

Minister of Health and Population
Resolution No (820) of 2016

Minister of Health and Population:

After Perusal of the following:

Law No. 127 of 1955 regarding practicing the pharmacy profession;

Ministerial Decree No. 425 of 2015 concerning the reorganization of the registration rules and procedures of the human pharmaceuticals and its amendments,

And as per the presentation of the Head of Central Administration for Pharmaceutical Affairs,

Decided

Article (1): Without prejudice to the procedures stipulated in the said Ministerial Decree No. 425 of 2015, the Central Administration of Pharmaceutical Affairs (CAPA) shall be committed to the following:

- Working on registering the pharmaceutical and biological products obtaining the approval of the international authorities (Food & Drug Administration (FDA) & European Medicine Agency) within a period of one month only.
- Working on registering the pharmaceutical and biological products obtaining the approval of international authorities (Food & Drug Administration (FDA) or European Medicines Agency (EMA)) within a period of two months only.
- Working on registering the pharmaceutical and biological products which presents CTD within a period of six months.


Article (2): The Central Administration of Pharmaceutical Affairs (CAPA) shall be committed to develop mechanisms and procedures for applying and presenting that decree to the Minister of Health and Population to make it come into force.

Article (3): That decree shall be applied and enforced as of 1st January, 2017.

Article (4): The competent authorities shall implement that decree.

Minister of Health and Population
(signature)

Prof. Dr. Adel Adawy



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وزارة الصحة والسكان
الوزير

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مادة (٢) : تلتزم الإدارة المركزية للشؤون الصيدلانية بوضع اليات وإجراءات تطبيق ذلك القرار وعرضه على وزير الصحة والسكان لإدخال القرار حيز التنفيذ.

مادة (٣) : يطبق هذا القرار ويندخّل حيز التنفيذ اعتباراً من الأول من يناير ٢٠١٧.

مادة (٤) : على الجهات المختصة تنفيذ هذا القرار.

وزير الصحة والسكان

أ. ل. أحمد محمد

رقم ٢٠١٧/١١/٤٤

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