**Regulation 2 (12)**

**Schedule I**

**APPLICATION FOR GRANT / RENEWAL OF A CERTIFICATE OF REGISTRATION OF A MEDICINE BY A LOCAL MANUFACTURER /AN AUTHORIZED IMPORTER**

I/ We, …………………of……………………hereby apply for a Certificate of Registration of the medicine specified below details of which are enclosed herewith.

1. **Name and address of manufacturer of the medicine:**………………………………………………………….
**…**………………………………………………………………………………………………
2. **Type of application** (check the box applicable)
1. New application □
2. Renewal application □
3. Variation to existing registration □ (If selected, complete the information below)
	* + - Previous registration number :………………………………………………….
* Previous registration type (Full) □ (Provisional) □
* Brief description of proposed variation: …………………………………………….
* Reasons for variation: ………………………………………………………………...

**C. Details on the product**

1. Proprietary name (trade name) :………………………………………
2. Approved generic name (s) (use INN if any):………………………..
3. Standard claimed (BP, IP, Ph.Eur., USP, etc.):……………………….
4. Strength(s) per dosage unit:……………………………………………
5. Dosage form :………………………………………………………….
6. Route of administration:………………………………………………..
7. Packaging and pack size(s) :…………………………………………….
8. Therapeutic category :…………………………………………………..

**D. Details of the applicant (check applicable box)**

1. Local manufacturer □ Authorized importer □
2. Name :…………………………………………………………………….
3. Mailing address:…………………………………………………………..
4. Telephone number /Fax number:………………………………………….
5. E mail:……………………………………………………………………..
6. Website:……………………………………………………………………

**E. Information submitted with the application**

**Modules of Common Technical Dossier**

* Module 1 (annex or page no.):……………………………………………
* Module 2 (annex or page no.):……………………………………………
* Module 3 (annex or page no.):……………………………………………
* Module 4 (annex or page no.):…………………………………………....
* Module 5 (annex or page no.):……………………………………………

**F. Samples :** Submitted □ number of samples ………………………….
 Not submitted□

**Declaration**I, the undersigned, certify that all the information in the accompanying documentation concerning the
application for Certificate of Registration of the above medicine is correct and true, and reflects the total information available.

Signature:………………………………………………….

Regulatory Affairs Officer:……………………………….

Name :…………………………………………………….

Date:………………………………………………………