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National Drug Policies in Thailand: Evolution and Lessons for the Future

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Abstract Many countries encountered various pharmaceutical problems which challenged them to find long-term solutions to achieve the goal of access to medicines. To address these issues, the World Health Organization suggested that countries generate and implement a National Drug Policy (NDP), and launched guidelines to assist the process of policy development. In most countries, the NDP has similar key objectives of access, quality, and rational use of medicines; but some local specific objectives might differ. This review explores the historical development of NDPs in Thailand using information from both public and not-public sources, analyzes outcomes and challenges, and provide recommendations for further development. The findings show that national drug policies in Thailand were initially developed in 1981 and evolved over time until getting the current NDP in 2017. The NDP development took existing pharmaceutical problems and national strategies of the Royal Government into account in order to create a policy which were sensitive to local situations and national directions. The evolution from the first to the fourth NDP has strengthened its platform to increase continuity and development of special projects and interventions to solve the problems in the drug system. Although NDPs in Thailand have been quite successful, there are stll some strategic inadequacies which require further support and participation from stakeholders and additional resources for implementation. Furthermore, a competent advocacy body and a Secretariat Office should be established to bolster policy coordination and implementation progressively.

***Keywords*: drug system, national drug policy, drug system strategy, reference drug price, targeted list of priority medicines**

Introduction

Right to health is considered as fundamental human right in which medicines are significant elements of for prevention and treatment to maintain people's good health.[1,2] However, many countries are still facing problems in the drug systems such as high cost of medicines, inequitable access, pervasively inappropriate marketing and promotion of pharmaceu-

ticals.[3-5] These issues have made it difficult for countries to fulfill the aim of access to medicines in response to the right to health. The World Health Organization (WHO) recommends that to address some of these pharmaceutical problems countries should develop a national drug policy (NDP) with a committed framework for achieving good access to medicines.[6]

The concept of a national drug policy was initially mentioned in the 28th World Health Assembly in 1975; and in 1986 WHO launched guidelines for member states to develop national drug policy. The NDP guidelines mainly comprise goals and objectives which depend on a country's situation and priorities. Key policy objectives are to improve access, quality, and rational use which require certain components, i.e. selection of essential drugs, quality assurance, and drug financing, in order to meet WHO's recommendations.[6,7]

In Thailand, national drug policies was initiated in 1981 (B.E. 2524); and evolved into the current NDP in 2017 (B.E. 2560) which aims to address the pharmaceutical problems and fully develop national drug systems.[8,9]

The objectives of this article are to present the review of the historical development of NDPs in Thailand and to identify challenges and provide recommendations for further development.

Methods

This qualitative study is a documentary review of the evolution and development of NDPs in Thailand using both public and non-public data. Drug policies and other relevant information were obtained from various sources including academic journals, research reports, minutes of committee and subcommittee meetings, official correspondence, and laws and regulations. All the efforts are aimed to describe the historical development of NDPs, analyze successful outcomes and challenges, and provide some recommendations.

History and Evolution

The development of national drug policies began with situation analysis on pharmaceutical problems e.g. low quantity of local production especially the active ingradients, irrational use of drugs, and high pharmaceutical prices and expenditure. These analysis helped to set goals and strategies of NDPs. There are committee and sub-committees which consist of governmental authorities, independent technical experts and other stakeholders. The sub-committee's tasks are to make recommendations to the committee for decisions to achieve NDPs' goals and objectives. This advisory body and its subordinates mainly are the national committee - National Drug System Development Committee (NDSDC) - and 6 sub-committees for the following purposes of developing on: Drug System Strategies and National Drug Policy, National List of Essential Medicines, Rational Use of Drugs, Pharmaceutical Reference Prices, Pharmaceutical Industry, and Steroid Monitoring System. The Committee's Chair is the Deputy Prime Minister and the Sub-Committees' Chair is the Deputy Permanent Secretary of Ministry of Public Health (MoPH). The secretariat office for the Committee and Sub-committees are mainly the Food and Drug Administration (FDA) and joint secretariat with other government

organizations. To date, there have been 4 NDPs in Thailand which can be separated into 3 significant periods.

The Initiatives of National Drug Policy

National Drug Policy B.E. 2524

The first National Drug Policy formulated and officially imposed in 1981 (B.E. 2524) by Minister of Public Health. It specified 5 projects to implement which included: (1) improving the medicine supply and distribution system, (2) improving drug manufacturing practices, (3) conducting research and development (R&D) of modern and herbal medicines, (4) increasing health professionals' knowledge on essential medicines, and (5) strengthening the drug regulartory system. This policy was implemented and led to limited scope of results, yet it was suit to the national situations and covered systemic problems, particularly the irrational use and waste of medicines. However, some problems – R&D of pharmaceutical raw materials in order to build the capacities and feasibilities for local pharmaceutical production – were mentioned in the NDP but were not a focus of the implementation.[9,10]

National Drug Policy B.E. 2536

This second NDP was launched in 1993 (B.E. 2536) with shrinkages and additions to the previous policy strategies. This NDP inluded roles and responsibilities of various organizations in order to make the policy clearer to implement and for main actors to take actions. The considerable changes of the NDP were to (1) promote and expand NLEMs to private hospitals and settings, (2) investigate the health promotion and preventive potential of herbs and herbal medicinal products, and (3) develop the drug registration and approval system, especially laws and regulations, for fostering consumer protection. The policy performed quite well with accomplishment, for instant developing surveillance and monitoring system for drug safety and adverse effects; stipulating a labeling requirement of generic names' indication; issuing the drug registration guidance for export purposes; developing National List of Essential Medicines (NLEMs) to have sub-categories in order for specialists' and subspecialists' suitable prescription to diseases. However, the policy outcomes showed little progress on the local production of pharmaceutical raw materials, regulations for clinical research and ethical issues, and finding the solution for high cost of drugs. Many of these problems remained, partly because of not having a secretariat office to continuously coordinate and support policy implementation nor policy monitoring and evaluation system.[11,12]

The Changes for Continuity

National Drug Policy B.E. 2554

There was a situation of discontinuous policy during 1993-2011 (B.E. 2536-2554), which was a consequence of the frequent expiration of National Drug Committee's tenure following dissolution of the parliament. Therefore, in 2008, to solve the problem of poliy discontinuity, Regulations of the Office of the Prime Minister on National Drug System Development Committee B.E. 2551 was formulated and approved to allow NDP to be developed by National Drug System Development Committee (NDSDC).[13] Consecutively the third NDP was developed by the NDSDC, and gianed officially approved from the

cabinet of Thailand in 2011.[14]

The third NDP derived from the country's pharmaceutical situation and additinal advocacy: the resolution of the 1st National Health Assembly in 2009 on universal access to medicines and the resolution of the 2nd National Health Assembly in 2010 on ethical issues for drug promotion and alternative and traditional medicines for healthcare services. This led to the situations brought out National Drug System Development Strategy B.E. 2555-2559 with the following strategies: (1) accelerating access to medicines, (2) promoting rational use of drugs (3) developing local pharmaceutical industry (4) improving national regulatory systems.[13] The monitoring in 2017 showed that most strategic indicators were achieved including locally produced generic medicines which had increased to 150 medicines (indicator: 30 medicines), irrational use of antibiotics had decreased by 50 percent. Nevertheless, there were obstacles hindering successful outcomes e.g. lack of staff to undertake responsible tasks for the committee, and inadequate NDP's advocacy power to make changes in drug systems, although they typically had enough capacity to encourage and coordinate stakeholders.[15]

Comprehensive Transformation and Movement

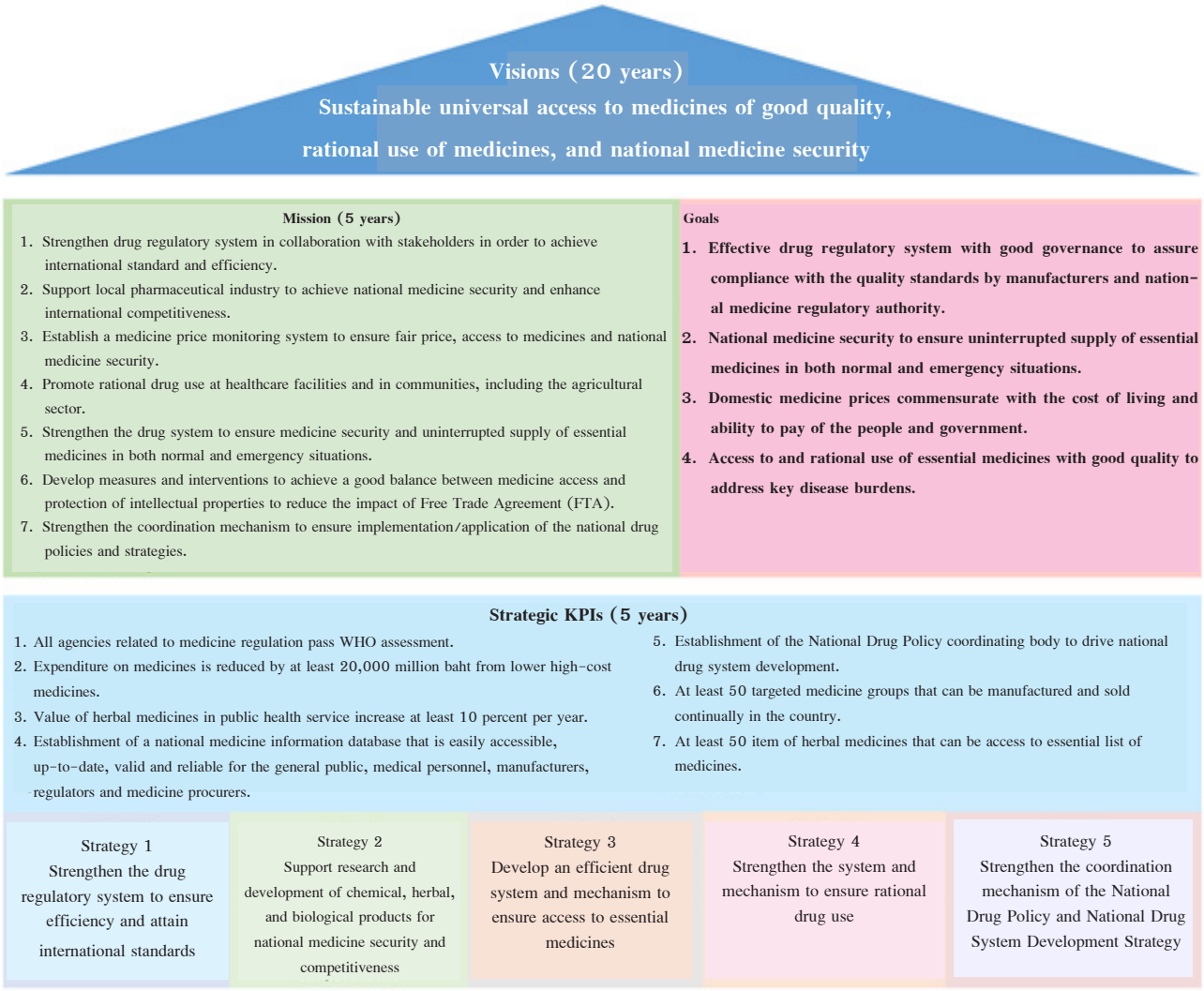
National Drug Policy B.E. 2560-2564

In 2016 the national policy vision, Thailand 4.0, launched by Royal Thai Government aimed to unlock the middle-income country and inequality traps with new economic model.[16,17] Successively, the 20-year Thai National Strategy and the National Master Plan also came into force, and it was mandatory for other local policies and plans to deliberately corresponded with the national vision.[18] In addition, it was necessary in the pharmaceutical context so that policy development could address nsome key challenges. For example, there was a high percentage of pharmaceutical expenditure (41%) from overall health expenditure (100%), percentage of imported medicines (37%) to locally produced medicines (63%) in the NLEM, and antimicrobial resistant as a result of problem from irrational use of drugs in healthcare and agriculture.[19]

These issues were included in the National Drug Policy B.E. 2560-2564 with the principal objectives of increasing the potential of local pharmaceutical industry, controlling pharmaceutical expenditure, reducing pharmaceutical imports, and promoting rational use of drugs, as shown in Figure 1. This NDP was approved in principle by the NDSDC in 2016 (B.E. 2559), not yet officially endorsed by the cabinet,[20] because the government has changed the screening and prioritization process of agendas proposed to the Cabinet for considerations. These Cabinet's processes took longer period of time for official approval of the NDP.[21]

As the NDP was not officially endorsed, the NDSDC had agreeably decided to advocate NDP temporarily with integrated measures on access to medicines, pharmaceutical cost containment, and national integrity and self-reliance which these measures were possible to be implemented successfully by government authorities, including Food and Drug Administration, Department of Medical Sciences, Department of Thai Traditional and Alternative Medicines, and Department of Intellectual Property. Therefore, yearly quick-win projects and interventions were made to help address some key issues.[22,23]

Figure 1 National drug policy and national drug system development



The Quick-Win Projects and Interventions

There are 2 importantly measurable projects: reference prices for public procurement and targeted list of priority medicines.

(1) Reference Prices (RPs) for Public Procurement

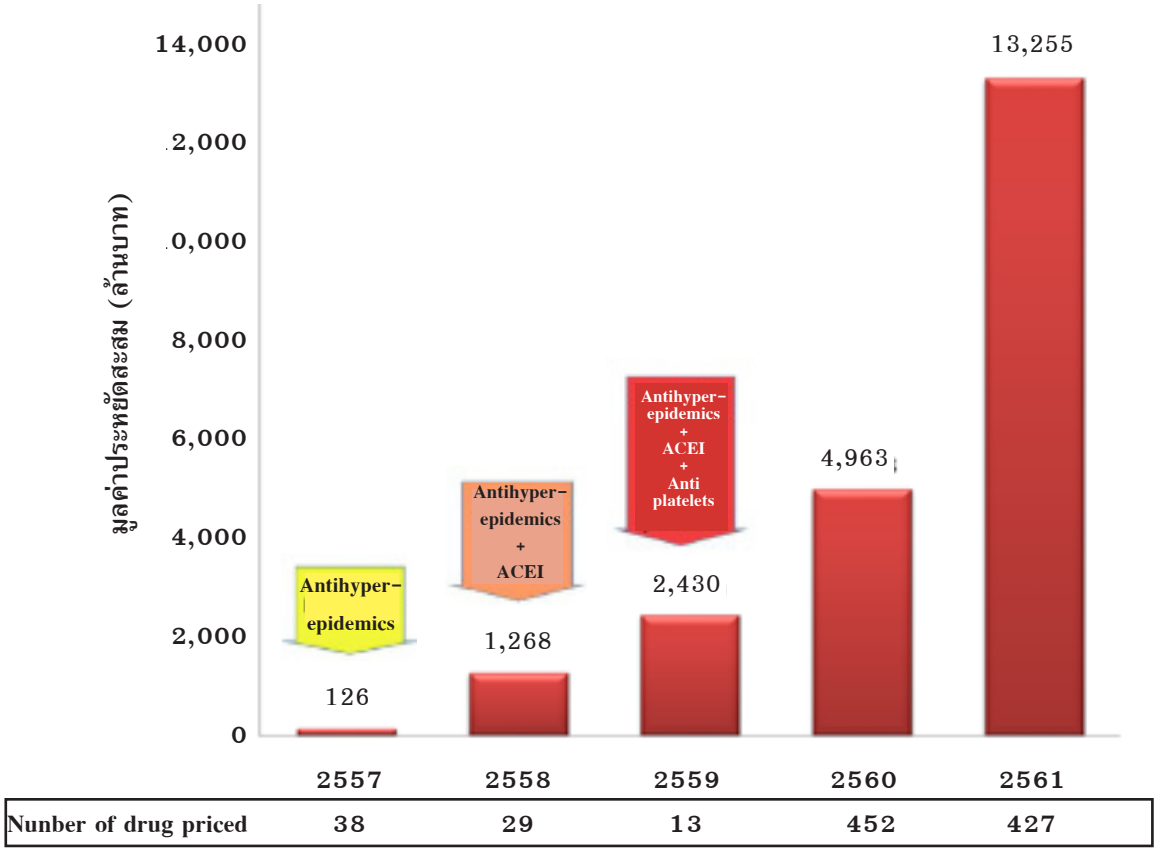
The Reference Prices for Public Procurement had originally been introduced in 2008 by the National Drug System Development Committee (NDSDC), which gave measures for pharmaceutical cost containment in order to save pharmaceutical expenditure as well as increase access to medicines. To implement these measures, the Committee appointed a Reference Pharmaceutical Prices Subcommittee to set the Reference Prices; these were only for NLEM medicines as maximum procurement prices and were set on the calculation basis of "mode".[24] The RPs was forced through the Regulations of the Office of the Prime Minister on Government Procurement B.E. 2535 and later through the Public Procurement and Supplies Administration Act B.E. 2560. It is mandatory that the public hospitals, especially hospitals under MoPH, procure pharmaceuticals and medical products with their prices which were below or equal to the RPs.[25]

Later in 2013 NDSDC improved concepts and main procedures to be more reliable and fair to both hospitals (purchaser) and manufacturers (merchant). Such improvements included: (1) a greater implementation extent of measure – setting RPs for conventional and traditional & herbal medicines both NLEM medicines and non-NLEM medicines, (2) separation of drug groups regarding market competition to employ suitable methods for RPs setting – group 1 is the competitive market and group 2 is the monopoly and oligopoly market, (3) modification of the calculation method from mode to "median", and (4) development of fairness and transparency – including public hearings and appeal procedures to the decisive process of pricing.[24,26]

The reference prices for public procurement is firmly a part of NDP strategy 3: controlling pharmaceutical expenditure and increase access to medicines, and is indirectly a part of NDP strategy 4: promoting the rational use of drugs. The measure has been implemented using new concepts and procedures during 2014–2018 which priced 959 drugs in 10 therapeutic groups. Consequently, a study conducted by the Thai FDA suggests that the government procurement budget for pharmaceuticals saved accumulatively 13,000 million Baht, which mostly derived from antihyperlipidemic drugs and angiotensin converting enzyme inhibitors (ACEIs) at approximately 7,300 and 2,000 million Baht respectively,[26] as shown in Figure 2.

The Reference Prices (RPs) for Public Procurement have purposely been implemented for pharmaceutical

Figure 2 Cumulative budget savings of pharmaceutical reference prices



cost containment during 5 years (2014-2018) with budget saving 13,000 million Baht. However, it is not possible to say that the saving was a unique result of the NDP B.E. 2560-2564, because the evaluation period was 2014-2018 and the NDP (B.E. 2560-2564) was implemented during 2017-2021. Therefore, the result of the RPs measure can partly be claimed for the current NDP of only 2 years during 2017-2018, which saved government procurement budget about 5,200 million Baht.

The RPs measures introduce maximum purchasing prices which means that medicine procurement is now actually purchased at lower prices than the RPs due to the negotiating and bargaining power of hospital purchasers. So, the savings made as a result of the measures (5,200 million Baht) was only a minimum saving on medicine procurement; the saving amount could potentially be higher than that.

(2) Targeted List of Priority Medicines

The national situation of pharmaceutical industry showed that pharmaceutical manufacture had the lowest potential among all other health-related manufacturing industries; in addition, the proportion of local production value to imported value was quite low 1:2. Furthermore, a tendency toward pharmaceutical consumption increased substantially due to the growing ageing society in Thailand and leading to increased demand on medicines for chronic diseases.[27-29]

To narrow the gaps, the Thai Food and Drug Administration (FDA) as the NDSDC's secretariat launched a "Targeted List of Priority Medicines" with integrated inventions.[23] This mainly works to achieve NDP strategy 2, developing and supporting the local pharmaceutical industry for the purposes of domestic consumption and exportation; this could also contribute to increasing access to essential medicines and reinforcing national drug systems more sustainably, in relation to NDP strategy 3.

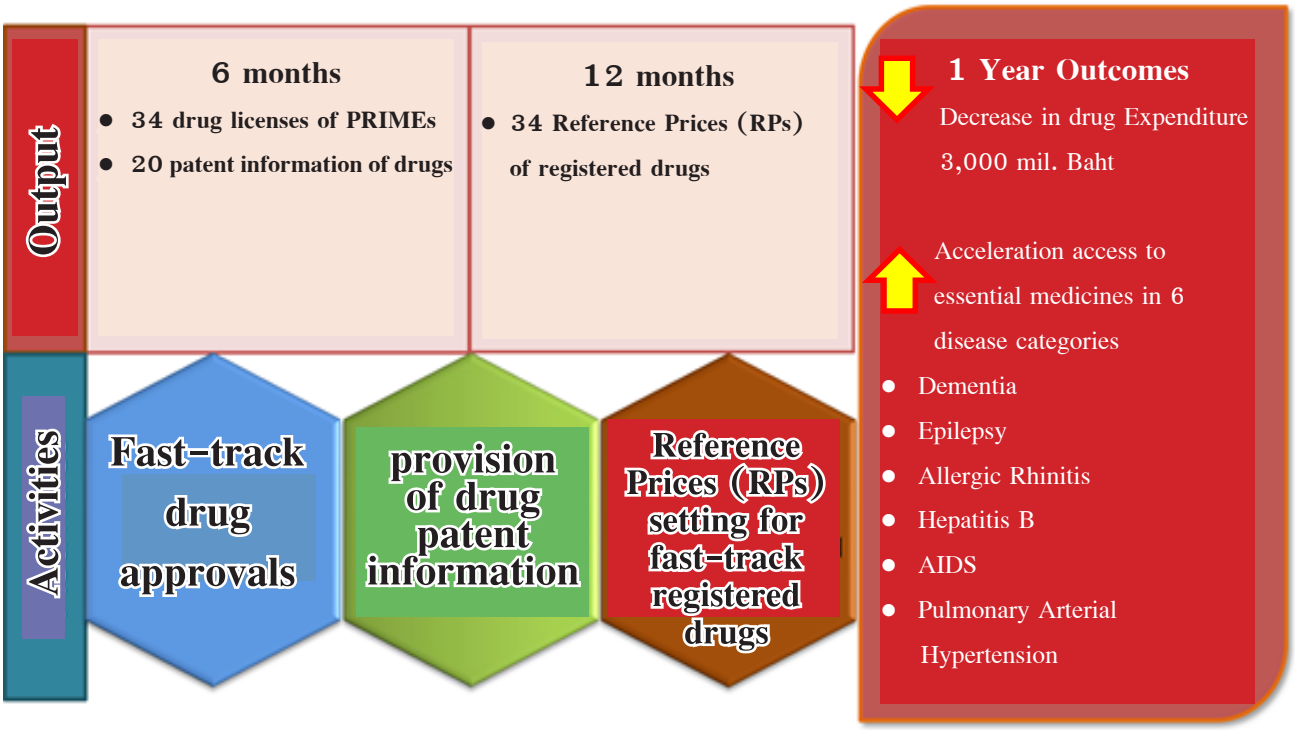
The Targeted List of Priority Medicines (PRIMEs) brought about in 2017 has a list of 144 medicines to support and enhance medicine availability and also increase access to medicines. The PRIMEs were selected mainly based on essential medicines with local unavailability or with a single brand and imported high-cost medicines for which government support were necessarily needed to motivate and incentivize local manufacturers.[23] A prioritization process later matched PRIMEs suitably with integrated inventions, as a matter of fact, each medicine needed different interventions to address their particular problems.

To encourage the availability of generic drugs, the Thai FDA issued 2 announcements putting integrated inventions in place to enhance local production and importation: including (1) provision of drug patent information to local manufacturers to induce their interests on generic production; (2) 50% reduction in registration fee; (3) fast-track drug approvals; and (4) RP setting for fast-track registered drugs.[30,31]

The PRIMEs, with their integrated interventions, had been expected to decrease medicine prices and save the government budget about 3,000 million Baht. It was also expected to increase access to medicines in 6 therapeutic groups: dementia, epilepsy, allergy rhinitis, hepatitis B, AIDS, and pulmonary arterial hypertension (PAH) as shown in the Figure 3.

The actual results after project implementation during 2017-2018 revealed that 102 licenses for generic drugs were approved, and were able to substitute original drugs in 5 therapeutic groups, except

Figure 3 One-year roadmap for targeted list of priority medicines (PRIMEs)



AIDS.[23,32] In addition to expediting drug approvals, the Reference Prices for Public Procurement was a critical intervention to increase access to medicines. Under the PRIMEs project, 29 medicines were priced RPs and surprisingly saved the government procurement budget about 4,400 million Baht, which was higher than expected.[32] Even though the PRIMEs project has not made interventions for all 144 priority medicines (for example, as a result of different problems and situations of each PRIMEs, it provided patent information on only 40 medicines, a reduction in registration fees for 53 medicines and fast-track approvals and RPs setting on 34 medicines), it has completed almost all of its goals in the project first phase.

To date, NDP B.E. 2560-2564 has not been officially evaluated yet, as it was not finished the implementation period of the NDP, despite having an obviously positive performance by saving the government's procurement budget and increasing access to essential medicines.

Discussion

The National Drug Policy in Thailand has evolved significantly over the past 35 years with 4 different versions. The first and the second NDP achieved their goals and objectives mainly solely on improving quality use and increasing access to medicines by developing the surveillance and monitoring system for drug safety and adverse effects, and separating National List of Essential Medicines (NLEMs) to have sub-categories suitably for diseases and special health issues. However, the NDP did not thoroughly solve all pharmaceutical industry-related problems. The NDPs performed well for the situation at that time but it did not deal with the inherent problems of the in-

dustry.

The third NDP (B.E. 2554) considerably changed the NDP platform from a political to a legal platform. The Regulations of the Office of the Prime Minister on National Drug System Development Committee B.E. 2551 were able to formulate the policy more continuously, but still needed official establishment of the cabinet approval. Although this NDP enjoyed many achievements and fulfilled most indicators, according to monitoring and evaluation's results some strategic objectives remained incomplete and unattained. More government support, greater participation of stakeholders and sufficient staff members with professional capabilities were needed for effective NDP implementation.

The latest and current policy, NDP B.E. 2560-2564, has been developed more exclusively and suitably with the country's context in line with both government strategic goals and the drug system itself. Although this NDP has not been approved officially, in 2016 the responsible committee, NDSDC, allowed implementation of the unofficial version because the Cabinet's policy approval required a long time of screening and prioritization process. The Cabinet's approval is essential to policy implementation for stakeholders' participation, particularly other stakeholders and agencies outside MoPH. Therefore, to implement policy temporarily, the integrated measures along with yearly quick-win projects and interventions were undertaken. Projects have included Reference Prices (RPs) for Public Procurement; and Targeted List of Priority Medicines (PRIMEs), which the ultimate purpose was to save government procurement budget; and to motivate availability of generic drugs substituted for original drugs by means of local production respectively. These 2 projects have performed well and delivered the fruitful outcomes of procurement budget saving (5,200 million Baht) and increase patient access to medicines in 5 therapeutic areas.

In conclusion, the national drug policy in Thailand has evolved considerably since 1981. It developed in the beginning as NDP B.E. 2524 to solve the pharmaceutical problems of the lack of timely access to medicines and rational use of drugs, and next as NDP B.E. 2536 to provide consumer protection though the drug registration and approval system. To strengthen continuity of NDP formulation, the Regulations of the Office of the Prime Minister on National Drug System Development Committee B.E. 2551 was launched to facilitate NDP's development continuously which resulted in NDP B.E. 2554. Similar to previous versions, this NDP mostly succeeded in increasing the potential of local pharmaceutical industry, and in promoting the rational use of drugs and in decreasing the irrational use of antibiotics. The current NDP B.E. 2560-2564 was formulated comprehensively by involving national strategies and master plans in addressing local pharmaceutical situations and problems. Presently, the Cabinet has not yet officially endorsed this latest NDP, although the Committee has implemented quick-win projects and interventions, namely Reference Prices (RPs) for Public Procurement and Targeted List of Priority Medicines (PRIMEs).

Overall, Thailand's numerous National Drug Policies have fulfilled their objectives and goals and improved drug systems considerably. The policy would however have achieved more, if the NDSDC set out higher and stronger levels of enforcement to be the

Act (not Regulation) in coordination with various stakeholders. The NDP was generated closely to fit the needs of current national policies, strategies, and master plans to be assured supports from the Royal Thai Government. In addition, to address pharmaceutical problems effectively and in a timely manner there should be a permanent secretariat office officially established in the FDA with sufficient numbers of government officers to coordinate and operate the committee and subcommittees for successful policy implementation.

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สำนักงานคณะกรรมการอาหารและยา กระทรวงสาธารณสุข
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หลายประเทศเผชิญกับปัญหามากมายในระบบยาที่จำเป็นต้องแก้ไข เพื่อทำให้ประชาชนสามารถเข้าถึงยาจำเป็นที่มีคุณภาพได้อย่างทั่วถึง โดยองค์การอนามัยโลกได้ให้ข้อเสนอแนะไว้ว่าเพื่อแก้ปัญหาในระบบยา แต่ละประเทศควรจัดทำนโยบายแห่งชาติด้านยา พร้อมทั้งได้จัดทำคู่มือนโยบายแห่งชาติด้านยาเพื่อเป็นแนวทางให้แก่ประเทศต่าง ๆ โดยนโยบายแห่งชาติด้านยาประกอบไปด้วยวัตถุประสงค์หลักสำคัญคือ การเข้าถึงยา ยาที่มีคุณภาพ และการใช้ยาอย่างสมเหตุผล อย่างไรก็ตาม แต่ละประเทศอาจมีวัตถุประสงค์หรือเป้าหมายเพิ่มเติมที่แตกต่างกันออกไปได้ตามบริบทของประเทศ โดยการศึกษานี้เป็นการทบทวนวรรณกรรมและเอกสารที่เกี่ยวข้อง จากฐานข้อมูลที่เผยแพร่และมิได้เผยแพร่เป็นสาธารณะ มีวัตถุประสงค์เพื่อศึกษาการพัฒนานโยบายแห่งชาติด้านยาของประเทศไทยและวิวัฒนาการ รวมถึงวิเคราะห์ผลการดำเนินนโยบายและความท้าทาย และให้ข้อเสนอแนะสำหรับการพัฒนาในอนาคตต่อไป ผลการทบทวนวรรณกรรมพบว่า นโยบายแห่งชาติด้านยาของประเทศไทยริเริ่มพัฒนาครั้งแรกในปี พ.ศ.2524 จนถึงปัจจุบัน นโยบายฯ ได้เริ่มจัดทำโดยการรวบรวมสถานการณ์และสภาพปัญหาในระบบยา และต่อมาได้ผนวกบูรณาการยุทธศาสตร์ชาติและแผนแม่บทแห่งชาติที่รัฐบาลได้ประกาศใช้เข้าในการจัดทำด้วย เพื่อให้ได้นโยบายฯ ที่สอดคล้องและครบถ้วน จากการดำเนินนโยบายแห่งชาติด้านยาของประเทศไทยตั้งแต่ฉบับที่ 1 ถึงฉบับปัจจุบัน พบว่านโยบายแห่งชาติด้านยาของประเทศไทยได้มีวิวัฒนาการและพัฒนาเป็นอย่างมาก ด้วยความพยายามสร้างความต่อเนื่องในการพัฒนานโยบายและจัดทำโครงการหรือมาตรการเพื่อให้สามารถแก้ปัญหาในระบบยาได้อย่างเหมาะสม อย่างไรก็ตาม แม้ว่านโยบายแห่งชาติด้านยาจะบรรลุตัวชี้วัดยุทธศาสตร์ แต่ยังคงมีความท้าทายที่ยังไม่บรรลุ เช่น การขับเคลื่อนสนับสนุนอุตสาหกรรมผลิตยา เพื่อความมั่นคงทางยาของประเทศ ซึ่งจำเป็นต้องได้รับความร่วมมือและมีส่วนร่วมจากภาคส่วนที่เกี่ยวข้อง รวมถึงทรัพยากรจำเป็นที่เพียงพอต่อการขับเคลื่อน นอกจากนี้ควรมีสำนักงานเลขานุการถาวรจัดตั้งขึ้นในสำนักงานคณะกรรมการอาหารและยา และผลักดันให้คณะกรรมการพัฒนาระบบยาแห่งชาติและคณะอนุกรรมการที่เกี่ยวข้องอยู่ภายใต้อำนาจการกำกับดูแลของพระราชบัญญัติยา เพื่อทำให้สามารถดำเนินและประสานขับเคลื่อนนโยบายแห่งชาติด้านยาได้มีประสิทธิภาพและเกิดผลสัมฤทธิ์มากยิ่งขึ้น

คำสำคัญ: **ระบบยา, นโยบายแห่งชาติด้านยา, ยุทธศาสตร์ระบบยา, ราคากลางยา, ยามุ่งเป้า**