



MALACAÑAN PALACE
MANILA

BY THE PRESIDENT OF THE PHILIPPINES

EXECUTIVE ORDER NO. 121

GRANTING AUTHORITY TO THE DIRECTOR GENERAL OF THE FOOD AND DRUG ADMINISTRATION TO ISSUE EMERGENCY USE AUTHORIZATION FOR COVID-19 DRUGS AND VACCINES, PRESCRIBING CONDITIONS THEREFOR, AND FOR OTHER PURPOSES

WHEREAS, Section 15, Article II of the Constitution declares it a policy of the State to protect and promote the right to health of the people;

WHEREAS, Section 11, Article XIII of the Constitution provides that the State shall adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all people at affordable cost;

WHEREAS, Proclamation Nos. 922 (s. 2020) and 1021 (s. 2020) declared a state of public health emergency and an extension of the state of calamity, respectively, throughout the country due to the COVID-19 pandemic, and enjoined all government agencies to mobilize the necessary resources to undertake critical, urgent and appropriate response measures to eliminate the COVID-19 threat;

WHEREAS, Section 3(c) and (j) of Republic Act (RA) No. 11494 or the "*Bayanihan to Recover as One Act*," declare it a policy of the State to sustain efforts to test, trace, isolate and treat COVID-19 cases to mitigate the transmission of the disease, and prevent further loss of lives, and to optimize the use of science, technology and innovation in government's response measures;

WHEREAS, Section 4(a) of RA No. 11494 authorizes the President to adopt and implement measures to prevent or suppress further transmission and spread of COVID-19 through effective education, detection, protection and treatment, following the World Health Organization (WHO) or United States Centers for Disease Control and Prevention (US-CDC) Guidelines and best practices;

WHEREAS, Section 4(d) of RA No. 11494 authorizes the President to implement an uninterrupted immunization program against vaccine preventable diseases, especially on children amidst the COVID-19 pandemic, including vaccine for COVID-19;

WHEREAS, Section 12 of RA No. 11494 provides that Phase IV trials for COVID-19 medication and vaccine stipulated in RA No. 11223 or the "*Universal Health Care Act*" is waived to expedite the procurement of said medication and vaccine, and the minimum standards for the distribution of the said medication and vaccine shall be determined by the Food and Drug Administration (FDA) and the Health Technology Assessment Council;

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WHEREAS, Section 4 of RA No. 3720, as amended by RA No. 9711 or the "FDA Act of 2009," provides that the FDA (i) has the authority to conduct appropriate tests on all applicable health products prior to the issuance of appropriate authorizations to ensure safety, efficacy, purity and quality; and (ii) shall have the power to develop and issue standards and appropriate authorizations that would cover establishments, facilities and health products;

WHEREAS, to strengthen their own interventions and responses against COVID-19, other countries such as Australia, China and the United States of America adopted, and the WHO recognized, the regulatory practice of issuing an Emergency Use Authorization to hasten the availability and use of COVID-19 drugs and vaccines, particularly those supported by strong evidence that patients have benefited therefrom, in the absence of available approved and adequate alternatives;

WHEREAS, it is a priority of the State to ensure that the lives of the Filipino people, especially the underprivileged, poor and marginalized, our frontliners, healthcare providers, police officers and soldiers, and those in the essential services shall be protected from COVID-19 by ensuring accessibility and adequacy of supply of related drugs and vaccines;

NOW THEREFORE, I, RODRIGO ROA DUTERTE, President of the Philippines, by virtue of the powers vested in me by the Constitution and existing laws, do hereby order:

Section 1. Emergency Use Authorization for COVID-19 Drugs and Vaccines. The Director General of the FDA is hereby authorized to issue an Emergency Use Authorization (EUA), subject to conditions provided in this Order.

Outside clinical trials and except in cases where a Compassionate Special Permit is issued, no unregistered COVID-19 drug and vaccine may be manufactured, sold, imported, exported, distributed or transferred without an EUA.

Section 2. Conditions for the Issuance of EUA. An EUA on a COVID-19 drug or vaccine shall be issued and remain valid only when all of the following circumstances are present:

- i. Based on the totality of evidence available, including data from adequate and well-known controlled trials, it is reasonable to believe that the drug or vaccine may be effective to prevent, diagnose or treat COVID-19;
- ii. The known and potential benefits of the drug or vaccine when used to diagnose, prevent or treat COVID-19 outweigh the known and potential risks of the drug or vaccine, if any; and
- iii. There is no adequate, approved and available alternative to the drug or vaccine for diagnosing, preventing or treating COVID-19.

Section 3. Applications for EUA. An application for the issuance of an EUA shall be submitted by the industry or government agency concerned, such as the national procurer or the public health program implementer.

The application should demonstrate compliance with current Good Manufacturing Practices, and accompanied by an undertaking by the manufacturer to complete the development of the drug and vaccine, among others.

Section 4. Reliance and Recognition. In evaluating applications for EUA, the FDA Director General shall have the power to implement reliance and recognition processes for emergency use of drugs and vaccines. For this purpose, the FDA Director General may accept the regulatory decision of the WHO, US-CDC, or other internationally recognized and established regulatory authorities.

Section 5. Expert Panel. The FDA shall convene a panel composed of experts on drug and vaccine development, which shall conduct a review of available data on the safety and effectiveness of a COVID-19 drug or vaccine applied for an EUA. After review, the panel shall submit to the FDA Director General its report and recommendations on the application for EUA.

Section 6. Validity of the EUA. An EUA issued pursuant to this Order shall be valid only within the duration of the declared public health emergency due to COVID-19, without prejudice to the discretion of the FDA Director General to revisit or revoke the same, as may be appropriate, to protect the general public health and safety.

Section 7. Post-Authorization Monitoring. The FDA, together with other concerned offices of the DOH, shall conduct post-authorization monitoring to track product deployment, additional relevant information, and the status from the manufacturer concerning full-product life-cycle. The holder of an EUA shall be required to complete specific pharmacovigilance obligations, with a view to providing comprehensive data confirming a positive benefit-risk balance.

Section 8. Implementing Guidelines. The FDA shall formulate and issue guidelines, as may be necessary, for the effective implementation of this Order.

Section 9. Reports. The FDA shall submit to the President, through the DOH, a monthly report on the implementation of this Order.

Section 10. Separability. If any part or provision of this Order shall be held unconstitutional or invalid, the other parts or provisions not affected thereby shall continue to be in full force and effect.

Section 11. Effectivity. This Order shall take effect immediately upon publication in the Official Gazette or in a newspaper of general circulation.

DONE, in the City of Manila, this 1st day of December in the Year of our Lord, Two Thousand and Twenty.

By the President:




SALVADOR C. MEDIALDEA
Executive Secretary

