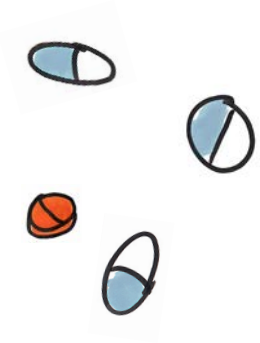
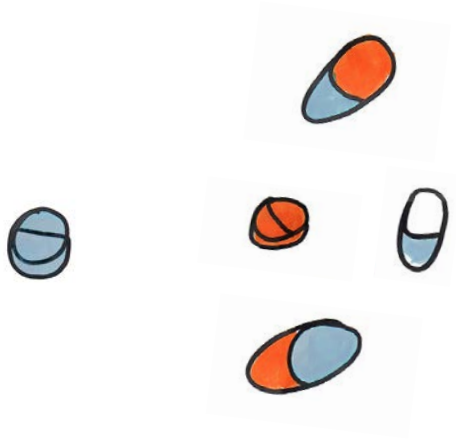


The case for quality

Around the world, up to two billion people lack access to quality essential medicines.

Poor-quality medicines undermine the treatment of some of the world's most pressing diseases, such as tuberculosis, malaria, and HIV/AIDS, and potentially contribute to anti-microbial resistance. The risk is greatest in low- and middle-income countries, where an estimated 10 percent of medicines are substandard or falsified.



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Unitaid
Innovation in Global Health

Ensuring that all medicines are safe and meet quality standards is complex. It requires developing, using, and applying public standards; increasing investments in quality assurance; and ensuring collaboration among stakeholders. Above all, it requires coordinated action.

On the occasion of the 71st World Health Assembly, USP, alongside co-hosts Unitaid and the Government of Ethiopia, convened a multi-sector discussion to address the issue of incentivizing investment in quality medicines, collaborative solutions to improve access, building local capacity, sharing best practices and knowledge, and coordinating on a global level. The standing-room-only event featured key thought leaders speaking from the perspective of regulators, pharmaceutical industry leaders, public health advocates, governments, donors, and manufacturers.

> **"We need to ensure that we work hard to reduce inequalities in access to quality medicines. We can only achieve that if we work together. It is our collective efforts that will help us achieve this vision."**
>
> Dr. Mariângela Simão, Assistant Director-General of Access to Medicines, Vaccines and Pharmaceuticals at the World Health Organization, said in opening remarks

Nigeria shows the scale of the challenge for access to quality medicines. Today, only 20 percent of children with HIV/AIDS in Nigeria have the quality-assured drugs they need to treat their disease. "Nigeria has the highest number of children with HIV in the world. Right now eight in 10 children in late-stage are going to die," said Dr. Mojisola Christianah Adeyeye, Director-General of the Nigerian National Agency for Food and Drug Administration and Control.

International journalist Shiulie Ghosh led the panel in a discussion on the progress being made in the quest for quality medicines, where the roadblocks lie, and the path forward to ensure a steady supply of quality medicines around the globe.

"Today we will try to outline practical actions and how we can implement solutions on the ground," Ghosh said.

Speakers emphasized the importance of coordination among all stakeholders to deliver high-quality medicines to the more than two billion people who lack access to them today.

Speakers included:

Mr. Mark Abdoo
Acting Deputy Commissioner, Global Regulatory Operations and Policy, U.S. Food and Drug Administration

Dr. Mojisola Christianah Adeyeye
Director-General, Nigerian National Agency for Food and Drug Administration and Control

Dr. Kesetebirhan Admasu
Chief Executive Officer, Roll Back Malaria Partnership

H.E. Dr. Kebede Worku
State Minister, Ministry of Health, Ethiopia

Ms. Emer Cook
Head, Regulation of Medicines and other Health Technologies, World Health Organization

Mr. Yehulu Denekew
Director General, Ethiopian Food, Medicine and Healthcare Administration and Control Authority

Mr. Mark Edington
Head, Grant Management, The Global Fund

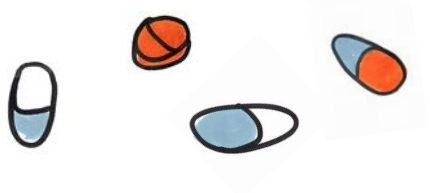
Dr. Alma Crumm Golden
Deputy Assistant Administrator, United States Agency for International Development

Mr. Kedir Tahir Hagos
NSPA-Pharma National Consultant, WHO/Ethiopia

Dr. Skhumbuzo Ngozwana
Member of the Board, Federation of African Pharmaceutical Manufacturers Association

Dr. Mariângela Simão
Assistant Director-General, Access to Medicines, Vaccines and Pharmaceuticals, World Health Organization

Ms. Sanne Fournier-Wendes
Chief of Staff, Unitaid



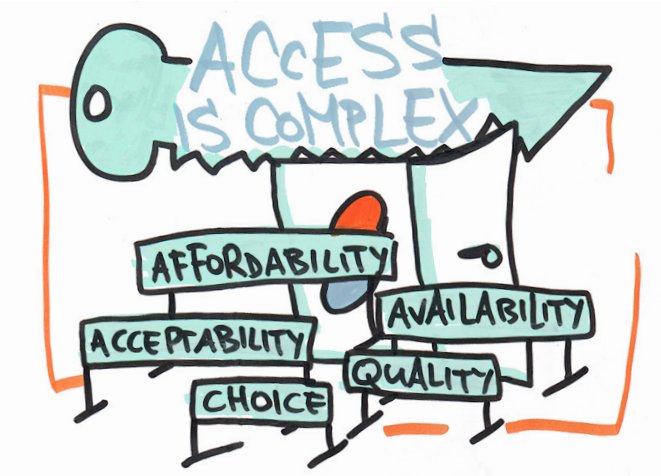
1

Coordinating Access to a Safe, Reliable Supply of Quality Medicines

> **"The problem of poor-quality medicines is huge . . . . In fact, it has been described as a global pandemic."**
>
> Shiulie Ghosh, International Journalist

Experts agree that limited capacity for regulatory oversight and enforcement as well as vulnerabilities in the supply chain are two factors that have significantly contributed to the spread of poor-quality medicines.

> **"When we bring in new, innovative drugs and tools, we have to make sure we understand how the uptake will happen and how they will be used. Ensuring the medicines are quality-assured is an important part of it, but you have to go further than that and understand how the patients will use them if we want these drugs to have an impact."**
>
> Ms. Sanne Fournier-Wendes, Chief of Staff, Unitaid



2

Building Local Capacity to Sustain Impact

In many cases, investments that build local capacity to produce medicines according to international quality standards provide the most efficient and durable solution to shortages of low-cost essential medicines.

"Good aid works itself out of a job," said Dr. Skhumbuzo Ngozwana of the Federation of African Pharmaceutical Manufacturers Association. Donor investments should target local and regional capacity, he explained, rather than the perpetual delivery of medicines.

Although building local manufacturing capacity may be the answer for many countries, it is not a one-size-fits-all solution. In order to assist small countries where there is a need to build capacity, there has to be coordination at a regional or global level.

> **"Even if we get quality-assured medicines at the right price into countries, the state of many countries' supply chains is the most critical impediment for us right now at the Global Fund."**
>
> Mr. Mark Edington, Head of Grant Management for The Global Fund

But it is not the only impediment. Dr. Kesetebirhan Admasu, Chief Executive Officer of the Roll Back Malaria Partnership, pointed out that regulatory capacity is often overlooked and underfunded. "If you have to look at how we invest, we invest a lot in procurements, and developing guidelines and trainings, but we don't invest enough in regulatory capacity."

3

Measuring Value

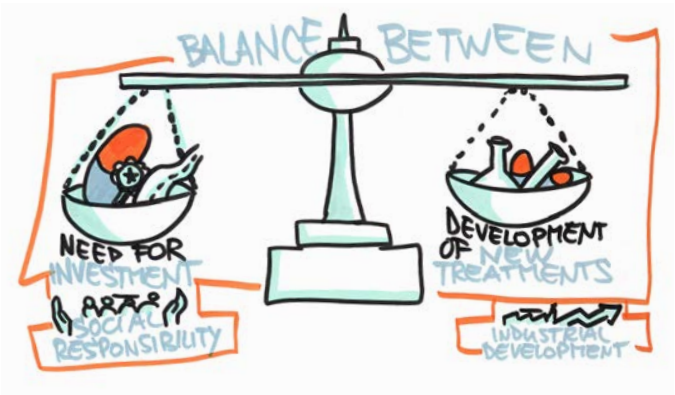
The proliferation of falsified and counterfeit products is driven by multiple factors including economic influences, cost of medicines, and a lack of incentives to produce quality medicines.

> **"In the U.S., we are trying to ensure there is more transparency and competitiveness in the marketplace by ensuring there are multiple producers of generic products, which will help bring prices down."**
>
> Mr. Mark Abdoo, Acting Deputy Commissioner of Global Regulatory Operations and Policy for the U.S. Food and Drug Administration

USAID-funded programs are also helping to improve access to quality-assured affordable essential medicines. "The PQM program supports about 100 manufacturers in 20 countries. What we are trying to do is to improve the capacity so that they can adopt the international standards that actually accomplish getting quality medicines there," said Dr. Alma Crumm Golden, Deputy Assistant Administrator at the United States Agency for International Development.

Incentivizing innovation and research and development must be approached with the goal of creating a continuous pipeline of new medicines, new treatments and more efficient ways to deliver them, she noted.

> **"The way that Unitaid looks at this is 'How do we bring about products that make the health systems more effective? How do we bring the point-of-care diagnostics to communities that can be used by less educated health workers?'"**
>
> Ms. Sanne Fournier-Wendes, Chief of Staff, Unitaid



4

Working Toward a Shared Goal

As crucial stakeholders, governments and their regulatory agencies must commit to improving supply and access to quality medicines, and work to create incentives within the market.

> **"One of the Ethiopian government's biggest initiatives is to develop a national strategy for pharmaceutical manufacturing, including coordination with industry, regulatory agencies, and market access areas."**
>
> Mr. Kedir Tahir Hagos, NSPA-Pharma National Consultant, WHO/Ethiopia

Mr. Yehulu Denekew, Director General of the Ethiopian Food, Medicine and Healthcare Administration and Control Authority, said that coordination between the Ethiopian government, the private sector, and other stakeholders has strengthened local capacity and production. "Capacity and securing the market is crucial," he said.

Lack of access to essential medicines, weak regulation, and information asymmetry drive demand for cheaper products, increasing the circulation of falsified and substandard medicines. With the help of collaborative public-private partnerships, governments can work to create an infrastructure that supports the availability of quality-assured medicines.

"We are looking at how we can ensure an end-to-end approach. You have to have the right trainings, diagnoses, and medicines. We haven't got all of the answers, but the main message is that we have to take a holistic approach; it has to be end to end," said Ms. Emer Cook, Head of Regulation of Medicines and other Health Technologies at the World Health Organization.

The path forward

Tackling the global pandemic of poor-quality medicines requires a coordinated approach including governments, the private sector, and non-profits that combines strong health systems with economically viable sources of quality medicines delivered through robust supply chains.

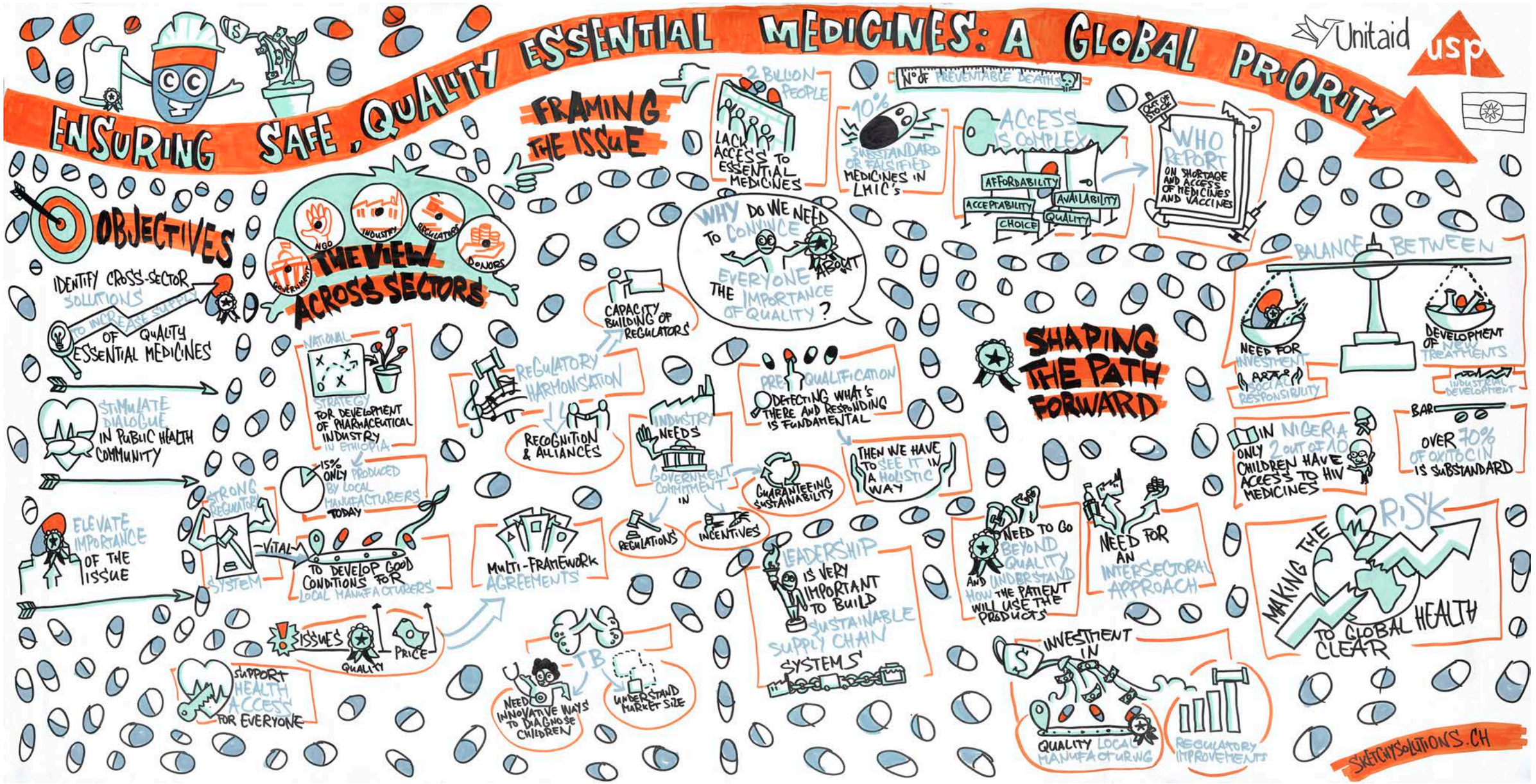
To achieve this, we need leadership at every level to pursue:

- Multi-sectoral efforts and coordination to address access
- Investment in strong regulatory systems
- Investment in local manufacturing of priority products, and in sustainable local capacity to produce quality-assured essential medicines

> **"It's important to have a balance between social responsibility and the economy."**
>
> H.E. Dr. Kebede Worku, State Minister, Ministry of Health, Ethiopia

These motivating forces can help bridge the gap between sectors to ensure healthier lives for the two billion people who lack access to quality medicines around the world.

Illustrations by SketchySolutions.ch


ENSURING SAFE, QUALITY ESSENTIAL MEDICINES: A GLOBAL PRIORITY
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OBJECTIVES
IDENTIFY CROSS-SECTOR SOLUTIONS TO INCREASE SUPPLY OF QUALITY ESSENTIAL MEDICINES
STIMULATE DIALOGUE IN PUBLIC HEALTH COMMUNITY
ELEVATE IMPORTANCE OF THE ISSUE
SUPPORT HEALTH ACCESS FOR EVERYONE
THE VIEW ACROSS SECTORS
NGO
INDUSTRY
REGULATORS
DONORS
GOVERNMENT
FRAMING THE ISSUE
2 BILLION PEOPLE LACK ACCESS TO ESSENTIAL MEDICINES
10% SUBSTANDARD OR FALSIFIED MEDICINES IN LMIC'S
Nº OF PREVENTABLE DEATHS
ACCESS IS COMPLEX
AFFORDABILITY
AVAILABILITY
ACCEPTABILITY
QUALITY
CHOICE
OUT OF STOCK
WHO REPORT ON SHORTAGE AND ACCESS OF MEDICINES AND VACCINES
WHY DO WE NEED TO CONVINCE EVERYONE ABOUT THE IMPORTANCE OF QUALITY?
SHAPING THE PATH FORWARD
BALANCE BETWEEN
NEED FOR INVESTMENT
DEVELOPMENT OF NEW TREATMENTS
ART OF SOCIAL RESPONSIBILITY
INDUSTRIAL DEVELOPMENT
NATIONAL STRATEGY FOR DEVELOPMENT OF PHARMACEUTICAL INDUSTRY IN ETHIOPIA
CAPACITY BUILDING OF REGULATORS
REGULATORY HARMONISATION
RECOGNITION & ALLIANCES
INDUSTRY NEEDS
GOVERNMENT COMMITMENT IN
REGULATIONS
INCENTIVES
GUARANTEEING SUSTAINABILITY
PRE-QUALIFICATION
DETECTING WHAT'S THERE AND RESPONDING IS FUNDAMENTAL
THEN WE HAVE TO SEE IT IN A HOLISTIC WAY
15% ONLY PRODUCED BY LOCAL MANUFACTURERS TODAY
STRONG REGULATORY SYSTEM
VITAL
TO DEVELOP GOOD CONDITIONS FOR LOCAL MANUFACTURERS
MULTI-FRAMEWORK AGREEMENTS
ISSUES
QUALITY
PRICE
TB
NEED INNOVATIVE WAYS TO DIAGNOSE CHILDREN
UNDERSTAND MARKET SIZE
LEADERSHIP IS VERY IMPORTANT TO BUILD SUSTAINABLE SUPPLY CHAIN SYSTEMS
NEED TO GO BEYOND QUALITY AND UNDERSTAND HOW THE PATIENT WILL USE THE PRODUCTS
NEED FOR AN INTERSECTORAL APPROACH
IN NIGERIA ONLY 2 OUT OF 10 CHILDREN HAVE ACCESS TO HIV MEDICINES
BAR
OVER 70% OF OXYTOCIN IS SUBSTANDARD
MAKING THE RISK TO CLEAR GLOBAL HEALTH
INVESTMENT IN
QUALITY LOCAL MANUFACTURING
REGULATORY IMPROVEMENTS
SKETCHYSOLUTIONS.CH