

**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<sup>1</sup>

-----

Whereas the Central Committee on the Price of Goods and Services already issued 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 28<sup>th</sup> June B.E. 2564 (2021), prescribing that medical supplies for treatment shall be goods under control.

Whereas the situation of the outbreak of communicable disease coronavirus 2019 (COVID-19) at the present time is still continuously serious; meanwhile, the Ministry of Public Health has made the announcement that test kits and reagents relating to the diagnosis of SARS-Cov-2 infection (a COVID-19 pathogen), COVID-19 antigen test self-test kits can be sold to people in order that the people can check and screen by themselves for the diagnosis whether they are infected with coronavirus 2019 (COVID-19) (Home Use), resulting in a continuously rising demand from clinics and people for using the aforesaid test kits. The Central Committee on the Price of Goods and Services therefore passed the resolution on 13<sup>th</sup> August B.E. 2564 (2021), prescribing the measure that the producer, the importer for distribution, and the wholesaler 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 declare the trade name of product, the code of product, the lot of production, the size of packing, the capacity of production, the source of origin, the quantity of production, the quantity of importation, the quantity of distribution, the capital cost, the expense, the price of distribution, the name and address of purchaser. And they are required to produce an account for controlling the products. This measure is aimed to monitor the movement of price and quantity and to stop obtaining an advantage of opportunity over consumers.

---

<sup>1</sup> Published in the Government Gazette, Volume 138, Special Part 242 d, Page 314, dated 3<sup>rd</sup> October B.E. 2564 (2021).

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.

**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, the name and address of purchaser, 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, 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, and the next times of declaration shall be made on the 15<sup>th</sup> day and at the end of every month.

(3) To declare the name and address of purchaser, whereby such information shall be declared 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) and (3) for the next times pursuant to the date and time as specified.

**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, the name and address of purchaser, 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, 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, and the next times of declaration shall be made on the 15<sup>th</sup> day and at the end of every month.

(3) To declare the name and address of purchaser, whereby such information shall be declared 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) and (3) for the next times pursuant to the date and time as specified.

**Article 5.** The wholesaler 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 distribution, the name and address of purchaser, 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 capital costs, all the expenses before distribution, the prices of distribution, 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, and the next times of declaration shall be made on the 15<sup>th</sup> day and at the end of every month.

(3) To declare the name and address of purchaser, whereby such information shall be declared at the end of every month.

The wholesaler 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 wholesaler shall undertake to declare the information under (2) and (3) for the next times pursuant to the date and time as specified.

The wholesaler as stated in paragraph one and paragraph two shall mean the person who purchases test kits and reagents relating to the diagnosis of SARS-Cov-2 infection (a COVID-19 pathogen), COVID-19 antigen test self-test kits from the producer or importer into the Kingdom for the distribution, and then sells them to places or through channels as specified by the announcement of the Ministry of Public Health about test kits and reagents relating to the diagnosis of SARS-Cov-2 infection (a COVID-19 pathogen), COVID-19 antigen test self-test kits.

**Article 6.** 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, Article 4 or Article 5, 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 7.** 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 or Article 5 shall be made, it is required to declare the information per one set of test kits.

**Article 8.** In the case of the due date of declaration under Article 3, Article 4 or Article 5 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 9.** The declaration under Article 3, Article 4 or Article 5 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, the importer into the Kingdom for distribution or the wholesaler has already submitted the original document to the Secretary-General.

The producer, the importer into the Kingdom for distribution or the wholesaler 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 10.** When the producer, the importer into the Kingdom for distribution or the wholesaler 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, the importer into the Kingdom for distribution or the wholesaler 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 11.** The producer, the importer into the Kingdom for distribution, and the wholesaler 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, the name and address of purchaser 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 18<sup>th</sup> Day of August B.E. 2564 (2021)

Jurin Laksanawisit

Minister of Commerce

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