Mechanism for facilitating the procedures for the registration and issuance of import approvals for medical devices, medical equipment, and IVDs Year 2025

Code: EDREX:NP.CAMD.005

Version Number: 2

Issue date: 01/09/2025

Effective date :01/09/2025

Table of contents

I. Facilitations for companies listed in the White List:(Registration/Import approval)

Renewed quality certificates

It shall be sufficient to rely on the correspondence received from the notified body regarding the previous certificate, provided that an undertaking is submitted stating that, in the event of receiving a different notification, importation will not be permitted.

Letter of relationship between the branches of the manufacturing company

It shall be sufficient to submit the relationship document via the official email of the issuing company (verified email), provided that it is stated that it is an original copy and is in the process of being authenticated. The procedures shall be completed without the need to submit a legalized version, on condition that the applicant provides an undertaking to submit the legalized document within a specified time period.

Certificates of circulation/quality that do not state the actual manufacturer's name(the manufacturing site is a legal manufacturer from a reference/non-reference country)

In case the actual manufacturer's name is not stated in the Certificate of Free Sale, it shall be sufficient for it to be stated in each of the following:

- ISO 13485:2016 certificate
- Declaration of Conformity
- CE certificate

In case the actual manufacturer's name is not stated in the CE certificate, it shall be sufficient for it to be stated in each of the following:

- ISO 13485:2016 certificate
- Declaration of Conformity
- Certificate of Free Sale

Verification of the validity of all letters extending the validity of certificates issued by the notified body.

The Registration Notification or Import Approval shall be issued based on the letter extending the validity of the CE certificate issued by N.B for devices originating from reference countries. In the event that the submitted documents are proven to be invalid, the company shall be placed on the Black List.

Expiry of the quality certificates for the device, with the company currently unable to provide evidence of their validity extension.

The procedures for issuing the Import Approval or Registration license shall proceed, provided that the device was manufactured prior to the expiry date of its quality certificates.

Certificate of Free Sale

- The valid Certificate of Free Sale shall be submitted without the requirement that it be valid for at least three months prior to file acceptance.
- In case it is not possible to verify the authenticity of the certificate through electronic means, or no response is received upon contacting the issuing authority, it shall be sufficient to authenticate the certificate at the Chamber of Commerce without the need for legalization at the Egyptian Embassy, provided that the company is listed in the White List.

II. Facilitations specific to the General Administration of Registration

Safety letters and undertakings

Safety undertakings from the foreign company shall be accepted directly via the official email of the registration departments.

Correspondence regarding certificates

Registration procedures shall be initiated, and correspondence related to covering the manufacturer’s certificates and verifying their authenticity shall be conducted during the registration stage.

Registration samples

A sample shall be requested from the company for review upon request by the Scientific Committee, provided that it is returned to the company without retention, as per the usual practice. Expensive samples shall be excluded from this requirement, where it shall be sufficient to provide an electronic copy of the sample on a CD, if the Committee deems it adequate.

1- Cases to be presented to the Scientific Committee based on a recommendation from the Medical Devices Safety Department.

The cases requiring submission to the Scientific Committee have been divided into two groups (6 cases).			
Cases that are not submitted to the specialized scientific committees.		Cases that are submitted to the specialized scientific committees.	
1	The medical device has not been marketed in any reference countries.	1	The number of incidents associated with the medical device exceeds 1% of total sales during the reporting period.
2	Low sales volume during the reporting period.	2	Incidents associated with the medical device have been reported.
3	No incidents related to the medical device were reported during the reporting period.		
4	The marketing period of the medical device is less than 3 years.		

Certificate of Analysis (CoA):

The Certificate of Analysis (CoA) submitted within the technical dossier shall be considered sufficient, without requiring a letter from the manufacturer confirming that the method used complies with the manufacturing specifications and that it is under the manufacturer's responsibility.

Shelf life:

Approval for the shelf life of all imported medical devices-whether newly registered or re-registered-to exceed five years, up to a maximum of ten years (as the validity period of the notification).

This is subject to the availability of storage facilities compliant with Good Storage Practice (GSP) requirements, which allow for the storage of sterile medical devices in accordance with the conditions stated on the packaging and as specified in the undertaking submitted by the company regarding compliance with the storage conditions of the medical device throughout its shelf life.

Compliance with these requirements shall be monitored by the Central Administration for Inspection of Pharmaceutical institutions.

Pre-registration analysis:

With regard to medical devices submitted for registration that are subject to pre-registration testing:

- For surgical sutures manufactured in non-reference countries, testing shall be conducted on any size. However, ophthalmic sutures shall be tested by sampling one size from each size range for sutures originating from reference or non-reference countries.

For medical devices in pharmaceutical dosage forms (oral, nasal), testing may be conducted either prior to registration or after registration from the first shipment, according to the applicant's preference. This is subject to the submission of a company undertaking specifying the timing of testing (pre- or post-registration), along with a commitment to establish a clear mechanism for handling non-conforming results, in coordination with the Central Administration for Inspection of Pharmaceutical institutions.

2- Cases submitted to the Scientific Committee for changes made to registered medical devices.

The cases requiring submission to the Scientific Committee have been divided into two groups			
Cases not submitted to the specialized scientific committees.		Cases submitted to the specialized scientific committees.	
1	In the case of requesting the addition or change of a manufacturing site located in a non-reference country, the site must be within the same country specified in the registration license.	1	In the case of requesting the addition or change of a manufacturing site located in a non-reference country, where the country is different from that stated in the registration license.
2	In the event that a statement from the Medical Devices Safety Department requires submission to the competent scientific committee, while the device has already been previously presented.	2	In the event that a statement from the Medical Devices Safety Department requires submission to the competent scientific committee, and the device has not been previously presented
3	In the case of submitting a request to rephrase the intended use, provided that this does not result in any change to the meaning or the approved scope of use.	3	In the case of submitting a request to change the intended use.
4	In the case of adding codes where the differences between the codes are limited to gauge, diameter, volume, or suture (number of strands).	4	In the case of adding codes where the differences between the codes are other than those previously mentioned.
5	In the case of requesting a change to the needle hub color.	5	In the case of requesting a change in the design or method of use.
6	In the case of a change in the A-constant value of the lenses	6	Changes to the Instructions for Use (IFU), other than rephrasing the intended use in a manner that does not alter the meaning.
7	In the case of adding a suffix to the device codes to distinguish a specific country or language, without affecting the device.	7	In the case of requesting the addition of unregistered needles for use with insulin pens.
8	In the case of changing the coding system of the device, or adding a code for a previously registered device that did not have an approved coding system, without making any modifications to the device.		

3- Cases submitted to the Stability Committee.

In the event of a change in the sterilization method of a registered medical device, it shall not be submitted to the specialized scientific committee for evaluation of stability and biocompatibility studies, provided that a confirmation is submitted from the Notified Body approving the change in the sterilization method.

III. Facilitation measures related to the General Administration for Market Authorization.

1- In the event that one of the supplementary requirements expires while completing the import approval file or the precautionary release.

Import approvals or precautionary release approvalshall be issued for submitted files in which one of the required supporting documents has expired during the completion of review procedures, including:

- The grace period for renewing the maintenance center contract
- C14
- Contract/relationship between the manufacturer and the supplier
- Validity of the industrial registry for local manufacturers

This applies to all files submitted prior to the expiry date of any of the above-mentioned documents.

- Validity of ISO 13485:2016 certificate
- Registration License after obtaining import approval for applying for precautionary release
- Validity of the Certificate of Free Sale (CFS)
- Validity of the Certificate to Foreign Government (CFG) from the USFDA

Provided that it is confirmed that production took place prior to the expiry of any of the aforementioned certificates.

2- Facilitation measures for medical equipment.

- In the event that the Scientific Committee decision for medical equipment —issued with conditional approval requiring re-evaluation after one year—expires, the Committee decision shall be renewed upon verification that no importation has taken place during the year, without the need for resubmission to the Scientific Committee.
- In the event that the Scientific Committee decision has expired, and the company wishes to import spare parts for the equipment, the importation of spare parts shall be permitted without requiring renewal of the Scientific Committee decision.
- In the case of medical equipment that has been granted Scientific Committee approval conditional upon re-evaluation after one year in five hospitals, the evaluation shall be conducted by the medical device's safety department at the actual supply sites, regardless of their number.
- Conditional approval shall be granted to locally manufactured medical equipment that does not hold international quality certificates, pending submission of the Electromagnetic Compatibility (EMC) test results.
- Locally manufactured medical equipment that does not hold international quality certificates shall be granted conditional approval pending submission of the Electromagnetic Compatibility (EMC) test results.

3-Facilitation measures for medical devices.

- A non-registered medical device may be granted a single import approval for urgent/emergency use with a pharmaceutical product or biological product, pending completion and submission of the registration dossier, with a maximum import period of six (6) months from the date of submission for registration.
- A medical device that was previously registered and for which no application for re-registration has been submitted within the timelines granted under the regulatory guideline may be allowed for circulation, provided that a single import approval is granted only prior to submitting a new registration application.
- Imported or locally manufactured medical devices may be allowed for circulation after the expiration of the time limits specified in the regulatory guidelines with regard to (re-registration, registration, and variation procedures), by granting a grace period not exceeding six (6) months for importation, starting from the date of payment of the prescribed fees.

4- Facilitation measures for in IVDs.

- In the case of issuance of a Free Sale Certificate for an IVD that does not include all manufacturers, importing companies shall be granted a grace period ranging from (3) to (6) months for importation, based on a Free Sale Certificate listing only the legal manufacturer's name.
- Importing companies shall be granted a grace period ranging from (3) to (6) months for importation under a Free Sale Certificate for an IVD not intended for the Arab Republic of Egypt, provided that it is issued by one of the reference countries and includes the manufacturer's details and product items.
- Importing companies of IVDs classified as List A and List B that have submitted registration applications:
  ** Importing companies of IVDs classified as Self-testing and General IVD, for which the deadline for completing marketing authorization procedures expired on 31/12/2023.

- A one-year grace period has been granted, ending on 31/12/2027, upon payment of the due fees.
- A two-year grace period has been granted, ending on 31/12/2027, upon payment of the due fees.

- It is not required to submit a Free Sale Certificate from one of the reference countries for locally manufactured IVDs submitted for registration under the system for locally produced IVDs holding international certifications. It is sufficient to submit the CE mark registration.

5- Facilitation measures for handling data on labels.

- Approval is granted for the handling data on labels of raw materials and production components for local manufacturers after notifying the Central Administration for Inspection of Pharmaceutical Institutions, provided that the handling authorization is issued upon payment of the prescribed fees.
- Approval is granted for the handling of data related to spare parts of medical equipment, provided that the handling authorization is issued once per company, along with the submission of a commitment to comply with the minimum data requirements thereafter.

6- General Facilitations Regarding Import Approvals

- In the event that any of the renewed certificates does not include the actual manufacturer's name, codes, or trade name, despite being stated in the expired certificate, the release of the quantities held in the warehouses of the licensed company shall be permitted pending receipt of the correspondence clarification.
- A Free Sale Certificate not addressed to the Arab Republic of Egypt shall be accepted pending status regularization.
- In the event of the expiration of a conditional Scientific Committee decision, the release of the medical devices or equipment stored in the warehouses of the licensed company shall be permitted based on a safety report, pending receipt of the official safety confirmation.

IV. Facilitating procedures for obtaining import approvals for medical devices and equipment for companies listed in the White List.

In the case of classifying a medical device or IVD in accordance with the updated European classification (MDR, IVDR).

Importation is permitted using the certificates available to the company, provided that the required timeframe for obtaining the quality certificates specific to each classification is stated.

One year has elapsed since the invoice issuance date.

Approval is granted for the release of an invoice that is more than one year past its issuance date.

Original documents.

It is sufficient to rely on the copies uploaded to the electronic platform.

History Table

Version No.	Issue date	Summary of Changes
1	9/2024	_____
2	9/2025	Introducing new facilitation measures.