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தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

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My No.

NMRA/CP/P6/IMP/CUS/2021

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16.03.2021

The Controller General of Import & Export / Director General of Customs
Department of Import & Export Control, Sri Lanka Customs,
No. 75 1/3, 1st Floor, Hemas Building, No. 40, Main Street,
York Street, P. O. Box 559, Colombo 11, Sri Lanka.
Colombo 01, Sri Lanka.

Extension of the validity period of registration certificates and import licenses and clearance of products with residual shelf life less than 75%

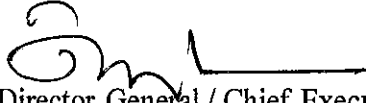
This is to convey that the National Medicines Regulatory Authority has taken the following decisions after reassessing the prevailing situation in the country due to COVID 19 pandemic.

1. To extend the validity of certificates of registration and import licenses pertaining to Medicines, Medical Devices, Borderline Products and Cosmetics up to 30th June 2021. The extension is applicable for certificates and licenses expiring after 30th June 2019. The decision was taken in order to minimize the movement of people. The decision would be reassessed again on or before 30th June 2021.
2. To grant approval to import & clear the above-mentioned products, at least twelve (12) months of shelf-life to be retained, with the product at the time of importing until 30th June 2021. For Parenterals, at least twelve (12) months of shelf-life to be retained, with the product at the time of importing. For Vaccines prior approval to be required from the NMRA if the shelf-life is below than the 66%.

As such, there is no requirement for the NMRA to consider individual requests in this regard.

Please note, this letter supersedes our previous communication letters on above subject matter.

Thank you,


Director General / Chief Executive Officer,
National Medicines Regulatory Authority,
Ministry of Health, Sri Lanka.

Dr. Kamal Jayasinghe
MBS, DFM, MSc-Med.Admn, MBA, DIPPCA
Chief Executive Officer
National Medicines Regulatory Authority
120, Norris Canal Road, Colombo 11