**Regulation 52 (3)**

**Schedule X**

**APPLICATION FOR RENEWAL OF LICENCE FOR A LICENCED IMPORTER OF MEDICINES**

I/We, ………………………………………………………………………………………………… of …………………………………..………………………… hereby apply for licence to function as a licenced importer of medicines.

1. **General Information**
2. **Particulars of the Company/Organization**
	* 1. Name of applicant company/organization
		2. Business model of the company/organization

 (e.g. private limited company, public limited company, joint venture, sole proprietorship,

 partnership etc.)

* + 1. Postal address (registered office)
		2. Postal address (operational office)
		3. Email address
		4. Telephone number(s)
		5. Fax number(s)

1.1.8 Address(es) of Warehouse(s)

1. **Particulars of Key Personnel of the Company**
2. Names and addresses of Board of Directors/Partners of the company etc. as applicable
3. Name of the regulatory pharmacist responsible for liaising with NMRA
4. Sri Lanka Medical Council (SLMC) registration number of the regulatory pharmacist
5. Telephone number(s) (mobile) of the regulatory pharmacist
6. Email address of the regulatory pharmacist
7. Name of the pharmacist responsible for pharmacovigilance/post marketing surveillance
8. SLMC registration number of the pharmacist responsible for pharmacovigilance/post
 marketing surveillance
9. Telephone number(s) (mobile) of the pharmacist responsible for pharmacovigilance/post marketing surveillance
10. Email address of the pharmacist responsible for pharmacovigilance/post marketing surveillance
11. **Annexes**

2.1 A declaration by the responsible person certifying that the information furnished are true and accurate

2.2 Copy of business registration certificate issued by the relevant government authority

2.3 List of key persons employed (indicating the name, designation, qualification, and experience of each person)

2.4 Post marketing surveillance plan of the company

2.5 Recall procedure of the company

2.6 List of manufacturers by whom the applicant has been appointed as the authorized importer in Sri Lanka.

……………………………

Signed

(Responsible Officer)

Name:…………………….
Designation:……………...

Date:……………….……..