ANNOUNCEMENT BY THE MINISTRY of HEALTH: NO REIMBURSEMENT FOR PRODUCTS WITHOUT PRODUCT APPROVAL

The following was anounced in the anouncements section of the website of our Directorate-General (http://www.sgk.gov.tr/doc/gss/gss_duyuru_180408_01.pdf), with the title of "system validity of products with temporary product numbers in the National Databank of Pharmaceuticals and Medical Device of Turkey (TİTUBB)" and notified in writing (document no.14787) to the Ministry of Health on April 17th, 2008 and to Tepe Technological Services Inc. (document no 14786) on April 17th, 2008:

"As known, when manufacturing companies introduce products to the National Databank of Pharmaceuticals and Medical Devices of Turkey (TİTUBB), EAN-13 or HIBC (Health Industry Bar Code) type numbers are required for medical devices. Most of the imported goods have one of these two types, and for those that do not bear any of these types, a transition period has been planned. During this transition period, in order to ensure registration to the National Databank, system gives a 13-digit temporary number starting with "245";

However, products registered in the National Databank with numbers starting with "245":

1) shall be valid until December 31st, 2008 once they passed the control of Social Security Institution, approved by the Ministry of Health and obtained their CE certificates and be reimbursed,

2) shall be vaild until May 31st, 2008 once they passed the control of Social Security Institution but did not bear CE certificates. After this date, if there is no change in the status of these products, then these products will be deactivated in the National Databank and no reimbursement will be effectuated."

Following this notice, another anouncement prepared by the Ministry of Health was published on the website of National Databank (http://www.huap.org/ubb/Default.aspx) on April 15th, 2008. Paragraph 2 of this notice (document no. 12963) and Article 2 of another

circulary numbered 15167 – 2008/36, dated May 1st, 2008 state that "…in all purchases that fall under the scope of Medical Device Regulations, registration to the National Databank of Pharmaceuticals and Medical Device of Turkey (TİTUBB) and ***approval by the Ministry of Health for medical devices to be purchased, shall be prerequisites.***

Therefore, following the date mentioned in the official announcements and circularies of the Directorate-General for Treatment Services, Ministry of Health, in electronic invoicing applications of healthcare services providers to our institution via MEDULA, ***products registered in TİTUBB but without the approval of the Social Security Institution (SGK) and the Ministry of Health, shall not be reimbursed via MEDULA***.

Thank you for your kind consideration.

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