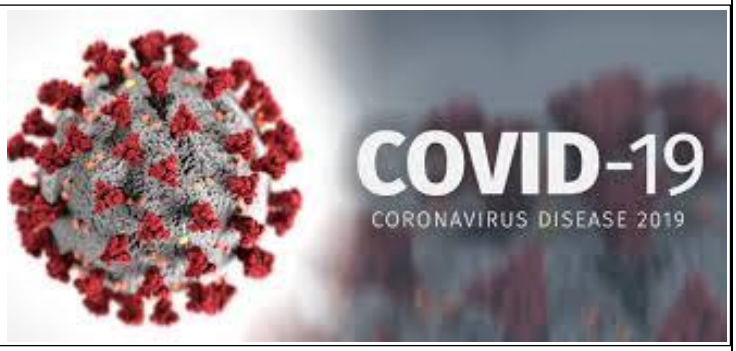
National Medicines Regulatory Authority

Coronavirus disease (COVID-19) pandemic

Information release
National Medicines Regulatory Authority
22, Mar 2020



NMRA and COVID-19 (Novel Corona Virus)

The NMRA is working closely with the Ministry of Health & Indigenous Medical Services, World Health Organization and other stakeholders on COVID-19.

Our priority focus areas include:

- Ensuring the continued availability of medicines and healthcare products.
- Supporting enhanced availability of products such as facemasks, hand sanitizers and personal protective equipment.
- Supporting clinical trials to develop vaccines and medicines

We also work with expert groups to provide information to manufacturers, distributors and pharmacies through our established information channels and alert systems.

NMRA services during the Coronavirus (COVID-19) response - *How to get in touch with the NMRA during this period*

Following the government's decision on the Sri Lanka's coronavirus response and the government advice to work from home for social distancing where possible, staff at the NMRA will work on roster on a rotation basis. A proportion of our staff will work from home as well.

This arrangement should have little to no impact if you wish to contact us. We are available through telephone and email during office hours and therefore you should not be affected.

If you are writing to us please do so by email to the relevant officer if possible, or contact us by telephone, as we will have infrequent access to physical mail sent into the office.

If you have a submission to make, please use the e-NMRA portal for electronic submissions. We encourage you to use e-NMRA, email or telephone to contact us as much as possible to avoid visits to Authority during this period.

If you need any guidance on e-NMRA, please contact:
Mr Santhusitha Ovitigala - adict@nmra.gov.lk
Mr Sumudu Sulochana - sulochana.s@nmra.gov.lk

Regulatory approval for Coronavirus (COVID-19) test kits as well as personal protective equipment

If you are a manufacturer of COVID-19 PCR test kits, facemasks, and other personal protective equipment, please submit an application for regulatory clearance with product performance data under a covering letter. Possessing approval/sanction from a 'reference' regulatory authority will strengthen the application.

The NMRA will provide priority review for these products and will provide regulatory services free of charge. It should be noted export or re-export of face masks and personal protective equipment without specific approval of the Authority is prohibited.

USEFUL INFORMATION

EPIDEMIOLOGY UNIT
MINISTRY OF HEALTH

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சுகாதார மேம்பாட்டுப் பணியகம்
Health Promotion Bureau

24 Hour Helpline: **117**

Assistance for Tourists: **1912**

Coronavirus: unlicensed medical products related to COVID-19

Regulatory authorities have identified a disturbing trend of criminals who are taking advantage of the COVID-19 outbreak by exploiting the high market demand for personal protection and hygiene products. Counterfeit face masks and unauthorized antiviral medication have been seized in different parts of the world.

It should be noted specific treatment for COVID-19 is not available at present.

Globally, approximately 2,000 online advertisements related to COVID-19 have been found and more than 34,000 unlicensed and fake products, advertised as “corona spray”, “coronavirus medicines” or, “coronaviruses packages” have been seized. In Sri Lanka too, our Enforcement Officers have detected and taken into custody coronavirus related products – face masks & hand sanitizers – from numerous locations.

Criminals who sell medicines and devices illegally are not only breaking the law but have no regard for your health and will take advantage of a major public health crisis to make a profit. Taking fake or unlicensed medicines and using a non-compliant medical device could put your health and safety in danger and may lead to serious health issues.

Therefore, NMRA safety advice when buying medicines:

- Be careful when buying medicines online

Medicines and medical devices are not ordinary consumer goods and their sale and supply is tightly regulated. Websites operating outside the legal supply chain may seem tempting, for example prescription medicine being offered without a prescription. Not only are they breaking the law - they are putting your health at risk.

- Do not self-prescribe

Self-diagnosis and self-medication can be very dangerous. If you have a concern about your health, please consult your doctor, get a correct diagnosis and if medicines are prescribed, buy them from a legitimate source.

Clinical trials applications for Coronavirus (COVID-19)

The NMRA wishes to work with other international regulatory agencies to support clinical trials to develop vaccines and medicines against COVID-19. We will prioritize and provide assistance for such studies.

We have legal provisions and procedures for rapid scientific advice, reviews and approvals for clinical trials and are ready to support manufactures and researchers. Although the NMRA has not done this before, we have dedicated resources to ensure this happens. We will have greater reassurance for clinical trials that have received approvals from ‘reference’ regulatory authorities. Such applications will receive very rapid review and support.

Please submit applications directly to the NMRA helpline by emailing info@nmra.gov.lk as well as through the usual route https://enmra.nmra.gov.lk

Managing clinical trials during Coronavirus (COVID-19)

How investigators and sponsors could manage clinical trials during COVID-19

This guidance note advises those involved in clinical trials on specific issues which may arise as a result of COVID-19, and what they are required to do.

The NMRA will be as flexible and pragmatic as possible with regard to regulatory requirements for clinical trials during this time. We recognize that clinical trial resource may be significantly reduced or redeployed from research activities during this time.

The first priority should be the safety of trial participants and this will remain our focus.

- If your trial has been halted due to issues related to COVID-19, you will not normally need to inform us. The site master file should include a note that the trial was halted and the reason.
- If a trial participant cannot attend a trial site, then delivery of IMP to a participant’s home is acceptable and no amendment notification to the NMRA will be required. Sponsors should do a risk-assessment and should have reasonable assurance on the integrity of the product during transit.
- Using phone calls instead of protocol-directed in-person study visits is acceptable where possible. This will not constitute a serious breach of the protocol. A substantial amendment to update the protocol will not be required. We would however expect that any protocol deviations are well documented internally.
- It is likely that there will be increased pressures on clinical staff during this period, so it is important to make sure that extra burdens are not placed on investigators around scanning and uploading many documents.
- The use of alternative means of oversight such as teleconferences / videoconferences is encouraged.