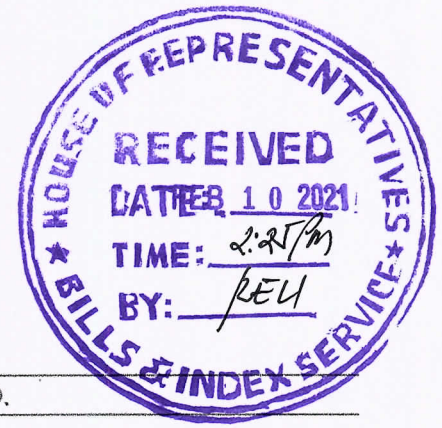


Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
Second Regular Session

HOUSE BILL NO. 8666



Introduced by: Hon. Angelina "Helen" D.L. Tan, M.D.

AN ACT

AUTHORIZING THE DIRECTOR GENERAL OF THE FOOD AND DRUG ADMINISTRATION TO ISSUE EMERGENCY USE AUTHORIZATION, FURTHER AMENDING REPUBLIC ACT NO. 3720, OTHERWISE KNOWN AS THE "FOOD, DRUG, AND COSMETIC ACT," AS AMENDED BY REPUBLIC ACT NO. 9711, OTHERWISE KNOWN AS THE "FOOD AND DRUG ADMINISTRATION (FDA) ACT OF 2009"

EXPLANATORY NOTE

The 1987 Constitution of the Republic of the Philippines mandates the State to protect and promote the health of the people and instill health consciousness among them (Article II, Section 15). The State is further mandated to adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost (Article XIII, Section 11).

Republic Act No. 3720, otherwise known as the "Food, Drug and Cosmetic Act," as amended by Executive Order No. 175, s. 1987, and Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009," mandate the Food and Drug Administration (FDA) to establish and maintain a drug regulatory system to ensure the purity, safety, efficacy and quality of drugs and vaccines in the country.

Section 21 of R.A. 3720, as amended, provides that any new drug should have an authorization from the FDA based on an application containing full reports of investigations to show whether or not such drug is safe, efficacious and of good quality for use based on clinical studies, prior to manufacture, sale, importation, exportation, distribution or transfer thereof.

Pursuant to Proclamation Nos. 922 (s. 2020) and 1021 (s. 2020), the Philippines was declared under a State of Public Health Emergency, and a State of Calamity due to the COVID-19 pandemic. Subsequently, Republic Act No. 11494 or the "Bayanihan to Recover as One Act" was enacted authorizing the President to suppress the COVID-19 pandemic through the procurement of drugs and vaccines.

Inasmuch as no registered drug and vaccine exist for COVID-19 in the country, President Rodrigo Roa Duterte issued Executive Order No. 121 on 01 December 2020 entitled "Granting Authority to the Director General of the Food and Drug Administration to Issue Emergency Use Authorization (EUA) for COVID-19 Drugs and Vaccines, Prescribing Conditions therefore and for other Purposes." E.O. 121 gave authority to the Director General of the FDA to issue an EUA and established the conditions under which said authorization may be issued.

The Department of Health (DOH) has welcomed the issuance of E.O. 121 and on such basis, FDA has granted EUA for the COVID-19 vaccine from Pfizer on 14 January 2021. FDA Director General Eric Domingo said that the interim data from the phase 3 trial shows that the vaccine from Pfizer has an efficacy of 95 percent in the study population and at least 92 percent among all racial groups. He said the application from Pfizer satisfied the requirements for acquiring an EUA in the Philippines.¹

E.O. 121 provides that an EUA for a COVID-19 drug or vaccine shall only be issued when all three circumstances are present: (1) It is reasonable to believe that the drug or vaccine may be effective to prevent, diagnose or treat COVID-19; (2) The known and potential benefits of the drug or vaccine when used to diagnose,

¹FDA grants emergency use authorization for Pfizer COVID-19 vaccine, Cathrine Gonzales, Inquirer, January 14, 2021 (<https://newsinfo.inquirer.net/1383596/fwd-break-fda-grants-eua-to-pfizer-covid-19-vaccine-2#ixzz6lwqXiy2K>) Accessed 10 February 2021

prevent or treat COVID-19 outweigh the known and potential risks of the drug or vaccine if any; and (3) There is no adequate, approved and available alternative to the drug or vaccine for diagnosing, preventing or treating COVID-19.

In the Philippines, the FDA is the sole agency authorized to regulate health products and issue authorization. Existing laws, however, do not provide for the grant of EUA by the FDA. Albeit E.O. 121 granted the Director General of the FDA the authority to issue EUA for COVID-19 drugs and vaccines, it may be inadequate to grant the FDA with such authority inasmuch as executive orders cannot amend, revise, repeal, or in any manner, alter what is stated under existing laws passed by Congress.

Also, the provision on procurement of COVID-19 drugs and vaccines under Section 12 of Republic Act No. 11494, otherwise known as the "Bayanihan to Recover as One Act," neither authorizes the FDA Director General to grant EUA to pharmaceutical companies. Although the FDA and the Health Technology Assessment Council (HTAC) are empowered to determine the minimum standards for the distribution of medications and vaccines, the law did not contemplate granting the FDA the authority to issue EUA for the procurement of COVID-19 vaccines.

An EUA is a risk-based procedure for assessing unlicensed (under development) vaccines, therapeutics during public health emergencies of international concern such as the COVID-19 pandemic. It aims to expedite the availability of vaccines and therapeutics to people affected by a public health emergency and is based on essential set of available quality, safety, and efficacy performance data.

The eligibility criteria of a product to apply for an EUA requires that the disease may cause an outbreak, epidemic or pandemic and that there are no products available capable of eradicating or preventing the disease. Likewise, it requires that products are manufactured in compliance with good manufacturing practices and that the applicant undertakes to complete the development of the product and apply for prequalification once it is licensed.

The World Health Organization (WHO) recommends as part of its regulatory preparedness and response in a pandemic to have regulatory frameworks with laws and/or policies that permit EUA for medicines and pandemic preparedness plan that acknowledges EUA, among others.

To date, countries that have existing mechanisms similar to an EUA include the US FDA, China National Medicinal Products Administration, European Medicines Agency (Conditional Marketing Authorization), Australia Therapeutic Goods Administration (Provisional pathway), and Japan Pharmaceuticals and Medicinal Devices Agency (Conditional Early Approval System).²

This bill seeks to address the lack of authority to grant EUA under the existing FDA law by amending R.A. 3720, as amended, in order to define EUA and provide the parameters for its issuance.

It is hoped that this important health measure will not only give legitimacy to the circulars issued by the FDA on EUA but also ensure accelerated and smoother procurement and distribution of vaccines to the Filipino people during a public health emergency.

In view of the foregoing, the approval of this bill is earnestly sought.



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4th District, Quezon

² FAQs: Emergency Use Authorization, Department of Health (<https://doh.gov.ph/faqs/emergency-use-authorization>)
Accessed on 10 February 2021

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Be it enacted by the Senate and the House of Representatives of the Philippines in Congress assembled:

SECTION 1. Section 10 of Republic Act No. 3720, as amended, is hereby further amended to include new subsections (nn), (oo), (pp), (qq), and (rr) to read as follows:

"SEC. 10. For the purposes of this Act, the term:

"XXX

"(NN) 'EMERGENCY USE AUTHORIZATION' MEANS THE AUTHORITY ISSUED BY THE FDA DIRECTOR GENERAL, ALLOWING UNAPPROVED HEALTH PRODUCTS TO BE USED DURING A PUBLIC HEALTH EMERGENCY OR THREAT, TO DIAGNOSE, TREAT, OR PREVENT SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS WHEN THERE ARE NO ADEQUATE, APPROVED, AND AVAILABLE ALTERNATIVE HEALTH PRODUCTS. THE EMERGENCY USE MAY EITHER BE FOR AN UNAPPROVED HEALTH PRODUCT OR UNAPPROVED USE OF AN APPROVED HEALTH PRODUCT.

"(OO) 'UNAPPROVED HEALTH PRODUCT' MEANS A HEALTH PRODUCT THAT IS NOT APPROVED BY, LICENSED, OR REGISTERED WITH THE FDA AND, THEREFORE, NOT COVERED BY ANY PERMIT, LICENSE, CERTIFICATION, OR ACCREDITATION ISSUED BY THE SAID AGENCY FOR ITS MANUFACTURE, IMPORTATION, EXPORTATION, SALE, OFFER FOR SALE, DISTRIBUTION, TRANSFER, AND/OR WHERE APPROPRIATE, THE USE, TESTING, PROMOTION, ADVERTISING, AND SPONSORSHIP THEREOF.

"(PP) 'UNAPPROVED USE OF AN APPROVED HEALTH PRODUCT' MEANS A HEALTH PRODUCT THAT IS APPROVED BY, LICENSED, OR REGISTERED WITH THE FDA, BUT WHICH INTENDED EMERGENCY USE IS NOT AMONG THOSE APPROVED UNDER ITS CERTIFICATE OF PRODUCT REGISTRATION, MARKET AUTHORIZATION, OR ANY OFFICIAL LICENSE ISSUED BY THE FDA.

"(QQ) 'PUBLIC HEALTH EMERGENCY' MEANS, PURSUANT TO REPUBLIC ACT NO. 11332, OTHERWISE KNOWN AS THE "MANDATORY REPORTING OF NOTIFIABLE DISEASES AND HEALTH EVENTS OF PUBLIC HEALTH CONCERN ACT," AN OCCURRENCE OR IMMINENT THREAT OF AN ILLNESS OR HEALTH CONDITION THAT:

"(1) IS CAUSED BY ANY OF THE FOLLOWING:

"(I) BIO TERRORISM;

"(II) APPEARANCE OF A NOVEL OR PREVIOUSLY CONTROLLED OR ERADICATED INFECTIOUS AGENT OR BIOLOGICAL TOXIN;

"(III) A NATURAL DISASTER;

“(IV) A CHEMICAL ATTACK OR ACCIDENTAL RELEASE;

“(V) A NUCLEAR ATTACK OR ACCIDENT; OR

“(VI) AN ATTACK OR ACCIDENTAL RELEASE OF RADIOACTIVE MATERIALS; AND

“(2) POSES A HIGH PROBABILITY OF ANY OF THE FOLLOWING:

“(I) A LARGE NUMBER OF DEATHS IN THE AFFECTED POPULATION;

“(II) A LARGE NUMBER OF SERIOUS INJURIES OR LONG-TERM DISABILITIES IN THE AFFECTED POPULATION;

“(III) WIDESPREAD EXPOSURE TO AN INFECTIOUS OR TOXIC AGENT THAT POSES A SIGNIFICANT RISK OF SUBSTANTIAL HARM TO A LARGE NUMBER OF PEOPLE IN THE AFFECTED POPULATION;

“(IV) INTERNATIONAL EXPOSURE TO AN INFECTIOUS OR TOXIC AGENT THAT POSES A SIGNIFICANT RISK TO THE HEALTH OF CITIZENS OF OTHER COUNTRIES; OR

“(V) TRADE AND TRAVEL RESTRICTIONS;

“(RR) ‘PUBLIC HEALTH THREAT’ MEANS, PURSUANT TO R.A. NO. 11332, ANY SITUATION OR FACTOR THAT MAY REPRESENT A DANGER TO THE HEALTH OF THE PEOPLE.”

SEC. 2. A new Chapter XV and six (6) new sections, Sections 38, 39, 40, 41, 42, and 43 shall be included to R.A. No. 3720, as amended, which shall read as follows:

“CHAPTER XV EMERGENCY USE AUTHORIZATION

“SEC. 38. SCOPE OF AUTHORIZATION. - AN EUA ISSUED PURSUANT TO THIS ACT SHALL STATE:

“(1) EACH DISEASE OR CONDITION THAT THE HEALTH PRODUCT MAY BE USED TO DIAGNOSE, PREVENT, OR TREAT WITHIN THE SCOPE OF THE AUTHORIZATION;

“(2) THE FDA DIRECTOR GENERAL'S FINDINGS THAT THE KNOWN AND POTENTIAL BENEFITS OF THE HEALTH PRODUCT, WHEN USED TO DIAGNOSE, PREVENT, OR TREAT SUCH DISEASE OR CONDITION, OUTWEIGH THE KNOWN AND POTENTIAL RISKS OF THE PRODUCT; AND

“(3) THE FDA DIRECTOR GENERAL'S FINDINGS, CONCERNING THE SAFETY AND POTENTIAL EFFECTIVENESS OF THE HEALTH PRODUCT IN DIAGNOSING, PREVENTING, OR TREATING SUCH DISEASES OR CONDITIONS, INCLUDING, TO THE EXTENT PRACTICABLE, GIVEN THE CIRCUMSTANCES OF THE EMERGENCY, AN ASSESSMENT OF THE AVAILABLE SCIENTIFIC EVIDENCE.

“SEC. 39. CRITERIA FOR ISSUANCE OF AN EUA. - THE ISSUANCE OF AN EUA UNDER THIS ACT BY THE FDA DIRECTOR GENERAL IS JUSTIFIED, ONLY IF, AFTER CONSULTATION WITH THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF SCIENCE AND TECHNOLOGY, AND OTHER CONCERNED GOVERNMENT AGENCIES, THE FDA DIRECTOR GENERAL CONCLUDES THAT:

“(1) A BIOLOGICAL, CHEMICAL, RADIOLOGICAL, OR NUCLEAR AGENT OR ANY AGENT THAT MAY CAUSE A SERIOUS OR LIFE-THREATENING DISEASE OR CONDITION EXISTS;

“(2) BASED ON THE TOTALITY OF SCIENTIFIC EVIDENCE AVAILABLE TO THE FDA DIRECTOR GENERAL, INCLUDING DATA FROM ADEQUATE AND WELL-CONTROLLED CLINICAL TRIALS, IF AVAILABLE, IT IS REASONABLE TO BELIEVE THAT:

“i. THE HEALTH PRODUCT, FOR WHICH AN EUA WILL BE ISSUED, MAY BE EFFECTIVE IN DIAGNOSING, TREATING, OR PREVENTING SERIOUS OR LIFE-THREATENING DISEASE OR CONDITION DURING A PUBLIC HEALTH EMERGENCY OR THREAT; AND

"ii. THE KNOWN AND POTENTIAL BENEFITS OF THE SAID HEALTH PRODUCT, WHEN USED TO DIAGNOSE, PREVENT, OR TREAT SUCH DISEASE OR CONDITION, OUTWEIGH THE KNOWN AND POTENTIAL RISKS OF THE PRODUCT;

"(3) THERE IS NO ADEQUATE, APPROVED, AND AVAILABLE ALTERNATIVE TO THE HEALTH PRODUCT FOR DIAGNOSING, PREVENTING, OR TREATING A DISEASE OR CONDITION DURING THE EXISTENCE OF A PUBLIC HEALTH EMERGENCY OR THREAT; AND

"(4) ALL REQUIREMENTS FOR THE ISSUANCE OF AN EUA UNDER THIS ACT AND OTHER PERTINENT REGULATIONS AND ISSUANCES ARE SATISFIED.

"SEC. 40. DECLARATION BY THE DIRECTOR GENERAL OF THE FDA. - THE FDA DIRECTOR GENERAL SHALL CONDUCT A SEPARATE AND INDEPENDENT DETERMINATION AND, THEREAFTER, ISSUE A DECLARATION ON SAID FINDINGS, PRIOR TO THE GRANT OF AN EUA. THE DETERMINATION AND DECLARATION SHALL BE SEPARATE FROM THE DECLARATION OF A PUBLIC HEALTH EMERGENCY BY THE NATIONAL GOVERNMENT. LIKEWISE, THEY SHOULD SATISFY THE CRITERIA ENUMERATED UNDER THE IMMEDIATELY PRECEDING SECTION AND ALL OTHER REQUIREMENTS PROVIDED FOR BY THIS ACT.

"SEC. 41. DURATION OF AUTHORIZATION. - AN EUA UNDER THIS SECTION SHALL BE EFFECTIVE UNTIL THE TERMINATION OF THE DECLARATION ISSUED PURSUANT TO THE PRECEDING SECTION OR A REVOCATION AS PROVIDED FOR UNDER THE SUCCEEDING SECTION.

"SEC. 42. REVIEW AND REVOCATION OF AUTHORIZATION. - THE FDA DIRECTOR GENERAL SHALL PERIODICALLY REVIEW THE CIRCUMSTANCES AND THE APPROPRIATENESS OF ALL EUA ISSUED PURSUANT TO THIS ACT.

"THE FDA DIRECTOR GENERAL MAY, WHEN NECESSARY, REVISE OR REVOKE AN EUA UPON THE OCCURRENCE ANY OF THE FOLLOWING CIRCUMSTANCES:

"(a) THE PUBLIC HEALTH EMERGENCY OR THREAT, AS MAY BE DETERMINED BY THE NATIONAL GOVERNMENT, NO LONGER EXISTS;

"(b) THE CRITERIA UNDER SECTION 39 OF THIS ACT FOR THE ISSUANCE OF AN EUA ARE NO LONGER SATISFIED; OR

"(c) OTHER CIRCUMSTANCES MAKE SUCH REVISION OR REVOCATION APPROPRIATE TO PROTECT PUBLIC HEALTH OR SAFETY.

"SEC. 43. EMERGENCY USE INSTRUCTIONS. - THE FDA SHALL, IN CONSULTATION AND COORDINATION WITH THE DOH, THE DOST, AND OTHER RELEVANT AGENCIES, ISSUE EMERGENCY USE INSTRUCTIONS TO INFORM HEALTH CARE PROVIDERS AND INDIVIDUALS, TO WHOM AN ELIGIBLE HEALTH PRODUCT UNDER THIS ACT IS TO BE ADMINISTERED, CONCERNING SUCH PRODUCT'S EUA."

SEC 3. *Separability Clause.* - If any provision of this Act is declared unconstitutional or invalid, other sections or parts thereof not affected thereby shall remain in full force and effect.

SEC 4. *Repealing Clause.* - All laws, decrees, executive orders, rules, and regulations, or parts thereof, inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

SEC. 5. *Effectivity Clause.* - This Act shall take effect fifteen (15) days after its complete publication in the Official Gazette or in at least one (1) newspaper of general circulation.

Approved,