



World Health
Organization



St. Jude Children's
Research Hospital

Orientation guide

for countries joining the Global Platform for Access
to Childhood Cancer Medicines in 2025

Global Platform
for Access to Childhood
Cancer Medicines



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The processes and policies described in this guide may evolve as the Global Platform matures and expands its reach to a larger number of countries. Significant changes will be communicated to participating countries by the Global Platform team.

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Preface

The most important factor in determining whether a child survives after a cancer diagnosis is where that child lives. Each year, approximately 400 000 children develop cancer, nearly 90% of whom live in low- and middle-income countries. While survival in high-income countries is more than 80%, only 10–30% of children with cancer in low- and middle-income countries survive (3).

It was in this context that St. Jude Children’s Research Hospital (St. Jude) and the World Health Organization (WHO), working with other global partners, launched the Global Initiative for Childhood Cancer. The target of the Initiative is to achieve a global survival rate of at least 60% for children with cancer (4).

One of the major obstacles to achieving that goal is access to childhood cancer medicines – for too many children, cancer services are simply not available or affordable. This results in children and their families not seeking, receiving, or completing care. Many hospitals that treat childhood cancer, particularly those in low- and middle-income countries, struggle to achieve consistent access to reasonably priced, safe, effective, and standard quality medicines for their patients. Children lack access to essential curative treatments, or experience prolonged interruptions in therapy, thus increasing their risk of treatment failure and death.

The Global Platform for Access to Childhood Cancer Medicines (Global Platform) was established to provide a transformative global solution to this problem by dramatically increasing access to childhood cancer medicines around the world.

St. Jude has committed to a US \$200 million investment to support the development and launch of the Global Platform in partnership with WHO, the United Nations Children’s Fund (UNICEF), and the Pan American Health Organization (PAHO) Strategic Fund.

The first of its kind, the Global Platform aims to provide an uninterrupted supply of quality-assured childhood cancer medicines, at no cost to low- and middle-income countries participating in the pilot phase, where childhood cancer survival rates are often less than 30%, far below the rates in high-income countries. The goal is to reach 50 nations in the next 5 to 7 years, eventually providing medicines to treat approximately 120 000 children with cancer in low- and middle-income countries and significantly reducing mortality rates (5).

WHO Member States selected to participate in the Global Platform have an unprecedented opportunity to work with the Global Platform team, its partner organizations, and key national stakeholders in an inclusive, collaborative and supportive process that promotes systems strengthening – and in so doing, to transform outcomes for children with cancer in their countries.



Abbreviations

Global Platform	The Global Platform for Access to Childhood Cancer Medicines
PAHO	Pan American Health Organization
SOP	standard operating procedure
St. Jude	St. Jude Children’s Research Hospital
SRA	stringent regulatory authority
SRA CRP	collaborative registration procedure using stringent regulatory authorities’ medicine evaluation
UNICEF	United Nations Children’s Fund
WHO	World Health Organization

Glossary

The definitions provided below are intentionally concise and are provided solely for the purpose of reducing ambiguity within the context of Global Platform processes.

active receipt phase	The stage to which countries progress after they receive their first shipment of medicines. This generally begins in year 2 of a country's engagement with the Global Platform. Countries in the active receipt phase receive regular shipments of medicines and monitor and report quarterly.
administrative operational unit	The team based at WHO headquarters that serves as the secretariat of the Global Platform.
assessment country visit	When Global Platform experts travel to the country to assess, through dialogue with country stakeholders and visits to facilities, the readiness of the country's existing capacity, infrastructure, policies and practices to safely receive, transport, store and administer medicines through the Global Platform.
country operational plan	A country-led operational plan that outlines the activities planned in response to the Global Platform recommendations.
cost estimate	A contractual offer produced by the procurement partner in response to a procurement request, it must be accepted by the ministry of health.
cytotoxic chemotherapy	Medicines that are toxic to cells, typically used to treat cancer.
evidence of completion	Documentation demonstrating that one or more of the minimum standards has been met.
facility eligibility criteria	The criteria that individual facilities (hospitals) must meet to be eligible for participation in the Global Platform (see 2.2.1). Not to be confused with patient eligibility criteria or country eligibility criteria.
financial support	Assistance that countries can request to help them meet the minimum standards needed to achieve readiness and fund any operational changes in procurement and supply chain management that are needed to adopt the Global Platform procurement processes and policies.
focal point	An individual nominated by the ministry of health to liaise with the Global Platform team.
forecasting	The process of taking into account factors such as practice patterns, treatment guidelines, consumption and the country's cancer burdens to estimate future demand. See also quantification.
forecasting data collection tool	A tool used to gather information needed for the quantification and forecasting work theme, designed to be used alongside the shared assessment primer.
Global Platform partners	The distinct organizations that together form the Global Platform – St. Jude, WHO, UNICEF and PAHO Strategic Fund.
Global Platform team	Members of the administrative operational unit and/or representatives and designated experts of the Global Platform partners.
governance mechanism	The steering committee, working group, or similar body set up to oversee the country's participation in the Global Platform.



green light	The go-ahead given by the ministry of health confirming that the country is ready to receive a specific shipment of medicines. Note that countries also require the approval of the Readiness Assessment Panel before they can begin receiving medicines.
hazardous medicines	Products that exhibit one or more serious hazards (carcinogenicity, teratogenicity, reproductive toxicity, organ toxicity at low doses, genotoxicity) in humans or animals; official designation that dictates handling requirements. Note: For the purpose of the minimum standards, may apply to chemotherapy or non-chemotherapy agents. Other classes of medicines can be hazardous (e.g., select antivirals, anticonvulsants, and contraceptives).
key national stakeholders	The individuals and institutions, selected horizontally across sectors and vertically within each area of work, who are instrumental to the country's work with the Global Platform. Key national stakeholders are identified as early as possible in the process and chosen to ensure the inclusion of diverse perspectives, expert insights and practical knowhow.
letter of agreement	The legal instrument formalizing the terms of the country's engagement with the Global Platform, generally signed before or during the country assessment visit.
list of medicines	The Global Platform list of childhood cancer medicines and product formulations that are available for procurement through the Global Platform.
Global Platform forum	A multi-country event arranged to allow key national stakeholders to engage with the Global Platform team and other participating countries to exchange best practice and finetune development of the country operational plan.
minimum standards	The specific safety and security practices that facilities and/or countries are expected to have in place in order to receive medicines through the Global Platform (see Annex 1).
minimum standards activity tracker tool	A tool to help the country track its progress towards readiness by recording which minimum standards it already meets and the activities undertaken to remedy those it does not.
orientation	A meeting scheduled as soon as possible after country selection, with the aim of orienting the ministry of health and key national stakeholders to the Global Platform process and approach. Orientation may comprise a country visit or be conducted virtually.
patient eligibility criteria	The criteria that determine which individual patients will and will not be eligible to receive treatment funded and supported through the Global Platform. Not to be confused with the facility eligibility criteria or country eligibility criteria.
prioritization criteria	The criteria that are used by the Global Platform to determine which eligible countries should be selected for participation in the next country cohort.
priority action	A time-bound action with a defined scope, schedule (start and close date) and roles and responsibilities, that country stakeholders will operationalize in order to ensure the country's readiness to receive, transport, store and administer medicines procured through the Global Platform. Priority actions should be detailed in the country operational plan in response to each recommendation.
procurement partners	The organizations acting as procurement service agents, through which all Global Platform medicines will be procured – either UNICEF or PAHO Strategic Fund. Each country is assigned one procurement partner, based on country location.



procurement planning window	The predetermined time points when participating countries must submit their procurement planning information.
procurement request	This may take the form of a procurement services request form (for UNICEF) or a request for estimate (for PAHO Strategic Fund), and constitutes a request to the procurement partner to provide a cost estimate for supply and delivery of medicines in the quantities indicated.
quantification	The process of calculating the appropriate quantities that should be ordered of each medicine or formulation in the Global Platform list of medicines, taking into account forecasting, inventory levels, and supply chain considerations.
readiness	Verifying that a country's distribution, regulatory and clinical systems are equipped to facilitate the successful receipt, transport, storage and administration of medicines and that its facilities are adequately progressing towards compliance with the Global Platform minimum standards.
readiness assessment panel	The body that reviews the evidence submitted by the country in order to determine whether the country is ready to proceed to the active receipt phase.
request for estimate	The name of the form used by countries to submit a procurement request to PAHO Strategic Fund, in which countries enter the quantities they wish to order. See procurement request.
shared assessment primer	A document template used to gather information about the country's existing capacity, infrastructure, policies and practices on Global Platform-related matters. The primer is designed to be completed in part by representatives of the ministry of health, and in part by practitioners at facility, ward and warehouse level. Answers will be clarified and gaps addressed during the country assessment visit.
standard operating procedures	A written instruction that describes the step-by-step process that must be followed to perform a routine activity properly, ensuring consistency in an organization's practices. The Global Platform provides sample standard operating procedures (SOPs) for adaptation at country or facility level, for example on safe delivery of chemotherapy or facility inventory management.
sterile products	Medicines requiring preparation under aseptic conditions due to route of administration bypassing physiologic defences against infection. Note: not all sterile products are parenteral (e.g., ophthalmic or compounded inhalation products)
sustained supply phase	The stage to which it is hoped countries will eventually progress, in which they are able to access medicines through a sustained supply mechanism co-designed with the Global Platform. The timing and nature of this is yet to be determined.
systems readiness phase	The stage of a country's engagement in the Global Platform in which the country works to ensure that its facilities meet the minimum standards and that the country is ready to safely receive, transport, store and administer childhood cancer medicines. For most countries this spans year 1 of their engagement with the Global Platform.
technical support	Assistance in the form of expertise. Technical support provided by the Global Platform takes the form of assistance countries have requested to support their adaptation of the sample SOPs.
validation	The process of checking that the quantities a country has entered in its procurement planning or procurement request forms fall within the Global Platform's own benchmark estimates.

1

Overview of the Global Platform process

1.1 Scope of this guide

This orientation guide outlines what participating countries can expect when joining the Global Platform from the time the ministry of health is notified of the country's selection until the country receives its first shipment of medicines through the Global Platform.

1.2 Goals of the Global Platform

The Global Platform's goal is to provide participating countries with an uninterrupted supply of quality-assured childhood cancer medicines with end-to-end support – from selecting what formulations are needed and quantifying demand, to procuring, distributing and storing products safely, and administering medicines according to the best possible care standards.

This means that the Global Platform will:

- initially purchase and supply medicines for childhood cancer at no cost to recipient countries
- supply medicines of assured quality and efficacy, from a specified list of medicines selected through a rigorous process
- support countries towards systems readiness, in advance of the delivery of medicines, including supporting national stakeholders to develop an operational plan tailored to country context.

The Global Platform is committed to working to avoid interruptions in supply, promote timely regulatory approvals, and explore innovative approaches to shape the market for childhood cancer medicines.

The Global Platform approach involves national and facility-level clinical and technical staff being empowered to work directly with members of the Global Platform team.

1.3 Guiding principles: our distinctive approach

The Global Platform is an innovative co-created investment in health systems for cancer control intended to foster local ownership of childhood cancer needs including and beyond medicines. The guiding principles of the Global Platform approach are co-creation and inclusive working, built on close collaboration and consultation with clinical and technical staff from national facilities. This involves national and facility-level clinical and technical staff being empowered to work directly with members of the Global Platform team.

Countries are selected to participate not only because of demonstrated need for the medicines, but because

their Government has expressed specified interest in working alongside the Global Platform in this collaborative process. It is also an opportunity for governments to work collaboratively with St. Jude, WHO, UNICEF, PAHO Strategic Fund, the pharmaceutical industry, hospitals, nongovernmental organizations, and nonprofit sector decision makers to co-design a sustainable model that can transform the market for childhood cancer medicines.

1.4 Who you will be working with

The Global Platform team will be working closely with the ministry of health, national stakeholders and designated clinical and technical staff from national facilities. The Global Platform team includes the administrative operational unit based at WHO headquarters that serves as the secretariat of the Global Platform, as well as clinical and technical staff from the Global Platform partners (St. Jude, UNICEF and PAHO Strategic Fund) who support on specific technical areas. A country liaison person within the administrative operational unit will be appointed as the country's primary point of contact.

1.5 Phases of engagement with the Global Platform

Countries selected to participate in the Global Platform can expect their engagement with the Global Platform to progress over time through three broad phases (see Fig. 1 below).

Fig. 1 Phases of country engagement with the Global Platform

The long view: phases of country engagement



Participating countries are encouraged to view their engagement with the Platform as a sustained partnership, the nature of which will change over time.

For most countries, the readiness phase spans Year 1 of engagement. Focused on priority actions to enable countries to safely receive, transport, store and administer medicines.

Most countries begin to receive medicines in Year 2 of engagement. Countries receive regular shipments of medicines and monitor and report quarterly.

Eventually, countries access medicines through a sustained supply mechanism co-designed with the Global Platform.

1.6 Getting ready to receive medicines

1.6.1 What happens in the systems readiness phase?

Getting your country ready to receive medicines, broadly speaking, involves:

- i) working with the Global Platform team to **gather the information** needed to understand the current situation in relation to children's cancer and related health systems in the country, including by reviewing whether facilities meet the Global Platform minimum standards.
- ii) using the information gathered to **identify specific changes** that will need to be made before the country's systems are ready to safely and sustainably transport, store and administer the children's cancer medicines it will receive through the Global Platform, and to **undertake forecasting and quantification** for each product in the Global Platform list of medicines.
- iii) **planning and delivering priority activities** to make the changes needed. The planned activities are set out in a country operational plan and progress is tracked and evidenced.

During this process, participating countries can expect to receive an orientation (which may be a country visit or may be conducted virtually), an assessment visit to the country by the Global Platform team, and technical support

(which may be a country visit or may be provided virtually). Countries will also have an opportunity to exchange experiences with other participating countries at a Global Platform forum, where the Global Platform team and other invited experts will provide guidance on the development of country operational plans. In addition, participating countries can expect regular calls with the Global Platform team on technical aspects of the work.

Once the Global Platform team has adequate evidence that the priority activities have been completed and the minimum standards are met, the country and its participating facilities can be approved as "ready" to receive medicines and the country can receive its first shipment.

The goal is for every participating country to have developed a country operational plan within six months of joining the Global Platform.

1.6.2 How long will it take?

Countries necessarily progress at different speeds depending on a range of country-specific factors. A realistic timeframe for delivery of medicines that is tailored to your country context will be discussed and agreed with the ministry of health as part of orientation.

The goal is for every participating country to have developed a draft country operational plan within six months of joining the Global Platform.

The key factor determining how long it will take for a country to receive its first shipment of medicines is how quickly the country is able to implement the readiness activities in its country operational plan. The speed of implementation will depend on the extent of the readiness gap, as this will determine the number and complexity of the priority activities needed to achieve readiness, as well as on political will, on the effectiveness of the governance mechanism, and on the successful engagement of the stakeholders who must implement the activities on the ground. Fig. 2 illustrates the sequence of key milestones and processes during the systems readiness phase,

which generally corresponds to year one of a country’s involvement with the Global Platform.

Another key component that determines how quickly a country receives its first shipment of medicines is prompt progress on procurement planning.

The Global Platform procurement planning cycle relies on countries sharing forecasting and quantification data with the Global Platform team. This is used to inform procurement planning and get medicines into countries faster. All participating countries therefore submit procurement planning information at predetermined time points, known as procurement planning windows.

Once the country has prepared its procurement planning information, it can join the next procurement window (see Fig. 3). This allows the quantity of medicines needed by each country to be taken into account, facilitates production planning by manufacturers and minimizes the impact of long lead times. The dates of the Global Platform’s next procurement planning windows will be communicated during orientation and an appropriate target window agreed with the ministry of health.

Fig. 2 Sequence of key milestones and workstreams during the systems readiness phase

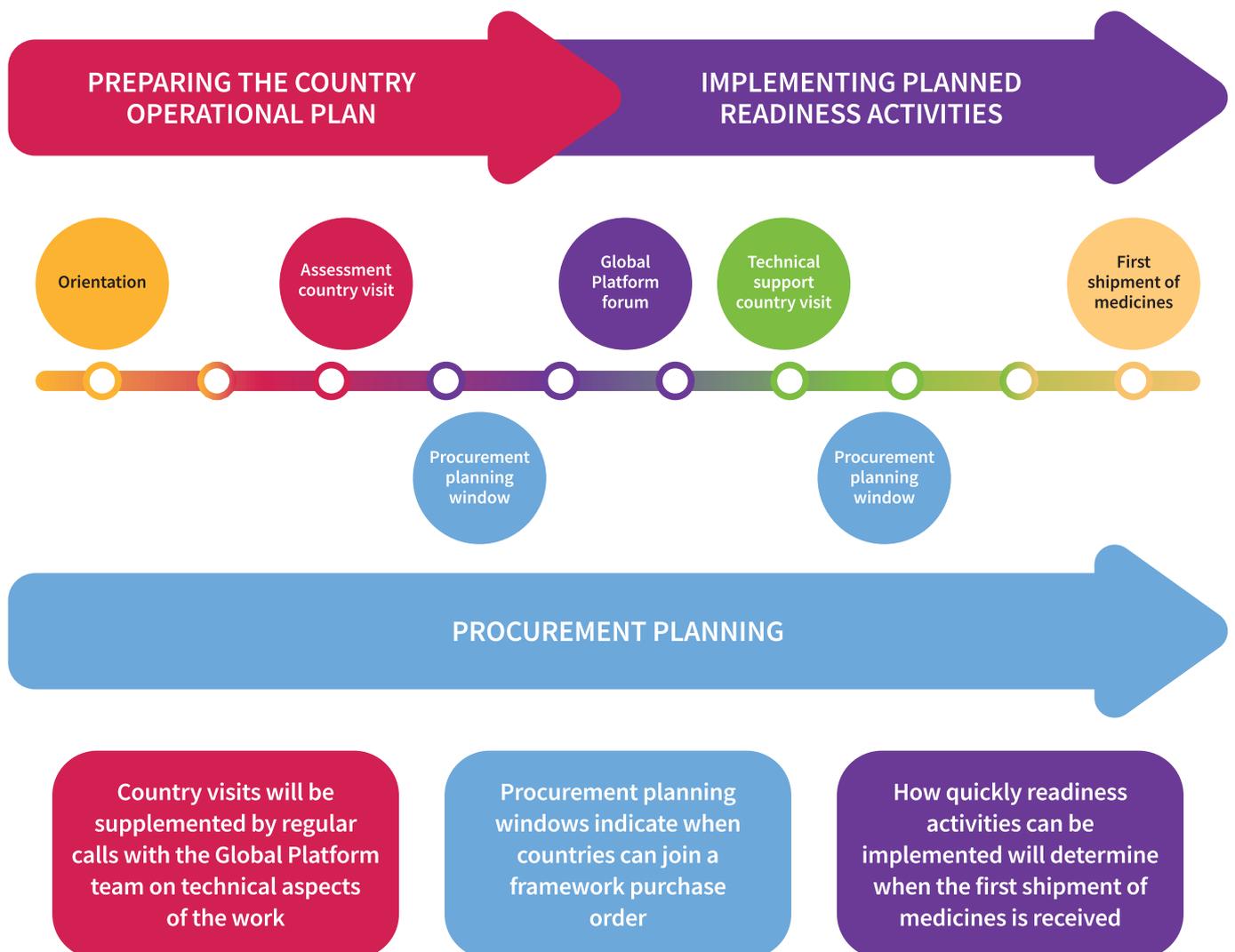


Fig. 3 Procurement planning cycle

Procurement planning information is prepared and submitted in time for a procurement planning window.



Procurement planning windows can be conceptualized as train departure times: countries that miss the first procurement planning window will catch the next.

1.6.3 What determines that a country is “ready”?

Determining that a country is “ready” simply means ensuring that a country’s health system, distribution system and regulatory system are equipped to safely receive, transport, store and administer medicines procured through the Global Platform.

To describe what “ready” looks like, the Global Platform has developed a set of minimum standards that specify the procedures, practices and systems that a country, national system, or specific facility is expected to have in place or be adequately progressing towards before it can be considered “ready” to begin receiving medicines through the Global Platform (see Annex 1. The Global Platform minimum standards).

The purpose of the minimum standards and readiness more generally is to provide assurance that countries have everything they need in place to utilize these life-saving medicines safely and effectively. Meeting minimum standards therefore just means that countries must evidence that:

- i. participating facilities meet certain requirements for systems and practices and
- ii. supply chain capabilities are in place to handle and distribute products appropriately.

Most participating countries are already meeting at least some of the requirements described in the minimum standards. Identifying which minimum standards the country’s facilities and systems do not yet meet, and then planning and implementing suitable activities to remedy this readiness gap, is a key focus of the systems readiness phase – alongside tasks such as signing a letter

of agreement formalizing the country’s engagement with the Global Platform, determining a regulatory approach to Global Platform products, and submitting procurement planning information using adequately robust forecasting and demand data, for example (a full list of readiness criteria is provided in 2.10 below).

1.6.4 Steps to systems readiness and beyond

Section 2 of this guide outlines the key documents and milestones that countries will encounter sequentially during the systems readiness phase, while Section 3 explains the key tasks required under each of the six work themes around which the Global Platform’s work is organized. Once the country receives its first shipment and moves into the active receipt phase, further guidance will be provided.

2

What to expect: milestones and key documents

2.1 Contact information and a welcome call

The first thing countries are asked to do is to provide contact information for the individuals at the ministry of health and national regulatory authority who will be working with the Global Platform team. This will allow arrangements to be made for a welcome call. This is facilitated through the WHO country office.

2.2 Orientation

2.2.1 Timing and purpose of orientation

Orientation will often be conducted virtually, or may involve a country visit. Orientation provides an opportunity for the Global Platform team to introduce the Global Platform approach, with a focus on governance and processes. It establishes the guiding principles of engagement, promoting mutual understanding of how the Global Platform will operate in the country.

During orientation, the ministry of health and other key stakeholders will be oriented to:

- a. the letter of agreement
- b. the establishment of a governance mechanism
- c. the appointment of national focal points
- d. the identification of key national stakeholders
- e. the facility eligibility criteria and facility selection process
- f. the timeline and milestones of the country engagement process
- g. the scope of financial and technical support
- h. the shared assessment primer
- i. the Global Platform's guiding principles of co-creation and inclusive working, which rely on collaboration and consultation with clinical and technical staff from national facilities.

2.2.2 Who takes part in orientation?

To ensure a successful orientation, the Global Platform orientation team would expect to meet with the following:

- a. the minister of health or their deputy
- b. the main liaison for the Global Platform within the ministry of health
- c. the director (or equivalent) of the national regulatory authority (for medicines)
- d. the main liaison for the Global Platform within the national regulatory authority
- e. any other individuals within the ministry of health designated as technical specialists on particular aspects of the Global Platform's work.

- f. representatives of participating facilities, including clinical team members (see the facilities selection criteria)
- g. the main point of contact at the central warehouse
- h. advocacy organizations and patient groups as appropriate.

The orientation team may include:

- a. representatives of the WHO country office
- b. a representative of the WHO regional office
- c. a representative of the regional office of St. Jude Global
- d. the member of the administrative operational unit designated as country liaison
- e. the administrative operational unit programme lead or their designated representative
- f. the country implementation working group lead from St. Jude or their designated representative.

2.2.3 Goals of orientation

By the end of orientation:

- The main liaison person(s) at the ministry of health and the national regulatory authority will have a clear understanding of the Global Platform approach, who they will be working with and the importance of empowering other national stakeholders to engage fully in the Global Platform's collaborative working methods.
- The Global Platform team will have a clear understanding of who they will be working with and will have a better appreciation of the country context.

The Global Platform has developed key documents, templates and tools to help countries as they work towards systems readiness.

See section 3.2.6 on page X for a full explanation of how facilities should be selected.

2.3 The shared assessment primer

During orientation, ministries of health will be introduced to the shared assessment primer, which is a tool for gathering the information that will be needed to assess in what respects the country's health system already meets Platform requirements, and what aspects will require systems strengthening and Platform support – whether financial support or technical support.

2.3.1 When should the shared assessment primer be filled in?

The information requested in the shared assessment primer should be provided as soon as possible, as it is needed to allow the Global Platform team to prepare fully for the assessment country visit. The information is categorized based on how urgently it is needed by the Global Platform team:

- a.** some basic information is needed immediately (within one week of orientation) in order to facilitate planning of your assessment country visit.
- b.** some information is needed by the country visit team well in advance of the assessment visit, but we understand you may need a little time to collect it.
- c.** some information can be provided at the start of the assessment country visit if necessary. However, we encourage you to gather this information sooner if possible and to submit it as soon as you have it.

Updated submissions of the shared assessment primer are expected at three time points:

- a.** within one week of orientation
- b.** at least 3 weeks before the assessment visit, or as soon as most of this information is available
- c.** at the start of the assessment country visit if any further gaps remain.

However, please provide as much of the requested information as possible, as soon as possible.

The Global Platform team will work with the ministry of health and national stakeholders to seek clarification and resolve any gaps during the assessment country visit.

2.3.2 Who should fill in the shared assessment primer?

In the experience of the Global Platform team, the information in the shared assessment primer is most useful when it is filled in not by the most senior-ranking official, but by individuals as close as possible to where that particular activity occurs – by the practitioners, not the policymakers.

This will require some coordination in-country because some information must be provided by ministry of health officials, but some questions should be answered by technical, clinical or nursing staff at warehouse, facility or ward level. The ministry of health is therefore encouraged to distribute and delegate to the person or persons best positioned to provide the answer to each set of questions. For example, this may include:

- a hospital's chief pharmacist
- a hospital pharmacy manager
- supply chain manager
- central warehouse manager
- oncology practitioners
- the head nurse on the oncology ward.

The success of shared assessment – both in the primer and during the assessment country visit – relies on the active participation of the facilities, warehouses, people and systems that will actually transport, store and administer the medicines.

It is important that the questions in the shared assessment primer are answered as completely, as accurately, and as promptly as possible, and that the answers given describe things as they actually are, and not how they are supposed to be – for example, describing usual practice on the ward even where this deviates from the written policy. This ensures that any practical impediments to good practice (such as unsuitable or malfunctioning equipment) are identified so that countries can remedy these in good time.

Answers given should describe things as they actually are, and not how they are supposed to be

2.4 Assessment country visit

Using the information gathered during orientation and supplied in the shared assessment primer, the administrative operational unit will liaise with the WHO country office to organize the assessment country visit.

The assessment country visit involves members of the Global Platform team and appointed experts travelling to the country to meet with key national stakeholders and visit facilities, in order to assess the country's clinical, regulatory and governance readiness to safely receive, transport, store and administer medicines through the Global Platform.

The assessment country visit is not an assessment that countries can pass or fail, but an inclusive and collaborative process based on constructive dialogue and on visiting facilities to see in person the real-world application of policies and practices on the ward or in the warehouse. During the assessment country visit, the Global Platform team, the ministry of health and the national stakeholders work closely together to examine the country's existing capacity, infrastructure, policies and practices and determine their readiness to receive medicines procured through the Global Platform.

2.4.1 Timing and purpose of the assessment country visit

The likely timing of the assessment country visit will be discussed during orientation. The visit cannot occur until after facilities have been selected (see 3.2.6 below).

The assessment country visit usually lasts 4 to 5 days. This may vary depending on the size of the country. During the assessment country visit, key national stakeholders will be oriented to:

- a.** the Global Platform's ethos of co-creation and its collaborative working methods, which are built on direct communication with clinical and technical staff to achieve systems strengthening.
- b.** the Global Platform minimum standards, which describe what needs to be in place at warehouse, facility and ward level in order for that facility to be considered ready to receive medicines through the Global Platform.
- c.** the use of the minimum standards activity tracker tool, which is annexed to the shared assessment primer, which the country will use alongside Global Platform experts to track each facility's compliance with the relevant minimum standards and, in due course, implementation of activities planned to address any identified gaps.

- d.** the Global Platform list of medicines
- e.** the use of the forecasting data collection tool, which is annexed to the shared assessment primer, which the country will use alongside Platform experts to calculate the quantities needed of each medicine.
- f.** The letter of agreement, which is the legal instrument that formalizes the country's participation in the Global Platform and outlines the responsibilities and obligations for both parties.

The Global Platform team will then engage in discussions with national stakeholders to:

- a.** provide an opportunity to discuss how the Global Platform will be governed and managed at national level, and how diverse partners will be brought in
- b.** fill any gaps in the shared information primer or request clarification of information provided
- c.** build understanding of the country's existing medicine procurement process
- d.** begin using the minimum standards tracking tool to record which minimum standards are already met by each facility
- e.** identify potential barriers to Platform implementation
- f.** identify potential mitigation strategies for any barriers identified
- g.** reflect on what success looks like and what is needed for Platform implementation to be successful.

At the end of the visit, the Global Platform team will present a summary of their observations. Written recommendations will be shared with the ministry of health via the WHO country office within two weeks of the country visit, providing the framework for the country operational plan.

2.4.2 Who takes part in the assessment country visit?

Countries are strongly encouraged to involve a broad range of stakeholders from the outset – from the national regulatory authority to procurement and supply chain specialists, representatives of patient groups, the oncologists who will prescribe the medicines and the oncology nurses who will administer them to patients. An inclusive approach at this stage supports more accurate information gathering, greater ownership of the process by those who will be called upon to enact any changes needed, and faster progress towards readiness and the receipt of medicines.

2.4.3 Typical itinerary for an assessment country visit

The itinerary for an assessment country visit is carefully prepared and coordinated with the WHO and UNICEF country offices. It typically comprises a combination of in-depth interviews and meetings with key stakeholders, including government agencies and potential recipient hospitals, as well as visits to hospitals that meet the facility eligibility criteria.

An assessment country visit typically begins with a courtesy meeting with the minister of health or senior officials, followed by a briefing with the governance mechanism and ministry of health team that will be working on Global Platform implementation. Site visits are arranged to participating facilities, to allow the Global Platform experts to meet paediatric oncologists and oncology nurses, hospital pharmacists and warehouse managers, and see the wards, hospital pharmacies, warehouses and other relevant sites. A hospital visit typically begins with a general overview of the hospital staffing capacity of the paediatric oncology department, patient volume and the existing medicine procurement process. This includes a tour and/or discussion with pharmacists, paediatric oncologists and nurses to assess how the facility meets and does not yet meet the Global Platform minimum standards (see Annex 1) and understand any specific issues relating to Global Platform implementation at each visited facility. During the assessment country visit, the Global Platform team will introduce key national stakeholders to the minimum standards activity tracker tool (see 2.10 below), which is used to inform discussions and record observations on site visits.

A meeting with the national regulatory authority is also recommended. Time is scheduled for technical discussions. On the last day of the visit, the preliminary conclusions and recommendations are discussed with the ministry of health and key national stakeholders. In the debrief, a high-level overview of the findings will be provided, commenting on the areas they have identified as needing work and setting out next steps. This will be followed up by written recommendations, which will be shared with the ministry of health via the WHO country office within 2 weeks of the country visit.

Countries are strongly encouraged to involve a broad range of stakeholders from the outset

2.5 Signing the letter of agreement

The letter of agreement must be reviewed and signed by the minister of health to formalize the country's involvement with the Global Platform. The minister of health may wish to complete this in advance of the assessment country visit, or to integrate a signing ceremony into the itinerary for the country visit (for information about what is covered by the letter of agreement see 3.2.4 below).

2.6 Procurement planning

During or shortly after the assessment country visit, the country will be supported to begin work on procurement planning. This involves estimating and forecasting demand and calculating the quantities the country will need for each product in the Global Platform list of medicines. For more explanation see 3.3.2 below.

During or shortly after the assessment country visit, the country will be supported to submit procurement planning information

2.7 The country operational plan

Within 2 weeks of the assessment country visit, the Global Platform team will share its written recommendations – via the WHO country office – with the country’s governance mechanism.

The recommendations will be organized by work theme (see 3.1 below) and presented in the relevant sections of a template country operational plan, thus forming the outline for the country operational plan.

Developing a country operational plan is a core requirement for successful participation in the Global Platform. Its purpose is to provide clarity on the actions that need to be taken – including roles, responsibilities and timelines in relation to each of those actions – in order for the country’s systems, staff and facilities to be ready to safely receive, store and administer medicines procured through the Global Platform, as demonstrated by satisfaction of the minimum standards.

Developing a country operational plan is a core requirement for successful participation in the Global Platform.

2.7.1 Who develops the country operational plan?

The country operational plan is intended to be a country-owned document. Ultimate accountability for execution and monitoring of the country operational plan lies with the ministry of health, working closely with the country governance mechanism. The Global Platform will provide a template plan, but does not prescribe how a governance mechanism should handle the development of the plan, so countries may adopt different approaches. For example, a governance mechanism might choose to:

- a. develop the plan itself with support from local technical, regulatory and policy experts
- b. delegate responsibility for development of the plan to a multi-disciplinary standing technical working group (or committee) composed of representatives from participating institutions (this could be a new entity, or a committee established as part of an existing planning structure, depending on the country context)
- c. convene cross-institutional, topic-specific technical advisory groups to inform specific actions.

The governance mechanism is encouraged to engage regularly with the Global Platform while the operational plan is under development; the nature of this engagement can be mutually agreed at the start of the planning process, to cover:

- a. orientation on the process for preparing the plan, including the tools and guidance in this document
- b. periodic virtual meetings with representatives of the Global Platform to promote joint alignment of the scope and contents of the plan
- c. coordination of any support the governance mechanism has requested from the Global Platform to facilitate content development.

Technical support for development of the country operational plan can be requested in the form of workshops on key topic areas. Meetings with designated representatives from the UNICEF or PAHO country or regional offices may also be a useful source of support.

2.7.2 What should the country operational plan include?

In order to guide countries’ operational planning in relation to Global Platform requirements, the Global Platform has developed a template country operational plan. This template is structured around the six work themes (see 3.1 below), and is designed so that the recommendations made by the Global Platform can be entered first, with space for the country to record the activities it plans to undertake in response to each recommendation.

The recommendations outline the priority changes that the country needs to make to achieve the minimum standards; planning priority activities in response to each of these recommendations and recording these plans in the corresponding fields will therefore result in a robust country operational plan that contains all the information needed included and provides a firm foundation for action. The recommendations also form the basis for decisions about financial support (see 2.8 below).

As the country operational plan is action-oriented, it is recommended that the plan only identify the priority actions that a country will undertake to deliver medicines procured through the Global Platform within the three-year timeframe of the plan. For the purposes of this initiative, a priority action is a time-bound action with a defined scope, schedule (start and close date) and

roles and responsibilities, that country stakeholders will operationalize to deliver medicines procured through the Global Platform. This action could be at the national and/or facility level (single or multiple facilities), and includes all actions from receipt of medicines at the port of entry to medicines reaching the facility or facilities, including national procurement and supply chain, and regulatory action. Priority actions should be informed by and respond to the recommendations made following the assessment country visit.

The plan should identify the priority actions the country will take in response to the recommendations

2.7.3 When is the country operational plan developed?

A template country operational plan will be provided within two weeks of the country assessment visit, into which the Global Platform team will have entered the recommendations made by the Global Platform team at the end of the assessment country visit. Countries are kindly requested to draft their country operational plan with some urgency after this is received and submit the draft in preparation for the country's participation in the Global Platform forum (see 2.9 below). At the Global Platform forum delegates will then have the opportunity to work with the Global Platform team and invited experts to finetune their plan before it is formally endorsed by the ministry of health.

An interim milestone for submission of the draft country operational plan will be communicated to you by the Global Platform's administrative operational unit. The letter of agreement provides that the country operational plan should have been developed and endorsed by the ministry of health within 180 days of signature of the letter of agreement.

2.7.4 What timeframe does the operational plan cover?

The country operational plan is considered to be 'active' for three years. The country operational plan covers all facilities that will receive medicines through the Global Platform during the timeframe of the plan. If a phased roll-out has been agreed – that is, it has been agreed that implementation will begin in some facilities earlier than others, the country operational plan should identify which facility or facilities this applies to, with an indicative timeframe for onboarding of each new facility.

2.7.5 Dissemination of the country operational plan

Dissemination of the country operational plan is overseen by the ministry of health as the accountable body. It is recommended that, once finalized, the country operational plan is communicated in full to all local institutions and participating facilities involved in operationalizing the activities it describes.

To support transparency, the governance mechanism is also encouraged to consider requests for access to the plan from local, regional and global implementation partners including civil society organizations, in order to facilitate customization of support.

The Global Platform may also request the governance mechanism to communicate the plan, either in-full or in-part, to its partners and stakeholders to foster engagement and increase visibility of country actions at the regional and global levels.

2.7.6 Significant amendments to the country operational plan

The country operational plan may be revisited if necessary. This allows national stakeholders to recommend amendments to the actions stated in the plan, for example. However, any significant planned amendment(s) and the rationale for these should be notified to and agreed by the governance mechanism before they come into effect. Examples of amendments to the country operational plan that are considered to be significant include changes in the number of activities, a major change of scope and/or timing of an activity, or change to which facilities are participating in an activity.

Significant amendments endorsed by the governance mechanism should be included in meeting minutes and in regular reporting to the Global Platform. In certain specific instances, the Global Platform should be notified of the amendment outside of the annual reporting cycle, namely:

- if the governance mechanism recommends that an additional candidate participating facility receives medicines from the Global Platform, or recommends that an existing participating facility is excluded from receiving medicines from the Global Platform
- if a change in national policy or law triggers significant amendments to the plan
- if severe risk(s) to the execution of an activity or activities is identified
- if an emergency situation arises causing the pause or halt of any actions in the implementation phase plan.

2.8 Financial support

2.8.1 Scope of financial support available through the Global Platform

Countries participating in the Global Platform can apply for financial support to:

- i) help them meet the minimum standards needed to achieve systems readiness (see 1.6.3 above) and
- ii) fund any operational changes in procurement and supply chain management that are needed to adopt the Global Platform procurement processes and policies.

The Global Platform's financial support mechanism funds expenditure that is closely aligned with recommendations in the country operational plan. It is designed to allow the country to meet the minimum standards and defray costs associated with operational changes to procurement and supply chain management that are required for the country to be able to adopt the Global Platform's procurement processes and policies. Each participating country can tailor its support request based on its own priorities. Table 1 shows the types of expenditure that can be funded. Countries may choose to request funding for one or more categories of expenditure depending on their priorities and needs.

2.8.2 How much funding is available?

Financial support is capped at US \$120 000 per country during the period covered by the letter of agreement with the Global Platform. The maximum duration of the funding is two years. Once a financial support proposal has been approved, countries can expect timely transfer of funds to the WHO country office, where the funds will reside. Transfers of funds to the ministry of health may be permissible under certain circumstances; this can be discussed with the WHO country office after a proposal is approved.

2.8.3 Developing a financial support proposal

Countries are encouraged to begin identifying their financial support needs and preparing a financial support request at the earliest opportunity. All funding requests to the Global Platform should be combined into one country-level proposal – individual facilities may not submit separate proposals. However, if the country submits an initial proposal for less than the capped amount,

a subsequent proposal may be submitted during the period of the letter of agreement if required.

The governance mechanism should oversee the development of the proposal but may manage the development of the proposal however it sees fit. For example, it may choose to:

- a. develop the proposal itself with input from participating facilities
- b. delegate responsibility for development of the proposal to a multidisciplinary ad hoc working group with representation from different facilities
- c. ask individual facilities to identify their own needs and submit these to the governance mechanism, with the governance mechanism handling prioritization in the event that more resources are requested than are available.

Where there are multiple participating facilities, a country may decide to implement a prioritization process based on local factors and considerations. To support preparation of a financial support proposal, the administrative operational unit will request a member of the Global Platform team or an expert consultant who participated in the country visit to participate in a virtual consultation.

Countries are encouraged to begin identifying their financial support needs at the earliest opportunity

Table 1. Types of expenditure funded through the Global Platform's Financial Support Mechanism and information required in financial support requests

Category	Types of Expenditure	Information required in financial support requests
1. Infrastructure	<p>New equipment¹</p> <p>Equipment maintenance. This is a mandatory inclusion for any equipment purchase(s).</p> <p>Repairs and upgrades to existing equipment.</p> <p>Minor upgrades to existing facility infrastructure e.g., storage room upgrades, temperature management infrastructure.</p>	<p>A brief description of the procedures for inspection, servicing and corrective maintenance to ensure the safe and proper operation of equipment is required.</p> <p>Where relevant, the facility should confirm in writing that any necessary changes required to install the equipment are approved and budgeted.</p> <p>For minor upgrades to existing facility infrastructure, the facility should provide confirmation in writing of approval of the proposed upgrades.</p>
2. Training	<p>Costs associated with organizing training to meet minimum standards that cannot be provided as in-kind training by the Global Platform partners.</p> <p>Costs associated with job aides tied to training to meet minimum standards including translation.</p>	<p>A description of how the funds will support training and/or training materials and job aides in the areas referenced in the minimum standards. The number of individuals who will participate in the training, the provider of the training, and the format of the training should be included (virtual or on-site; number of hours).</p>
3. Distribution	<p>Costs for distribution associated with operational changes in procurement and supply management required to adopt the Global Platform procurement processes and policies.</p>	<p>A description of how the funds will support operational changes in procurement and supply management that ensure medicines secured through the Global Platform are safely distributed to participating facilities under the appropriate conditions (temperature, etc.).</p>
4. Quality control	<p>Product Quality Control testing.</p>	<p>The number of unique products undergoing quality control testing and the sites(s) for testing should be provided.</p>
5. Human resources	<p>Cost for human resources required to manage the coordination requirements imposed by the Global Platform where there is demonstrated insufficient existing capacity.</p> <p>Costs for human resources required to operate new procurement and supply management processes and systems (e.g., to coordinate distribution between facilities).</p>	<p>Where relevant, evidence of consultation and agreement with a Global Platform partner country office to support the process should be included.</p>
6. Inventory management	<p>Data capture mechanisms to support monitoring, and consumption and inventory reporting.</p>	<p>A description of the data capture mechanism, how it will support monitoring, and consumption and inventory reporting required by the Platform, and if this mechanism is to be executed at the facility level (identify each facility) or at the warehousing and distribution level.</p>

1 An indicative list of new equipment aligned with the minimum standards is available to a country on request as guidance

2.8.4 What must a financial support proposal include?

A detailed work plan is not required: the total proposal should not exceed five pages, excluding any written approval for proposed infrastructure expenditure, if required (see Table 1 above).

To be considered complete, a proposal for financial support from the Global Platform must include:

- a. a **cover sheet** summarizing key information relevant to the proposal (see Table 2)
- b. a **brief justification** describing how the proposed expenditure will contribute to the country meeting the Global Platform minimum standards and achieving systems readiness.
- c. details of the proposed expenditure:
 - i. a brief description and category(s) of each proposed expenditure
 - ii. the name and position of the individual(s) responsible for overseeing use of the expenditure

- d. **budget**: a table listing the projected costs for each proposed expenditure item (see Table 3).
- e. for specific categories, additional information required as listed in Table 1.
- f. minutes of the meeting of the governance mechanism at which the proposal was discussed and its content agreed, preferably by consensus.

Financial support requests are not competitively assessed: each proposal is assessed individually against the criteria

Table 2. Financial support request: summary cover sheet

Global Platform financial support cover sheet	
Country name	
Focal point for proposal (name and position)	
Date submitted (date proposal submitted to the Global Platform Administrative Operating Unit)	
Requested duration of grant (maximum 2 years)	
Start date (month, year)	
The proposed expenditure supports (tick all that apply)	<input type="checkbox"/> Infrastructure <input type="checkbox"/> Training <input type="checkbox"/> Distribution <input type="checkbox"/> Quality Assurance <input type="checkbox"/> Human resources <input type="checkbox"/> Inventory management
Budget (total amount requested in USD)	

Table 3. Financial support request: budget template

	Description	Unit	No of Units	Cost per Unit (USD)	Total Cost (USD)
	Insert a separate row for each cost, adding more rows as needed	Specify the unit	Total number of units (i.e., across facilities)		
1	Infrastructure				
	e.g. Refrigerator, Mains powered	250L	3	560	1680
				Sub-total	
2	Training				
				Sub-total	
3	Distribution				
				Sub-total	
4	Quality Control				
				Sub-total	
5	Human Resources²				
				Sub-total	
6	Inventory management				
				Sub-total	
				Total	

2 For Human Resources, the proposed salary should include all relevant costs (e.g., social insurance). All salary costs should be within reasonable local market rates. The units should be calculated in number of full-time equivalents (FTE).

2.8.5 Submitting a financial support proposal

Submissions are accepted on a rolling basis. The proposal should be submitted by the ministry of health, typically by the designated focal point for the Global Platform, in PDF format by email to gpacm@who.int.

2.8.6 How financial support proposals are assessed

The Global Platform is committed to working with countries to help them prepare successful proposals.

Financial support requests are not competitively assessed: each proposal is assessed individually against three criteria, whether the proposal:

- a.** is within the scope and level of funding for the financial support mechanism
- b.** is complete based on the guidelines in 2.8.3 above

- c.** is aligned with the stated purpose of the financial support mechanism.

When a country submits a financial support proposal it will be assigned to a financial support assessment panel convened by the administrative operational unit and the Global Platform's partners. The financial support assessment panel has 2 weeks to review the application, during which time it has the option to:

- a.** request clarification(s) to complete its assessment
- b.** request that a country resubmit its proposal.

For proposals deemed to be out-of-scope, outside the level of funding and/ or incomplete, the country will be requested to resubmit the proposal. The final decision will be communicated to the country's designated focal point within 20 days of submission.

2.9 The Global Platform forum

The Global Platform forum is a multi-country event in which representatives of participating countries have the opportunity to meet with other countries and with the Global Platform team and other invited experts in order to learn more about the Global Platform and exchange experiences with other participating countries.

The forum may be held in-person or in a virtual format; countries will receive an invitation and specific details of the date and arrangements for the forum in due course.

The agenda, speakers, and activities of the Global Platform forum may be adapted to address particular needs or knowledge gaps highlighted in the shared assessment primer or in countries' draft country operational plans. However, the broad objectives of the Global Platform forum are for national delegates to learn from other countries and work with the Global Platform team and invited experts to:

- finetune the activities in their draft country operational plan
- clarify the requirement for financial or technical assistance.

2.9.1 Who takes part in the Global Platform forum?

The Global Platform strongly encourages an inclusive approach to participation. The governance mechanism or ministry of health is responsible for nominating representatives and are therefore recommended to facilitate the participation of as many key national stakeholders as possible, ensuring broad representation across facilities and areas of expertise. This could include pharmacists, paediatric oncologists and oncology nurses, officials from national regulatory authorities and supply chain managers.

By the end of the Global Platform forum, participants will have a better understanding of priority activities and strategies for implementation

2.9.2 Outcomes of the Global Platform forum

After participating in the Global Platform forum, participants will have a more detailed understanding of planned priority activities and of strategies to overcome any barriers to implementation of these activities. This will be reflected in the finetuning of their draft country operational plan.

The Global Platform forum is an opportunity for participating countries to learn from each other

2.10 Minimum standards activity tracker tool

The minimum standards activity tracker tool (illustrated in Fig. 4) is used throughout the systems readiness phase to record the country’s progress at facility level against each Global Platform minimum standard; an explanation of the Global Platform minimum standards can be found in Annex 1.

2.10.1 During the assessment country visit: recording a baseline

Countries will first encounter the minimum standards activity tracker tool during their assessment country visit, when it is used by the Global Platform team, in collaboration with key national stakeholders, to record a baseline of whether the central warehouse and each participating facility (at pharmacy and ward level) meets – or does not yet meet – each of the applicable minimum standard.

2.10.2 Informing recommendations

After the assessment country visit, the facility-level information recorded in the tracker tool is distilled into broad, country-level recommendations, which are communicated in a draft country operational plan.

Priority activities are then planned to address these recommendations (see 2.7 above).

2.10.3 Tracking progress on implementation

The minimum standards activity tracker tool is then used to track progress on implementation of the planned priority activities. Each planned activity is entered into the tracker tool, with indication of the timeframe, entity responsible, and any financial or technical support requested for that activity. As activities are completed, this is recorded in the tracker tool. This allows the Global Platform team, the ministry of health and national stakeholders to monitor progress by facility and by minimum standard.

Tracking activities in this way ensures that, in the event of slower than expected progress at any facility or in respect of a particular minimum standard, this is apparent early and so can be addressed promptly. The Global Platform team will refer to the tracker tool in their calls. The same tool can also be used for tracking of any priority activities not related to minimum standards.

Fig. 4 Minimum standards activity tracker tool

Country	Last Update	MINIMUM STANDARDS TRACKER	CW - Central Warehouse	HP - Hospital Pharmacy	HW - Hospital Ward						
Select one of the options in the drop-down box	18-Feb-25	Meets Minimum Standard	✓								
		Does Not Meet Minimum Standard	✗								
		Conditions Unknown	?								
		Resolution activity identified and in progress	🔄								
For Minimum Standards that are not met, add activity and status	Activity Number #	Resolution activity identified and in progress	🔄								
		Resolution activity completed	🟢								
Area of Assessment	Minimum Standard Number	Minimum Standard Description	Product Categories	Location	Suggested forms of evidence	Central Warehouse		Hospital Pharmacy		Hospital Ward	
						Name/Location	Status	Notes	Name/Location	Status	Notes
1. Incoming transport and receiving	MS 1.1	Medicines (pyrotec) that are hazardous are labelled as such at all times during their transit.	🔥	CW HP HW?	Local and facility policies Government attestation of compliance with local requirements	🚩	Could not assess	✓	Activity 008 Complete	✓	Assessed
	MS 1.2	A consistent process or checklist is included in a standard operating procedure (SOP) and used to inspect on receipt: i) quantity and accuracy of shipment and ii) any visible damage to packaging iii) temperature and/or humidity labels if applicable, before signing the proof of delivery (POD).	All	CW HP HW?	Training record log Training materials used	✗	Needs an Activity to resolve	✗	Activity 025 In-Progress		
	MS 1.3	There is a method of accurately booking in the deliveries in a timely manner that includes delivery information recorded/logged in an appropriate manual or electronic system, with the following information recorded: i) product name ii) date received iii) pack size iv) unit of measure v) quantity received vi) batch number vii) expiry date	All	CW HP HW?	Hospital-level data Facility and local policies Government attestation of compliance with local requirements	🚩		🚩			
2. Ambient inventory management	MS 2.1	Procedures for inventory management are maintained in a regularly updated SOP and followed consistently.	All	CW HP HW?	SOP documents Evidence of distribution of training to relevant personnel List of personnel trained on SOPs Evidence of plan to implement any needed operational changes to comply with new SOPs Local and facility policies	🚩		🚩		🚩	
	MS 2.2	Procedures for inventory management are aligned to WHO Good Practice ¹¹ .	All	CW HP HW?	Local and facility policies SOP documents	🚩		🚩		🚩	
	MS 2.3	There is adequate ambient storage space to hold the volume of each medicine that the facility will be receiving based on the country's procurement planning work with the Global Platform.	All	CW HP HW?	Government attestation of compliance with local requirements Photographs of the storage space	🚩		🚩		🚩	
	MS 2.4	The facility has a designated, lockable quarantine area for inspection rejects, non-conformance, and expired products.	All	CW HP HW?	Photographs of quarantine area In-person assessment and attestation by WHO country office	🚩		🚩		🚩	
	MS 2.5	Areas where hazardous medicines are stored are designated with signage.	🔥	CW HP HW?	Photographs of signage List of areas where signs are posted In-person assessment and attestation by WHO country office	🚩		🚩		🚩	
	MS 2.6	There is adequate equipment for conditioning (i.e. air conditioning/dehumidifiers) and for temperature and humidity monitoring (i.e. hygrometers/thermometers) and this is maintained appropriately, including annual calibration where required.	All	CW HP HW?	Photographs of equipment Government attestation of compliance with local requirements	🚩		🚩		🚩	
	MS 2.7	The facility conducts and documents routine monitoring of the temperature of the storage space in which Global Platform medicines are kept (a minimum of once per shift to capture hottest and coldest temperatures).	All	CW HP HW?	Photographs of temperature probes and logs	🚩		🚩		🚩	
	MS 2.8	The facility maintains a controlled ambient temperature environment in the storage space between 15 °C and 30 °C.	All	CW HP HW?	In-person assessment and attestation by WHO country office	🚩		🚩		🚩	

2.11 Technical support

Participating countries that identify a need for technical support in relation to any aspect of Global Platform work are encouraged to raise this with the administrative operational unit. Technical support may be requested at any time, during discussions with the Global Platform team or by email to the administrative operations unit. However, to facilitate planning and avoid delay, countries are encouraged to identify and communicate their technical support needs at the earliest opportunity.

2.11.1 Scope of technical support from the Global Platform

When a request is made for technical support, the administrative operations unit will first review the request to determine whether it is within the scope of the technical support the Global Platform can provide. The scope of technical support provided by the Global Platform is limited to:

- a. providing sample SOPs for procurement and supply chain management and clinical procedures, and
- b. facilitating access to the appropriate Global Platform partners – WHO for questions of procurement and supply chain management and St. Jude for clinical matters relating to the SOP/minimum standards activities – to provide advice on adaptation of the SOPs to the country context and on minimum standards activities
- c. virtual resources compiled through the Global Platform partners
- d. a workshop (maximum five days), which can be requested for delivery in a virtual, hybrid or in-person format, to support countries in the adaptation of the sample SOPs for procurement and supply chain management or clinical procedures.

In order to ensure they have access to the right information, participants in such workshops should include individuals with direct knowledge of and responsibility for actioning the minimum standard in question, who are either part of the process or lead the deliverables. This may include, as appropriate, members of the technical working group at the ministry of health, warehouse managers, pharmacy staff, facility level staff, pharmacy staff, paediatric oncologists, paediatric oncology nurses, etc. Staff training falls outside the scope of Global Platform technical support.

2.11.2 What other technical support is available?

If a technical support need is deemed to fall outside the scope of Global Platform technical support, the administrative operations unit will endeavour to signpost countries to alternative avenues for technical support, such as recommended technical support opportunities from one of the four Global Platform partners (WHO, St. Jude, UNICEF or PAHO Strategic Fund) or other global stakeholders. Alternatively, for specific needs a potential implementing partner may be identified and financial support requested to cover the cost of this.

2.12 Readiness panel approval

2.12.1 How systems readiness is assessed

An initial baseline assessment of systems readiness is made during the assessment country visit, using the information provided in the shared assessment primer and gleaned in dialogue with national stakeholders and facility staff, as well as observations made on visits to hospitals and to the central warehouse. However, no participating country will meet all the readiness criteria at this stage, and it is likely that facilities will not yet meet all of the Global Platform minimum standards (see Annex 1).

Next, there is a period of continuous assessment during which progress against the minimum standards is tracked (see 2.10 above) as the country begins to implement the priority activities set out in its country operational plan. The responsibility for tracking and reporting completion of the readiness activities described in the country operational plan lies with the governance mechanism, which has oversight of this work. However, regular communication with the administrative operational unit is encouraged.

Once the governance mechanism and administrative operational unit are in agreement that the country and/or facility satisfy all the minimum standards and other readiness criteria, the country's readiness is formally approved by a readiness assessment panel.

If some of the country's participating facilities meet all required minimum standards but certain participating facilities need longer to implement required changes, a phased approach may be agreed. (see 3.2.6 D below). This means that the panel approves certain facilities to receive medicines through the Global Platform, but stipulates that other facilities may not receive medicines pending the outcome of a subsequent readiness panel approval in due course.

2.12.2 Evidencing readiness

The readiness assessment panel makes its assessment on the basis of satisfactory evidence of completion of each of the readiness approval criteria shown in Box 1. For each of the readiness criteria, the governance mechanism is asked to provide evidence of completion. Providing "evidence" is nothing onerous, often just a photo or a copy of the policy will suffice. The materials submitted will then be evaluated virtually by the readiness assessment panel.

See Annex 1 for suggestions as to suitable forms of evidence for demonstrating completion for each minimum standard. Note that the governance mechanism is not required to submit all the forms of evidence suggested, but should select the most suitable.

Although individual facilities may be responsible for certain aspects of this process, it is the governance mechanism that has responsibility for compiling evidence of completion for all the criteria and submitting this to the Global Platform via the administrative operational unit. Materials should be submitted on a rolling basis, as soon as a criterion is met – there is no need to wait until all items have been completed.

Note that the country cannot receive medicines until the panel has approved the country's readiness. Countries should therefore plan to have submitted all readiness assessment materials in plenty of time to allow adequate time for the panel's review.

2.12.3 About the readiness assessment panel

The readiness assessment panel will comprise technical experts and Global Platform partners who have engaged in the country dialogues and so are familiar with the country context. The panel will conduct a virtual assessment of the evidence submitted for each of the readiness criteria, and may request additional information or engage in follow-up dialogue until it can affirm that the country readiness criteria have been met to its satisfaction. Once the panel gives its approval, the country is deemed ready to begin receiving medicines from the Global Platform.

A full list of country readiness criteria, which includes non-minimum standards aspects relating to the administration of Global Platform participation is shown in Box 1.

Box 1. Checklist of systems readiness approval criteria

- A governance mechanism has been established in line with the recommended terms of reference and is operating to support Global Platform activities
- The letter of agreement has been signed
- A country operational plan has been developed and endorsed by the ministry of health.
- Agreement has been reached on the validity of procurement planning information.
- A regulatory pathway for medicines received through the Global Platform has been established and agreed with Platform team.
 - All medicines to be received have received market authorization
 - Any discrepancies related to labelling and importation requirements have been resolved
- The government and participating facilities have reporting infrastructure in place to collect and compile the data requested by the Global Platform
 - A focal point for reporting has been identified
 - Operational changes required at warehouse or facility level to achieve the level of reporting requested, such as product tracing or inventory tracking, have been implemented or are adequately in progress
 - Government and facility staff who require training on aspects of Global Platform reporting have been identified and trained accordingly.
- The priority activities set out in the country operational plan in response to the Global Platform team's recommendations have been completed or are adequately in progress.
- Satisfactory evidence has been supplied that the country's facilities and systems meet of all applicable minimum standards, as recorded in the minimum standards activity tracker tool.

2.13 The procurement request

Once the country has received readiness panel approval, countries can finalize their procurement request. To do this, the ministry of health will need to update the quantities to take account of current inventory and submit the appropriate procurement request form to their assigned procurement partner (UNICEF or PAHO Strategic Fund). For explanation of the forecasting and quantification work that lays the groundwork for this step, see 3.3.2 below.

Once the country has received readiness panel approval, it may finalize its procurement request

2.14 Accepting the cost estimate

The procurement partner then generates a cost estimate and sends this to the ministry of health. This will detail the shipment schedule, product expiration dates and documents to be provided.

The ministry of health should then:

- check the cost estimate carefully, querying any errors or discrepancies with the relevant procurement partner (UNICEF or PAHO Strategic Fund)
- sign to accept the cost estimate and submit this by email to the UNICEF or PAHO country office.

Once the ministry of health's written acceptance of the cost estimate is received, the order will be raised with the supplier and the shipment booked with the freight forwarder(s).

If documentation is needed to obtain the necessary import licences and customs clearance permits, or where applicable exemption from registration in accordance with the laws of the country, the ministry of health (or designated consignee) may be asked to supply these.

Note that a cost estimate will not be issued until a country has achieved readiness approval or been deemed sufficiently on track to receive it within the timeframe for delivery (see 2.12 above).

2.15 Giving the green light for first shipment

Before dispatching a country's first shipment of medicines, the procurement partner (UNICEF/ PAHO Strategic Fund) will await the green light for shipment from the ministry of health/consignee, by way of an email to the UNICEF or PAHO country office confirming that all necessary arrangements are in place and the country and facility are ready to receive the shipment.

2.16 Receipt of first shipment: moving into the active receipt phase

When the country receives its first shipment of medicines through the Global Platform, the country moves out of the systems readiness phase and into the active receipt phase, during which countries will:

- continue working towards meeting unmet recommendations in the country operational plan
- submit updated forecasting and demand data when requested to inform procurement planning
- submit regular procurement requests in accordance with the Global Platform procurement cycle
- submit regular monitoring reports (see 3.1 below).

Further guidance on the active receipt phase will be provided in due course.

3

How Platform work is organized: six work themes

3.1 Organized around six work themes

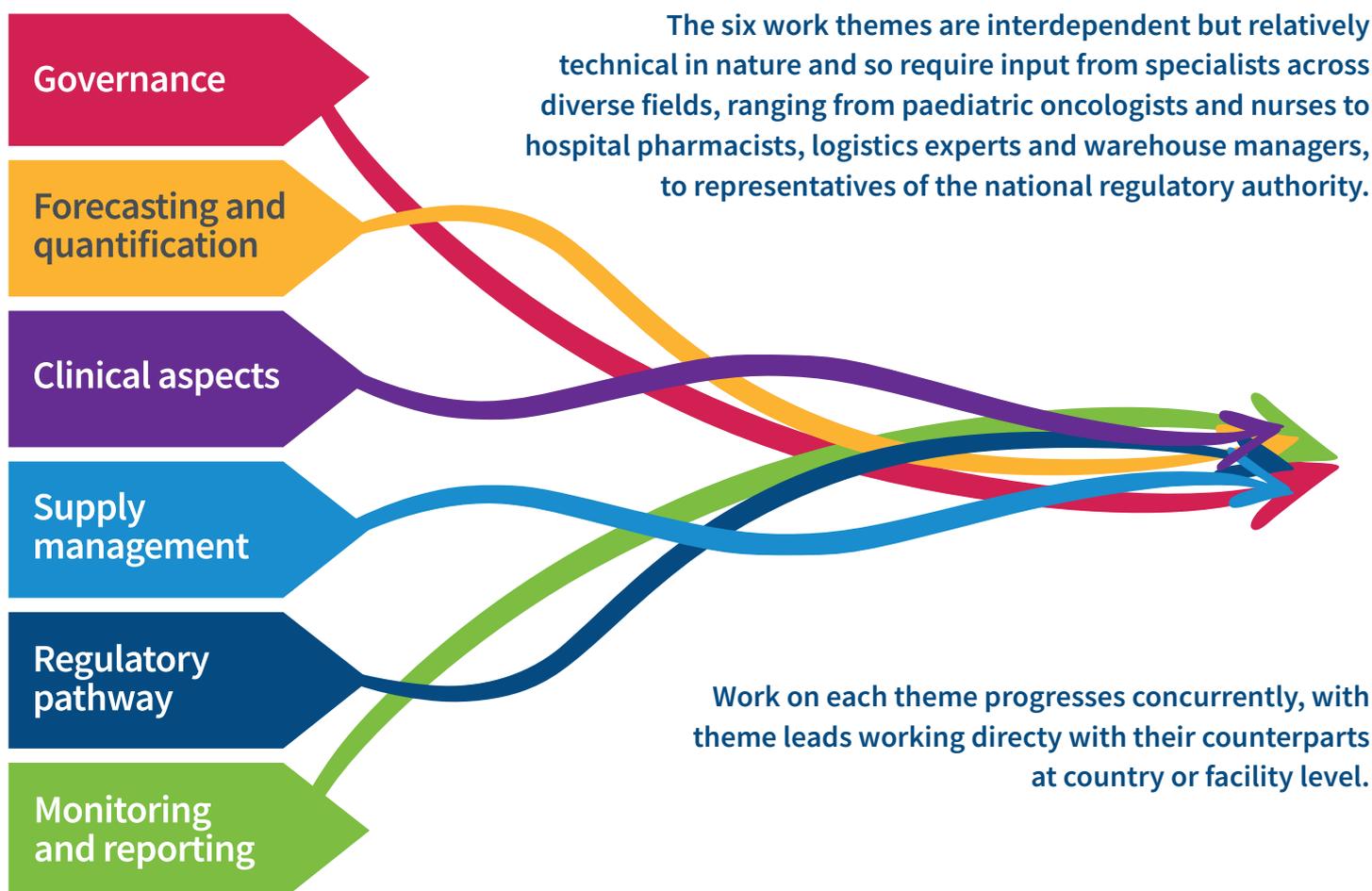
Achieving systems readiness encompasses a range of different fields, each knowledge-intensive and technically skilled. Success therefore requires input from a variety of specialists who understand the country and local context, ranging from paediatric oncologists and nurses, logistics experts and warehouse managers, hospital pharmacists, logistics experts and experts on the country's import regulations and regulatory environment.

For practical reasons, the Global Platform therefore organizes its work around six separate but interdependent work themes – governance, forecasting and quantification, clinical aspects, supply management, regulatory pathway and monitoring and reporting (see Fig. 5). This enables work to progress on each of these aspects concurrently.

In practice, this means that the technical and clinical focal points designated at national and facility level will engage in dialogue with the individuals in the Global Platform team who are leading the relevant work theme. At times, these processes will operate in parallel, with one group of experts working on forecasting while another focuses on regulatory solutions and yet another on supply chain logistics. At other points these separate work streams will converge – such as in the assessment country visit (see 2.4), during the Global Platform forum (see 2.9), and readiness approval (see 2.12).

The key tasks required under each work theme are explained below.

Fig.5 Six interdependent work themes



3.2 Governance

Governance refers to how the countries will conduct programme-related affairs, manage resources, adjudicate issues of common concern, and implement mechanisms by which stakeholders are aligned and accountable. The governance work theme ensures the legal foundation for and sound administrative functioning of the Global Platform's work with the country. This includes identifying key stakeholders and participating facilities, establishing the governance mechanism and signing the letter of agreement.

3.2.1 Who should lead work on this theme?

To facilitate communications with the Global Platform, the ministry of health is asked to designate at least one focal point. This would typically be a representative of the ministry of health and should be someone who is equipped to work with us on a) governance matters and b) operational matters. This could be one person, or two individuals may be designated as focal points, with one handling governance matters and the other operational matters.

It is at the country's discretion to decide on the level of seniority of the person designated as focal point and their role in relation to the governance mechanism. For example, the ministry of health might choose to appoint a senior official as the focal point who also serves as a chair of the governance mechanism (see 3.2.3 below) or might prefer to appoint a more junior official who serves as the secretariat of the governance mechanism but is not formally a member of it. The names and contact details of the designated focal points are requested in the Welcome pack (see 2.1 above).

3.2.2 Empowering technical experts and facility focal points to work with the Global Platform team

The minister of health is encouraged to designate additional national focal points with technical knowledge relating to each of the six work themes – for example, supply chain logistics, or forecasting – both nationally and at facility level (e.g. for each hospital, warehouse), and to empower these individuals to liaise directly with the Global Platform on questions relating to their work theme. This can help to reduce the workload at the central level by enabling quicker answers to practical questions.

3.2.3 Setting up a country-level governance mechanism

A. ABOUT THE GOVERNANCE MECHANISM

To oversee the country's implementation of its participation in the Global Platform at country level participating countries are required to set up a country-level governance mechanism under the leadership of the country's ministry of health. The governance mechanism comprises a steering committee, working group, or similar body set up under the leadership of a country's ministry of health, bringing together key stakeholders in the national response to childhood cancer. It can be an existing structure in the country or one that is newly created to oversee participation in the Global Platform.

B. PRINCIPLES

The following principles should guide the work of the governance mechanism:

- a. ensuring accountability and responsiveness in all aspects of the programme
- b. reaching decisions in a transparent, inclusive way, ideally by consensus
- c. including members of all relevant constituencies in appropriate roles
- d. prioritizing equality of access, treatment and follow up for all children with cancer, with a particular view to addressing historical inequities.

C. FUNCTIONS

The functions of the governance mechanism will vary depending on national contexts but would typically include:

- a. assess and monitor domestic demand for the medicines
- b. validate the selection of facilities that will receive the medicines, in alignment with the ministry of health and with relevant input from the Global Platform
- c. develop and oversee implementation of country- and community-specific plans, including a country operational plan, and Global Platform readiness activities
- d. oversee receipt, distribution, and use of the medicines, in collaboration with domestic regulatory authorities and in accordance with domestic legislation
- e. generate regular analyses of the major risks involved in the implementation of the Global Platform

- f. develop country and community-appropriate communications and advocacy materials to ensure that all relevant domestic medical facilities and practitioners are aware of the Global Platform
- g. monitor country-level implementation, including relevant health outcomes³ and use these data to improve programme performance
- h. facilitate coordination and communication between country-level stakeholders and the Global Platform, including reporting on progress and providing feedback to the Global Platform on the country's implementation of Global Platform-related activities.

D. COMPOSITION AND MEMBERSHIP

The governance mechanism is required to:

- a. be inclusive, comprising representatives from the ministry of health and other government ministries as appropriate, the key public and private hospitals (and/or other health facilities) that treat childhood cancer,⁴ patient and parent groups, WHO and UNICEF country offices, and any other relevant stakeholders, as appropriate and designated by the ministry of health
- b. allow participation on an ad hoc basis to members of the Global Platform as observers
- c. elect at least one and ideally two co-chairs, with one co-chair typically being a senior official of the ministry of health (e.g. the director general or permanent secretary of the ministry of health)
- d. have an agreed term (e.g. a two-year term) for each representative of involved stakeholder groups, with provisions for renewal as appropriate
- e. allow members to identify and agree on new members to replace exiting members or to expand the governance mechanism, should the co-chairs in consultation with members deem that necessary
- f. allow any member to terminate their participation with written notice and
- g. have a provision to enable the membership of any member who is unable or unwilling to participate in a productive manner to be reviewed and potentially terminated.

The governance mechanism can be an existing structure in the country or one that is newly created to oversee participation in the Global Platform.

E. SET-UP AND METHOD OF WORK

Each country should determine whether there are existing mechanisms that could absorb governance for the Global Platform or whether a new mechanism should be established. To facilitate these discussions, the following framework has been developed:

1. if the country has an existing mechanism (e.g., a standing committee associated with the Global Initiative on Childhood Cancer or to oversee the country's National Cancer Control Plan) that brings together the key stakeholders working on childhood cancer (including the different groups mentioned in Section D. above) and can demonstrate that it meets the other guidance described in this document (or can be modified to do so), that structure can be used; or
2. if there is not an existing mechanism, the ministry of health will work with relevant national stakeholders to develop an appropriate mechanism (e.g., establishing a dedicated committee or team from existing or planned resources).

In either scenario, the governance mechanism is required to:

1. be established or be part of an existing governance structure at the national level as soon as possible (typically within sixty days) following notification that the country has been selected to participate in the Global Platform, for the period at least through the end of 2027;
2. agree on a written terms of reference for the governance mechanism, including documenting its mandate and approach to decision-making and, if requested, provide this to the Global Platform for informational purposes;
3. convene regular meetings as well as ad hoc or extraordinary meetings, as and when required as determined by the governance mechanism, though regular meetings should happen not less than quarterly;
4. prepare minutes/notes for the record of all meetings. All participants in the governance mechanism will have an opportunity to review and provide suggested edits before final publication to all members and, if requested, the Global Platform.

To support the development of the governance mechanism, ensure its smooth operations, and facilitate communications with the Global Platform, at least one focal point must be appointed (and some countries may wish to appoint two focal points, with one handling governance matters and the other operational ones). The focal point(s) would typically be a representative of the country's ministry of health.

³ In accordance with agreed key performance indicators, as determined by the Global Platform and agreed with the governance mechanism.

⁴ "Key" public and private hospitals are those facilities that manage a significant volume of childhood cancer cases (such as 20% or more of overall cases), according to the country context, or are designated as specialized, referral hospitals in the public and/or in the private sectors

The Global Platform does not get involved in the selection of the focal point(s), so it is the country's decision as to the level of seniority of the focal point and their role in relation to the governance mechanism.

In addition, to enable rapid engagement with facilities that are receiving medicines from the Global Platform, each participating facility should designate a facility contact person.

3.2.4 Signing the letter of agreement

The letter of agreement is the legal instrument that formalizes a country's participation in the Global Platform and outlines the responsibilities and obligations for all parties. It establishes a framework for cooperation between WHO and the Government of the participating country for the purposes of improving access to childhood cancer medicines, and must be signed as soon as possible.

Soon after the ministry of health is notified of the country's selection, the WHO country office will guide development of a draft letter of agreement customized to the country context. The draft letter of agreement should then be reviewed by the minister of health and signed either before or during the assessment country visit.

The letter of agreement is valid for five years from the date of signature, extendable by written agreement. The agreement may be amended with the written agreement of the parties, and may be terminated by either party, without accrued rights and obligations being affected, with 45 days' advance notice. Certain provisions – including adverse event reporting, liability, indemnification, and confidentiality – survive indefinitely regardless of termination.

Under the terms of the letter of agreement, the government of a participating country agrees to:

- a. develop a country-specific, technical and operational plan within 180 days of signature
- b. facilitate financial and operational review, by WHO or parties authorized by WHO, of the activities undertaken by the Government in relation to Platform work
- c. ensure regulatory compliance for medicine importation and usage
- d. provide necessary approvals and support for export, import, and administration of medicines
- e. adhere to laws and recommendations for proper handling, use and reporting of medicines
- f. indemnify WHO, St. Jude, and procurement partners against liabilities
- g. maintain confidentiality of shared information
- h. comply with pharmacovigilance procedures
- i. ensure zero tolerance for sexual exploitation and abuse
- j. ensure proper receipt, customs clearance, and distribution of medicines
- k. remain liable for taxes, tolls, or other duties related to medicine receipt

- l. not engage in illegal, corrupt, fraudulent or coercive practices
- m. not divert medicines or use medicines inappropriately
- n. establish appropriate focal points to oversee the country's implementation of the Global Platform process.

3.2.5 Involving key national stakeholders from the outset

The success of the Global Platform is built on collaboration – both the collaboration between St. Jude, WHO, UNICEF, and the PAHO Strategic Fund as the Global Platform partners, and the collaboration with and among national stakeholders within each participating Member State.

Although responsibility for and oversight of the country's engagement with the Global Platform rests firmly with the ministry of health, which is supported in this work by the WHO country and regional offices, the Global Platform approach reflects our experience that Member States tend to progress more quickly to implementation when they involve a wide range of key national stakeholders – both horizontally across sectors and vertically within each area of work – at the earliest possible opportunity. Building in this inclusivity from the outset ensures that the minister of health is positioned to delegate the right task to the right people at the right time, reducing delays.

It is strongly encouraged that the ministry of health involve a broad range of stakeholders from the outset – from regulatory authorities to procurement and supply chain specialists, representatives of patient groups, the oncologists who will prescribe the medicines and the oncology nurses who will administer them to patients.

An inclusive approach supports faster progress towards systems readiness and so gets medicines into countries sooner. Close collaboration with the WHO country office is encouraged in order to set in place all the necessary legal and practical arrangements to enable a fruitful collaboration going forward.

Longlist of key national stakeholders

Identifying a longlist of key national stakeholders that the ministry of health may wish to invite to participate can be a useful first step, and countries are encouraged to do this at the earliest opportunity. The WHO country office can assist in this process. Global Platform best practice would be for the ministry of health to consider including as many as possible of the following:

- pharmacists
- hospital pharmacy manager
- supply chain managers
- warehouse managers
- oncology practitioners
- oncology nurses
- someone from the national regulatory authority
- someone from each participating facility
- patient group representatives.

3.2.6 Selecting facilities to participate

The process of determining which facilities will receive medicines through the Global Platform is called facility selection and comprises two steps: first, identifying all facilities that may be eligible to participate (based on the eligibility criteria outlined below), and then determining which of these eligible facilities will be invited to participate and when.

The Global Platform is committed to supporting countries to improve access to medicines, and so is willing and able to provide medicines to the entire population of children with cancer in a country. That means that the starting point for engagement is a presumption that all facilities in a country that are eligible to receive medicines will receive products.

The ministry of health is encouraged to consult widely to identify which facilities may be eligible to participate, noting that some countries may decide either that some eligible facilities should not receive products in the initial phase of engagement (see phased onboarding below), or that certain facilities, although eligible, should not receive products at any point in time.

The facility selection process should occur as early as possible in the process of preparing for the receipt of Global Platform medicines, as this allows each eligible facility to be fully included in orientation and assessment visits, and to provide crucial input into planning of activities, including procurement planning.

As a first step in facility selection, it is strongly encouraged that the ministry of health, in consultation with national stakeholders, undertakes a mapping of all public and private facilities that currently treat children with cancer to fully understand the health care services landscape in the country.

A. FACILITY ELIGIBILITY CRITERIA

i. Only facilities that have established services for treating children with cancer are eligible to participate. It is usually expected that services have been established for a minimum of one year.

ii. Only facilities that are not-for-profit are eligible to participate. While ministries of health are strongly encouraged to consider participation of private facilities that currently treat children with cancer, private facilities are only eligible to participate in the Global Platform if they are not-for-profit. For-profit private facilities are not eligible to receive medicines.

Facilities that meet the above criteria must then meet certain requirements for systems and practices, which are different for principal facilities and satellite facilities:

iii. To participate as a principal facility, the facility must diagnose and manage at least 30 new childhood cancer patients a year

Exceptions include:

- countries in which the total childhood cancer burden is <50 new patients per year and
- hospitals that are growing their services as part of a documented government commitment to centralize services and build capacity accordingly.

iv. To participate as a satellite facility there is no volume threshold, but the facility must have all of the following:

- a.** a professional who is authorized to prescribe chemotherapy (for example, a paediatric oncologist)
- b.** a formal association with a principal centre as defined by the government within the context of the national health system
- c.** a process for sharing or coordinating treatment planning data with the principal facility, and
- d.** a pathway for expedited referral including standards for referral.

Satellite facilities may be those that only treat subsets of children with cancer or treat patients only at selected timepoints (e.g., in the maintenance phase); for satellite facilities, how many patients the facility treats does not affect its eligibility to receive products through the Global Platform.

An inclusive approach supports faster progress towards systems readiness and so gets medicines into countries sooner

B. COMMITMENT FOR PARTICIPATION

Before any eligible facility – whether principal or satellite, public or private sector – begins to receive medicines through the Global Platform, it will have to meet the applicable minimum standards (see Annex 1). The ministry of health should advise each facility of the commitments required of them as a participating facility so that they are aware that they will be assessed and required to meet the minimum standards. Each facility should therefore confirm that they are open to:

- a.** participate in assessments of clinical practices and supply chain capabilities
- b.** make improvements in practices and processes and to meet the Global Platform's minimum standards as a pre-condition to receiving medicines through the Global Platform, and
- c.** share data as part of the Global Platform monitoring and evaluation process.

C. PHASED ONBOARDING OF FACILITIES: CONSIDERING THE TIMING OF PARTICIPATION

For some countries, the best course of action may be phased onboarding of facilities – that is, gradually onboarding eligible facilities in stages, with receipt of medicines timed accordingly so that some facilities begin to receive medicines sooner than others. This approach is fully supported by the Global Platform and orientation and assessment processes can be adapted to ensure eligible facilities are able to join over time. Reasons that a ministry of health and the Global Platform might jointly agree on a phased onboarding approach are:

- to support an initial focus on a particular region(s) or district(s) in the first phase of activities, especially if there are numerous eligible facilities
- to allow for any necessary changes in national logistics processes required for the distribution of medicines to geographically dispersed facilities
- to allow additional time for some facilities to meet the eligibility criteria (e.g., to diagnose and manage sufficient numbers of patients); this might be a particular consideration where countries are actively managing decentralization of health services, or
- to support an initial focus on strengthening access through public hospitals, with private sector facilities coming online subsequently.

All participating facilities will progress through the same process of systems readiness before receipt of medicines, including assessment of the minimum standards – only the timing of activities will differ.

D. DOCUMENTING ELIGIBLE FACILITIES

It is expected that the names of the participating facilities are documented in the minutes of the country governance mechanism.

Any change in the number of facilities is also expected to be recorded in the minutes of the governance mechanism meeting at which this change was agreed. This includes where there is agreed phased onboarding of facilities.

Satellite facilities will not typically receive the full set of medicines available through the Global Platform; the governance mechanism should therefore also clearly document which medicines it is proposed will be used at each satellite facility.

The administrative operational unit may request a copy of the minutes through the relevant WHO country office.

Including representation from all eligible facilities helps ensure that the medicines reach as many as possible of the country's children, regardless of the sector in which they are treated

3.3 Forecasting and quantification

Forecasting and quantification is a vital aspect of the Global Platform's work to transform the global market for childhood cancer medicines – and critical to ensuring uninterrupted supply of quality-assured childhood cancer medicines for your country's facilities. Quantification of the medicines that will be needed is the first step towards placing a procurement request.

3.3.1 Why it matters: accurate data for accurate forecasts to improve market predictability

Accurate forecasting tells facilities and countries how much stock they will need to order and when, which in turn tells manufacturers how much of each medicine or formulation they should produce to meet demand. Accurate forecasting and quantification helps to ensure timely deliveries and minimizes the risks of either ordering too little (so that facilities risk stock outs, meaning they run out of the medicines they need before the next delivery) or ordering too much (so that facilities risk having to store more stock than they have capacity to either store safely or use before the expiry date, leading to avoidable expense and wastage). In helping improve the predictability of the demand for childhood cancer medicines, accurate forecasting thus helps to ensure uninterrupted supply of medicines.

3.3.2 What it takes

Forecasting and quantification requires understanding the country's paediatric cancer burden, determining what products on the Global Platform list of medicines are needed and calculating what quantity of each medicine should be stocked by each participating facility. This entails supporting countries and facilities to gather facility-level data on consumption, paediatric cancer burden estimates and treatment regimens/schemes. The consumption-based estimates can then be further refined with information about clinical practice. This results in a one-year quantification of the requirements for each of the medicines or product formulations listed in the Global Platform list of medicines.

3.3.3 Using forecasting tools to gather demand data

The ministry of health will be supported to gather demand data in relation to products on the Global Platform list of medicines. This may include the country's paediatric cancer burden, patient cohort information, treatment schemes,

previous procurement records, consumption, morbidity data, inventory information, safety stock requirements and any other information as required by the forecasting tools used by the Global Platform (ChemoGlobe and Quantmet).

To do this, countries will be asked to provide information in a forecasting data collection tool. This includes information to determine disease burden by facility, preferred treatment regimens and established clinical practices.

3.3.4 Who should be involved in forecasting and quantification?

An orientation briefing on forecasting and quantification will form part of the assessment country visit or be provided by means of a call with the Global Platform team. Participants in the orientation briefing would ideally include:

- a. technical working group focal person (ministry of health)
- b. person(s) who will undertake forecasting and/or have responsibility for submitting the procurement planning and procurement request forms (ministry of health)
- c. inventory/procurement services manager (ministry of health)
- d. person(s) responsible for procurement (ministry of health)
- e. clinicians familiar with treatment of paediatric oncology for each participating facility (that is, someone who can help anticipate any changes to treatment approaches that might be needed to make optimal use of Global Platform products and understands which products are a priority for the facility).
- f. the person responsible for purchasing at the facility or facilities (that is, someone who has an understanding of products, typical consumption, and the typical procurement process).
- g. staff who oversee the storage and/or preparation of chemotherapy (that is, someone who can help anticipate changes needed to practice, such as changes in standard concentrations).
- h. pharmacy focal point for each participating facility
- i. other partners involved in producing estimates (as appropriate).

Participants will be oriented to the Global Platform list of medicines and take part in a clinical review to discuss any variations to existing clinical practices in relation to the products in the Global Platform list of medicines.

3.3.5 Validation of forecasting

If the country has more than one participating facility, consideration will need to be given to how and when facility-level forecasts are aggregated at national level in order to arrive at the total quantities required to ensure adequate national supplies. Consolidating demand data at national level can enhance purchasing efficiency, for example, in consideration to minimum order quantities and shipping frequency – where the need for a particular product arises only infrequently, or expiration dates are short, it may be preferable to order a combined quantity adequate to meet national need, with hospital pharmacies requesting that item from the central warehouse as required. The Global Platform team will advise on how this might best be achieved based on country context.

3.3.6 Aggregation at national level

If the country has more than one participating facility, consideration will need to be given to how and when facility-level forecasts are aggregated at national level in order to arrive at the total quantities required to ensure adequate national supplies. Consolidating demand data at national level can enhance purchasing efficiency, for example, in consideration to minimum order quantities and shipping frequency – where the need for a particular product arises only infrequently, or expiration dates are short, it may be preferable to order a combined quantity adequate to meet national need, with hospital pharmacies requesting that item from the central warehouse as required. The Global Platform team will advise on how this might best be achieved based on country context.

3.3.7 Turning the forecasts into a procurement request

The primary output of the Global Platform’s forecasting and quantification work theme is the preparation of a procurement request. Once the national stakeholders have gathered the requested demand data, the ministry of health will be supported to convert these into a procurement plan, which will be validated by the Global Platform team. To do this, countries will work with the Global Platform team to gather and apply facility-level stock and pipeline data. The Global Platform team will work with countries to develop an optimal plan for stock-on-hand and buffer stocks at both hospital and warehouse levels.

Later, once the country has received readiness approval, it can proceed to complete a procurement request. If significant time has passed since the data were collected, the ministry of health may need to update these validated quantities to take into account inventory currently held or already on order. Once quantities have been validated by the Global Platform team, they can be entered into a procurement services request form (for UNICEF) or request for estimate (for PAHO Strategic Fund). Any queries raised

during the validation and discussions will be clarified and resolved with the country. If further guidance is needed, please contact the Global Platform’s administrative operational unit.

3.3.8 PAHO countries: request for estimate

For countries whose assigned procurement partner is PAHO Strategic Fund, this means filling out a “request for estimate” form and submitting this directly to PAHO just as they would for other medicines procured through the PAHO Strategic Fund.

3.3.9 UNICEF procurement services request form

Countries whose assigned procurement partner is UNICEF will instead fill out UNICEF’s procurement services request form (see Box 2). Once the procurement services request form has been completed it should be submitted directly to the UNICEF country office by email.

Once the country has readiness approval, the quantities may need to be updated to take into account current inventory

Box 2. Completing the UNICEF procurement services request form

Section A of the procurement services request form: about the requester

Fig. 6 shows Section A of the UNICEF procurement services request form. This section requests contact information about the requester. The information in Section A is likely to remain unchanged from one order to the next, but should be reviewed whenever a new procurement services request form is submitted in order to ensure this information remains up to date.

- Under Organization, you should enter “ministry of health of [country name].”
- Under Contact Name and Contact Title and Address, please provide the name, title (Mr, Ms etc) and contact details of the designated official(s) from the ministry of health (address, e-mail, phone/mobile number, fax).
- Under Project Name, enter “Global Platform for Access to Childhood Cancer Medicines (GPACCM).”
- Under Funding Source, enter “GPACCM (Other/Grants).”

Fig. 6 Section A of the procurement services request form: requester details

Request for Procurement Services		unicef 	
Section A : Requestor			
<small>Fields marked * in Section A are mandatory</small>			
* Organisation:			
* Contact Name:			
* Contact Title:			
* Address:			
* Telephone:		Fax :	
* Email:		Date:	
* Project Name:			
* Funding Source:	Select from Drop Down	If other please specify:	
Allocated Budget :		Grant/Loan Expiry Date:	
* Do you have a signed Memorandum of Understanding with UNICEF:			
* Have you previously procured via UNICEF:			
If known, please specify your UNICEF Partner code:			

Section B of the procurement services request form: delivery instructions

Fig. 7 shows Section B of the procurement services request form, which requests delivery instructions.

- Under **Special Markings** enter specific instructions about any special markings that are required. For example, labelling requirements, product information leaflet /Package Insert (PI) including GS1 bar coding (6).
- Under **Requested Delivery Date** please enter the required delivery schedule. For instance, you may require 50% of the order to be delivered by quarter 3 of 2025, 25% by quarter 4 of 2025, and 25% by quarter 1 of 2026. Take into consideration the anticipated lead times for order processing by UNICEF (1 week), product delivery by the manufacturer/supplier (2-16 weeks) and shipment by the freight forwarder (2-8 weeks) after acceptance of the cost estimate by the ministry of health.
- Under **Mode of Shipment**, please select from the drop-down menu (sea, air, truck/other). If two modes of transportation are required, please select “other” and specify in the mode of shipment.
- Under **Specific Requirements for Custom Clearance**, enter details of any specific documentation required for customs clearance in the receiving country. This may include airway bill, certificate of analysis, etc. Note that entering a request does not guarantee that these documents can be provided; the cost estimate will specify which documents will be included in the shipment.
- Under **Delivery Terms/Place** enter the INCOTERMS 2020 Carriage and Insurance Paid to (CIP) and Named Destination (i.e., CIP Country 1, Named place of destination, where the product will be delivered to by sea, air, road etc) (7).

Box 2. Completing the UNICEF procurement services request form *continued*

Section B of the procurement services request form: delivery instructions *continued*

- Under **Consignee**, enter the name of the facility the consignment is to be delivered to (e.g. central warehouse) and its full mailing address, which will be used for the distribution of shipping documentation. The consignee may be the ministry of health or its designated representative. This may be a central warehouse, a third-party logistics contractor, a single hospital, or the WHO country office. Designating the UNICEF country office as the consignee is not permitted.
- Under **Contact name**, enter the name and contact details of the person who will be responsible for customs clearance of the goods, including email address, phone number, fax and alternative telephone numbers.

Fig. 7 Section B of the procurement services request form: delivery instructions

Section B : Delivery Instructions	
<small>Fields marked * in Section B are mandatory</small>	
Special Markings:	<i>Enter specific instructions about any special PO markings for shippers and pallets</i>
Special Labeling:	<i>Enter specific instructions about any special labeling for primary and secondary packaging. Please note that special labeling is not available for items delivered from UNICEF Warehouse. For items shipped from UNICEF's suppliers possibility of custom labeling is subject to confirmation from the supplier</i>
*Requested Delivery Date:	<i>Enter the required delivery date taking into account processing time. Average lead time is 6-8 weeks after the receipt of funds at Supply Division for an accepted Cost Estimate, dependent on availability and commodity.</i>
*Mode of Shipment :	Select from Drop Down
If other please specify:	
*Delivery Terms/Place:	Incoterms 2020 CIP
*Named Destination :	
Specific Requirements for Custom Clearance:	<i>Advise if any specific requirements/documentation is required for customs clearance purposes in the receiving country (Please note that this does not guarantee that your requested documents can be provided).</i>
*Consignee	<i>Please enter the organisation's name of the consignee.</i>
*Contact Name:	<i>This contact person shall be notified in advance of the arrival of the goods at the port of entry.</i>
*Address:	<i>Include the full mailing address. This information shall be used for distribution of shipping documentation.</i>
P.O. Box:	
*City:	
*Country:	
*Telephone 1:	
Mobile:	
Telephone 2:	
*Fax:	
*Email:	
Registration/Tax number:	
<small>Please provide back up communication channels: e.g. generic consignee's e-mail, alternative e-mail and telephone.</small>	

Section C of the procurement services request form: list of requirements

Fig. 8 shows Section C of the procurement services request form. This section requests quantitative information about the medicines required and should be completed in accordance with the validated procurement planning information.

- Under Product description, enter the name of the product selected from the Global Platform list of medicines (using the generic/international non-proprietary name or proprietary name in the case of patented medicines).
- Under Unit indicate the unit of measurement (UOM) for that product formulation.
- Under Quantity, enter the quantity of product required, taking into consideration the shipping frequency indicated in the list of medicines.

The Global Platform team will provide guidance on how to update the quantities validated in the procurement planning process to take account of inventory and stock already on order. Technical queries about forecasting methodology can be addressed to the Global Platform administrative operational unit.

Note that the quantities entered in Section C will need to be reviewed before each new submission to reflect updated data from facility level on product demand and stock levels.

Fig. 8 Section C of the procurement services request form: list of requirements

SECTION C: List Of Requirements					
<small>Please refer to the UNICEF Supply Catalogue - available on-line at https://supply.unicef.org catalogue for information on the supplies you require.</small>					
<small>Please provide detailed specification for all items not included in our catalog.</small>					
Item	Product Number	Product Description	U.O.M	Quantity	Req. Del. Date.

3.3.10 Accepting the cost estimate

PAHO Strategic Fund or UNICEF will use the procurement request to generate a cost estimate detailing the shipment schedule, product expiration dates and documents to be provided.

The ministry of health should then:

- check the cost estimate carefully, querying any errors or discrepancies with UNICEF/PAHO Strategic Fund.
- sign to accept the cost estimate and submit this by email to the UNICEF/PAHO country office.

Once the ministry of health's written acceptance of the cost estimate is received, the order will be raised with the supplier and the shipment booked with the freight forwarder(s).

If documentation is needed to obtain the necessary import licences and customs clearance permits, or where applicable exemption from registration in accordance with the laws of the country, the ministry of health (or designated consignee) may be asked to supply these.

Note that a cost estimate will not be issued until a country has achieved readiness approval or been deemed sufficiently on track to receive it within the timeframe for delivery.

3.3.11 Giving the green light for first shipment

Before dispatching a country's first shipment of medicines, the procurement partner (UNICEF/PAHO) will await the green light for shipment from the ministry of health/consignee, confirming that all necessary arrangements are in place and the country and facility are ready to receive the shipment. This should be by email to the UNICEF or PAHO country office as applicable.

3.4 Clinical aspects

Clinical aspects include the country's paediatric oncology staffing capacity, resources, regimens and procedures.

The clinical work theme therefore includes dialogues related to:

- a.** adherence to minimum standards
- b.** standards of care
- c.** understanding practice in order to appropriately forecast needs
- d.** orienting the introduction of drugs and formulations on the Global Platform list of medicines into clinical practice where these are new to the country.

For example, where appropriate, the Global Platform may provide support on challenges associated with clinical aspects such as changing to a preferred clinical protocol based on availability of new products through the Global Platform or updating drug information materials to reflect new product specifications. This support will not be required for all countries/facilities or for every new product.

3.4.1 Clinical review to identify variations to existing practice

Clinical review to discuss any variations in existing clinical practices in relation to the products in the Global Platform list of medicines is conducted alongside the technical dialogue on forecasting and quantification (see 3.3 above).

3.5 Supply management

Supply management involves ensuring that products procured through the Global Platform can be transported between and stored safely at the port of entry, central warehouse, hospital pharmacy and ward. This is assessed against the Global Platform minimum standards (see Annex 1), which describe what procedures, practices and systems must be in place at warehouse, hospital pharmacy and ward level.

3.5.1 Mapping supply chain storage architecture

The first task is to understand the country's health supply chain architecture and who is responsible for what. This information is requested in the shared assessment primer, which also asks countries to nominate the individuals who will be working with the Global Platform team to assess the relevant facilities.

In many countries, health supply chains will have a three-tier storage architecture as shown in Fig. 9, comprising a central warehouse, from where medicines are shipped to hospital pharmacies, from where they are sent to wards.

However, in some countries geographical considerations might mean there is no need for a central warehouse, while others may distribute via regional hubs.

Understanding the basic architecture of the country's supply chain, and how medicines are delivered between the tiers is the first step to understanding what particular challenges the country faces in relation to its supply chain.

Fig.9 Three tiers of in-country supply chain storage

Central warehouse

- Highest in-country tier of supply chain storage.
- Built-for-purpose, and best equipped with supply chain equipment such as air conditioning, refrigeration, heating, temperature and humidity monitoring.
- Staff are trained in product storage and handling.
- Most of a country's stock should be stored at central warehouse level.



Hospital pharmacies

- Hospital pharmacies should be restocked on a scheduled, "as needed" basis, ideally monthly.
- Hospital pharmacies provide well-equipped, centrally managed storage at hospital level.
- Chief pharmacists have good knowledge and oversight of storage protocols.
- Most of a hospital's stock should be stored at hospital pharmacy level.



Wards

- Wards need to have adequate storage for medicines being administered but should restock frequently from the hospital pharmacy (eg. daily).
- Although ward staff must know and follow storage protocols, their natural focus is on treating patients.
- Only minimal stocks of products should be stored at ward level.

3.5.2 Assessing supply chain readiness

The Global Platform team will use the information provided in the shared assessment primer to plan the assessment country visit, taking into account the country's supply chain architecture and the number and location of participating facilities. During the assessment country visit, the Global Platform team will work with key national stakeholders to review the supply chain and visit the hospital pharmacies and paediatric oncology wards of participating facilities, as well as the central warehouse and in some cases customs clearance at the port of entry in order to assess each component of the country's supply chain infrastructure against the Global Platform minimum standards set out in Annex 1.

The questions asked in the shared assessment primer and during the assessment country visit will help the Global Platform team and key national stakeholders to better understand:

- a. specific products and their logistical characteristics
- b. lead times (both to procure and to deliver)
- c. stages of transit, storage and consumption
- d. stock holding requirements due to lead times and supply chain operational uncertainty and risks
- e. inventory and consumption reporting and communication
- f. risks due to issues such as temperature control excursions, expiration, stock outs etc.
- g. effectiveness of supply chain operations: people, process and technology.

The objective of assessment is to determine whether the national health supply chain is capable of delivering childhood cancer products to the required facilities on time and in full, and to identify what specific changes are needed in order for it to be able to do so. These changes will be expressed as recommendations, which inform the country operational plan.

3.5.3 Logistics and distribution from the port of entry

Products procured through the Global Platform are delivered "cost and insurance paid" to the port of entry designated by the participating country. If supplies are to be shipped by air, the port of entry is usually the nearest major international airport. For sea shipments, the port of entry is usually the nearest major international seaport in the participating country. For land-locked countries, the seaport of entry is decided on a case-by-case basis. In general, air shipments carry a higher delivery cost than ground or sea shipments.

This means that assessment of supply management will also include a review of appropriate storage capacity and SOPs at the port of entry, including consideration of the time usually required for customs clearance and, in the

event of delay, what arrangements are in place to expedite customs clearances for medicines with short expiry dates.

Supply chain assessment will review how medicines are transported from the port of entry to the warehouse, from the warehouse to the central pharmacy, from the pharmacy to the ward. This is particularly critical where there is a risk of temperature control excursion.

3.5.4 Holding stock at the highest tier of the supply chain

Best practice in low- and middle-income countries is to hold stock at the highest tier of the in-country supply chain, and ship from there on a scheduled "as needed" basis. This is because product quality is easier to guarantee and control if most items are stored in a single, "built for purpose" warehouse facility. Central warehouses tend to receive the most funding for supply chain equipment – such as air conditioning, heating, refrigerators, freezers, temperature and humidity monitoring – and are therefore better equipped to handle bulk storage of both ambient and cold chain items. Central warehouse staff are trained in product storage and handling, minimizing the risk of human error.

3.5.5 How much and how often

Successful supply management is intimately linked with accurate forecasting and quantification (see 3.3 above), as a key aspect is deciding how much and how often to deliver: overstocking can be as problematic as understocking, because this leads to additional costs and challenges associating with storing the excess stock, especially in the case of cold chain products.

When deciding how much and how often to deliver, it is therefore important to consider the capacities and limitations of the storage facilities available at the delivery location. Larger shipments require more storage space, increase cold chain refrigeration costs, and risks a larger quantity of product being damaged in the event of a temperature excursion.

3.5.6 Supply planning

Drawing closely on work done on forecasting and quantification, countries will be supported to conduct supply planning that covers all aspects of:

- a. initial stocking or "priming" of the supply chain
This requires clinical forecasting of the volume and timing of products that will be required to adequately stock all levels of the supply chain prior to launch.
- b. steady state operation of the supply chain
This requires clinical forecasting of the volume and timing of restocks that will be required once distribution is operational.

3.6 Regulatory pathway and quality assurance

The regulatory pathway work theme encompasses all aspects of the country's rules and regulations governing the importation of medicines, including market authorization and quality control, and how these will apply to medicines received through the Global Platform.

This section outlines best practice approaches to guide countries as they make the regulatory preparations necessary to be able to receive medicines through the Global Platform.

3.6.1 Designating a national regulatory authority focal point

The first task is to designate an individual at the national regulatory authority who is empowered to liaise with the Global Platform on regulatory matters. Including a representative of the national regulatory authority at the earliest opportunity means that regulatory issues can be anticipated, giving the ministry of health adequate time to consider how these can best be addressed.

3.6.2 Identifying regulatory barriers early

The designated focal point will liaise with the Global Platform team to identify the specific regulatory barriers that stand in the way of Platform-procured medicines reaching children with cancer in the country. For example, depending on the country context, regulatory barriers to the importation of medicines may arise in connection with:

- quality assurance
- labelling or packaging requirements
- registration of medicines.

For example, some countries have legislation requiring that all medicines be labelled in the local language before an import license can be granted. Others may have specific requirements around barcoding or packaging of medicines. Any relevant labelling or packaging requirements should be identified in relation to each of the products included in the Global Platform list of medicines and appropriate consideration be given to how these will be addressed in a timely manner.

A clear and complete understanding of what the regulatory barriers are is critical. It is also useful to understand, if applicable, what solutions the country has used previously to overcome regulatory barriers for medicines procured through international donors. This will facilitate work

planning and help ensure that the country can receive medicines through the Global Platform without regulatory delay.

3.6.3 Selecting a regulatory pathway

A. THREE MAIN OPTIONS

Under the guidance of their national regulatory authority focal point, participating countries are encouraged to make a broad determination as to which regulatory pathway they propose to take in relation to medicines supplied by the Global Platform. The main options to consider are:

Regulatory waivers

A waiver approach may be preferred to address regulatory requirements or import rules that are anticipated to take a long time to fulfil relative to the timeframe for the implementation of the country's Global Platform systems readiness phase. Due consideration should also be given to the length of time needed for the process of obtaining such waivers and to which regulatory aspects the waiver will cover – such as registration, import fees and/or quality control testing. When considering what aspects the waiver will cover, it is important to note that the responsibility for quality control of the medicines it receives rests with the country.

Participating countries are encouraged to make a broad determination of the regulatory pathway they wish to take

Facilitated regulatory pathways (8)

In some countries, regulatory systems may provide for regulatory approval to be achieved using facilitated regulatory pathways. These make use of the concepts of reliance and collaboration in order to facilitate regulatory decisions and accelerate the introduction of quality-assured products in countries. In essence, this means that the country's national regulatory authority relies on and recognizes the assessment and decisions made by another regulatory authority as to the quality of the medicines. This approach is advantageous for countries with lower levels of regulatory maturity, with limited resources and expertise and lacking international collaboration, as it helps their national regulatory authorities to manage the growing complexity of supply chains and address various global health challenges.

Registration

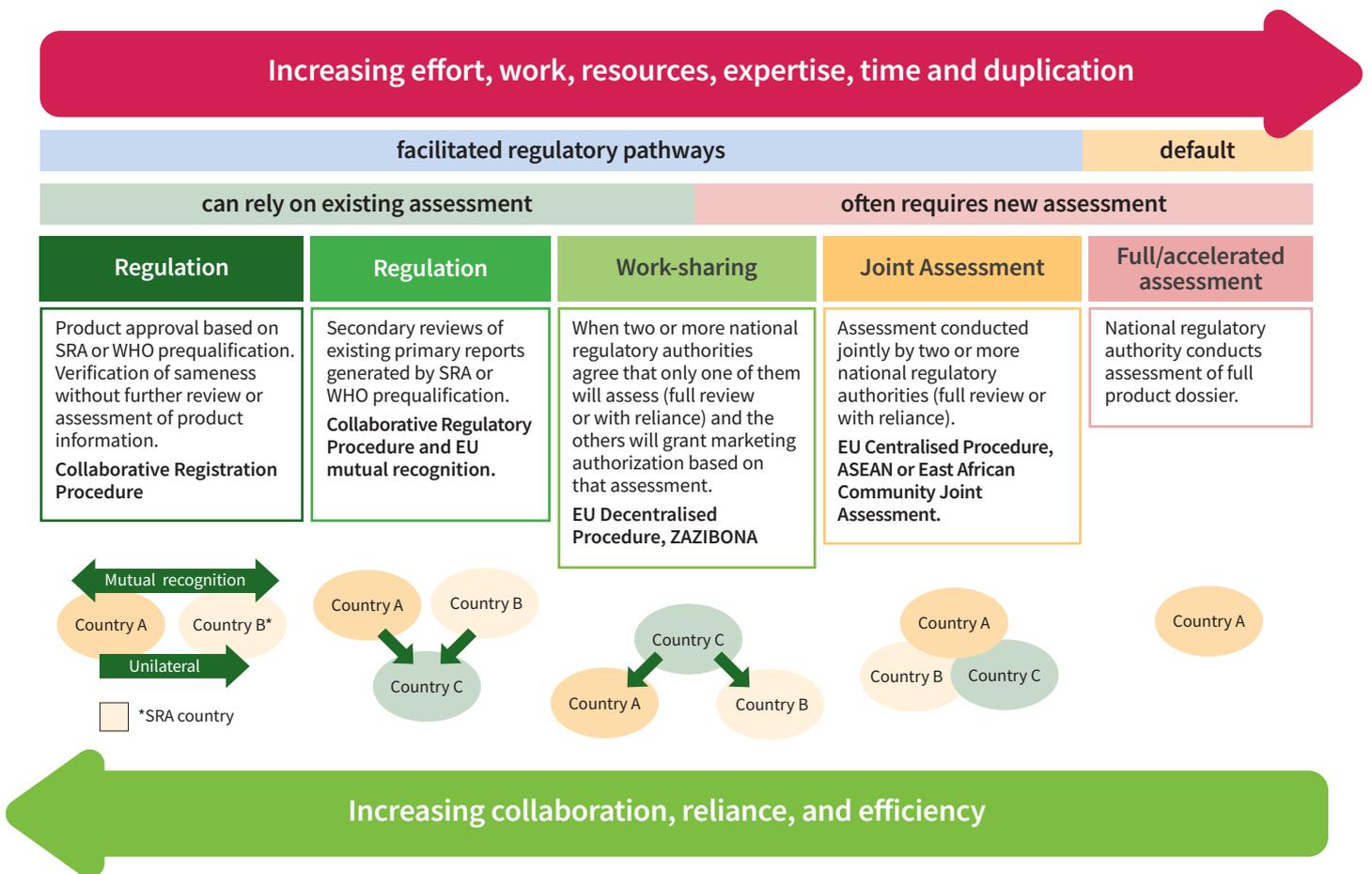
In the interests of long-term sustainability, countries are recommended to progress towards registration for each of the products in the Global Platform list of medicines. However, due consideration should be given to the time needed for the processes involved in achieving this. In order to avoid delaying the receipt of medicines, some countries may wish to opt for an alternative approach for the initial shipments, while proceeding towards registration for subsequent shipments. In other cases, countries may choose to move straight to registration.

It is recommended that medicines be fully registered in the country as soon as possible

About facilitated regulatory pathways

There are multiple options available when considering facilitated regulatory pathways. These include WHO mechanisms for collaboration and reliance between countries such as the Collaborative Registration Procedure for products assessed and/or approved by Stringent Regulatory Authorities (SRA CRP), and for prequalified products. There are also WHO-supported arrangements for regional collaboration on joint assessment and work sharing in specific regions, such as the Association of Southeast Asian Nations (ASEAN) Joint Assessment Procedure (9), the European Union decentralised procedure (10), and the collaborative medicines registration initiative of the Southern Africa Development Community, ZAZIBONA (11).

Fig.10 Facilitated regulatory pathways



Notes: ASEAN – Association of Southeast Asian Nations, EU – European Union, ZAZIBONA – a collaborative initiative for the registration of medicines in Southern Africa, founded in October 2013 by four countries: Zambia, Zimbabwe, Botswana, and Namibia.

B. PROVIDING THE NECESSARY SUBMISSION DOCUMENTS

Once the country has determined its preferred regulatory pathway, the necessary submission documents for that regulatory approval pathway should be provided.

If an alternate approval pathway is proposed for future shipments, information should also be provided on the proposed approach with a list of accompanying documents.

Most countries achieve market authorization by means of a registration waiver for the first few shipments

3.6.4 Determining the market authorization strategy

Countries should consider what marketing authorization strategy they will use in relation to medicines on the Global Platform list of medicines. For most countries, market authorization is achieved by means of a registration waiver for the first few shipments.

However, in the interests of sustainability, it is recommended that medicines be fully registered in the country. This can be achieved through any of the facilitated regulatory pathway options mentioned in Fig. 10 above or through the country's ordinary pathway.

All these pathways require that a manufacturer submits a full dossier for each pharmaceutical product. This process allows the national regulatory authorities to have access to the information on quality assessment that is conducted on the manufacturers. For this activity, the Platform and its procurement partners will liaise with the manufacturers and stringent regulatory authorities, and national regulatory authorities of participating countries to ask them to join the WHO collaborative registration procedure.

3.6.5 Customs clearances and contingency plans

In the shared assessment primer, countries will be asked to provide information about:

- the time generally required for getting medicines cleared from customs duties
 - a. exhaustive list of required documents
 - b. a contingency plan in case of customs clearance being delayed for medicines that are urgently needed or that have a short shelf life
- c. detailed custom fees requirements and the responsible party if they are not part of the waiver
- what party is responsible for demurrage charges if the customs clearance process is delayed.

Customs clearance requirements must also be considered

3.6.6 Quality assurance and quality control

Although the Global Platform is committed to supplying medicines that meet the highest quality standards and ensuring that quality is maintained from the manufacturer to the end user, the responsibility for satisfying the country's national regulatory requirements on the quality assurance of medicines lies with the government of the participating country, or its relevant national institution(s) in accordance with the domestic legislation. Countries therefore follow their existing policy in determining whether and when quality control testing will be required, ensuring that the country has the necessary testing capacities in place (and that these are adequately funded), and/or obtaining the necessary waivers.

Box 3. Quality assurance versus quality control

Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of the product. It is the totality of arrangements that are made with the purpose of ensuring that products are of the quality required for their intended use. Quality assurance therefore incorporates Good Manufacturing Practices and other elements such as product design and development (1).

Quality control refers to all measures taken – including the setting of specifications, sampling, testing and analytical clearance – to ensure that raw materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics (2).

3.6.7 How the Global Platform assures quality

A. ASSURING QUALITY AT EVERY STAGE

The quality of medicine can be affected at any stage during manufacturing, transportation, storekeeping and distribution. The Global Platform therefore follows the principle that the quality of medicines should be assured at every stage – from the initial procurement processes, through transportation and storage, to the point of administration of medicines to patients. The Global Platform and its trusted procurement partners UNICEF and the PAHO Strategic Fund have therefore taken measures to ensure that the quality of medicines is maintained throughout, including by exercising appropriate due diligence in ensuring the quality of medicines, informed by the WHO Model Quality Assurance System (MQAS) (12).

B. SOURCE OF MEDICINES

First, the Global Platform ensures that medicines procured through the Global Platform are of stringent regulatory authority (SRA) origin and have SRA approval. This also applies to the selection of the supplier. An SRA is a regulatory authority which is either:

- a member of the International Conference on Harmonisation (ICH) (as specified on www.ich.org); or
- an ICH observer, being the European Free Trade Association (EFTA), as represented by SwissMedic, and Health Canada (as may be updated from time to time); or
- a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway (as may be updated from time to time) (13-15).

C. TRANSPORTATION OF MEDICINES

The quality of medicines can also be affected during the transportation process, by factors such as temperature, humidity, light exposure, vibration and physical shock, as well as packaging integrity.

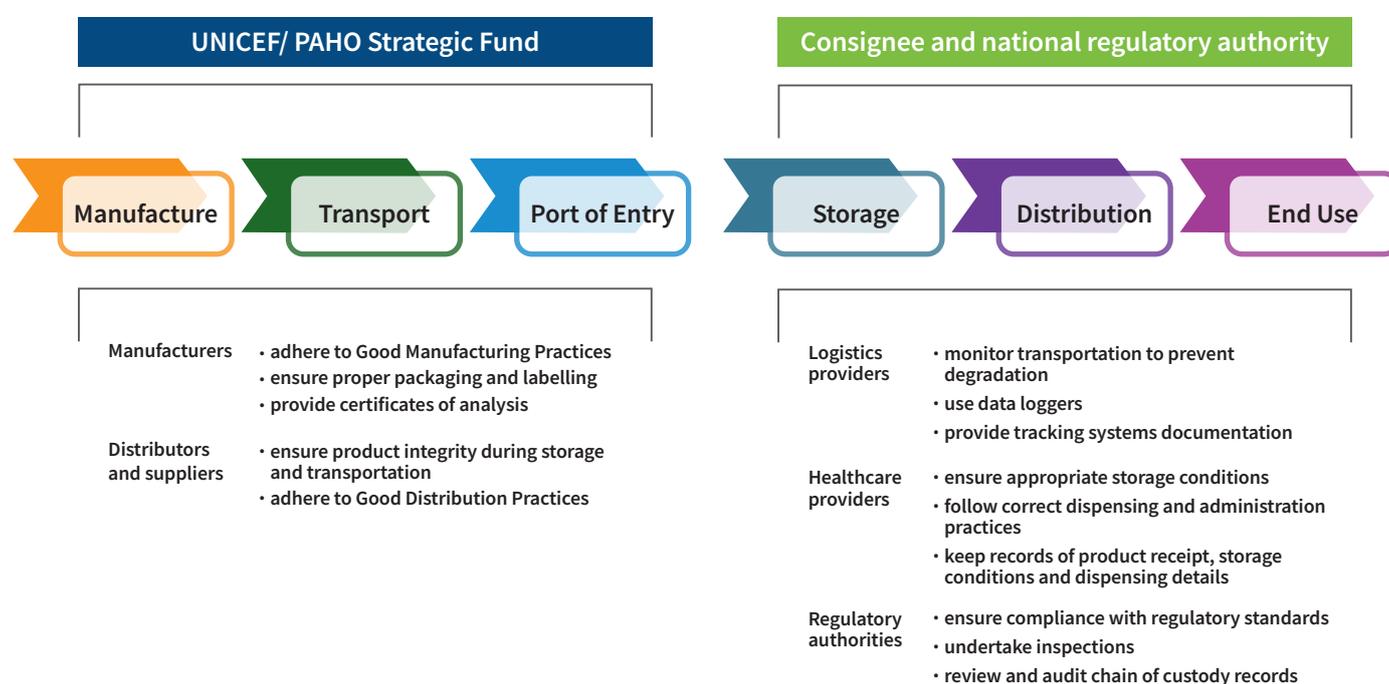
As the Global Platform procurement service agents, UNICEF and PAHO Strategic fund:

- have risk mitigation measures in place in respect of temperature, humidity, light exposure, vibration and physical shock, and packaging integrity
 - ensure that all transportation guidelines indicated for each specific product are respected
 - follow the international standards for transportation of medicines, which involve using data loggers to monitor temperature among others
- ensure supply chain visibility and traceability, making it secure and airtight to exclude any possibility of infiltration of counterfeit products.

D. WORKING WITH COUNTRIES TO ASSURE QUALITY

The Global Platform has developed SOPs that countries can use to ensure that activities directly affecting the quality of medicines are well-managed – for example, storekeeping and distribution at different tiers in the country, from the port of entry to the central warehouse, hospital pharmacy and finally the wards. These activities form part of minimum standards activities relating to the procurement supply chain to be performed by different tiers of the supply chain with a primary focus on Good Distribution Practices and Good Storage Practices.

Fig.11 Chain of custody responsibilities



3.6.8 Chain of custody responsibilities for quality assurance and quality control testing

As shown in Fig. 11 above, the responsibility for quality assurance and quality control shifts along the supply chain in accordance with the chain of custody principle. In the pharmaceutical industry, the chain of custody refers to the documented and unbroken transfer of responsibility for a product from its origin to its final destination. The chain of custody is important in that it ensures traceability of the product, its integrity, and compliance to regulatory requirements throughout the supply chain. If any deviation to the quality of medicines is noticed that may require quality control testing, the chain of custody specifies whose responsibility it falls under to investigate in such a situation.

In the Global Platform supply chain, the chain of custody shifts as follows:

- a. manufacturers:** ensure Good Manufacturing Practices and properly package and label the medicines for transport. They also provide the certification for the quality of medicines such as Certificate of analysis.
- **suppliers and distributors:** maintain the integrity of the products during storage and transportation, adhering to Good Distribution Practices, while taking appropriate measures for tracking and recording all the information along the process.
- **logistics providers:** ensure that transportation conditions required for the medicines are respected, monitored and controlled to prevent product degradation. They achieve this by using data loggers and tracking systems to provide real-time monitoring and documentation of the transport conditions.
- **healthcare providers:** store medicines under appropriate conditions and ensure that they are dispensed correctly to patients. In doing so, they need to maintain records of the condition of the medicines at the time of reception, storage conditions in the hospital pharmacies. And dispensing details.
- b. regulatory authorities:** oversee the compliance with regulatory standards and conduct inspections to ensure adherence to quality standards.

If a situation that might necessitate quality control testing occurs in the first two phases (a and b in the list above), this falls under the responsibility of the procurement service agent, namely UNICEF or the PAHO Strategic fund as applicable.

If a situation occurs during any of the remaining three phases (c, d, and e), responsibility for quality control testing falls to the country's national regulatory authority.

This needs to take into consideration the Incoterms previously agreed among all parties.

3.6.9 Quality control testing

When quality control testing is required

Each participating country follows its own national guidelines and regulations on quality control testing. In situations where quality control testing is necessary for a given country, the Global Platform team will engage with the country's national regulatory authority to understand the requirements, the kind of tests to be conducted, the timeline to be followed, the procedure for sharing the results, the actions after the results are shared, and the impact of the whole process on the availability of the medicines to the patients. Any quality control tests undertaken should be conducted at the standards set out by the manufacturers and the pharmacopoeia monographs (16). This collaborative approach ensures that decisions regarding quality control testing are made in the best interest of patient care and access to essential medicines.

A. PLATFORM SUPPORT ON QUALITY CONTROL TESTING

Where the country has expressed a need, the GlobalPlatform team will collaborate closely with the national regulatory authority on quality assurance and quality control testing to support participating countries as they build their capacity for strong quality assurance.

Variations include:

i) Ad-hoc quality control testing

Ad hoc quality control testing may be triggered by an observed or suspected quality issue at the point of entry or at any time throughout the use of the products after distribution, or in response to adverse events reported by the end users. A decision to conduct quality control testing may be made after evaluation of the storage and distribution process and the potential impact of the event.

ii) Routine quality control testing

The procurement partner will conduct a risk analysis on the products being supplied and flag to the country any product identified as high risk. The procurement partners will recommend that countries handle such products strictly under the conditions specified by the manufacturer, with regular monitoring of those conditions. In the event of any deviation from the specified conditions, quality control testing of the products would be required. This would be the responsibility of the country's national regulatory authority.

During both the ad hoc and routine testing process, the sampling procedure would follow the WHO guidelines (17) and the facilities used would be those fulfilling the WHO guidelines (18) and/or the WHO prequalified laboratories (19).

B. FUNDING FOR QUALITY CONTROL TESTING

Where there is an expressed need for quality control testing, either as an ad-hoc or routine process, the Global Platform would discuss this with the national regulatory authority to identify how financial support can be provided.

3.7 Monitoring and reporting

3.7.1 Monitoring requirements

After the country receives its first shipment of medicines procured through the Global Platform, the governance mechanism (see 3.2.3 above) will be responsible for providing regular monitoring information about how Global Platform activities are progressing in the country. The country operational plan must clearly identify the individual responsible for monitoring and reporting.

To keep the burden of reporting to a minimum for national stakeholders, the Global Platform will only require routine reporting on a subset of indicators. Specifically, national stakeholders will be asked to monitor and report on seven indicators:

1. How many children received Global Platform products during the reporting period.
2. Number of unexpected adverse drug reactions related to Global Platform medicines.
3. The stock out rate for products on the Global Platform list of medicines.
4. Whether the country governance mechanism met at least quarterly during the reporting period.
5. The number of days it took to distribute Global Platform products from the port of entry to the central distribution point or first facility.
6. Consumption of Global Platform medicines
7. Progress towards completion of activities in the country's Global Platform country operational plan.

3.7.2 How often is reporting required?

Quarterly (brief) and annual (more comprehensive) reports will be due according to schedule shown in Table 4 below. A country's annual report will be its 4th report submitted after receiving its first shipment. An annual review of the country operational plan will be conducted jointly with national stakeholders and the Global Platform team. This may be conducted remotely or, if agreed with national stakeholders, in an in-person workshop.

Table 4. Reporting periods and due dates

Reporting period	Report due date
January – March	April 30
April – June	July 30
July – September	October 30
October – December	January 30 of the subsequent year

3.7.3 What format is required for monitoring and reporting?

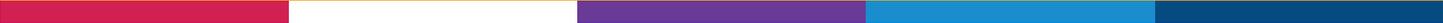
Monitoring and reporting will be implemented using the world's largest health management information system platform, DHIS2 – a web-based, free and open-source software platform that supports the collection, management and analysis of both aggregate and individual level data and allows the user organization (for example the ministry of health) to follow, own and govern their DHIS2 system (server, database, data). Training on DHIS2 will be provided.

The chain of custody specifies who is responsible for quality assurance and quality control testing at each stage of the supply chain.

References

1. Quality assurance of pharmaceuticals: a compendium of guidelines and related materials: volume 2: Good manufacturing practices and inspection, 10th edition. Geneva WHO; 2024 Section 3.2 (<https://www.who.int/publications/i/item/9789240086081> accessed 16 December 2024).
2. WHO launches Pharmaceutical Quality Assurance guidelines, 10th edition, Annex 1. In: WHO Technical Report Series, 957, 2010 (under revision) Section 5. Geneva: WHO; (<https://www.who.int/news/item/29-02-2024-who-launches-pharmaceutical-quality-assurance-guidelines--10th-edition>, accessed 20 December 2024).
3. ZJ Ward JY, N Bhakta, AL Frazier, R Atun. Estimating the total incidence of global childhood cancer: a simulation-based analysis. *Lancet Oncol.* 2019;20: 483–93. doi: 10.1016/S1470-2045(18)30909-4.
4. At the Third high-level meeting on the prevention and control of NCDs during the United Nations General Assembly in September 2018 and in line with World Health Assembly Resolution 70.12 (2017) (4) (Cancer prevention and control in the context of an integrated. In: (WHA 7012, Agenda item 15.6). Geneva WHO; 2017 (https://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_R12-en.pdf, accessed 10 February 2025).
5. Cancer prevention and control in the context of an integrated approach. Geneva: WHO; 2017; (WHA 70.12, Agenda item 15.6) (https://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_R12-en.pdf, accessed 10 February 2025).
6. From the Interagency Supply Chain Group (ISG): Visibility for Health Systems: Adoption of Global Data Standards (GS1), ISG position paper, August 2017. (<https://www.gs1.org/healthcare/articles/2362/interagency-supply-chain-group-isg-adoption-global-data-standards-gs1>, accessed 14 February 2025).
7. Incoterms 2020. International Chamber of Commerce; (<https://iccwbo.org/business-solutions/incoterms-rules/incoterms-2020/> accessed 14 February 2025).
8. Regulatory system strengthening for medical products – Sixty-seventh World Health Assembly, Agenda item 15.6 (WHA67.20). Governing Bodies documentation. Geneva WHO; 2014; (https://www.who.int/publications/i/item/A67_R20 accessed 20 December 2024).
9. ASEAN Joint Assessment Procedure for Pharmaceutical Products. In: Singapore Government Agency website. Last updated 16 August 2024. (<https://www.hsa.gov.sg/therapeutic-products/international-collaboration/ASEAN-JA> accessed 20 December 2024).
10. Authorisation procedures – The decentralized procedure. In: website of the European Union. (https://health.ec.europa.eu/other-pages/basic-page/authorisation-procedures-decentralised-procedure_en accessed 20 December 2024).
11. Zazibona. (<https://zazibona.com/>, accessed 20 December 2024).
12. Annex 3, WHO Technical Report Series 986: WHO model quality assurance system for procurement agencies. Geneva: WHO (<https://www.who.int/publications/m/item/trs-986-annex-3>, accessed 16 December 2024).
13. Clarification with Respect to a Stringent Regulatory Organization as Applicable to the Stringent Regulatory Authority (SRA) Guideline. Guidance Document. Geneva: WHO; 2016 (https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf, accessed 16 December 2024).
14. Annex 4, WHO Technical Report Series 970: Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product for the WHO Prequalification of Medicines Programme: quality part. Geneva World Health Organization; 2012 (<https://www.who.int/publications/m/item/annex-4-trs-970> accessed 16 December 2024).
15. Annex 5, WHO Technical Report Series 986: Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities. Geneva World Health Organization; 2014 (<https://www.who.int/publications/m/item/annex-5-trs-986>, accessed 16 December 2024).
16. White Paper for the WHO International Meeting of World Pharmacopoeias: Value of Pharmacopoeial Standards for Access to Quality Medicines. Geneva: World Health Organization; 2020 (https://www.who.int/docs/default-source/medicines/norms-and-standards/value-of-pharm-stds-updated-final-oct-2020.pdf?sfvrsn=2d4e5052_4, accessed 14 February 2025).

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- 17.** Annex 4, Technical Report Series 929: WHO guidelines for sampling of pharmaceutical products and related materials. Geneva: World Health Organization; 2005 (<https://www.who.int/publications/m/item/trs-1025-annex-4>, accessed 16 December 2024).
 - 18.** Annex 1, Technical Report Series 957: WHO good practices for pharmaceutical quality control laboratories. Geneva: World Health Organization; 2010 (<https://www.who.int/publications/m/item/trs957-annex1> accessed 16 December 2024).
 - 19.** Quality Control Laboratories for Medicines. Geneva: World Health Organization; (<https://extranet.who.int/prequal/medicines/prequalified/quality-control-labs>, accessed 16 December 2024).



Annex 1.

The Global Platform minimum standards

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The Global Platform minimum standards describe what “ready” looks like: they specify the procedures, practices and systems that ensure countries can receive, transport, store and administer cancer medicines safely and effectively

1.1 About the minimum standards

Before a country can begin receiving medicines through the Global Platform for Access to Childhood Cancer Medicines (Global Platform), it must first demonstrate that its systems are ready. The minimum standards describe what “ready” looks like: they specify the procedures, practices and systems that ensure the country can receive, transport, store and administer these life-saving medicines safely and effectively.

Facilities may find they are already doing a lot of these things. For minimum standards already being met, the Global Platform team will simply record this during the assessment country visit and those minimum standards will not need to be checked again. For minimum standards that the country – or a certain facility – does not yet meet, participating countries will be supported to identify and implement priority activities to address these and to provide a suitable form of evidence that this has been done. Providing “evidence” is nothing onerous, often just a photo or a copy of the policy will suffice.

Facilities may find that they are already doing a lot of these things

1.2 Do all the minimum standards have to be met?

All applicable minimum standards must be met.

However, some minimum standards only apply to certain locations (that is, the central warehouse, the hospital pharmacy and/or ward), or to certain product categories – for example, depending on whether the warehouse, distribution system or facility will be handling one or more cold-chain products, and on whether products are classified as:

- i) sterile, hazardous products
- ii) nonsterile, hazardous products
- iii) sterile, non-hazardous products or
- iv) nonsterile, non-hazardous products.

A list of specific medicines that fall into each of these categories is provided in Table A1.13, while Table A1.14 lists examples of cold-chain products – although which products require cold chain storage and distribution is always determined by the manufacturer’s product-specific guidance.

Where a standard should apply might vary based on your facility’s workflows and infrastructure. For example, if drugs are stored on the ward, inventory-related minimum standards should apply to this area in addition to the pharmacy storage area.

What is the basis for the minimum standards?

The minimum standards were developed by a group of international experts convened by Global Platform and represent a consensus expert view as to the procedures, practices and systems without which a health system cannot safely transport, store or administer cancer medicines.

References on which the minimum standards are based:

1. Safe Handling of Chemotherapy Drugs in Limited-Resource Settings. Washington (DC): PAHO. 2013 (<https://iris.paho.org/handle/10665.2/28554>, accessed 13 December 2024).
2. ISOPP Standards for the Safe Handling of Cytotoxics. *J Oncol Pharm Practice* 2022, Vol 28 3(Supplement):1-126. doi: 10.1177/1078155221107093
3. WHO Good Storage and Distribution Practices for Medical Products (WHO Technical Report Series, No. 1025, 2019, Annex 7). Geneva: WHO. 2019 (<https://www.who.int/publications/m/item/trs-1025-annex-7>, accessed 13 December 2024).
4. WHO Model Guidance for Storage and Transport of Time- and Temperature-Sensitive 5. Pharmaceutical Products (WHO Technical Report Series, No. 961, 2011, Annex 9). Geneva: WHO. 2011 (<https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstorageandtransport>, accessed 13 December 2024).
5. The Supply Chain Manager’s Handbook, A Practical Guide to the Management of Health Commodities. Arlington (VA): John Snow, Inc. 2019 (<https://www.jsi.com/resource/the-supply-chain-managers-handbook/>, accessed 14 December 2024).

The initial assessment provides a baseline that helps identify areas in which support may be required

1.3 How soon must participating countries meet the minimum standards?

All minimum standards must be met by the time of first shipment.

1.4 How are minimum standards initially assessed?

An initial assessment is made in collaboration with national stakeholders as part of the assessment country visit. This provides a baseline and helps the country and the Global Platform team identify areas in which support may be required.

For minimum standards already being met, the Global Platform team will simply record this during the assessment country visit and those minimum standards will not be checked again

1.5 How is progress tracked?

The minimum standards tracker tool, to which national focal points will be oriented at the assessment country visit, allows the country and the Global Platform team to monitor progress against each minimum standard at facility or ward level. The governance mechanism is responsible for overseeing this, tracking completion of the activities using the tracker tool and reporting this back to the Global Platform team.

1.6 How should compliance with minimum standards be evidenced?

Once the Global Platform has determined that a minimum standard has been met, there is no need to provide any further evidence.

For every minimum standard not initially deemed met, evidence of completion must be submitted. The country's governance mechanism has responsibility for evidencing that minimum standards readiness activities have been completed, by submitting supporting materials to the administrative operational unit on a rolling basis, as soon as activities are completed.

Different forms of evidence will be suitable for evidencing compliance with different minimum standards. Examples of suitable forms of evidence are suggested in the tables below: the governance mechanism does not need to submit all the forms of evidence listed, but should select the most appropriate kind of evidence based on the specific activities needed to achieve the standard.

Once the Global Platform team determines that a minimum standard has been met, it will not be re-assessed.

1.7 How and when are minimum standards re-assessed?

Once the Global Platform team determines that a minimum standard has been met, it will not be re-assessed. Standards previously determined as "not met" will be fully re-assessed by the Global Platform team. The initial assessment by the Global Platform team during the assessment country visit is conducted through facility and warehouse visits. However, subsequent re-assessment of minimum standards compliance is typically conducted virtually. Therefore, even if there is an in-person country visit planned with the Global Platform during the assessment period, all materials for assessment should be submitted to the administrative operational unit prior to that visit. The final assessment will be conducted by a panel convened by the Global Platform to approve the country's readiness to begin receiving medicines.

Providing "evidence" is nothing onerous, often just a photo or a copy of the policy will suffice

1.8 The Global Platform minimum standards

The Global Platform minimum standards are set out in tables A1.1–A1.12 below, with indication of the product categories and locations to which each standard applies.

The tables also provide suggestions as to suitable forms of evidence that could be used to demonstrate compliance. Keep in mind that: i) countries do not need to submit all the suggestions listed; ii) other forms of evidence may also be acceptable; and iii) if the Global Platform country visit team confirms it is satisfied that a particular facility or site meets the minimum standard based on the assessment country visit, no further evidence need be submitted.

The Global Platform recognizes the importance of countries not only having the necessary policies in place, but also implementing these in practice. The Global Platform minimum standards therefore include a mix of policy-based standards and practice-based standards. Taken together, these standards provide a comprehensive framework for the minimum acceptable standards for the handling of Platform medicines.



Policy-based standards set overarching expectations, often linked to regulatory compliance or national guidelines. Practice-based standards tend to be focused on necessary infrastructure and implementation of certain essential practices, ensuring that policies are translated into effective workflows.

Several of the policy-based standards refer to a requirement for “regularly updated standard operating procedures (SOP)”; the expectation here is that the facility have up-to-date policies which undergo a regular review and update to ensure they are clear and current with facility practices. In order to obtain a full picture of the situation in the country, the Global Platform team may wish to seek input from frontline staff about their ability to practice their workflows in accordance with SOPs even for policy-based standards.

Table A1.1 Incoming transport and receiving: minimum standards

Standard		Examples of suitable evidence <i>Only one form of evidence is required, select the most appropriate suggestion</i>	Applies to	
			product categories	location
1. Incoming transport and receiving				
MS S1.1	Medicines (cytotoxic) that are hazardous are labelled as such at all times during their transit.	<ul style="list-style-type: none"> Local and facility policies/procedures Photographs demonstrating this at key points in transit 	Hazardous	Warehouse, pharmacy and ward
MS S1.2	Procedures for inspection upon receipt are maintained in a regularly updated standard operating procedure (SOP) and include a consistent process or checklist used to inspect on receipt: <ol style="list-style-type: none"> quantity and accuracy of shipment and any visible damage to packaging temperature and/or humidity labels if applicable. before signing the proof of delivery (POD).	<ul style="list-style-type: none"> SOP documents Training record log Training materials used 	All	Warehouse and pharmacy
MS S1.3	There is a procedure for accurately booking in the deliveries in a timely manner, such that delivery information is logged in an appropriate manual or electronic system, with the following information recorded: <ol style="list-style-type: none"> product name date received pack size unit of measure quantity received batch number expiry date 	<ul style="list-style-type: none"> Facility and local policies/procedures Photographs of logging-in sheet 	All	Warehouse and pharmacy

Table A1.2 Ambient inventory management: minimum standards

Standard		Examples of suitable evidence <i>Only one form of evidence is required, select the most appropriate suggestion</i>	Applies to	
2. Ambient inventory management			product categories	location
MS S2.1	Procedures for inventory management are maintained in a regularly updated SOP and broadly aligned to WHO Good Practice. ¹	<ul style="list-style-type: none"> • SOP documents • Local and facility policies/procedures • List of personnel trained on SOPs 	All	Warehouse, pharmacy and in some cases ward
MS S2.2	There is adequate ambient storage space to hold the volume of each medicine that the facility will be receiving based on the country's procurement planning work with the Global Platform.	<ul style="list-style-type: none"> • Ministry of health confirms compliance with local requirements after discussion with Global Platform team. • Photo of intended cold storage space/equipment and the estimated size in cubic metres 	All	Warehouse and pharmacy
MS S2.3	The facility has a designated, lockable quarantine area for inspection rejects, non-conformance, and expired products.	<ul style="list-style-type: none"> • Photographs of quarantine area • SOP documents detailing its use 	All	Warehouse and pharmacy
MS S2.4	Areas where hazardous medicines are stored are designated with signage.	<ul style="list-style-type: none"> • Photographs of signage • List of areas where signs are posted 	Hazardous	Warehouse, pharmacy and in some cases ward
MS S2.5	There is adequate equipment for conditioning (i.e. air conditioning/dehumidifiers) and for temperature and humidity monitoring (i.e. hygrometers/thermometers) and this is maintained appropriately, including annual calibration where required.	<ul style="list-style-type: none"> • Photographs of equipment • SOP documents detailing its use 	All	Warehouse, pharmacy and in some cases ward
MS S2.6	The facility conducts and documents routine monitoring of the temperature of the storage space in which Global Platform medicines are kept (a minimum of once per shift to capture hottest and coldest temperatures).	<ul style="list-style-type: none"> • Photographs of temperature probes and logs • SOP documents detailing their use 	All	Warehouse, pharmacy and in some cases ward

¹ See WHO Technical Report Series, no. 1025 Annex 7 Good storage and distribution practices for medical products. Geneva: WHO; 2020 (<https://www.who.int/publications/m/item/trs-1025-annex-7>, accessed 21 January 2025).

Table A1.2 Ambient inventory management: minimum standards *continued*

Standard		Examples of suitable evidence <i>Only one form of evidence is required, select the most appropriate suggestion</i>	Applies to	
			product categories	location
2. Ambient inventory management				
MS S2.7	The facility maintains a controlled ambient temperature environment in the storage space between 15 °C and 30 °C.	<ul style="list-style-type: none"> • Photo of ambient temperature log page 	All	Warehouse, pharmacy and in some cases ward
MS S2.8	The facility has a plan in place to mitigate the impact on the quality of medicines if temperatures fall below 15 °C or above 30 °C, deferring to the manufacturer's guidelines for each product.	<ul style="list-style-type: none"> • SOP document that describes procedure for excursions • Evidence of staff training on temperature excursions 	All	Warehouse, pharmacy and in some cases ward
MS S2.9	The facility conducts and documents routine monitoring of humidity of the storage space in which Platform medicines are kept (a minimum of once per shift).	<ul style="list-style-type: none"> • Photographs of humidity probes and logs • SOP document that describes procedure for excursions • Evidence of staff training on humidity excursions 	All	Warehouse, pharmacy and in some cases ward
MS S2.10	The facility has a plan to mitigate the impact on quality of medicines if the humidity exceeds 60%. ²	<ul style="list-style-type: none"> • SOP document that describes procedure for excursions • Evidence of staff training on humidity excursions 	All	Warehouse, pharmacy and in some cases ward
MS S2.11	There is an accurate paper-based or electronic method of recording stock levels and adjustment.	<ul style="list-style-type: none"> • Screenshots of the stock records • Government attestation of compliance with local requirements 	All	Warehouse and pharmacy

2 See Table A7.1 on page 188 of WHO Technical Report Series, no. 1025 Annex 7 Good storage and distribution practices for medical products. Geneva: WHO; 2020 (<https://www.who.int/publications/m/item/trs-1025-annex-7>, accessed 21 January 2025).

Table A1.3 Cold chain management: minimum standards

Standard		Examples of suitable evidence <i>Only one form of evidence is required, select the most appropriate suggestion</i>	Applies to	
			product categories	location
3. Cold chain management				
MS S3.1	There is adequate cold storage space to hold the volume of each medicine that the facility will be receiving based on the country's procurement planning work with the Global Platform.	<ul style="list-style-type: none"> Ministry of health confirms compliance with local requirements after discussion with Global Platform team. Photo of intended cold storage space/ equipment and the estimated size in cubic metres 	All cold chain	Warehouse and pharmacy
MS S3.2	Personnel conduct monitoring of the temperature in all cold storage spaces (a minimum of once per shift) and record the results.	<ul style="list-style-type: none"> Photographs of cold chain temperature log 	All cold chain	Warehouse, pharmacy and in some cases ward
MS S3.3	The facility maintains controlled cold chain refrigerator temperature of 5 °C +/-3 °C.	<ul style="list-style-type: none"> Photographs of cold chain temperature log 	All cold chain	Warehouse, pharmacy and in some cases ward
MS S3.4	The facility has a plan in place to mitigate the impact on the quality of medicines if temperature deviates outside the ranges identified on the product packaging.	<ul style="list-style-type: none"> SOP document that describes procedure for excursions Evidence of staff training on temperature excursions 	All cold chain	Warehouse, pharmacy and in some cases ward
MS S3.5	Cold chain equipment (i.e. refrigerators) is calibrated annually (or units are replaced annually if one year validated disposable units are used).	<ul style="list-style-type: none"> Evidence of equipment maintenance plan, such as SOP document 	All cold chain	Warehouse, pharmacy and in some cases ward
MS S3.6	Procedures for power outages are maintained in regularly updated SOPs, and back-up power sources are available to maintain cold chain specifications.	<ul style="list-style-type: none"> Evidence of power outage plan, such as SOP document Evidence of staff training on power outage plan Photographs of backup power sources 	All	Warehouse, pharmacy and in some cases ward

Table A1.4 Dispensing and distribution: minimum standards

Standard		Examples of suitable evidence <i>Only one form of evidence is required, select the most appropriate suggestion</i>	Applies to	
			product categories	location
4. Dispensing and distribution				
MS S4.1	The facility consistently uses first expiry/first out (FEFO) when dispensing / distributing of medicines.	<ul style="list-style-type: none"> SOP documents on inventory management Evidence of distribution of training on this practice to relevant personnel List of personnel trained on this practice 	All	Warehouse and pharmacy
MS S4.2	Mechanisms are in place to maintain temperature control during movement of products (e.g. during transportation from the central warehouse to the hospital pharmacy and from the pharmacy to the ward); this may be refrigerated trucks or ability to pack with sufficient supply refrigerants to reach all facilities due to receive medicines from the Global Platform.	<ul style="list-style-type: none"> Evidence of distribution of training on temperature control List of personnel trained on this practice 	All	Warehouse and pharmacy
MS S4.3	Storage facilities (i.e. warehouse or pharmacy) maintain a paper-based or electronic mechanism for accurately logging details of every item dispatched or dispensed to ensure their inventory record is accurate and up to date; this should include recording product, quantity, destination, batch number.	<ul style="list-style-type: none"> Evidence of such mechanisms, including policies or photographs Evidence of plan to implement any needed operational changes to comply with tracking plan 	All	Warehouse and pharmacy
MS S4.4	The facility is able to report consumption and inventory levels delineated by patient population.	<ul style="list-style-type: none"> Example of a consumption and inventory report 	All	Warehouse and pharmacy
MS S4.5	Procedures for forecasting to ensure continual supply of medicines are maintained in a regularly updated SOP.	<ul style="list-style-type: none"> SOP or other policy documents on forecasting strategies Evidence of plan to implement any needed operational changes to comply with forecasting plan 	All	Warehouse and pharmacy
MS S4.6	The facility/warehouse has developed and maintains a plan to ensure that Global Platform medicines are used only for the intended populations.	<ul style="list-style-type: none"> Copy of a written plan Photographs of designated storage areas 	All	Warehouse, pharmacy and in some cases ward

Table A1.5 Infection control: minimum standards

Standard		Examples of suitable evidence <i>Only one form of evidence is required, select the most appropriate suggestion</i>	Applies to	
			product categories	location
5. Dispensing and distribution				
MS C5.1	Procedures for general hygiene are maintained in regularly updated SOPs and include handwashing when handling medications and providing patient care.	<ul style="list-style-type: none"> Facility and local policies/procedures 	All	Pharmacy and ward

Table A1.6 Protection measures for cytotoxic medicines: minimum standards

Standard		Examples of suitable evidence <i>Only one form of evidence is required, select the most appropriate suggestion</i>	Applies to	
			product categories	location
6. Protection measures for cytotoxic medicines				
MS C6.1	Signage designating hazard should be prominently displayed at the entrance of any room where cytotoxic medicines are prepared or stored	<ul style="list-style-type: none"> Photographs of signage List of areas where signs are posted 	Hazardous	Warehouse, pharmacy and ward
MS C6.2	Based on their tasks and responsibilities, all staff involved in the handling of cytotoxic medicines receive adequate initial training upon hire. Personnel who require this training based on their job descriptions must be described in an SOP. The training must include: <ol style="list-style-type: none"> Risks related to handling cytotoxic medicines Suitable protective measures Proper handling methods 	<ul style="list-style-type: none"> Facility training policies/procedures Training record log Training materials used 	Hazardous	Warehouse, pharmacy and ward
MS C6.3	Procedures for the use of personal protective equipment (PPE) when handling chemotherapy are maintained in regularly updated SOPs and are in alignment with local regulatory requirements.	<ul style="list-style-type: none"> Facility and national policies/procedures to allow cross referencing of regulatory requirements 	Hazardous	Warehouse, pharmacy and ward

Table A1.7 Chemotherapy preparation: minimum standards

Standard		Examples of suitable evidence <i>Only one form of evidence is required, select the most appropriate suggestion</i>	Applies to	
			product categories	location
7. Chemotherapy preparation				
MS C7.1	Preparation of cytotoxic medicines takes place in a controlled area dedicated to this activity	<ul style="list-style-type: none"> Photographs of medicine preparation area 	Hazardous	Ward and in some cases pharmacy
MS C7.2	Sterile cytotoxic medicines are prepared in a biological safety cabinet in a room separate from patient care; where this is not possible, limited preparations are prepared in a designated location immediately prior to administration.	<ul style="list-style-type: none"> Photographs of medicine preparation area 	Products classified as both sterile and hazardous	Ward and in some cases pharmacy
MS C7.3	Procedures for cytotoxic medicine preparation are maintained in a regularly updated SOP and include: <ol style="list-style-type: none"> designating which personnel are permitted to prepare cytotoxic medicines operational standards for aseptic preparation cleaning procedure for preparation areas requirements for the primary packaging and labelling of the final prepared product 	<ul style="list-style-type: none"> Facility policies/procedures 	Sterile	Warehouse, pharmacy and ward

Table A1.8 Infection control: minimum standards

Standard		Examples of suitable evidence <i>Only one form of evidence is required, select the most appropriate suggestion</i>	Applies to	
			product categories	location
8. Chemotherapy prescribing				
MS C8.1	Procedures for chemotherapy prescribing are maintained in a regularly updated SOP and include: <ol style="list-style-type: none"> designating which personnel are permitted to prescribe chemotherapy a mechanism for tracking and verifying patient's diagnosis, treatment protocol, and progress through chemotherapy 	<ul style="list-style-type: none"> Facility policies/procedures 	All	Ward

Table A1.9 Chemotherapy administration: minimum standards

Standard		Examples of suitable evidence <i>Only one form of evidence is required, select the most appropriate suggestion</i>	Applies to	
9. Chemotherapy administration			product categories	location
MS C9.1	Procedures for chemotherapy administration are maintained in a regularly updated SOP and include: <ol style="list-style-type: none"> i. designating which personnel are permitted to administer chemotherapy ii. procedures for verifying the accuracy of information on a prepared product label prior to administration iii. procedures for verifying patient identity against the administration plan and the product label with the patient or caregiver prior to administration 	<ul style="list-style-type: none"> • Local and facility policies/procedures 	Hazardous	Ward

Table A1.10 Disposal: minimum standards

Standard		Examples of suitable evidence <i>Only one form of evidence is required, select the most appropriate suggestion</i>	Applies to	
10. Disposal			product categories	location
MS C10.1	Procedures for cytotoxic waste disposal are compliant with local standards and are maintained in an up-to-date SOP	<ul style="list-style-type: none"> • Facility and national policies/procedures to allow cross referencing of regulatory requirements 	Hazardous	Warehouse, pharmacy and ward
MS C10.2	Procedures for handling contaminated patient waste are maintained in an up-to-date SOP	<ul style="list-style-type: none"> • Facility policies/procedures 	Hazardous	Warehouse, pharmacy and ward

Table A1.11 Incident management: minimum standards

Standard		Examples of suitable evidence <i>Only one form of evidence is required, select the most appropriate suggestion</i>	Applies to	
11. Incident management			product categories	location
MS C11.1	Procedures for cytotoxic drug spills, and patient/staff exposures are maintained in regularly updated SOP	<ul style="list-style-type: none"> • Facility policies/procedures 	Hazardous	Warehouse, pharmacy and ward
MS C11.2	Supplies needed to manage cytotoxic medicines spills are easily identified and located by staff in all areas where the medicines are stored, prepared, and administered	<ul style="list-style-type: none"> • Photographs of spill kits • List of all areas where spill kits are kept 	Hazardous	Warehouse, pharmacy and ward
MS C11.3	Context-specific procedures for management of extravasation are maintained in a regularly updated SOP	<ul style="list-style-type: none"> • Facility policies/procedures 	Product-specific	Pharmacy and ward
MS C11.4	Procedures detailing standardized practices for high-risk chemotherapy processes are maintained in a regularly updated SOP. These high-risk processes include: <ol style="list-style-type: none"> Vincristine dispensing and administration to prevent accidental intrathecal administration Dispensing and administration of intrathecal chemotherapy 	<ul style="list-style-type: none"> • Facility policies/procedures 	Product-specific	Pharmacy and ward

Table A1.12 Pharmacovigilance: minimum standards

Standard		Examples of suitable evidence <i>Only one form of evidence is required, select the most appropriate suggestion</i>	Applies to	
12. Disposal			product categories	location
MS C12.1	Procedures for pharmacovigilance, which may include event reporting, participation in crisis communication, and case investigations, are maintained in a regularly updated SOP and are compliant with local regulatory requirements.	<ul style="list-style-type: none"> • Facility and national policies/procedures to allow cross referencing of regulatory requirements 	All	Pharmacy and ward
MS C12.2	Dispensed lot numbers are traceable to patient to facilitate product tracking and adverse event monitoring.	<ul style="list-style-type: none"> • SOP documents • De-identified photographs of tracing mechanisms or logs 	All	Pharmacy and ward

Table A1.13 Hazardous and sterile product classification

	Hazardous	Non-hazardous
Sterile	<ul style="list-style-type: none"> • Arsenic trioxide injection • Asparaginase powder for injection • Bleomycin powder for injection • Carboplatin injection • Cisplatin injection¹ • Cyclophosphamide injection • Cytarabine injection • Dacarbazine powder for injection • Dactinomycin injection¹ • Daunorubicin injection¹ • Doxorubicin injection¹ • Etoposide injection • Fluorouracil injection • Ifosfamide powder for injection • Irinotecan injection • Methotrexate injection • Pegaspargase injection • Vinblastine injection¹ • Vincristine injection¹ 	<ul style="list-style-type: none"> • Calcium folinate injection • Filgrastim injection • Hydrocortisone injection • Mesna injection • Rituximab injection • Pegfilgrastim injection
Non-sterile	<ul style="list-style-type: none"> • Cyclophosphamide tablets • Dasatinib tablets • Etoposide capsules • Hydroxycarbamide tablets • Hydroxycarbamide capsules • Imatinib tablets • Mercaptopurine tablets • Methotrexate tablets • Procarbazine capsules • Thioguanine tablets • Tretinoin capsules 	<ul style="list-style-type: none"> • Allopurinol tablets • Calcium folinate tablets • Dexamethasone tablets • Dexamethasone solution • Mesna tablets • Prednisolone tablets • Prednisolone oral solution

1 Per standard 7c, accessible extravasation resource required

Table A1.14 Cold chain products: guidance and examples

Identification of cold chain products
The Global Platform defers to the manufacturer's product-specific guidance: if the manufacturer's guidance indicates the product to be a cold chain product, the Global Platform minimum standards relating to cold chain requirements shall apply.
Examples of cold chain products
<ul style="list-style-type: none"> • Asparaginase powder for injection • Bleomycin powder for injection • Calcium folinate solution for injection • Doxorubicin solution for infusion • Filgrastim solution (vials) for injection • Pegaspargase solution for injection • Pegfilgrastim pre-fill syringes for injection • Prednisolone oral solution • Rituximab solution for infusion • Vincristine solution for injection • Vinblastine solution for injection

Annex 2.

Global Platform patient eligibility criteria

The Global Platform patient eligibility criteria determine which individuals will and will not be able to receive childhood cancer medicines funded through the Global Platform.

A. GUIDING PRINCIPLES OF PATIENT ELIGIBILITY

The Global Platform's guiding principles are that:

- a. as many children as possible should be treated
- b. all children who initiate treatment should be allowed to finalize treatment, regardless of whether they age out of the eligibility criteria, and
- c. national and institutional standards on parental/caregiver consent and the assent of children should be respected; to the extent possible, children should be involved in the decision-making process.

These principles should be read in concert with the relevant provisions of the Convention on the Rights of the Child (1-3), specifically non-discrimination (Article 2), best interests of the child (Article 3.1), the right to survival and development (Article 6.2), and the views of the child (Article 12.1).

Determined by national standards

Notwithstanding the above principles, the Global Platform defers to national standards on eligibility to receive treatment as a child with cancer, requiring only the following.

- If a national standard exists for decisions regarding the eligibility for treatment of children with cancer, it should be consistently applied in all clinical settings receiving medicine through the Global Platform.
 - i. In the absence of a national standard, the eligibility standards applied in each clinical/institutional setting receiving medicine through the Global Platform should be clearly articulated and consistently applied.

National and institutional policies around eligibility will be reviewed as part of the readiness assessment process. Countries that do not have national policies in place are encouraged to develop a country-wide approach or policy that promotes equity in the treatment of all children and is in accordance with the four principles of the 1989 United Nations Convention on the Rights of the Child (CRC). (2)

B. EXPECTED AGE LIMIT

The expectation is that in most countries the age limit will be set at 18 or 19 years old. If a country or institution has established a limit significantly higher than this, the Global Platform reserves the right to institute a limit to avoid potential abuse of this system; in such cases, the maximum age at which treatment could be initiated would be set at 24 years old, in line with the upper limit of the term "youth" in the UN General Assembly Resolution A/RES/50/81 of 14 December 1995. (4)

C. EXCEPTIONAL CIRCUMSTANCES

The Global Platform similarly defers to national/institutional eligibility standards in relation to any patients experiencing exceptional circumstances, which might be related to social or political reasons (such as refugees, internally displaced persons, or asylum seekers/grantees), or to medical fragility unrelated to a child's diagnosis of cancer; the Global Platform would discuss any potential exceptions on a case-by-case basis.

REFERENCES

1. Convention on the rights of the child. New York: United Nations; 1989 (<https://www.ohchr.org/en/instruments-mechanisms/instruments/convention-rights-child>, accessed 29 April 2024).
2. Four principles of the Convention on the Rights of the Child. UNICEF; 24 June 2019 (<https://www.unicef.org/armenia/en/stories/four-principles-convention-rights-child>, accessed 29 April 2024).
3. Singh JA, Siddiqi M, Parameshwar P, Chandra-Mouli V. World Health Organization Guidance on Ethical Considerations in Planning and Reviewing Research Studies on Sexual and Reproductive Health in Adolescents. *J Adolesc Health*; 2019 Apr;64(4):427-429. doi: 10.1016/j.jadohealth.2019.01.008.
4. United Nations General Assembly Resolution A/RES/50/81. World Programme of Action for Youth to the Year 2000 and Beyond. New York: United Nations; 1996 (<https://documents.un.org/doc/undoc/gen/n96/771/43/pdf/n9677143.pdf?token=LCJ83TTFx2e0Y6qqXD&fe=true>, accessed 2 July 2024).



St. Jude Children's
Research Hospital



World Health
Organization

Global Platform for Access to Childhood Cancer Medicines

In collaboration with



Strategic
Fund

CONTACT

gpacm@who.int
gpacm@stjude.org