

Announcement to All Market Authorization Holders: Medicines

All Market Authorization Holders (MAHs) of medicines are hereby informed that if any medicine registration application is under Stop Clock status and the two (02) month response period from the date of the Stop Clock request communicated by email has expired without submission of the requested additional documents, you are kindly requested to inform the NMRA accordingly. (Who are not received Awaiting additional data evaluation yet)

Please send the required information to the relevant email address based on the application category:

- New and New Additional Applications: pa15@nmra.gov.lk
- Additional Applications: aa8@nmra.gov.lk
- Re-registration Applications: pa18@nmra.gov.lk

When submitting the information, please:

- Use the email subject as:
"Expired Stop Clock Response Period – Pending Medicine Applications"
- Provide all relevant details of the application using the attached Excel template in the format below:

No.	Application No.	Product Name	Brand Name	Manufacturer	Local Agent	Application Category (New / New Additional / Additional / Re-registration)	Stop Clock Request Email Date	Stop Clock Response Due Date	Stop Clock E mail Sent Evaluator Code

Please note that the completed Excel template and related information must be submitted on or before 4.00 p.m. , **Friday, 07 August 2026.**

The information received will be used to verify the status of the above applications and facilitate the necessary regulatory actions.

Medicines Regulatory Division
National Medicines Regulatory Authority (NMRA)
Sri Lanka