

Important Notice for Product Numbers (Product IDs)

This announcement is with reference to medical devices product numbers (barcodes) registered or to be registered to the National Databank of Pharmaceuticals and Medical Device of Turkey and upcoming practices of these product numbers (barcodes) to be placed in the form of barcodes on the product packages.

As known, products registered in the National Databank of Pharmaceuticals and Medical Device of Turkey require a unique product number such as EAN-13 or HIBC type. However, due to lack of certain product numbers, the system gives a temporary product number starting with 245 and then enables registration.

A unique product number is used in the National Databank for two reasons: the first reason is to enable the operation of electronic business processes; the second reason is to ensure patient safety. In order to ensure that these two are achieved, unique product numbers need to be used in all of the electronic systems and they need to be placed on the product label in the form of a barcode.

Since the priority objective was to create a media where data pertaining to products would be accurate and accessible to everyone, temporary product numbers were given so far to enable the registration. However, it is observed during the tenders that hospitals require barcodes on the products and some companies affix the aforementioned temporary numbers on labels. To affix the temporary numbers (numbers starting with 245) on packages in the form of a barcode is an incorrect practice.

Within the framework of the following programme, unique product numbers such as EAN-13 or HIBC type shall be provided, these numbers shall be placed on labels and products that do not meet requirements in the set time shall not be reimbursed by the Social Security Institution.

First Phase

In this phase, the number is provided from the Center of Global Standards (GS1) or HIBCC and registered in the National Database, then recognized in the electronic media.

Requirements for Products (Manufactured Goods) with a Temporary Product Number

Original product number for manufactured goods (in the form of a EAN-13 or HIBC) should be provided and the necessary rectifications in the National Databank should be done until January 1st, 2009. Moreover, there is no deadline to acquire a number and rectifications but as of January 1st, 2009, there will be no reimbursement for the goods without an original product number (in the form of a EAN-13 or HIBC) until an original product number is acquired (in the form of a EAN-13 or HIBC).

Original product number for manufactured goods (in the form of a EAN-13) can be acquired from the Center of Global Standards (GS1) established under the umbrella of the Union of Chambers and Commodity Exchanges of Turkey (TOBB) in one or two days at a certain fee. Further information about product number acquisition can be obtained from the website of the Center of Global Standards. Click for more information. <http://gs1.tobb.org.tr/>

Requirements for Imported Goods with a Temporary Product Number and for OEM Companies

Products that are registered with a number starting with “245” in the National Databank and that have a brand registration from the Turkish Patent Institute should obtain an original product number (in the form of a EAN-13) and do the necessary rectifications in the National Databank until January 1st, 2009. There is no deadline to acquire a number and rectifications but as of January 1st, 2009, there will be no reimbursement for the goods without an original product number (in the form of a EAN-13) until an original product number is acquired (in the form of a EAN-13).

Requirements for Imported Goods with a Temporary Product Number

Imported goods that are manufactured in another country through a sub-contractor should obtain an original product number (in the form of a EAN-13 or HIBC) and do the necessary rectifications in the National Databank until January 1st, 2009. There is no deadline to acquire a number and rectifications but as of January 1st, 2009, there will be no reimbursement for the goods without an original product number (in the form of a EAN-13 or HIBC) until an original product number is acquired (in the form of a EAN-13 or HIBC).

Original product number (in the form of a EAN-13 or HIBC) should, first of all, be required from the product owner/manufacturing company. Information pertaining to the structure and objectives of the National Databank and product numbers can be obtained in English from the “Foreign Manufacturers” link, right next to “Contact” placed on the bottom right of the website (<http://www.huap.org/ubb/>). Information available here can be used during contacts with the manufacturing company as well as the requirements with regards to the second phase.

Second Phase

It is not sufficient to have the original product number (in the form of a EAN-13 or HIBC) placed in an electronic information system. The original product number should also be affixed on the product packages in the form of a barcode.

Requirements for Products (Manufactured Goods) with a Temporary Product Number

Companies that obtain an original product number (in the form of a EAN-13 or HIBC) shall make sure that these numbers are affixed on product packages. As of January 1st, 2009, there will be no reimbursement for manufactured goods that do not bear the original product number (in the form of a EAN-13 or HIBC) in the form of a barcode on the product package.

Requirements for Imported Goods with a Temporary Product Number

Companies that obtain an original product number (in the form of a EAN-13 or HIBC) shall make sure that these numbers are affixed on product packages until January 1st, 2009. As of January 1st, 2009, there will be no reimbursement for imported goods that do not bear the original product number (in the form of a EAN-13 or HIBC) on the product package.

In order to ensure patient safety, barcode information and original labels of medical devices/products used for patients should be kept in the patient’s file, retained by the hospitals and during inspections, submitted to the relevant authority upon request.