

## 1 Pay the application fees

Pay the application fees through ADWEYA 50BD

## 2 Submit your application on ADWEYA

The documents should be submitted by the new local agent through ADWEYA.  
**The Required documents for international manufacturers site Line addition are:**

1. Covering letter from the local agent in Bahrain signed.
2. Letter from the company indicating the name and address of the manufacturing site and clarifying the relation between them (Company letter head, signed).
3. Company profile (SMF and other documents to inform us about the company activities and responsibilities.)
4. Copy of legalized contract between the company and the local agent (pharmacy) including product list.
5. Contact details for responsible persons at the company.
6. Appointment Letter of the agent from the Company.
7. Copy of valid Certificate of registration of the company from the Ministry of Industry & Commerce.
8. Letter from the company declaring the name of medicine (s) released from this site (Registered or to be submitted for registration).
9. Letter from the company declaring the activities performed at the site including batch release or bulk manufacturing.
10. Copy of variations done since last 5 years relevant to the site's name and address only. (Applicable to renewal only), if no variation has been submitted a declaration must be submitted
11. Copy of valid Saudi FDA (SFDA) / Gulf Health Council (GHC) manufacturing site registration certificate. (If the applicant cannot comply with this requirement, then copy of valid GMP certificate is required from one competent authority).
12. Copy of valid GMP certificate from health authority in the country of origin.
13. Copy of valid Manufacturing License.



## 3 Assessment of the application & Final Approval

The assessor reviews the submitted documents and, if they comply, approves the for international manufacturers site Line addition application through ADWEYA.

The license is valid for 5 years

