comply with the regulations of the international standards of the US, Europe and the WHO.

There were once efforts to produce flu vaccines within the country through the technological transfer from Russia Federation along with more than 100 million Baht in funding from the WHO. Government pharmaceutical organizations took more than 10 years but were still unsuccessful in producing the seasonal influenza vaccines. In contrast to India who also received technology from Russia through Thai scientists but were able to successfully produce and distribute vaccines for the flu within the span of a year or so.

3.3 National List of Essential Medicine, reference price and compulsory licensing

The pharmaceutical industry is a profit maximi-
POLITICAL ECONOMY OF THAILAND DRUG SYSTEM: WHAT LESSONS LEARNED?

Decision to trigger and implement compulsory licensing is a heroic act as this directly challenged the powers of the foreign drug industries and the US government. It results in an aggressive retaliation from both the foreign drug industries and the governments who were manipulated by or having vested interests with the drug companies. The Director General of the World Health Organization did not have comments on the responses by the pharmaceutical companies. Thailand however acted professionally by addressing every single criticism given in both Thai and English. Interestingly, there were 22 US senators signed a letter in favor of Thailand’s argument and decision towards compulsory licensing. Thailand used many methods to gain supporters, such as making an effort to meet with former US president Bill Clinton and directly addressing to the US Speakers of the House of Representatives who was representative of the constituency where the pharmaceutical company were based in, additionally a request was made to clarify details with the Washington Post.

Nevertheless the use of compulsory licensing is difficult to replicate with other drugs nowadays because India, the global producer of generic drugs needs to comply with the Trade Related Aspects of Intellectual Property Rights Agreements of the World Trade Organization, due to this it is hard to produce generic drugs that are reasonably priced. Thus it is essential to study the other flexibilities mode provided by the TRIPS agreement so that more measures can be applied.

3.4 The PPA incident

The PPA incident is an example of FDA’s legitimity to protect health of the people from unsafe...
medicines; in this case the fatal complications from intra-cerebral hemorrhage. Difficulties and challenges faced by Thai FDA from pharmaceutical industries, certain academia, and some members of the Medical Council who had self interests and filed the law suit to the Administrative Court. If there were no ethical courage, perseverance, professionalism and determination it would have been impossible to protect the public.

3.5 The glucosamine incident

The glucosamine incident is an example of the influence that the political economy has towards the drug system. A system where the drug industry seeks to gain advantages over the CSMBS; so that certain groups may benefit from it, this view conflicts with the principles of equality of all citizens (no matter they are civil servant or farmers) endorsed by the Thai Constitution. The Thai FDA allowed the registration of glucosamine as drug and food supplement. Additionally the organization responsible for the CSMBS also permitted the disbursement despite the fact that glucosamine is not included in the National Essential Drug List. Furthermore when this benefit was cancelled the court decided by using the “poor integrity” of evidence. The court interpreted the recommendations by the Royal College of Orthopedists with a score of “+/-” which meant evidence was still unclear whether or not the drug was useful for medical practice and should be used on a case by case basis. However, the court interpreted as “Yes” and should be covered. Further the Court cites Article 78(8) of the 2007 Constitution which refers to the role of states in provision of appropriate benefit to civil servants and government officials. However, Article 78(8) creates inequity and contradicts with Article 51 which aims to ensure equal rights to health service by all citizens. However, the 2016 Constitution does not include this in the role of state.

Conclusion

Although Thailand has many difficulties in improving the governance, transparency, crack down corruption in the government, private and political sectors; as after the Revolution of 1932 (from Absolute to Constitutional Monarchy) to 2019 there have been 13 incidents of coup d’etat, termination of Constitution, and new draft a new version of constitution along these political changes, which gave Thailand up to 20 versions of the constitution. Thai politics has been in a chronic vicious cycle of political instability. However the leaders of this country in many eras have given importance to the development of health and the improvement of the drug system, since the time of absolute monarchy to the present day from political leaders who came through democratic election and coup d’etat.

The act of gathering pharmacopeia and distributing the information amongst the population has been around since the birth of Ratanakosin particularly during the era of King Rama III and King Rama V, despite this however Thai traditional medical procedures did not have any form of prescription, moreover passing on knowledge was mostly passed through memory with some even going so far as to withhold information as well. In addition to this, publications were not utilized and the incorporation of science was very little. This almost leads to a stagnation of knowledge and an almost complete lack of use despite the support from government after the WHO called for primary care and encouraged the use of traditional
In 2000 the Thai government attempted to revitalize Thai tradition medicine which ranged from passing laws to setting up a department; additionally it was clear that the government supported the use of Thai traditional medicine through integrating them into the National Health Coverage Scheme. Nonetheless the advancement and use of Thai traditional medicine was still extremely scarce and is heading in the wrong direction thus is required to have a major reform.

In the area of modern medicine Thailand has accepted medicine from foreign countries since the age of King Narai the Great; where modern pharmaceutical sciences were taught in universities since 1913, however advancements and research has been developing at an exceedingly sluggish pace as we are still unable to produce our own active pharmaceutical ingredients, on top of this the quality of the medicine does not meet the standards of both the US and Europe unlike India and China. The study of pharmaceutical science especially in the graduate school needs major reforms.

Thailand’s biggest achievement is the development of the National List of Essential Medicine and its implementation into the Universal Health Coverage Scheme. Most importantly the enforcement of the use of reference price for all public facility procurements effectively contain drug expenditure. The removal of reference price opens opportunities for drug scandal. When there are problems with the availability of drugs for public health emergencies; use of compulsory licensing had resulted in access to affordable medicines and save lives; though with aggressive retaliation by US government and pharmaceutical industries.

It should be noted that gathering and distributing medical textbooks for the benefit of the population began in the age of absolute monarchy. While the National List of Essential Medicine and the reference drug price were both born in the time of semi-democracy and the Universal Coverage Scheme began in the era of complete democracy, the use of compulsory licensing implemented during a coup d’etat government.

**Recommendations**

An important accomplishment of Thailand is the development of the drug system which later had established its own National List of Essential Medicine with regular updates and improved governance in the updating process through declare conflicts of interests in the height of dissatisfactions by certain Professors. By learning from the ideologies of the WHO and developing it to fit Thai society, this included the development of the reference price and compulsory licensing. And with the termination of PPA registration and the glucosamine incident, thus it is clear that the lessons learned should be documented to be used as teachings for Pharmacy, Medicine, Economics and Law.

The success factors can be summarized. Aside from following the principles of “the Triangle That Moves the Mountain,” which are the three power poles; (a) knowledge and evidence, (b) societal movement, and (c) policy movement. A vital component however is the creation of a reformist group so that it reaches a critical mass and triggers an initial and repercussion movements. An important strategy is to co-work and create a synergy between both government officials and civil society. Working in the public sector creates a deep understanding of the system which paves way
for a reform from within, by working from the civil society perspectives from outside has another power of holding government account and mobilize societal supports and demands.

The health system in Thailand has been extremely successful in refining knowledge and applying of health economics. In the future there must be a development of knowledge and the application of political economy to the analysis of public health system including drug system, so that they may reach the level of effectiveness provided by the application of health economics.

The biggest flaw to the drug system is the limitation of research and development capabilities, including the production of drugs. This is a product of the failure of the education system which gives no value to sciences. Education still could not uproot the insidious mindsets of the superstitious, the education system promotes the act of mindless memorization which discourages the practical and inquisitive mind among the young learners, moreover memorizing the information encourages the use of guesswork. To fix this we must reform the education system of Pharmaceutical Science from the ground up, especially in at the graduate school.

The education and teaching system in Thai traditional medicine and herbal remedies must also be reformed entirely. A change must be made from a system that focuses on memorizing into a system that (a) emphasizes more on understanding (b) promotes the use of science and research and development, so that traditional Thai medicine textbooks could end the stagnation of information and withholding of information, to become more scientifically based so that knowledge can be genuinely developed. Learning from the experiences from China, Japan and Korea should be considered.

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บทความด้านเศรษฐศาสตร์การเมืองกับระบบยาของประเทศไทย

วิชัย โชควิวัฒน พ.บ., M.P.H.
สถาบันพัฒนาการคุ้มครองการวิจัยในมนุษย์
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เศรษฐศาสตร์การเมืองเป็นโครงสร้างเบื้องบนของสังคม ย่อมมีอิทธิพลทั้งโดยตรงและโดยอ้อมต่อระบบยา
บทความนี้ศึกษาอิทธิพลของเศรษฐศาสตร์การเมืองต่อระบบยาในประเทศไทย โดยวิธีการศึกษาจากเอกสาร ผลการ
ศึกษาพบว่ายาเป็นหนึ่งในปัจจัยสี่ที่จําเป็นต่อการดํารงชีพ ในสมัยราชาธิปไตยผู้ปกครองใช้การเผยแพร่ความรู้เรื่อง
ยาเป็นเครื่องมือในการปกครอง เนื่องจากความรักกับการหางานหัวใจที่เห็นสถานการณ์ การเปลี่ยนแปลงการปกครอง
เมื่อ พ.ศ.2475 การสาธารณสุขมิได้กําหนดไว้ในหลักหกประการของคณะราษฎร แต่ทุกรัฐบาลต่างให้ความสําคัญ
กับการพัฒนาระบบสาธารณสุข โดยการสร้างโรงพยาบาลจนครอบคลุมจังหวัด อําเภอ และตําบล ในด้านการคลังของ
ระบบสาธารณสุขก็พัฒนาจนเกิดหลักประกันสุขภาพอันนั้นเมื่อ พ.ศ.2545 ในส่วนของระบบยาประเทศไทย
ตามแนวทางที่วัยกลางเต็มตัวการปฏิรูปประเทศไทยให้ทันสมัย ในรัชสมัยพระบาทสมเด็จพระเจ้าอยู่หัว
ทําให้ยาอยู่ภายใต้ยุทธศาสตร์การวิจัย การดํารงชีพ และการพัฒนา เฉพาะนักด้านสาธารณสุขของไทยสามารถฉลาดปฎิบัติ
อย่างรวดเร็วและผลลัพธ์ มีการพัฒนาระบบบัญชียาหลักแห่งชาติตามปรัชญาและหลักการขององค์การอนามัยโลก
อย่างแข็งแกร่งในนโยบายแพทย์ตัวกลางและกลไกทางการยา รวมทั้งการพัฒนาภาคประชาชนส่งเสริมคุณค่า
ทําให้สามารถควบคุมการใช้ยาได้อย่างเข้าใจได้อย่างมีประสิทธิภาพ เมื่อกิจการดูแลรักษาผู้ป่วยจากการเมืองที่สามารถ
ซัดช่วยและนําผู้ทําคุณภาพของยาได้อย่างมีประสิทธิภาพ เมื่อมีการเปลี่ยนแปลงทางการเมืองที่สามารถพัฒนา
ออกมาได้อย่างรวดเร็ว แม้จะมีการป้องกันไว้ให้ทันด่วนต่อการส่งยาที่มีความจำเป็นต้องใช้มีการดูแลที่สามารถเพลิด
พ超越ได้อย่างรวดเร็ว แม้จะมีการป้องกันไว้ให้ทันท่วงทีที่สำคัญกับการส่งยาที่มีความจำเป็นต้องใช้มีการดูแลที่สามารถ
ส่งยาได้อย่างรวดเร็ว แม้จะมีการป้องกันไว้ให้ทันท่วงทีที่สำคัญกับการส่งยาที่มีความจำเป็นต้องใช้มีการดูแลที่สามารถ
ส่งยาได้อย่างรวดเร็ว แม้จะมีการป้องกันไว้ให้ทันท่วงทีที่สำคัญกับการส่งยาที่มีความจำเป็นต้องใช้มีการดูแลที่สามารถ