Central Administration Of Medical Devices
General Administration of Registration

Notice to Applicant

Regulation Procedures for Registration of Medical Devices with Pharmaceutical Dosage Form That have been previously Registered or Currently Under Registration as Pharmaceutical Products Year 2025.

Code: EDREX:NP. CAMD.004

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Scope

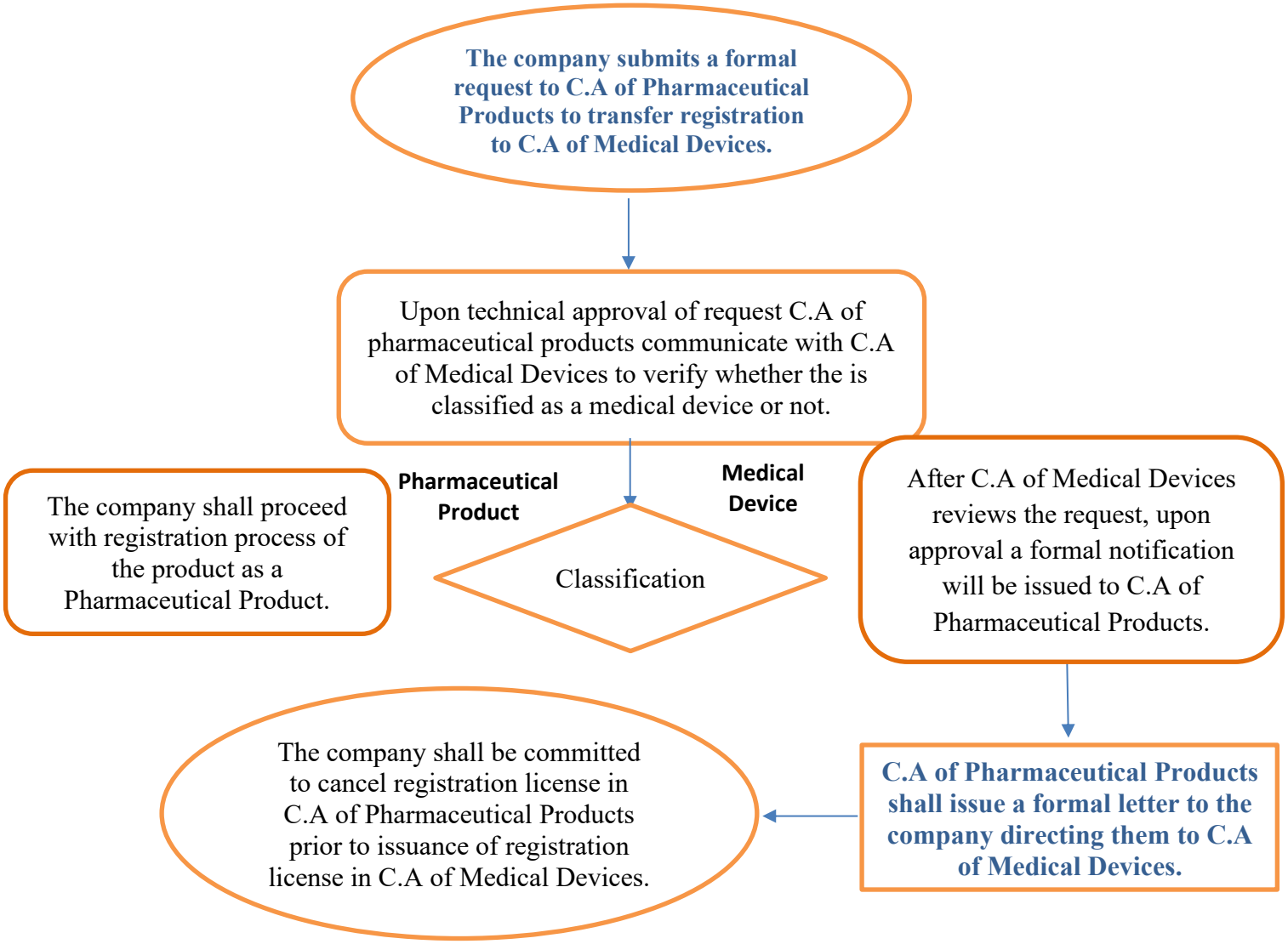
This procedure shall be applied on all medical devices in dosage form that contains active pharmaceutical ingredients or inactive pharmaceutical ingredients.

A (Dosage Form) is a combination of API and often excipients to facilitate dosing, administration, and delivery of the medicine to the patient

Dosage forms include:

- ✓ Sterile dosage form (ampoules, vials, drops, prefilled syringes, …).
- ✓ Semi solid dosage form (creams, ointments, gels, …).
- ✓ Liquid dosage form (liquids for external use, syrups, …).
- ✓ Solid dosage form (tablets, capsules, …).

Regulation procedures for registration of medical devices with pharmaceutical dosage form that have been registered or currently under registration as pharmaceutical products.



- **Regarding pharmaceutical products that have obtained registration license from Central Administration of Pharmaceutical Products and still valid or those undergoing registration if the company wishes to register the product as a medical device in accordance to it classification in Central Administration of Medical Devices the following procedures should be undertaken:**

1- The company shall submit a formal request to Central Administration of Pharmaceutical products to transfer registration of the product to Central Administration of Medical Devices.

2- Upon technical approval, Central Administration of Medical Devices will issue a formal notification to verify whether the product in the company's/manufacturer's request is subjected for registration in accordance to registration procedures of medical devices.

3- The Central Administration of Inspection of Pharmaceutical institutions shall be formally addressed to advise on the feasibility of manufacturing the product as a medical device, the administration shall in turn provide a response confirming whether or not the product can be manufactured.

4- The Central Administration for Medical Devices shall review the request in the event of approval the Central Administration for Pharmaceutical Products will be formally notified accordingly.

5- The Central Administration for Pharmaceutical Products shall issue a letter to the company/manufacturer directing them to the Central Administration for Medical Devices to initiate registration procedures. Meanwhile, the valid registration certificate issued by the Central Administration for Pharmaceutical Products, as well as the mandatory pricing, shall remain in effect until the registration process with the Central Administration for Medical Devices is finalized.

6- The Company shall be committed to canceling the pharmaceutical product registration with the Central Administration for Pharmaceutical Products in accordance with the applicable regulations prior to the issuance of the medical device registration license. The medical device license shall not be issued until the Technical Committee for Drug Control has issued the cancellation decree and a formal notification of cancellation is submitted to the Central Administration for Medical Devices.

7- The new registration license as a medical device shall come into effect alongside the deregulation of its price, in implementation of the legal opinion issued by the Legal Advisor to the Egyptian Drug Authority approved by the President of the Egyptian Drug Authority on October 18, 2020 concerning the non-pricing of medical devices.

- **Regarding pharmaceutical products whose registration licenses issued by Central Administration of Pharmaceutical products have expired and the company/manufacturer wishes to register it as a medical device in accordance with its classification in Central Administration of Medical Devices:**

1- **The company/manufacturer shall apply directly for registration with the Central Administration of Medical Devices, without the requirement of a referral letter from the Central Administration of Pharmaceutical Products.**
2- **The device shall be considered as an application for re-registration and shall be marketed for one calendar year providing that there are no substantial changes from the version previously registered as a pharmaceutical product.**

***To review the procedures and required documents for the registration of imported and locally manufactured medical devices holding international quality certificates, please click on the following link:** Regulatory Guideline for Procedures of Registering Imported and Local Medical Devices holding International Quality Certificates

***To review the procedures and required documents for the registration of locally manufactured medical devices not holding international quality certificates, please refer to:**

Regulatory Guideline of Registration of Locally Manufactured Medical Devices not holding International Quality Certificates

History Table

Version No.	Issue date	Summary of Changes
1	3/2024	_____
2	9/2025	Change the name of the Central Administration of Operations to become the Central Administration of Inspection of Pharmaceutical institutions