

Notification of the Central Committee on the Price of Goods and Services

No. 53, B.E. 2565 (2022)

Regarding Declaration of Information and Production of Account for Controlling
Test Kit Products and Reagents Relating to Diagnosis of SARS-Cov-2 Infection (COVID-19
Pathogen), COVID-19 Antigen Test Self-Test Kits¹

Whereas the Notification of the Central Committee on the Price of Goods and Services No. 8, B.E. 2564 (2021) regarding Determination of Goods and Services under Control dated 28th June B.E. 2564 (2021) comes to an end, resulting in the end of enforcement of the Notification of the Central Committee on the Price of Goods and Services No. 63, B.E. 2564 (2021) regarding Declaration of Information and Production of Account for Controlling Test Kit Products and Reagents Relating to Diagnosis of SARS-Cov-2 Infection (COVID-19 Pathogen), COVID-19 Antigen Test Self-Test Kits dated 18th August B.E. 2564 (2021). In the meantime, the Central Committee on the Price of Goods and Services has already reconsidered the exercise of its power regarding the stipulation of the aforesaid measure, it is of the view that the measure should be adjusted to be consistent with the announcement of the Ministry of Public Health concerning test kits and reagents relating to the diagnosis of SARS-Cov-2 infection (a COVID-19 pathogen), COVID-19 antigen test self-test kits which stipulates the cancellation of the distribution channel of such products, by supervising at source which requires a producer and an importer for distribution to declare the name, the code of product, the lot of production, the size of packing, the capacity of production, the source of origin, the quantity, the capital cost, the expense, the price of distribution and the production of an account for controlling the products. This measure is aimed to monitor the movement of price, quantity and to stop obtaining an advantage of opportunity over consumers.

By virtue of Section 9 (2), (3), Section 25 (3), (4), (5), and paragraph one of Section 26 of the Price of Goods and Services Act, B.E. 2542 (1999), the Central Committee on the Price of Goods and Services therefore issues this Notification, as follows.

¹ Published in the Government Gazette, Volume 139, Special Part 215 d, Page 278, dated 13th September B.E. 2565 (2022).

Article 1. This Notification shall come into force in all areas of the Kingdom for the period of one year as from the day following the date of its publication, except for there being the issuance of a new notification.

Article 2. In this Notification,

“test kits and reagents relating to the diagnosis of SARS-Cov-2 infection (a COVID-19 pathogen), COVID-19 antigen test self-test kits” mean reagents, reagent products and test kit components, including relevant calibrators or controlling materials. These objects can be used alone or together in order to check, verify or take quantitative detection of things from a human body to be tested for the diagnosis of SARS-Cov-2 infection (a COVID-19 pathogen). These objects shall not be applied directly to the human body but be applied to things from a human body to be tested. And these objects have been developed into perfect condition to be applied for the diagnosis, whereby they shall be applied initially to discover a state of infection. The objective of these objects is to be applied by general people (Home Use).

Chapter 1

Declaration of Information

Article 3. The domestic producer of test kits and reagents relating to the diagnosis of SARS-Cov-2 infection (a COVID-19 pathogen), COVID-19 antigen test self-test kits is required to declare the following information.

(1) To declare the trade name of product by specifying the code of product, the lot of production, the size of packing, the capacity of production, the quantity of production, being existent on the date of this Notification coming into force, whereby such information shall be declared within seven days as from the date of this Notification coming into force.

(2) To declare the capital costs of production, the prices of distribution at the factory, as of the 1st day to the 15th day of July B.E. 2565 (2022) within the 15th day of July B.E. 2565 (2022), and the next times of the declaration of information shall be made on the 15th day and at the end of every month.

The producer of test kits and reagents relating to the diagnosis of SARS-Cov-2 infection (a COVID-19 pathogen), COVID-19 antigen test self-test kits, who carries on business after the date of this Notification coming into force, is required to declare the information under paragraph one in advance for the period of not less than five days before the products go on sale. In addition, the producer shall undertake to declare the information under (2) for the next times pursuant to the date and time as specified.

In the case where the producer has already declared the information under Article 3 (1) of the Notification of the Central Committee on the Price of Goods and Services No. 63, B.E. 2564 (2021) regarding Declaration of Information and Production of Account for Controlling Test Kit Products and Reagents Relating to Diagnosis of SARS-Cov-2 Infection (COVID-19 Pathogen), COVID-19 Antigen Test Self-Test Kits dated 18th August B.E. 2564 (2021), it shall be deemed that the declaration of information under (1) of this Notification has already been made.

Article 4. The importer into the Kingdom for the distribution of test kits and reagents relating to the diagnosis of SARS-Cov-2 infection (a COVID-19 pathogen), COVID-19 antigen test self-test kits is required to declare the following information.

(1) To declare the trade name of product, the source of origin, by specifying the code of product, the lot of production, the size of packing, the quantity of importation, being existent on the date of this Notification coming into force, whereby such information shall be declared within seven days as from the date of this Notification coming into force.

(2) To declare the capital costs of importation, the expenses of importation, all the expenses before distribution, the prices of distribution, as of the 1st day to the 15th day of July B.E. 2565 (2022) within the 15th day of July B.E. 2565 (2022), and the next times of the declaration of information shall be made on the 15th day and at the end of every month.

In making the declaration of the information regarding importation under (1) and (2), the importer shall declare the information whereby the attachment of a copy of an invoice as issued by a producer or a distributor in an exporting country, a copy of an import declaration, and documents and evidence in relation to importation or distribution or documents and evidence as prescribed by the Secretary-General shall also be sent every time.

The importer into the Kingdom for the distribution of test kits and reagents relating to the diagnosis of SARS-Cov-2 infection (a COVID-19 pathogen), COVID-19 antigen test self-test kits, who carries on business after the date of this Notification coming into force, is required to declare the information under paragraph one in advance for the period of not less than five days before the products go on sale. In addition, the importer shall undertake to declare the information under (2) for the next times pursuant to the date and time as specified.

In the case where the importer into the Kingdom for the distribution has already declared the information under Article 4 (1) of the Notification of the Central Committee on the Price of Goods and Services No. 63, B.E. 2564 (2021) regarding Declaration of Information and Production of Account for Controlling Test Kit Products and Reagents Relating to Diagnosis of SARS-Cov-2 Infection (COVID-19 Pathogen), COVID-19 Antigen Test Self-Test Kits dated 18th August B.E. 2564 (2021), it shall be deemed that the declaration of information under (1) of this Notification has already been made.

Article 5. In the case where capital costs have risen, resulting in the prices of distribution of test kits and reagents relating to the diagnosis of SARS-Cov-2 infection (a COVID-19 pathogen), COVID-19 antigen test self-test kits being higher than those as declared under Article 3 or Article 4, it is required to give a reason in writing together with relevant documents and evidence to the Secretary-General at the Office of the Central Committee on the Price of Goods and Services, the Department of Internal Trade, the Ministry of Commerce.

Article 6. In making the declaration of the capital costs, the expenses and the distribution prices of test kits and reagents relating to the diagnosis of SARS-Cov-2 infection (a COVID-19 pathogen), COVID-19 antigen test self-test kits under Article 3, Article 4 and Article 5 shall be made, it is required to declare the information per one set of test kits.

Article 7. In the case of the due date of declaration under Article 3 or Article 4 falls on a public holiday, it is required to declare within the last official time and date prior to the aforesaid public holiday.

Chapter 2

Methods of Declaration

Article 8. The declaration under Article 3 or Article 4 shall be made to the Secretary-General pursuant to the forms as prescribed by the Secretary-General at the Office of the Central Committee on the Price of Goods and Services, the Department of Internal Trade, the Ministry of Commerce.

The declaration under paragraph one shall be made by electronic data, electronic mail (e-mail) or facsimile. In the case of the declaration by electronic data, the date when the electronic data enters the data system of the Office of the Central Committee on the Price of Goods and Services, the Department of Internal Trade, the Ministry of Commerce shall be deemed as the date of declaration. In the case of the declaration by electronic mail (e-mail), the date when the electronic mail (e-mail) is received shall be deemed as the date of the intention of declaration. In the case of the declaration by facsimile, the date when the facsimile is received shall be deemed as the date of the intention of declaration.

The declaration by electronic mail (e-mail) or facsimile under paragraph two shall be valid when the producer or the importer into the Kingdom for distribution has already submitted the original document to the Secretary-General.

The producer or the importer into the Kingdom for distribution who has an intention to declare via the electronic data shall sign the memorandum of agreement on declaring via the electronic data pursuant to rules and procedures as prescribed by the Secretary-General.

Article 9. When the producer or the importer into the Kingdom for distribution has requested the Secretary-General to extend the specified period of time in this Notification; or when the Secretary-General has deemed as appropriate; the Secretary-General may give an order to make an extension of the specified period of time prior to the expiry of such a period. Nevertheless, such an extension shall be made only when there is a special circumstance or an unavoidable event; and the producer or the importer into the Kingdom for distribution has requested; or the Secretary-General has given an order prior to the expiry of such period, except for the case of force majeure.

Chapter 3

Production of Account for Controlling Products

Article 10. The producer and the importer into the Kingdom for distribution of test kits and reagents relating to the diagnosis of SARS-Cov-2 infection (a COVID-19 pathogen), COVID-19 antigen test self-test kits are required to produce the account for controlling the products. In the account, there must be the trade name of product, the source of origin, the code number of product, the lot of production, the size of packing, the prices of distribution, the quantity of production, the quantity of importation, the quantity of distribution, the remaining quantity on a daily basis. It is required to completely record such data into such an account within three days after the date of each production, acquirement, purchase or distribution. In addition, it is required to keep the account with the evidence of acquirement and distribution at a storage place or a place of business operation in order that a competent official is able to examine the account and evidence at all times.

Given on the 1st Day of July B.E. 2565 (2022)

Jurin Laksanawisit

Minister of Commerce

Chairperson of the Central Committee on the Price of Goods and Services