



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

02 February 2021

DEPARTMENT CIRCULAR

No. 2021 - 0051

FOR: ALL VACCINE MANUFACTURERS, PHARMACEUTICAL COMPANIES OR EMERGENCY USE AUTHORIZATION (EUA) APPLICANTS, AND OTHERS CONCERNED

SUBJECT: Submission of data to the Health Technology Assessment Council (HTAC) for COVID-19 vaccine evaluation under emergency use authorization (EUA)

In light of the public health emergency, the HTA Unit has been receiving various requests for assessments of COVID-19 technologies, including COVID-19 vaccines. As the HTA Council aims to generate evidence-informed health technology recommendations amidst rapidly evolving evidence, we are planning to conduct an early HTA of COVID-19 vaccines, and this involves gathering information on clinical efficacy and safety of investigational COVID-19 vaccines.

To facilitate the timely provision of HTAC recommendations to DOH policy-makers and the Inter-Agency Task Force on the Management of Emerging Infectious Diseases, parallel submission of safety, efficacy and cost data as well as other information that will impact on the implementation of the COVID-19 vaccination program, is hereby being requested by the HTAC from COVID-19 vaccine manufacturers concurrently with submission of an application for EUA at the FDA with the following components of the dossier:

A. Clinical Data

A.1. Trial data

- Phase III clinical trial data (including published and unpublished data, study protocols, etc.)
- Aggregated raw data and Vaccine Efficacy (VE) with regard to the subgroup analysis on special populations: Asians, Elderly, Comorbidity type (e.g., diabetes, hypertension, cardiovascular, respiratory)

A.2. Real-world evidence

- Real-world data such as Adverse Events (AE)

B. Costing Data

- Unit cost of the vaccine
- Committee volume of doses to government

C. Other Information

- List of countries with Emergency Use Authorization (EUA) and/or has started implementation
- Number of vaccine recipients in all countries where the vaccine has been granted an EUA and/or has started implementation

- Manufacturer's reports on handling and distribution

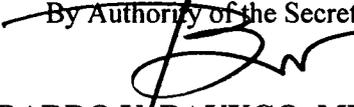
Attached herewith are the **letter of undertaking** and the **data extraction form** which you may use as reference. You may also download the form through this link: <http://bit.ly/hta-manuf-data>

Kindly share the accomplished form and/or consolidated files via hta@doh.gov.ph **on or before 10 February 2021**. Your submission will surely help in expediting our assessments and in making timely and evidence-based recommendations.

We look forward to your usual support as HTAC commits to deliver on its mandate to assist the government in achieving Universal Health Care with the best available evidence even as the nation is in the midst of this unprecedented health crisis.

Your full cooperation in this endeavor is expected and highly appreciated. Thank you very much.

By Authority of the Secretary of Health:



GERARDO V. BAYUGO, MD, MPH, CESO I
Undersecretary of Health
Health Regulation Team