



The Republic of The Union of Myanmar

Ministry of Health

Department of Food and Drug Administration



## **Accessibility, Affordability and Equitable distribution for Covid-19 Vaccines & Therapeutics**

Under the guidance of MOH, DFDA (Myanmar) has made notable efforts to improve access to medicines & vaccines including reviewing the SOP & launching the online registration system of Drug and promoting the practice of Good Reliance.

DFDA (Myanmar) mainly focuses on Public health concerned medical products including vaccines and drugs and also relies on benchmark regulatory authorities's approval.

National Drug law was promulgated since 1992 & its amendment in 2014. DFDA (Myanmar) reviewed & revised the rules & regulation for emergency access to medicine & vaccine during public health problems.

During Covid-19 pandemic period (July 2021 to October 2021), DFDA & other related Departments provided and formed the Task Force that sped up the importation process; by facilitating the one time importation permit of Covid-19 medicine and related therapeutics.

Under the guidance of MOH, DFDA (Myanmar) promotes & supports local manufactures to produce Covid-19 related therapeutics like Antiviral (favipiravir, monupiravir, paclovid). DFDA prioritized the review process & checked the data of manufacturers according to ASEAN common technical requirements .

DFDA practices the Good reliance & recognition practice in line with WHO, so give Notification of Covid-19 vaccine importation including WHO PQ Vaccines. Covishield, Covaxine, Sinopharm, Sinovac that are already approved & used in



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Public Vaccination programmes in the whole country. The government has encouraged the local production of essential medicines & vaccine to meet the domestic needs, so under the Ministry of Industries, Myanmar Pharmaceutical Factory (MPF) has produced Covid-19 vaccine, Fill Finished product of Sinopharm, Myancopharm. The Vaccine produced was applied for notification to DFDA, and DFDA (Myanmar) checked the GMP Status of plant, the lot release procedure and approved for Public use.

The Government also concerns about the prices of Vaccine & Therapeutics, especially during pandemic. The Task Force checked the importation and utilization data of Covid-19 related therapeutics. Task Force search for Speculators and took action. Therefore the Therapeutics & vaccine are available at affordable prices.

The MOH has strengthened the procurement, distribution, storage & management system of Pharmaceuticals at all levels of healthcare services. An effective coordination mechanism for procurement & equitable distribution between the National, Regional, State health authorities & hospitals has already been established.

We have a strong cooperative networking system of the public and private sector (esp: vaccination programmes and access to medicine). But in the regulatory aspect, we mainly focus on the quality, efficacy & safety of medical products to ensure the public health safety first. In Asia, Mutual Recognition & trust among the regulatory agencies and information exchanges, rapid alert system are very beneficial to developing countries.



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On Behalf of MOH, DFDA also gave special thanks to India government for valuable donation of Covid-19 vaccine and Covid-19 Medicine. DFDA (Myanmar) also acknowledged the India FDA (CDSCO- Central Drugs Standard Control Organization) for timely approval of Covid-19 vaccine and Covid-19 therapeutics during the pandemic time. Finally I also want to congratulate the Indian Manufacturers for great investment in Research & Development to develop newer Covid-19 Vaccines and Therapeutics.