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Why an Essential Medicine May Remain Inaccessible Across Selection, Procurement, Quality Assurance, Distribution, and Household Affordability

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ABSTRACT

Designation as an essential medicine expresses a policy priority, yet it does not by itself establish that a patient can obtain an appropriate, quality-assured product when treatment is needed. Access emerges from several functions that operate under different institutional responsibilities and can fail independently or interact. Selection determines which medicines receive formal priority; financing and procurement determine whether that priority becomes a sustainable purchasing commitment; quality assurance determines whether available products are suitable for use; distribution determines whether procured stock reaches facilities reliably; and dispensing conditions and household resources determine whether a patient can ultimately obtain treatment. Failure at one function may also shift burdens downstream. A public-sector stockout can redirect demand toward higher-priced private outlets, procurement choices can alter the market for substitute products, and inadequate formal access can encourage medicine purchasing through less controlled channels. Conversely, interventions that remove patient charges can improve adherence while leaving other determinants of clinical outcomes unresolved. This policy analysis disaggregates these functions and examines how their interaction can explain the recurrent gap between formal essential-medicine policy and patient-level treatment access. It argues for function-specific diagnosis and measurement rather than treating listing, availability, affordability, quality, and treatment continuity as interchangeable manifestations of a single access problem.

Keywords: Essential medicines, Medicine access, Pharmaceutical procurement, Medicine quality assurance, Stockouts, Affordability

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Introduction

Essential medicines policy is intended to concentrate health-system attention on therapies that address priority health needs while supporting equitable, financially sustainable care. Achieving that objective requires considerably more than the existence of a national list. The Lancet Commission on Essential Medicines positioned appropriate selection alongside financing, affordability, quality, supply, prescribing and use as interdependent components of progress toward universal health coverage [1]. These components involve different actors and institutional mechanisms, making patient-level access vulnerable even when one part of the policy chain appears successful.

How access is measured can conceal this fragmentation. A scoping review of medicine availability and affordability in the WHO African Region identified 241 studies but found substantial variation in geography, therapeutic focus and measurement. Availability was often represented by whether a product was present on the

day of a survey, whereas affordability was assessed through several non-equivalent methods [2]. A single access percentage can therefore combine, or obscure, very different policy problems.

Formal essentiality also does not ensure timely entry into national markets. An analysis of 119 medicines across 75 markets documented substantial country-level delays between initial global use and subsequent launch, with longer delays in lower-income settings [3]. Market entry itself remains only one stage: a launched medicine may still be inadequately financed, purchased intermittently, fail quality requirements, remain concentrated geographically, or prove unaffordable to households.

When formal channels do not meet need, patients may adapt in ways that alter the quality and cost of treatment they eventually receive. Survey evidence from Ghana, Nigeria, Sierra Leone and Uganda indicates that structural constraints and information gaps can contribute to medicine purchasing through less controlled sources [4]. The relevant policy question is consequently not whether an essential medicine is simply "available" or "unavailable." It is where access became unreliable, what burden was displaced to the next actor, and whether downstream adaptation restored treatment or created another form of risk.

This analysis examines selection, financing, procurement, quality assurance, distribution, facility availability, dispensing and household affordability as distinct functions. The central proposition is conditional: failures at these functions can accumulate or transfer burden downstream, but their magnitude and sequence vary by country, procurement model, product, sector and disease area. The analytical objective is to identify those distinctions without turning them into a universal causal pathway.

Selection defines a policy commitment, not a supply condition

National essential medicines lists establish a formal priority for public action, but their composition already varies before procurement or distribution begins. Comparison of national lists with the WHO Model List of Essential Medicines demonstrated substantial differences among 137 countries and across therapeutic categories [5]. Such divergence can represent legitimate adaptation to disease burden, resources and national treatment policy, so discordance with the WHO list should not automatically be interpreted as failure. It nevertheless shows that "essential medicine" does not represent an identical basket of products across health systems.

A separate analysis of essential medicines lists in 137 countries similarly documented extensive variation in list composition [6]. Selection therefore defines an intended policy commitment rather than a physical supply condition. Inclusion indicates that a medicine has crossed a prioritization threshold; it does not establish that financing has been secured, suppliers have entered the market, tenders have succeeded, appropriate products have passed quality requirements, or stock has reached patient-facing facilities.

High-cost oncology provides a particularly clear example of the distinction. Analysis of cancer medicines on the WHO Model List emphasizes that clinical benefit must be considered together with affordability, budget consequences, implementation feasibility and health-system capacity [7]. A medicine can therefore meet a compelling clinical need while remaining difficult to translate into routine provision. Selection and access are connected, yet they represent different policy decisions.

Essential-medicine classification can also support downstream quality of use. The WHO AWaRe approach for antibiotics links medicine categorization to stewardship and prescribing guidance, extending the function of a list beyond simple enumeration [8]. This illustrates the constructive role of selection while reinforcing its boundary: prescribing guidance cannot substitute for procurement, regulatory assurance or reliable local stock.

The distinction between formal priority and operational access becomes clearer when the major access functions are compared directly.

Table 1. Policy functions that separate essential-medicine designation from patient-level access

Access function	Principal policy responsibility	Observable failure signal	Likely downstream consequence	Context that can alter interpretation
Essential-medicine selection	Define priority medicines and appropriate scope of public provision	Relevant therapy absent from, delayed in, or narrowly represented on a national list	Medicine may receive limited financing or institutional purchasing attention	Disease burden, treatment guidelines, budget capacity and national priorities

National market entry	Permit or support practical introduction of the selected product	Long delay between global availability and national launch	Selection exists without an orderable local product	Market size, regulatory environment, manufacturer strategy and expected demand
Financing	Convert priority status into funded purchasing capacity	Listing exists but budget commitment is incomplete or unstable	Tender quantities may be inadequate, delayed or intermittently funded	Fiscal space, reimbursement arrangements and competing health priorities
Procurement	Contract suppliers and obtain suitable products under sustainable commercial conditions	Tender failure, weak supplier participation or unstable purchasing conditions	Delayed supply, reduced product choice or reliance on substitutes	Procurement scale, payment reliability, legal rules and supplier incentives
Quality assurance	Ensure that the supplied product meets appropriate quality requirements	Weak regulatory oversight, unresolved quality concerns or inadequate post-market surveillance	Nominal supply may be unusable, unsafe or withdrawn	Regulatory maturity, laboratory capacity and product complexity
Distribution and facility inventory	Move and maintain stock where treatment is delivered	Stockouts, long replenishment intervals or geographic concentration	Delayed treatment, sector switching or interruption of therapy	Logistics capacity, facility type, geography and demand forecasting
Dispensing and household access	Convert facility or market stock into medicine actually obtained by the patient	High direct payment, unaffordable substitutes, forgone purchase or risky sourcing	Non-initiation, interruption, financial hardship or lower-quality sourcing	Insurance, household resources, private-sector alternatives and disease chronicity

Financing and procurement determine whether selection becomes an orderable product

After selection, financing and procurement determine whether a health-system commitment becomes an executable transaction. Pooled procurement is often proposed as a means of increasing purchasing power, but a systematic review of 44 empirical studies found that success depends on capabilities distributed across participating buyers, the procurement organization and suppliers. Legal compatibility, payment reliability, organizational capacity and supplier incentives can be as important as aggregate purchasing volume [9]. Pooling therefore cannot be treated as an automatic price-reduction mechanism.

Implementation also develops over time. Analysis of pooled procurement mechanisms shows that creating and sustaining them requires governance arrangements, collaboration, administrative capacity and adaptation as purchasing organizations mature [10]. A procurement mechanism that appears efficient on paper can underperform if participants cannot coordinate specifications, financing, payment or supplier management.

China's national volume-based procurement policy demonstrates how purchasing design can materially change market conditions. The policy generated major price reductions and widened access to selected medicines, while also raising questions about supplier sustainability, competition and the longer-term organization of pharmaceutical markets [11]. These trade-offs matter because a low tender price is useful only if adequate quality-assured supply remains commercially and operationally sustainable.

Procurement choices can also affect products beyond those directly selected. Interrupted time-series analysis of China's “4+7” procurement programme found price changes among winning medicines as well as non-winning and clinically alternative products [12]. The policy consequence is broader than the contracted unit price: procurement can change substitution incentives and the commercial environment in which alternative treatment options are supplied.

Financing and pricing policies are also mediated by institutional power. In Ghana, qualitative analysis of four medicine-pricing policies found that stakeholders differed substantially in their ability to shape design and implementation, with formal mandates, expertise and institutional position influencing policy outcomes [13]. Financial rules thus require implementation capacity and authority; their presence in policy documents does not establish effective execution.

Quality assurance narrows nominal supply to usable supply

A medicine that has been financed and procured still cannot be regarded as accessible solely because units exist somewhere in the supply system. Regulatory capacity determines whether products entering or circulating in the market have undergone adequate authorization, oversight and post-market control. Analysis of regulatory-system strengthening in low- and middle-income settings identifies medical-product regulation as an investment priority for expanding access to quality-assured medicines while maintaining timely availability [14]. The policy challenge is therefore to maintain both regulatory rigor and sufficient operational capacity to avoid preventable delays.

Quality screening represents one component of that system. A ten-country assessment involving regulators, manufacturers, pharmacies and distributors found wide variation in the roles assigned to medicine-quality screening technologies and in the resources needed to use them effectively [15]. Screening may help identify products requiring further investigation, yet it does not replace confirmatory testing, regulatory interpretation or enforcement. Treating screening as synonymous with quality assurance would overstate what the technology can establish.

The importance of this distinction is evident from the documented burden of substandard and falsified medicines. A systematic review and meta-analysis found that poor-quality medicines constitute a material problem across low- and middle-income-country evidence, although prevalence varied substantially according to product, geography, sampling and testing methods [16]. These findings do not justify transferring a single prevalence estimate to every market. They do establish that physical presence and usable supply are analytically different conditions.

Quality risk can also interact with scarcity. Where regulated channels are difficult to access, patients may seek medicines from alternative sources, especially when constraints coexist with limited information about product quality [4]. The resulting problem is therefore not simply “insufficient stock” or “poor quality” considered independently. Weak formal access can change where medicines are purchased and which quality safeguards remain in force.

These distinctions allow procurement price, supplier reliability and quality assurance to be considered together without assuming that success on one dimension guarantees success on another.

Table 2. Procurement and quality-assurance conditions that determine whether purchased supply remains usable and sustainable

Procurement or assurance condition	Primary policy concern	Failure signal	Potential consequence for supply	Substitution or market consequence
Pooled purchasing arrangement	Sufficient buyer coordination, payment reliability and procurement capability	Participating buyers cannot align rules, financing or specifications	Tender delays, weak supplier response or unstable pooled demand	Buyers may return to fragmented purchasing or narrower supplier pools
High-volume national tender	Achieving affordable prices while maintaining viable supply	Extremely concentrated awards, weak supplier resilience or unstable delivery	Low contracted price may coexist with future supply vulnerability	Non-winning or alternative products may experience changed demand and prices
Pricing-policy implementation	Translating formal pricing rules into executable purchasing practice	Policy authority fragmented or key implementation actors have limited capacity	Delayed or inconsistent application of agreed pricing arrangements	Different sectors or purchasers may face unequal effective prices
Regulatory authorization and oversight	Ensuring market entry of appropriate quality-assured products	Limited regulatory capacity or unresolved review and surveillance requirements	Supply may be delayed, restricted or inadequately monitored	Purchasers may face fewer acceptable suppliers or products

Field quality screening	Rapidly identifying suspect products within supply chains	Screening unavailable, poorly maintained or used beyond its validated purpose	Potentially poor-quality stock may remain undetected or valid stock may require further confirmation	Product substitution should not occur solely on an unconfirmed screening result
Confirmatory quality action	Converting suspicion into defensible regulatory or procurement action	Testing, investigation or enforcement capacity is insufficient	Uncertainty persists over whether stock is suitable for continued use	Procurement decisions may be delayed or shifted toward alternative suppliers

Distribution and facility stock convert procured volume into treatment continuity

Procurement creates supply at a system level; distribution determines whether that supply remains reachable where patients receive care. A systematic review of 78 evaluations of community health worker programmes in low- and middle-income countries found substantial stockouts of essential commodities and identified distribution and logistics problems as prominent contributors [17]. Reported consequences extended to patient spending, adherence and use of services. The finding is important because it locates access failure after selection and procurement have already occurred.

Inventory reliability also has a temporal dimension that point surveys can miss. In two Ethiopian facilities, many tracer medicines were available on the survey day, yet review of the preceding six months showed that stockouts had occurred and could persist for meaningful periods [18]. A point-availability percentage can therefore describe whether a shelf contains a product at one moment while failing to represent whether treatment can be initiated or continued reliably across time.

Stockouts may also affect markets outside the facility in which they originate. Evidence from Uganda's antimalarial market showed that public-sector stockouts increased prices in the private sector and reduced medicine receipt and care seeking among affected consumers [19]. This provides direct evidence of downstream burden displacement: the absence of publicly supplied medicine can shift demand to another sector, alter the price encountered there and change whether a patient ultimately obtains treatment. The magnitude documented in that market should not be generalized to unrelated products or countries, but the mechanism demonstrates why public and private availability cannot always be analyzed independently.

Geography further complicates inference. The African evidence base on medicine availability is concentrated in a subset of countries and therapeutic areas, while methods differ considerably across studies [2]. Areas with limited evidence should not be assumed to have either reliable or poor access. Monitoring systems therefore need to distinguish lack of measurement from absence of a problem.

The distribution evidence supports several complementary indicators rather than a single availability statistic.

Table 3. Distribution and facility-level indicators that distinguish visible stock from reliable treatment availability

Distribution question	Appropriate observation	What a favorable result establishes	What it does not establish	Policy failure that may remain hidden
Is the medicine present today?	Point-in-time facility or outlet availability	Product is physically present at the observed location and time	Continuity before or after the survey	Recurrent or prolonged stockouts between survey dates
Has supply been reliable over time?	Stockout frequency, duration and replenishment history	Degree of inventory continuity	Household affordability or product quality	Repeated short interruptions, delayed replenishment or unstable forecasting
Does stock reach the intended service level?	Availability by facility type, community service or geographic level	Distribution reaches the measured delivery tier	Equitable reach to all populations	Central stock with peripheral or community-level shortages

What happens when the public sector stocks out?	Private-sector prices, substitution, care seeking and medicine receipt during stockout periods	Whether failure propagates into alternative markets	Universal magnitude of the spillover	Higher private prices, changed product choice or forgone treatment
Is the monitoring system geographically representative?	Coverage of countries, regions, facilities and therapeutic classes	Extent to which observed access patterns are documented	Access status in unmeasured settings	False reassurance created by evidence concentration

Distribution is therefore the point at which centrally procured volume becomes, or fails to become, usable treatment opportunity at the facility level. Yet even uninterrupted facility stock remains insufficient to demonstrate patient-level access. Whether the stocked medicine is dispensed, what substitute is offered when the preferred product is unavailable, and whether the household can absorb the resulting financial and practical costs remain separate determinants of patient-level access.

Dispensing, substitution, and household affordability determine patient-level access

Facility stock becomes patient access only when the medicine is clinically appropriate, dispensable through an accessible channel, and obtainable without unacceptable financial or practical sacrifice. A systematic review of asthma and chronic obstructive pulmonary disease medicines in low- and middle-income countries found especially poor access to preventive inhaled therapies [20]. Contemporary data from 60 low- and middle-income countries likewise showed preventive respiratory medicines to be generally less available and affordable than symptom-relief medicines [21]. Disease-level availability can therefore conceal whether the stocked product supports long-term control.

Diabetes provides the same warning. Global synthesis indicates substantial regional variation in access to insulin and other diabetes therapies [22], while multinational evidence shows that availability and affordability differ across national income settings [23]. Insulin surveys in 13 low- and middle-income countries further demonstrated variation by insulin type and sector [24].

Cardiovascular medicines illustrate why selection, price, availability and affordability should remain separate. Cross-country analysis treated these as distinct access dimensions [25]. A product can be listed yet unavailable, stocked yet unaffordable, or inexpensive in one sector but inaccessible to patients who depend on another.

Household expenditure adds another layer. In Ethiopia, medicines accounted for a large share of out-of-pocket health spending and contributed to catastrophic expenditure and impoverishment [26]. Insurance can reduce this burden without resolving every supply constraint. Among National Health Insurance Scheme enrollees in Enugu State, Nigeria, access was commonly perceived to have improved, yet medicine availability and implementation limitations remained [27].

Randomized evidence establishes an important boundary. In the CLEAN Meds trial, distributing essential medicines at no charge increased adherence among patients reporting cost-related nonadherence, but several clinical surrogate outcomes did not improve significantly [28]. The adherence advantage persisted at two years while differences in diabetes control, systolic blood pressure and LDL cholesterol remained non-significant [29]. Removing a price barrier can improve medicine-taking without correcting every downstream determinant of outcome.

Medication cost also competes with other household needs. Trial-embedded analysis found that free distribution improved participants' reported ability to make ends meet [30]. A scoping review of financial-risk protection showed that catastrophic expenditure and impoverishment capture only part of burden; coping strategies and forgone care also matter [31]. A three-year CLEAN Meds secondary analysis found lower median total healthcare spending with free medicines, although this Canadian result should not be treated as a universal budget effect [32].

These findings separate direct medicine price from the broader household conditions that determine whether stock becomes treatment.

Table 4. Household conditions that determine whether nominal medicine availability becomes treatment obtained

Patient-facing condition	Observable response when access is constrained	Burden transferred to household	What nominal availability misses	Policy implication
Medicine price at dispensing	Partial purchase, delay or non-initiation	Direct out-of-pocket payment	Whether stocked medicine is financially obtainable	Track price and affordability alongside stock
Insurance or copayment design	Covered substitution, delayed claims or additional payment	Residual payment and administrative burden	Whether coverage becomes usable entitlement	Assess benefit design with stock and dispensing rules
Public-to-private switching	Purchase from another outlet after public non-availability	Higher price, travel and search costs	Cost created by location of shortage	Monitor cross-sector prices during shortages
Product or formulation substitution	Acceptance of another brand, strength, formulation or therapeutic alternative	Price, convenience or treatment-burden change	Whether substitute fits clinical and practical needs	Record what is dispensed, not merely category-level stock
Transport and time requirements	Repeated visits, delayed collection or abandonment	Travel expenditure and lost time	Effort required to obtain treatment	Combine geographic reach with repeated-access requirements
Competing household necessities	Medicine rationing or reduced essential spending	Financial insecurity and coping	Welfare loss despite completed purchase	Use financial-protection measures beyond price
Forgone treatment	No purchase or facility visit	Untreated disease without recorded medicine spending	Non-access invisible to expenditure data	Measure unmet need and forgone care

Patient non-access can also distort information returned to the supply system. Sector switching or forgone treatment can lower observed public-facility demand even when clinical need persists. Forecasting based only on dispensed volume may then misread suppressed access as low demand. Because current evidence does not establish a universal feedback loop, this relationship remains a testable hypothesis. **Figure 1** brings these functions together: access failures may prevent treatment acquisition or shift burden downstream.

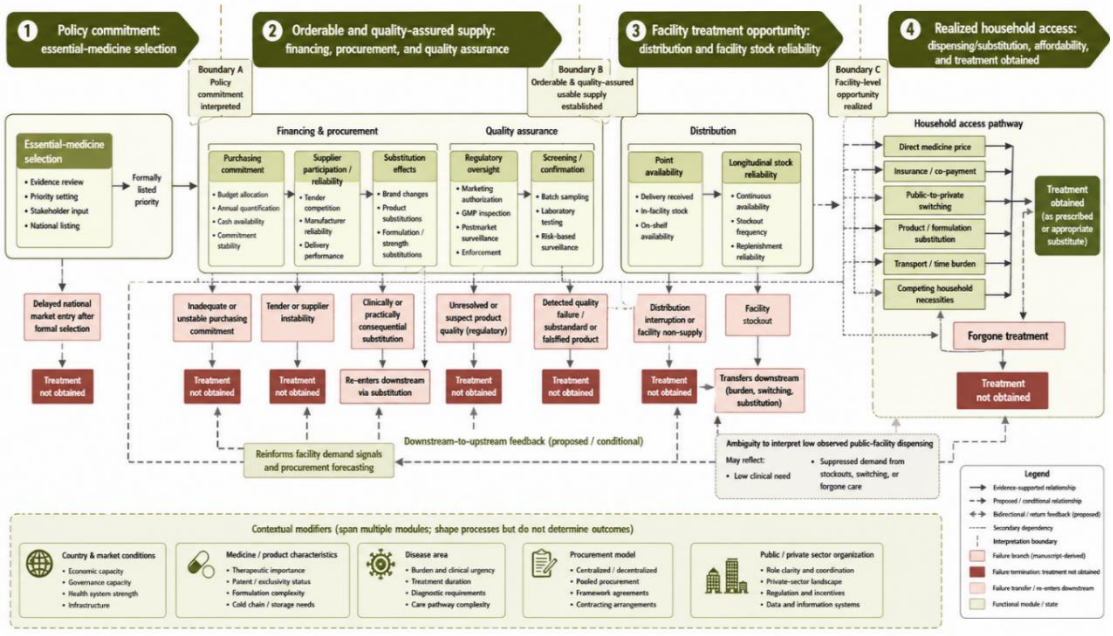

Figure 1. Where essential-medicine access can lose reliability between policy priority and treatment obtained

Measuring access across functions without collapsing the chain

Access monitoring should preserve the distinction between the event measured and the policy inference drawn from it. Survey-day stock indicates presence at one location and time; it does not establish continuity. The African evidence base frequently relies on point availability [2], while Ethiopian facility records show favorable survey-day availability can coexist with meaningful prior stockout duration [18].

The same principle applies upstream and downstream. National-list inclusion identifies formal selection; launch data capture market entry; facility availability captures local presence; household affordability addresses whether patients can obtain the product financially. Cardiovascular evidence shows that list inclusion, price, availability and affordability can vary independently [25]. Combining them into an opaque score can obscure which intervention is required.

Financial protection also extends beyond the amount paid. Catastrophic expenditure and impoverishment identify severe spending consequences, but coping and forgone care can occur earlier [31]. A household that never purchases an unaffordable medicine may appear to have low medicine expenditure while experiencing complete non-access.

Monitoring should therefore match measures to suspected failure: list status for selection, launch or registration for market entry, tender and supplier indicators for procurement, quality signals for usable supply, stockout frequency and duration for distribution, patient price and insurance burden for affordability, and unmet need for final access. The objective is diagnostic clarity, not a new weighted index.

Discussion and policy implications

The evidence supports a conditional answer. An essential medicine can remain inaccessible because the commitment expressed by selection must still be translated through financing, procurement, quality assurance, distribution, dispensing and household acquisition. These functions are linked but not interchangeable.

Procurement reforms illustrate the point. Pooled or volume-based purchasing can improve prices and leverage, yet performance depends on governance, payment reliability, supplier participation and market structure [9]. A successful tender does not establish continuous quality-assured stock or affordability. Regulatory capacity protects usable supply while carrying resource and timeliness requirements [14].

The strongest evidence for downstream displacement comes from settings in which one sector's failure changes another sector's prices or patient behavior. Public antimalarial stockouts in Uganda altered private-market prices and treatment access [19]. This demonstrates a mechanism in one market, not a universal effect size.

Affordability policy requires similar discipline. Free essential-medicine distribution improved adherence among patients with cost-related nonadherence [28]. At two years, the advantage persisted while several measured clinical surrogates remained statistically similar [29]. Price removal was consequential without being sufficient; outcomes still depend on treatment choice, persistence, monitoring, disease biology and other care.

Monitoring systems should be organized around the decision a policymaker must make. High survey-day availability may coexist with recurrent stockouts. Low public-sector demand may indicate low need, or previous shortages and sector switching. Low household medicine spending may represent financial protection or forgone acquisition.

The proposed concept of failure transfer requires evidence that a constraint changes where costs, delays or risks are borne. Improved central supply alongside persistent facility stockouts would identify an unresolved distribution bottleneck, but would not by itself demonstrate transfer. More specific support would come from linked changes in shortages, sector switching, patient costs and medicine receipt, including whether restoring public stock reduces private-sector price pressure. The hypothesis would receive less support where these downstream responses remain absent despite changes in the upstream constraint. Linking procurement, inventory, dispensing, patient price and unmet-need data would distinguish burden transfer from a bottleneck that simply persists.

Policy responses should begin by identifying the failed function and its downstream consequences. Selection should be assessed against market entry and purchasing commitments; procurement against supplier reliability and quality-assured delivery; distribution against longitudinal inventory continuity; and affordability interventions against medicine acquisition, financial protection and forgone treatment. The aim is to prevent success at one administrative stage from being mistaken for patient-level access.

Conclusion

Essential-medicine designation states a policy priority, but patient access depends on whether that priority survives institutionally distinct decisions and constraints. Selection, financing, procurement, quality assurance, distribution, facility stock, dispensing and household affordability can fail separately, and burdens can appear downstream as delay, substitution, higher private expenditure, riskier sourcing or forgone treatment.

The evidence does not support a universal cascade. Country institutions, medicine type, disease area, procurement arrangements, public and private markets and household resources alter the pathway. It supports a more precise policy principle: access should be diagnosed where reliability is lost and measured with indicators that distinguish that failure from neighboring ones.

Policies that reduce price, improve procurement or increase stock can be consequential, but none alone proves that treatment has become reliably obtainable. The final test is whether an appropriate, quality-assured medicine can be obtained when needed without unacceptable financial or practical sacrifice.

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