Notice to applicants

Updating Procedures of Submitting Case Study File

Code: EDREX:NP.CAMD.002

Version No: Second

Issue Date: August 10th, 2023

Effective date: August 10th, 2023

1- Procedures of receiving a case study file:

- A pharmacist from the reception unit shall meet the representative of the applicant to add the medical device name on the payment receipt.
- The services fees shall be paid in accordance with the Decree issued by the chairman of Egyptian Drug Authority No. (331) of 2022.

Service provided	Service Fees in L.E.
If the company desires to receive informal feedback on the submitted documents	2000

1. The application is to be submitted by e-mail to md.variationa@edaegypt.gov.eg or the electronic platform MeDevice on all days of the week.
2. The application shall be directed to the unit manager and the reviewer pharmacist for studying the submitted documents.
3. The applicant shall receive a response via the electronic platform or e-mail indicating the documents required for the study within three working days.
4. The applicant shall fulfill the required documents within 5 working days.
   In case of not fulfilling the requirements, the file shall be archived and the request shall be cancelled.

- **In case of file acceptance after fulfilling the required documents:**

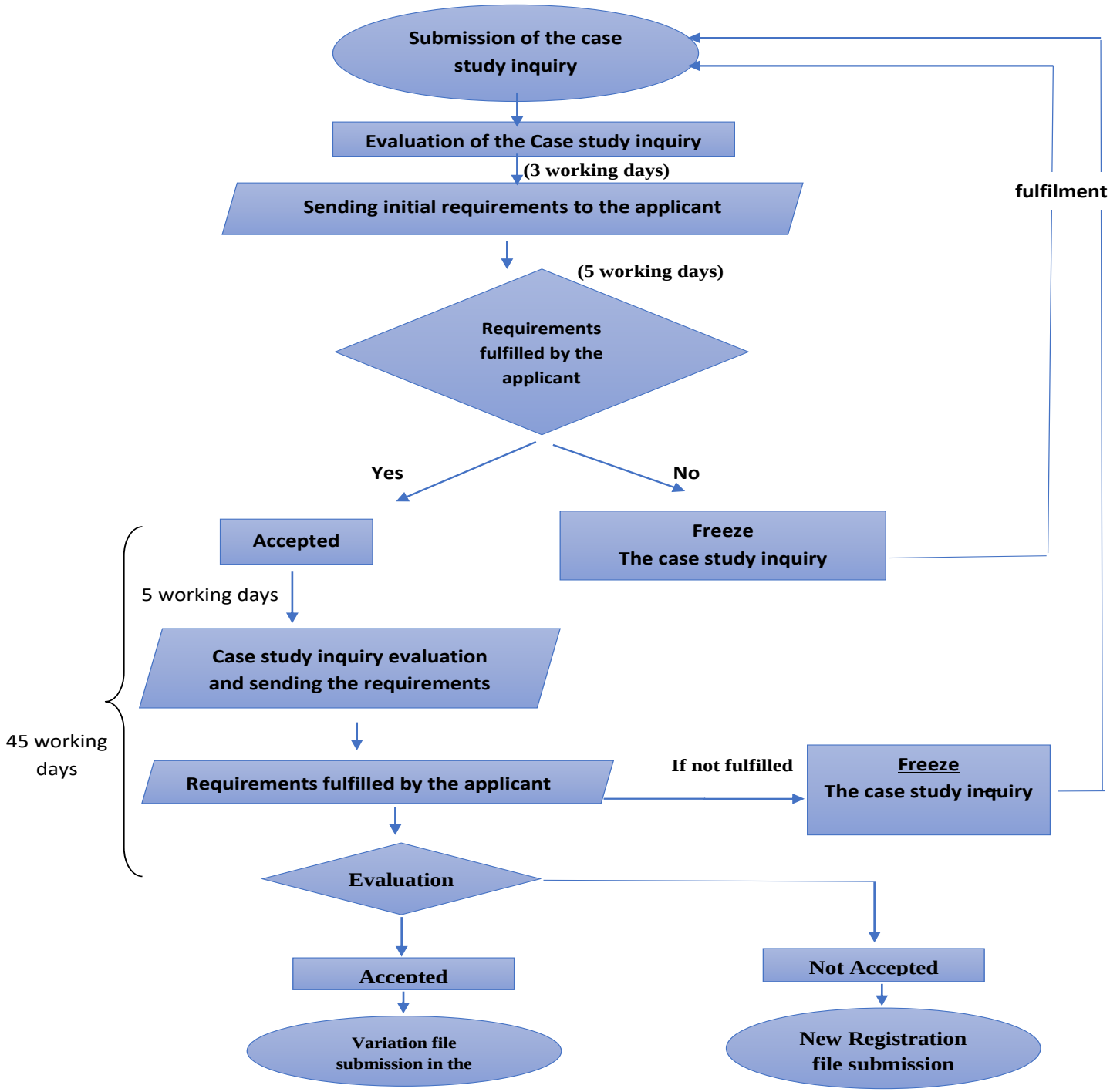
1. The applicant shall receive a response and an initial number either on the electronic platform or by an e-mail then the evaluation process will be initiated.
2. A grace period of 45 working days from the application acceptance date shall be granted to allow placing the device on the market. The companies shall be allowed to submit the import approvals applications for imported medical devices or production inputs in the case of locally manufactured medical devices after obtaining the initial number. During this period, the case study file shall be evaluated.

2- Procedures of evaluating Case Study file:

1. The file shall be reviewed and the required documents shall be sent via the electronic platform or by an e-mail within 5 working days (of the total granted grace period) from the file acceptance date.
2. The change shall be evaluated by the specialized scientific committees or through a notification from the Notified Body within the aforementioned grace period of 45 working days. In case of not fulfilling the required documents, the file shall be archived and the request shall be cancelled.
3. The final evaluation shall be undertaken by the Central Administration of Medical Devices. In case of approval, a variation file shall be submitted to the medical devices' variation Administration.

Note: **Case study files shall be submitted for all changes that do not follow the rules of medical devices variation (stated in the published guidelines) .**

Flow Chart of Evaluation of a case study for a registered medical device



Versions

Version	Issue Date	Amendments
Version No. (1)	Jan 10th, 2022	---------
Version No. (2)	August 10th, 2023	Extending the scope of application of case study file.