JOINT MEMORANDUM CIRCULAR NO. 1
Series of 2021

SUBJECT: **ESTABLISHMENT OF A GREEN LANE FOR SECURING PERMITS, LICENSES, AND AUTHORIZATIONS FOR THE ESTABLISHMENT AND OPERATION OF A BULK IMPORT, FILL, AND FINISH LOCAL CORONAVIRUS DISEASE 2019 (COVID-19) VACCINE MANUFACTURING FACILITY AND FOR THE REGISTRATION FOR AVAILMENT OF INCENTIVES**

DATE: **19 May 2021**

SECTION 1. BACKGROUND

1.1. It is the priority of the State to ensure that the lives of the Filipino people, especially the underprivileged, poor and marginalized, frontliners, health care providers, police officers and soldiers, and those in the essential services shall be protected from the Coronavirus Disease 2019 (COVID-19) by ensuring accessibility and adequacy in the supply of related drugs and vaccines.

1.2. In his national address last 15 April 2021, President Rodrigo Roa Duterte called for the establishment of a Green Lane for the processing of permits relative to the establishment of local COVID-19 vaccine manufacturers. He directed the Anti-Red Tape Authority (ARTA) to coordinate with concerned agencies to ensure that the review, processing, and issuance of necessary permits for COVID-19 vaccine manufacturing facilities in the country are streamlined and expedited.

1.3. This directive stemmed from the report by Department of Trade and Industry (DTI) Secretary Ramon M. Lopez that vaccine manufacturing proponents expressed their interest in putting up manufacturing facilities in the country. DTI recommended the establishment of a Green Lane to expedite the permitting process to encourage local commercialization and manufacturing of vaccines.

1.4. Given the clear and present risk to the health and lives of the general public brought about by COVID-19 and the urgent need to address the public's need for quality, safe, and effective medicines for the disease, the need to deliver government services in a timely and effective manner is paramount. The speedy processing and streamlining of necessary permits, licenses and authorizations for the establishment and operation of local vaccine

manufacturing facilities is vital in order to address this demand and enable government procurement of locally produced vaccines subject to standards, specifications, and prices in order to lessen the Philippine's dependency on vaccine importation.

SECTION 2. PURPOSE

The overall objectives of this Joint Memorandum Circular (JMC) are the following:

2.1. To create a Green Lane that would set the expedited and streamlined process and requirements in the issuance of permits, licenses, and authorizations relative to the establishment and operation of a bulk import, fill and finish local COVID-19 vaccine manufacturing facility.

2.2. To provide for the facilitated registration in the availment of incentives for a bulk import, fill and finish local COVID-19 vaccine manufacturing facility.

SECTION 3. LEGAL BASES

3.1. 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.

3.2. 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.

3.3. Presidential 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.

3.4. Section 3 (c) and (j) of Republic Act (RA) No. 11494 or the "*Bayanihan to Recover as One Act*" declared 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.

3.5. Section 4 (eee) of R.A. No. 11494 authorizes the President of the Republic of the Philippines to exercise powers that are necessary and proper to undertake and implement COVID-19 response and recovery intervention which includes the issuance of a directive that all government agencies and Local Government Units (LGUs) **shall act on all pending and new applications for resolutions within a non-extendible period of seven (7) working days,** in order to support business continuity and encourage resumption of all economic activities: *Provided,* that the applicant shall be allowed to undertake its compliance to any additional requirement that may be imposed by the

government agency or LGU and such will not delay the approval of the application.

3.6. Section 4 (cc) R.A. No. 11494 authorizes the President of the Republic of the Philippines to liberalize the grant of incentives for the manufacture or importation of critical needed equipment or supplies for the carrying-out of the policy declared therein, including healthcare equipment and supplies.

3.7. Section 4 of Republic Act No. 3720, as amended by Republic Act No. 9711 or the *Food and Drug Administration (FDA) Act of 2009"* provides that the FDA has the authority (i) to issue certificates of compliance with technical requirements to serve as basis for the issuance of appropriate authorization and spot-check for compliance with regulations regarding operation of manufacturers, importers, exporters, distributors, wholesalers, drug outlets, and other establishments and facilities of health products, as determined by FDA; (ii) to conduct appropriate tests on all applicable health products prior to issuance of appropriate authorizations to ensure safety, efficacy, purity and quality; and (iii) to develop and issue standards and appropriate authorizations that would cover establishments, facilities, and health products.

3.8. Executive Order No. 121 series of 2020 granted authority to the Director General of the FDA to issue an **Emergency Use Authorization (EUA) for COVID-19 drugs and vaccines** subject to conditions provided in the order. The Executive Order also provides that "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, distributed or transferred without an EUA".

3.9. Section 2 of Republic Act No. 11517, *An Act Authorizing the President to Expedite the Processing and Issuance of National and Local Permits, License and Certifications In Times of National Emergency* provides that notwithstanding any law, decree, order or ordinance to the contrary, the President in times of national emergency shall have the authority to: (i) accelerate and streamline regulatory processes and procedures for new and pending applications and renewals of permits, licenses, clearances, certifications or authorizations, including fixing or shortening the periods provided for under existing laws, regulations, issuances, and ordinances; (ii) Suspend or waive the requirements in securing such permits, licenses, clearances, certifications or authorizations; and (ii) in consultation with or upon the recommendation of the affected government agencies, may prescribe to be permanent the streamlined regulatory processes and procedures, and the **suspension or waiver of the requirements in securing permits, licenses, clearances, and certifications or authorizations:** *provided, That* the authority herein granted under subparagraphs (a), (b), and (c) of this section shall not be used to undermine the existing procedures and processes, under applicable laws, rules and regulations, meant to protect the environment, especially those that aim to safeguard protected area and its buffer zones, and environmentally critical areas.

3.10. Section 2 of Republic Act No. 11534, the *Corporate Recovery and Tax Incentives for Enterprises Act* or CREATE provides that it is hereby declared the policy of the State to develop the national economy towards global competitiveness by implementing tax policies instrumental in attracting investments, which will result in productivity enhancement, employment generation, countrywide development, and a more inclusive economic growth, while at the same time maintaining fiscal prudence and stability. To achieve these objectives, the State shall: (i) improve the equity and efficiency of the corporate tax system by lowering the rate, widening the tax base, and reducing tax distortions and leakages; (ii) develop, subject to the provisions of this Act, a more responsive and globally-competitive tax incentives regime that is performance-based, targeted, time-bound, and transparent; (iii) provide support to businesses in their recovery from unseen events such as an outbreak of communicable diseases or a global pandemic, and strengthen the nation's capability for similar circumstances in the future; and (iv) create a more equitable tax incentive system that will allow for inclusive growth and generation of jobs and opportunities in all regions of the country, and ensure access and ease in the grant of these incentives especially for applicants in lease developed areas.

3.11. Section (a) and (f) of Republic Act No. 9485, as amended by Republic Act No. 11032 or the *Ease of Doing Business and Efficient Government Service Delivery Act of 2018* provides that the Anti-Red Tape Authority (ARTA) has the authority (i) to implement and oversee a national policy on anti-red tape and ease of doing business and (ii) to recommend policies, processes and systems to improve regulatory management to increase the productivity, efficiency, and effectiveness of business permitting and licensing agencies. Pursuant thereto, ARTA is spearheading the implementation of the National Effort for the Harmonization of Efficiency Measures of Interrelated Agencies or the NEHEMIA Program. It is a sectoral based inter-agency streamlining effort that aims to reduce fifty-two percent (52%) of processing time, costs, requirements or procedures within fifty-two (52) weeks in 2020, for key sectors of the society. One of the key sectors of NEHEMIA is the Food and Pharma Sector.

3.12. **Presidential Directive No. 2021-029, dated 19 April 2021, was issued directing ARTA to coordinate with the Department of Health (DOH), Department of Science and Technology (DOST), Department of Trade and Industry (DTI),** and other concerned agencies to ensure that the review, processing, and issuance of necessary permits and clearances **for the establishment of COVID-19 vaccine manufacturing facilities in the country are streamlined and expedited,** subject to existing laws, rules, and regulations, and ordering ARTA to submit a report on its compliance with the directive not later than fifteen (15) days upon receipt thereof.

SECTION 4. SCOPE/ COVERAGE

This Joint Memorandum Circular covers the Central and Regional Field Offices of the Field Regulatory Operations Office of the Food and Drug Administration (FDA), the Department of Trade and Industry - Board of Investments (DTI-BOI), Department of

Health (DOH), Department of Science and Technology (DOST), the National Task Force (NTF) Against COVID-19, and the Anti-Red Tape Authority (ARTA).

It shall apply to enterprises that intend to establish and operate a bulk import, fill and finish local COVID-19 vaccine manufacturing facility in the country that will produce a shared product as defined in this JMC.

This JMC may be revised, amended or expanded to cover other business models for local manufacturing of COVID-19 vaccines and other related vaccines and drugs.

SECTION 5. DEFINITION OF TERMS

For purposes of this JMC, the following definitions shall apply, unless otherwise stated:

a. *Bulk import, fill, and finish model* – This business model for vaccine manufacturing entails that local companies will partner with pharmaceutical or biological manufacturers, subject to approval by the FDA. Bulk supplies of vaccines will be imported from abroad and the local companies will fill and package vials locally for distribution.[1]

b. *Critical Deficiency* - shall refer to a Good Manufacturing Practice (GMP) requirement that needs to be complied since non-compliance may result to significant risk of producing either a finished product which is unsafe when used in patients or a finished product that may contain harmful by-products.

c. *Emergency Use Authorization (EUA)* - is an authorization issued for unregistered drugs and vaccines in a public health emergency. The EUA is not a Certificate of Product Registration (CPR) or a marketing authorization. The evaluation process of the product may be facilitated by reliance and recognition principles, but stricter conditions on the use and monitoring following authorization shall be imposed.[2]

d. *Good Manufacturing Practice (GMP)* - Good Manufacturing Practice is that part of quality assurance which ensures that products, including vaccines and biologics, are consistently produced and controlled to the quality standards appropriate for their intended use, including all phases of vaccine clinical trials, and as required by registration and marketing authorization.

e. *Good Laboratory Practices (GLP)* – Good Laboratory Practice are standards and procedures whereby the laboratory achieves a defined, consistent and reliable standard in performing laboratory test and activities.

f. *Initial Application* – refers to the License to Operate (LTO) applied to the FDA prior to engaging in the business or operation involving the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where

[1] Minutes of the 2nd Stakeholder Consultation re: Institutionalization of Green Lane for the Permitting of Local COVID-19 Manufacturers dated 26 April 2021
[2] Food and Drug Administration Circular No. 2020-36

applicable the use, testing, promotion, advertisement, and/or sponsorship of health products.[3]

g. *Packer/Repacker* - refers to any establishment that packs or repacks a finished product into small quantities in a separate container and/or secondary packaging, including but not limited to relabelling, stickering, and bundling for promo packs with the end view of storage, distribution, or sale of the product.[4]

h. *Risk Management Plan* – refers to the document that contains the details on how to identify, characterize, prevent or minimize the risk relating to the products that the establishment is engaged in. It shall include post-market surveillance activities and interventions to manage identified risks.[5]

i. *Site Master File* – refers to the specific information about the quality assurance the production and/or quality control of manufacturing operations carried out at the named site and any closely integrated operations at adjacent and nearby buildings. If only part of an operation is carried out on site, a Site Master File need only describe those operations, e.g. analysis, packaging, etc.[6]

j. *Lot / Sub- Lot* – a defined quantity of starting material, packaging material or product, processed in a single process or series of processes so that the quantity is expected to be homogeneous. It may sometimes be necessary to divide a lot into a number of sub- lots, which are later brought together to form a final homogeneous lot. In continuous manufacture, the lot must correspond to a defined fraction of the production, characterized by its intended homogeneity. The lot size can be defined either as a fixed quantity or as the amount produced in a fixed time period.

k. *Lot Release* – refers to the process of the FDA evaluation of an individual lot of a licensed vaccine before giving approval for its release on the market.

l. *Shared Product* – refers to a finished product whose final phase of production, including labeling, is done by a local manufacturer using biological materials, including naked or bulk biologic products, produced by another manufacturer. It also refers to a finished product whereby some of the active components, as in mied vaccines, were processed by another manufacturer of laboratory. A shared product is a locally produced or manufactured biologic product.

m. *Stability Testing* – this is done to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors, such as temperature, humidity, and light; and to establish a retest period for the drug substance or a shelf life for the drug product and recommended storage conditions

[3] Department of Health Administrative Order No. 2020-0017
[4] *Id.*
[5] *Id.*
[6] *Id.*

n. *Summary Lot Protocol* – refers to a document summarizing all manufacturing steps and test results for a lot of vaccine, which is certified and signed by the responsible and accountable person of the manufacturing. The FDA and manufacturer shall be guided by the WHO Technical Report Series 978, Annex 2. Guidelines for Independent Lot Release of Vaccines by Regulatory Authorities.

o. *Technology Transfer Arrangement* - refers to contracts/agreements involving the transfer of systematic knowledge for the manufacture of a product, the application of a process, rendering of a service including management contracts; and the transfer, assignment or licensing of all forms of intellectual property rights, including licensing of computer software except computer software developed for mass market, as defined under Section 4.2. Part I of the Intellectual Property Code.

p. *Vaccine Manufacturing Proponents* - The private sector entity/entities which shall have contractual responsibility for the establishment of vaccine manufacturing facilities, and which shall have an adequate financial base to implement said project consisting of equity and firm commitments from reputable financial institutions to provide, upon award, sufficient credit lines to cover the total estimated cost of the project.[7]

SECTION 6. GREEN LANE GUIDELINES

6.1. A Green Lane is hereby established which provides for the use of facilitated registration and evaluation pathway for permits, licenses, and authorizations relative to the establishment and operation of a bulk import, fill and finish local COVID-19 vaccine manufacturing facility, including the distribution or transfer of the shared COVID-19 vaccine product produced therefrom.

6.2. FDA shall adopt the same guidelines for Emergency Use Authorization, following Executive Order No. 121 s. 2020 and its implementing guidelines provided in FDA Circular No. 2020-036, and Facilitated Registration Pathways, provided for under Department of Health Administrative Order No. 2020-0045, in the review of the application for permits, licenses, and authorizations covered by this JMC.

6.3. FDA shall likewise consider the submission post-approval of critical deficiencies found after inspection, subject to guidelines to be issued by the agencies.

6.4. FDA shall assign a dedicated staff for licensing, authorization, and/or registration who will assist the applicant throughout the entire process. Interaction with the applicant in the processing of the applications covered herein shall not be considered a violation of the Zero-Contact Policy when the inspection or meeting with the applicant is an integral part of the application

[7] Implementing Rules and Regulations of Republic Act No. 6957, as amended by Republic Act No. 7718, An Act Authorizing the Financing, Construction, Operation, and Maintenance of Infrastructure Projects by the Private Sector and for Other Purposes.

process for a complex or highly technical transaction or when such interaction was done upon the written request of the applicant; *Provided,* that inspection or meeting may be recorded with prior consent of the applicant and shall be properly documented through various means such as, but not limited to, recording the minutes of the meeting and signing of an attendance sheet.[8]

6.5. **Green Lane for License to Operate (LTO) as Vaccine Manufacturer**
FDA and applicants shall observe the following process flow and processing time:

6.5.1. **Pre-Site Inspection**

1. Applicant submit a letter to the FDA Director General requesting for a Pre-Site Inspection with an attached blueprint. For facilities that are already manufacturing vaccine products (e.g. for R and D purposes), the Site Master File shall be attached to the letter. For applicants who wish to locally manufacture a shared product, the Contract or Agreement with the foreign vaccine manufacturer shall be submitted.

2. FDA GMP Inspectors for vaccine and biological plant facilities shall immediately conduct a Pre-Site Inspection. A report shall be prepared on the findings by the GMP Inspectors and recommendations shall be made. Depending on the findings and recommendation, requests for inspections to the Office of the Director General may be made prior to the application for a LTO.

6.5.2. **Application for a License to Operate (LTO) as Vaccine Manufacturer**
(Processing time: maximum twenty (20) working days)

The application and requirements shall be fled with the Center for Drug Regulation and Research of the FDA.

1. **Requirements** shall be based on FDA Administrative Order No. 2020-0017
   i. Accomplished e-Application Form
   ii. Proof of Business Registration
   iii. Proof of Income (Latest Audited Financial Statement with Balance Sheet) or duly notarized Statement/Certification of Initial Capitalization
   iv. Proof of payment of fees
   v. Site Master File (updated)
   vi. Risk Management Plan, which shall be presented to the FDA inspectors during inspection

[8] Section 2, Rule V of the Implementing Rules and Regulations of R.A. No. 11032.

2. **Process.** The following process and maximum processing time shall be observed:

STEP	ACTION	PROCESSING TIME	PROCESS OWNER
1	Online Application – Assessment of Application and Requirements	3 Working Days	CDRR
2	Receive Order of Payment	1 Working Day	AFS
3	Payment – Posting of Payment – Acknowledgement of Payment	1 Working Day	AFS
4	Scheduling of Inspection	1 Working Day	FROO
5	Inspection	7 Working Days	FROO
6	If found non-compliant, the establishment is given time to comply and submit Corrective Action and Preventive Plan (CAPA) If compliant, proceed to Step 8	-stop clock-	FROO
7	CAPA Review	3 Working Days	FROO
8	Preparation of Recommendation (Certificate of Compliance or COC)	1 Working Day	FROO
9	COC Approval	1 Working Day	FROO
10	Center evaluation	1 Working Day	CDRR
11	LTO approval and issuance	1 Working Day	CDRR

3. For the purpose of determining compliance to GMP as Vaccine Manufacturer, Administrative Order (AO) No. 2012-008, or the rules on the “Adoption and Implementation of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) Guide for Good Manufacturing Practice (GMP) for Medicinal Products”, shall be used as the standard and guide. The PIC/S Guide to Good

Manufacturing Practice for Medicinal Products (PE 009-14) Annexes is hereby provided: https://www.gmp-compliance.org/files/guidemgr/PE_009_14_GMP_Guide_xAnnexes_.pdf. All updates to the annexes are automatically adopted by the FDA.

4. **FDA Lot Release Certification.** All FDA-licensed manufacturers of vaccines shall submit to FDA the Lot Summary Protocol with the labelled product sample from each and every lot produced by the manufacturer for FDA Lot Release Certification for the purpose of testing the product, the FDA shall accept test results from countries with WHO-recognized vaccine National Control Laboratories like Indonesia and Australia.

   No lot of vaccines produced in the Philippines that has not been Lot Release certified by the FDA and tested by an NCL shall be released.

6.6. **Green Lane for Emergency Use Authorization (EUA) Applications**
The application for Emergency Use Authorization shall be governed by Executive Order No. 121 s. 2020.

6.6.1. **Requirements for the Issuance of EUA for Vaccines for COVID-19**.
Applications for EUA for vaccines shall comply with the following documentary requirements which shall be in the English language:

1. Cover letter requesting to issue an EUA with comprehensive discussions on the public health need for the product;

2. Valid License to Operate (LTO) as vaccine manufacturer-fill and finish issued by FDA. For Drug Manufacturers intending to pack bulk products, a copy of the exclusive/authorized manufacturer agreement between the local manufacturer (packer) and manufacturer of the bulk product shall also be submitted;

3. GMP Certificate or equivalent document issued by the national regulatory authority or other competent regulatory authority.
   i. For drugs or vaccines coming from non-PIC/S countries or non-WHO-Prequalified, the application must be supported by a Foreign current GMP (FcGMP) Certificate following Administrative Order No. 2013-022 (See Annex “B” for list of PIC/S Member Countries).
   ii. For locally packed product, GMP certificate issued by the FDA must cover the manufacture of biologic products/vaccines.

4. List of Countries where the EUA is approved, with proof of approval for emergency use (or equivalent document) from the corresponding approving counterpart NRAs;

i. For locally packed products and for products not listed in Annex C of FC No. 2020-036, the complete quality documents should be submitted.

5. Reports on actual use from the issuance of EUA of approving counterpart NRA to the application for EUA in the Philippine FDA;

6. Complete assessment report including question and answer documents from the approving counterpart NRA;

7. Clinical trial data and results, from the vaccine developer, with the inclusion of racial distribution showing Filipino/Asians/Pacific Islanders;

8. Currently available stability studies and list of ongoing studies;
   i. For locally packed products, stability studies of the product packed in its final form conducted locally and list of ongoing stability studies.

9. Risk Management Plan in accordance with FC No. 2020-03;

10. Summary of Product Characteristics;

11. Summary Lot Protocol;

12. Product labeling with minimum information including name of vaccine, type of vaccine, method of administration, dose per vial, storage, batch or lot number, manufacturing and expiration dates (compliance with Administrative Order No. 2016-0008 or the Revised Rules and Regulations Governing the Generic Labelling Requirements of Drug Products for Human Use shall not be required), and instruction for usage—smart labelling is encouraged; and

13. Proof of Payment of fees for EUA application and, if applicable, Brand Name Clearance.

6.6.2. **Application Process**

1. There shall be no need for the scheduling of submission of applications.

2. Applications shall be filed as Emergency Use Application (EUA) and shall be submitted to the Food and Drug Action Center (FDAC). Submission of applications may be done either:

   i. Submission through FDA ePortal. The applicant may opt to submit the application through the current ePortal of FDA through fdac.pacd.cdrr@fda.gov.ph. Guidance for e-mail submission is provided under FDA Circular No. 2020-026.

ii. Submission through FDA eServices. The applicant may opt to submit the application through FDA eServices upon full operation of the system.

6.6.3. **Fees.** The appropriate fees as prescribed under existing regulations shall apply, including Legal Research Fund (LRF). LRF is equivalent to one percent (1%) of the filing fee imposed, but in no case lower than ten pesos.[9]

Application Type	**Fees**
Emergency Use Authorization	PhP 50,000.00 + LRF

6.6.4. **Post-Approval Compliance.** Post-Approval Compliance shall be strictly required.

1. **Post-Authorization** – Pursuant to Section VI (H) of FDA Circular No. 2020-036, the following shall be submitted within the validity of the EUA, or as prescribed below:

i. Monitoring. The holder of the EUA has the ultimate responsibility for monitoring the safety of their products. These responsibilities include inventory control and maintenance of appropriate storage until delivery, among others.

The FDA together with 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. Post-authorization monitoring shall include adverse events following immunization (AEFI) or adverse drug reactions (ADR).

iii. Commitments of the Holder of the EUA

a. Complete specific pharmacovigilance obligations (ongoing or new studies, or additional activities) with a view to providing comprehensive data confirming a positive benefit-risk balance. Pharmacovigilance obligations shall adhere to the guidelines and subsequent circulars as issued by the FDA;
b. Complete pending studies and trials. The holder of the EUA shall subsequently proceed to a marketing authorization following FDA guidelines on the condition that it has proven to be safe and effective for the proposed indication;
c. Complete unavailable documents or submit additional necessary documents as may be required by FDA, including provision of further data and response to inquiries; and

[9] FDA Circular No. 2020- 036.

d. Secure Lot/Batch Release Certification for all biologicals from the FDA prior to distribution.

iv. Pharmacovigilance. The holder of the EUA shall have a comprehensive pharmacovigilance system for their product following the system or protocol for a registered drug and biological product.

The holder of the EUA shall ensure compliance with the Risk Management Plan (RMP) including additional pharmacovigilance activities. A summary of RMP shall be provided containing information on product safety profile and explain the measures to characterize the risk including ongoing, new studies or additional activities. The summary of RMP shall be published in the FDA website.

v. Post Authorization Changes. Any deviation from or changes to the manufacture and changes in label of the product must be notified with the FDA.

vi. Responsibility of the national procurer and health program implementors. The pharmacovigilance obligations and post-authorization commitments of the holder of the EUA shall be shared by the national procurer and health program implementors to the fullest extent possible and applicable.

2. Post-Market Surveillance (PMS) – Health institutions (Hospitals, other Health Facilities) and healthcare professionals that shall use the products approved under this JMC shall coordinate with and submit to the respective supplier/ Marketing Authorization Holder (MAH) for Adverse Drug Reaction (ADR) reports. The MAH shall be responsible for the submission of the ADR reports consistent with the latest issuance of FDA.

The MAH shall undertake the PMS activities in a separate issuance.

SECTION 7. FACILITATED REGISTRATION FOR INCENTIVES ENTITLEMENT FOR BULK IMPORT, FILL AND FINISH LOCAL COVID-19 VACCINE MANUFACTURERS AND ASSISTANCE IN THE IMPORTATION REQUIREMENTS

7.1. DTI-BOI shall facilitate the expedited registration for the availment of incentives by bulk import, fill, and finish local COVID-19 vaccine manufacturers. Bulk import, fill and finish local COVID-19 vaccine manufacturers may avail of the incentives under Republic Act No. 11534 or the "*Corporate Recovery and Tax Incentives for Enterprises Act*" (CREATE Law) and applicable laws and implementing rules and regulations.

7.2. DTI-BOI, through its Investments Assistance Service, shall provide assistance to the applicant by facilitating the immediate resolution of issues and concerns relating to the establishment and operation of a COVID-19 vaccine manufacturing facility including those related to applicable administrative processes of the Bureau of Customs (BOC) and other concerned government institutions, agencies, and LGUs.

7.3. For this purpose, the BOC shall expedite the processing of the shipments covered herein, including customized equipment for vaccine production, through the Provisional Goods Declaration System (PGDS) under Section 403 of Republic Act No. 10863 or the "*Customs Modernization and Tariff Act*" (CMTA). This is a system wherein the applicant/declarant does not have all the information or supporting documents required to complete the goods declaration, the lodging of goods declaration may be allowed; *Provided,* That it substantially contains the necessary information required by BOC and the declarant undertakes to complete the information or submit the supporting documents within forty five (45) days from the filing of the goods declaration which period may be extended by BOC for another forty five (45) days for valid reasons.

Goods under a Provisional Goods Declaration may be released upon posting of any required security equivalent to the amount ascertained to be the applicable duties and taxes.[10]

SECTION 8. ADVANCE MARKET COMMITMENT FOR COVID-19 VACCINE

8.1. The advanced market commitment order for COVID-19 vaccine shall be covered by Section 3 or Republic Act 11525 or "*An Act Establishing the Coronavirus Disease 2019 (2019) Vaccination Program Expediting the Vaccine Procurement and Administration Process, Providing Funds Therefor, And For Other Purposes*" which provides that, "notwithstanding any law to the contrary, the DOH and the NTF, either through themselves jointly or in cooperation with any national government agency or instrumentality or LGU, are authorized to procure COVID-19 vaccines, including ancillary supplies and services necessary for their storage, transport, deployment, and administration through Negotiated Procurement under Emergency Cases pursuant to Section 53(b) of Republic Act No. 9184 and Section 53.2 of the 2016 Revised Implementing Rules and Regulations of Republic Act No. 9184: *Provided*, That in the procurement of COVID-19 vaccines, the DOH and the NTF shall be authorized to negotiate and approve the terms and conditions thereof in behalf of LGUs and other Procuring Entities including, but not limited to, the price and payment terms, making sure that there is price uniformity and to provide price competition: *Provided*, further, That after the negotiations by the DOH and the NTF, the LGUs and other Procuring Entities are authorized to enter into supply agreement, advanced market commitment, advance payment, research

[10] Section 493 of R.A. 10863 or the Customs Modernization and Tariff Act (CMTA)

investment, purchase order or any similar arrangements or other requirements as may be identified by the DOH and the NTF".

8.2. For purposes of this JMC, the terms and conditions of the advanced market commitment for the COVID-19 vaccine to be manufactured by the bulk import, fill and finish local COVID-19 Vaccine Manufacturers shall be embodied in a separate Memorandum of Agreement between the local Covid-19 vaccine manufacturer and the concerned agencies, which shall include, but not limited to, agreements on the following:

1. Commitment from DOH as to the volume (doses per month) to procure from local manufacturers;
2. Duration of the agreement and frequency of the order;
3. Renewability/ termination of the agreement – possibility of multi-year obligation agreements, bulk volume; and
4. Price margins.

SECTION 9. OVERSIGHT COMMITTEE

An oversight committee on the Green Lane for Local Vaccine Manufacturing shall be created with the Secretary of the Department of Trade and Industry and Chairperson of the Board of Investments as the Chairperson of the oversight committee and Director General of the Anti-Red Tape Authority as the Vice-Chairperson.

The committee shall have as members the heads of the following agencies or their duly authorized representatives with rank no lower than an Undersecretary of the following entities:

Agency	Designation	Name / Authorized Representative
Department of Trade and Industry - BOI	Chairperson	Secretary Ramon M. Lopez / Undersecretary Ceferino Rodolfo
Anti-Red Tape Authority	Vice-Chairperson/ Secretariat	Director General Jeremiah B. Belgica / Deputy Director General Ernesto V. Perez
Department of Health	Member	Secretary Francisco T. Duque II / Undersecretary
Food and Drug Administration	Member	Director General Rolando Enrique D. Domingo / Deputy Director General Oscar G. Gutierrez, Jr.

Department of Science and Technology	Member	Secretary Fortunato T. De la Peña/ Undersecretary Rowena Cristina L. Guevara
National Task Force Against COVID-19	Member	Secretary Carlito G. Galvez, Jr. **/** Undersecretary
Office of the Presidential Adviser on Streamlining of Government Processes	Member	Secretary Leoncio B. Evasco, Jr. / Undersecretary

The Oversight Committee shall have the following functions:

a. Oversee and monitor the implementation of this JMC;
b. Promote the JMC to the national government agencies and local government units concerned;
c. Review applicability of this JMC and recommend policies to improve the standards set therein
d. Undertake other measures necessary to enforce the standards set in the JMC.

SECTION 10. SEPARABILITY

If any clause, sentence, or provision of this JMC shall be invalid or unconstitutional, its remaining parts shall not be affected thereby.

SECTION 11. REPEALING CLAUSE

All issuances, circulars, orders, or memoranda, part or parts of which are inconsistent with any provisions of this JMC are hereby repealed and modified accordingly.

SECTION 12. EFFECTIVITY

This JMC shall take effect immediately following its publication in the Official Gazette or in a newspaper of general circulation and its filing with the Office of the National Administrative Register.

Signed this 19th day of May 2021.

Digitally signed by Duque Francisco Tiongson III

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ROLANDO ENRIQUE D. DOMINGO M.D., DPBO
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