Egyptian Drug Authority
Authority Presidency

Chairman Decree No. (642) of 2021 on Data of the Labels of Medical devices, Laboratory, in vitro Diagnostic medical devices, Production Components and Inputs

Chairman of Egyptian Drug Authority:

Having perused:

- Law No. (127) of 1955 on Pharmacy Profession Practice and its amendments;
- Law on Establishing the Egyptian Drug Authority No. (151) of 2019; and its Executive Regulation;
- The minutes of the Authority's Board of Directors meeting held in its session on 20/07/2020;
- The report of the committee formed to set the provisions for the minimum data that must be present on the labels of medical devices, Laboratory, in vitro Diagnostic medical devices, Production Components and Inputs;
- Based on what's submitted by the head of the central administration of medical devices;
- Based on what's submitted by the head of the Central Administration of Operations and the head of the Central Administration of Medical Devices;
- And in the interest of work;

Has decided

(Article One)

This decision shall be applied on the data of labels of the medical devices, laboratory, in vitro Diagnostic medical devices, production components and Inputs.

(Article Two)

The holder of the registration license shall be obligated to mention the mandatory data in Arabic language on the labels of the medical, laboratory in vitro Diagnostic medical devices for the purpose of circulation in the Arab Republic of Egypt, and the components and production inputs that are imported for the purpose of use in production. The English language may be used after submitting acceptable justifications to the competent department of the Egyptian Drug Authority.

Mandatory data is divided into: Data related to the item; Data related to the manufacturer; data related to sterile items only; and data related to the importer or agent. These data are the minimum requirements for circulating the aforementioned products and allowing their import, and release of the components and their production inputs.

(Article Three)

The head of the Central Administration of Medical Devices shall issue, within five days as of the date of approving of this decree, a regulatory guideline of the procedures and rules regulating the data of label of medical devices, Laboratory, in vitro Diagnostic medical devices, Production Components and Inputs.

(Article Four)

This decree shall come into effect from the date of its issuance. Any other provisions that may contradict this decree shall be repealed.

Chairman of
Egyptian Drug Authority

Prof. Tamer Mohamed Essam
Written on: 29 /12 /2021