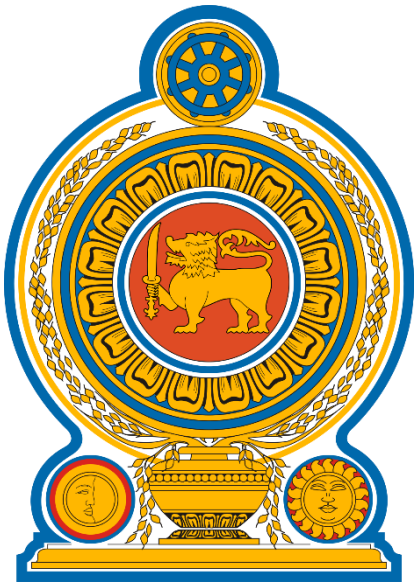


Guidelines for the Waivers of Registration (WOR) of Pharmaceutical Products Imported to Sri Lanka

OCTOBER 15, 2019

NATIONAL MEDICINE REGULATORY AUTHORITY
No.120, Norris Canal Rd, Colombo 01000, Sri Lanka

GUIDELINES FOR THE WAIVERS OF REGISTRATION (WOR) OF PHARMACEUTICAL PRODUCTS IMPORTED TO SRI LANKA.

Contents

Introduction

Under section 109 of National Medicines Regulatory Authority Act No. 5 of 2015, the Authority may grant permission in special circumstances to import and supply a particular pharmaceutical product in specified quantities of a medicine without the registration. The special circumstances include a medicine used to save a life, to control an outbreak of an infection or an epidemic or any other national emergency or for national security.

Granting permission to import and supply a particular pharmaceutical product in specified quantities in special circumstances without the registration is referred to as WOR.

Purpose

This guidance describes the procedure of requesting for a WOR by an individual or an institution and also the reviewing procedure followed by National Medicines Regulatory Authority (NMRA) for consideration of such request for WOR.

The importer shall be responsible for the accountability and management of the product imported under WOR.

The importer shall maintain records of all the details of products imported under WOR and submit such data within 28 calendar dates of importation to NMRA.

Purpose

Granting permission to import and supply a particular pharmaceutical product in specified quantities in special circumstances without the registration after considering the need of that product to the country.

Scope

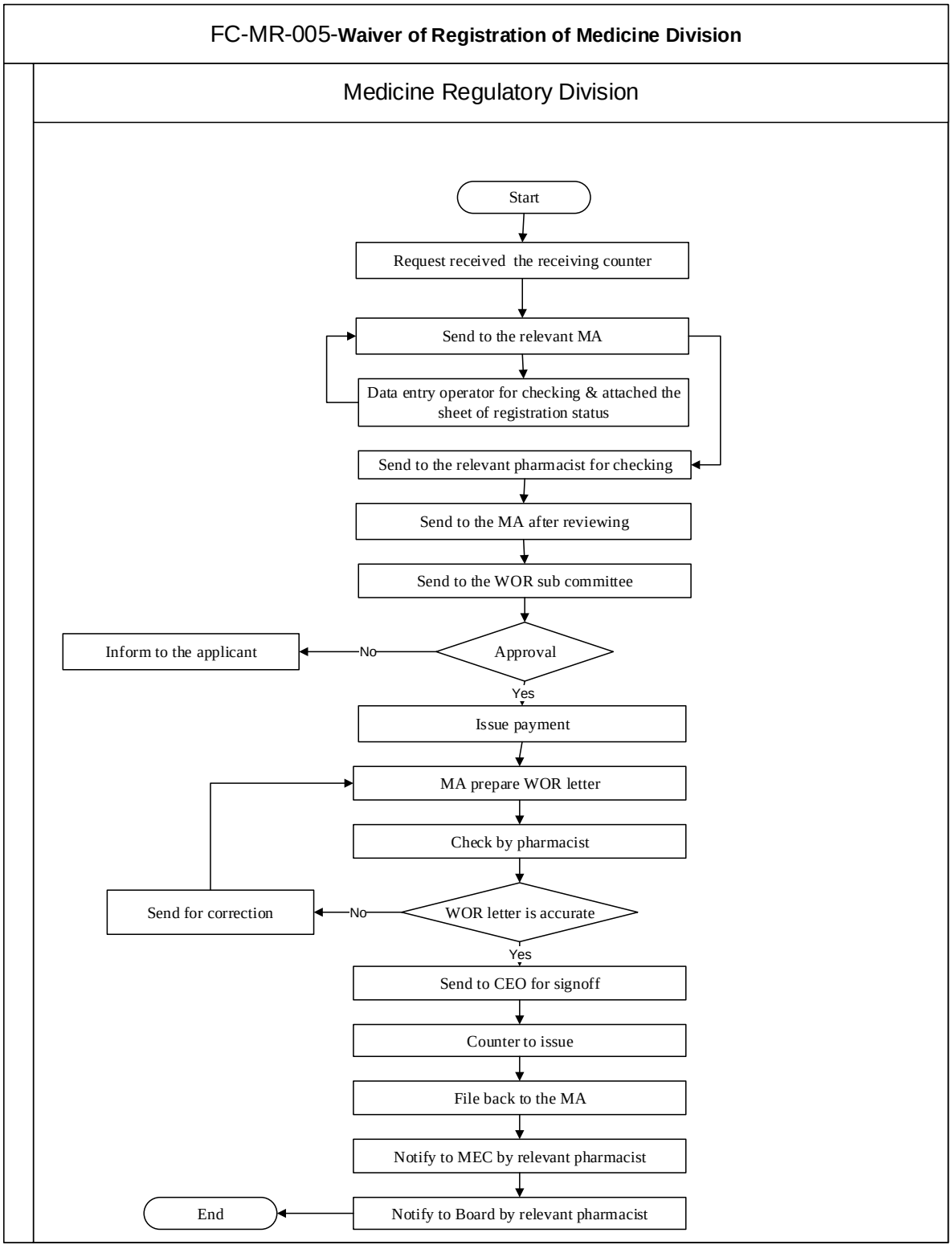
The procedures set out herein apply to medicines and similar products intended for human use. It is recommended. The permission for WOR may be granted;

a) On a request made by the Ministry of Health.
b) On a request made by an individuals or an organization.

Responsibilities

Head of the division and all staff assigned to carry out duties according to the Responsibility Matrix of Medicine Regulatory Division.

Waiver of Registration of Medicine Division - Flowchart



Required documents

1. Request letter from the applicant
2. Recommendation of Technical Evaluation Committee (TEC) when the request is made by the Ministry of Health or the request is made on behalf of the Ministry of Health.
3. Recommendation of the end-user
4. Indent/ commercial invoice

5. Certificate of Analysis (COA) of the relevant product
6. Cerificate of Pharmaceutical Product (COPP)
7. Real time stability report
8. Quotation Document
9. Approval of relevant Procurement Committee
10. Purchase order
11. Custom detain document
12. Label of the product
13. Product Information Leaflet (PIL)

All the above documents need to be submitted by the applicant wherever possible. The Authority has powers to request for more details in special situations for a complete review.

Procedure

- The request with the relevant documents should be submitted to the NMRA.
- All submitted requests will be reviewed by the Waiver of Registration Sub Committee

(WORSC) appointed by the NMRA. This committee meets once in two weeks.

- It is the responsibility of the NMRA to verify the registration status of the requested product (s) and inform to the WORSC.
- The final decision about the request is taken by the "Waiver of Registration Sub Committee (WORSC)" after considering relevant documents and registration status of the product.
- Once the approval is granted, the applicant should pay the relevant payment as per the gazette No. 2052/33 dated 2018.01.05
- After the payment is made by the applicant, the NMRA issues the WOR.
- This WOR approval addresses to the Director General/Customs and the Controller of Import and Export. The WOR letter will be copied to the Law and Enforcement Division of NMRA and the applicant as well.
- The validity period of a WOR is ONE YEAR from the date of issue of such a letter by the NMRA.
- In cases where the request for WOR is rejected, the reason for rejection will be informed to the applicant in writing within 14 calendar dates.
- Monthly summary report send to focal point for MEC submissions and the board of NMRA.