

NMRA – MEDICINES REGULATORY DIVISION

**REQUEST FORM
SINGLE CONSIGNMENT WITH REDUCED RESIDUAL SHELF-LIFE**

PART A - TO BE FILLED BY THE APPLICANT

1. Product Details

Product Name	
Generic Name	
Pack Size	
Manufacturer	
Local Agent/MAH	

2. Documents Submitted by MAH

No.	Required Document / Information	✓ Availability	Remarks
1	Request letter with calculated residual shelf life		
2	Valid Registration Certificate		
3	Valid Import License		
4	Commercial / Proforma Invoice with relevant consignment details. <i>Invoice No</i>		
5	Consignment is for Private market supply		
	Consignment is for Government supply <u><i>Related supportive documents</i></u> <i>1. PO No</i>		
6	Arrival status - If arrived, Debit application submitted date If not arrived expected date of arrival		
7	Justification for importing the short residual shelf-life consignment to Sri Lanka		
8	Average monthly consumption data for past 6 months		
9	Distribution plan for the full quantity		
10	Commitment letter declaring that the particular lot can be distributed within the remaining shelf life from MAH		

RSL% calculation

Manufacturing Date	
Expiry Date	
Product shelf life	
Debit application submitted date to Department of Import and export / if not yet arrived, expected date of arrival	
NMRA approved shelf life	
Remaining shelf life in months and days	
RSL%	

Applicant Declaration

I hereby certify that the information provided above and in the attached documents is accurate and complete.

Name:

Designation:.....

Signature:

Date:.....

PART B- OFFICE USE ONLY

3. Additional documents / clarification required:

❖ *For the government supply a consent from MSD/SPC.....*

MA/MRD

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Focal Point/New

Additional documents / response received:

Focal Point/New

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MA/MRD

4. Forwarding for advice and approval

HOD/MRD

RSL% of the requested single consignment -.....

(As per the decisions of 84th and 87th Medicines Evaluation Committee 66.66% - 50% are the acceptable shelf life)

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Focal Point/New Application

Focal Point /New application, MA/MRD

Approved/ Not approved to proceed with the payment and draft the letter for release of the single consignment with reduced remaining shelf life.

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HOD/MRD

5. For the consignments below 50% RSL

For less than 50% RSL for government supply - Letter from the MSD declaring that the particular lot can be distributed within the remaining shelf life (in order to forward the request to MEC (Policy decision 84th MEC)

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Minute Secretary/MEC,

To the next Medicines Evaluation committee recommendation.

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Focal Point/ New applications

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HOD/MRD