



Food And Drug Administration

Annual Report 2015

Food and Drug Administration Thailand



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PREFACE

This report is in accordance with the Ministry of Public Health requirement provision in terms of issuing an annual performance report. The purpose is of being a summary of the 2015 fiscal year activities. Although the primary objective of this report is for the Ministry of Health and its due consumption, Thai FDA and its partners will also be provided with documented information regarding the endeavors that had transpired for the past year.

Reporting Structure

Thai FDA's 2015 Annual Report consists of three parts. The following are exemplified: 1. Overview 2. Outstanding Outcome Reports and 3. Financial Report.

Part One – Overview

The overview is a description of the office's accountability, actions, strategic direction, key issues and achievements for the last year.

Part Two – Performance Output Report

This part discusses the major actions, including main achievements and challenges, of four major outputs of the Department and its partners which are the Provincial Public Health Offices in local areas. The effectiveness of the outputs are contained in the related output report in 2015.

Part Three – Financial Report

This section provides the brief set of financial statements of Thai FDA comparing expenditures, assets and liabilities for the previous year 2014 and the year being assessed.

ROLES AND RESPONSIBILITIES

Thai FDA is a government agency under the Ministry of Public Health. Its major thrust is to protect the public citizens' health in consuming health products by ensuring high quality and safety; furthermore encouraging them to adapt an appropriate consumptive behavior through the health product information provision.



As the national leader in health products, the agency:

- takes action according to the legislation provision on food, drug, cosmetics, hazardous substances, psychotropic substances, narcotics, medical devices, prevention of usage of volatile substances, and other relevant subject matters;
- improves systems and mechanisms to enforce the legislation;
- examines and inspects the quality standard of health products, manufacturers, advertisements, and follows up undesirable effects of health products, monitors domestic and global health product information as well;
- effectively studies, analyzes, researches, and improves knowledge, technology, and consumer protection system in terms of health products;
- encourages and informs people to have a capacity to choose and consume health products appropriately, safely, correctly, and reliably; besides working on any complaints to protect on consumer rights;

- works with public, private sectors, citizens, and civic health networks to encourage and promote the consumer protection in perceptions of health products through their participation; and

- performs other tasks according to the law and assignment by the ministry or its cabinets.

2015 Expenditure

Over 798 Million Baht (26 Million US Dollars) – approximately one percent of Thai government expenditure, was allocated for the following: 1. three fourths of our expenditure was for the health product and health product manufacture control and inspection, and 2. one fourth was distributed to drug control, public campaigns, and health product control development as conditions set by the AEC initiate.

Thai FDA's Vision

To be a publicly trusted organization excellent in protecting consumers' safety and quality in health products consumption and production, also promoting Thai producers in advancing towards globalization and world-class standardization.

Thai FDA's Mission

- Control, monitor, and promote all sectors' participation to provide health products with quality, standard, and safety.

- Promote people to have knowledge, understanding, and to have the proper health product consumption.

- Encourage producers to get a better competitive chance to promote increasing economic value to the nation.

- Improve an organization management for excellence.

PART ONE - OVERVIEW



Boonchai Somboonsuk
Secretary General



Phatom Sawanpanyalerd
Deputy Secretary General



Paisarn Dunkume
Deputy Secretary General



Prapon Aangtrakul
Deputy Secretary General

Thai FDA's Major Responsibilities

Thai FDA's major accountability is to protect consumer's health by assuring licenses for health products which meet the safety and quality standards and efficacy. This includes: foods, medicine, medical devices, cosmetics and hazardous substances, psychotropic substances, narcotics, and volatile substances made available in Thailand. The implementation is in accordance with the national legislation and international agreements as follows:

1. Food Act, 1979
2. Drug Act, 1967, 2nd Amendment (1975), 3rd Amendment (1979), 4th Amendment (1984), and 5th Amendment (1987)
3. National Food Committee Act, 2008
4. Medical Devices Act, 2008
5. Cosmetics Act, 2015
6. Hazardous Substances, Act 1992, 2nd Amendment (2001), and 3rd Amendment (2008)
7. Psychotropic Substances Act, 1975, 2nd Amendment (1985), 3rd Amendment (1992), and 4th Amendment (2002)

8. The Emergency Decree on Prevention of Volatile Substance Abuse, 1990, revised in 1999, 2nd Amendment (2000), and 3rd Amendment (2007)

9. Narcotics Act, 1979, 2nd Amendment (1985), 3rd Amendment (1987), 4th Amendment (2000), and 5th Amendment (2002)

As provided by the law, certain important issues are decided by the committees, whose members, all experts in their fields, are appointed by the Minister of Public Health. Currently, there are seven committees: Food, Drugs, Medical Devices, Cosmetics, Psychotropic Substances, Prevention of Volatile Substance Abuse, & Narcotics. In addition, there are two committees whose members are appointed by other Ministries. The Prevention of Abuse of Volatile Substances committee appointed by two ministers (Industry Ministry and Public Health Ministry), likewise the Hazardous Substance Committee appointed by three ministers: Public Health, Industry, and Agriculture.

At the national level, the Cabinet has set up broad-based committees to evolve into supporting policies and promote improvement in drugs, food, and chemicals, as a mechanism in the overall policy-making of the country. Besides, there is an integration of collaboration with all elements of public and private sectors. The committees are the National Food Committee and the National Chemical Safety Committee.

Operational Measures

Thai FDA has implemented technical principles as guidelines for decision-making across the committees. It focuses on comparison of risks and benefits of product consumption. However, it is ensured that consumers will receive the maximal probable value and will get the lowest possible risk.

The responsibilities of the Thai FDA can be categorized into five core areas:

1. Pre-marketing Control

This includes control of manufacturing facilities, product quality and advertising before the product will be launched to the market. In each case, compliance is required with the relevant legislation and regulations.



2. Post-marketing Control

The aim of this activity is to investigate manufacturing facilities and product quality and to ensure that they maintain compliance with previously-approved standards and with legislation and regulations. For example, samples of products are regularly inspected and taken to check for compliance and quality. Previously-approved products are revisited periodically to ascertain the consistency of manufacturing and product standards over time.

3. Surveillance Program for Consumers' Safety

The aim of this program is to detect any adverse effects or unexpected outcomes from consumer use of products. Research and epidemiological data on adverse effects, including technical information, is collected, summarized, interpreted and reported. There are also operational centers, such as the Health Product Vigilance Centre (HPVC) and the International Program on Chemical Safety (IPCS). Information is exchanged with other agencies at local and international level.

4. Consumer Education

Consumers are supplied with the sufficient and accurate information to enable them to make the right choices of health products. Access to such information, provided by the FDA, is available from

many sources: television, radio, newspaper, leaflets, internet, and so on. FDA's campaigns on priority topics have been regularly conducted in department stores, schools and villages in many parts of the country. There are many sources for consumers to use so that they can obtain further useful information and be in a better position to protect their selves.

5. Technical Support and Cooperation with Other Agencies

The FDA has conducted many interesting seminars and workshops, with participants from both public and private sectors. On the other hand, officials from the Thai FDA are sent to join seminars and conferences, both local and abroad. As a result, with a widened perspective, they can work more effectively at home. The Good Manufacturing Practice (GMP) program is another example demonstrating successful cooperation with other organizations, in this case, with universities and drug manufacturers. In relation to cooperation in terms of research and development, the FDA is continually supportive of such endeavor, and some research projects are partly or wholly funded by the agency

Conclusion

To sum up, Thai FDA has been several Acts to responds to protect consumer's health by

controlling the health products licenses and monitoring safety and quality standards and efficacy of health products and enterprises. We act on pre-marketing, post-marketing, surveillance for adverse effects of health product consuming, educate to people, and cooperate with other to support new technical or knowledge to entrepreneurs.



PART TWO - Performance Output Report



The major performances illustrate our achievements and challenges on two outputs from the office and the Provincial Public Health Offices as its partners in local areas of Thailand. The effectiveness of the output performances in 2015: control quality standard and safety of the health products; creative knowledge for people.

Performance on Control Quality Standard and Safety of the Health Products

Regulatory function at the national level in health product control system consists of two major functions:

pre-marketing and post-marketing control. The licensing services are subjected to the central administration and provincial agencies, as well as monitoring and checking the health products and manufacturers in domestic market to claim quality and safety conformity.

License: for the safety of public consumers, it is required for any seller, producer, importer, etc., their health products in domestic or export to get licenses from the Thai FDA or Provincial Health Offices. An application for permit must be submitted for approval according to the enterprise and health product standard. The quality and standard of enterprises and products are inspected and tested before the granting of licenses for business operation start-ups. Lastly, the inspection has to be confirmed that the applicants has met the criteria, then approved.



In 2015, the number of entrepreneurs that submitted to the licensing authority was at 556,924 licenses. Over 98.34 percent were approved to run their businesses in markets but others were disapproved because of safety issues and some were incomplete documents. Some entrepreneurs also cancelled the submission. The amount of authorized product licenses was eight times of enterprise licenses, in the year. In detail, the new license group was the top submission of entrepreneurs that required making products to operate businesses. The percentage of approved new license group was 80.11 of all permitted license groups, from total 547,697 approved licenses to 438,793 new licenses. Among of these, the medical device group and cosmetic group was the top of allowable new license groups. It might cause it was submit free but the next year we are going to collect fees. The statistics is provided below in table 1.

Table 1 The number of the permitted health product licenses and enterprise licenses of Thailand in 2015

Categories	New licenses		Renew licenses		Modified licenses		Disapproved licenses		Total	
	Products	Enterprise	Products	Enterprise	Products	Enterprise	Products	Enterprise	Products	Enterprise
Food	67,630	3,678	-	4,555	22,923	2,148	1,428	643	91,981	11,024
Medicine	2,519	1,935	-	24,251	6,007	4,655	1,419	1,216	9,945	32,057
Medical device	257,148	358	105	642	30,083	284	43	25	287,379	1,309
Cosmetics	96,509	6,346	-	6,599	213	366	2,683	62	99,405	13,373
Toxic and hazardous substance	930	966	71	960	556	356	218	249	1,775	2,531
Narcotics	2	722	7	3,800	27	296	2	239	38	5,107
Total	424,738	14,055	183	40,807	59,809	8,108	5,793	2,434	490,523	65,401
	547,697						8,227		556,924	

Quality and Safety of Health Products and Enterprises: Thai FDA performs by monitoring and checking whether the approved health productive enterprises and health products in domestic market really conform to quality and safety. The approach includes randomness to inspect the manufacturing facilities and randomness to analyze the physical and quality of health products. Moreover, Thai FDA prosecutes entrepreneurs who break the regulations on health products. These approaches assert the consistency of manufacturing and product standards that the enterprises met on the Thai FDA's standards.

Quality and Safety of Health Productive Enterprises

Thai FDA regularly sends officers to visit the licensed sites without notice to inspect whether the approved conditions are still maintained enterprise facilities appropriately. The health productive factories, health productive import enterprises, health productive selling enterprises, drug stores, and possessive toxic and hazardous substances enterprises to hire are inspected around the country every year.

In 2015, we were randomly sampling to food enterprises, medicine enterprises, cosmetics enterprises, medical device enterprises, toxic and hazardous substances enterprises, and narcotics enterprises at 73,609 enterprises. According to distribution of entrepreneurs in country that we monitored, most of which were food enterprises at approximately 60 percent, medicine enterprises was 22 percent; cosmetic enterprises about 16 percent. Overall, the average of health productive enterprises standard was 93.53 percent. It is found that every medical device enterprises were able to secure appropriate facilities and passed standards at 100 percent while cosmetic enterprises was the lowest group where could maintainable standards. It seems to be that most medical device enterprises are a big company group where as a lot of cosmetic enterprises was a local SMEs. The statistic is in table 2.

Table 2 The percentage of the health productive enterprises standard in Thailand in 2015

Enterprises	No. of inspected enterprises	Enterprises met standards	
		Number	Percent
Food	44,125	41,377	93.77
Medicine	15,621	14,518	92.94
Medical device	1,034	1,034	100.0
Cosmetics	11,965	11,068	92.50
Toxic and hazardous substances	394	385	97.72
Narcotics	470	468	99.57
Total	73,609	68,850	93.53

Quality and Safety of Health Products

To ensure that health products in markets were safe and having qualities to consumption of people, we play with the Provincial Health Offices to planed and collect health product samples around country. We use the test-kit devices to analysis products immediately so that we can create knowledge and advice to enterprise and people. What is more, we co-operate with laboratory of Department of Medical Sciences to analysis the product's qualities and standards from our sample collections. Whenever we received any health products information from the Department of Medical Sciences laboratories that illustrated standards failure, those enterprises will be fine, sue, prosecute, and sometimes recall out of markets.

The samples of food products, medicine products, medical device products, cosmetic products, toxic and hazardous substances products, and narcotic products that available in markets were collected and analyzed at 111,232 samples by 2015. The most of collected samples was food products approximately 90 percent. Overall, the average of health products standard was 95.18 percent. We found that the number of medicine samples met the highest standards; food products and medical device products were the second and third respectively. At the same time, cosmetic product analyzed samples group met the lowest standards, the OTOP products (local food product, local herb medicine, local cosmetic product,



and local narcotic as used in house) met standard a bit more cosmetic product analyzed samples.

The one impotent reason that most cosmetic and OTOP products did not met standards because it was a local SMEs. The statistic is in table 3.

Table 3 The percentage of the health product standards of Thailand in 2015

Product	No. of analyzed samples	Samples met standards	
		Number	Percent
Food	100,453	95,999	95.57
Medicine	5,778	5,636	97.54
Medical devices	476	450	94.54
Cosmetics	1,897	1,505	79.34
Toxic and hazardous substances	191	171	89.53
Narcotics	94	87	92.55
OTOP	2,343	2,025	86.43
Total	111,232	105,873	95.18



Significant Adverse Drug Reaction: we have the surveillance system to investigate the problems or dangers from health product consumptions. This information was voluntarily reported by public hospitals and community pharmacies. The data were analyzed on epidemiological data, research, and examination of other significant statistics. The results were used as the supportive data for risk management measures. The case that we found any significant adverse drug reactions (ADR) or other adverse health product reaction signals, we will push forward to the Committees such as Drug Committee, Psychotropic Substance Committee, and Narcotic Control Committee to make the decision to withdraw the product licenses or takes other actions to reduce the serious adverse product reaction problems. In addition, we communicate this information to healthcare professionals overall the country. We also submit all ADR that we met to WHO database.

The Health Product Vigilance Center (HPVC) of the Thai FDA received adverse product reaction reports that could analysis at 662,607 reports since 1984. There were 44,020 reports in 2015. According to WHO database for global monitoring, most of the proportion of ICSRs (Individual Case Safety Reports) of Thailand was set on 0.5 to 0.9 range score which it almost reached the maximum score (1.0) of the high quality data and completeness information. In addition, since 2010, the trend of Thai ADRs deceased because medical professionals were able to detect patients by searching ADR records on database and advising before dispensed medicine. The data provides on figure 1 and 2.

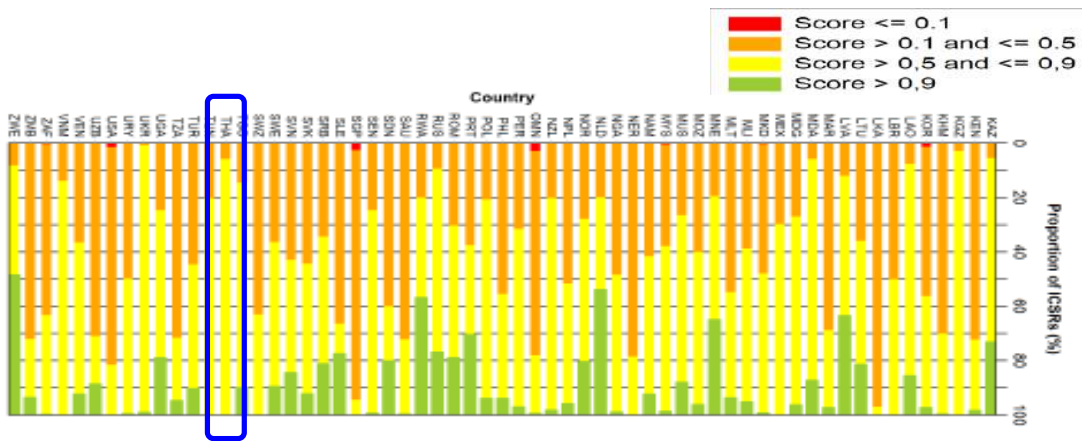


Figure 1 VigiGrade completeness score over time by country, Calculated on all ICSRs entered into the WHO global ICSR database between 20110101 and 20160627

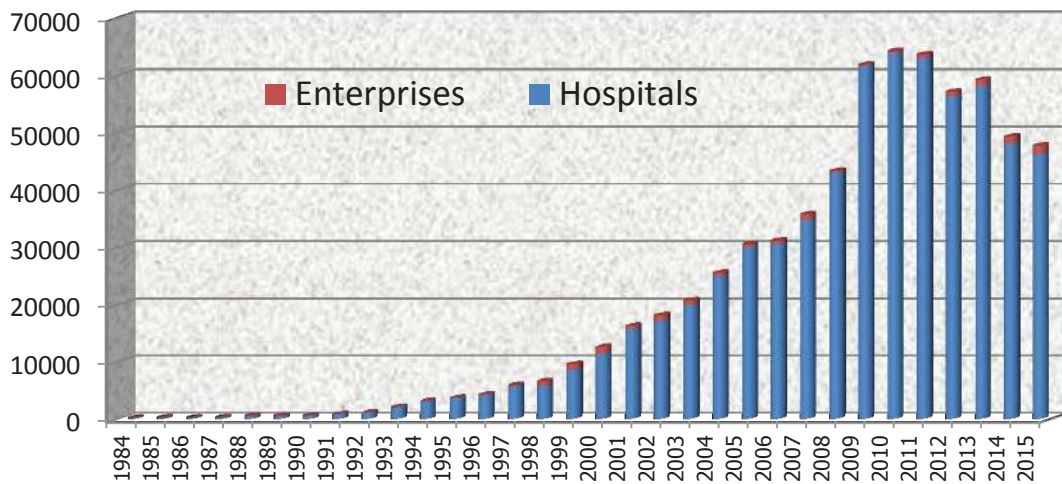


Figure 2 The number of Thai ADR reports from 1984 to 2015

In this year, we have emphasized getting the adverse drug and narcotics reaction reports to the Thai Vigibase that was 99 percent of all reports. In this among group, there were serious ADR reports about 19.88 percent (8,748 cases). We can categorize the top three drugs and narcotics that we received the amount of report: general anti-infective system, musculo-skeletal system, and central nervous system respectively. The ADR reports can classify to the top three organ ranges were a skin and appendages disorders, general disorders, metabolic and nutritional disorders as well. Meanwhile the adverse health reactions report from medical devices, food, and cosmetics had a little case. The statistic is provided in table 4.

Table 4 The number of Thai adverse medicine and health product reaction reports as categorized in 2015

Categories	No. of Cases
Drug and narcotics	43,994
Top three reports	
- general anti-infective system	22,553
- musculo-skeletal system	8,329
- central nervous system	5,586
Top three of System organ reports	
- skin and appendages disorders	31,076
- general disorders	7,948
- metabolic and nutritional disorders	3,849
Medical devices	8
- serious cases	-
Food	12
- serious cases	7
Cosmetics	6
- serious cases	3
Total	44,020

Moreover, in this year, we had withdrawn one medical license through the Drug Committee since it was serious effects on health risk in term of efficiency and healthy safety. The medical licenses which they composed the Camphor or Sodium Camphosulphonate in injection type at 7 product licenses were withdrawn due to unsafe to users. We found that patients may cause a central nervous system symptom to get a coma symptom and may die.

Furthermore, there were some medicine licenses that shown serious healthy risks from consumptions. The Thai FDA had mandated to drug entrepreneurs change conditions labels by educating conditions and word warning on Hydroxyethyl Starch (HES) label, Ketoconazole label in taking medicine type, Hydroxyzine label, Protelos/ Osseor (Strontium Ranelate) label, Hormone label that combined formulate of Cyproterone Acetate and Ethinyl Estradiol, and Domperidone label.

Performance on Creative Knowledge to People

We encouraged and communicated people to get healthy information so that they can improve their capacities in term of choosing and consuming health product appropriately. Our purpose need people adept their behavior to meet better life and to build capacity of people which they can protect health by themselves. We created information and broadcasted through several feature channels.



Giving Education through Television Broadcast

We created short films at 10 stories to broadcast via television on channel 7 stations. These were on air on “Nam Prik Tuay Mai Program” every Friday in 9.30 – 10.15 AM in December 26, 2015 to February 27, 2016. Thai people who watched these programs would get knowledge about hazard of slimming coffee consumption, vegetable oil that reuses, cosmetics that non quality, Big-eye contact lens, and over use steroid medicine. In addition, the people got knowledge about how to read labels smartly, how to wash vegetable as safety to consume, health risk of lack of Iodine substance as well.

Giving Education through Radio Broadcast

Not only broadcasted these short stories via TV program but also we shown them on radio over 53 radio stations in country. It was educated and rerun at three times from January to March in 2016 in Bangkok and provinces around Bangkok, also in urban zone two times.

Giving Education through Printing Media

Information via some newspaper and magazine were printed to public. We lunched health products information on column of them at 26 topics such as cosmetic review, steroid as devil, antibiotic is not pain relief medicine, refried oil is black and bad smell, and rebel reading intelligently.

Giving Education through Social Media

Young people are our target. Thus, we provided a lot of information about good health product consumption in form of multimedia and entertainment such as animation and cartoon on www.oryor.com. Besides, we created “Oryor Smart Application” on mobile phone which supported both iOS and Android. The application can search location of drug stores, check the license of health products, check BMI, complain or announce about illegal health products or that people got problems to the Thai FDA, and etc. There were a number of download over 220,000 download view that it hit the top chart of health application download of Thailand.



Campaign through Schemes

The other was creation by campaigning. We made posters over 105 stories and exhibited in public places at 36 times. What is more, we lunched four schemes:

Young FDA Schemes: the program that each elementary school and junior high school in country has young FDA members and set a group to tell health product information to their friends. For example, they encouraged friends to avoid consume salty food and sweet, avoid buying and using products from propaganda, read product rebels before buying or using. They are volunteers as detect health products in school and community shops by using test-kit as well. In 2016, 478 primary schools got an excellent school certificate by the Thai FDA. We found that these pupils had better health product consumption behaviour which was 78.5 percent.



Food Safety Schemes: we collaborated with Faculty of Education of Kasetsart University and Institute of Physical Education Bangkok Campus to set up pilot junior high school model. A purpose wanted students to improve their food consume behaviour suitably. We choose a school model from school as Young FDA’s school to experiment: Pu Keaw School in Chaiyapoom, Krong “Withaya Sathaporn” School in Rayong, Aummart Panitnu-

koon School in Krabi, and Sanpatong School in Chiangmai. Nine education plans were tried out with 2,400 students which were stressed on participation of students, practice in classes, and edutainment camp. They got many good experiences while they learnt such as imagine a future picture if they had unsuitable food, VTR about the bad effect from having food in front of school, and Smart shopping that they understood on food labels and analyzed health risk trend. After program finished, it is clear that the students can improve suitable consume food from 68.5 to 75.5 percent (middle move to more level). They knew an opportunity risk of having unsafe food from 71.6 to 93.2 percent and they trust in own ability to have consume food safety from 78.2 to 86.4 percent. This scheme was interested by TV media groups and 11 newspapers that it was made a story to broadcast to public such as Family News Today on channel 3, Good Morning Thailand on Mono 29 channel, Young News on TNN 24 channel, Meet Ra Ma Doctor on Ra Ma channel.

Don't Trust Advertisements Easily Schemes: to protect Thai people to become propaganda victim, the campaign was revealed to public. It was stressed on people to analyze information and can prevent by themselves. We created motion info-graphic and on air via TV channel 3, 7, and 8. We created radio spot and lunched on FM 95 MHz in Bangkok and FM 105 MHz in countryside. We made information on Matichon Newspaper and Khaosod Newspaper in "would you risk on defacement, if you use dietary supplement from given to showing off" topic. Also, web blog, magazine, instagram, and our partnerships helped us to educate to public.

Decision Before Taking Medicine: this pilot project to create people understanding about using steroid correctly, the campaign was worked in north and northeast areas due to having compound steroid in health products. We have

public health volunteers in Chingmai and Khonkean province over 600 people, also medicine store association and other partners over 100 people to participate in root areas. Moreover, we still made scoop news brief and TV spot to broadcast to public via Free TV and cable TV; we had brochures over 400,000 pieces, posters more 23,000 pieces, and roll up at 78 topics that distributed in country. We hope that the project will help Thai people to get good information and improve steroid medicine consumption correctly so that it will reduce resist drug action in among people and reduce retreat cost in health sectors.

In the year, our results met the purposes. Thai people got knowledge and had health product consuming behavior correctly at 90 and 80.2 percent respectively.



Conclusion

In summary, the major effectiveness of our output performances achieved on approved amount licenses, met quality standard and safety of the health products and enterprises, withdrawn medical licenses that composed the Camphor or Sodium Camphosulphonate in injection type, and created new knowledge to people until most of which had good behaviors in term of health product consumption.



A statement of financial of the Thai FDA in 2015 had several features. Firstly, an asset of us increased 0.09 percent from last year (from 7.703 to 7.710 million US Dollar or from 275.410 to 275.665 million Baht) because of increasing of intangible asset in computer programs. Secondly, our debt decreased approximately double time because we pressed expenditure progressively. Thirdly, our capital in 2015 was as the same as 2014. Then, in this year the income increased by 11.97 percent that some of which came from revenue of the Thai Government about 12.58 percent; it came from other revenue around 43.71 percent. Finally, we had a little increasing expenditure due to depreciation cost and amortization. The number is provided in table 5 as below.



Table 5 Thai FDA financial statement in 2014-2015

Statement	2015	2014
Performance		
Revenue	944,399,152.84	843,471,830.99
Expenditure	892,092,782.65	846,049,730.96
Financial position		
Asset	275,665,469.37	275,410,986.21
Debt	42,758,436.79	93,749,447.94
Capital	164,902,698.68	164,902,700.11
Asset		
Cash and cash equivalent	58,990,954.88	58,336,377.03
Short term debtor	7,978,156.62	11,519,344.98
Debtor transfer and the list of subsidized short term	-	5,999.92
Remain Asset	5,145,044.19	4,062,967.48
Property plant and equipment	148,404,170.92	184,404,532.81
Intangible asset	55,111,153.60	16,009,906.77
Debt		
Current liability	33,721,386.63	85,767,891.50
Non-current liability	9,037,046.95	7,981,556.44
Net asset and/equity	233,872,311.17	181,661,538.27
Revenue		
Annual budget	930,443,729.57	826,478,674.45
Sale of goods and services	7,799.94	58,080.17
Subsidy and donation	10,007,719.15	14,193,511.48
Other revenue	3,939,903.83	2,741,564.90
Expenditure		
Personnel expense	334,701,690.54	317,580,772.44
Pension expense	83,493,145.45	75,695,329
Compensation expense	2,284,289.87	1,713,258.69
Operational expense	373,664,558.05	369,857,318.55
Material expense	16,432,842.86	16,664,012.72
Utility expense	21,769,470.22	20,214,875.40
Depreciation and amortization expense	59,063,702.20	45,780,165.86
Other expense	683,082.40	331,502.24



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