National Medicines Regulatory Authority, Sri Lanka

State Engineering Corporation Building (2nd Floor),
No. 130, W.A.D Ramanayaka Mawatha, Colombo 02, Sri Lanka

Checklist for Accepting Application for Renewal of an Overseas Manufacturer of Medicines

Application Number: ☐ Date

Receipt No: ……... Payment date: ……

Site Address : ……

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Name of the local agent: ……

1. Signed declaration in letterhead of the local agent ☐
2. Duty filled application: Part A ☐ Part B ☐
3. Attached documents

Document	✓or X	Page	Remarks
1. Changes or variations made to the manufacturing site, including its location, since the site approval granted by the NMRA (declaration if not applicable)			
2. Site master file (SMF)			
3. Previous manufacturing site approval document issued by NMRA			
4. Legible layouts certified by the site engineer/QA manager			
5. Agency transfer letter if applicable			
6. Letter of authorization by the manufacturer			

7. Letter by responsible person of the manufacturer, certifying that the content submitted are true and accurate (as per the annexure III format)			
8. Declaration by the applicant as per the format given in annexure II			
9. Copy of business registration of the authorized importer by registrar of companies with articles (including form 1, form 6, form 20)			
10. Copy of the wholesale license of the authorized importer by NMRA.			
11. Valid GMP certificate for the site indicating the product range issued by the country of origin.			
12. Valid manufacturing license with product range issued by the country of origin.			
13. Minimum of two copies of COPPs issued to two different product.			
14. Copy of the last inspection report by the competent authority of the country of origin.			
15. A full inspection report for an inspection performed by a reference NRA/WHO within last five year (if available)			
16. An undertaking by the manufacturer that is agreeable to an onsite GMP inspection if and when required.			

17. CAPA and proof of CAPA implementation related to the last inspection report observations/deficiencies or any warning letters or equivalent regulatory actions (production line specific)			
18. The most recent product quality review(s) (PQRs) for each dosage form relevant to concerned product			
19. BMRs for each dosage form relevant to concerned product			
20. Validation Master Plan			
21. Process validation reports for each dosage form relevant to concerned products			
22. List of reprocessed or reworked product batches			
23. A list of any recalls in the last three years related to quality defective products (or a declaration)			
24. A copy of any warning letter or equivalent regulatory action issued by any competent authority to which the site provides or has applied to provide the product or declaration			

Indexed ☐ Pages numbered both ways ☐

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Accepting Officer (MA) Date