

Heat-proofing health products: Adapting to a hotter planet



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# **About this paper**

This knowledge paper is shared as part of Unitaid's ongoing effort to contribute to the global conversation on health and climate adaptation. It is based on an initial collection of knowledge and evidence gathered by Unitaid, and we make this information available as a public resource for the benefit of all.

The insights reflect our current understanding, but as new information, research, and developments come to light, this paper may be updated to incorporate those changes. Our goal is to continue advancing the conversation and solutions around the intersection of health and climate.

The information synthesized and shared in this paper was generated via multiple sources, including surveys to Unitaid's partners, manufacturers, and members of the World Health Organization (WHO)-hosted Alliance for action on climate change and health (ATACH) platform. Additionally, there were extensive consultations with stakeholder groups, including donors, innovators, implementers/NGOs, governments, regulatory agencies, researchers, manufacturers, and procurers, who graciously shared their experiences and perspectives. This paper also builds on a technical meeting on this topic through ATACH on September 2, 2025. Insights were utilized to develop generalized findings and conclusions.

Unitaid is taking a hypothesis-driven approach to understand the possible impact that heat, humidity, and climate change could have on health products. The goal is to ensure that any challenges are clearly defined and, where appropriate, linked to practical solutions to ensure lifesaving products stay safe, effective, and accessible in the hottest locations, both now and in the future.

## 2.

## Introduction

Health products, including pharmaceuticals, diagnostics, and medical devices, are highly sensitive to environmental conditions, requiring stable and controlled environments to maintain their efficacy, safety, and quality from the point of manufacture to the point of use.

Extreme temperatures and fluctuating humidity intensified by climate change-threaten to exacerbate existing vulnerabilities of these products, risking them becoming ineffective, unreliable, or unsafe. As the planet warms, critical questions emerge: Can today's lifesaving health products and breakthrough health innovations withstand warm and humid conditions, now and in the future, and reach the communities most vulnerable to the effects of climate change? Are new solutions needed to ensure that access to climate-smart<sup>1</sup> health products is a foundation of community health and resilience? This paper highlights the urgent need to better understand the possible impact of heat and humidity on health products-across research, manufacturing, distribution, storage, and use-to understand the risks and ensure they can withstand the unpredictable demands of a hotter planet.

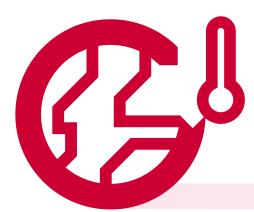
Global policy documents and frameworks focused on climate and health all include references to the importance of building the resilience of health systems and services to extreme events, including heat. For example:

- G20 Health Ministerial Declaration on Climate Change, Health, Equity and One Health: Identifies the direct impact that heatwaves have on human health and the impact that this and other extreme events can have on access to health products and services.
- Belem Health Action Plan for the Adaptation of the Health Sector to Climate Change: Specifies the importance of climate-proofing infrastructure, equipment, supplies, and services, including promoting advances in product thermal stability to strengthen strategic stockpiles and equitable access to essential health products.

<sup>1</sup> https://unitaid.org/climate-and-health/

<sup>2</sup> https://g7g20-documents.org/database/document/2024-g20-brazil-sherpa-track-health-ministers-ministers-language-241031-hwg-ministerial-declaration-on-climate-change-health-and-equity-and-on-one-health-eng#section-1

<sup>3</sup> https://www.gov.br/saude/pt-br/assuntos/cop30/publicacoes/plano-de-acao-em-saude-de-belem-ingles



 WHO's Operational framework for building climate resilient health systems:<sup>4</sup>

Discusses multiple aspects of addressing extreme heat and thermal stress, including recommendations for possible interventions to manage health conditions and adapting current infrastructures, technologies and processes to prepare for and respond to extreme heat (e.g. early warning systems, heat-health action plans, etc).

Building Climate-Resilient,
Environmentally Sustainable and
Low-Carbon Health Supply Chains:<sup>5</sup>

Emphasizes how extreme heat and other climate-driven events are disrupting global supply chains, which are the backbone to accessing essential health products. It also highlights the need to prioritize hotspots where extreme events pose the greatest risk to supply chain resilience, which could be due to heat-related vulnerabilities.

None of these policies, frameworks, and priorities will be successful without ensuring resilient products are a cornerstone of their implementation. In many instances, where there are no products, there are no health services. Heat-stable health products must be prioritized in the global climate and health agenda. This paper serves as a step to continue building momentum for this as a possible priority focus for the global health community.

## The current state of heat stable products

#### Heat stability: a critical parameter for health products

Heat stability refers to a product's ability to retain its integrity, efficacy, and safety when exposed to critically-defined temperatures throughout the duration of its lifecycle.

Health products, from medicines to diagnostics, are highly regulated to ensure they can maintain their quality throughout manufacturing, distribution, and use. As a component of demonstrating quality, products undergo a rigorous series of stability tests and process and shipping validations throughout their lifecycle to determine shelf life, set optimal storage conditions, and confirm that they stay safe and effective across established supply chains. These products are regulated by global and local agencies, such as WHO, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other country-specific stringent regulatory authorities (SRAs). The ICH, for example, has defined four different climatic zones, which guide standards for stability testing (Table 1).6

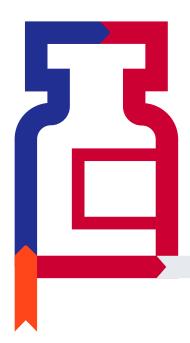


Table 1: Climatic zones for heat stability testing

Zone	Description	Temperature	Relative Humidity	Geography
1	Temperate	21°C	45%	Southern Canada, Europe, parts of Russia
II	Mediterranean / Subtropical	25°C	60%	Mediterranean region, parts of Australia, southern USA
III	Hot/Dry	30°C	35%	North Africa, Middle East, desert areas in the USA
IVa	Hot Humid / Tropical	30°C	65%	Southeast Asia, Central Africa, parts of South America
IVb	Hot / Higher Humidity	30°C	75%	Regions near the equator, dense rainforest areas

Table Source: https://precisionstabilitystorage.com/ich-climatic-zones/

Product manufacturers and other key stakeholders, such as procurers, have designed their processes and systems to comply with regulations and standards defined by these agencies. However, it is known that complying with these can be challenging in certain settings, especially in geographies with warm and humid climates and where infrastructure challenges increase the risk to maintaining controlled environments. A Gates-funded study completed by Chemonics from 2018 to 2021 showed maximum temperatures of ~65°C, excursions beyond 30°C for up to a cumulative total of 30 days for long global shipments, and humidity levels up to 88% across the supply chains of

multiple climate zone IV countries.<sup>7</sup> The challenges in maintaining controlled environments disproportionately impact communities that are at greatest risk for the negative effects of climate change, primarily those in Zones IVa and IVb. Additionally, global trends are seeing health services become more decentralized as a component of achieving universal health coverage. This includes prioritization of stronger primary care, more robust community health platforms, and self-care models, which improve service coverage and health equity, but extend the supply chain into more uncontrolled environments.

## The growing risk of climate-driven heat and humidity challenges

From a scientific standpoint, the impacts of climate change are already well-documented, with the evidence on temperature extremes and fluctuations being undeniable. We're seeing more frequent, longer and more intense heatwaves, particularly in tropical, subtropical, and arid regions.8

These extreme conditions are further exacerbated by shifting precipitation patterns and flooding events that increase humidity levels in unpredictable ways. These shifts in temperature, precipitation, and humidity are also shifting where and when diseases occur, which impacts where and when products are needed. Additionally, the

urban heat island effect,9 deforestation,10 and rising ocean temperatures are driving localized warming, adding another layer of complexity.<sup>11</sup> This convergence creates increasingly difficult environmental conditions for health products that will intensify moving forward.

<sup>8</sup> https://public.wmo.int/content/climate-change-and-heatwaves?utm

<sup>9</sup> World Bank. (2023, December 4). Unlivable: What the urban heat island effect means for East Asia's cities. East Asia and Pacific. Retrieved from https://www.worldbank.org/en/region/eap/publication/unlivable-what-the-urban-heat-island-effect-means-for-

<sup>10</sup> Reddington, C.L., Smith, C., Butt, E.W. et al. Tropical deforestation is associated with considerable heat-related mortality. Nat. Clim. Chang. (2025). https://doi.org/10.1038/s41558-025-02411-0

<sup>11</sup> National Aeronautics and Space Administration. (2025, January 29). The ocean and climate change. NASA. Retrieved from https://science.nasa.gov/earth/explore/the-ocean-and-climate-change/

### **Climate factors** for heat and humidity issues



**Increased global temperatures:** Rising global temperatures due to climate change cause more frequent and intense heatwaves, especially in tropical, subtropical, and arid regions, leading to prolonged heat.

Changes in weather patterns: Climate change alters weather patterns, leading to shifts in precipitation and more intense rainy seasons, increasing humidity levels.

**Higher frequency of extreme events:** The increased occurrence of heatwaves, tropical storms, and other extreme weather events brings both high heat and high humidity, creating harsh conditions.

Shifts in seasonal variability: Unpredictable or extreme shifts in seasonal patterns cause abrupt fluctuations in temperature and humidity levels, leading to sustained high temperatures or humidity.

**Urban heat island effect:** The growth of urban areas traps heat due to concrete, asphalt, and other materials, creating hotter local climates and exacerbating temperature extremes.

#### **Deforestation and land use changes:**

Deforestation and land use changes disrupt natural cooling processes, increasing local temperatures and contributing to higher heat levels.

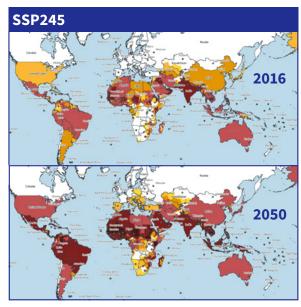
Ocean temperature rise: Rising ocean temperatures lead to higher humidity in coastal and island regions, contributing to more humid and storm-prone conditions.

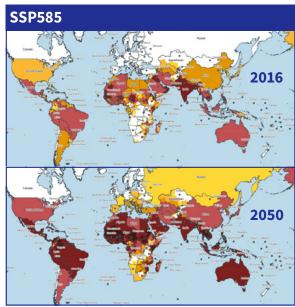
Atmospheric changes: An atmosphere with higher greenhouse gas concentrations can hold more moisture, increasing humidity levels and intensifying the greenhouse effect.



#### Shifts in extreme heat exposure from 2016 to 2050

Extreme heat days based on 30°C threshold (accounts for temperature and humidity)





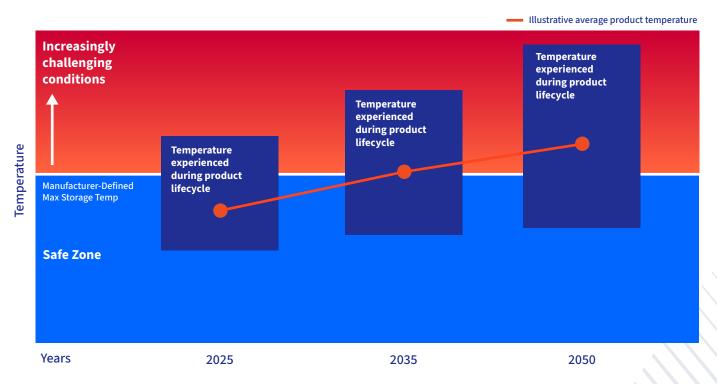
#### **Number of Extreme Days**

Less than 0.1	0.1-0.3	0.4-1.4	1.5-5.3
5.4-24.9	25-99	More than 100	`

Source: https://fews.net/heat-exposure-projections

## There are implications for how these shifts will impact the conditions that products are exposed to over time.

Products are tested to perform safely within a manufacturer-defined temperature range. Beyond this range, it's unclear how heat or humidity will affect them. As the climate warms, heatwaves grow longer and more intense, and humidity increases, products are increasingly likely to face conditions outside their tested limits for longer periods of time, raising the risk of damage or degradation—especially in hot, humid regions.



<sup>\*</sup>Note: This image is purely illustrative to frame the potential challenge and is not based on data from any specific products and/or geographies.

## 5.

## Impact on diagnostics, medicines, and other critical health products

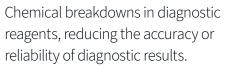
Health products, such as drugs and diagnostics, are made up of complex chemical and biological components that can be highly sensitive to their environment. Exposure to extreme heat can accelerate chemical reactions, causing active ingredients to degrade or lose potency, while humidity can trigger oxidation, hydrolysis, or changes in molecular structure.

In diagnostics, excess moisture can damage reagents, interfere with test strip function, or cause biological materials to break down. Even packaging designed to protect products has limits, meaning that high temperatures and humidity can compromise safety, effectiveness, and reliability before products ever reach the people who need them. Table 2 provides illustrative examples of how medicines and diagnostics may be impacted when exposed to heat and humidity beyond their defined specifications. This is not an exhaustive list, but is reflective of the general risks that may exist, recognizing they will be product-specific.

#### Table 2: Manifestations of heat / humidity stability issues on medicines and diagnostics

#### **Diagnostics**

#### **Degradation of** active ingredients:



Packaging failure: Humidity can degrade diagnostic test packaging (e.g., foil pouches for tests), compromising the sterility or integrity of the contents. Extreme heat can lead to warping or softening.

**Product melting or liquefaction:** Diagnostic products, such as certain reagents or biological samples, may melt or become unstable.

#### **Condensation and moisture buildup:**

Condensation can form inside kits or test storage containers, leading to reagent degradation, compromised accuracy, or contamination.

**Bacterial or mold growth:** Excess moisture risks bacterial or mold growth, leading to contamination and inaccurate test results.

**Loss of accuracy:** Affected stability of diagnostic reagents or the functioning of diagnostic equipment, resulting in false negatives or inaccurate readings.

Heat inactivation / degradation of biological samples: Exposure to high temperatures can cause changes in the structure and function of proteins or other molecules in the sample, potentially leading to the loss of biological activity and ineffective test (e.g., false negatives).

#### **Medicines**

#### **Degradation of** active ingredients:

Chemical breakdowns in active ingredients, reducing efficacy or safety.

Packaging failure: Weakened or degraded packaging materials, such as plastic packs or seals, leading to compromised product integrity. Soft, melted, or warped packaging.

#### **Product melting or liquefaction:**

Heat can cause temperature-sensitive products (e.g., biologics, injectables) to melt or become unstable.

Loss of potency: Active pharmaceutical ingredients (APIs) or biologics lose potency over time, making the product ineffective.

#### **Equipment malfunction & service** interruption:

Power, manufacturing, or storage equipment (e.g., refrigerators, freezers, climate control units) can malfunction, resulting in improper storage conditions.

#### Climatic stress on human health:

Discomfort or physiological stress, impacting user experience and/or product effectiveness or safety.

#### 5.1 Diagnostics

More generally for diagnostics, heat exposure can cause reagent and sample degradation, packaging failures, condensation, and microbial contamination – compromising both reliability, accuracy, and sterility. The challenges extend to the operating environments, where logistics, storage and operating conditions become increasingly difficult and costly to manage. The use environment has a significant impact on the viability of specific diagnostics and the challenges that exist. For example, rapid diagnostic tests (RDTs) are often used at the point-of-care in different environments, ranging from health facilities to people's homes when self-administered (e.g. for HIV) or administered by a community health worker (CHW). Other diagnostics, such as CD4 machines, are primarily utilized in more central locations with more stable and controlled infrastructure.

Globally, there is a greater push to decentralize care, which has significant implications on the challenges for diagnostics. As products are developed to drive decentralization, they are likely to be exposed to more uncontrolled environments, where they will require different specifications to ensure they remain safe and effective in those settings.

#### 5.2 Medicines

Similarly, under temperature extremes, medicines are prone to chemical instability, degradation of active ingredients, increased impurities, reduction in shelf life, and compromised packaging, leading to a loss of sterility. These factors can lead to ineffective treatments and even produce harmful byproducts that exacerbate health outcomes.

These issues don't just threaten the effectiveness of treatments; they also contribute to waste, inflated costs, and disruptions in healthcare delivery – especially in areas where maintaining temperature control is a significant challenge.

#### 5.3 Other products

Drugs and diagnostics receive much of the attention on this topic and are thought to be at greater risk to extreme conditions than other types of products. However, implementation of solutions that are product agnostic could also have a direct impact on other priority products. This includes, but is not limited to:

- Insecticide treated nets (ITNs), which are prone to insecticide degradation when exposed to high temperatures and direct sunlight and can be physically impacted at high temperatures.
- **Vaccines,** which typically require a stable cold chain to maintain their efficacy and safety until the point of use - maintaining the cold chain is a known challenge to successfully scaling vaccines.
- Oxygen solutions, where manufacturing processes can be hindered by high temperatures and portable oxygen generators may be inoperable above certain temperatures.
- Blood products, which are critical in life-threatening situations like postpartum hemorrhage (PPH), require strict, temperature-controlled storage to stay viable - many facilities do not have the capabilities to store blood onsite.
- Nutrition products, where environmental conditions can spoil ingredients, decrease palatability, and/or reduce nutritional value.

#### 5.4 There are growing examples of heat stability challenges

Surveys and consultations identified multiple anecdotes indicating that heat stability must be an important product parameter in countries with high temperatures. However, recognizing these are anecdotal, additional investigation and research is required to make conclusions and better understand if the risks to products are increasing:

- Discoloration and change in consistency of tablets: Oral tablets that are stable at ambient temperatures are changing colors and physical consistency when exposed to sunlight and/or excessive heat and humidity in uncontrolled facility storage rooms.
- **Low efficacy of uterotonics:** Oxytocin is a product with known quality issues due to lack of a consistent cold-chain. In some instances, providers have been known to administer multiple doses to the same patient in hopes that one will work.
- **Accuracy and performance issues with** malaria RDTs: Multiple countries have flagged potential false negatives<sup>12</sup> with specific malaria RDTs, while some products have experienced faint or non-existent test lines due to exposure to environmental conditions.
- **Decreased potency of HIV and tuberculosis** (TB) treatments (ART and Rifampin): There are some emerging signals in hot geographies where health facility storage conditions are consistently beyond product specifications, that communities may be experiencing increased viral loads and persistent TB symptoms after treatment, which may be consistent with low-quality products.

- Physical deformation and reduced efficacy of rectal artesunate suppositories for malaria: Suppositories have been impacted in warm locations, which has reduced their shelf life.
- Caking/clumping of drugs during use: Products that require mixing prior to use have been observed to have a change in consistency at the time of use, especially in warmer locations. This impacts their ability to be mixed and used.
- Failure of equipment: Certain laboratory equipment (e.g. CD4 machines, molecular diagnostics equipment, laboratory machines) are physically unable to operate in sites with temperatures that exceed 35°C. Some sites have been forced to install air conditioners to ensure the equipment remains functional.
- Insecticide treated nets (ITNs) melting and/or degrading: ITNs can be exposed to extreme temperatures, especially when sitting in bulk at ports and in open-air trucks during distribution at campaign sites. This has led to melted and/or degraded products in some instances.

#### 5.5 Limited evidence on which products are most impacted

There is a lack of consensus on the types of products that are at greatest risk to extreme conditions, from diagnostics, to pharmaceuticals, vaccines, and medical devices, with all products having some type of risk. This is likely because evidence on the actual impact of real-world conditions on product stability, effectiveness, and safety is scarce. The gaps include an absence of public data on how extreme environmental conditions impact specific products within different contexts, as well as clarity on the

methods that can be utilized to evaluate heat stability in alignment with future climate scenarios. Both gaps will need to be filled to strengthen the global evidence base. However, qualitative feedback from experts in specific technical areas (e.g. pharmaceutical sciences, diagnostics) largely indicates that they see the greatest risks to products in their areas of expertise, lending some credibility to the existence of these risks.



The largest body of evidence seems to be on malaria RDT use in multiple countries, showing that test sensitivity can be negatively affected when stored or exposed to higher temperatures (e.g. 35 - 60°C) for a measurable period of time. <sup>13,14,15,16,17</sup> There is research showing that amoxicillin degradation may have been accelerated by storage in more humid regions of India. 18 Additionally, the sensitivity of COVID-19 rapid tests<sup>19</sup> and the sensitivity and specificity of dengue assays<sup>20</sup> may be reduced when exposed to high temperatures.

On the flip side of this, there is limited research showing that some types of HIV RDTs<sup>21</sup> and dengue RDTs<sup>22</sup> are quite resistant to exposure to temperatures that are higher than recommended by the manufacturer. This demonstrates the variability that can exist across individual products and the importance of ensuring the right products are selected during procurement – environments with hotter climates require products that are more resistant to extreme heat.

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- 15 Peter L. Chiodini, Katherine Bowers, Pernille Jorgensen, John W. Barnwell, Katharine K. Grady, Jenny Luchavez, Anthony H. Moody, Audie Cenizal, David Bell, The heat stability of Plasmodium lactate dehydrogenase-based and histidine-rich protein 2-based malaria rapid diagnostic tests, Transactions of the Royal Society of Tropical Medicine and Hygiene, Volume 101, Issue 4, 2007, Pages 331-337, ISSN 0035-9203, https://doi.org/10.1016/j.trstmh.2006.09.007
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## 6.

## **Heat-stability is critical** to all stages of the product lifecycle

Heat stability must be prioritized and managed throughout the product lifecycle, as it is becoming more apparent that there are risks at every stage and unpredictable vulnerabilities are emerging, especially in use settings where control over the product is limited. The image below highlights some of the challenges at the different stages.

## Product development

- Standards may not be reflective of all real-world conditions.
- Regulatory agencies lack evidence of specific challenges.
- ➤ Lack of post-market surveillance to identify problems.
- Limited evidence showing excursions beyond specs to inform product redesign.

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#### **Storage**

- ➤ End users are unaware of how to store products.
- Infrastructure limitations prevent end users from maintaining specified storage conditions.
- ➤ End users can be agnostic to or ignore storage conditions.

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# Materials and product manufacturing

- Degradation of materials and supplies during acquisition.
- Challenge controlling processes and material storage and handling.
- ➤ Water shortages.

3.

## Transportation

- Transport routes are highly variable and often lack temperature control.
- ➤ Last mile distribution is where control is the least.
- Balance between severity of risk at central level and frequency at the last mile.

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#### **Product use**

- Use settings are more uncontrolled the more decentralized care is.
- Some equipment cannot operate in certain conditions.
- Impact of heat on the behavior of communities.



#### End of life



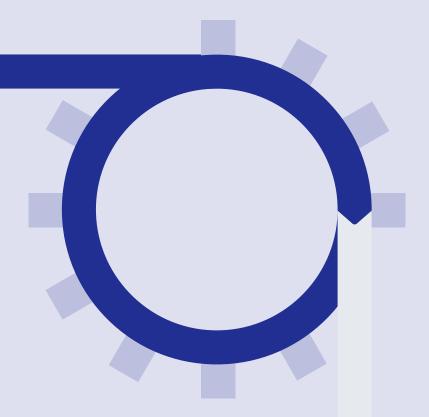
- ➤ Limited ability to test quality at point of use.
- Inability to objectively know when products are at end of life.
- Slow supply chain forces users to use expired of low-quality products or risk stockouts.

### 6.1 Product development

Most product manufacturers incorporate climate risk scenarios into their research and development (R&D) strategies, completing stress tests, excursion studies, and stability and accelerated aging testing during development to establish defined storage and operating parameters/limits. Regulatory bodies, such as WHO, US FDA, and EMA are largely reliant on global standards to establish testing requirements. These standards are designed to reflect real-world conditions, such as room temperature (25°C, 60% humidity), cold chain requirements (2-8°C) for vaccines and biologics, and recommended extreme conditions (40°C, 75% humidity for 6 months). The standard for drug stability testing<sup>23</sup> defines four different

climatic zones globally, with recommended storage conditions for each. Additionally, WHO has defined the stability conditions for pharmaceuticals<sup>24</sup> for each of its member states, which are incorporated into their prequalification (PQ) processes.

Manufacturers may test their products beyond these defined standards, but that information is usually not made public. While there is confidence amongst regulators that current standards reflect real-world conditions, some agencies, such as the FDA, have encouraged testing products up to 50°C during development. However, this is not yet a regulatory requirement.



<sup>23</sup> https://database.ich.org/sites/default/files/ICH\_Q1EWG\_Step2\_Draft\_Guideline\_2025\_0411.pdf

<sup>24</sup> https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/regulatorystandards/trs953-annex2-appendix1-stability-conditions-table-2018.pdf?sfvrsn=74032aec\_12



#### 6.2 Materials and product manufacturing

Materials may be prone to degradation during acquisition in high-heat and humidity settings. This may be especially true for tier 1 or tier 2 suppliers who are manufacturing components, such as active pharmaceutical ingredients (API), in locations that are at greater risk of climate change (e.g. India). Additionally, temperature-sensitive ingredients and processes may become more difficult to control, and droughts could lead to water shortages that affect production processes that are reliant on access to water.

Environmental control and monitoring are a critical component of maintaining Good Manufacturing Practices (GMP),<sup>25</sup> which are a set of regulations that govern the processes, systems and structures that manufacturers utilize to ensure their products are safe and effective. Manufacturing sites are designed to ensure they can maintain appropriate conditions, with local

climactic factors taken into account. In the face of a warming environment, long-term planning must ensure sites are able to maintain these conditions now and during extreme scenarios in the future. In one case study from Astra Zeneca, the cooling demand that was needed to maintain desired conditions exceeded the site's cooling capacity during a heat wave in 2018.26 This reduced production for several weeks and led to Astra Zeneca expanding its cooling capacity.

This is an especially important consideration for regional manufacturing initiatives<sup>27,28</sup> that are seeking to increase production capacity in Africa. Extreme conditions could prove to be a challenge to maintaining GMP if these risks are not effectively mitigated.

<sup>25</sup> https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations

<sup>26</sup> https://www.astrazeneca.com/content/dam/az/PDF/Sustainability/AZ-TCFD-case-study-1.pdf

<sup>27</sup> https://unitaid.org/regional-manufacturing/

<sup>28</sup> https://www.nepad.org/publication/24-priority-medical-products-and-roadmap-regional-manufacturing-africa

#### 6.3 Transportation

It is estimated that Africa imports 70-90% of its medicines and 99% of its vaccines, 29 with most products coming from suppliers in the European Union, China, and India. 30 This means that products are traveling long distances across highly variable transportation routes that often lack temperature control and subject products to extreme temperatures and erratic fluctuations. For example, the image below, pulled from the Gates-funded Chemonics study, shows the amount of time products can be within specific temperature ranges during transit. There is variability in both temperature conditions and transit time, with some routes maintaining acceptable control, while others present challenge scenarios.

During Unitaid's engagement with key stakeholders, transportation (along with end user storage) was consistently identified as one of the top two areas of greatest risk for heat stress across the product lifecycle. The risk is especially great during last mile distribution, especially inland deliveries where there is less control over how products are managed and handled by different distributors. While the frequency of extreme temperature risk happening is greater at more decentralized locations, the severity can be greater at central locations where there are larger quantities of products. An unexpected heat wave at a port, for example, could expose thousands of products to extreme temperatures at one time.

#### **Global Transit Temperature Exposure in Hours**



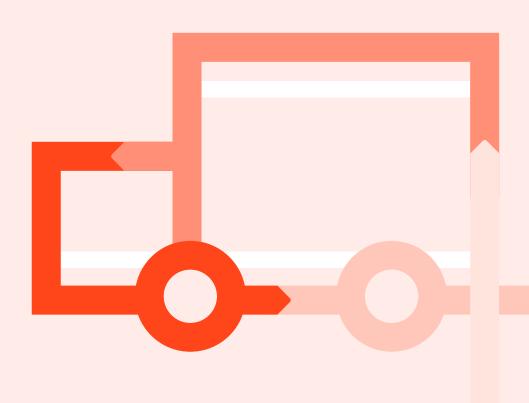
<sup>29</sup> https://www.logupdateafrica.com/logistics/how-can-ppps-transform-africas-pharma-logistics-sector-1353191?utm

<sup>30</sup> International Trade Centre. Medical Industries in Africa: A Regional Response to Supply Shortages: International Trade Centre. 2020. Available: https://intracen.org/resources/publications/medical-industries-in-africa-a-regional-response-to-supply-shortages

#### **Anecdotally, transportation routes present many challenges:**

- Products are prone to getting stuck in maritime ports for weeks or months while they wait for necessary clearances, exposing them to high temperatures while they dwell in metal shipping containers. The more time products remain sealed in containers, potentially exposed to heat and direct sunlight before reaching their destination, the greater the risk will be.
- Manufacturers and implementers have reported instances of goods being left on airport runways for extended periods of time during summer, resulting in the need to dispose of products for fear of degradation.
- Products are often moved in unregulated trucks, which can expose them to high temperatures and direct sunlight.

- In the most decentralized locations, CHWs are tasked with collecting products at facilities and bringing them to their communities without the ability to maintain needed storage conditions while the products are transported in their bags or kits.
- Different points along transportation routes can consistently expose products to temperatures of 60°C+.
- There are some existing solutions, such as temperature-controlled containers, but they significantly increase the cost, presenting a tradeoff that could benefit product quality, but negatively impact product affordability and access.



#### 6.4 Storage

Storage, especially by the end user, was consistently identified as the greatest risk to products during Unitaid's engagement with stakeholders. Every type of stakeholder, from manufacturers, to innovators, to regulators, expressed the greatest concern here because of the lack of control to ensure products are maintained within specified conditions. Some rural pharmacies and health posts, for example, have had product storage conditions greater than 40°C for approximately 18% of the time in the hottest locations, with max temperatures beyond 47°C.31

The risk presents itself in three key ways:

#### 1. End users are unaware of how to store products:

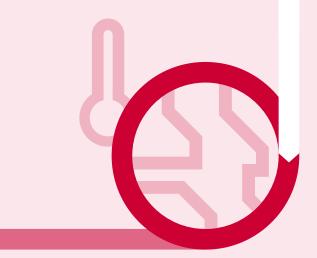
- There is a lack of clarity on what "room temperature" and other vague or missing labeling conditions mean. What if people are bringing antiretrovirals (ARVs) in their bag at a hot bus station? What happens if their drugs get wet?
- Clients may not be educated on the storage requirements of specific products, such as ARVs or TB medicine. This can lead to them being stored in inappropriate locations in homes, such as near places of cooking.
- CHWs may be unaware of the storage requirements for all the diagnostics and drugs included in their packages of services.
- ITNs may be put in the sunlight to dry after washing, which can impact the insecticide quality.

#### 2. Infrastructure limitations prevent end users from maintaining specified storage conditions:

- Storage facilities at health clinics are often inadequately designed – anecdotes point to the use of rooms with limited airflow that have consistent temperatures from 35-45°C.
- Clients' homes are not temperature controlled and do not have refrigerators – mothers have been known to store their children's medication under their bed, bury it in the sand, and submerge it in water to keep it cool in hot districts and provinces across multiple countries.
- Central warehouses are often more stable than end user sites, but still experience persistent challenges – one country had more than a dozen sub-national commodity warehouses simultaneously without reliable power to run air conditioners.
- Migrant populations and refugee communities are already at greater risk of lack of access to products and services and they do not have dedicated locations to store medications, especially while they are on the move.
- 3. End users are agnostic to or intentionally ignore specified storage conditions:
- Unregulated sales of products occur in uncontrolled settings, such as open markets.
- Products may be purchased and used that have not been tested to international standards.



31 Albertini, A., Lee, E., Coulibaly, S.O. et al. Malaria rapid diagnostic test transport and storage conditions in Burkina Faso, Senegal, Ethiopia and the Philippines. Malar J 11, 406 (2012). https://doi.org/10.1186/1475-2875-11-406



#### 6.5 Product use

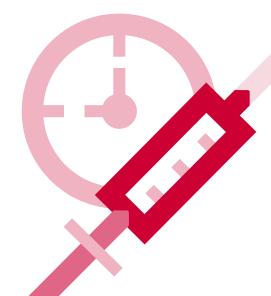
Much like during transportation and storage, the environmental conditions where products are used can be difficult to control, especially in more decentralized locations, including primary health clinics (PHCs) and communities where CHWs operate. As indicated in previous sections, this can lead to equipment not operating, medicines changing consistency or appearance at the time of use and evaporation of reagents.

Furthermore, using products in locations where there are high temperatures can adversely influence behaviors. This is a specific challenge with ITN use, where communities in many countries are known to stop sleeping under nets when it is too hot. Anecdotally, they prefer to risk getting bitten by mosquitoes and having to buy malaria medication than trying to sleep under a hot net.

#### 6.6 End of life

Many of the challenges described above can result in products reaching their end of life prior to what is specified on the product labeling. As a result, users may be unaware of when to dispose of products and end up using ineffective or unsafe products. They may be presented with the difficult decision of disposing of a product before its expiration date, even if they are unsure of its remaining efficacy. Temperature indicators can be used to identify exposure to extreme conditions, but in general, it is difficult to know if products have prematurely reached their end of life at the point of use.

Standards exist to guide shelf-life testing of medical products through accelerated aging.<sup>32</sup> Modeling shows that temperature excursions can greatly shorten product shelf life. For example, modeling demonstrates that a drug with a two-year shelf life and a maximum storage temperature of 30°C that is stored at that maximum temperature will lose about 15 days of its shelf life for every two consecutive days it is exposed to 50°C.33 The same modeling shows that if that product is normally stored a few degrees below that limit (e.g., at 27°C), it would only lose 15 days after 30 days at 50°C. With climate change, this safety buffer may be shrinking, making more frequent excursions more damaging to products.



<sup>32</sup> https://westpak.com/test-standards/astm-f1980/

<sup>33</sup> Jenkins, D., Cancel, A. & Layloff, T. Mean kinetic evaluations through simulated temperature excursions and risk assessment with oral dosage usage for health programs. BMC Public Health 22, 300 (2022). https://doi.org/10.1186/s12889-022-12660-9

# The impact of heat and humidity challenges

The rising impact of extreme heat and humidity has the potential to quietly undermine the effectiveness of medicines, diagnostics, and other products with cascading consequences for health systems and the health of communities.

### 7.1 Health impact

The health impacts of degraded products can be severe. Ineffective drugs and inaccurate tests can lead to poor outcomes, treatment interruptions, and higher mortality. Examples include:

- Misdiagnosed or undertreated patients continuing to transmit infectious diseases and/or not being cured.
- Sub-therapeutic dosing from degraded drugs potentially fueling drug resistance.
- Suspected links in several countries between rising malaria cases and deaths and quality issues with products in high-heat, highhumidity settings.

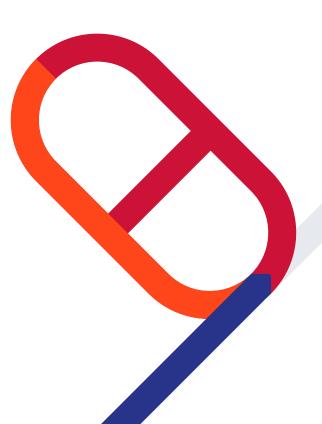
The ripple effects can reach regulators, manufacturers, and markets. Regulators are under mounting pressure to monitor product quality and investigate failures. Manufacturers face higher costs for stability testing, packaging innovations, and supply chain monitoring, while also navigating reputational risks when compromised products reach communities. At the same time, these pressures can create an urgent incentive for innovation.

#### 7.2 Health system impact

Health systems are being unnecessarily stressed as facilities struggle to store and safeguard temperature-sensitive products. In many places, lack of climate-controlled infrastructure forces facilities to choose between using medicines and tests of uncertain quality or not stocking them at all-leaving patients without access. Additionally, facilities may experience persistent stockouts and there may be an increased burden on already overburdened staff. Examples include:

- Facilities opting not to stock certain products because they will spoil or degrade, forcing patients to travel long distances or go without treatment.
- Clinicians and CHWs are forced to develop their own solutions to try and keep products cool – some community facilities have stored products on the ground or even covered their floors with more heat-resistant coatings made of local materials, such as cow dung.
- Central labs are forced to install air conditioners and make other costly infrastructure upgrades to prevent equipment from breaking down. Where these investments are not possible, critical equipment is not operational.

- Products are discarded prior to their shelf life being reached due to physical changes (e.g. discoloration) or suspected exposure to extreme conditions, creating waste and unexpected stockouts.
- Providers are losing confidence in specific products – for example, trust in malaria RDTs is decreasing in some countries that have known challenges with false negatives.



#### 7.3 Community impact

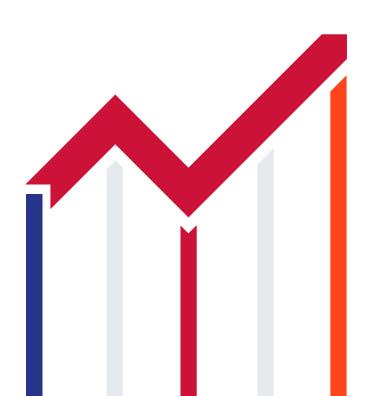
The consequences for community members can be life threatening. For many, who are already stigmatized, they now carry the added burden of figuring out how to store their medicines in extreme conditions if they're available, worrying if they are effective or not, and facing a direct impact on their health. Examples include:

- Elevated viral loads and persistent TB symptoms in high-heat settings where ARVs and Rifampin are stored in facilities that lack temperature control.
- While not confirmed, several countries are investigating the linkage between increasing malaria cases and death rate and quality issues of products in high-heat and highhumidity settings.
- Certain communities, such as rural, hard-toreach, and refugee settings, simply do not have access to products because unstable supply chains and inadequate storage conditions do not allow it.
- Loss of community confidence in the health system because of inaccurate tests - in one country, communities have told health workers to stop taking their blood for viral load testing because samples were consistently exposed to high temperatures during transport and had to be recollected. In another country, HIV self-test kits had been distributed to the community before it was discovered that they had been exposed to high temperatures in transit and needed to be disposed of. People who had already used the kits had to be re-tested.
- People are forced to take their medication and/or give it to their children blindly, without having confidence that it is safe and efficacious.

#### 7.4 Economic impact

The economic impacts can also be significant. Wasted products, shortened shelf lives, and repeated testing all drive up costs, while families and governments alike pay hidden adaptation costs. Examples include:

- High costs for facilities that are forced to install cooling systems or upgrade infrastructure.
- Direct product wastage when supplies are discarded after suspected or confirmed exposure to heat.
- Logistical costs of managing shorter shelf lives, including frequent resupply and inventory challenges, and having to maintain environmentally-controlled supply chains.
- Community costs, such as lost income from repeated travel to facilities, retesting, or extended illness.



8.

## Addressing these issues requires a systematic approach to innovation

Challenges exist across the entire product lifecycle that have the potential to directly impact health systems and the health of communities. Therefore, ensuring that high-quality products can maintain their integrity, efficacy, and safety throughout their lifetime will require a portfolio approach of product and system innovations, along with diverse partnerships across stakeholders, from manufacturers to communities to regulatory agencies.

Innovation must be centered on the needs of communities and health-care workers to ensure solutions can be locally adapted and delivered. The best solutions will be community-led, where there is an opportunity to identify what works and generalize best practices that can enable the most impactful approaches to scale. Solutions are needed in many areas, but may include the following (not an all-inclusive list):

#### 8.1 Product design changes

Formulation changes and development of new products specifically designed to withstand higher temperatures during storage and use will lead to more resilient products, especially in locations where maintaining the cold chain is an issue. One example is heat-stable carbetocin (HSC)34,35 (shelf stable for 3 years at 30°C and 75% RH), which was designed to address the gap of access to highquality oxytocin, which requires storage at 2-8°C. Accelerating HSC access is an active investment area for Unitaid.

More heat-resilient products may benefit from future technological advancements, which some manufacturers are already working on. This could include novel delivery mechanisms, such as microarray patches and lyophilized drugs, moisture-resistant or nano coatings to improve drug stability, and advancement of diagnostics that are not reliant on environmentally-sensitive biologics, such as those utilizing electrochemical

biosensors. Additionally, long-acting products<sup>36</sup> are an opportunity area to reduce the impact of temperatures on products, primarily as a replacement to products that are given to clients in larger quantities (e.g. ARVs, TB treatment) and are susceptible to degradation when being stored in homes or other uncontrolled use sites. However, one potential tradeoff of long-acting injectables, is that they may actually be less heat-stable as a liquid formulation versus a solid one. This tradeoff must be considered along with the possible benefit of having a product that is administered on a less frequent dosage schedule.

Strengthening the evidence base for which product types and classes are at greatest risk to extreme temperatures and, therefore, could benefit the most from product design changes could serve as an incentive for future R&D investments, such as what was done for development of HSC.

#### 8.2 Packaging innovations

Packaging and labeling are another area for potential solutions. There are opportunities to consider selection of more heat-resistant packaging for products intended for use in high-heat settings, as well as development of alternative packaging solutions, such as those incorporating advanced insulation or phasechange materials. Additionally, labeling could

be more intentional about educating end users regarding storage requirements and the risks of exposure to high temperatures and/or humidity. Moisture resistant packaging can also be employed, where necessary, along with indicators of excessive temperature and humidity exposure.

<sup>34</sup> https://www.who.int/news/item/27-06-2018-who-study-shows-drug-could-save-thousands-of-women%E2%80%99s-lives

<sup>35</sup> https://unitaid.org/innovations/heat-stable-carbetocin/

<sup>36</sup> https://unitaid.org/innovations/33121-2/

#### 8.3 Cold chain alternatives

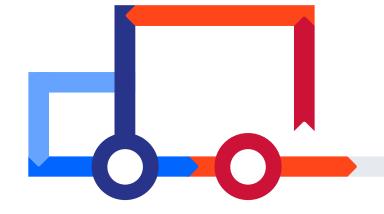
Maintaining stable cold chains continues to be a problem in many low- and middle-income countries. As one community leader stated, "any medication that will come out requiring refrigeration will just exclude parts of Africa." Some countries with hotter climates are seeing increased demand for refrigerated shipping containers<sup>37</sup> to aid in maintaining necessary storage requirements for products during transport, but this comes at a much higher cost (up to double that of to that of non-climate controlled containers) that is unsustainable for all shipments.

There is a need for alternatives, such as passive cooling solutions, use of solar powered options where possible, and portable, decentralized storage solutions for rural facilities and locations where temperature control is difficult due to infrastructure gaps. Solutions may also be adapted from other sectors, such as the food and agricultural industries where there may be similar cold-chain needs.

#### 8.4 More agile delivery models

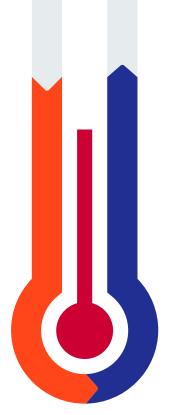
Slow moving and stopped products (e.g. in ports, uncontrolled storage facilities, etc) present a significant risk of exposure to extreme conditions for an extended period of time. If supply chains were more responsive to the consumption needs of communities and were able to deliver products more rapidly, the risk of products degrading and/ or exceeding their shelf life could be reduced. This is especially true as products move from more controlled locations to more uncontrolled rural and hard-to-reach locations.

There is an opportunity to reimagine transportation and delivery models to reduce the time between when a product is manufactured and when it is used, thereby decreasing the total time it may be dwelling in uncontrolled settings and environments. There are many African-based innovators who are working on these challenges where there may be opportunities to support testing and scaling new models.38



<sup>37</sup> https://www.kuehne-nagel.com/how-to/sea-freight/what-is-a-reefer-container

<sup>38</sup> https://www.salientadvisory.com/report-media/leading-innovations-enabling-health-product-access-in-africa,



#### 8.5 Temperature monitoring

Real-time temperature monitoring is already utilized by different procurers and suppliers, but some stakeholders have consistently identified this as an area of greatest potential for innovation. This approach has been utilized with vaccines for decades to identify possible quality issues. WHO requires that all vaccines procured through UNICEF use vaccine vial monitors (VVMs), which are estimated to save \$US14 million per year by preventing the unnecessary disposal of undamaged vaccines.<sup>39</sup> In other anecdotes, temperature monitoring has been shown to be a successful stand-alone intervention in some countries, where suppliers and manufacturers gained better visibility into conditions along their supply chains and were able to introduce interventions (e.g. air conditioning, training) that resulted in a measurable improvement in their storage conditions.

However, incorporating temperature monitoring must be combined with the ability to appropriately respond to any excursions or excessive temperatures that occur. This requires a clearer understanding of how real-world conditions may or may not impact products. One risk of implementing temperature monitoring without a clear response plan for conditions that are beyond product specifications, is unnecessarily limiting product access. For example, full batches of products have been disposed of when they were exposed to high temperatures, without knowing the full extent of the impact on the products. Some donors have even gone so far as to stop temperature monitoring of their shipments because the excursions that were being experienced were resulting in too many shipments being stopped and/or products being pulled for fear of degradation. This can exacerbate access issues in locations where products may only be delivered on a quarterly basis, for example. Point-ofcare quality testing could be a complementary innovation area to consider for temperature monitoring to balance the need for ensuring storage conditions are maintained while also avoiding unnecessary disposal of products.

#### 8.6 Forecasting, planning, and other data-driven solutions

Incorporation of data, especially climate, weather, and infrastructure data, into forecasting and planning solutions could strengthen the ability of key stakeholders to ensure the right product is at the right place at the right time. For example, products that are more heat stable may be prioritized for delivery to locations that experience higher temperatures or are at greater risk for heat waves and bouts of high humidity. Additionally, geographies and communities that have unreliable cold-chain access or are more

susceptible to stresses on their infrastructure (e.g. their power grid) during extreme temperatures may benefit from targeted interventions to ensure products are not exposed to extreme conditions. For example, one country in Africa is largely reliant on hydropower to run their power grid. Load shedding during periods of drought or high heat can limit electricity access at health facilities to a few hours per day. Advanced planning could prioritize the facilities that might benefit from solutions when this occurs.

### **Regulation and standards**

There is limited evidence on how well current regulations and testing standards align with real-world scenarios, but there is research from Burkina Faso, Senegal, Ethiopia, and the Philippines showing that products are consistently exposed to conditions beyond defined standards.<sup>40</sup> Additionally, the previously referenced Chemonics<sup>7</sup> climate monitoring study funded by the Gates Foundation, identified temperature excursions as high as 65°C that must be accounted for. This research and other anecdotal evidence in this paper poses the question of whether or not the speed of climate change is adequately considered when defining requirements for products intended for use in high-heat settings. The standards driving those requirements may not reflect worst-case scenarios, but more research is needed to make that link. One gap to generating more evidence is the limited

breadth of post-market surveillance systems in many countries. This makes it difficult to monitor any possible impact that environmental conditions may be having on product quality. Strengthening surveillance systems could be an area where solutions are needed.

Additionally, there are implications for procurement standards that could be informed by additional evidence. For example, specific products within an individual class may be better positioned for distribution in high-heat settings. Procurement criteria should reflect these realities when selecting products for high-heat locations, both now and in the future as temperatures change.

# There are critical evidence gaps

There are four key evidence gaps that must be filled to move forward in a strategic manner and to help shape a global agenda that can align key stakeholders on priorities and opportunities for heat-proofing health products. These gaps were consistently identified as priority needs by all stakeholders Unitaid engaged to inform this paper.

#### **Evidence Gap #1: What real-world conditions** and worst-case scenarios are products being exposed to across their lifecycle and how will those evolve over time due to climate change?

There is limited public data on the actual conditions that products experience from the moment they leave manufacturing sites until they are used and disposed of. Strengthening the evidence base on these conditions will:

Inform global guidance and standards on product storage and use requirements that will drive future product design and testing decisions.

- Identify hotspots across the supply chain where products are at greatest risk, both operationally and geographically.
- Provide visibility into the conditions and risks at decentralized locations where there is less control, including rural and hard-to-reach communities.

Answering this question must consider both current and future climate scenarios.



#### **Evidence Gap #2: What impact are these** conditions/scenarios having on the quality of priority products?

Despite some of the research that has been done on specific products, such as RDTs, there is a lack of objective evidence on the actual impact of extreme heat and humidity on critical health products. This evidence is important to determine if specific products are better designed for extreme settings than others (to possibly inform procurement) and if entire product classes are at risk or need holistic solutions. Additionally, when overlaid with hotspots across the supply chain, this information is critical to informing the most appropriate solutions at each level of care.

#### Evidence Gap #3: Is there a direct impact on community health due to products being exposed to extreme conditions?

Despite anecdotes, there is no established linkage between the possible impact of degraded products due to exposure to extreme conditions and the actual impact on community health. This should be explored under the broader topic of drug quality, with a clearer understanding of how much of a contributor this is to substandard products being used. There are implications here for other global priorities, such as drug resistance.

#### **Evidence Gap #4: What are the most** impactful areas for innovation and what scale-ready solutions exist versus new solutions that are needed?

There are a variety of solutions at various stages of development, but they must be mapped to the most impactful opportunity areas based on current and future evidence. Specifically, existing solutions must be assessed to determine if they are technically feasible, cost-effective, and implementable within communities that are most vulnerable to the impacts of high heat and humidity. Additionally, gaps need to be identified to specify where new innovations are needed to address all critical challenges throughout product lifecycles. Finally, there must be an effort to build awareness of specific innovations to mobilize partnerships and financing for climatesmart solutions. Many stakeholders are currently unaware of existing innovations, highlighting an awareness gap that is critical to catalyzing scale-up.

## 10. Conclusion

The need to answer these questions could not be more urgent, as climate change continues to disproportionately affect the world's most vulnerable communities by exacerbating the impact of illnesses and infectious diseases. The time for the global health community to act on this is now. Heat-stable products are a cornerstone to achieving climate resilience of communities and a prerequisite to delivering on the promise of equitable access to quality health products for all.

As climate change accelerates, the risks to health products—and to the systems and people that depend on them-will only grow. Generating stronger evidence on the scale and impact of these challenges to drive strategic action is essential, but action must be guided by a commitment to access and equity above all. This means navigating a careful balance: raising awareness, improving products, and strengthening systems, while avoiding unintended consequences, such as stockouts, inefficient supply chains, misinformation, and unnecessary skepticism of products. By linking evidence to solutions that protect both product quality and access to services, we can ensure that lifesaving health products remain reliable, available, and effective for those who need them most.

Future Unitaid investments will investigate the heat stability of health products considering different climate scenarios, and will advance solutions to address this growing challenge.

#### Reference to Unitaid's previous and ongoing Work:

#### **Heat-stable carbetocin:**

Unitaid has supported the development of a heat-stable version of carbetocin. a vital product for preventing postpartum hemorrhage. Traditionally requiring refrigeration, carbetocin's access in heat-prone, resource-limited areas was constrained. By introducing a heat-stable version, Unitaid ensures that this lifesaving medicine remains effective even in regions affected by extreme temperatures. This initiative is a significant step in promoting resilient health products that can withstand the unpredictable impacts of climate change.

https://unitaid.org/project/ evaluate-a-proven-postpartumhaemorrhage-preventionproduct-for-use-as-treatment/

#### **Climate Resilient** and Environmentally **Sustainable Supply Chains** (Report):

ATACH/WHO and Unitaid partnered on a multi-day consultation with other organizations and stakeholders to discuss health supply chains, including strategies to address risks from and contributions to climate change.

https://www.who.int/ publications/m/item/reportof-climate-resilient-andenvironmentally-sustainablesupply-chains-in-the-healthsector-expert-consultation

#### Milligrams to Megatons study:

Through its Milligrams to Megatons (M2M) study. Unitaid has assessed the climate-related vulnerabilities of critical health products, such as Artemisinin-based Combination Therapies (ACTs). These antimalarial treatments, essential for combating malaria, may face stability challenges due to fluctuating temperatures and humidity. Unitaid's work in this area has focused on identifying and addressing these risks, ensuring that ACTs remain effective despite climate-induced stress on their stability.

https://unitaid.org/uploads/ Report\_From-milligrams-tomegatons A-climate-andnature-assessment-of-ten-keyhealth-products.pdf



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