

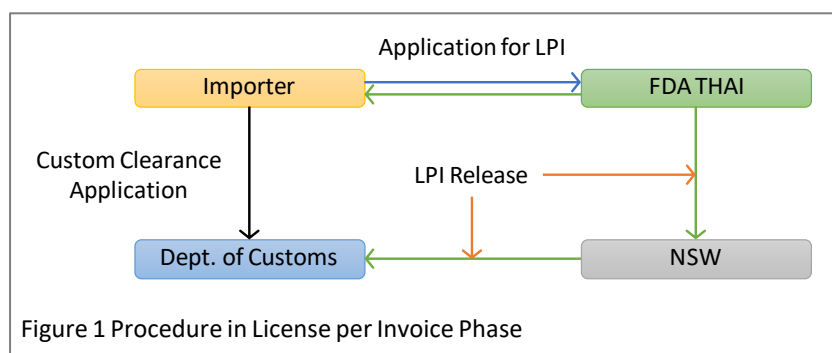
# FDA Thai's trade facilitation through a supportive action on the establishment of Thailand's National Single Window

## Introduction

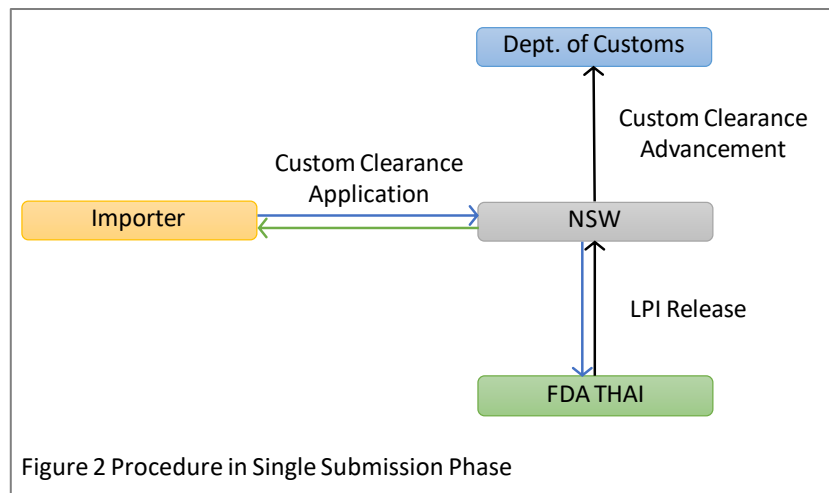
The cross-border trade facilitating measure of Food and Drug Administration of Thailand (FDA THAI) for Thailand's National Single Window (NSW) has a long history of its action. It began in 2005 when the FDA THAI, alongside with other 34 government agencies, were designated as a participants in the establishment of Thailand's NSW. However, it took 10 years before the relevant parties could witness its achievement when a robot had been deployed, on the 6<sup>th</sup> day of July 2015, to carry out the job that was previously in human's hand. One year later, the long journey came to an end when it officially proceeded into the NSW's single submission process on the 1<sup>st</sup> day of October 2016. Except for the Department of Customs—the designated authority for Thailand's NSW—the FDA THAI is hitherto the only government agency proceeding into the single submission process of Thailand's NSW.

## Development of NSW

Since the beginning, the implementation of NSW is defined into 2 phases namely **License per Invoice** and **Single Submission**. There were 3 steps in the License Per Invoice phase. Firstly, the importers had to submit the information of the products to be imported into Thailand directly to the respective agencies for verification. The agencies would conclude the allowance of the importation. A license for each shipment might be released accordingly and delivered to the Department of Customs via National Single Window. The importers would proceed into the Custom Clearance via the e-CUSTOM service provided by the Department of Customs. As deemed necessary, the inspectors of the respective agencies would examine the imported products before concluding the clearance and would notify the Department of Customs of their decision.



In the Single Submission phase, the importers shall submit the information of the products to be imported to the respective agencies and receive the conclusion via NSW instead of the direct submission. Then, the importers shall proceed into the Customs Clearance via NSW as well. The inspectors of the respective agencies might, if need be, examine the products before concluding the clearance and would notify the Department of Customs of their decision. In both phases, the respective agencies would notified the Department of Customs on their needs to inspect the imported products by labelling the shipment as green or red according to the result of risk assessment.



The FDA THAI's measure for Thailand's NSW began in 2005. The measure comprised 5 steps as followed:

1. **Vision formulation;**
2. **Gap analysis;**
3. **System design;**
4. **System development and deployment;**
5. **Performance evaluation and corrective action.**

1. **Vision formulation.** The co-operative procedure between the relevant parties were proposed and approved. Though the development plan had been defined as such, the FDA THAI formulated its own vision on how the IT system under its jurisdiction could align with the business process as well as optimised its resources. It was visioned since its inception that electronic service system would be the core process of the expected system.

2. **Gap analysis.** The gap between the expected architecture and the FDA THAI's current status was identified and analysed. Data architecture was identified as the crucial aspect of the expected system. It was found that, apart from the system application which was the requirement, data of the approved health products was inappropriate for deployment. The Data of 4 million items of health products was prioritised for revising and cleansing. The revision and cleanse of data of such magnitude could not be handled by the FDA THAI alone. Hence, the owners of the approved health products were mobilised to participate in the cleansing process. It took five years before the first kind of health products, namely cosmetics, could proceed into the **License Per Invoice** phase of NSW. The rest of the health products followed suite in the next 3 years.

3. **System design.** The most important step in solving a problem is the design stage. If the to-be-deployed system including processes and IT system are well designed, the problems elaborated in the preceding service should be eradicated. Hence, the holistic approach was exploited. The design process did not focus on the hurdles experienced or how all actors in the preceding process should do, but on how the process should be deployed in the shortest time and fewest steps as possible. Consequently, some actors were deemed replaceable by machine—a robot—especially the government officials. There were 3 processes for 2 phases namely **License Per Invoice process**, **Automated License Per Invoice** aka Auto-LPI and **Single Submission with Auto-LPI**. In License Per Invoice phase, electronic submission (e-Submission) for License Per Invoice were submitted via FDA THAI's LPI digital notification prior to

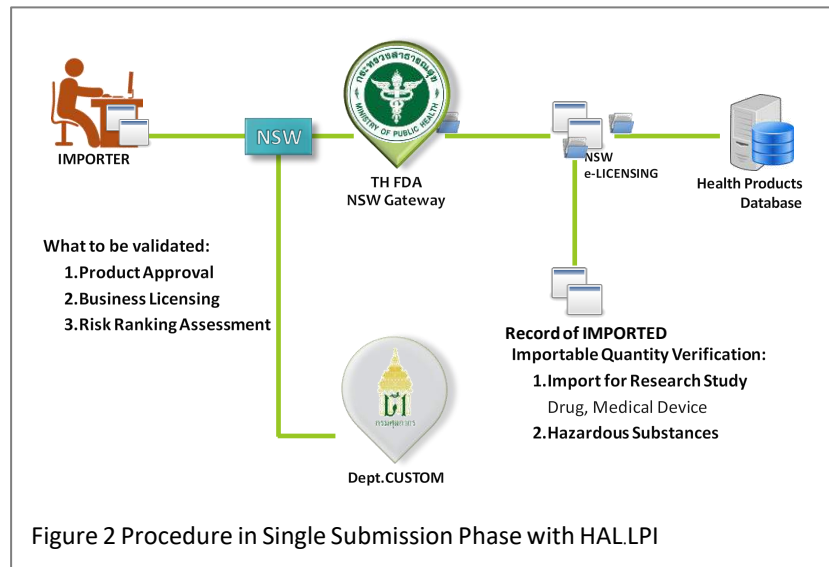
proceeding into the custom clearance. In this stage, all submissions for LPI for the imported health products were verified and approved by the FDA THAI's officials. This service was later superseded by Auto-LPI where the FDA THAI's officials were replaced by a robot. Thereafter, the FDA THAI proceeded into the second phase, Single Submission, the importers will submit their application for the import of health products via NSW instead of submitting directly to the FDA THAI. The importers will proceed into custom protocol via NSW whence the Licenses per Invoices were released. Auto-LPI was terminated, but the robot continued its function as a back-end system.

**4. System development and deployment.** The development of the FDA THAI's system was divided into 2 phases. In the first phase, a new back-end system for health products approval was developed as a replacement for the old system. All data and information of the approved health products were verified and migrated to the new system for NSW deployment. Incomplete data or information was identified. Gap was filled-in with an assistance from the health products registration holders. It took 5 years before the FDA THAI could proceed into the NSW's License Per Invoice phase. At the same time, the health products approval for sale in Thailand, which is the pre-requisite for NSW, was altered one-by-one from manual submission to e-Submission. This was an assurance that all data or information of the products would be adequate and available in a just-in-time manner for NSW with no need for verification after the release of the product approval. The second development came 8 years after the first phase was initiated. In the second phase, the IT system architecture was re-designed aiming at upgrading to conform to the enterprise architecture maturity. Mesh apps and services architecture model was applied to the new system resulting in the enhanced data exchange capabilities of the system internally and externally, and also the capabilities to develop and deploy Auto-LPI, a robot system for NSW.

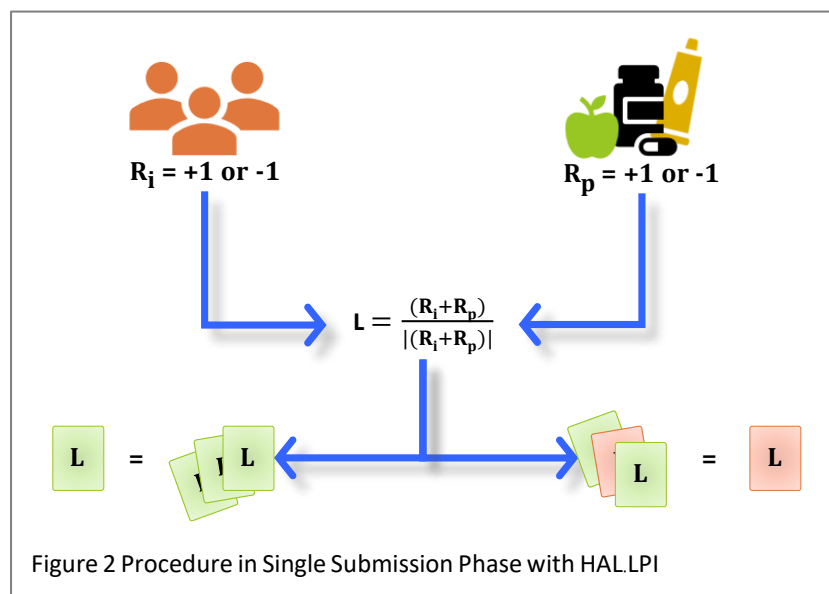
**5. Performance evaluation and corrective action.** In the early months of 2015, the notifications on the import of health products had risen to more than 158 submissions per day. Whereas the limit number of the workforce for the notification process required 9 days for the completion of each submission. It led to the importers' deprecation. Twice the complaints were brought to attention of the secretary general. They came to an arrangement that it was time for a robot be put into human's shoes. Three months later, the development of robot came to its completion. It was officially deployed on the 6<sup>th</sup> day of July 2015 decreasing the waiting time for completion of the LPI process from 9 days to 3 seconds. Thereafter, it has been working as the back-end operation for Thailand's NSW for the imported health products.

#### **Robot development and deployment**

On 6 July 2015, The HAL.LPI stepped in as a result of the huge magnitude of submission for the import of health products under the jurisdiction of the FDA THAI. The number of notifications submitted to the FDA THAI had arisen to 158 submissions with 1,089 items per day whereas only 10 people were on duty which made the waiting time 9 days for each submission. Two panels were convened to settle the problems in February and March 2015. In the second panel, FDA THAI suggested that a robot be installed as a replacement of human workforce. Three months later, a robot, named **Health products Automated Licensing system for License Per Invoice (HAL.LPI)** was installed and deployed on 6 July 2015. By the time the FDA THAI proceeded into the Single Submission phase on 1 October 2016, HAL.LPI had served and concluded 257,358 submissions with 1,415,739 items of health products valued nearly 15 billions dollars for 24 hours a day/7 days a week without a break. It reduced the waiting time for LPI from 9 days to 3 seconds. Later on 1 October 2016, the FDA THAI proceeded into the Single Submission phase. HAL.LPI was not removed from operation but became the back-end supporter.



The main function of HAL.LPI is to verify the information of the imported products and validate the product approvals as well as quota for importation of some kind of approved products. It also has an ability to calculate the risk assessment of each shipment in order to determine the necessity for product inspection. The importers will be required to declare the registration number of each health product item listed in the invoice along with the amount of the product. HAL.LPI will use the registration number of each product to validate the status of the product approval as well as the other relevant documents stored in the FDA THAI system. For some type of products such as drugs or medical devices imported for certain research programmes or hazardous substance products, quota for importable amount will also be verified before releasing a License Per Invoice for that shipment. But the operation of HAL.LPI is yet to complete. The requirement for product inspection will be calculated by using the predefined risk ranks of each product item and importer. A risk assessment taskforce has been established to assess the risk rank of each approved health product and each individual importer. The conceivable harm of each product item as well as the performance of each individual importer are assessed to conclude their risk ranks. The products containing less conceivable harm will be assigned to the low risk rank with parameter valued +1 whereas the opposite will be assigned to the high risk rank with parameter valued -1. The importers having the good performance will be assigned to the high profile rank with parameter valued +1 whereas the opposite will be assigned to the low profile rank with parameter valued -1.



It should be noted that the risk ranking system was formulated in a simplified dictation as a result of time constraint for the establishment. The calculation for the inspection requirement will concede a green or red label for each product. A red labelled product will conclude the overall inspection requirement for each shipment. In short, a License Per Invoice containing at least one red labelled product will be assigned into the red line for inspection. As such, a shipment will be assigned into the green line for release with no inspection requirement must contain no red labelled product.

### Summary

The successfulness of FDA THAI in facilitating cross-border trade of health products was not a mere act of luck. An understanding in business process and information technology is the key factor which enabled the satisfactory alignment between both aspects. The introduction of robot to replace human workforce did not come out of thin air during the situation but had long been foreseen and designed since the beginning. With closely monitoring of the implementation of the work in progress, the robot was brought in in the proper time when the database of the health products was in good shape and reliable. Hence the deployment of the robot could help earning the relevant parties' confidence in the FDA THAI's effort. In such manner, cross-border trade of health products has been facilitated ever since. The expected function of the robot was not founded on IT system design alone, but also on the germane incorporation of risk ranking of both the importers' performance and the health products' conceivable harm to human health. Both ranks are integrated in a calculable manner.

The return of investment (ROI) should not be evaluated by the benefits the FDA THAI earned, benefit but the economic return of the country. The overall cost for development of the FDA THAI's new IT system is less than 0.005% of the average value of the imported health products at 12 billions dollars a year. You need no mathematics expertise to evaluate the cost-benefits of the system deployment in terms of economic value.

Furthermore, the FDA THAI has formulated and endorsed its IT vision since 2014 with a minor rephrasing in 2016. It read **"Through transforming into a digital organisation, FDA THAI is one of the major force to materialise Thailand 4.0"**. In this vision, seven strategies are defined and deployed to realise the vision. They are listed as followed:

1. Economic facilitation;
2. People empowerment and participation;
3. Organisational innovation;
4. IT Infrastructure refurbishment;
5. Data and information exchange system development;
6. IT governance re-establishment;
7. Human workforce's digital skills development.

The IT vision and three out of these seven strategies give rise to the unique performance of the FDA THAI in supporting the establishment of Thailand's National Single Window which in turn become a genuine measure for cross-border trade facilitation for health products.