



Central Administration of Pharmaceutical Care
General Administration for Pharmaceutical References and Leaflets

Notice to applicant

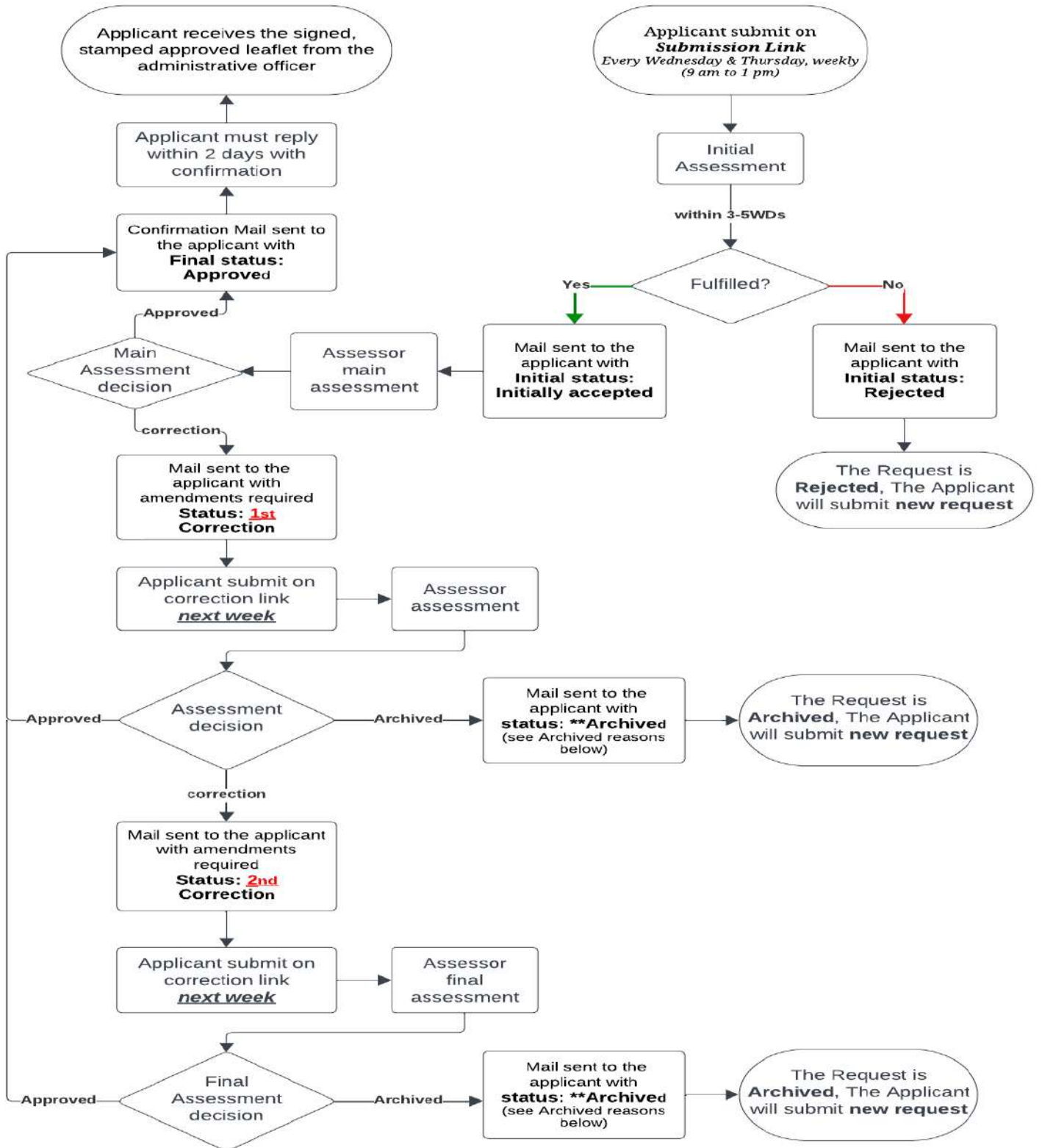
Flowchart of Referenced Human Medical Leaflets Assessment Year 2023

Code: EDREX:NP.CAP.Care.014

Version No: 1

Issue Date: 11/12/2023

Effective date: 31/12/2023



Normal track referenced leaflet total assessment time is within 28 days from initial acceptance /fulfillment

WDs abbreviation: Working Days

Notes

- 1- New requests are submitted on submission link <https://forms.gle/dx5c8LJWbv1P8fw27>
- 2- In case of receiving comments/amendments for the reviewed Leaflet, The following should be followed:
 - The applicant company should submit **All** required amendments with accordance to the following timelines:
 - Local products: one month
 - Imported & under-license products: three months
 - Applicants Should NOT exceed **2 corrections** (Applicants have ONLY 2 chances to fulfill all required amendments (1st Correction, 2nd Correction))
 - Applicants should submit on **Correction link**: <https://forms.gle/ENHLxpYXacHCKxwP7> and endorse the **exact same code** sent in the correction e-mail to fill the field named Reference code.
- 3- In case of Archiving the file by Leaflets administration assessors for any of the below reasons; Applicant should resubmit as a new request with all required documents and unduplicated receipt on submission link <https://forms.gle/dx5c8LJWbv1P8fw27>

3.1 Archiving reasons:

- Applicant has not fulfilled the required amendments after **the two corrections**.
 - Applicant exceeds **timelines** to submit required amendments
 - Applicant changed the **reference** after leaflet assessment.
 - Applicant cancelled the request after leaflet assessment.
- 4- Normal track referenced leaflet total assessment time is within 28 days from initial acceptance /fulfillment;
 - 5- In case of non-referenced human pharmaceutical products, assessment time is paused waiting for Pharmacology Committee Member decisions and approval.
 - 6- Fast track Leaflets assessment is accomplished within 5-7 working days from company request (submission) till the main assessment decision (check Flow chart of Fast track Medical Inserts Submission and assessment on submission link <https://forms.gle/dx5c8LJWbv1P8fw27>)