SERVICE NAME / REGISTRATION OF A MEDICAL DEVICE

DEPARTMENT NAME
Drug Department

SECTOR NAME
Public Health and Licensing Sector

SERVICE DESCRIPTION

This service enables clients to submit their applications to register medical devices for importation and circulation within the UAE.

SERVICE CHANNELS

Website

SERVICE FEES

01 **Application:** AED100

02 **Registration of a medical device:** AED5,000

CONDITIONS AND REQUIREMENTS

Companies that have the right to manufacture and market products must be registered by MOHAP before their products can be registered

The applicant must be a medical warehouse licensed by MOHAP and holding a valid license

REQUIRED DOCUMENTS

01 Completed online application form

02 Copy of the valid manufacturer's registration certificate

03 Free sale certificate/registration from the competent authorities in the country of origin authenticated by the UAE embassy

04 Copy of the product authorization between the company and the agent

05 Certificate of conformity/quality of marketing permit, such as: EC, 510 (K), PMA as per the classification of medical devices, Class I, II, III, IV

06 Post-marketing monitoring requirements

07 Copies of product registration certificates from other countries

08 Product data, including description, composition, types, sizes, models, accessories, uses, side effects, prohibitions, warnings, precautions, instructions for use, packaging pictures, pamphlets and manuals

09 Laboratory requirements and analysis, and pricing of certain medical devices

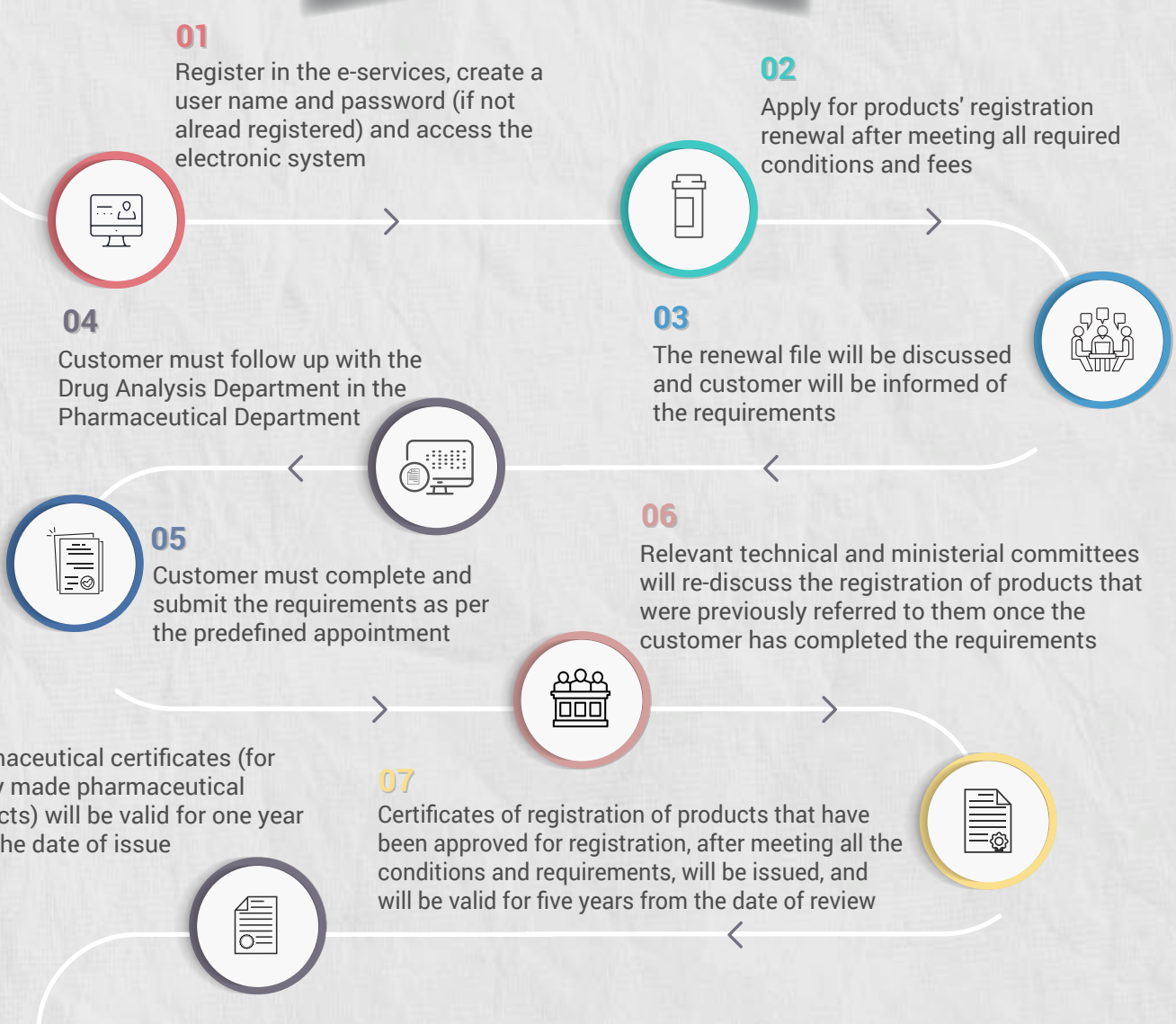
10 Three samples (per device), certificate of analysis (per device), outer and inner packaging and leaflets

11 Acknowledgment of the company to conform to the specifications of the Medical Devices Manual (EC Declaration of Conformity)

12 Safety and efficacy data (for products in Class III and IV)

13 Special requirements: Certificate of Conformity for devices manufactured with animal derivatives

SERVICE STEPS



SERVICE LOCATIONS

Website