# COVAX VACCINE REQUEST FORM

*Please complete, sign and submit all parts of this application, which is required for confirmation of participation to COVAX.­­­*

For Countries that have an agreed Partnership Framework Agreement (PFA) with Gavi, the terms and conditions of the PFA remain in full effect and shall apply to any and all Gavi support made pursuant to this Application. The Terms and Conditions of the COVAX AMC Facility 2022 shall also apply to the Approved Vaccines, equipment, and supplies made available through COVAX on or after 31 March 2022. In the event of any conflict between any term, condition, or provision of the PFA and the Terms and Conditions of the COVAX AMC Facility 2022 (including this Application), the Terms and Conditions of the COVAX AMC Facility 2022 (including this Application) shall prevail. For Countries where there is no agreed PFA between Gavi and the Country, the Terms and Conditions of the COVAX AMC Facility 2022 (including this Application) shall apply to any and all Gavi support made pursuant to this Application. By signing this Application, returning it to Gavi and accepting delivery of any Approved Vaccines or related equipment or supplies, the Government of [ ] (the “Country”) acknowledges that the supply of Approved Vaccines, equipment and supplies shall be subject to the ***Terms and Conditions of the COVAX AMC Facility 2022***, which are available here: <https://www.gavi.org/gavi-covax-amc#documents> or on Gavi COVAX website.

All terms capitalized but not otherwise defined shall have the meanings given to them in the Terms and Conditions of the COVAX AMC Facility 2022.

# AMC GROUP PARTICIPANT NAME COVID-19 VACCINE REQUEST FORM

*Please email completed Vaccine Requests to* *covaxproposals@gavi.org* *copying the relevant Gavi Senior Country Manager or focal point (whichever is applicable)****,*** *to confirm participation in the COVAX Facility. Contact your Gavi Senior Country Manager or focal point (whichever is applicable) in case of questions. Note that economies eligible for the COVAX AMC may request Technical Assistance to complete the Vaccine Request.*

1. **GENERAL INFORMATION**
2. Date of the request (DD/MM/YYYY):
3. AMC Group Participant Name:
4. Requesting institution:

Address:

Contact name:

Contact phone:

Contact email:

*When submitting the Vaccine Request, please attach a list of members and contact information for your COVID-19 Vaccine National Taskforce including relevant technical partners and donor financing institute(s). Please include a focal point(s) for regulatory and safety preparedness, and indemnity.*

1. **TARGET POPULATION VACCINATION PLANNING**

*In choosing target populations for vaccination, AMC Group Participants are recommended to follow the* ***WHO SAGE roadmap for prioritizing uses of COVID-19 vaccines in the context of limited supply*** *and* ***WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination****, which can be found here:* <https://www.who.int/immunization/sage/covid-19_documents/en/>.

1. Planned date for the start of the vaccination (DD/MM/YYYY):
2. In light of the WHO SAGE Roadmap (link above), what % of the total population is being targeted for vaccination once supply allows? *This number may be smaller or larger than 20%*:
3. In the table below, please list the groups being targeted for vaccination in order of priority:

|  |  |
| --- | --- |
| **Target population (description)** | **Proportion of total population (%)** |
|       |       |
|       |       |
|       |       |
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|       |       |
|       |       |

1. Please enter a rationale for your target populations (e.g., aligns with WHO SAGE recommendations):

1. Please complete the questions below on injection devices (syringes) and safety boxes:

Total number of injection devices (syringes) available which could be used for COVID-19 vaccinations:

Total number of safety boxes available which could be used for collection of injection devices for COVID-19 vaccinations:

If you anticipate a need for additional injection devices (syringes) and safety boxes to be used for COVID-19 vaccination, what procurement mechanism do you intend to use?

UNICEF[ ]  PAHO[ ]  Self-procurement [ ]

For AMC Group Participants that ticked “UNICEF” or “PAHO” above, please provide the dry storage capacity at the national/central level):

* Total dry storage capacity:      m3 net available
* Dry storage capacity available for injection devices (syringes) and safety boxes to be used for COVID-19 vaccination:      m3 net available
1. **COST SHARING**

*The data on cost-sharing requested in this form is for information only and does not constitute a legally binding commitment at this stage.*

AMC Group Participants are requested to cost share against the doses received through the Facility. However, an inability to cost share will not affect COVAX AMC Participants’ abilities to access the fully subsidized donor-funded doses provided through the COVAX AMC. Cost sharing can be used to fund supplementary doses beyond those funded by COVAX AMC donors, thus enabling AMC Group Participants to reach a greater share of their populations. If the aspired target population for vaccination cannot be fully met through donor-funded COVAX AMC doses, would you be interested in purchasing any additional doses through COVAX, fully financed via cost-sharing contributions? *(Non-binding; for information only)*

Yes [ ]  No [ ]

1. **DOMESTIC COVID-19 VACCINE PRODUCTION AND BILATERAL DEALS**

*As noted in Terms and Conditions of the COVAX Facility 2022, the COVAX Facility requests transparency about bilateral deals, existing and future, from all participants, noting that access to doses from bilateral deals will not impact access to the agreed volume of doses of Approved Vaccine from the COVAX Facility.*

*Provision of the below information will help to highlight where further discussions may be helpful, for example to align on any logistical supply chain issues or to explore opportunities to partner for mutual benefit, i.e. fungibility in complementary deals. It could, for example, enhance the understanding of whether there are circumstances or constraints in your system due to other vaccines or planned campaigns that would affect your ability to receive Approved Vaccines.*

1. Do you have domestic COVID-19 vaccine production capacity? If yes, please complete the table below.

Yes[ ]  No [ ]

|  |  |  |  |
| --- | --- | --- | --- |
| **Manufacturer** | **Vaccine type(s)** | **Planned capacity (doses/time period)** | **Expected date of availability of first doses (DD/MM/YYYY)** |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

1. Are there bilateral deals in place to purchase COVID-19 vaccines directly from manufacturers? If yes, please complete the table below.

Yes [ ]  No [ ]

|  |  |  |  |
| --- | --- | --- | --- |
| **Manufacturer**  | **Vaccine type(s)** | **Volume agreed in doses** | **Expected date of availability of first doses (DD/MM/YYYY)** |
|       |       |       |       |
|       |       |       |       |
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1. **VACCINE CHARACTERISTICS**

*The Allocation Framework will endeavour to integrate product preference into vaccine allocations. While efforts will be made to establish ‘best-matches’ between products and preferences, AMC Group Participants are not guaranteed to receive products with preferred characteristics, given preference is one of many factors, including limited supply availability, that need to be considered when allocating Approved Vaccine.*

1. Please complete the table below.

|  |  |  |  |
| --- | --- | --- | --- |
| **Vaccine characteristic grouping** | **Vaccine characteristic** | **Please rank all 12 vaccine characteristics (a to m) from most desirable at the top least desirable at the bottom** | ***Example (This is purely for illustration purposes and is not meant to influence AMC Group Participant preferences)*** |
| Vaccine Platform | a. mRNA |       | *l. Lower price* |
| b. Inactivated |       | *k. Fewer doses per regimen* |
| c. Viral Vector |       | *d. Vaccines that have been Prequalified by WHO* |
| Regulatory process | d. Vaccines that have been Prequalified by WHO |       | *g. Vaccines with traditional cold chain requirements (2-8°C)* |
| e. Vaccines that have received approval from a Stringent Regulatory Authority so far |       | *b. Inactivated* |
| f. Vaccines that have been granted only Emergency Use Listing so far |       | *e. Vaccines that have received approval from a Stringent Regulatory Authority so far* |
| Cold chain requirements | g. Vaccines with traditional cold chain requirements (2-8°C) |       | *c. Viral Vector* |
| h. Vaccines with traditional cold chain requirements (-20°C) |       | *h. Vaccines with cold chain requirements ( -20°C)* |
| i. Vaccines with ultra cold chain requirements (-70°C) |       | *f. Vaccines that have been granted only Emergency Use Listing so far* |
| Doses per vial / presentation | j. Fewer doses per vial (less than 10) |       | *j. Fewer doses per vial (less than 10)* |
| Doses per regimen / course | l. Fewer doses per regimen |       | *a. mRNA* |
| Price | m. Lower price |       | *i. Vaccines with ultra cold chain requirements (-70°C)* |

1. Assuming two Approved Vaccines which have equivalent characteristics become available through the COVAX Facility within 3-6 months of each other, which of the following options would you choose? Please tick one response.

[ ] Implement COVID-19 vaccination with both products in your vaccine schedule to accelerate receiving and delivering Approved Vaccines

[ ] Accept slower rate of receiving Approved Vaccines (e.g., by about 6 months) to avoid programmatic and logistics complications of delivering two different products

Rationale (optional):

1. **REGULATORY AND SAFETY PREPAREDNESS INFORMATION**

*Lack of regulatory and safety preparedness has delayed timely receipt of vaccines by countries in the past. The information gathered here will be used to optimise allocation by understanding regulatory processes and timelines of AMC Group Participants in advance.*

1. Is there a defined mechanism to recognize or rely on WHO Emergency Use Listing or (EUL) or WHO prequalification?

WHO Emergency Use Listing: Yes [ ]  No [ ]

WHO prequalification: Yes [ ]  No [ ]

1. Is there a defined mechanism to recognize or rely on regulatory decisions (marketing authorization or emergency approval) of Stringent Regulatory Authorities (SRAs)?

Marketing authorization: Yes [ ]  No [ ]

If yes, please list the countries with the applicable SRA(s):

Emergency approval: Yes [ ]  No [ ]

If yes, please list the countries with the applicable SRA(s):

1. Do expedited regulatory pathways exist for approval of COVID-19 medical products (therapeutics and vaccines) other than reliance on WHO Emergency Use Listing, WHO Prequalification and/or SRA marketing authorisation or emergency approval?

Yes [ ]  No [ ]

1. What is the maximum number of working days required to obtain emergency approval, considering such mechanisms exist (preferably in less than 15 working days)?

      working days

1. What are the requirements and list of minimum documents needed for regulatory approvals of COVID-19 products under emergency or expedited pathways defined? *Please attach a copy of the emergency and/or expedited pathway requirements/documents or provide the link if available in the public domain.*

1. Can an import permit be issued in less than five (5) working days?

Yes [ ]  No [ ]

      working days

1. What are the requirements and list of minimum documents needed to import COVID-19 therapeutics or vaccines? *Please attach the list of documents needed for import permit or provide a link if available in the public domain.*

1. Does a lot release waiver exist or can the COVID-19 vaccine be released in less than two days by reviewing the summary lot protocol only (testing is not required)?

Yes [ ]  No [ ]

1. Is there a system that can monitor and investigate safety of emergency medical products and/or access to global pharmacovigilance information available?

Yes [ ]  No [ ]

Are you a member of WHO-UMC pharmacovigilance network?

Yes [ ]  No [ ]

1. **COLD CHAIN CAPACITY AND LOGISTICS**

**NATIONAL/CENTRAL COLD STORAGE CAPACITY**

*COVID-19 vaccines are currently under development and have differing cold chain storage requirements, including storage at -70°C (ultra-cold chain), -20°C and/or 2-8°C[[1]](#footnote-1). Please describe your present expectations of capacity at the national/central level for storage of a COVID-19 vaccine requiring each type of cold chain storage. For the purposes of calculation, assume a secondary packaging size per dose of 4.6cm3 and a two-dose regimen.*

1. At the national/central level, are vaccines stored in their secondary (box) or tertiary (pallet) packaging? Secondary[ ]  Tertiary [ ]
2. Please complete the table below.

|  |  |
| --- | --- |
| **Storage requirement** | **What is your current total cold storage capacity at the central/national level?** |
| 2-8°C  |      m3 net available |
| -20°C |      m3 net available |
| -70°C (ultra-cold chain) |      m3 net available |

1. Please complete the table below.

|  |  |  |
| --- | --- | --- |
| **Storage requirement** | **What is the maximum shipment size that could be received, captured (in m3)?** | **At what delivery frequency (in weeks) could shipments of this size be received?** |
| 2-8°C  |      m3 |       weeks |
| -20°C |      m3 |       weeks |
| -70°C (ultra-cold chain) |      m3 |       weeks |

1. Please complete the questions below on contingency cold chain storage (additional storage capacity not currently available but that could be made available if there is a need and the national cold chain capacity is insufficient).

Is there contingency cold chain storage capacity?

Yes [ ]  No [ ]

Do you require a storage reefer container for cold chain storage?

Yes [ ]  No [ ]

Please complete the table below:

|  |  |
| --- | --- |
| **Storage requirement** | **Total contingency cold chain storage capacity** |
| 2-8°C |       m3 net available |
| -20°C |       m3 net available |
| -70°C (ultra-cold chain) |       m3 net available |

1. Please complete the questions below on contingency ambient storage:

Is contingency storage capacity available for ancillary items?

Yes [ ]  No [ ]

Do you require a storage container for the storage of ancillary items?

Yes [ ]  No [ ]

**AIRPORT(S) FOR DELIVERY (INTERNATIONAL SHIPMENTS)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Code** | **Name** | **Opening hours** | **Consignee** | **Repacking/cold storage available?** | **Clearing Agent** |
|       |       |       |       | Yes [ ]  | If yes, please describe the cold storage capacity in the following table.  |       |
| No [ ]  | If no, please specify: * Do you have a pre-clearance process to pick up the Approved Vaccines upon arrival?

Yes [ ]  No [ ] * How many days in advance the pre-advice document for the Approved Vaccine shipment are needed?

      days |

**COLD CHAIN STORAGE CAPACITY PER AIRPORT OF ENTRY**

|  |  |
| --- | --- |
| **Port of Entry Name:**       | **Port of Entry Code:**       |
| Cold chain storage capacity |       m3 net available (2-8°C) |
|       m3 net available (-20°C) |
|       m3 net available (-70°C) |
| Cold chain storage capacity available for COVID-19 Approved Vaccine |       m3 net available (2-8°C) |
|       m3 net available (-20°C) |
|       m3 net available (-70°C) |
| Is the cold chain storage bonded? | Yes [ ]  No [ ]  |
| Loading/unloading handling method | Manual [ ]  Mechanical [ ]  |
| Estimated transportation lead time from this port of entry to first storage |      hours |

**DOCUMENTS REQUIRED FOR SHIPMENT**

The default documents are acceptable [ ]

|  |
| --- |
| **Vaccines** |
| **Document** | **Original or Copy?**[Original/Copy] | **How long in advance?**[24 hrs/48 hrs/1week/1 month/N/A] |
| Certificate of Analysis |       |       |
| Certificate of Origin |       |       |
| Packing list (batch number & expiration date) |       |       |
| Free sale certificate |       |       |
| Proforma invoice |       |       |
| Airway bill |       |       |
| Other documents if applicable[[2]](#footnote-2) – *please list them:* |       |       |
| **Ancillary Items** |
| **Document** | **Original or Copy?**[Original/Copy] | **How long in advance?**[24 hrs/48 hrs/1 week/1 month/N/A] |
| Certificate of Analysis |       |       |
| Certificate of Origin |       |       |
| Packing list (batch number & expiration date) |       |       |
| Free sale certificate |       |       |
| Proforma invoice |       |       |
| Airway bill |       |       |
| Other documents if applicable1 – *please list them:* |       |       |

**INDEMNIFICATION**

*The supply of Approved Vaccines to the Country will be contingent on the Country first agreeing to indemnify the applicable manufacturer against product liability claims associated with the use or administration of the Approved Vaccine. As such, the Country will be required to enter into an indemnity agreement (the “Indemnity Agreement”) substantially in the form of the Annex to this Part B of the Application with the relevant manufacturer(s) and in accordance with the Terms and Conditions of the COVAX AMC Facility 2022.*

*The COVAX Facility has established a no-fault compensation mechanism to provide compensation to those individuals in any of the AMC Group who suffer a serious adverse event which is found to be associated with the Approved Vaccine or its administration (SAE). The compensation payment to be provided to the aforementioned individuals will be in full and final settlement of any claims (whether against the manufacturer and/or any other party involved in the distribution or administration of the Approved Vaccine) arising from or in connection with the SAE in question.*

*The information gathered here will be used to optimise allocation by understanding in advance: (i) the Country’s ability to enter into such an Indemnity Agreement(s) with manufacturer(s) and the processes and timelines for doing so; and (ii) the ability of individuals within the Country to accept payment under the compensation mechanism in full and final settlement of all claims in connection with the SAE in question. Please provide data on the following aspects.*

1. Does the Country provide immunity from tort litigation to vaccine manufacturers and other actors for development activities and administration of a vaccine relating to COVID-19?

Yes [ ]  No [ ]

1. Will legislation be required to be passed within the Country in order for the Country to be able to (a) enter into Indemnity Agreement(s) with manufacturer(s) of Approved Vaccines; and/or (b) be able to indemnify the manufacturer(s) of Approved Vaccines as required under the Indemnity Agreement;

Yes [ ]  No [ ]

1. If legislation is required in response to the question above, please indicate how long in weeks it would take the Country to pass all relevant legislation for the Country to enter into, and/or provide the indemnification required under, the abovementioned Indemnity Agreement(s) with manufacturer(s).

      weeks

1. Please indicate who (position title, and name of current holder of position) has the necessary authority to, in the name and on behalf of the Country, enter into such an Indemnity Agreement with manufacturer(s) of Approved Vaccines allocated to the Country.

Position title:

Name of current holder of position :

1. Please indicate how long it would take in weeks for the Country to enter into such an Indemnity Agreement with the manufacturer(s).

      weeks

1. Will legislation need to be passed within the Country in order to enable individuals who suffer an SAE found to be associated with an Approved Vaccine or its administration to accept payments under the compensation mechanism in full and final settlement of any claims arising from or relating to such SAE?

Yes [ ]  No [ ]

1. If legislation is required in response to the question above, please indicate how long it would take in weeks for the Country to pass all relevant legislation to enable individuals who suffer SAEs found to be associated with an Approved Vaccine or its administration to accept payments under the compensation mechanism in full and final settlement of any claims arising from or relating to such SAE.

      weeks]

AMC GROUP PARTICIPANT NAME SIGNATURE FORM

Name of the AMC Group Participant would like to expand the existing partnership with Gavi for the improvement of the immunisation programme of the Country, and specifically hereby requests COVAX Facility support for: COVID-19 Approved Vaccine.

Name of the AMC Group Participant commits itself to developing national immunisation services on a sustainable basis in accordance with the national health and immunisation strategic plans.

The English language version of this Application shall prevail if there is a conflict between the English language version and a translated version.

Please note that COVAX Facility will not review this Application without the signatures of both the Minister of Health and Minister of Finance or their delegated authority.

*We, the undersigned, affirm that the objectives and activities in this Application are fully aligned with the national health and immunisation strategic plans (or equivalent), and that funds for implementing all COVAX Facility-related activities, including domestic funds, will be included in the annual budget of the Ministry of Health.*

*We, the undersigned, confirm the Country’s agreement and understanding that supply of Approved Vaccine is contingent upon the Country first entering into an Indemnity Agreement with each manufacturer of an Approved Vaccine allocated to the Country and in accordance with the Terms and Conditions* of the COVAX AMC Facility 2022*.* The form of the Indemnity Agreement can be requested from the relevant Gavi Senior Country Manager or focal point (whichever is applicable).

|  |  |
| --- | --- |
| Minister of Health (or delegated authority) | Minister of Finance (or delegated authority) |
| Name:       | Name:       |
| Date:       | Date:       |
| Signature:  | Signature:  |

1. Of candidates currently under development, one requires storage at -70°C, one at -20°C, and the rest at 2-8°C. [↑](#footnote-ref-1)
2. *Any non-standard documentation requirements may slow down speed of delivery and increase costs to countries.*  [↑](#footnote-ref-2)