



# COVAX VACCINE REQUEST: GAVI GRANT TERMS AND CONDITIONS FOR COVAX AMC GROUP PARTICIPANTS

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*Please note that this Application has been split out into two sections: Part A which must be submitted by 7 December 2020; and Part B which must be submitted by 14 December 2020. Please note that submission of a completed Part A is required for confirmation of participation to COVAX and Part B is needed to complete the application.*

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 Gavi Grant Terms and Conditions set out below shall also apply to the Approved Vaccines, equipment, and supplies made available through COVAX. In the event of any conflict between any term, condition, or provision of the PFA and any term, condition, or provision of this Application, the term, condition, or provision contained in this Application shall prevail. For Countries where there is no agreed PFA between Gavi and the Country, the terms and conditions of 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 **[Republic of Moldova]** (the “Country”) acknowledges that the supply of Approved Vaccines, equipment and supplies shall be subject to the following **Gavi Grant Terms and Conditions**.

In addition, for all countries, those with an agreed PFA with Gavi and those without an agreed PFA, the terms and conditions set out in the COVAX Facility Terms and Conditions attached to Annex A of Part A to 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 Vaccine or related equipment or supplies, the Country accepts and agrees that the supplies of Approved Vaccines and related equipment and supplies shall also be subject to the terms of the **COVAX Facility Terms and Conditions**.

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

## **GAVI GRANT TERMS AND CONDITIONS**

### **FUNDING USED SOLELY FOR APPROVED PROGRAMMES**

The Country confirms that all funding and Approved Vaccine provided by Gavi will be used and applied for the sole purpose of fulfilling the programme(s) described in the Country's Application. Any significant change from the approved programme(s) must be reviewed and approved in advance by Gavi. All funding decisions for the Application are made at the discretion of Gavi and are subject to any review process as required by Gavi and/or the COVAX Partners and the availability of funds.

### **AMENDMENT TO THE APPLICATION**

The Country will notify Gavi as part of its reporting mechanism if it wishes to propose any change to the programme(s) description in its Application. Gavi will document any change approved by Gavi according to its guidelines, and the Country's Application will be amended.



## **RETURN OF FUNDS**

The Country agrees to reimburse to Gavi all funding amounts (i.e., any cash or the value of any equipment, supplies or Approved Vaccine) that Gavi determines not to have been used for the programme(s) described in its Application or otherwise misused. The Country's reimbursement must be in US dollars and be provided, unless otherwise decided by Gavi, within sixty (60) days after the Country receives Gavi's request for a reimbursement and be paid to the account or accounts as directed by Gavi.

## **SUSPENSION/ TERMINATION**

Gavi may suspend all or part of its funding or Approved Vaccine allocation to the Country if it has reason to suspect that funds, equipment, supplies or Approved Vaccine have been misused or used for purpose other than for the programme(s) described in the Country's Application, or any Gavi-approved amendment to the Application. Gavi retains the right to terminate its support to the Country for the programme(s) described in its Application if a misuse of Gavi funds, equipment, supplies or Approved Vaccine is confirmed.

## **UNDERTAKINGS OF THE PARTICIPANT**

These undertakings shall remain in force from the date of signature of this Application for so long as any obligation hereunder remains outstanding.

- (a) The Country shall promptly obtain, comply with and do all that is necessary to maintain in full force and effect any Authorisation required under any law or regulation to enable it to perform its obligations under this Application.
- (b) The Country represents and warrants to Gavi that:
  - (i) it has full power and authority to execute, perform and deliver this Application and the transactions contemplated herein;
  - (ii) this Application has been duly authorised, executed and delivered by it and constitutes valid and legally binding obligations of it and enforceable against it in accordance with its terms;
  - (iii) all actions required to be taken (including the obtaining of any Authorisation) for the execution of this Application, the carrying out of the other transactions contemplated herein, or the compliance by it with the terms hereof, as the case may be, have been taken and any Authorisations are in full force and effect;
  - (iv) its execution and delivery of this Application, the consummation of the transactions herein contemplated and compliance with the terms hereof do not infringe any existing applicable law, rule, regulation judgment, order or decree applicable to it or any international treaty convention or agreement to which it is a part or by which it is bound; and
- (c) The Country shall promptly notify Gavi in writing immediately on becoming aware of any breach of any of the representations and warranties set out herein.

## **LIABILITY**

To the fullest extent permitted by law, neither Gavi, any other COVAX Partner, nor any Procurement Agency will be liable to the Country, and the Country shall not bring a claim or action against Gavi, any other COVAX Partner, nor any Procurement Agency for any claim or loss of whatever nature relating to the use or administration of any Approved Vaccine or programme(s) described in the Application, including without limitation, any financial loss, reliance claims, any harm to property, or personal injury or death. The Country is solely responsible for all aspects of managing and implementing the programme(s) described in its Application.



Neither Gavi, nor any donors to the COVAX AMC, any Procurement Agency, distributors, vaccinators nor other stakeholders (including the other COVAX Partners) make any assessment, representation or warranty as to the safety, efficacy or suitability of the Approved Vaccine which is allocated to the Country. On this basis, the Country acknowledges that neither Gavi, nor any donors to the COVAX AMC, any Procurement Agency, distributors, vaccinators nor other stakeholders (including the COVAX Partners) shall have any liability to the Country or any third parties in respect of the use or administration of any Approved Vaccine provided pursuant to this Application (including any claim relating to, or arising from, inadequate warnings regarding the Approved Vaccine).

As between Gavi and the Country, the Country shall be solely responsible for any liability that may arise in connection with: (i) the implementation of any programme(s) in the Country; and (ii) the use, administration or distribution of Approved Vaccines allocated and distributed to the Country, and related equipment and supplies after title to such Approved Vaccines, equipment and supplies has passed to the Country. In addition, the Country shall be responsible for all claims and liabilities in accordance with the Indemnity Agreement to be entered into between the Country and manufacturer with respect to Approved Vaccines allocated and distributed to the Country.

#### **INDEMNIFICATION**

The Country agrees to indemnify and hold harmless Gavi, any donors to the COVAX AMC any other COVAX **Partner, any Procurement Agency**, distributors, vaccinators or other stakeholders against any claims and liabilities, including legal fees and costs, which may be made, filed or assessed against Gavi any donors to the COVAX AMC, and other COVAX **Partner, any Procurement Agency**, distributors, vaccinators or other stakeholders on account of any bodily injury, illness, suffering, disease or death caused by the use or administration of the Approved Vaccine, equipment or supplies in the Country.

#### **NO REPLACEMENT OF DEFECTIVE PRODUCT**

Neither Gavi, any Procurement Agency, distributors, vaccinators or other stakeholders (including the COVAX Partners) shall be responsible for any defect in Approved Vaccines and related supplies. Neither Gavi, any Procurement Agency, distributors, vaccinators or other stakeholders (including the COVAX Partners) shall be responsible for providing any additional funding to replace any Approved Vaccines and related equipment or supplies that are, or became, defective or disqualified for whatever reason.

#### **FAILURE TO SUPPLY**

Neither Gavi, any Procurement Agency, distributors, vaccinators or other stakeholders (including the COVAX Partners) will be liable or held responsible for any delay or failure in the supply of any Approved Vaccine or related equipment or supplies as a result of force majeure or act by government or other authorities that may prevent or restrict the delivery of the Approved Vaccine, equipment or supplies or that may preclude or restrict the free movement of the Approved Vaccine, equipment or supplies to the agreed site of delivery.

#### **NO EXPORTATION**

The doses of Approved Vaccines made available pursuant to this Application shall not be exported or otherwise made available for use outside the Country.

#### **NO RESALE**

The doses of Approved Vaccine, equipment and supplies supplied pursuant to this Application will not be sold but will only be provided to the targeted population in the Country free of charge or at nominal cost to recuperate reasonable expenses incurred in connection with delivery to the targeted population.

#### **INSURANCE**

Unless otherwise agreed with Gavi, the Country shall maintain, where available at a reasonable cost, all risk



property insurance on the programme assets (including Approved Vaccines and related equipment and supplies) with financially sound and reputable insurance companies. The insurance coverage will be consistent with that held by similar entities engaged in comparable activities. In any case, the Country will be solely responsible for the replacement of any damaged or missing Approved Vaccines, equipment and/or related supplies.

### **ANTI-CORRUPTION**

The Country confirms that if any funding or Approved Vaccine is provided by Gavi for the programme, such funds or doses of Approved Vaccine shall not be offered by the Country to any third person for the purposes of receiving any benefit directly or indirectly, nor will the Country seek in connection with its Application any gift, payment or benefit directly or indirectly that could be construed as an illegal or corrupt practice.

### **ANTI-TERRORISM AND MONEY LAUNDERING**

The Country confirms that if any funding is provided by Gavi for the programme, such funds shall not be used to support or promote violence, war or the suppression of the general populace of any country, aid terrorists or their activities, conduct money laundering or fund organisations or individuals associated with terrorism or that are involved in money-laundering activities, or to pay or import goods, if such payment or import, to the Country's knowledge or belief, is prohibited by the United Nations Security Council.

### **AUDITS AND RECORDS**

If any funding is provided by Gavi for the programme, the Country will conduct an annual financial audit of the Gavi grant funds and share the audit report(s) from such audit with Gavi, as requested within six months of the close of each financial year. The Country shall also share any audits or assessments carried out on the use of Approved Vaccine, equipment and supplies. Gavi reserves the right, on its own or through an agent, to perform audits or other assessments to ensure the accountability of funds, Approved Vaccine, equipment and supplies disbursed to the Country.

If any funding is provided by Gavi for the programme, the Country will maintain accurate accounting records documenting how Gavi funds are used. The Country will maintain its accounting records in accordance with its government-approved accounting standards for at least three years after the date of last disbursement of Gavi funds. The country will maintain accurate records documenting how doses of Approved Vaccine, equipment and supplies are managed and disbursed as relevant.

If there is any claim of misuse of funds, equipment, supplies or Approved Vaccine, Country will maintain such records until the audit findings are final. The Country agrees not to assert any documentary privilege against Gavi in connection with any audit.

### **CONFIRMATION OF LEGAL VALIDITY**

The Country and the signatories for the Country confirm that its Application, or any other agreed annual reporting mechanism, is accurate and correct and forms legally binding obligations on the Country, under the Country's law, to perform the programme(s) described in its Application, as amended, if applicable.

### **COMPLIANCE WITH GAVI POLICIES**

The Country should familiarise itself with all Gavi policies, guidelines and processes relevant to the programme(s), including without limitation the Transparency and Accountability Policy (TAP) and comply with the requirements therein. All programme related policies, guidelines and processes are available on Gavi's official website and/or sent to the Country.

### **USE OF COMMERCIAL BANK ACCOUNTS**



The Country is responsible for undertaking the necessary due diligence on all commercial banks used to manage Gavi cash-based support. The Country confirms that it will take all responsibility for replenishing Gavi cash support lost due to bank insolvency, fraud or any other unforeseen event.

## LANGUAGE

The English language version of these Gavi Grant Application Terms and Conditions shall prevail if there is a conflict between the English language version and a translated version.

## ARBITRATION AND GOVERNING LAW

This Application and any non-contractual obligations arising out of or in connection with it shall be governed by English law.

Any dispute, controversy or claim ("**Dispute**") between the Country and Gavi arising out of or in connection with this Application shall be submitted to arbitration at the request of either Gavi or the Country. The arbitration will be conducted in accordance with the then-current rules of the United Nations Commission of International Trade Law (UNCITRAL). Gavi and the Country shall each appoint one arbitrator, and the two arbitrators so appointed shall jointly appoint a third arbitrator who shall be the chairperson. If either party fails to appoint an arbitrator, the appointing authority shall instead be the President of the Swiss Arbitration Association. The arbitration proceedings shall take place in Geneva (which is the seat of the arbitration) and shall be conducted in English. The parties agree to be bound by any arbitration award, as the final adjudication of any such Dispute.

## DEFINITIONS

For purposes of these Gavi Grant Terms and Conditions:

- (a) "**Application**" means Part A and Part B of the application for vaccine support, cold chain equipment (CCE) support, technical assistance (TA) or such other support that the Gavi Board may offer from time to time to realise the objectives of the COVAX AMC;
- (b) "**Authorisation**" means an authorisation, consent, approval, resolution, licence, exemption, filing, notarisation or registration;
- (c) "**Country**" means the Government of the country or territory of **[Republic of Moldova]**.
- (d) "**COVAX Partner**" means the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi and the World Health Organisation (WHO);
- (e) "**COVAX Terms and Conditions**" means the COVAX Facility Terms and Conditions for the AMC Group Participants attached to this Application at Annex A of Part A;
- (f) "**Procurement Agency**" means the Pan American Health Organization (PAHO) and the United Nations Children's Fund (UNICEF).



# COVAX VACCINE REQUEST:

## AMC GROUP PARTICIPANT NAME COVID-19 VACCINE REQUEST FORM – PART A

Please email completed Vaccine Requests to [covaxproposals@gavi.org](mailto:covaxproposals@gavi.org) copying the relevant Gavi Senior Country Manager or focal point (whichever is applicable) by **December 7, 2020**, to confirm participation in the COVAX Facility. Please note that there is a Part B to the Application which will be provided separately. Your Application will only be complete upon submission of both Part A and Part B of the Application. 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

- a. Date of the request (DD/MM/YYYY): 07/12/2020
- b. AMC Group Participant Name: Republic of Moldova
- c. Requesting institution: Ministry of Health, Labour and Social Protection
  - Address: str. Vasile Alecsandri, 2 MD-2009, Chişinău
  - Contact name: Constantin Rîmiş
  - Contact phone: +37368333403 ; +37322268887
  - Contact email: [constantin.rimis@msmps.gov.md](mailto:constantin.rimis@msmps.gov.md)

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.

### 2. 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/](https://www.who.int/immunization/sage/covid-19_documents/en/).

- a. Planned date for the start of the vaccination (DD/MM/YYYY): 01.04.2021
- b. 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%: 50%
- c. In the table below, please list the groups being targeted for vaccination in order of priority:

Target population (description)	Proportion of total population (%)
Health Care Workers	2%
Older adults with comorbidities – 65+ years	16%
Beneficiaries of temporary, long-term	0.5%



placement centers and nursing homes	
Groups with comorbidities	21.5%
Social workers	0.5%
School and teaching staff	3%
Workers in ensuring security	1.5%
Others categories	5

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

Alignment with WHO SAGE recommendations and with national technical working group

e. 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: 100.000

Total number of safety boxes available which could be used for collection of injection devices for COVID-19 vaccinations: 1.000

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: 402m<sup>3</sup> net available
- Dry storage capacity available for injection devices (syringes) and safety boxes to be used for COVID-19 vaccination: 80m<sup>3</sup> net available

### 3. 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



## 4. DOMESTIC COVID-19 VACCINE PRODUCTION AND BILATERAL DEALS

As noted in Annex A (COVAX Terms and Conditions) of this Part A, 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.

- a. 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)

- b. 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)

## 5. VACCINE CHARACTERISTICS

The Allocation Mechanism 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.





a. Please complete the table below.

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

b. 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):

## 6. 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.*

a. 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

b. 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): [Australia](#)

[Austria](#)

[Belgium](#)

[Bulgaria](#)

[Canada](#)

[Cyprus](#)

[Czech Republic](#)

[Denmark](#)

[Estonia](#)

[Finland](#)

[France](#)

[Germany](#)

[Greece](#)

[Hungary](#)

[Iceland](#)

[Ireland](#)

[Italy](#)

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[Liechtenstein](#)

[Lithuania](#)

[Luxembourg](#)

[Malta](#)

[Netherlands](#)

[Norway](#)

[Poland](#)

[Portugal](#)



Romania  
Slovakia  
Slovenia  
Spain  
Sweden  
Switzerland  
United Kingdom  
United States of America

Emergency approval: Yes  No

If yes, please list the countries with the applicable SRA(s): [Australia](#)

Austria  
Belgium  
Bulgaria  
Canada  
Cyprus  
Czech Republic  
Denmark  
Estonia  
Finland  
France  
Germany  
Greece  
Hungary  
Iceland  
Ireland  
Italy  
Japan  
Latvia  
Liechtenstein  
Lithuania  
Luxembourg  
Malta  
Netherlands  
Norway  
Poland  
Portugal  
Romania  
Slovakia  
Slovenia  
Spain  
Sweden  
Switzerland  
United Kingdom  
United States of America

- c. 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



- d. What is the maximum number of working days required to obtain emergency approval, considering such mechanisms exist (preferably in less than 15 working days)?  
14 working days
- e. 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.*  
[Quality Certificate](#)  
[Certificate of Analysis](#)  
[Release Certificate](#)  
[Donation letter of humanitarian assistance](#)
- f. Can an import permit be issued in less than five (5) working days?  
Yes  No   
4 working days
- g. 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.*  
[Donation letter](#)  
[Invoice](#)  
[Packing list](#)  
[AWB](#)  
[MoH approval letter](#)
- h. 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
- i. 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

## 7. 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  $-70^{\circ}\text{C}$  (ultra-cold chain),  $-20^{\circ}\text{C}$  and/or  $2-8^{\circ}\text{C}$ <sup>1</sup>. Please describe your present expectations of

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<sup>1</sup> Of candidates currently under development, one requires storage at  $-70^{\circ}\text{C}$ , one at  $-20^{\circ}\text{C}$ , and the rest at  $2-8^{\circ}\text{C}$ .



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 4.6cm<sup>3</sup> and a two-dose regimen.

- a. At the national/central level, are vaccines stored in their secondary (box) or tertiary (pallet) packaging?  
 Secondary  Tertiary

b. Please complete the table below.

Storage requirement	What is your current total cold storage capacity at the central/national level?
2-8°C	23m <sup>3</sup> net available
-20°C	2m <sup>3</sup> net available
-70°C (ultra-cold chain)	0m <sup>3</sup> net available

c. 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	4.5m <sup>3</sup>	8 weeks
-20°C	1m <sup>3</sup>	8 weeks
-70°C (ultra-cold chain)	0m <sup>3</sup>	N/A- weeks

- d. 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	24 m <sup>3</sup> net available
-20°C	1 m <sup>3</sup> net available
-70°C (ultra-cold chain)	0 m <sup>3</sup> net available

- e. 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
KIV	Chişinău International Airport	24/24	National Agency for Public Health	Yes <input type="checkbox"/>	If yes, please describe the cold storage capacity in the following table.	<b>INFORM-BUSINESS-C S.R.L</b> Adress : 12 Tighina street, Chisinau, MD-2001 Tel :+37322 534175 : +373228346 43 Email :asyuda@mail.ru, mihai70@mail.ru
				No <input checked="" type="checkbox"/>	If no, please specify: <ul style="list-style-type: none"> <li>Do you have a pre-clearance process to pick up the Approved Vaccines upon arrival? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></li> <li>How many days in advance the pre-advice document for the Approved Vaccine shipment are needed? 5 days</li> </ul>	

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

Port of Entry Name:	Port of Entry Code:
Cold chain storage capacity	<input type="text"/> m <sup>3</sup> net available (2-8°C)
	<input type="text"/> m <sup>3</sup> net available (-20°C)
	<input type="text"/> m <sup>3</sup> net available (-70°C)
Cold chain storage capacity available for COVID-19 Approved Vaccine	<input type="text"/> m <sup>3</sup> net available (2-8°C)
	<input type="text"/> m <sup>3</sup> net available (-20°C)
	<input type="text"/> m <sup>3</sup> net available (-70°C)
Is the cold chain storage bonded?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Loading/unloading handling method	Manual <input type="checkbox"/> Mechanical <input type="checkbox"/>
Estimated transportation lead time from this port of entry to first storage	<input type="text"/> 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	Copy	1 week
Certificate of Origin	Copy	1 week
Packing list (batch number & expiration date)	Copy	1 week



Free sale certificate	Copy	1 week
Proforma invoice	Copy	1 week
Airway bill	Copy	1 week
Other documents if applicable <sup>2</sup> – <i>please list them:</i>		The original documents must accompany the lot of the vaccine at arrival
<b>Ancillary Items</b>		
<b>Document</b>	<b>Original or Copy?</b> [Original/Copy]	<b>How long in advance?</b> [24 hrs/48 hrs/1 week/1 month/N/A]
Certificate of Analysis	Copy	1 week
Certificate of Origin	Copy	1 week
Packing list (batch number & expiration date)	Copy	1 week
Free sale certificate	Copy	1 week
Proforma invoice	Copy	1 week
Airway bill	Copy	1 week
Other documents if applicable <sup>2</sup> – <i>please list them:</i>		

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<sup>2</sup> Any non-standard documentation requirements may slow down speed of delivery and increase costs to countries.

**Work Group**  
**COVID-19 Vaccine National Taskforce**  
**Republic of Moldova**

<b>Nr.</b>	<b>Name</b>	<b>Institution</b>	<b>Email</b>
1.	Constantin Rîmiș	Ministry of Health, Labour and Social Protection	<a href="mailto:constantin.rimis@msmps.gov.md">constantin.rimis@msmps.gov.md</a>
2.	Daniela Demişcan	Ministry of Health, Labour and Social Protection	<a href="mailto:daniela.demiscan@msmps.gov.md">daniela.demiscan@msmps.gov.md</a>
3.	Tatiana Zatic	Ministry of Health, Labour and Social Protection	<a href="mailto:tatiana.zatic@msmps.gov.md">tatiana.zatic@msmps.gov.md</a>
4.	Semeniuc Marina	Ministry of Finance	<a href="mailto:marina.semeniuc@mf.gov.md">marina.semeniuc@mf.gov.md</a>
5.	Iurie Osoianu	National Health Insurance Company	<a href="mailto:iurie.osoianu@cnam.gov.md">iurie.osoianu@cnam.gov.md</a>
6.	Stela Gheorghită	WHO country office	<a href="mailto:gheorghitas@who.int">gheorghitas@who.int</a>
7.	Angela Capcelea	UNICEF country office	<a href="mailto:acapcelea@unicef.org">acapcelea@unicef.org</a>
8.	Violeta Teutu	Consultant, World Bank	<a href="mailto:vteutu@gmail.com">vteutu@gmail.com</a>
9.	Anatolie Melnic	National Agency for Public Health	<a href="mailto:anatolie.melnic@ansp.gov.md">anatolie.melnic@ansp.gov.md</a>
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16.	Ludmila Bîrcă	Municipal Clinical Hospital for Infectious Diseases of Children	<a href="mailto:lbirca@mail.ru">lbirca@mail.ru</a>
17.	Alexei Ceban	National Agency for Public Health	<a href="mailto:alexei.ceban@yahoo.com">alexei.ceban@yahoo.com</a>
<b>Focal points for regulatory and safety preparedness, and indemnity</b>			
18.	Dumitru Saghin	Medicines and Medical Devices Agency	<a href="mailto:dumitru.saghin@amdm.gov.md">dumitru.saghin@amdm.gov.md</a>
19.	Laura Țurcan	National Agency for Public Health	<a href="mailto:laura.turcan@ansp.gov.md">laura.turcan@ansp.gov.md</a>





Wednesday, 2 December 2020

# COVAX AMC GROUP PARTICIPANT SIGNATURE FORM – PART A

Republic of Moldova 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.

Republic of Moldova 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 Part A of the Application without the signature of the Minister of Health or his or her delegated authority.

*The undersigned affirms that the objectives and activities in this Part A of the 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.*

<b>Minister of Health (or delegated authority)</b>	
Name:	Viorica Dumbrăveanu
Date:	07/12/2020
Signature:	





## COVAX VACCINE REQUEST:

# REPUBLIC OF MOLDOVA COVID-19 VACCINE REQUEST FORM – PART B

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Please email completed Vaccine Requests to [covaxproposals@gavi.org](mailto:covaxproposals@gavi.org) copying the relevant Gavi Senior Country Manager or focal point (whichever is applicable) by **December 14, 2020**, to confirm participation in the COVAX Facility. Please note that your participation will only be confirmed upon submission of both Part A and Part B of the Application. 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. 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 Gavi Grant Terms and Conditions.*

*The COVAX Facility is attempting to establish 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.*

- a. 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
  
- b. 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



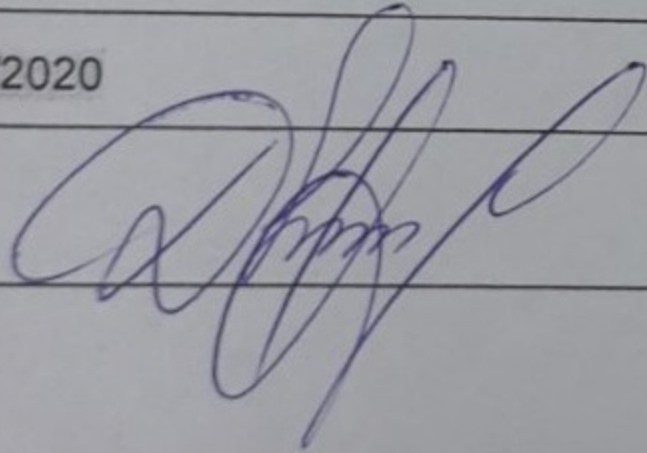
- c. If legislation is required in response to the question above, please indicate how long in weeks it would take the Country to pass all relevant legislation for the Country to enter into, and/or provide the indemnification required under, the abovementioned Indemnity Agreement(s) with manufacturer(s).  
[30 weeks](#)
- d. 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: [Ministry of Health, Labour and Social Protection](#)  
Name of current holder of position : [Viorica Dumbrăveanu](#)
- e. Please indicate how long it would take in weeks for the Country to enter into such an Indemnity Agreement with the manufacturer(s).  
[2-6 weeks](#)
- f. 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
- g. 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.  
[N/A weeks](#)

# COVAX AMC GROUP PARTICIPANT SIGNATURE FORM – PART B

Please note that COVAX Facility will not review this Part B of the 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, substantially in the form of the Annex to Part B of the Application with each manufacturer of an Approved Vaccine allocated to the Country and in accordance with the Gavi Grant Terms and Conditions as set out in Part, A of the Application.

Minister of Health (or delegated authority)	Minister of Finance (or delegated authority)
Name: <u>Viorica Dumbrăveanu</u>	Name: <u>Sergiu Pușcuța</u>
Date: <u>30/12/2020</u>	Date: <u>30/12/2020</u>
Signature: 	Signature: 