IMPROVEMENT STRATEGIES MODEL: DRUGS & SUPPLIES

PHCPI is a partnership dedicated to transforming the global state of primary health care, beginning with better measurement. While the content in this document represents the position of the partnership as a whole, it does not necessarily reflect the official policy or position of any partner organization.
Drugs and supplies are essential elements of all functioning health systems. (1,2) Making sure facilities have the right drugs and supplies at the right time and that patients can access affordable products when needed is imperative to delivering high-quality primary health care and achieving the Sustainable Development Goals.

To achieve this, the World Health Organization (WHO) identifies two related core principles of focus: ensuring quality, safety, and efficacy of health products and improving equitable access. Each focal area includes a subset of strategic levers that can be employed to support strong regulatory systems, quality manufacturing, efficient supply chains, and effective post-market surveillance. (1)

ENSURING QUALITY, SAFETY, AND EFFICACY OF HEALTH PRODUCTS

Ensuring the quality, safety, and efficacy of health products can be achieved through the following levers (1):

- **Regulatory system strengthening:** National Medicines Regulatory Authorities are responsible for the safety, quality, and efficacy of medical products. An effective regulatory authority gives communities confidence that the products they need and use are safe and effective. This lever focuses on developing countries’ ability to deliver regulation that protects the public and enables timely access to, and innovation for, quality products. Various tasks and competencies may be required of regulatory systems to ensure high-quality access to drugs and supplies. These include:
  - Appropriate innovation to foster R&D for affordable, suitable new treatments, diagnostics and devices
  - Evidence based selection for resource allocation to satisfy the priority health care needs of the population
  - Supply chain support and governance
  - Strategic local/regional production of essential medicines and health products
  - Pricing-financing reimbursement to promote affordability and fair pricing
  - Quality use of medicines and health products (particularly antibiotics)
  - Data systems for supporting decision making and managing access to medicines, vaccines, and other health products (3)

- **Assessment of the quality, safety and efficacy/performance of health products through prequalification:** Prequalification “aims to ensure that diagnostics, medicines, vaccines and immunization-related equipment, diagnostics, and medical devices meet global standards of quality, safety and efficacy” (1) by providing a list of products that comply with unified international standards.
• **Market surveillance and assessment of quality, safety & performance:** This lever focuses on activities to strengthen post-market surveillance, including monitoring of substandard and falsified health products. A country’s capacity to collect, organize, analyze, and use quality data is a critical element of understanding the availability, quality, and safety of drugs and supplies on the market and take corrective action, when needed. Surveillance requires robust safety data and corresponding infrastructure for pharmacovigilance in support of the prevention, detection and response to substandard and falsified health products, as well as dedicated personnel to oversee supply chain implementation and monitoring.

The relevant resources section below contains links to a curated set of resources tagged to each of these levers.

### IMPROVING EQUITABLE ACCESS

Improving equitable access requires policy and programmatic efforts throughout the value chain from development through delivery, and can be achieved through the following levers (1):

- **Research and development (R&D) that meets public health needs & improves access to health products:** Health R&D is especially important for neglected diseases, emerging infectious disease pathogens, new antibiotic therapies, medical product innovations, and neglected target populations such as children and pregnant women. Effective research and development require setting priorities that align with population health needs and incentivizing investment in this area to ensure that available drugs and supplies keep pace with changing demand.

- **Application and management of intellectual property to contribute to innovation and promote public health:** Intellectual property (IP) protection has a large impact on innovation and access to health products. Activities related to this lever promote medical research and development, innovation, and increased access to drugs and supplies by incentivizing needs-driven innovation and access to affordable health products through appropriate trade and IP policies that reflect public health objectives.

- **Evidence-based selection and fair and affordable management:** Essential medicines and supplies are those that satisfy the priority health care needs of the population. They must be selected with regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. When a drug or supply is considered priority or essential, it is especially important to ensure fair pricing to alleviate the expensive burden of out-of-pocket payments. A fair price is one that is affordable for health systems and patients and that also provides sufficient market incentive for industry to invest in innovation and the production of medicines. Countries can use the following lists to guide their procurement of drugs and supplies.
  - [WHO Model list of essential medicines: 21st list 2019](#)
  - [WHO Model list of essential medicines for children: 7th list 2019](#)
  - [Essential Medicines and Health Products: Prequalified Lists of Medicines](#)
  - [Prequalified Vector Control Products List of Prequalified In Vitro Diagnostic Products](#)
  - [Second Model List of Essential In Vitro Diagnostics](#)
  - [Medical devices by health care facility level: health post and health center](#)
Procurement and supply chain management (SCM): The continuous supply of quality, safe, effective, and affordable drugs and supplies is one of the key building blocks of every well-functioning health system. Good procurement practices play a key role in securing affordable prices and ensuring adequate and timely supply, while good supply chain management ensures that quality products are available at all levels of the health system. This lever focuses on the need for improved capacity for procurement and supply chain management and for better data and market analysis to inform policy decisions. For more information on supply chain management, see the section “Deeper Dive on Supply Chain Management” below.

Appropriate prescribing, dispensing, and rational use: Appropriate prescribing, dispensing, and use of medicines is essential for ensuring health impact and effective use of resources. Achieving this requires provider competence to reach accurate diagnoses, affordable and available medications, and adequate marketing, education, and promotion for appropriate use. More information on training and competence can be found in the provider competence Improvement Strategies module.

The relevant resources section below contains links to a curated set of resources tagged to each of these levers.

DEEPER DIVE ON SUPPLY CHAIN MANAGEMENT

The supply chain refers to the resources needed to deliver goods or services to a consumer. In healthcare, supply chain management (SCM) involves obtaining resources, managing supplies, and delivering goods and services to providers and patients. Good supply chain management ensures that quality products are available at all levels of the health system.

SCM activities include (4):

- **Serving customers** - Customer needs are central to selection, procurement, storage, distribution, and dispensing products. Maintaining this focus and adhering to relevant protocols helps ensure that customers receive the right products at the right times.

- **Product selection** - Country committees, usually with membership drawn from regulatory agencies and regulatory professionals in pharmacy, medicine, and nursing practices, are typically the responsible group for decision making regarding product selection. Often the outputs of this committee are national essential medicines and essential supplies lists, typically developed following the essential medicine lists patterned on the World Health Organization (WHO) Model List.

- **Quantification** - Post-selection, product quantities and costs must be determined. Quantification ensures an uninterrupted supply of products by projecting the quantity and cost of the products needed by a health unit or program and determining when the products should be procured and delivered.

- **Procurement** - Once a quantification supply plan is complete, drugs and supplies must be procured. A strategic approach is critical to this process of procurement - through careful research, planning, monitoring and attention to applicable regulations, health systems and programs will enable timely and quality-assured supply procurement.

- **Inventory strategy** - Inventory policies are central to meeting supply chain objectives and enable organizations to balance supply and demand. Integrated inventory strategies define policies that guide product selection, quantification, and storage plans.
• **Warehousing & distribution** - After procurement, there must be a structured approach to the physical management of a product through each of the supply chain. This protects the item from environmental harm or handling to ensure its quality and condition upon use.

Underlying each of these supply chain elements are management components that support the operational functions (4):

• **Logistics Management Information Systems (LMIS)** - A LMIS facilitates supply and demand data tracking and analysis, which informs supply chain decisions and future commodity-related logistics actions. LMIS are frequently used for facility operations such as ordering and replenishing supplies.

• **Supply chain workforce** - Ensuring an effective flow of public health supply chain logistics requires motivated and competent staff at all levels. Their performance must be supported and honed through supervision, continuous learning, and opportunities for professional development.

• **Financing** - Distribution and administration of finances affects all elements of the supply cycle. As such, drugs and supplies - and the supply chains that deliver them - need to be sufficiently resourced. Assuring a budget line item for health commodities and associated management is critical to availability of drugs and supplies and smooth systems operations.

• **Performance management** - Continuous monitoring of the supply chain’s key performance indicators is important to rigorously evaluate the status, effectiveness, and efficiency of supply chain operations and gauge if adjustments are needed.

• **Risk management** - In an effort to hone manager’s focus and efforts where they are most needed, risk management is a formal approach to recognizing and alleviating dysfunction within the supply chain.

The supply chain can also be an opportunity to engage the private sector. The following resources orient implementers to ways in which the private sector operates and how they can be engaged:

• [Private Sector Role in Health Supply Chains](#)
• [Getting the Products to the People: How Private Sector Solutions Can Strengthen Supply Chains for Public Health](#)
• [Landscaping Innovations in Health Product Distribution in Sub-Saharan Africa](#)
• [Tackling the Triple Transition in Global Health Procurement](#)

### RELEVANCE TO PHC

Strong PHC that is capable of providing a comprehensive suite of **promotive, preventive, and curative services** is dependent on affordable, timely, and dependable **access** to safe, effective, and high-quality drugs and supplies. Countries often face a range of obstacles in achieving this, including rising prices for new drugs and supplies; shortages and stock outs of essential medicines and health products - especially for noncommunicable diseases; and the growing problem of substandard and falsified medical products entering the global supply chain. Ensuring that the right high-quality drugs and supplies are available when needed in primary health care settings requires sufficient financing, effective management of funds at the facility level, appropriate **facility infrastructure** to store drugs and supplies, and **information systems** to track procurement and distribution. Additionally, appropriate use depends on **provider competence** and **training**.
Supply chain management (SCM) - Supply chain management encompasses the planning and management of all activities involved in sourcing and procurement...and all logistics management activities. Importantly, it also includes coordination and collaboration with channel partners, which can be suppliers, intermediaries, third party service providers, and customers. In essence, supply chain management integrates supply and demand management within and across companies.(4)

Regulatory systems - National regulatory authorities (NRAs) provide regulatory oversight of all medical products. They perform their mandate based on a legal framework and a set of recommended regulatory functions that span the medical product lifecycle including clinical trial oversight, marketing authorization and registration, licensing and inspection of premises, market surveillance and enforcement activities when required.(5)

Essential medicines - Essential medicines should satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness, and compiled in the WHO Essential Medicines List. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.(6)

Essential consumable commodities - Essential consumable commodities are the items and products identified as necessary to treat, cure, and/or prevent health system priorities. These may include vaccines, contraceptives, malaria products, sterile gauze, disposable needles, etc.(7)

Basic equipment - Basic equipment are the essential supplies needed for “the safe and effective prevention, diagnosis, treatment and rehabilitation of illness and disease” at all primary care facilities.(8)

Diagnostic supplies - Diagnostic supplies are the materials needed to conduct essential diagnostic tests, with the aim of providing information on a patient’s condition for diagnosis, monitoring, screening, prediction, or prognosis purposes at the primary care facility level.(9)

Prequalification - Prequalification of medicines and health products is a United Nation program managed by WHO. The purpose is to assess the quality, safety and efficacy of medicinal products and work with national regulatory authorities to support countries in building regulatory capacity through networking, training and information-sharing.(10)
WHAT HAS BEEN DONE ELSEWHERE TO IMPROVE ACCESS TO DRUGS AND SUPPLIES

TANZANIA

Brief overview

To ensure quality and safety of medicines, Tanzanian health authorities built on existing infrastructure and undertook a long process of converting informal vendors into accredited drug dispensing outlets (ADDOs). By June 2014, this program had trained over 19,000 providers - each linked directly to local primary care facilities - in almost 6,100 shops. In December 2018, the United Republic of Tanzania became the first WHO-recognized country in Africa to achieve a well-functioning regulatory system for medical products.

Why reforms were needed

Prior to the reform of quality, safety, and efficacy of medical products:

- Tanzania lacked access to reliable medicines dispensed by providers trained in their use
- Many Tanzanians depended on unregulated local vendors who had no formal training

Tanzania’s approach

Tanzanian health authorities built on existing infrastructure to:

- Convert informal vendors into accredited drug dispensing outlets (ADDOs)
- Provide ADDOs with financial incentives and tailor-made training programs to address their individual capacity needs to become accredited
- Train over 3,000 drug shop inspectors

Background

Effective regulatory systems are critical to ensure the quality, safety, and efficacy of medical products. Almost all countries in Africa have National Medicines Regulatory Agencies (NMRAs), but their organizational set-ups and functionalities vary with some functioning semi-autonomously and others operating within the Ministry of Health. (11) Their effectiveness also varies - globally, the World Health Organization (WHO) estimates that at least 30% of NMRAs have limited capacity to perform their core regulatory functions. (12)

The United Republic of Tanzania is the only country in Africa that has two NMRAs, the mainland Tanzania Food and Drugs Authority (FDA) and the island of Zanzibar Food and Drugs Board. Established in July 2003, the Tanzania FDA has come a long way and is now a recognized leader in medicines regulation in Africa. In Tanzania, there is little to no government funding; most of the funds for the FDA come from industry fees. (11)

Innovation

Historically, many Tanzanians lacked access to reliable medicines that are dispensed by providers trained in their use, and instead depended on local vendors who had no formal training and were dispensing drugs purchased from suppliers connected to unregulated channels. (13)

To ensure quality and safety of medicines, Tanzanian health authorities built on existing infrastructure and - rather than banning untrained vendors and isolating communities from access to essential drugs -
undertook a long process of converting informal vendors into accredited drug dispensing outlets (ADDOs). The process was comprehensive and designed for sustainability, involving purposeful behavior and expectation change for Tanzanian communities. The ADDOs were provided with financial incentives and tailor-made training programs to address their individual capacity needs to become accredited. All ADDOs are required by law to adhere to standards related to product and service quality in order to maintain government accreditation. To attract and retain customers, they must also meet client demands and expectations for quality products and services. (13)

By June 2014, this program had trained over 19,000 providers - each linked directly to local primary care facilities - in almost 6,100 shops, with a further 3,100 in training. Over 3,000 drug shop inspectors were also trained, and the program has been robustly overseen by a range of regulatory authorities, wholesalers, political and local leaders, and consumer groups, each focusing on specific geographies. (13)

Outcome

In December 2018, the United Republic of Tanzania became the first WHO-recognized country in Africa to achieve a well-functioning regulatory system for medical products. (2) This means that medical doctors, pharmacists, chemists, and technicians working for the regulatory authority possess the expertise and hands-on skills to evaluate medical products, prevent and counteract associated hazards, and are capable of protecting the public from substandard and falsified medicines. (14)

The WHO’s assessment of the FDA of the United Republic of Tanzania was based on its Global Benchmarking Tool (included in the relevant tools and resources), which checks regulatory functions against a set of more than 200 indicators, such as product authorization, market surveillance, and the detection of potential adverse-effects, to establish their level of maturity. Early in 2018, WHO facilitated self-assessments and conducted a formal evaluation of the FDA on the mainland and the Zanzibar Food and Drug Agency. The regulatory authorities made a number of adjustments to identified gaps and in the last assessment, the FDA met all indicators that define a maturity level 3 agency. This categorizes Tanzania as the second highest on WHO’s scale and the target for regulatory systems globally. (2)
DOMINICAN REPUBLIC

Brief overview
After creating a Single System for Managing Medicines and Medical Supplies (SUGEMI, in Spanish), the Dominican Republic has decreased the frequency of stock-outs and waste of unused, expired commodities and has decreased overall purchasing prices for drugs and supplies.

Why reforms were needed
Before implementation of SUGEMI, supply chains in the Dominican Republic were inefficient due to:

- Fragmented purchasing
- The use of multiple fleets of vehicles traveling to the same destinations
- The existence of separate warehouses, inventory management systems, dispatch, and requisitions for each Disease Control Program (DCP)

Dominican Republic's approach
System efficiency was created by introducing standard operating procedures for all components of the supply chain management system. These included:

- Transferring distribution chain components to specialized units of SUGEMI (such as the National Pharmaceutical Supply Management Unit)
- Keeping selection and use coordination components with each individual Disease Control Program

Background
In 2001, following the creation of the country's Social Security System, the Dominican Republic began a major health system modernization and reform. The core elements of the reform focused on separating the national health system's central functions - oversight, insurance, procurement, and financing - and reorganizing the system around functional decentralization of administration. Meanwhile, the country's health system experienced frequent drug and supply stock-outs, parallel procurement processes due to multiple “vertical” systems of supply chain management, and overall poor planning. Specifically, while a central medical store, Programa de Medicamentos Esenciales/Central de Apoyo Logistico (Program for Essential Medicines/Central Logistics Support [PROMESE/CAL]), oversaw procurement of bulk quantities of generic categories of goods, there were other programs and health facilities that also procured health commodities at hugely inflated purchase prices, far more than what PROMESE/CAL was paying. From the outset of the health system reform, there was a proposal for the integration of the pharmaceutical supply, but this did not materialize until 2008, when a study by USAID found that system fragmentation contributed to stock-outs and to losses from expired products. The Ministry of Public Health was catalyzed to create a single supply management system that would address the fragmentation, inefficiency, and inequality in medical drugs and supplies.

Innovation
In 2010, the formal proposal for the Ministry to organize this integrated, single supply system was endorsed. The system was named Single System for Managing Medicines and Medical Supplies (SUGEMI, in Spanish). Before implementation of SUGEMI, supply chains in the Dominican Republic were inefficient due to (a) the overall inefficiency of the system as a result of fragmented purchasing; (b) the use of multiple fleets of vehicles traveling to the same destinations; and (c) the existence of separate warehouses, inventory management systems, dispatch, and requisitions for each Disease Control Program (DCP).
System efficiency was created by transferring certain distribution chain components to specialized units of SUGEMI (such as the National Pharmaceutical Supply Management Unit, or UNGM in Spanish) and keeping selection and use coordination components with each individual DCP. More specifically, this meant decisions about which products and quantities to procure remained with the Regional Health Service Centers and Disease Control Programs, and the procurement itself was managed by this central SUGEMI system. (16) This system change effectively decentralized responsibility for supply selection to ensure local knowledge and needs could be taken into account while centralizing bulk procurement - where local knowledge is less helpful - to simplify logistics and reduce costs. The newly created UNGM developed standard operating procedures for all components of the supply chain management system. For example, SUGEMI and UNGM have an annual purchasing planning meeting, a collaborative activity that involves reviewing epidemiological data provided by DCPs. (15)

With the integration of the DCPs into SUGEMI, the multiple vertical manual and electronic information systems have been eliminated and replaced with a unified electronic system. Efficiency has been improved in other ways as well, such as: streamlining medicine delivery to include multiple medicines in each re-supply; the simplification of requests for dispatch to just a single form; special staff designation for pharmaceutical management; and consolidation of medical warehouses into larger, more equipped facilities with robust inventory management. Each of these strategies saves time and resources. (15)

Outcome

The integrated SUGEMI approach helped surface a number of deficiencies in the system and created strategies to promote efficiency and equality in the pharmaceutical supply chain management and the Dominican health system overall. As a result of SUGEMI, the Dominican Republic has decreased the frequency of stock-outs and waste of unused, expired commodities and has decreased overall purchasing prices for these drugs and supplies. This approach in the Dominican Republic demonstrates the value of integrating individual DCPs (e.g. malaria, tuberculosis, HIV/AIDS) into a single supply system, a priority task for contributing to the integration of the health services systems overall. (15)
WHAT QUESTIONS SHOULD BE CONSIDERED TO BEGIN IMPROVEMENTS?

The questions below may be a useful starting place for assessing accessibility of drugs and supplies in your context and how one might begin to plan and enact reforms.

HOW EFFECTIVE ARE EXISTING REGULATORY SYSTEMS?

Effective regulatory systems are an essential component in ensuring the availability and quality of drugs and supplies. A particularly helpful tool in identifying gaps in the regulatory system is the WHO Global Benchmarking Tool (GBT), the primary means by which WHO objectively evaluates regulatory systems. It incorporates the concept of ‘maturity level’, allowing WHO and regulatory authorities to assess the overall maturity of a regulatory system on a scale of 1 to 4. The case study on Tanzania describes how the GBT can lead to system improvements.

In addition to completing the GBT, to start considering where regulatory system strengthening could occur, implementers can explore: What is our system of adherence to WHO guidelines and norms? Is there collaboration between regulatory systems and health systems? Is there a system in place to identify gaps in our supply chain management of drug and supplies? How would our country fare in dispersing drugs and supplies in the event of a public health emergency?

IS THERE A COUNTRY-WIDE SUPPLY CHAIN MODEL?

Having a clear understanding of the current state of the supply chain is the first step towards knowing what questions need to be asked to guide innovation and change. Effective supply chains not only help ensure commodity security, they also contribute to the success or failure of any public health program that depends on drugs and supplies. Tools such as the Supply Chain Compass can provide a high-level diagnosis of supply chain maturity. Other assessment tools can help to further diagnose bottlenecks and pain points in the supply chain.

In addition to completing supply chain diagnostic tools such as the Supply Chain Compass, implementers may ask themselves the following questions to explore the state of supply chains in their country: Is there one central governing body or regulatory system that oversees the human and financial resources and operations of the supply chain? Is there a supply chain strategy? Is it being implemented? Are key performance indicators defined and used to monitor supply chain performance? How might the private sector bolster effectiveness in the supply chain?

WHAT PROCESSES ARE IN PLACE FOR EVIDENCE-BASED SELECTION OF DRUGS AND SUPPLIES THAT ARE DELIVERED IN THE PHC SYSTEM?

Drugs and supplies, including medicines, vaccines, diagnostic supplies, and consumable commodities (the items and products identified as necessary to treat, cure, and/or prevent health priorities) are essential elements of all functioning health systems. As such, it is important to have a structured approach to ensure all essential drugs and supplies necessary for high quality primary health care are available when needed.

To assess performance in this area, implementers might ask: are evidence-based essential medicines and health products lists in use? Is there a system for monitoring the need, availability and inventory of essential medicines and health products?
IS THERE RESPONSIBILITY FOR MARKET SURVEILLANCE AND ASSESSMENT OF QUALITY, SAFETY AND PERFORMANCE OF DRUGS AND SUPPLIES?

As identified through the WHO's Roadmap for Access 2019-2023, a global priority is having regulatory systems prioritize authoritative guidance in meeting standards for ensuring drugs and supplies are accounted for, knowing if they are effective by the time they reach end-users, and subsequently taking action to improve the system. Surveillance requires robust safety data and corresponding infrastructure for pharmacovigilance in support of the prevention, detection and response to substandard and falsified health products. As such, these systems require dedicated personnel to oversee supply chain implementation and monitoring.

Implementers may ask themselves the following questions to understand the state of market surveillance and quality assurance in their country: What data are being collected for surveillance and assessment of quality, safety and performance? Who is responsible for collecting this data and with which entities is it shared? Are there opportunities to improve efficiency in these processes?

IS THERE A SYSTEMATIC APPROACH TO SUPPORTING, SUPERVISING, AND MAINTAINING SUPPLY CHAIN MANAGEMENT (SCM) STAFF?

Because of the wide array of staff needed to ensure successful SCM, implementers at the management level of regulatory systems should be dedicated to estimating appropriate system-wide human resource needs, recruiting and deploying staff competent in supply chain and logistics tasks, and increasing the professionalization of these cadres to include data skills for continual market surveillance and assessment and evidence-based selection. Staff need to be supported by strong human resource policies and plans and supervised using performance management designed specifically to support them and build their capacity in SCM.

The following resources have valuable insights on strengthening the human resources in the supply chain:

- People That Deliver
- Who is preparing the next generation of immunization supply chain professionals?

Implementers may ask themselves the following questions to further assess supply chain management in their country: What are the SCM tasks that need to be completed at various levels of the health system? What competencies are necessary for implementing these SCM tasks? Are the personnel assigned to these SCM tasks properly trained to complete them?

WHAT IS THE ROLE OF THE PHARMACIST IN THIS COUNTRY? DO PHARMACISTS HAVE THE TRAINING, REGULATION, AND INCENTIVES THEY NEED TO PERFORM THIS ROLE?

In LMICs, the pharmacist’s role has changed significantly in recent years. The WHO identified appropriate prescribing, dispensing, and rational use as a lever for improving access and ensuring health impact and effective use of resources. Providing consumers with medicines alone is not sufficient to achieve treatment goals. Pharmacists now often hold responsibility for patient uptake and adherence in medication use; in order to fulfil this role, they must often be readily available to patients with or without an appointment and manage/triage health-related problems. To address these medication-related needs, pharmacists must accept greater responsibility for the outcomes of medicine use and are evolving their practices to provide patients with enhanced medicines-use services. (17)

Implementers can explore the state of pharmacist role by asking: Are pharmacists integrated into care delivery networks to ensure coordinated and comprehensive patient care across settings and to promote...
primary health care as the first point of contact? Are pharmacists in this setting charged by the relevant authorities with the management of the distribution of medicines to consumers? Are they required to engage in appropriate efforts to assure the safe and efficacious use of medicines? Do they have the appropriate training to provide these functions? What regulations already exist to ensure the quality of pharmacist practice? What incentives do pharmacists have to perform this expanded role?

**IS THE NEED FOR ASSISTIVE PRODUCTS BEING MET?**

Assistive products are any external product (including devices, equipment, instruments or software) with the primary purpose of maintaining or improving an individual’s functioning and independence, and thereby promote their well-being. These products range from a simple as a pair of eyeglasses (needed by 970 million people worldwide) to more complex technologies such as wheelchairs (needed by 75 million people).

Countries can use the WHO Priority Assistive Products List (APL) to determine which assistive products are needed. The list responds to a growing need for quality-assured, useful, and affordable assistive products as life expectancy increases across many regions and countries strive to fulfil global commitments to people living with disabilities.

To get started, implementers can explore whether there is a system for monitoring the need, availability and inventory of assistive products in their country.
RELEVANT TOOLS & RESOURCES


OPTIMIZING SUPPLY CHAINS FOR IMPROVED PERFORMANCE (USAID DELIVER PROJECT, 2014)

Overview: This resource explores how to design or improve supply chains in public health. Using simulation software and routine data, the optimization process described in this document identifies flexible strategies and necessary data for increasing the performance and cost effectiveness of all supply chain functions.

Tags: Surveillance & assessment, Supply Chain Management

THE SUPPLY CHAIN MANAGER’S HANDBOOK: A PRACTICAL GUIDE TO THE MANAGEMENT OF HEALTH COMMODITIES (JOHN SNOW INC, 2017)

Overview: This logistics handbook provides a system overview and overall approach to supply chain management. It offers practical guidance on the design and implementation of managing the supply chain, with an emphasis on health commodities. In particular, the document includes detailed information about the design and implementation of logistics management information systems and inventory control systems.

Tags: Prescribing & use, Supply Chain Management

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Tags: Prescribing & use, Supply Chain Management

PROMISING PRACTICES IN SUPPLY CHAIN MANAGEMENT: SERIES OVERVIEW (WHO SYSTEMS FOR IMPROVED ACCESS TO PHARMACEUTICALS AND SERVICES PROGRAM, 2014)

Overview: The Supply and Awareness Technical Reference Team of the UN Commission on Life-Saving Commodities developed this set of briefs on promising practices in supply chain management. The seven modules guide countries in identifying and addressing key bottlenecks in the supply and distribution of the Commission’s 13 life-saving commodities across the reproductive, maternal, neonatal, and child health continuum of care. The briefs provide both proven and promising practices that may be used to address specific supply chain barriers faced by each country.

Tags: Surveillance & assessment, Prescribing & use, Supply Chain Management
EMERGING TRENDS IN SUPPLY CHAIN MANAGEMENT: OUTSOURCING PUBLIC HEALTH LOGISTICS IN DEVELOPING COUNTRIES (USAID DELIVER PROJECT, 2010)

Overview: This publication examines the potential opportunity for engaging third party service providers to support logistics functions of public health supply chain management—with an emphasis on distribution, warehousing, and inventory management. It provides information on when to consider outsourcing, the process of deciding whether outsourcing is a viable option in a particular context, and how to begin the outsourcing process. These points are illustrated by country examples of engaging the private sector in providing the logistics functions to support their public sector supply chains.

Tags: Supply Chain Management

USAID’S STRENGTHENING PHARMACEUTICAL SYSTEMS (SPS) PROGRAM (SIAPS: SYSTEMS FOR IMPROVED ACCESS TO PHARMACEUTICALS AND SERVICES PROGRAM)

Overview: This website includes a repository of information on USAID’s SPS and SIAPS programs, which were designed to support and scale successful national pharmaceutical management programs. The SPS and SIAPS programs have been comprehensive, and the resources available here include Case Studies of sustained LMIC pharmaceutical improvements as well as a suite of electronic tools that help pharmaceutical managers develop sound policies and monitor supplies and services.

Tags: Regulatory systems, Surveillance & assessment, Prescribing & use, Supply Chain Management

WHO MODEL LIST OF ESSENTIAL MEDICINES: 21ST LIST 2019 (WHO, 2019)

Overview: This list, released in July 2019, is an updated version of the WHO’s essential medicines list. The ‘Core List’, which identifies minimum medicine needs for a basic health-care system, outlines the most efficacious, safe, and cost-effective medicines for priority conditions.

Tags: Prescribing & use, Selection & affordability, Technical document

WHO MODEL LIST OF ESSENTIAL MEDICINES FOR CHILDREN: 7TH LIST 2019 (WHO, 2019)

Overview: This list, released in July 2019, is an updated version of the WHO’s essential medicines list for children. The ‘Core List’, which identifies minimum medicine needs for a basic health-care system, outlines the most efficacious, safe, and cost-effective medicines for priority pediatric conditions.

Tags: Prescribing & use, Selection & affordability, Technical document

THE SELECTION AND USE OF ESSENTIAL MEDICINES 2019: REPORT OF THE 22ND WHO EXPERT COMMITTEE ON THE SELECTION AND USE OF ESSENTIAL MEDICINES (WHO 2019)

Overview: This resource is an updated version of ‘Selection and Use’ in the suite of the essential medicines list resources. It delineates the changes made from past versions of the essential medicines lists.

Tags: Prescribing & use, Selection & affordability, Technical document
WHO HEALTH TOPIC: ESSENTIAL MEDICINES (WHO)

Overview: This resource includes highlights, general information, and technical and published information about WHO work related to Essential Medicines. Especially relevant are the region-specific pages about Essential Medicines, which include country profiles, regional areas of interest, and news specific to efforts in those regions.

Tags: Prescribing & use, Supply Chain Management, Selection & affordability, Research & Development

ESSENTIAL MEDICINES AND HEALTH PRODUCTS: PREQUALIFIED LISTS OF MEDICINES (WHO)

Overview: The WHO’s compilation of lists - including medicines/finished pharmaceutical products, active pharmaceutical ingredients, and medicines quality control laboratories - that include medicines and ingredients that have been assessed by WHO and found to be acceptable for procurement.

Tags: Technical document, Prescribing & use

PREQUALIFIED VECTOR CONTROL PRODUCTS (WHO, 2019)

Overview: This list contains vector control products that have been assessed by WHO and found to be acceptable, in principle, for procurement by UN and other international agencies and countries.

Tags: Selection & affordability, Technical document

WHO PRIORITY ASSISTIVE PRODUCTS LIST (WHO, 2016)

Overview: The Priority Assistive Products List was created to increase access to technologies that can help older people and people with disabilities lead better and more productive lives. The list responds to a growing need for quality-assured, useful and affordable assistive products as life expectancy increases and to fulfil global commitments to people living with disabilities. It ranges from products as simple as a pair of eyeglasses to more complex technologies such as wheelchairs.

Tags: Selection & affordability, Intellectual Property, Technical document

GUIDELINES ON GOOD PHARMACY PRACTICE: STANDARDS FOR QUALITY OF PHARMACY SERVICES (INTERNATIONAL PHARMACEUTICAL FOUNDATION / WHO, 2011)

Overview: This resource, which focuses on good pharmacy practice, is intended to assure the value of medicines is fully realized. Included in this approach is the important role of the pharmacist in assuming responsibility for patient uptake and adherence in medication use, including being readily available to patients with or without an appointment and managing/triaging health-related problems.

Tags: Surveillance & assessment, Prescribing & use

GUIDELINES ON THE CONDUCT OF SURVEYS OF THE QUALITY OF MEDICINES (WHO, 2016)

Overview: These guidelines outline the steps to consider for preparing and conducting a survey of medicines quality, a process that helps ensure that good quality medicines are available to patients. The resource provides recommendations and examples of various methodological approaches with a discussion of their advantages and disadvantages, and suggestions regarding how to prepare reports on the results obtained from such surveys.
WHO GOOD DISTRIBUTION PRACTICES FOR PHARMACEUTICAL PRODUCTS
(WHO, 2010)
Overview: Distribution is an important activity in the integrated supply-chain management of pharmaceutical products. Various people and entities are generally responsible for the handling, storage, and distribution of such products. The objective of these guidelines is to assist in ensuring the quality and identity of pharmaceutical products during all aspects of the distribution process. These aspects include, but are not limited to, procurement, purchasing, storage, distribution, transportation, repackaging, relabeling, documentation and record-keeping practices.
Tags: Regulatory systems, Prescribing & use, Supply Chain Management

WHO ESSENTIAL MEDICINES AND HEALTH PRODUCTS: MEDICINES SUPPLY
(WHO, 2015)
Overview: This resource is an overview of actionable areas for solutions to shortages and stock outs of medicines, including tools to assess the medicines supply management systems. These tools will help countries identify strengths and weaknesses in their system with the goal of sustaining a reliable health supply system that: 1) integrates supply management into health system development; 2) develops an efficient mix of public-private partnerships; 3) maintains medicines quality in distribution channels; and 4) ultimately increases access to essential drugs.
Tags: Regulatory systems, Surveillance & assessment, Supply Chain Management, Selection & affordability

WHO ESSENTIAL MEDICINES AND HEALTH PRODUCTS: DISTRIBUTION (WHO)
Overview: On this resource page, users will find information about comprehensive systems for quality assurance of medication and health product distribution. Topics included in the resources are: pharmacy services, starting materials, compounding, monitoring, finished products, procurement, storage.
Tags: Surveillance & assessment, Prescribing & use, Supply Chain Management

MEDICAL DEVICES BY HEALTH CARE FACILITY LEVEL: HEALTH POST AND HEALTH CENTER (WHO)
Overview: These documents contain lists of medical equipment typically required to provide health services in different types of health care facilities (such as health posts, health centers, district hospitals, provincial hospitals, and specialized hospitals). The medical equipment is listed in conjunction with the two most commonly-used classifying codes in international nomenclature, UMDNS and GMDN. These codes allow unambiguous identification and classification of equipment worldwide.
Tags: Selection & affordability, Technical document

SECOND MODEL LIST OF ESSENTIAL IN VITRO DIAGNOSTICS (WHO, 2019)
Overview: This resource is a list of essential in vitro diagnostics and is designed to complement and enhance the impact of the WHO Model List of Essential Medicines. It is not intended to be prescriptive - country programs should make ultimate decisions about which Diagnostics are selected and where they are implemented based on national or regional burden of disease, unmet needs, and priorities. It is noted that the list “cannot have an impact without an integrated, connected, and tiered laboratory system, with adequate HR, training, laboratory infrastructure, and regulatory/quality assurance systems.”
LIST OF PREQUALIFIED IN VITRO DIAGNOSTIC PRODUCTS (WHO, 2019)

Overview: This list of prequalified in vitro diagnostic products helps countries to easily make evidence-based selections when purchasing IVDs. By referencing the list when making purchasing decisions, countries can easily select IVDs that are safe, effective and cost-efficient.

Tags: Technical document, Selection & affordability

GLOBAL BENCHMARKING TOOL (GBT) FOR EVALUATION OF NATIONAL REGULATORY SYSTEMS (WHO, 2018)

Overview: The GBT, with over 200 indicators, is the means by which WHO objectively evaluates regulatory systems, which play a key role in assuring the quality, safety, and efficacy of medical products. The tool incorporates the concept of ‘maturity level’, allowing assessment of the overall maturity of a regulatory system on a scale of 1 to 4, and is designed to be implemented in partnership with the WHO Regulatory Systems Strengthening team as part of a step-by-step approach to improvement.

Tags: Regulatory systems, Surveillance & assessment, Technical document

SERVICE AVAILABILITY AND READINESS ASSESSMENT (WHO)

Overview: The Service Availability and Readiness Assessment is a widely used assessment tool across low and middle-income countries. This resource’s sections on ‘general service’ and ‘service-specific’ readiness are tools for assessing the capacity of facilities to provide a specific service, measured through tracer items that include trained staff, guidelines, equipment/supplies, diagnostic capacity, medicines and commodities. The annex tables of this assessment include itemized tracer items for medicines and commodities within 14 specific services.

Tags: Surveillance & assessment, Technical document

SERVICE PROVISION ASSESSMENT (SPA) (DEMOGRAPHIC AND HEALTH SURVEYS)

Overview: The SPA surveys are part of a health facility assessment that provides a comprehensive overview of a country’s health service delivery. The SPA surveys collect information on the overall availability of different facility-based health services in a country and their readiness to provide those services. The SPA questionnaires were updated in 2012 in collaboration with international agencies to make them easier to use and to include additional information. The inventory questionnaire collects information for the calculation of USAID and WHO’s service readiness indicators.

Tags: Surveillance & assessment, Technical document

DIGITAL TECHNOLOGIES: SHAPING THE FUTURE OF PRIMARY HEALTH CARE (TECHNICAL SERIES ON PRIMARY HEALTH CARE, GLOBAL CONFERENCE ON PRIMARY HEALTH CARE (WHO, UNICEF), 2018)

Overview: This resource touches upon the broad topic of technology as a tool for strengthening primary health care, which is integrally related to ensuring drugs, vaccines, and supplies are tracked, delivered, and used in sustainable ways. Digital technologies of all kinds have become essential resources in primary care and it is critical to integrate technology into approaches for strengthening health systems for every level of operation.
QUALITY IN PRIMARY HEALTH CARE (TECHNICAL SERIES ON PRIMARY HEALTH CARE, GLOBAL CONFERENCE ON PRIMARY HEALTH CARE (WHO, UNICEF), 2018)

Overview: This resource describes how the availability of high-quality medicines and products can contribute to the goal of high-quality care in Primary Health Care. National policies and guidelines for the manufacturing, procurement, supply-chain development, surveillance and safe use - as well as national regulatory bodies - may support the development of these required systems.

Tags: Regulatory systems, Surveillance & assessment, Research & Development

OPERATIONAL FRAMEWORK, PRIMARY HEALTH CARE: TRANSFORMING VISION TO ACTION (WHO, UNICEF, 2018)

Overview: Module 3.6 of the operational framework (page 34-37) outlines actions and interventions at various levels to improve physical infrastructure and appropriate medicines, products, and technologies. Supporting the ‘Digital technologies: shaping the future of primary health care’ document, the operational framework emphasizes appropriate diagnostic and therapeutic products technologies within the realm of drugs and supplies.

Tags: Research & Development

WHO MEDICINES, VACCINES AND PHARMACEUTICALS: ANNUAL REPORT 2018 (WHO, 2018)

Overview: In this report, WHO identifies priorities regarding improvement of availability and accessibility of drugs and supplies. Topics addressed in this report include rising medication prices, shortages and stock outs of essential medicines, the growing problem of substandard and falsified medical products, opioid abuse, and antimicrobial resistance.

Tags: Surveillance & assessment, Prescribing & use, Supply Chain Management, Selection & affordability, Intellectual Property, Research & Development


Overview: This report gives an overview of the WHO Department of EMP areas of focus in 2017, highlighting global priorities around antibiotic-resistant bacteria, cancer and hepatitis treatments, child-friendly vaccine availability partnerships, and substandard or falsified medical products. It also speaks on a broad level about WHO processes for supporting countries in strengthening regulatory systems, prequalification capacities, technical assistance on affordable pricing, preparedness for emergencies, and approaches to controlled substances.

Tags: Regulatory systems, Surveillance & assessment, Selection & affordability, Research & Development
**RISK MANAGEMENT FOR PUBLIC HEALTH SUPPLY CHAINS: A TOOLKIT FOR IDENTIFYING, ANALYZING, AND RESPONDING TO SUPPLY CHAIN RISK IN DEVELOPING COUNTRIES (USAID DELIVER PROJECT, 2013)**

**Overview:** Risk management for public health supply chains focuses on organizing the logistics activities of the supply chain to ensure that commodities needed for health programs are continuously available, without disruption. Risk management is a continuous process of assessing and responding to risk within the supply chain. This toolkit can provide public health supply chain managers in developing countries with a simple process for identifying and analyzing the sources of risk within the supply chain and for developing a robust response to manage risk.

**Tags:** Supply Chain Management, Surveillance & assessment

**WHY RESEARCH AND DEVELOPMENT? (GLOBAL HEALTH TECHNOLOGIES COALITION)**

**Overview:** This resource answers key R&D questions: What is R&D? Why do we need R&D? What are health technologies? What does the R&D process look like? Who are the players? What are the challenges? What is the role of Global Health Technologies Coalition?

**Tags:** Research & Development

**FAIR PRICING OF MEDICINES (WHO, 2019)**

**Overview:** This link introduces the Fair Pricing Forum Report from the latest WHO convening in 2019. It also links to resources such as *Medicines Pricing and Financing* and *Access to medicines: making market forces serve the poor*.

**Tags:** Selection & affordability

**GETTING THE PRODUCTS TO THE PEOPLE: HOW PRIVATE SECTOR SOLUTIONS CAN STRENGTHEN SUPPLY CHAINS FOR PUBLIC HEALTH (JSI, 2016)**

**Overview:** This resource is an overview of the various ways the public sector can leverage the private sector to be involved in supply chain solutions. The four models identified for private sector engagement are: adapting and learning, contracting, collaboration, and stewardship.

**Tags:** Supply Chain Management

**LANDSCAPING INNOVATIONS IN HEALTH PRODUCT DISTRIBUTION IN SUB-SAHARAN AFRICA (IMPACT FOR HEALTH, 2018)**

**Overview:** This resource is an overview of key trends in innovation of health product distribution in sub-Saharan Africa and their potential impact on availability, quality, cost, or geographic access of priority health products. The six categories identified in which the private sector can provide solutions include: consumer information, direct-to-consumer distribution, stock financing & ownership, inventory management, marketplace & fulfillment, and group purchasing.

**Tags:** Supply Chain Management
PRIVATE SECTOR ROLE IN HEALTH SUPPLY CHAINS  (DALBERG GLOBAL DEVELOPMENT ADVISORS & MIT-ZARAGOZA INTERNATIONAL LOGISTICS PROGRAM, 2009)

Overview: This report sets a baseline understanding of healthcare supply chains and characterizes the private sector role in supply chains in lower middle income countries. It is informed by in-depth case studies of Ghana and Zambia, as well as interviews of over 40 supply chain and health experts in 12 countries about private sector initiatives in those countries. The major findings characterize supply chains, analyze the potential to invest in private sector initiatives, and make recommendations for key stakeholders.

Tags: Supply Chain Management

TACKLING THE TRIPLE TRANSITION IN GLOBAL HEALTH PROCUREMENT (CENTER FOR GLOBAL DEVELOPMENT: WORKING GROUP ON FUTURE OF GLOBAL HEALTH PROCUREMENT, 2019)

Overview: This report focuses on procurement reform needs in the midst of rapid evolution in three areas: transition away from donor aid, epidemiological transition toward noncommunicable diseases, and health system organization shifts to universal health coverage.

Tags: Supply Chain Management
REFERENCES


