Ethiopian Food and Drug Authority

Guideline for COVID-19 Vaccine Donation

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1. Introduction

Vaccines are an essential element in alleviating suffering by protecting the public from being infected from a particular disease. COVID-19 is an infectious disease caused by a novel coronavirus (SARS-CoV-2). It affects more than 200 countries, with more than 10 million cases to date. To combat such pandemic, COVID-19 vaccines are considered as paramount importance.

However, less developed countries including Ethiopia, access to COVID-19 vaccines on timely, equitable, and sufficient quantity remains a challenge. Hence, donation is one of the strategic consideration to alleviate such challenges.

Properly managed and well-coordinated COVID-19 vaccine donation practice can save lives from the devastative pandemic SARS-COV-2. Donations can become a strategic benefit for the recipient country to ensure access to vaccines. However, if there is no control over the specifications of the vaccine, or if the donated vaccine does not meet the needs of the government's immunization programme, the donation could have a negative impact.

Donations may come from governmental, non-governmental organizations, private institutions or individuals. The intended beneficiaries of donations of the vaccine may range from individual facilities to the entire health systems. Therefore, the Authority developed this guideline to ensure good vaccine donation practices.

2. Definitions

Without prejudice to the definitions provided under Proclamation No 1112/2019, in this guideline, unless the context otherwise requires;

1. "Donation" means the act of supplying and acceptance of a quantity of COVID-19 vaccine to recipients by donors for which the recipient does not pay.
2. "Donor" means a governmental or nongovernmental organization or individual who voluntarily donates COVID-19 vaccine as a donation.
3. "Recipient" means a government organization that voluntarily receives COVID-19 vaccine as a donation.
4. "Stringent Regulatory Authority (SRA)" means regulatory authorities which are recognized and listed as stringent by EFDA.

5. “Authority” means the Ethiopian Food and Drug Authority.

3. Donation principles

a) Donations of COVID-19 vaccine shall benefit the recipient to the maximum extent possible. All donations shall be based on an expressed need of the recipient.
b) Donations of COVID-19 vaccine shall be given with due respect for the wishes and authority of the recipient, and in conformity with the government policies and administrative arrangements of Ethiopia.
c) There shall be effective coordination and collaboration between the donor and the recipient and there shall be an official agreement between them.
d) There shall be no double standard in quality. If the quality of the vaccine is unacceptable in the country of origin, it is also unacceptable as a donation.

4. Objective

The objectives of this guideline are:-

1. To protect the public health from unsafe, poor quality and ineffective COVID-19 vaccine by ensuring Good Donations Practices.
2. To facilitate the regulatory process and help ensure that COVID-19 vaccines are distributed and reach to those in need.
3. To ensure that the COVID-19 vaccines donated are safe and effective and are authorized for use.
4. To make sure that donated COVID-19 vaccine are in compliance with the need of the country.

5. Requirements for COVID-19 Vaccine Donation

5.1. General requirements

- The COVID-19 vaccine shall be approved for use by EFDA or stringent regulatory authority or listed by World Health Organization.
- COVID-19 vaccine donation shall have a pre-import permit from the Authority.
- COVID-19 vaccine donations shall be based on an expressed need and shall have terms and conditions of the donation agreed between donor and recipient.
- The presentation, strength, and formulation of donated COVID-19 vaccines should, as far as possible, be similar to those of vaccines used for immunization in Ethiopia.
- The COVID-19 vaccine shall be obtained from a quality-ensured source and shall comply with quality standards in both country of origin and Ethiopia or SRA or listed for use by WHO.
- Donated COVID-19 vaccines should be presented in pack sizes that are suitable for the recipient and appropriate to the healthcare setting in which they will be distributed or administered.
- Injectable vaccines should be provided with auto-disable syringes and safety boxes for safe disposal.
- At arrival on port of entry, COVID-19 vaccines should have at least 12 months shelf-life remaining or have a shelf life sufficient to fulfill the intended purpose of the donation.
- When the donated vaccines is large in quantities, the national consumption and available quantities in stock or in the supply chain pipeline, all donated quantities should match the needs to be consumed before they are expired.

5.2. Pre-import Permit Application

1. Any recipient of COVID-19 vaccine shall apply online for pre-import permit using electronic regulatory information system (eRIS).
2. The pre-import permit application shall be accompanied by the following documents:
    - Application letter
    - Supporting letter that conforms the existence of an agreement from Federal Ministry of Health or Regional/City Administration Health Bureaus as appropriate

- Certificate of donation
- Performa invoice, where applicable
- Evidence of approval of the COVID-19 vaccine in country of origin or SRA or WHO
- Certificate of lot release

5.3. Requirement at Port of Entry

1. The donated COVID-19 vaccine shall have port clearance from the Authority.
2. The donated COVID-19 vaccine shall be accompanied by the following documents when it reaches the port of entry:-
    - Valid pre-import permit
    - Donation certificate
    - Packing list
    - Commercial invoice, if applicable
    - airway bill or bill of lading
    - Certificate (s) of Analysis of batch(es)

6. Labeling and Packaging requirements

6.1. Labeling requirements

1. The COVID-19 vaccine shall be labelled in English or Amharic language.
2. The product information for COVID-19 vaccine shall include the following.
    - Summary of product characteristics (SmPC) and/or Patient Information leaflet (PIL)
    - Container labelling including Vaccine Vial Monitoring (VVM) system
    - Any other instructional materials provided to the user.
3. Any information appearing in the vaccine container closure system (labels, PIL, and SmPC) shall be based on scientific justification.
4. The PIL shall not be described or presented in a manner that is false, misleading, or deceptive or is likely to create an erroneous impression regarding its use in any respect, either pictorially or in words.
5. The label on each container of the COVID-19 vaccine shall contain at least:-

a) The name of the product (International Non-proprietary name (INN) or brand name)

b) Pharmaceutical dosage form

c) Route of administration

d) Qualitative and quantitative composition of the active ingredient(s). If exist in formulation, the qualitative and quantitative of preservative(s) and antioxidant (s)

e) The volume of the contents, and/or the number of doses or quantity in container

f) Directions for use

g) Handling and storage conditions

h) Batch number

i) Expiry date

j) Name and address of manufacturer.

6. The Patient information leaflet (PIL) shall contain

    a) International Non-proprietary Name (INN) or brand name of the vaccine

    b) Pharmaceutical dosage form and route of administration

    c) Qualitative and quantitative composition of active ingredient(s). If preservative(s) and antioxidant (s) exist in formulation, the qualitative and quantitative of such ingredients.

    d) Clinical pharmacology, indication, posology and method of administration, contraindications, special warnings and precautions for use, side effect and adverse effects.

    e) The volume of the contents, and/or the number of doses, or quantity in container.

    f) Handling and storage conditions.

    g) Name and address of manufacturer.

6.2. Packaging requirement

1. The packaging of COVID-19 vaccines shall protect the vaccine during the transportation.
2. The packaging of COVID-19 vaccines shall be suitable for the proposed mode of transport.

3. The COVID-19 vaccine donations should be packed in accordance with international shipping requirements and shall be accompanied by a detailed packing list that specifies the contents. The weight per carton shall preferably not exceed 30 kilograms. Shipments of vaccine shall not be packed with other supplies in the same carton or secondary/tertiary packaging.

7. Responsibilities of receivers and donors

COVID-19 vaccine donation shall be in accordance with the recipient's need and comply with the existing national laws and guidelines. In principle, the donation shall meet the needs of government; and support and enable recipients to promote the quality of health of the people. All donors and recipients shall ensure that all donation on COVID-19 vaccine shall have permission from the EFDA prior to the shipment of these products.

Roles and responsibilities regarding requesting for import permit, customs clearance, reception, transport, storage and distribution, administration, and disposal of donated COVID-19 vaccine shall be agreed in writing and signed by both the donors and the recipient. In addition to the agreement between the donor and recipient, the following responsibilities of the COVID-19 vaccine donation recipients and donors shall be complied.

7.1. Responsibility of the Recipients

The recipient of the COVID-19 vaccine donation shall have the following responsibilities:

- Enter into agreement with the COVID-19 vaccine donor.
- Summit application for import permit of the donations.
- Receive donations after its approval for importation by EFDA.
- Provide the information about the requested and approved donations to the donors.
- Ensure all information for importation submitted to EFDA are correct and genuine.
- Make sure that all information submitted to EFDA for import permission and the information during port clearance are the same.
- Provide all required documents to EFDA during application for donation import permit including donation certificate, certificate of origin; packing list; and airway bill or bill of lading.
- Clear the imported COVID-19 vaccine from the port of entry.

- Not to accept COVID-19 vaccine donation with unknown source
- Not to accept donation that reach the port of entry without prior communication with the donor.
- Responsible for any defect encountered.
- To report any adverse events to EFDA following its use.
- Comply with the requirements of this guideline.

7.2. Responsibilities of Donors

The donor of the COVID-19 vaccine donation shall have the following responsibilities:

- Enter into agreement with the COVID-19 vaccine with recipient.
- Ensure all information for importation submitted to EFDA are correct and genuine.
- Make sure that all information submitted to EFDA for import permission and the information during port clearance are the same.
- Inform recipients about the details of the contents of planned donations as well as the arrival information.
- Responsible for any defect encountered after the donated COVID-19 vaccine entered into Ethiopia.
- Not to donate COVID-19 vaccine with unknown source.
- Not to donate COVID-19 vaccine without prior communication with the recipient.
- To support investigation on quality and safety issues during or after use.
- Comply with the requirements of this guideline.

8. Reporting

The recipient shall report relevant information to the Authority including defects, adverse effect, problems related to quality and safety and other reportable cases related to the donated COVID-19 vaccine.

9. Disposal

If the donated COVID-19 vaccines are found to be defective on safety, quality and efficacious, the recipient shall dispose or return the vaccine to the country of origin on its own expense. The

donor shall have the responsibility for safe disposal or returning the defective vaccine to the country of origin.

Reference

1. Considerations for Evaluation of COVID-19 Vaccines. Points to consider for manufacturers of COVID19 vaccines, Version 24 September 2020, World Health Organization, Geneva, Switzerland.
2. Guideline for Registration of Medicines, 4th Edition, 2020, Ethiopian Food and Drug Authority (EFDA), Addis Ababa, Ethiopia.
3. Guidelines for Medicines Donations. 3rd Edition, 2011. WHO, Geneva, Switzerland**.**
4. Vaccine donations-WHO-UNICEF Joint Statement, 2010.
5. GAVI Alliance Vaccine Donation Policy, Version 1.0, 2010.