

1 Get pharmacy license

Apply for importer pharmacy license for alternative medicine through Sijilat system.

2 Application SLA timeline: 30 Working days

1-Apply through Adweya system:

The following documents must be uploaded:

- 1-Valid pharmacy license with related activity.
 - 2-Valid copy of manufacturing license of the manufacturer. (With validity of at least 3 months)
 - 3-Valid Good Manufacturing Practice certificate (GMP) (legalized) (with validity of at least 3 months.
 - 4-Valid product registration license/Free sales certificate from country of origin (legalized) (with validity of at least 3 months and must mention the date of marketing.
 - 5-Product composition certificate (including exact concentration, source & function of both active ingredient and excipient).
 - 6-Mock-ups of outer label, inner label and package leaflet.
 - 7-Declaration letter from the company that the product is GMO free.
 - 8-Declaration letter from the company declaring the following:
This product is free from hormones, heavy metals, antibiotics, steroids, pork and other animal origin derivatives, TSE and any other natural or synthetic material that have harmful effects on biochemical functions or behavior of human beings.
 - 9-Declaration for intended use.
 - 10-Declaration for Alcohol content.
 - 11-Lab file with the following documents:
 - a-Certificate of analysis for Active ingredient(each) and finished product with inclusive of test for pesticide.
 - b-Finish product specifications.
 - c- Analytical procedure.
 - d-Certificate of analysis for one batch from independent lab
 - 12-Manufacturing process.
 - 13- Worldwide registration and marketing status with date of marketing
 - 14-Declaration letter for contact details for the company person responsible for communication with NHRA on quality related matters.
 - 15-Copy of pharmacopeia reference.
 - 16-Application form.
 - 17-Copy of NHRA approval certificate (for renewal application only).
- 2-After uploading required documents, the notice to pay is issued automatically.
3-The agent must pay the required fees. (50 BD).



4 approval

The applicant will receive the approval letter with 5 years validity.
The renewal application is with the same procedure.

3 Assessment

- 1-The application will be distributed by the staff concerned and email will be sent to the staff.
- 2-The assessor will pick the application and start checking the documents and assess the quality and safety of the products using the related references.
- 3-If any enquiries are raised the applicant will inform the agent through the system.
- 4-After assessment is completed, the staff will transfer the application to the head of the unit for final approval.

