

# Call to Action:

Improve access and use of quality medicines  
to save lives of newborns and children



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Each year, more than 700,000 children under age five<sup>1</sup> die needlessly from pneumonia and other treatable respiratory infections. Ninety percent of these children<sup>2</sup>—most of them newborns and infants—live and die in 40 low- and middle-income countries (LMICs), where nearly seven million babies under two months old experience episodes of possible serious bacterial infection (PSBI) every year. Without accelerated action, as many as 54 countries, mostly in sub-Saharan Africa, will not achieve their 2030 targets under Sustainable Development Goal 3 for reducing under-five mortality.<sup>3</sup>

### It is in our power to prevent these tragic deaths

Inexpensive, widely available **antibiotic medicines—amoxicillin (in pediatric form of dispersible tablet or suspension) and gentamicin—are proven effective at the primary health care level for treating children with pneumonia and newborns with PSBI.**

It has been ten years since the UN Commission on Lifesaving Commodities (UNCoLSC) galvanized global and country efforts to improve access to and quality of these and other priority medicines. Yet, in many communities around the world, too many newborns and children continue to die because of inadequate access, inconsistent quality, and inappropriate use of these safe, effective medicines.

This **Call to Action** describes **practical, feasible, and affordable actions** that national governments, civil society, donors, and implementing partners should take to increase use of these lifesaving medicines to save the lives of children with pneumonia and newborns with PSBI. While not an exhaustive list of every action needed in every context, these recommendations—identified through a consultative process by diverse global and country-level stakeholders—effectively address critical challenges that countries face in ensuring access to, quality of, and appropriate use of essential medicines and medical supplies for primary health care—and specifically of amoxicillin and gentamicin, the first-line medicines that WHO recommends for treating community-acquired severe pneumonia and PSBI in newborns and children.



Photo by GHSC-PSM

At a series of three consultations\* in May 2022, the Newborn and Child Health Commodities subgroup of the Child Health Task Force (CHTF)—including technical experts from government agencies, global health institutions, NGOs, the private sector, and academic institutions—reviewed current evidence, identified root causes, and agreed on actionable solutions, including a research agenda, for improving access to and ensuring appropriate use of amoxicillin and gentamicin, as tracers/proxies for other essential child health commodities. This Call to Action sets out these recommended solutions, and describes the critical roles of country stakeholders, donors, implementing partners, and civil society organizations in driving purposeful action and saving children's lives.

<sup>1</sup> <https://data.unicef.org/topic/child-health/pneumonia/#:~:text=A%20child%20dies%20of%20pneumonia,of%20these%20deaths%20are%20preventable> <sup>2</sup> <https://stoppneumonia.org/wp-content/uploads/2020/12/Every-Breath-Counts-Careseeking-Scorecard-1.pdf> <sup>3</sup> Levels & Trends in Estimates developed by the UN Inter-agency Group for Child Mortality Estimation Child Mortality 2021 UN Inter-agency Group for Child Mortality Estimation <https://data.unicef.org/resources/levels-and-trends-in-child-mortality/> \* <https://www.childhealthtaskforce.org/events/2022/05/improving-uptake-amoxicillin-and-gentamicin-three-part-consultation>

# The Problem:

## Four Key Bottlenecks

Four key bottlenecks, while not the only ones, are critical in preventing wider access to and appropriate use of essential medicines for primary health care, particularly amoxicillin and gentamicin:

### ▶ Poor quantification of need

Weak health supply chains prevent medicines from reaching the children who need them. Quantification—the process of estimating needs for medicines and health supplies (forecasting) and planning procurement and deliveries—is essential for effective budgeting, resource allocation and mobilization, and planning for procurement and delivery. Countries—from health ministries down to health facilities and community service points—lack the information, data systems, and capacities needed to accurately quantify how much medicine they need to procure, where it will be needed, and when it has to be there.

### ▶ Insufficient financing

Sufficient and sustainable funding for newborn and child medicines is a complex challenge, and remains a primary barrier to reliable product availability. Despite the low cost of amoxicillin and gentamicin, neither governments nor donors allocate sufficient funds to purchase and maintain necessary supplies. Significant resource mobilization is needed to alleviate both short- and long-term financing gaps

### ▶ Lack of quality assurance

An estimated 10% of medical products that reach users in LMICs are substandard or falsified.<sup>4</sup> Substandard and falsified antibiotics are ineffective, prolonging treatment and causing growth of medicine-resistant microbes, and dangerous, ultimately killing children by making infections difficult or impossible to treat. Quality assurance—actions to ensure that medicines are safe, effective, and meet quality standards—requires compliance with good manufacturing practices; specification of proper packaging (e.g., blister packs for amoxicillin

dispersible tablets and appropriate syringes for gentamicin administration to newborns); coordination among procurers and regulators; and appropriate storage, transportation, and product surveillance throughout the product lifecycle.

### ▶ Inappropriate use

Worldwide, more than half of all medicines are prescribed, dispensed, or sold inappropriately—patients do not receive the most appropriate medicine for their condition, or medicines are not prescribed and dispensed in the appropriate amount or administered in the appropriate dose and frequency and length of treatment—and half of all patients fail to take them correctly, according to WHO estimates. Between 25% and 60% of children seeking care for pneumonia receive inappropriate treatment,<sup>5</sup> despite clear global treatment recommendations, for a range of reasons including caregivers' use of inappropriate health care providers, providers' failure to follow standard treatment guidelines, and product unavailability at facilities and in communities.



Photo by GHSC-PSM

<sup>4</sup> World Health Organization. (2017). A study on the public health and socioeconomic impact of substandard and falsified medical products. <sup>5</sup> Kruk, M.E. et al., 2018. High-quality health systems in the Sustainable Development Goals era: time for a revolution. *The Lancet Global Health*, 6(11), pp.e1196–e1252. [https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(18\)30386-3/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30386-3/fulltext)

# Take Action Now:

## Practical, Feasible, Affordable Interventions

By taking action now, countries—designing and owning their own solutions, in collaboration with all stakeholders and partners—can effectively address the bottlenecks inhibiting access to and use of quality-assured amoxicillin and gentamicin. Many of these recommended actions are not new: in fact, they are widely known but—a decade after UNCoLSC—still not widely implemented.

### Strong Health Systems

Strong health systems are the key to ensuring that quality health products and services are available, accessible, affordable, and appropriately used by the people who need them. While taking specific actions to overcome barriers to access and use of quality-assured amoxicillin and gentamicin, governments and partners should prioritize treatment of the leading causes of newborn and child death, including pneumonia, and sustainably strengthen health systems by:

- ▶ Adopting globally recommended policies and guidelines throughout the health system
- ▶ Allocating sufficient funding to support procurement of safe and effective antibiotics
- ▶ Providing appropriate training for health workers, including on how to counsel patients on treatment adherence and its importance
- ▶ Strengthening transparency and accountability across the health system
- ▶ Improving logistics management systems and supply chain data quality
- ▶ Working with donors, implementing partners, and civil society to harmonize and coordinate interventions and services, particularly at the health facility and community levels

Photo by GHSC-PSM



unicef





Photo by GHSC-PSM

## Strengthen Quantification

To strengthen quantification, including for primary health facility and community levels, countries should:

- **Coordinate forecasting and supply planning**—across governments, procurement agents, partners, and suppliers—by improving transparency on types of commodities, quantities, timing, and intended recipients
- **Improve timeliness and accuracy of data collected at all levels of the health supply chain** through electronic logistics management information systems (eLMIS) and health management information systems (HMIS), linked to enable planners to model increases and decreases in demand and consumption
- **Build skills for data organization**, routine review and analysis of consumption data and use established tools to conduct quantifications
- i Donors should continue to support countries in sustainably strengthening forecasting and supply planning through training on best practices and provision of financial resources.

## Increase Financing

To increase financing for amoxicillin and gentamicin, countries should:

- **Build capacity to manage available domestic resources** efficiently and transparently
- **Improve transparency of financial commitments for procurement of medicines** and build accountability mechanisms for tracking budget allocations, while supporting civil society in developing capacities and tools (such as commodity and funding gap impact analyses) to engage, advocate, and monitor allocated funding for newborn and child health commodities
- **Include community-level requirements** for amoxicillin (as well as for oral rehydration solutions and zinc) in grant applications to the Global Fund to Fight AIDS, TB, and Malaria, taking advantage of its recently announced intention to fund a comprehensive package of commodities for integrated community case management of childhood illnesses (iCCM)
- i Donors should invest in co-financing agreements, support advocacy for increased domestic financing, and provide short-term supplies of medicine to bridge immediate gaps.

## Improve Quality Assurance

To improve quality assurance throughout the product lifecycle, countries should:

- **Strengthen national regulatory agencies** by streamlining product registration and supporting risk-based approaches such as Good Manufacturing Practice (GMP) inspections and routine post-marketing surveillance
- **Advance regulatory convergence and harmonization** through information exchange and work-sharing platforms that support regional inspections and market authorizations
- **Strengthen coordination mechanisms (including between health and finance ministries)** to eliminate constraints to procurement of quality-assured products, such as rules that do not take quality into consideration when requiring purchase of lowest price or locally manufactured products
- **Ensure that all procurers accurately specify quality requirements in tender documents and purchase only quality-assured products** (e.g., with WHO prequalification or national market authorization, approval by a WHO-listed regulatory authority, or acceptance by UNICEF)
- **Raise public awareness**—nationally and among communities and consumers—of the presence, consumption, and dangers of substandard and falsified products
- **Use long-term procurement agreements and tax and tariff waivers to incentivize local manufacture** using raw materials and finished pharmaceutical product (FPP) that meet quality standards
- **Ensure uninterrupted availability of quality-assured gentamicin and amoxicillin** at all health facilities and community service delivery points—along with 1ml syringes, calibrated with 0.2ml markers, needed for administration of gentamicin—through proper storage and planned, systematic distribution
- i Donors should deploy resources to strengthen regulatory practices and coordination, support improved procurement and supply chain practices focused on quality-assured products, and incentivize use of GMPs by local manufacturers.

## Enable Appropriate Use

To enable appropriate use of amoxicillin and gentamicin, countries should:

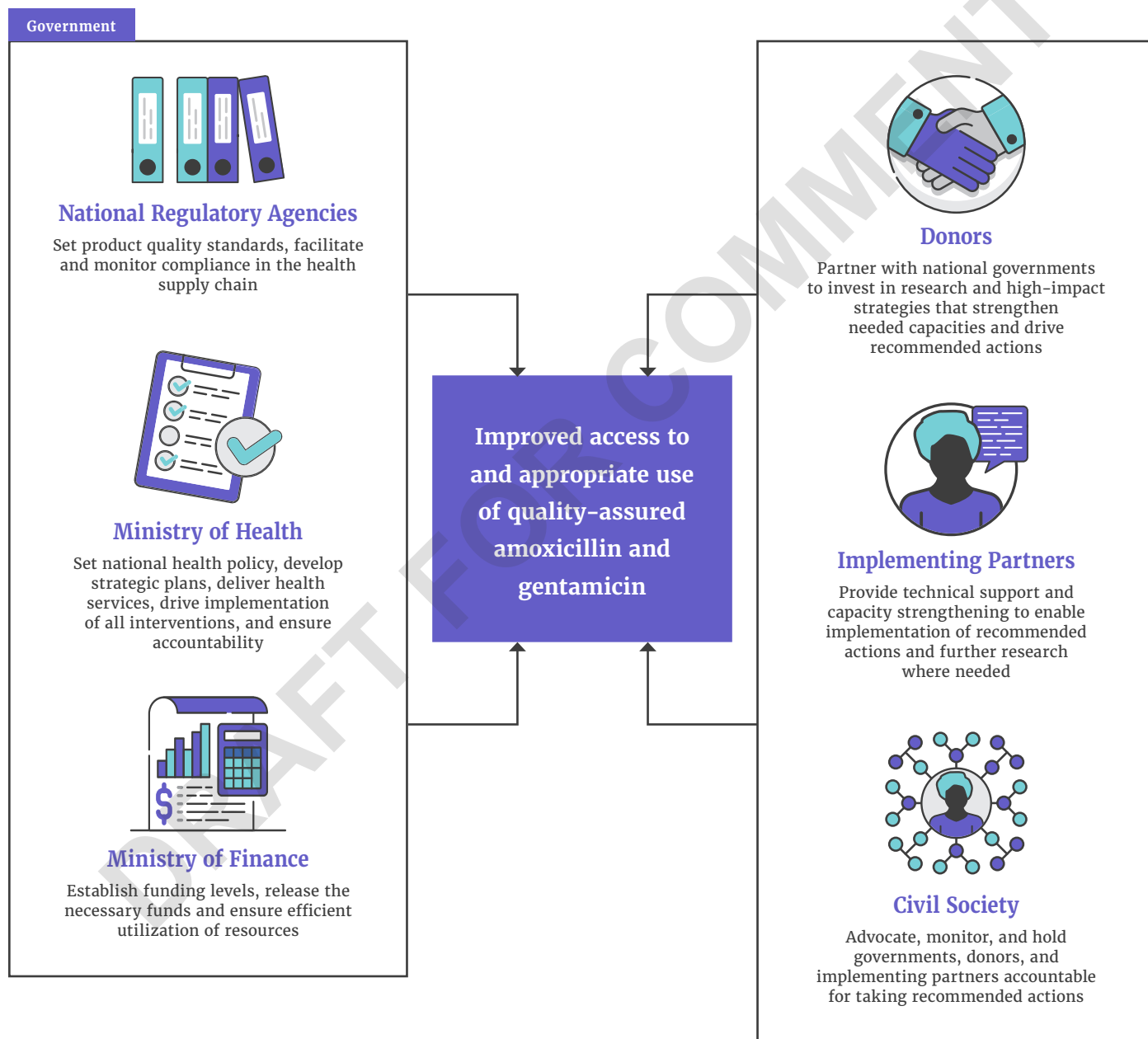
- **Align national policies and guidelines with global recommendations** that promote appropriate use of these antibiotics, and disseminate them to all providers through pre-service and refresher training and across a range of media channels
- **Provide electronic decision-making tools** to support providers in complying with protocols and standards of care
- **Ensure effective supervision**, mentoring, and coaching for all health workers
- **Set standards and indicators to monitor availability and use practices of providers and caregivers** for management of pneumonia and PSBI, and systematize continuous quality improvement and performance monitoring
- **Design and implement evidence-based, multifaceted interventions**—including engaging opinion leaders and civil society—that target key root causes of inappropriate practices among providers and caregivers, link to messaging on reducing antimicrobial resistance, and respond to specific challenges relating to administration of gentamicin
- **Research the linkages between rational use of medicines and payment mechanisms and insurance schemes**, and best practices for engaging private-sector health care providers to support their adherence to quality standards, including appropriate use of amoxicillin and gentamicin
- i Donors should support implementation research and social and behavior change communication (SBCC) interventions that address the root causes of inappropriate use of amoxicillin and gentamicin by providers and caregivers.

# Doing Your Part:

## Roles of Key Stakeholders

### To All Stakeholders

As countries and partners take focused action to drive progress and save children's lives, all stakeholders have critical roles to play.



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