Geneva, 11 June 2025

Hon. Minister,
Ministry of Health, Republic of Moldova

Letter of Agreement

Participation in the Global Platform for Access to Childhood Cancer Medicines

1. The World Health Organization (WHO) is pleased to invite the Government of **the Republic of Moldova** (the "Government") to participate in the Global Platform for Access to Childhood Cancer Medicines (GPACCM) as a recipient country. The GPACCM is an initiative between WHO and St. Jude Children's Research Hospital, Inc. (St. Jude), aimed at increasing access to quality-assured childhood cancer medicines (the "Medicines") in low- and middle-income countries (LMICs). The GPACCM is not a legal entity and its day-to-day operations are managed through an Administrative Operations Unit (AOU) located within WHO and comprised of WHO staff. The GPACCM is partnering with UNICEF and the Pan-American Health Organization ("PAHO") (PAHO also serves as the Regional Office for the Americas of the WHO) to support in the procurement and delivery of the Medicines (each a so-called "GPACCM Procurement Partner").

2. We recognize that childhood cancer is an issue that reflects the inequalities and inequities in society and health systems. A child's survival after a cancer diagnosis is often linked to their birthplace and their family's socio-economic status. As a recipient country of the GPACCM, your country should be able to benefit from support to improve access to childhood cancer treatment, particularly through improved accessibility of essential cancer medicines.

3. The GPACCM aims to provide a supply of childhood cancer medicines to LMICs, with the goal of providing quality-assured products to approximately 120,000 children between 2023 and 2027. The Platform intends to improve the availability and affordability of quality-assured essential medicines including by supporting governments and other key stakeholders in key steps along the value chain from the selection and quantification of health products, to develop or update treatment standards, to build information systems to track that effective care is being provided, and to drive innovation. This would help provide children with access to the right medicine, at the right time to complete therapy, thereby contributing to limiting the risk of substandard and/or falsified products, and financial hardship.

4. Together with WHO, St. Jude is the founding partner in the establishment of the GPACCM, and St. Jude is contributing US$200 million over six years to make the realization of this Platform possible. This initiative builds on the successful collaboration between St. Jude and WHO, with St. Jude

committing US$15 million to create the Global Initiative for Childhood Cancer (GICC) in 2018. The GPACCM synergizes with GICC, leveraging the momentum and capacities built through GICC.

5. It is understood that the GPACCM does not aim to replace or divert resources from countries that have existing initiatives relating to the management of childhood cancer in place. The resources provided through this initiative shall be considered as supplementary to the resources received by the Country from external and domestic sources for the implementation of activities outlined under the GPACCM. Participation in the GPACCM is therefore designed to enhance and complement the efforts already undertaken by the Country, ensuring that the collective resources contribute synergistically to improve access to childhood cancer medicines.

6. In the event that UNICEF is designated as the Procurement Agency for the implementation of the GPACCM in your country, the GPACCM will request UNICEF to procure the Medicine allocated for delivery to **the Republic of Moldova** pursuant to a Procurement Agency Memorandum of Understanding (MOU) to be signed between St Jude and UNICEF (the "GPACCM – UNICEF Procurement Agency MOU"). In addition, your country will be expected to have in place or conclude a Memorandum of Understanding for the Provision of Procurement Services with UNICEF [the "UNICEF PS MOU") which shall apply to the delivery of Medicine by UNICEF to the Government under the GPACCM. The UNICEF PS MOU will, among other things, cover the points listed in Annex 1a to this LOA.

7. In the event that PAHO is designated as the Procurement Partner for the implementation of the GPACCM in your country, the GPACCM will request PAHO to procure the Medicine allocated for delivery to [country] pursuant to a Memorandum of Understanding (MOU) to be signed between St Jude and PAHO (the "GPACCM–PAHO Collaboration MOU"). In addition, the Agreement between the Government and PAHO for the Participation in the Regional Revolving Fund for Strategic Public Health Supplies (the "Strategic Fund Participation Agreement") shall apply to the delivery of Medicines by PAHO to the Government under the GPACCM. The Strategic Fund Participation Agreement, among other things, covers the points listed in Annex 1b to this LOA.

8. Under this initiative, WHO will establish an Administrative Operations Unit (AOU) to support the implementation of the GPACCM, and the AOU will have the responsibility for delivering on the GPACCM aim by developing and implementing work plans endorsed by the Platform Steering Committee, and otherwise carrying out its activities, ensuring efficient and transparent operational communications between the Government and the GPACCM.

9. The GPACCM AOU will use all reasonable efforts to implement the objectives of the GPACCM, including but not limited to:

    a. Establishing the GPACCM List of Priority Medicines for children (the "GPACCM priority medicine list") (The GPACCM priority medicine list contains the medicines considered to be most effective and safe to meet the most important needs for childhood cancer control in a health system and is in line with the most recent WHO Model List of Essential Medicines); and

b. Working with the designated GPACCM Procurement Partner to procure the GPACCM priority medicine list.

10. To participate in the GPACCM, the Government agrees to the following terms and conditions:

a. Within 180 days of final signature of this LOA or as otherwise agreed with WHO, the Government working with WHO will develop a GPACCM country specific technical and operational plan.

b. The Government agrees and acknowledges that the manufacturers of the Medicines, or (as applicable) their agent/representative, remain responsible for any reporting obligations as marketing authorization holders of the Medicines in accordance with applicable laws and regulations.

c. The Government acknowledges that the Medicines have been demonstrated to be clinically safe and effective in the treatment of cancer in humans, but may possibly give rise to adverse events, life threatening or fatal adverse reactions, and that such adverse reactions may be unexpected. The Government however shall facilitate the registration or issue equivalent authorization (e.g. waiver) of these Medicines prior to importation, shall issue import permit and shall exercise all its regulatory powers to ensure quality and safety of medicines, including monitoring and reporting of adverse events, quality testing and post-marketing surveillance as indicated in clause "d" hereof. The Government confirms that it has weighed the risks associated with the acceptance and use of the Medicines, including the possible occurrence of (expected or unexpected) serious, life threatening or fatal adverse reactions in a proportion of cases. In deciding to use the Medicines, the Government has come to its own conclusion that such use is justified under the circumstances.

d. To the extent the Government receives any reports regarding the safety of one of the Medicines, which includes but is not limited to Suspected Unexpected Serious Adverse Reactions ("SUSAR"), the Government shall promptly submit the safety report to its national regulatory authority as a part of the country's pharmacovigilance process and to the WHO designated focal point that will be stipulated in the Operational Plan.

e. As required in consultation with the designated GPACCM Procurement Partner, the Government will take the necessary measures to facilitate export, import and administration of the Medicines by providing assistance and support including, but not limited to, the provision of written statements to the effect that:

i. the Medicines are intended for specific clinical indications and will be used in accordance with good clinical practice (GCP), which includes informed consent from persons and their legal representatives to whom the Medicines are administered[1];

ii. the Medicines meet the requirements of the national regulatory authority in **the Republic of Moldova**;

iii. approval for the importation of the Medicines in **the Republic of Moldova** is ensured;

iv. the Medicines and their use in **the Republic of Moldova** are not in conflict with any laws in the country; and

v. the Government accepts and has authorized the existing label of the Medicines for use in **the Republic of Moldova.**

f. The Government agrees to prepare all written statements needed to facilitate compliance with the export requirements in the countries of manufacture in consultation and collaboration with WHO, and the designated GPACCM Procurement Partner. The Government furthermore understands and agrees that the provision of any supplies of the Medicines hereunder is subject to the granting of the required export authorization in the respective country of manufacture and that no party, including WHO, St. Jude, or the designated GPACCM Procurement Partner shall, in any way, be responsible for failure to obtain this authorization.

g. The Government will ensure adherence to all applicable laws and recommendations for the proper handling, administration, use, and destruction of the Medicines. It shall also record, as well as report on, serious adverse effects as well as the evolution and management of the health condition of treated individuals having incurred a serious adverse event. The Government will further undertake to inform all persons to whom the Medicines are administered of possible safety concerns to which the Medicines may give rise, that there may be unexpected safety concerns, as well as of the fact that the Medicines might not work. The Government further agrees and will ensure that the Medicines will only be administered after freely given, prior informed consent is obtained from any and all persons to whom the Medicines are administered (or from their legal representatives) and undertakes to fulfill any national regulatory requirements and ethical clearance as required by national law. In connection with the foregoing, the Government will ensure that any necessary approvals by relevant ethics committees are secured and provided to WHO[2].

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[1] For the avoidance of doubt, the reference to GCP in this provision does not imply that the Platform, or stakeholders collaborating with it, will conduct clinical trials with the donated Medicines.

[2] Consent form is a general practice and is considered a safety provision. A notification must be provided to the patient that the product is freely given.

h. The Government shall also be responsible for ensuring that the Medicines are administered, handled, stored, and destroyed in accordance with the manufacturers' written instructions (including the Pharmacy Manual).

i. Title to, and risk of loss of and damage to, the Medicines supplied hereunder will transfer to the Government upon their delivery at the agreed delivery destination as agreed in the relevant UNICEF PS MOU Agreement.

j. Upon transfer of title to the Government, WHO, St. Jude and the designated GPACCM Procurement Partner, and their officers, employees and agents will not be responsible for the storage, transportation and distribution of Medicines. The GPACCM may at its sole discretion provide resources to support the Government in these areas. If during storage, transportation, distribution or use as aforesaid, any quantities of the Medicines will be damaged or lost, no party, including WHO, St. Jude, or the designated GPACCM Procurement Partner, shall be responsible for replacing the quantities that are affected. Any such damage or loss must be reported by the Government to GPACCM AOU.

k. The Government agrees that WHO, St. Jude, and the designated GPACCM Procurement Partner, and their officers, employees and agents, will not be liable or responsible for any consequences arising from the use of the Medicines supplied hereunder. In accordance with the UNICEF PS MOU all claims related to any defect in quality or other non- conformity of the Medicines or for any loss or damage shall be handled directly by the Government with the original manufacturer, supplier, or insurance underwriter.

l. Thus, the Government agrees to indemnify, defend and hold harmless WHO, St. Jude, and the designated GPACCM Procurement Partner, as well as their officers, employees and agents, from all claims, liabilities, damages, costs and expenses (including reasonable attorneys' fees and costs) of any kind (including but not limited to for personal injury or death), associated with or related in any way to the Medicines, their possession, shipment, handling, use, administration and/or distribution. This indemnification obligation shall survive the termination or expiration of this Letter of Agreement and the implementation of the GPACCM.

m. In accordance with the UNICEF PS MOU , the Government understands and agrees that, with the exception of applicable warranties, assurances and liability provided by the manufacturers of the Medicines (or their agents/representatives), the Medicines will be supplied "as is", without any additional warranties or representations whatsoever, whether express or implied, including, but expressly not limited to, any implied warranties as to the Medicines' fitness for a particular purpose or use, or as to their safety and/or efficacy in any respect.

n. The Government will use the Medicines to enhance and complement the efforts already undertaken by **the Republic of Moldova**, ensuring that the collective resources contribute synergistically to improve access to childhood cancer medicines according to best international practice and as recommended in the WHO Model List of Essential Medicines. The Government furthermore understands and agrees that any supply, distribution or sale of the Medicines to a third party or entity (other than supply and distribution to those facilities have been agreed with WHO) shall be strictly prohibited.

o. The Government will require all third parties assisting it in connection with GPACCM activities to warrant that:

   i. they are not and will not be involved in, or associated with, any person or entity associated with terrorism, as designated by any UN Security Council sanctions regime; that they will not make any payment or provide any other support to any such person or entity; and that they will not enter into any employment or subcontracting relationship with any such person or entity; and

   ii. they shall not engage in any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of the work in relation to the GPACCM.

p. Any instance of diversion or inappropriate use of the Medicines may result in the immediate suspension of the provision of Medicines to **the Republic of Moldova** until corrective action has been taken. GPACCM reserves the right to immediately suspend an eligible country's participation in the GPACCM for any other violation of this Letter of Agreement or any other applicable laws and or regulations.

q. The Government undertakes to maintain any and all information received from WHO or parties collaborating with WHO in relation to the GPACCM or otherwise in relation to this Letter of Agreement ("the Information"), in confidence. In connection with the foregoing, the Government shall take all reasonable measures to ensure that the Information shall not be used for any purpose other than for the Purpose and shall not be disclosed to any person or third party, except for those employees, agents, consultants, principal investigators and/or other parties who have a need to know such Information for the Purpose and who are bound by obligations of confidentiality and restrictions on use which are at least as stringent as those contained in this Letter of Agreement ("Other Recipients").

r. The obligations of confidentiality and restrictions on use contained herein shall not apply to any part of the aforesaid Information which the Government is clearly able to demonstrate:

i. was lawfully in its possession and known to it prior to disclosure by WHO or parties collaborating with WHO, as evidenced by documents antedating the date of disclosure; or

ii. was in the public domain or the subject of public knowledge at the time of disclosure by WHO or parties collaborating with WHO; or

iii. becomes part of the public domain or the subject of public knowledge through no fault of the Government; or

iv. becomes available to the Government from a third party not in breach of a legal obligation of confidentiality in respect thereof; or

v. was subsequently and independently developed by or on behalf of the Government, as shown by written records, by persons who had no knowledge of such Information.

s. Notwithstanding the above, nothing herein shall prohibit the Government from disclosing any of part of the aforesaid Information to the extent it is required to be disclosed by law, provided that the Government shall in such case immediately notify WHO in writing of such obligation and shall provide adequate opportunity to allow WHO and/or the owners of such Information to object to such disclosure or request confidential treatment thereof (provided always, however, that nothing contained herein shall be construed as a waiver of the privileges and immunities enjoyed by WHO, PAHO or the United Nations, including its funds and programs (such as UNICEF), and/or to submit WHO, PAHO or the United Nations and St. Jude to any national court jurisdiction).

11. WHO may request a financial and operational review or audit of the activities undertaken by the Government, to be conducted by WHO and/or parties authorized by WHO, and the Government undertakes to facilitate such audit or review. This audit or review may be carried out at any time during the implementation of the activities foreseen under this Letter of Agreement, or within five years of completion thereof. In order to facilitate such financial and operational audit or review, the Government shall keep accurate and systematic accounts and records in respect of the activities to be implemented under this Letter of Agreement. The Government shall also ensure that it has similar operational review and audit rights with country stakeholders that it is collaborating with in connection with the use and distribution of the donated Medicines. The relevant governmental authority shall make available, without restriction, to WHO and/or parties authorized by WHO:

a. its books, records and systems (including all relevant financial and operational information) relating to the Agreement and related activities; and

b. reasonable access to its premises and personnel.

The Government shall provide satisfactory explanations to all queries arising in connection with the aforementioned audit and access rights.

WHO may request the Government to provide complementary information about the activities undertaken that are reasonably available, including the findings and results of an audit (internal or external) conducted by the Government and related to the activities undertaken.

12. Zero tolerance for sexual exploitation and abuse.
WHO has zero tolerance towards sexual exploitation and abuse. In this regard, and without limiting any other provisions contained herein, the Government warrants that it will: (i) take all reasonable and appropriate measures to prevent sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response (the "Policy") by any of its employees and any other persons engaged by it to perform any activities under this Letter of Agreement; and (ii) promptly report to WHO and respond to, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Government becomes aware. The Policy as amended from time to time by WHO is publicly available on the WHO website at the following link: http://www.who.int/about/ethics/en/. The Government acknowledges and agrees that this clause constitutes an essential term of this Letter of Agreement and that in case of breach of this provision, WHO may, in its sole discretion, decide to terminate this Letter of Agreement and/or any other agreement concluded by WHO with the Government, immediately upon written notice to the Government, without any liability for termination charges or any other liability of any kind.

13. This Letter of Agreement shall remain in force from the date of its last signature until 31 December 2027 and may be extended at that time by written agreement of the Parties. Notwithstanding the foregoing, either party may terminate this Letter of Agreement with the provision of 30 days advance notice in writing.

14. Notwithstanding the termination of this Letter of Agreement, it is agreed that any such termination shall be without prejudice to (i) the ethical and orderly wind-down of ongoing operations, and (ii) any rights and obligations of the GPACCM and the Government accrued prior to the termination of this Letter of Agreement.

15. Those rights and obligations of the Parties that are intended by their nature to survive the expiration or earlier termination of this Letter of Agreement shall survive indefinitely. This includes, but is expressly not limited to, the provisions relating to adverse event reporting, liability and indemnification, confidentiality, the prohibition to reverse engineer, deconstruct or in any way determine the structure or composition of the Medicines.

16. Nothing in this Letter of Agreement shall be deemed to constitute a waiver of any privileges or immunities enjoyed by WHO, PAHO or the United Nations, including its funds and programs (such

as, UNICEF), under national or international law, and/or as submitting WHO, PAHO, St. Jude, UNICEF and/or the United Nations to any national court jurisdiction.

17. Finally, **the Republic of Moldova** agrees to nominate and provide GPACCM by confirming below, at least one appropriate contact who is assigned to oversee coordination and implementation of this initiative with expertise in cancer control, as appropriate, to liaise with us on the GPACCM. Such contacts will also need to be empowered to interface with the GPACCM, the Platform Steering Committee and any subsidiary bodies or governance mechanisms. In addition, through such subsidiary bodies or governance mechanisms, specific SOPs will need to be developed and will fall under this LOA. Such SOPs will, among other things, describe the arrangements that will need to be put in place by the Government to ensure its implementation of this LOA vis a vis country stakeholders working with it in connection with distribution and use of the Medicines. We believe that your government's active participation in the Platform will contribute significantly to the success of the project and improve cancer care for children in your country and around the world.

18. We would be grateful if, in order to indicate your agreement with the above, you could arrange for a duly authorized representative of the Government to counter-sign both originals of this Letter of Agreement and return one fully executed copy to WHO. Upon receipt of the countersigned letter, WHO will consider your country as a recipient country of the GPACCM, and the Parties will be bound by the terms and conditions set out in this Letter of Agreement. In the case this Letter of Agreement is provided in two languages, in the event of a conflict between the English and second language versions, the English one would prevail.

19. This Letter of Agreement may be amended in writing with the agreement of the Parties.

We look forward to working with you to improve access to childhood cancer medicines and to strengthen cancer care for children in your country and around the world.

Sincerely,

Dr Jérôme Salomon

Assistant-Director General
Universal Health Coverage/Communicable
and Noncommunicable diseases
World Health Organization

Acknowledged by Director, Division of Country Health Policies and Systems, World Health Organization Regional Office for Europe

Name: Dr Natasha Azzopardi-Muscat

Date: 12/06/2025

Signature: 

Acknowledged by World Health Organization Country Representative

Name: Dr Miljana Grbic

Date: 12.06.2025.

Signature: 

I, the undersigned, represent and warrant that I have the right, power, legal capacity, and appropriate authority to execute this Letter of Agreement on behalf of the Government of the Republic of Moldova,

Name: Dr Ala Nemerenco

Title: Minister of Health of the Republic of Moldova

Date: 12 June 2025

Signature: 

For any questions regarding this matter please contact:

Name of focal point to accept delivery: Dr Ion Prisacaru, State Secretary of the Ministry of Health of the Republic of Moldova

Delivery address: E-mail: ion.prisacaru@ms.gov.md

CC: St. Jude, UNICEF, and PAHO]

Annex 1a : Issues that will be addressed in the UNICEF PS MOU

a. The Cost Estimate issued by UNICEF on the basis of the allocation instruction provided by the GPACCM and accepted by the Government will constitute a binding contract under the UNICEF PS MOU.
b. Once the Government confirms it has obtained all relevant clearances to take delivery of the Medicines, UNICEF will arrange for shipment of the Medicines. The Government or its nominated representative will be the consignee of the Medicines. UNICEF will not serve as a consignee of the Medicines.
c. The GPACCM will pay all costs and fees related to the Medicines and services requested by the GPACCM and accepted by UNICEF and the Government in accordance with the GPACCM Procurement Agency MOU.
d. Unless otherwise agreed in the Cost Estimate:
    i. UNICEF will arrange for shipment of the Medicines, and the GPACCM will be liable for the costs of that shipment, to the port of entry designated by the Government.
    ii. The Government will be fully responsible for reception at the port of entry, customs clearance and distribution of all Medicines. For the avoidance of doubt, this includes all costs associated with the foregoing (including terminal freight, taxes, toll or other duties related to the receipt of the Medicines at the port of entry) as well as any approvals for the use of the Medicines in the Country (i.e., product registration, waiver, or otherwise).

Annex 1b: Issues addressed in the PAHO Strategic Fund Participation Agreement:

a. The Cost Estimate issued by PAHO on the basis of the allocation decision provided by the GPACCM and accepted by the Government will constitute a binding contract under the Strategic Fund Participation Agreement.
b. Once the Government confirms it has obtained all relevant clearances to take delivery of the Medicines, PAHO will arrange for shipment of the Medicines. The Government or its nominated representative will be the consignee of the Medicines. PAHO will not serve as consignee of the Medicines.
c. The GPACCM will pay all costs and fees related to the services requested by the GPACCM and accepted by PAHO and the Government in accordance with the GPACCM Procurement MOU.
d. Unless otherwise agreed in the Cost Estimate, PAHO will arrange for shipment of the Medicines, and the GPACCM will be liable for the costs of that shipment, to the port of entry designated by the Government.
e. The Government will be fully responsible for reception at the port of entry, customs clearance and distribution of all Medicines. For the avoidance of doubt, this includes all costs associated with the foregoing as well as any approvals for the use of the Medicines in the Country (i.e., product registration, waiver, or otherwise).
f. The Government remains liable for paying any taxes, toll or other duties related to the receipt of the Medicines at the port of entry.