Patient pathways to accessing unregistered medicines in low and middle income countries

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Introduction

Despite 80% of the global population residing in low- and middle-income countries (LICs and MICs), pharmaceutical manufacturers often prioritise high-income countries due to greater revenue potential, leading to delays or limited access to medicines in LICs and MICs. A 2024 analysis found voluntary licensing practices in LICs and MICs have stalled, with manufacturers five times more likely to launch new products in upper-middle-income countries.[1]

Objective

This research examines the pathways for accessing unregistered medicines in low- and middle-income countries, assessing: the key barriers encountered by patients and physicians attempting to utilise them, the real-world extent of their use, and the disparities between LICs and MICs.

Method

A targeted review of the national legislation and regulations governing access and reimbursement for unregistered medicines was conducted to evaluate accessibility in 10 LICs and MICs across four regions: Africa, Asia Pacific, Latin America, and the Middle East (Table 1). The findings were validated through primary research via the Lightning Insights On-Demand Platform with 16 healthcare professionals experienced in accessing unregistered medicines.

Table 1. Scope countries[2]

Low-income countries (LICs)	Ethiopia, Syria
Lower-middle income countries (LMICs)	Egypt, India, Jordan
Upper-middle income countries (UMICs)	Argentina, China, Mexico, South Africa, Turkey

Results

Section 1: Summary of Findings

Figure 1. Overall ease of access to unregistered medicines

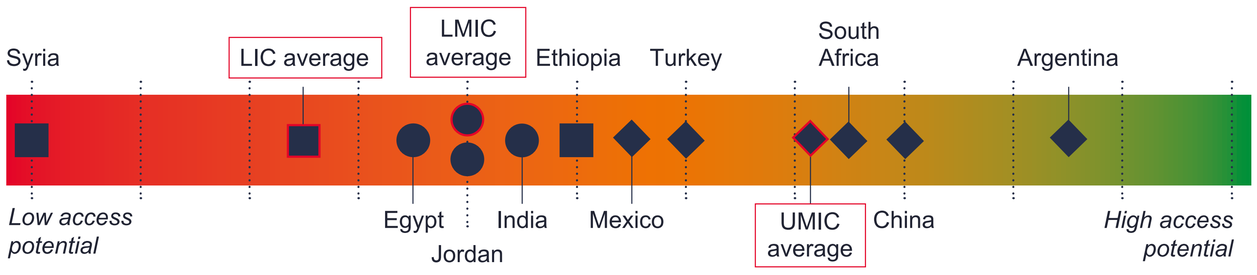

Figure 1 illustrates the overall ease of access to unregistered medicines, with scoring taking into consideration the number of available pathways, the strictness of the clinical requirements for access, clarity and simplicity of the process, individual patient vs cohort access, availability of funding options, and the necessity of local language labelling.

Across the 10 countries assessed, substantial variation in how health systems facilitate access is demonstrated. Average scores increase with income group, indicating a relationship between national income level and the ease of access to unregistered medicines, though variation is still evident within groups.

There is a high level of variation among LICs, with access severely constrained in Syria while Ethiopia scores above the LMICs. In contrast, ease of access to unregistered medicines in LMICs is consistently moderate. The highest-scoring countries are among the UMICs, with Argentina, China, and South Africa facilitating the highest opportunity to access unregistered medicines, suggesting greater maturity of access frameworks. However, the access challenges identified in Turkey and Mexico highlight that stronger economies do not guarantee streamlined patient access to unregistered medicines.

Thus, while income level broadly correlates with improved access, regulatory choices and implementation details play a decisive role in shaping patient pathways in practice.

Section 2: Available access pathways

Table 2. Formal access pathways to unregistered medicines in LICs and MICs

	Named patient pathway (single-patient access)	Emergency pathway	Compassionate Use Programme (CUP)	Other multi-patient pathways
Ethiopia	Special Import Permit			
Syria	MOH approval			
Egypt	Personal Importation	Emergency Use Application		
India	Third Party Importation		Importation for Compassionate Use	
Jordan	Named Patient Pathway			
Argentina	Exceptional Access Regime (RAEM)		Compassionate Use Process	Expanded Access Programme
China	Named Patient Programme		Compassionate Use	Hainan Pilot Medical Zone
Mexico	COFEPRIS Import Permit			
South Africa	Section 21 Access (Named Patient)			Section 21 Access ('Bulk Stock')
Turkey	Named Patient Programme		Compassionate Use Pathway	

Table 2 summarises the formal pathways identified for access to unregistered medicines. In all cases, approval from the regulatory authority is required ahead of importation.

Named patient pathways are present in almost all countries, but their requirements vary considerably. In some settings, importation is relatively straightforward - for example, in India, where third-party importers may bring in medicines with a prescription, or in South Africa, where access is permitted when no registered alternative exists.[3] By contrast, in Syria, no clear legislation exists - according to article 31 of Decree 24 of 2010, importation of unregistered medicines is prohibited in the absence of MoH approval, with no further publicly available details identified.[4] Other countries, such as Jordan, Egypt, and Turkey, tie eligibility specifically to rare, serious, or urgent medical need, with Egypt and Jordan limiting access specifically to life-threatening diseases.[5-7]

Emergency pathways are less widespread. Egypt permits emergency approval only in cases of life-threatening disease with outbreak potential, while Argentina allows an exceptional access regime during health emergencies.[8,9] In Ethiopia and Mexico, special import permits cover emergency situations.[10,11]

Compassionate use programmes (CUPs) which involve the manufacturer providing the unregistered medicine for free, are also a key pathway to access. India, China, and Argentina restrict CUPs to life-threatening or severely debilitating diseases linked to products already in clinical trials, while Turkey specifies that eligible patients must have failed registered treatments and be ineligible for ongoing trials. Argentina's CUPs impose a high bar, requiring Phase II trial data.[12-15] Ethiopia's special import permit accounts for compassionate use, but no specific legislation ratifying CUPs exists.10 While such programmes are recognised as an important access pathway, their reliance on manufacturer support may constrain real-life use.

Multi-patient pathways outside emergency use or CUPs are limited to UMICs. Argentina's expanded access programme allows temporary use of unregistered medicines for life-threatening or debilitating disease with Phase II data, and South Africa has a bulk stock mechanism enabling providers to hold unregistered medicines in exceptional circumstances.[3,16] China's Hainan Pilot Medical Zone is the most ambitious, permitting import of overseas medicines unavailable domestically, with 476 unregistered medicines imported under this pathway as of April 2025.[17,18]

While nearly all markets provide a route for individual patient access, the breadth and flexibility of additional pathways increase with income level. Even where multiple mechanisms exist, however, stringent clinical requirements and documentation needs remain major obstacles to practical use.

> "Access to unapproved medicines is typically limited to patients with serious or life-threatening conditions, especially when there are no alternative treatments available. This restriction reduces the overall ease of access, as many patients may not qualify under these stringent criteria."
>
> **Physician, China**

Section 3: Funding Sources

Figure 2. Available funding sources for unregistered medicines

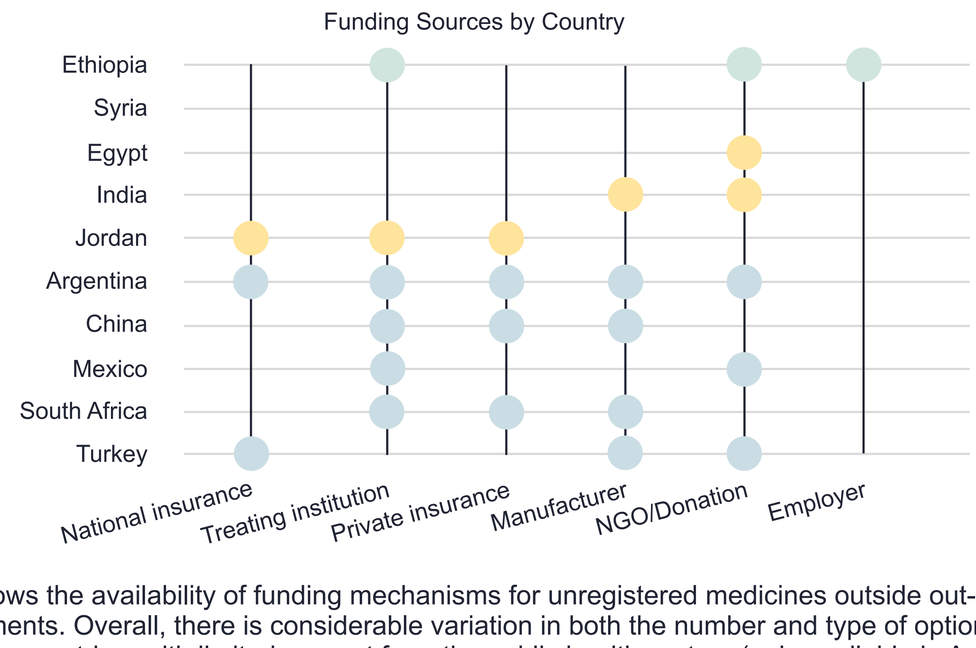

Figure 2 shows the availability of funding mechanisms for unregistered medicines outside out-of-pocket (OOP) payments. Overall, there is considerable variation in both the number and type of options across the 10 scope countries, with limited support from the public health system (only available in Argentina, Turkey, and Jordan).

Low-income settings are the most restricted. In Ethiopia, while patients can occasionally rely on support from treating institutions, NGOs, or employers, formal national or private insurance coverage is severely limited. In Syria, no funding sources beyond direct out-of-pocket payments are reported. These findings highlight the structural limitations of resource-constrained health systems, where legislation may exist, but lack of funding renders these pathways inaccessible in practice.

> "The near-total lack of public or insurance funding means patients must pay out-of-pocket. This makes the market vanishingly small, limited to a tiny, affluent elite."
>
> **Pharmacist, Ethiopia**

LMICs present a mixed picture. Outside of OOP payments, Egypt and India primarily rely on charitable funding, with India also permitting manufacturer-sponsored CUPs. Jordan has a broader framework, with national insurance, treating institutions, and private insurance able to contribute. However, the reliance on ad hoc or voluntary mechanisms raises questions of equity, as access may depend on geography or institutional budgets.

UMICs generally provide the greatest diversity of funding sources. Argentina stands out, with every major channel represented. China, Mexico, South Africa, and Turkey also demonstrate multiple options, though the specific mix varies. Importantly, the presence of multiple funding mechanisms does not guarantee access.

> "In practice, smaller or less well-funded hospitals may not have the resources or administrative support needed to navigate the application process for unapproved medicines, despite formal regulations allowing access."
>
> **Physician, China**

These findings suggest that income level broadly predicts the range of available funding channels, but the practical reliability of those channels is inconsistent.

Section 4: Practical Implementation

Stakeholders reported import restrictions, local language labelling requirements, bureaucratic delays, and physician/institutional reluctance or lack of experience as logistical barriers when accessing pathways to unregistered medicines. Additionally, stakeholders in LICs and LMICs reported that the absence of reliable pathways and financial support often forces patients to resort to informal or illegal importation. This reliance on unregulated channels carries risks for patient safety and underscores the inadequacy of existing systems in meeting urgent medical needs.

> "The urgency of a patient's medical need often clashes with the pace of administrative review. The regulation exists on paper, but dissemination and operational understanding are weak. Moreover, due to the barriers of the formal system, a significant informal market exists."
>
> **Pharmacist, Ethiopia**

Conclusion

The existence of pathways to access unregistered medicines across the low- and middle-income countries assessed indicates a clear need to improve access to innovative and life-saving medicines in countries that may be deprioritised within global launch programmes for new medicines. Where pathways exist without sustainable financial backing, patients continue to face significant barriers, reinforcing inequities between countries, with logistical barriers confounding these issues. It is imperative for governing bodies and manufacturers to engage in joint efforts to ensure patients have access to these vital treatments.

Scan for abbreviations and reference list