วารสารวิชาการสาธารณสุข
ปีที่ 25 ฉบับที่ 4 กรกฎาคม - สิงหาคม 2559

Journal of Health Science
Vol. 25 No. 4, July - August 2016

นิพนธ์ต้นฉบับ *Original Article*

Pharmaceutical Preparedness for Public Health Emergency in Thailand: What Can Be Learned From Other Countries?

Pathom Sawanpanyalert, M.D., Dr.P.H.

Health Technical Office, Ministry of Public Health, Thailand

Abstract Threats to any facet of national security tend to create public health emergency. Most public health emergencies require pharmaceutical preparedness. This study aimed to review existing system for pharmaceutical preparedness for public health emergency and compared it to experiences from other countries. Reviews of literature and documents from concerned authorities and solicitation of opinions and consensus from experts were carried out to identify deficiencies in the current system of Thailand and how they can be remedied. In terms of legal provisions, the system of Thailand had several laws and regulations that dealt, at least, indirectly with pharmaceutical preparedness. However, these legal provisions were quite disconnected and did not deal adequately with the public health emergency. As a result, there was no strategic direction that addressed pharmaceutical preparedness specifically. For instance, there was no clear strategy as to whether stockpiles should be set up for all essential medicines or for certain medicines that needed to be readily available at hands when they were to be used (e.g. antidotes). The Ministry of Public Health, directly responsible for the preparedness, set up only a functional unit to implement the task. However, the unit was underfunded and understaffed. It was found that operations of the unit were adequate only for emergency of seasonal and predictable nature; but not for emergency situations which were of big magnitude, extreme urgency, marked severity, and/or unpredictable nature.

Key words: **public health emergency, preparedness, pharmaceuticals, medical supplies**

Introduction

National security is a state that national interests are protected and enhanced. National interests cover not only integrity of land, institutions of governance, and sovereignty; but also extend to cover people's values, beliefs, ways of life, welfare, and economic and social well-being. There are several components of national security including territorial integrity, economic growth and development, sociopolitical stability, ecological balance, cultural security, and others. Public health security, or simply "health security", is an essential part of national security. Any threat to a facet of national security tends to also compromise public health security. As an example, an act of ter-

rorists using biological weapons to undermine public peace also threatens public health security and creates public health emergency. A public health emergency can be a consequence of a non-health disaster or can result directly from disease outbreaks or other threats to health (e.g. chemical, biological, radiological, nuclear, and explosives; or CBRNE). It can be natural or manmade (either intentional or unintentional)[1].

Health security is a term that may have different meanings in different contexts. In developing countries, health security is understood in a broader public health context; while many developed countries emphasize the term in the context of protection of their populations especially against external threats[2]. It is in the latter context that the concepts of health security, and, its companion, public health emergency are used in this study.

One of the essential components of public health security is security of pharmaceutical products which can be achieved by pharmaceutical preparedness to ensure adequate, timely and affordable access to safe, quality, and efficacious essential drugs by people in need in both normal and emergency situations. Such accessibility to medicines implies that the products are available (locally manufactured or imported) at a price that could be afforded by the people or the government at the time they are needed.

This study aimed to review security of pharmaceutical products of Thailand for emergency situations and compared important characteristics of the Thai system of pharmaceutical preparedness and response to those of other countries, as well as to identify characteristics of the Thai system that need to be improved or strengthened.

Materials and Methods

The system for pharmaceutical preparedness of Thailand was reviewed through documents including literature, and public documents available from concerned governmental agencies. Similar systems of other countries, i.e. USA, Canada, Norway, and Australia, were studied and analyzed for key characteristics in the areas of legal provisions, strategic direction, and implementing agencies.

A group of 11 experts in public health, product regulation and control, pharmacy, and public administration was formed to examine characteristics of the pharmaceutical preparedness of Thailand, as compared to those of the other countries. Important characteristics, especially those being deficient in the Thai system, were identified. The decisions to address and include the deficiency of these characteristics in the recommendations of this study were made through consensus in the meetings of the experts.

Conflicts of interest

The author declares no conflict of interest in the study.

Results

Global Pharmaceutical Markets and Their Impacts on Thailand

According to various estimates, the size of global pharmaceutical market could be as big as 400-1,000 billion US dollars[3,4]. A World Health Organization (WHO) report showed that ten largest pharmaceutical companies control more than one-third of total global sales with profit margin at approximately 30%. Drug companies in North America (especially USA), South America, Europe and Japan accounted for more than 85% of total market values[4]. The WHO had admit-

ted that there was an inherent conflict of interest between the legitimate goals of pharmaceutical manufacturers and the social, medical and economic needs of health care providers and the public to select and use drugs in the most rational way. The decisions to manufacture drugs were likely to be driven by profits rather than by the needs of the poor people, especially in the less developed part of the world. These global statistics showed that there was an inherent risk to pharmaceutical security of the countries with no or low manufacturing capacity for pharmaceuticals.

With a population of about 67 million, Thailand was a big consumer of drugs. A recent estimate showed that Thai people consume 160 billion Baht of pharmaceuticals in a year (accounting for 24.4% of total health expenditure)[5]. It was estimated that two-thirds of the drugs consumed in Thailand (based on market prices) were imported. Among those one-third that were locally manufactured in Thailand, more than half of the production costs were for raw materials (active pharmaceutical ingredients, APIs) imported from other countries. With thousands of drug formulations currently registered by the Food and Drug Administration of Thailand (Thai FDA), Thailand could only produce 25 APIs on its own (Thai FDA, personal communication). Similar to other countries, Thailand still faced problems with no access to certain medicines for several rare diseases as there were not available in the market (mainly because it was not cost-effective to manufacture these orphan drugs). Furthermore, despite the sheer number for drug registrations, there were episodes of drug shortages faced by the health care system of the country, as demonstrated in the following examples. There was a delay to secure access to botulinum antitoxin from abroad in a big outbreak of botulism in northern Thailand in 2006[6]. The H1N1 influenza pandemic in 2011 pushed the Thai FDA to issue authorization for the first-ever influenza vaccine manufacture in Thailand on an urgency basis (emergency use authorization)[7]. There were shortages of several drugs (especially injectable fluids) in the mega flood in Thailand in 2011[8]. These examples demonstrated insecurity in the pharmaceutical system of the country in emergency situations.

Pharmaceutical Preparedness for Public Health Emergency in the US[9]

In 1999, a national pharmaceutical stockpile system was established within the United States Centers for Disease Control and Prevention (US CDC) of the Department of Health and Human Services (HHS). It was later renamed as the "Strategic National Stockpile" (SNS). The SNS had the core mission to deliver critical medical assets to the site of a national emergency. Materials in the stockpile were standardized in terms of number and type. The stockpile was composed of (1) 12-Hour Push Packs (guaranteed to reach the site of emergency with 12 hours of the federal decision to deploy the package) containing broad-spectrum antibiotics, other emergency medicines, injectable fluids, airway equipment, and bandages; (2) managed inventory maintained by the SNS or by specific vendors or manufacturers including vaccines, antitoxins, ventilators, and additional quantities of 12-Hour Push Pack items; and (3) agents to be used for radiological and nuclear events, including chelating agents, Prussian blue, potassium blue, and growth factors. In addition, in 2004, a voluntary CHEMPACK project for the forward placement of sustainable re-

positories of nerve agent antidotes was established to ensure immediate access for treatment of persons affected by nerve agents.

Furthermore, the SNS also had Federal Medical Stations (FMS) that were a cache of medical supplies and equipment that can be used to set up a temporary, non-acute care facility for 250 people up to three days.

In December 2006, the Pandemic and All-Hazards Preparedness Act (PAHPA) established a new authority, so-called "Biomedical Advanced Research and Development Authority" or BARDA, within the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the US HHS. BARDA was tasked to promote collaboration between US government agencies and interested parties in advanced development of medical countermeasures (MCMs), direct advanced research and development activities on MCMs of the US HHS, facilitate registration of new MCMs with US FDA, and support and fund technologies and tools that facilitate development of MCMs. BARDA promoted utilization and deployment of MCMs basic research sponsored by the US National Institutes of Health (US NIH) and procured MCMs for the SNS for the US CDC. Of particular note, BARDA ensured the availability of MCMs for public health emergencies through several approaches, e.g. supporting the construction of new facilities, retrofitting existing facilities, and exploring use of multiproduct manufacturing facilities.

The US had well-defined processes for determination and declaration of public health emergencies. Public health emergencies might be determined by the Secretary for Defense, the Secretary for Homeland Security, or the Secretary for Health and Human Services, but they needed to be declared only by the Secretary for Health and Human Services. Once a public health emergency was declared, several legal requirements were waived and procedures were bypassed. For instance, it empowered the US FDA Commissioner to authorize emergency use of an unapproved drug or MCM (emergency use authorization, EUA). It also provided legal immunity protection for persons who acted legitimately in accordance with the declaration of public health emergency.

Pharmaceutical Preparedness for Public Health Emergencies in Canada[10]

The program for National Emergency Strategic Stockpile (NESS) of Canada was conceptualized in 1950s in the civilian sector to be prepared for possible nuclear attacks during the Cold War. The Canadian Cabinet authorized the Minister of Health and Welfare to formally establish the stockpile on 11 January 1952. The stockpile was centrally located and contained medical supplies and social services supplies (e.g. feeding units, beds, blankets). As the threats of nuclear attacks were vanishing, the Canadian Government began to shift stockpiling of materials from centrally-located federal depots to other locations in the provinces and territories. There were clear agreements between the federal government and the provinces and the territories as to roles and responsibilities to manage and use the stockpile.

The attack on the World Trade Center on 11 September 2001 in the US prompted governments around the world, including the Canadian Government, to pay more attention to the types of MCMs to be stockpiled. More types of MCMs, e.g. smallpox vaccine, botulinum antitoxin, anthrax antitoxin, and antidotes were

added to the stockpile. In addition, the later emergence of the SARS outbreak prompted inclusion of personal protective equipment, ventilators and oxygen supply, and others into the stockpile. The response to a public health emergency was usually started with responsibilities of a municipality. If the situation exceeded the capacity of the municipality, it might request help from the province and the territory up to the federal government respectively.

Currently, there were 11 federal depots (two in Ottawa and nine across the country) and 1,300 warehouses maintained by the provinces and the territories (with materiel supplied by the federal government). There were four groups of materiel in the stockpile, i.e. medical supplies (e.g. ventilators, personal protective equipment, gloves, operating tables, and stretchers), drugs (antivirals, antibiotics, antitoxins, and antidotes), social services supplies (electricity generators, beds, blankets, and torches), and modules and units and kits (e.g. casualty collection units, mini clinics).

Pharmaceutical Preparedness for Public Health Emergencies in Australia[11]

After the World Trade Center incident in the US in 2001, the Australian Government established the National Medical Stockpile (NMS) one year later. In 2004, when the fear of influenza pandemic was growing, the Australian Government took another major step by making advanced market commitment to purchase a huge amount of influenza vaccines, antivirals and personal protective equipments.

The NMS was under the responsibility of the Office of Health Protection of the Department of Health and Ageing (DHA) of Australia. The central government made an agreement with states and territories as to roles and responsibilities to procure, maintain, utilize and replenish the stockpile. Similar to other countries, Australia established a system so that local governments (states and territories) could request for help from the central government if their local capacity was exceeded. It should be observed that the NMS contained no social services supplies. Rather, it was the responsibility of the Australian Red Cross Society to stockpile the social services supplies.

Pharmaceutical Preparedness for Public Health Emergencies in Norway[12]

The impetus to establish the Norwegian Emergency Preparedness Stockpile (NOREPS) followed the Gulf War in 1991. The main motivational forces for the establishment were to support humanitarian assistance of the United Nations and to play the leader's role in the global humanitarian mission of Norway. NOREPS was formally created in February 2000 with the target of relief materials being airborne within 24 hours; and experts would be dispatched to sites within 72 hours after a decision was made. NOREPS is under the responsibility of the Norwegian Department of State with a public entity, so-called "Innovation Norway", serving as the stockpile manager. Materiel contained in the NOREPS included supplies procured by the Norwegian Government or donated by other entities, roster of experts to be dispatched to the field, and services package (including personal protective equipment) to be rendered for assist by NOREPS partners, e.g. Norwegian Church Aid, Norwegian Red Cross, Norwegian People's Aid.

Supplies maintained by NOREPS might be stocked at vendors' or suppliers' facilities (vendor-managed

inventory, VMI) or at the warehouses of NOREPS (stockpile-managed inventory, SMI) located in various places, e.g. Brindisi (Italy), Dubai (United Arab Emirates).

Analysis of pharmaceutical preparedness of these countries demonstrated the following characteristics:

Legal Provision

It was evident that certain kinds of legal provisions or cabinet resolutions were needed to establish pharmaceutical preparedness system. These provisions could be nested in a broader context of health security or national emergency; or were made specifically for public health emergency.

Strategic Direction

Countries like the US had developed pharmaceutical preparedness system in a very comprehensive manner, i.e. covering all essential medicines to be needed during public health emergency and ensuring immediate access to urgency medicines (e.g. antidotes) through the CHEMPACK. However, certain countries might focus on some types of medicines, e.g. Australia emphasized influenza-related medicines.

Implementing Agency

All countries had a clear unit to implement pharmaceutical preparedness system. The unit was usually located within the department of health.

Pharmaceutical Preparedness for Public Health Emergencies in Thailand: Lessons Learned from Other Countries

The system for preparedness and responses to emergencies in Thailand was reviewed and analyzed as follows:

Legal Provision

There were at least 4 acts that dealt indirectly with public health emergencies, i.e.

1. Disaster Prevention and Mitigation Act 2007 (B.E. 2550)

In this Act, disaster was defined to encompass all kinds of events that pose dangers to the state and/or people's lives and properties. This Act commissioned a national committee to be led by the Prime Minister or one of his Deputies. The committee was composed of representatives of various ministries, including health, military, and security; and a few external experts. The committee provided direction, approved national strategic plan, and supported operations for disaster prevention and mitigation. The Department of Disaster Prevention and Mitigation of the Ministry of Interior served as the national focal point of the Act. Similarly, there were corresponding committees at the provincial level with the governor serving as the chair of the provincial committee.

As far as stockpiling was concerned, the national strategic plan mandated that the Department of Disaster Prevention and Mitigation stockpile social services supplies in at least 4 locations across the country. However, in practice, stockpiling of pharmaceuticals and medical supplies remained the responsibility of the Ministry of Public Health (MoPH). The MoPH dealt with annual public health emergencies through its functional office and *ad hoc* committee and relied on the Government Pharmaceutical Organization (GPO) and, possibly the Military Pharmaceutical Plant as the main suppliers of the drugs.

2. Medical Emergency Act 2008 (B.E. 2551)

This Act covered medical emergency conditions

that occurred to individuals. It established a medical emergency committee and the Emergency Medical Institute of Thailand. The committee gave policies, set standards, provided recommendations, and supported operations. Although public health facilities used for medical emergencies might be used when a public health emergency hit, the Emergency Medical Institute of Thailand was not directly responsible for public health emergency.

3. Communicable Diseases Act 2015 (B.E. 2558)

This Act provided for authority to prevent and control communicable diseases using various means including isolation, quarantine, and immunization. It established a national committee on communicable diseases that was chaired by the Minister of Public Health and was represented by various ministries including health, environment, and livestock; and a few external technical experts. The Department of Disease Control served as the secretary of the committee and the main implementing agency. Likewise, there were similar committees at the provincial level and for the Bangkok Metropolitan Administration (BMA). The Minister of Public Health also established communicable diseases control officers to implement measures per this Act. As suggested by the title, this Act dealt mainly with public health emergencies associated with a communicable disease. The Act did not specifically provide for pharmaceutical preparedness.

4. Royal Decree for Public Administration in Emergency Situations 2005 (B.E. 2548)

This emergency decree was aimed to ensure smooth and continuous administration during emergencies of national concern. It covered all kinds of emergency situations. However, based on its experiences since inception, this decree was only activated in emergencies caused by political unrests. It established a committee that was chaired by one of the Deputies Prime Minister, and represented by various ministries. However, the Ministry of Public Health was not represented in the committee. Upon declaration of an emergency situation, certain legal authority of other existing laws (e.g. those concerning authorization of products that might be used in emergency situations) that belonged to any minister could be transferred to the Prime Minister. In addition, the Prime Minister could designate government officials to act as officers for this decree. The decree also empowered the Prime Minister to issue regulations for curfews, prohibition of assembly for unlawful purposes, media censorship, transportation blockade, building abandonment, and evacuation of people.

Strategic Direction

The Disaster Prevention and Mitigation Act demanded for a national strategic plan for disaster prevention and mitigation. The plan was developed by the Department of Disaster Prevention and Mitigation and had been approved initially by the concerned committee and finally by the cabinet. It contained a brief description of various disaster scenarios and trends of disasters, policy and strategy for risk management of disasters, principles of disaster risk management, disaster risk reduction, strategies for emergency management (standards, systems and tools, and operating procedures), recovery (post-disaster needs assessment, operating system for disaster recovery, and build-back-better-and-safer approach), and international cooperation in disaster risk management. The strategic plan provided general outlines that might apply for all sorts

of emergencies but had no specific approach for public health emergency pharmaceutical preparedness.

Implementing Agencies

There were a number of agencies directly or indirectly concerned with disaster prevention and mitigation in general and public health emergency management in particular. At the overall level, the Department of Disaster Prevention and Mitigation served as the national focal point with similar structure at the provincial level with the governor as the chairman of the provincial committee serving as the provincial focal point. As far as public health emergency was concerned, the Ministry of Public Health was the prime responsible agency. The Ministry established a functional body so-called "Bureau of Public Health Emergency" to implement the tasks. In addition, the Thai Red Cross Society and the military also contributed significantly in the relief efforts during and after disasters including public health emergencies.

As Thailand regularly faced annual events that pose certain degrees of public health emergency, e.g. flood, drought, and seasonal disease outbreak, Thai authorities had established procedures to handle the situations, including pharmaceutical preparedness and response. The Government Pharmaceutical Organization (GPO), the only state enterprise within the Ministry of Public Health, and the Military Pharmaceutical Plant of the Ministry of Defense were the main responsible agencies for such preparedness and response. Financing for the preparedness and response came from the government budget and/or the national universal health insurance scheme.

In the events of unusual (e.g. extreme, unpredicted, and/or rare) occurrence, however, the pharmaceutical preparedness and response mechanisms have proved to be far from adequate. A big outbreak of botulism in Nan province in northern Thailand in 2006 highlighted the importance of stockpiling of drugs for rare diseases. Instead of receiving botulinum antitoxins within 24-48 hours of exposures, the botulism cases that needed mechanical ventilation received antitoxin treatment on days 5-9 after exposures. Fortunately, there were no fatalities. As another example, the H1N1 influenza pandemic in 2009, demonstrated various shortfalls in the operations to handle public health emergencies of unusual nature. The GPO was tasked by the MoPH to prepare an adequate supply of influenza antivirals for the pandemic, for which almost 6,000 kilograms of oseltamivir (an antiviral drug for treating influenza) raw material were imported. However, as the threat of influenza pandemic later declined, an approximate amount of 3,500 kilograms of the raw material remained and needed to be discarded due to expiry of shelf life (Thai FDA, personal communication). In addition, as the GPO was also mandated to develop its manufacturing capacity for influenza vaccine (the first ever locally-manufactured influenza vaccine in Thailand), the drug regulatory agency of Thailand, i.e. the Thai FDA, needed to develop a mechanism to issue emergency use authorization (EUA) for the vaccine for public health emergency resulting from the influenza pandemic.

Lessons Learned for Thailand

Despite various laws and regulations that dealt with disaster prevention and mitigation and public administration in emergency situations, there were no specific and comprehensive legal provisions for determination and declaration of public health emergency,

preparedness and response of drugs and other medical supplies for public health emergency, and preparedness of pharmaceutical procurement and production capability and capacity during normal situations to be prepared for public health emergency.

Thailand had national security strategies prepared by the Office of the National Security Council and threats to public health security, e.g. disease outbreaks, were briefly mentioned in the strategic plan. In addition, the national disaster prevention and mitigation plan provided for direction for planning and management of all disasters in the country. However, health security strategy was not specifically formulated nor detailed for use in either normal or emergency situations in any of the documents.

Unlike an institute for medical emergency that was established officially by a specific act, the Bureau of Public Health Emergency that served as the national focal point for public health emergency was still a understaffed and underfunded functional body. As a result, the operations to be prepared for and responsive to public health emergencies by the authorities concerned were probably adequate for predictable seasonal emergency situations, but become clearly insufficient for emergency situations of big magnitude, extreme urgency, marked severity, and/or unpredictable nature.

Discussion

The results of this study demonstrated that Thailand had attached high level of importance to preparedness and response for emergency situations. The pharmaceutical preparedness seemed adequate for emergency situations of predictable scope and scale, e.g. annual flood. However, several emergencies of unusual occurrence, e.g. major disease outbreaks, mega flood, had challenged the adequacy of the preparedness and response systems. Although there were many legal provisions in place, there were no specific laws or regulations that dealt with public health emergency specifically. The existing legal provisions were quite disconnected and did not address preparedness and response for public health emergency in a systematic manner and were not up to the situations of extreme scope and scale. There was no specific strategic plan for public health emergency. The current national strategic plan on disaster prevention and mitigation does identify disease outbreaks as a potential disaster but does not deal with public health emergency specifically. In the plan, the Ministry of Public Health is tasked to stockpile pharmaceuticals and medical supplies for disaster-related emergency. There was no clear direction as to whether all essential medicines were to be stockpiled or only those medicines that must be at hands when they were needed, e.g. antidotes. The implementing agency of the MoPH for public health emergency was merely an internal functional unit with staff on secondment from other units and with *ad hoc* budget appropriation. This could not develop and maintain adequate preparedness and response efforts, especially for emergency of wide scope, large scale, and/or extreme nature.

Experiences had shown that public health emergencies of big magnitude, extreme urgency, marked severity and/or unpredictable nature did not spare Thailand. Therefore, the country needed clear, adequate, effective, and well-functioning legal provisions, strategic direction, implementing agency, and operating procedures for public health emergency in general and for pharmaceutical preparedness and re-

sponse for emergency in particular. The legal provisions must be well-connected with clear regard to public health emergency and pharmaceutical preparedness. This might require modification of existing laws and regulations or formulation of new laws and regulations. As the current strategic plan on disaster prevention and mitigation did not address public health emergency adequately, it might need to be expanded or a separate strategic plan on public health security might be needed. Determination, declaration, preparedness and response for public health emergency in a systematic way required long-term commitment. Hence, the implementing unit needed to be a well-established structure with adequate staff and funding. As well, the operations for public health emergency needed to be put in place and regularly updated for changing risks and patterns of threats that brought along public health emergency.

This study identified a number of deficiencies in the current efforts of the country to be prepared for the threats to public health security. It might, however, suffer from a few limitations. First, the outside experiences were drawn mainly from developed countries that might have different security risks, capability, and resources from Thailand. Therefore, their experiences might not be directly relevant to Thailand. Therefore, Thailand might need to make its own decisions that were consistent with its risk context. Second, experiences that were reviewed and presented in this study are mainly from documented civilian sources. Experiences from other sources, e.g. military secrets and undocumented sources, that were also pertinent to the topic might be missed out from the study. Therefore, further development or strengthening of the preparedness and response of pharmaceuticals and medical supplies for public health emergency needed to involve national security agency and the military. Third, the study and its recommendations were set mainly for the context of Thailand as a sovereign state, not as a member of a bigger regional group, e.g. Association of Southeast Asian Nations (ASEAN). As certain threats were not unique nor confined to Thailand; and responses to these threats might not be adequate or fully effective if acted unilaterally. Therefore, it might be necessary and more cost-effective if the preparedness and response could be designed and developed on a subregional or regional or global basis, as appropriate and possible.

Acknowledgment

The author wishes to thank the administrators and the staff of the Bureau of Public Health Emergency, the Government Pharmaceutical Organization, the Military Pharmaceutical Factory, and the Food and Drug Administration of Thailand who kindly participated in the study and/or provided useful documents and information for this study.

References

1. Centers for Disease Control and Prevention. Public health emergency [Internet]. [cited 2016 Feb 2]. Available from: http://www.phe.gov.
2. Aldis W. Health Security as a public health concept: a critical analysis. Health Policy Plan 2008;23:369-75.
3. Statista. Global pharmaceutical industry - statistics & facts [Internet]. [cited 2016 Feb 2]. Available from: http://www.statista.com>topics>global-pharmaceutical-industry
4. IMS Health. Total unaudited and audited global pharmaceutical market [Internet]. [cited 2016 Feb 2]. Available from: https://www.imshealth.com>web>news
5. World Health Organization. Pharmaceutical industry

[Internet]. [cited 2016 Feb 2]. Available from: http://www.who.int>trade>glossary>story 073

6. Board of Investment. Industry focus [Internet]. [cited 2016 Feb 2]. Available from: http://www.boi.go.th>tir>issue
7. Ungchusak K, Chunsuttiwat S, Braden CR, Aldis W, Ueno K, Olsen SJ, et al. The need for global planned mobilization of essential medicine: lessons from a massive Thai botulism outbreak. Bull World Health Org. 2007;85:161-244.
8. Ungchusak K, Sawanpanyalert P, Hanchaoworakul W, Sawanpanyalert N, Maloney SA, Brown RC, et al. Lessons learned from influenza A(H1N1)pdmD9 pandemic response in Thailand. Emerg Inflect Dis [Internet]. 2012 [cited 2016 Feb 2];18:1058-64. Available from: http://dx.doi.org/10.3201/eid1807.110976
9. Wikipedia. 2011 Thailand floods [Internet]. [cited 2016 Feb 2]. Available from: https://en.m.wikipedia.org>wiki>2011 Thailand floods
10. Centers for Disease Control and Prevention. Strategic national stockpile [Internet]. [cited 2016 Feb 2]. Available from http://www.cdc.gov>phpr>stockpile
11. Public Health Emergency of Canada. National emergency strategic stockpile [Internet]. [cited 2016 Feb 2]. Available from http://www.phac-asp.gc.ca>ep-mu>ness-eng
12. Department of Health. National medical stockpile [Internet]. [cited 2016 Feb 2]. Available from http://www.health.gov.au>main>Content>Media Centre>National Medical Stockpile
13. Norwegian Emergency Preparedness System. NOREPS - Innovasjon Norge [Internet]. [cited 2016 Feb 2]. Available from http://www.innovasjonnorge.no

บทคัดย่อ: การเตรียมความพร้อมด้านยาและเวชภัณฑ์สำหรับสถานการณ์ฉุกเฉินทางสาธารณสุขในประเทศไทย: เราเรียนรู้อะไรบ้างจากประเทศอื่น

ปฐม สวรรค์ปัญญาเลิศ พ.บ., Dr.P.H.
สำนักวิชาการสาธารณสุข กระทรวงสาธารณสุข
วารสารวิชาการสาธารณสุข 2016;25:749-59.

ภัยคุกคามต่อความมั่นคงของชาติด้านใดด้านหนึ่งมักจะมีผลก่อให้เกิดสถานการณ์ฉุกเฉินทางสาธารณสุข สถานการณ์ฉุกเฉินทางสาธารณสุขส่วนมากต้องการการเตรียมพร้อมด้านยาและเวชภัณฑ์ การศึกษานี้เป็นการทบทวนระบบการเตรียมพร้อมด้านยาและเวชภัณฑ์สำหรับสถานการณ์ฉุกเฉินทางสาธารณสุขของประเทศไทย โดยเปรียบเทียบกับประสบการณ์ของประเทศอื่น การศึกษานี้ใช้การทบทวนวรรณกรรมและเอกสารจากหน่วยงานที่เกี่ยวข้องและการประชุมกลุ่มเพื่อหาความเห็นร่วมของผู้เชี่ยวชาญที่เกี่ยวข้องกับการเตรียมความพร้อมสำหรับสถานการณ์ฉุกเฉินทางสาธารณสุข ประเทศไทยมีกฎหมายหลายฉบับที่เกี่ยวข้องกับสถานการณ์ฉุกเฉิน แต่ไม่มีฉบับใดที่เกี่ยวข้องกับสถานการณ์ฉุกเฉินทางสาธารณสุขโดยตรง ทำให้ไม่มีการกำหนดยุทธศาสตร์ที่กล่าวถึงการเตรียมความพร้อมด้านยาและเวชภัณฑ์สำหรับสถานการณ์ฉุกเฉินทางสาธารณสุขอย่างชัดเจน เช่น ไม่มีการกำหนดอย่างชัดเจนว่าจะเตรียมพร้อมด้านยาและเวชภัณฑ์สำหรับยาจำเป็นทุกชนิด หรือเตรียมพร้อมเฉพาะยาฉุกเฉินที่ต้องมีใช้ทันทีที่ต้องการ (เช่น ยาต้านพิษ) กระทรวงสาธารณสุขในฐานะหน่วยงานหลักที่รับผิดชอบการเตรียมความพร้อมด้านยาและเวชภัณฑ์ ไม่มีหน่วยงานที่เป็นทางการที่ดูแลเรื่องนี้ มีเพียงหน่วยงานที่ตั้งขึ้นเป็นการภายในที่ขอยืมบุคลากรมาจากหน่วยงานอื่นและไม่มีงบประมาณประจำ ในส่วนของการปฏิบัติในกรณีที่เกิดภาวะฉุกเฉินทางสาธารณสุขพบว่า มีการปฏิบัติที่ดีพอสมควรสำหรับสถานการณ์ฉุกเฉินทางสาธารณสุขที่เกิดประจำทุกปีในระดับที่คาดการณ์ได้ แต่ไม่เพียงพอสำหรับสถานการณ์ฉุกเฉินที่มีขนาดใหญ่ เร่งด่วนมาก รุนแรงสูง หรือคาดเดาลักษณะได้ยาก

คำสำคัญ: **สถานการณ์ฉุกเฉินทางสาธารณสุข, การเตรียมพร้อม, ยา, เวชภัณฑ์**