

TIRUCHELVAM ASSOCIATES  
COLOMBO, SRI LANKA

PHARMACEUTICAL AND HEALTHCARE DIVISION UPDATE IN THE CONTEXT  
OF THE COVID-19 CRISIS

The healthcare sector being an essential services sector is of vital importance in any country. We note many of our clients in the healthcare and pharmaceutical sector have had legal and practical queries resulting from the impact of the COVID-19 (“C-19”) pandemic.

This note outlines the status of operations of the National Medicines Regulatory Authority (“NMRA”), addresses how the C-19 crisis affects the industry and provides some updates in the pharmaceutical sector.

## **1. OPERATIONS OF THE NMRA**

The NMRA like all other government departments are closed (except on a need only basis) and is working remotely. The NMRA has issued a notice to the public to refrain from coming to the NMRA premises except for urgent matters.

Further, the NMRA has been issuing notices online on how medicines can be delivered to the doorstep. See- [https://nmra.gov.lk/index.php?option=com\\_content&view=article&id=264:how-to-get-medicines-to-your-door-step-during-this-curfewhours&catid=2:uncategorised&Itemid=264&lang=en](https://nmra.gov.lk/index.php?option=com_content&view=article&id=264:how-to-get-medicines-to-your-door-step-during-this-curfewhours&catid=2:uncategorised&Itemid=264&lang=en)

## **2. EFFECT ON THE HEALTHCARE AND PHARMACEUTICAL INDUSTRY**

All state resources in the Healthcare and Pharmaceutical industry in Sri Lanka including the Medicines and Medical Devices regulator – the NMRA – has been allocated towards combatting C-19 in Sri Lanka. All non-urgent matters have been put on hold or extended (as the case may be).

### **3. UPDATES IN THE PHARMACEUTICAL SECTOR**

**(a) Only essential Pharmaceutical Products are being registered**

The registration of all non-essential pharma products is presently halted.

In terms of Section 109<sup>1</sup> of the National Medicines Regulatory Authority Act<sup>2</sup> medicines, medical devices (which includes face masks and test kits) and cosmetics required on an **urgent-basis** to assist combat C-19 in Sri Lanka have been **permitted to be imported without registration** pursuant to following the Waivers of Registration (“WOR”) process.

– See the attached link for the NMRA Guidelines on WOR of Pharmaceutical Products imported to Sri Lanka (<https://nmra.gov.lk/images/PDF/guideline/GL-009-Guidelines-for-the-Waivers-of-Registration-WOR.pdf>).

Any requests to import Pharmaceutical Products in the aforesaid manner can be emailed to NMRA with scanned copies of the relevant documents for processing.

**(b) Extension of Certificates of Registration and Import Licences**

NMRA has decided to extend the validity of certificates of registration and import licences pertaining to Medicines, Medical Devices, Borderline Products and Cosmetics which have expired as at 30th of June 2019 or is to expire as at 30th of April 2020, till further notice. The decision was taken in order to minimise the movement of people considering the C-19 pandemic. The decision would be reassessed on or before 30th April 2020.

**(c) Market Authorization for Face Masks and Hand sanitisers**

NMRA has notified that applications for market authorization for face masks and hand sanitizers are being reviewed on a priority basis and are being expedited.

**NOTE:**

- 1. Any reference to any laws and regulations/directives/circulars/government press releases etc are as at the date of the issue of this document.*

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<sup>1</sup> Section 109 provides that NMRA 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.

<sup>2</sup> No. 5 of 2015

2. *Only references to any directives/circulars/government press releases etc which may have a bearing on strictly pharmaceutical and healthcare related matters have been referred to herein.*
3. *The contents of this document should not be considered as legal advice and is provided for information purposes only. If you require legal advice on any specific matter for purposes of decision making, do feel free to contact us.*

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