

## 1 Prepare the Documents

- Fill the official Medicine Variation Application Form signed and stamped, available on NHRA's website: <https://www.nhra.bh>.
- Cover letter from the local agent and Cover letter signed and stamped from the MAH Company.
- Country of origin approval for the change or proof of the change in country of origin (where applicable).
- All the specific documents as per the medicine variation guideline (Appendix 1) for each variation.

## 2 Prepare an eCTD Submission

- Compile the dossier in eCTD format as per NHRA requirements and as eCTD best practice.
- Ensure all the required supporting documents, justifications, Data and updated product information are included in the sequence

## 3 Submit your request

- Submit the application via the Adweya portal: <https://adweya.nhra.bh/> , You will receive an application number.
- Upload the ECTD, once it shows to the Applicant.

## 4 Review & Assessment by NHRA

- NHRA validates and assesses the submission.
- Queries or requests for clarification may be raised, a notification will be sent to the agent to fulfil the missing/Addition required data, the response shall be received within 30 days from receiving the IRF.

## 6 Implementation

- Type IA: minor variations can be implemented without NHRA approval ("Do and Tell" procedure) but require notification submitted by the marketing authorization holder (MAH) within 60 working days after implementation.
- Type IB & Type II (Major): Company must implement the submitted variation within 12 months of the approval date.

## 5 Final approval and certificate of Variation

- Approval of variation Certificate will be generated by the system along with notification to the applicant
- Rejection Applicant is notified with reasons.
- NHRA will provide the Final decision within 45 Working days (excluding clock stop periods).

