



UNLOCKING GLOBAL HEALTH

Strengthening Availability of Essential Medicines by Enhancing Healthcare Financing and Reducing Supply Chain Costs

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LIST OF ABBREVIATIONS

API	Active pharmaceutical ingredient
ARV	Antiretroviral
CLs	Compulsory licenses
CTs	Clinical trials
DRA	Drug regulatory agency
EML	Essential medicines list
EU	European Union
FDI	Foreign direct investment
GMP	Good Manufacturing Practice
HAI	Health Action International
HIV/AIDS	Human immunodeficiency virus/Acquired immunodeficiency syndrome
IP	Intellectual property
IPRs	Intellectual property rights
LIC	Low-income country
LMICs	Low and middle-income countries
LDC	Least developed country
MIC	Middle-income country
NGO	Non-governmental organization
OOP	Out-of-pocket
R&D	Research and development
UN	United Nations
US	United States
VAT	Value added tax
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization



EXECUTIVE SUMMARY

Lack of equitable and consistent access to essential medicines represents one of the most pressing global health challenges of our time. Despite major economic and technological advances over the past decades, significant discrepancies continue to exist among low and middle-income countries (LMICs) in access to, and availability of, even the most basic medicines, particularly through the public sector.

Availability refers to the supply of essential medicines in medicinal outlets in a given country; it is one factor affecting ability to actually access medicines, though not the only one (other factors include affordability to patients and awareness of available medicines).ⁱ Though definitions vary “essential medicines” are generally regarded as those that address fundamental health care needs of the world’s population, including in relation to communicable and non-communicable diseases. The large majority of the medicines identified as essential by the WHO may be made available as generics in most countries.ⁱⁱ

Recognizing this critical gap, major efforts are underway globally to improve conditions among LMICs for achieving a basic level of access to, and as part of that availability of, medicines. One prominent example is the recent UN High-Level Panel on Access to Medicines, which issued its final report in 2016. Countries and regional organizations also invest in local initiatives and agendas aimed at specific areas of health care and pharmaceutical policy reform.

Broadly speaking a number of challenges affect availability of essential medicines in LMICs today. Indeed, a significant body of empirical literature identifies a wide range of policy-related, structural and environmental factors. Existing efforts often attempt to target a number of these factors or, alternatively, highly specific areas seen as “low hanging fruit”.

Nevertheless, very few studies provide broader insights into the relative importance or impact of a given barrier on availability compared to other barriers. For example, do certain factors, on average, play a larger role in availability of essential medicines when considering LMICs together?

Recognizing that many important factors feed into disparities in access to essential medicines, and that the “puzzle” of access will vary from country to country, it is crucial for policymakers and stakeholders to have a better understanding of where resources can be allocated most efficiently in order to optimize efforts and enable greater availability, and in turn, wider access to essential medicines for their populations.

This study seeks to help fill this gap by creating a global analysis of the relative importance of a range of barriers to one critical component of access – availability of essential medicines – using two methods: 1) a statistical analysis of the relative impact of a range of policy-related variables on availability of essential medicines in around 50 LMICs; and 2) a case study analysis that examines the challenges and impact on the ground of key variables identified in the first component in a sample of LMICs. Within the statistical analysis, multivariate regression and correlation analysis were performed (more details on the methodology employed can be found in section 1 and the Annex to the study). The purpose of the combined analysis is to identify the most substantial barriers to availability of essential medicines that may serve as a tool for maximizing national and international efforts to improve access.

Key Findings

As the figure below indicates, of over 20 barriers analyzed the most substantial barriers to availability of essential medicines surround two main areas:

- inadequate healthcare financing, as a proxy for the level of financial coverage and delivery of health services and interventions, including medicines; and
- imposing additional costs in the supply chain including tariffs and taxes on medicine (which are relayed to patients and medicines outlets).

In particular, the category displaying the strongest statistically significant relationship to availability of essential medicines is healthcare and medicines financing, with an R^2 of 0.62, suggesting that it explains over 60% of the variation in availability of essential medicines – in other words, has a strong impact on availability. Indicators of healthcare financing include the overall level of health spending in a country by all actors, public, private and other (measured here as a share of the total

economy) as well as a special focus on public sector spending, an area identified by different experts as particularly crucial for ensuring basic healthcare and drug coverage and delivery in LMICs.¹ In addition, the extent to which health spending is sufficient is captured by the level of out-of-pocket spending (OOP), which is one measure reflecting the potential for catastrophic household spending on health in a country.

Elements of the supply chain – particularly those impacting the cost of medicines – also demonstrate a particularly strong relationship to availability of essential medicines, with a R^2 of 0.52 (or an over 50% explanatory power for essential medicines availability). This category comprises import-related factors (tariffs and non-tariff barriers as well as customs procedures affecting both finished products and raw materials) and costs arising from, for instance, VAT and other duties on medicines. Looking at these variables' relationship with essential medicines availability on an individual basis, the level of tariffs and taxes on medicines display the most substantial statistical association (as measured by correlation analysis).

Top policy barriers to availability of essential medicines: Results of multivariate regression

Category	Variables included	R^2	p-value
Healthcare and medicines funding	<ul style="list-style-type: none"> • Public health expenditure (% of government expenditure) • Total health spending as % of GDP • Out-of-pocket expenditure as % of total health expenditure 	0.62	<0.001
Trade and supply chain (cost-related)	<ul style="list-style-type: none"> • Tariffs on medicinal products • Trade-weighted average applied tariff rate • VAT and other duties on medicines • Prevalence of non-tariff barriers • Burden of customs procedures 	0.52	<0.002
Healthcare workforce	<ul style="list-style-type: none"> • Physicians per 1,000 population • Pharmaceutical personnel per 1,000 population 	0.4	<0.005
Regulatory system	<ul style="list-style-type: none"> • Burden of government regulation • Wastefulness of government spending • Effectiveness of anti-corruption/antitrust policy 	0.35	<0.01
Distribution infrastructure	<ul style="list-style-type: none"> • Quality of airport infrastructure • Quality of road infrastructure • Quality of seaport infrastructure 	0.3	<0.022

Source: Pugatch Consilium analysis

The results indicate that where significant costs in the supply chain exist, including through high tariffs and VAT on medicines, one would expect to see a lower rate of availability of essential medicines. The same goes for countries allocating relatively low funding to health care and medicines. The reverse would also be expected: countries removing or lowering taxes and tariffs on medicines or introducing dedicated budgets and platforms for medicines delivery are likely to experience higher rates of essential medicines availability than before (all other factors being equal).

In addition to the statistical tests, case study analysis from several LMICs suggests that countries facing some of the most striking gaps in availability of essential medicines (each in their own way) are also characterized, among other elements, by an ongoing lack of prioritizing adequate resources for health and medicines as well as high tariffs, taxes and other mark-ups in the supply chain. While each country's specific situation varies, these areas remain insufficiently addressed or overlooked altogether, even where efforts aimed at resolving other perceived factors of access are taking place. At the same time, where countries – even least developed countries (LDCs) – have taken steps, however small, to build practical initiatives addressing these specific areas results are visible in terms of better health provision and wider availability of basic interventions relative to their peers.

Taken together, how can these results be interpreted and understood in light of improving availability of essential medicines?

Insight #1: Crucial barriers to affordability of essential medicines – namely inadequate healthcare financing and delivery and supply chain costs – are also top impediments to their availability

Both inadequate healthcare financing and supply chain costs reduce patients' ability to afford essential medicines in LMICs – an aspect of access that is distinct from availability. But as the study discusses, in many cases lack of affordability occurs in parallel with inadequate stocking or shortages of medicines, and both are driven by inadequate healthcare financing and supply chain costs. For

example, import tariffs, VAT and other duties on essential medicines not only affect the end price of a drug but also raise costs earlier in the supply chain, affecting medicine outlets or procurement entities' ability to purchase them and make them available to patients.

While tariffs, VAT and other duties affecting drug prices hinder availability of medicines from the supply side, a high share of OOP spending on health (including medicines) hinders availability from the demand side by limiting patients' ability to pay for needed treatments and driving additional costs. In turn, this leads to low uptake in LMICs (especially in poorer areas) and various knock-on effects, including potentially fewer resources allocated to essential medicines supply as a result. High OOP spending on health also impacts availability in that it may reflect weak healthcare coverage, including the existence of a system for identifying, purchasing and supplying essential medicines.

Given that a significant part of the discussion on access to medicines often revolves around affordability, these results also provide interesting insight into two variables among others that contributes to lack of affordability of generic and other essential drugs in many LMICs. These results shed light on two important areas that governments can focus their efforts on when seeking to improve availability of, and more widely access to, essential medicines.

In addition, the finding that one of the most significant barriers to availability of essential medicines is lack of basic universal health care and avoidance of catastrophic household spending on health aligns with a key target within Goal 3 of the United Nation's Sustainable Development Goals, which links health financing and coverage to access to essential medicines:

Achieve universal health care, including financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.²

Insight #2: Strengthening healthcare providers and the regulatory system also matter for availability of essential medicines

The study findings also suggest that an ample, skilled healthcare workforce and the removal of unnecessary administrative costs and regulatory barriers are important for securing greater availability of essential medicines. Though somewhat less than healthcare financing and supply chain elements, variables covering the availability of skilled health care providers display a significant effect and explanatory power for availability of essential drugs – of around 40%. The effectiveness and efficiency of the regulatory system also demonstrates a similar relationship to essential medicines availability, particularly when it comes to ensuring availability of high-quality essential medicines.

Insight #3: IP protection is not a barrier to availability of essential medicines

In contrast, the research finds that no statistical relationship exists between the level of intellectual property (IP) protection and the availability of essential medicines (in terms of generics). We calculate a correlation of 0.13 and a R^2 of nearly 0 between rates of essential medicines availability and the strength of IP rights (as measured by the Patent Rights Index and the US Chamber's International IP Index), suggesting that the latter does not explain the variance in availability of medicines in LMICs and that relaxing IP protection for medicines does not appear to have a statistical effect on the availability of essential medicines on the whole.

Global Lessons and Proposed Strategies for Improving Availability of Essential Medicines

Recognizing that every country faces its own unique set of conditions – macroeconomic, geographical, cultural, or other – what do the above findings suggest for LMICs, organizations and other partners at the front line of efforts to improve access to, and as part of that, availability of essential medicines? In a context of limited resources and acute needs, what should countries' strategic approach be to moving the needle in the availability of essential medicines

While this system will inherently and necessarily vary by country and situation, the following table outlines a number of international targets and best practices based on empirical literature and institutional guidance that policymakers and other partners may refer to when considering reforms.

It is also important to reiterate that there is no "silver bullet" for strengthening availability of essential medicines. The study results imply that where additional resources are available, areas such as improving infrastructure as well as distribution and delivery of medicines should be addressed in policy reform in partnership with international and philanthropic organizations and the private sector.

It is hoped that the findings of this study can further illuminate and aid in targeting the extensive efforts that are already taking place to improve access to essential medicines in LMICs. International, government and civil society discussions about access to essential medicines should explore how to integrate these findings into existing work on introducing universal health coverage and reducing duties for medicines in LMICs, both at an international and national level. There is also need for further understanding how these priorities can be applied in a given country and what they mean for allocation of resources, problem-solving and generation of additional country-specific data and insights.

International targets and best practices for addressing key barriers to availability of essential medicines: Guide for action

Recommended quantitative targets for LMICs	Recommended best practices
Health and medicines financing	
<p>Total expenditure on health At least 4-5% of GDP³</p> <p>Public expenditure on health</p> <ul style="list-style-type: none"> • 8-15% of total government expenditure (WHO⁴, Abuja Declaration⁵) • At least 5-6% of GDP (WHO⁶) • US\$86 per capita (in 2012 terms)⁷ <p>Out-of-pocket expenditure Less than 15-20% of total health expenditure⁸</p>	<p>Dedicate/secure a sufficient level of funding in line with international targets with the aim of establishing basic universal health coverage</p> <ul style="list-style-type: none"> • Should involve creation of a type of pool of funds (prepaid for LICs, with small amount of user fees for MICs) covering primary health services and medicines⁹ • Sources and mechanisms may vary (e.g. government revenues, social contributions, private insurance, philanthropic, etc) but government should play an important role in LMICs in order to minimize reliance on OOP spending¹⁰ <p>Allocate funding efficiently in the management and delivery of health services and interventions (including medicines)</p> <ul style="list-style-type: none"> • In LMICs the onus is on governments to put in place an effective system and infrastructure • Payments should be structured to different levels of care and providers in line with domestic needs and should incentivize efficient use of resources¹¹ • Exact health care delivery mechanisms (whether public, private or philanthropic health and medicines outlets) inherently vary by domestic needs and capacity • Aim is to secure effective coverage and minimize household financial risk <p>Within the wider health system, establish a dedicated system, infrastructure and technical capacity for funding and delivery of medicines, including:</p> <ul style="list-style-type: none"> • Clear and up-to-date framework for identifying essential medicines as a guide for procurement, stocking and use of medicines¹² • Ensure application by all relevant institutional actors
Trade and supply chain barriers	
<p>Tariffs on medicines None (medicines exempted)¹³</p> <p>VAT and other duties on medicines Minimal to none (medicines exempted)¹⁴</p>	<p>Tariffs and taxes on medicines should be minimized or eliminated altogether, particularly for essential medicines¹⁵</p> <ul style="list-style-type: none"> • Evidence suggests that both tariffs and taxes on medicines are inefficient (representing a tax on the poor and reducing productivity) and raise the price of medicines¹⁶ • Medicines-based tariff revenues should not merely be substituted by medicines-based taxes <p>Taxes on medicines may be minimized through, for instance:</p> <ul style="list-style-type: none"> • Shifting burden of taxation to other areas of the economy (such as unhealthy habits or areas that are more efficient over the long-term)¹⁷ • Balancing the tax regime such that medicines face a more equal tax burden compared to other sectors <p>Refrain from using trade and tax policies to boost domestic companies by levying high duties on, e.g., imported finished pharmaceutical products</p>
Healthcare workforce	
<p>Density of physicians, nurses & midwives 4.5 per 1,000 population¹⁸</p> <p>Density of pharmaceutical personnel ~0.85/1,000 population (estimated OECD average based on available data¹⁹)</p>	<p>Strengthen and intensify recruitment and training of local health care personnel through inter alia accreditation systems in line with international standards and ensuring course completion²⁰</p> <p>Enhance the distribution of healthcare personnel in line with current and future country-specific needs²¹</p> <p>Ensure healthcare workforce supply covers a diverse range of relevant skills (including up-to-date medicines delivery) within the wider umbrella of primary and preventative care²²</p>
Regulatory system	
<p>NA</p>	<p>Harmonize regulatory standards governing the quality, safety and efficacy of medicines in line with international norms including ICH and WHO good practices²³</p> <p>Ensure regulatory frameworks governing medicines are clear, consistent and efficient and that decision-making takes place in a transparent manner and on a sound legal basis²⁴</p> <p>Enhance international cooperation in order to promote the timely entry of drug and vaccine products to the market</p>



INTRODUCTION – MAXIMIZING EFFORTS TO STRENGTHEN GLOBAL ACCESS TO ESSENTIAL MEDICINES: THE NEED FOR AN EMPIRICAL BASIS

Lack of equitable and consistent access to essential medicines represents one of the most pressing global health challenges of our time. Though definitions vary “essential medicines” are generally regarded as those that address fundamental health care needs of the world’s population, including in relation to communicable and non-communicable diseases.

According to the World Health Organization, “[e]ssential 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 at a price the individual and the community can afford”.²⁵ The large majority of the medicines identified as essential by the WHO maybe made available as generics in most countries.²⁶

Yet, despite major economic and technological advances across the world over the past decades, significant discrepancies continue to exist among low and middle-income countries (LMICs) in availability of even the most basic medicines,

particularly through the public sector.²⁷ All told, according to some estimates about a third of people globally do not have access to essential medicines, with much higher rates among the poorest countries.²⁸ While various facets of access exist (including affordability and patient awareness), a significant contributor to lack of access is lack of availability or supply of these medicines in medicines outlets in a given country.²⁹ Of medicines considered to be essential in most countries, on average only about 40% are estimated to be available through public sector outlets in LMICs, though this figure can range between around 20% and 80% depending on the country.³⁰

Recognizing this critical gap, international organizations, aid partners and academics have focused extensively on considering different policy approaches aimed at effectively closing the gap among LMICs. For example the recent UN High Level Panel on Access to Medicines, including its final report issued in 2016, identified the urgent need to enable access to health technologies while at the same time promoting biomedical innovation for diseases predominantly affecting LMICs.³¹

As part of this and wider efforts over the past few decades, a number of factors have been identified and pursued as barriers to access to essential medicines.³² Cost of medicines to patients and other factors considered to be related represent one major focus of international organizations and academic research. Indeed, many LMICs today do not provide universal health coverage or another form of safety net for medicines reimbursement,



whether through the public or private sector. According to some estimates, up to 90% of medicines in LMICs are purchased out-of-pocket (OOP). At the same time, drug costs particularly in the private sector can be very high; in some cases cost of treatment to patients of common diseases such as hypertension and asthma can amount to nearly a month's salary.³³ In this context, the burden of OOP spending can result in millions of households incurring catastrophic payments and being pushed into poverty.³⁴

Beyond this, many other policy, structural and environmental factors are recognized as key barriers to access to essential medicines. A substantial body of research identifies a wide range of policy, structural and environmental factors that impede access to medicines in LMICs.³⁵ These include:

- Limited access to health care and necessary infrastructure and technologies;
- Inadequate financing and unaffordable prices;
- Gaps in procurement and supply chain frameworks;
- Regulatory deficiencies; and
- Lack of awareness of opportunities to obtain care and socio-cultural obstacles.³⁶

While the empirical literature has explored in depth these and other barriers in different contexts, very few studies provide broader insights into the relative importance or impact of a given barrier on access to and availability of essential medicines vis-à-vis other barriers. For example, do certain factors on average play a larger role in availability of essential medicines when considering a range of countries? Recognizing that many important factors feed into disparities in access to essential medicines, and that the "puzzle" of access will vary from country to country, it is crucial for policymakers and stakeholders to have a better understanding of where resources can be allocated most efficiently in order to optimize efforts and enable wider access to essential medicines for their populations.

This study seeks to help fill this gap by creating a global analysis of the relative importance of different barriers to one critical component of access – availability of essential medicines – using two methods: 1) a statistical analysis of the relative impact of 20+ policy-related variables within the pharmaceutical value chain on availability of essential medicines; followed by 2) a case study analysis that examines the challenges and impact of key variables on the ground in a range of LMICs. Within the statistical analysis, multivariate regression and correlation analysis were performed (more details on the methodology employed can be found in section 1 and the Annex to the study). The purpose of the combined analysis is to identify the most substantial barriers to availability of essential medicines that may serve as a tool for maximizing national and international efforts to improve access.

The remainder of the report is organized as follows. The first section provides a brief overview of the scope of the analysis and a stepwise description of the study's methodology. The second section details the findings of the quantitative analysis, highlighting the five most substantial barriers to medicines availability identified in the analysis. The third section complements the statistical analysis with case study and anecdotal evidence on the extent and impact of these barriers on actual levels of availability of essential medicines in a number of LMICs. The final section draws on the above analysis to synthesize global policy insights on best leveraging today's efforts and resources aimed at strengthening access to and availability of essential medicines in LMICs.





1

STUDY METHODOLOGY

In order to establish an empirical basis for identifying the most substantial barriers to availability of essential medicines globally, this study employs two main analytical tools: 1) a statistical, cross-country analysis of how strongly different policy-related factors relate to levels of availability of essential medicines in LMICs; and 2) a set of case studies of select LMICs.

In the first, correlation and regression analysis are used to examine the strength of the relationship between an established measure of essential medicines availability in 50 LMICs and a set of 20+ indicators that seek to capture the main elements of the pharmaceutical value chain and are identified in the empirical literature as key barriers. This section will outline in brief the methodological approach taken in the statistical analysis. Further details on the methodology employed is also provided in the Annex to this study.

1.1 Measuring access to essential medicines

One of the most well established measures of availability of essential medicines – and one of the only, if not the only, cross-country measures – is generated from the WHO/Health Action International (HAI)'s Medicine Prices, Availability, Affordability and Price Components Database.³⁷ The WHO/HAI data is based on national or sub-national surveys (of major urban zones or regions) of public sector pharmacies and other medicines outlets concerning availability/stock of a selection of medicines (usually between 30 and 50) from the WHO's Essential Medicines List.³⁸

Specifically, this study employs the WHO/HAI data on the average availability of the lowest priced generic (based on prices faced by patients) of the selected medicines among surveyed public sector outlets for the latest available year (data for most countries is within the range of 2008-2013).³⁹ Though data is also available on availability in private sector outlets for some countries, we focus on public sector outlets based on the assumption that these are the primary or minimum points of accessing essential medicines in most LMICs (or should be, if basic health care and medicines coverage were available).

In addition, it should be noted that our analysis looks at availability of the generic version(s) of the selected medicines as a proxy for essential medicines, based on the fact that the large majority of medicines on essential medicines lists today – including but not limited to the WHO's EML – are off-patent and therefore would be expected to be available in generic form. For instance, of the WHO's 29th (2015) Model List of Essential Medicines, which contains a little over 400 medicines, only 5-8% are estimated to be on-patent in developing countries.⁴⁰

1.2 Measuring potential barriers to access to medicines

Numerous factors across the pharmaceutical value chain – from manufacturing to dispensation and use – affect the availability of, and access to, essential medicines. These include different structural, resource, capacity and behavioral-related factors such as those related to:

- **Import and/or production:** the ability to import a medicine or produce it domestically and various associated costs and impact on the price of the medicine (including import tariffs on finished medicines as well as ingredients);⁴¹
- **The supply chain:** including adequate infrastructure and systems for distributing medicines across a country, particularly to rural areas. This can also include additional costs, such as different taxes and mark ups, that also affect the purchase price (which costs can sometimes exceed 100% of the price of the dispensed medicine and which can limit ability to supply and purchase the medicine);⁴²

- **Health care and medicines financing:** the existence of an insurance or other type of financing scheme that includes coverage of essential medicines for all populations in need and can absorb at least a portion of the institutional and patient costs of supplying and accessing essential medicines and associated costs.⁴³ This may include a system for purchasing essential medicines using these resources and supplying them in a timely manner through a formal platform that covers relevant populations;
- **The healthcare and pharmaceutical delivery system:** the availability of high quality and adequately funded hospitals, clinics and pharmacies with well trained health care providers and pharmacists, including in rural areas, for the prescription, dispensation and delivery of essential medicines and ongoing treatment;⁴⁴
- **The regulatory system:** an efficient and effective framework for governing the healthcare system as well as the pharmaceutical supply chain, including ensuring the quality, safety and efficacy of medicines available in a country and protecting against anti-competitive practices in the supply of medicines; and
- **Patient awareness and uptake of medicines:** the level of cultural acceptance of medicines and awareness of their role in health and the extent to which dedicated programs exist for education and awareness raising.⁴⁵

The list is certainly not exhaustive but represents many of the key factors of availability of (and more widely, access to) essential medicines identified by other studies today.⁴⁶ Table 1 lists the 21 independent variables examined in relationship to the availability of medicines indicator:⁴⁷

It is worth noting that while there are no doubt various factors affecting a country's structural and financial capacity to supply essential medicines and the eventual rate of uptake – including level of development, income, geography, etc. – this study mainly focuses on policy-related factors, or on the policy-related aspects of these factors. Indeed, most of the indicators tested in this analysis may be directly or indirectly shaped by policy choices as vehicles for improving conditions for availability of essential medicines and health care generally.

1.3 Statistical analysis used

To measure the impact of the independent variables on the availability of essential medicines the study uses a combination of Pearson correlation and multivariate linear regression tests. Correlations were performed on each individual indicator identified in Table 1. For the multivariate regression tests the indicators were grouped by theme in order to measure the aggregate effect of key policy areas on availability of essential medicines. All tests were performed under a confidence level of 0.95 (a p-value of less than 0.05) and validated using standard tests.⁴⁸



TABLE 1 20+ potential barriers to access to medicines

Category	Indicator	Source
Taxes, tariffs and related trade barriers	Tariffs on medicinal products	WTO ⁴⁹
	Trade-weighted average applied tariff rate	Global Competitiveness Report (GCR)/ Executive Opinion Survey ⁵⁰
	VAT and other duties on medicines	WHO ⁵¹
	Burden of customs procedures	GCR/Executive Opinion Survey
	Prevalence of non-tariff barriers	GCR/Executive Opinion Survey
Import and distribution systems	Quality of airport infrastructure	GCR/Executive Opinion Survey
	Quality of road infrastructure	GCR/Executive Opinion Survey
	Quality of seaport infrastructure	GCR/Executive Opinion Survey
Healthcare and medicines financing	Health expenditure, public (% of government expenditure)	World Bank Databank
	Total health expenditure as % of GDP	World Bank Databank
	Out-of-pocket expenditure as % of total health expenditure	World Bank Databank
Healthcare delivery: infrastructure and providers	Hospitals per 100,000 population	WHO Global Health Observatory
	Provincial hospitals per 100,000 population	WHO Global Health Observatory
	Physicians per 1,000 population	WHO Global Health Observatory
	Pharmaceutical personnel per 1,000 population	WHO Global Health Observatory
Effectiveness and efficiency of the regulatory system	Burden of government regulation	GCR/Executive Opinion Survey
	Effectiveness of anti-monopoly/ antitrust policy	GCR/Executive Opinion Survey
	Wastefulness of government spending	GCR/Executive Opinion Survey
Intellectual property protection	Strength of life sciences IP protection	US Chamber International IP Index/ Ginarte-Park Index ⁵²
Preventative health programs	Testing and counseling facilities, est. no. per 100,000 adult population	WHO Global Health Observatory
	Existence of health operational policy/ action plans	WHO Global Health Observatory ⁵³



2

KEY FINDINGS: IDENTIFYING TOP BARRIERS TO ESSENTIAL MEDICINES AVAILABILITY

This section presents the results of the two tiers of statistical analysis explored in this study.

2.1 Results of the correlation analysis: Identifying the top five factors most closely related to availability of essential medicines

As Table 2 details, of the 20+ potential barriers tested, twelve were found to have statistical

significance, with four correlations suggesting relationships of moderate strength (in yellow) and six correlations (in green) suggesting a strong linear connection between the indicators and availability of essential medicines.

TABLE 2 Results of the Pearson Correlation test: Top barriers to availability of essential medicines

Variable	Correlation	R ²	p-value
1 Public health spending	0.78	0.61	<0.01
2 Tariffs on medicines	-0.77	0.59	<0.01
3 General tariff rate	-0.69	0.48	<0.01
4 VAT/other duties on medicines	-0.65	0.42	<0.01
5 Out-of-pocket expenditure	-0.60	0.36	<0.01
6 Health spending % of GDP	0.60	0.36	<0.01
7 No. of physicians	0.55	0.30	<0.01
8 Burden of government regulation	0.45	0.20	<0.01
9 Anti-monopoly policy	0.44	0.19	<0.01
10 Burden of customs procedures	0.43	0.18	<0.01
11 Efficiency of gov't spending	0.36	0.13	<0.05
12 Airport infrastructure	0.34	0.12	<0.05
13 Testing/counseling facilities	0.33	0.11	>0.05
14 Health operational policy	0.32	0.10	>0.05
15 Non-tariff barriers	0.31	0.10	>0.05
16 Road infrastructure	0.31	0.10	>0.05
17 Seaport infrastructure	0.27	0.07	>0.05
18 Hospitals	0.27	0.10	>0.05
19 Pharmaceutical personnel	-0.19	0.04	>0.05
20 Life sciences IP protection	0.13	0.02	>0.05
21 Provincial hospitals	0.11	0.07	>0.05

Strength of the relationship with availability of essential medicines

Strong Moderate Weak Very weak

The factors exhibiting the closest link to availability of essential medicines are described below, beginning with the five factors with the strongest relationship (starting from the factor most closely linked):

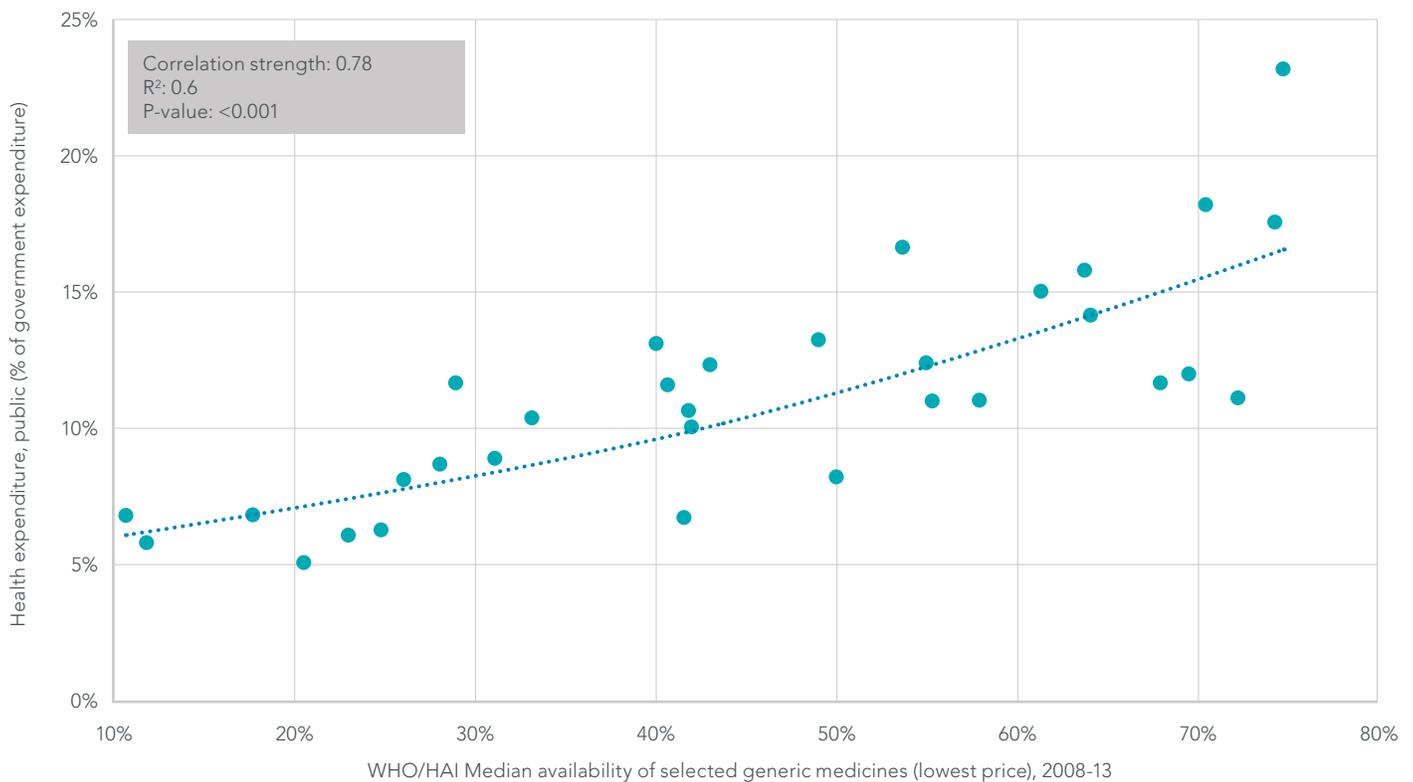
1. Level of healthcare financing and de-prioritization of health care in governments' budgets

The indicator that was found to have the strongest relationship to access to essential medicines is the share of spending on health of total government spending, as measured by the World Bank. This indicator represents all of the funds earmarked for maintaining or improving the health status of the population, provided by the central government and/or at state/regional/municipal levels.⁵⁴ As mentioned, given that universal health care systems and/or health "safety net" programs are typically financed in some degree by the public

sector where they exist in developing countries, the level of public spending on health provides a signal of the existence and scope of resources dedicated to providing basic health care, including essential medicines and vaccines, to all populations in need in a given country. With a correlation strength of 0.78, the share of health expenditure within public spending displays a relationship that is strong to "very strong". Indeed, an R-square value of 0.6 suggests that under that model spending on health explains about 60% - a high degree - of the variance in access to medicines.

This strong relationship suggests that patients in countries whose governments prioritize and provide dedicated resources for healthcare and medicines tend to have significantly higher availability of essential medicines. As is evident in Figure 1, countries whose annual public spending on health takes approximately 15% on average of the government's budget experience double

FIGURE 1 Association between availability of essential medicines and level of public expenditure on healthcare



Sources: WHO/HAI, 2017; The World Bank, 2017; analysis: Pugatch Consilium

the level of availability of essential medicines (65%-70% on average) compared to countries whose spending on health is 10% or lower of the annual budget (30% or lower rates of availability of essential medicines).

2. High tariffs on medicines and raw materials of pharmaceutical products

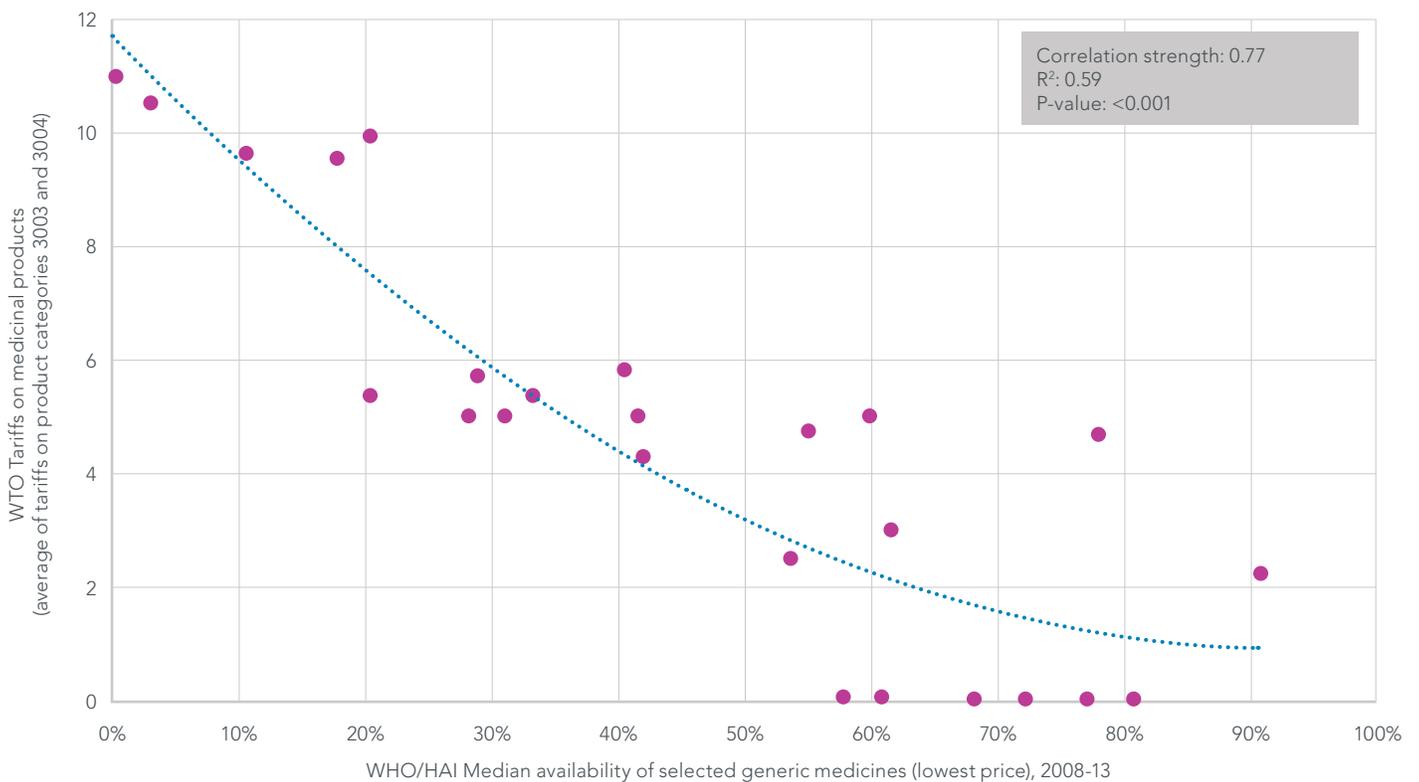
Tariffs on medicines have been found by empirical literature and international organizations to be of little value to patients and governments alike and, in fact, to generate negative outcomes. One comprehensive study covering more than 150 countries has found that tariffs on medicines generate less than 0.1% of the GDP in 92% of the countries.⁵⁵ A recent study found that high tariff rates on medicines in India (30%-35%) resulted in increases in drug prices yet generated less than 0.01% of India's GDP.⁵⁶ As noted by the WHO/HAI, taxes and other types of duties on medicines

“reduce utilization, particularly by the poor and elderly, and reduce compliance with cost-effective preventive and chronic disease treatment regimes”.⁵⁷ The WHO recommends that essential medicines should be exempt from taxation.

Despite the call for eliminating tariffs and other duties on essential medicines, as is evident in Figure 2, many LMICs still impose relatively high duties on imported medicinal products, whether as finished products or as raw materials for local production.⁵⁸ For instance, under the WTO's “Pharmaceutical Zero-for-Zero Initiative”, which was launched in 1995, nearly 10,000 drug products are today traded duty-free by 34 countries, with a total value of over USD50 billion, yet no LMICs are signatories to this initiative.⁵⁹

In fact, tariffs on medicines were found to be one of the strongest factors linked to and explaining gaps in availability of essential medicines. The

FIGURE 2 Association between availability of essential medicines and average tariff rate on pharmaceutical products⁶⁰



Source: WHO/HAI, 2017; WTO, 2017; analysis: Pugatch Consilium

correlation between the two variables showed a strength of -0.77, suggesting a strong, statistically significant relationship. The negative value indicates a reverse relationship: the higher the tariffs on medicines, the lower the rate of essential medicines availability. Furthermore, the correlation test yielded an R-square value of 0.59; as with public spending on health, this value indicates that the tariff rate applied to medicines has a strong explanatory power – in other words, a strong impact – on availability of essential medicines.

A relationship of similar strength was also found when analyzing the correlation between access to essential medicines and the trade-weighted average applied tariff rate (as measured by the

World Economic Forum’s Executive Opinion Survey, 2016-17), which showed a correlation strength of -0.69, suggesting a strong, statistically significant reverse relationship as well, when accounting for volume of trade. (In the final results, this indicator is subsumed into the medicines tariffs indicator, given the similarity in their relationship to essential medicines availability.)

Looking more closely at Figure 2, the picture is clear: many of the sampled countries with the weakest availability of essential medicines are also those with the highest tariffs on medicines. The majority of the countries that impose tariffs on medicines of 4% and above experience essential medicines availability rates of 40% or less, while the few countries that impose significantly high tariffs on medicines – over 8% ad valorem duty – experience the lowest availability rates (20% or less). In contrast, countries that impose a reduced tariff rate or that have eliminated tariffs for medicines entirely tend to experience relatively higher rates of availability of essential medicines – 60% and more.

3. High Value-Added Tax (VAT) and additional duties on medicines

On top of duties on imported goods, VAT applied within a country is an additional regressive duty whose impact on access to and availability of medicines is twofold. First, it has been shown to result in direct price increases of 30%-45% of the retail price along with tariffs and additional duties.⁶¹ Second, its regressive form places a heavier burden on the poor – populations lacking essential medicines the most – by requiring a larger share of their income.⁶² These factors may feed into availability of essential medicines in a number of ways: to the extent duties affect medicines outlets or procurement entities they can make essential drugs too costly for outlets to purchase; and more indirectly, higher drug costs limit patient demand, leading to reduced stocking of these medicines. For these reasons numerous developed and developing countries have lowered or eliminated duties on all or on some medicines, such as prescription or reimbursed medicines. For example, of 30 European countries with a VAT regime in place, 26 apply either a reduced VAT rate or provide a full exemption to medicines.⁶³



TABLE 3 VAT and additional duties on medicines, selected countries

Country	VAT on medicines	Additional duties*	Total taxes on medicines
Ethiopia	0%		0%
Kenya	0%		0%
Mali	8%		8%
Indonesia	10%		10%
Bolivia	13%		13%
South Africa	14%		14%
Ghana	15%	National Insurance levy	15%
DR Congo	0%	17% turnover + additional taxes	17%
Congo	18%	1% community tax	19%
Mongolia	15%	6% stamp duty and other fees	21%
India	5%	3% educational tax + 5%-16% state excise duties	24%
China	17%	3% regional sales tax	29%
Brazil	18%	6% state tax + 3%-10% sales & services tax + social contributions in certain states	34%
Nigeria	5%	~30% "multiple tax regimes"	34%
Peru	12%	19% goods & services tax + 2% local tax	34%

Sources: WHO, Guideline on Country Pharmaceutical Pricing Policies, 2015; WHO, Value Added Taxes (VAT) on health services and medicines, 2015; analysis: Pugatch Consilium

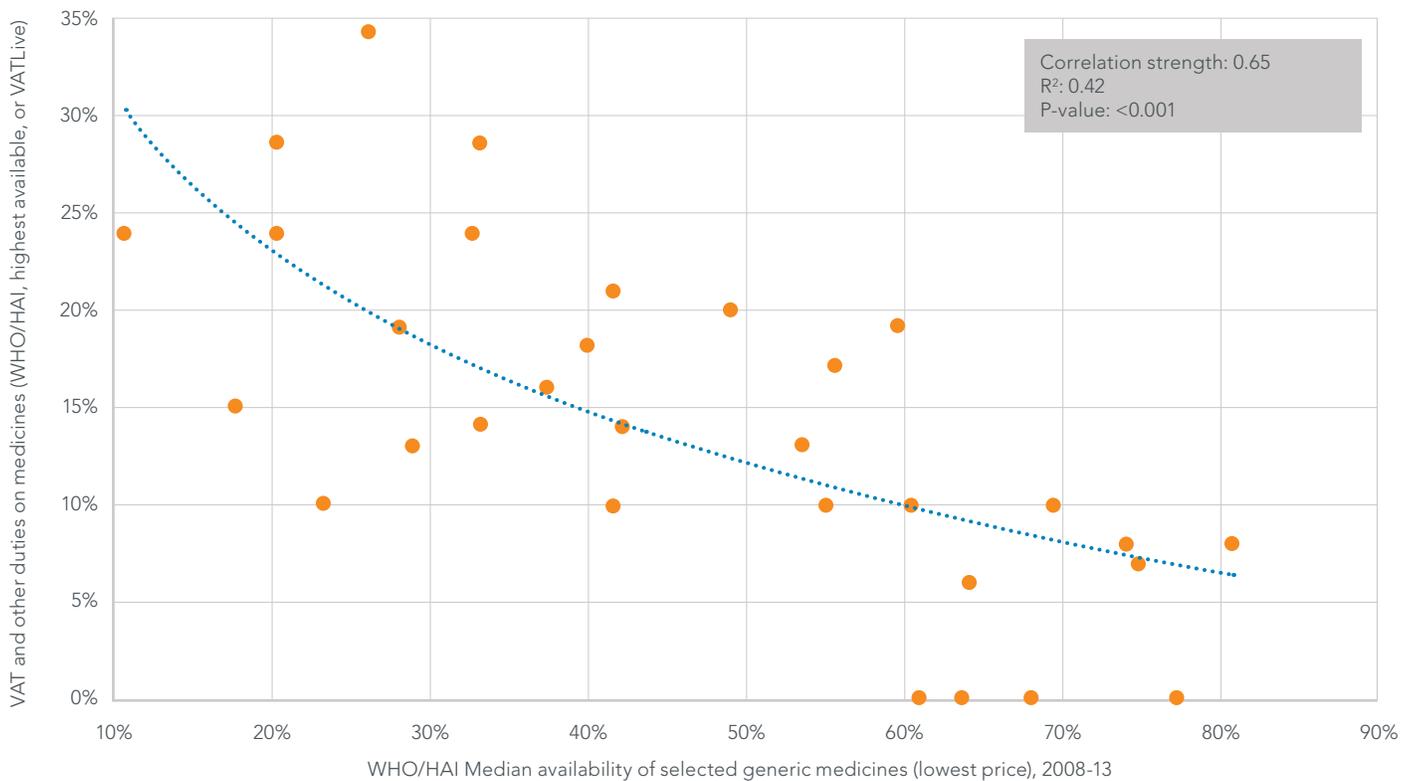
* Does not include import tariffs

However, these same exemptions often do not exist in LMICs, and at the same time VAT rates can be significantly high, as VAT is seen as an abundant source of revenue which does not require a great deal of effort in collecting it. Some countries also impose additional duties – such as state/community excise tax, stamp duty, sales tax or goods & services tax – which can result in a very high total tax rate, as much as 34% (such as in Brazil and Peru).⁶⁴ Table 3 provides a list of the VAT rates and additional duties on medicines in selected LMICs, based on several resources.

VAT and additional duties and their ballooning effect on drug prices (as described above) can represent an extreme burden for poor populations and for pharmacies/medicines outlets that would supply essential medicines. This is especially the case where patients are paying out-of-pocket and/or insufficient resources exist to allow pharmacies to purchase these medicines. Indeed, VAT and additional duties are strongly associated with

availability of essential medicines, displaying a statistically significant negative relationship of 0.65, with an R-square value of 0.42, suggesting that these additional costs explain approximately 40% of the variance in access to medicines. As is evident in Figure 3, a clear distinction exists in terms of availability of essential medicines between countries that impose high rates of tax on medicines of 20% and above and those that impose either reduced taxes or exempt medicines from taxes entirely. A stepwise relationship is particularly evident in this correlation, whereby countries imposing an average of around 20% taxes on medicines experience very poor rates of availability of medicines, compared to countries that impose lower taxes of around 15% and ~5%, which on average tend to experience availability rates of 50% and 70%, respectively.

FIGURE 3 Association between availability of essential medicines and rates of VAT and additional duties



Source: WHO, Guideline on Country Pharmaceutical Pricing Policies, 2015; WHO, Value Added Taxes (VAT) on health services and medicines, 2015; analysis: Pugatch Consilium

4. High out-of-pocket spending on health and medicines

The requirement to pay out-of-pocket (OOP) for medicines also represents a central barrier to access to and availability of medicines for billions of people living in poverty. While tariffs, VAT and other duties affecting drug prices hinder access from the supply side, a high share of OOP spending on health (including medicines) hinders access to medicines from the demand side by limiting patients’ ability to pay for needed treatments and driving additional costs. An analysis of surveys of 86 countries revealed that as much as 13% of the households in some countries incur catastrophic payments due to high share OOP spending on health and medicines, and about 5% of households are pushed to poverty.⁶⁵ In turn, this leads to low uptake in LMICs (especially in poorer areas) and various knock-on effects, including potentially fewer resources allocated to essential

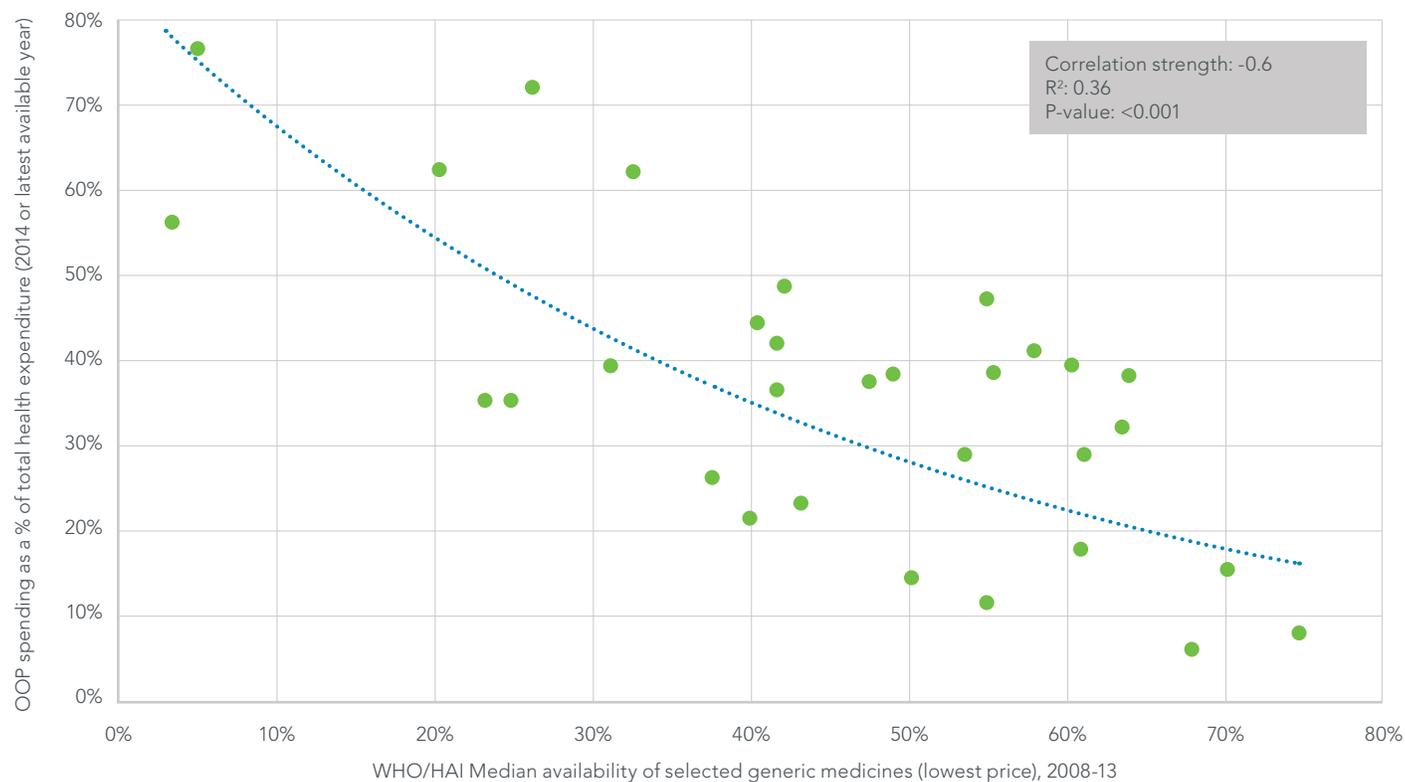
medicines supply as a result. Table 4 provides a comparative look at the most recent data on OOP spending rates in 20 selected countries.

The share of OOP expenditure shows a strong relationship to availability of medicines, with a correlation strength of -0.6, and an R-square value of 0.36, suggesting a negative relationship between the two variables where at least a third of the variance in access to medicines is explained by the share of OOP spending. Figure 4 suggests that most of the countries that experience poor rates of availability of medicines are the countries in which the rate of OOP spending is at 60% or higher. In comparison, countries with relatively low share of OOP spending tend to provide their patients with twice as much access to essential medicines.

TABLE 4 Share of out-of-pocket expenditure as a percent of total health expenditure, selected countries (2014 or latest available year)

Country	OOP spending as a % of total expenditure on health	Country	OOP spending as a % of total expenditure on health
Kenya	26.1%	Mexico	44.0%
Peru	28.6%	Indonesia	46.9%
Ethiopia	32.3%	Iran	47.8%
Malaysia	35.3%	Ecuador	48.4%
Tunisia	37.7%	Pakistan	56.3%
DR Congo	38.8%	Morocco	58.4%
Burkina Faso	39.1%	India	62.4%
Chad	39.2%	Nigeria	71.7%
Uganda	41.0%	Yemen	76.4%
Mongolia	41.6%		

Source: The World Bank, 2017; analysis: Pugatch Consilium

FIGURE 4 Association between availability of essential medicines and out-of-pocket expenditure as a share of total health expenditure (2014 or latest available year)

Sources: WHO/HAI, 2017; The World Bank, 2017; analysis: Pugatch Consilium

5. Health care and medicines representing a small share of the total economy

Total health expenditure (public and private spending) as a share of GDP is an additional indicator for the breadth and robustness of healthcare systems. An under-financed healthcare system, whether from public or private resources, results in a lower budget for public medicines outlets which leads to insufficient supplies and poor availability rates of essential medicines. The share of health in the total economy is the fifth variable of those sampled in the study that displays a strong association with availability of essential medicines, with a correlation strength of 0.6. Adding to the share of public spending on health and the level of OOP spending, the strong relationship between access to medicines and the scope of healthcare systems further strengthens the understanding that it is critical for countries to allocate sufficient resources to health care

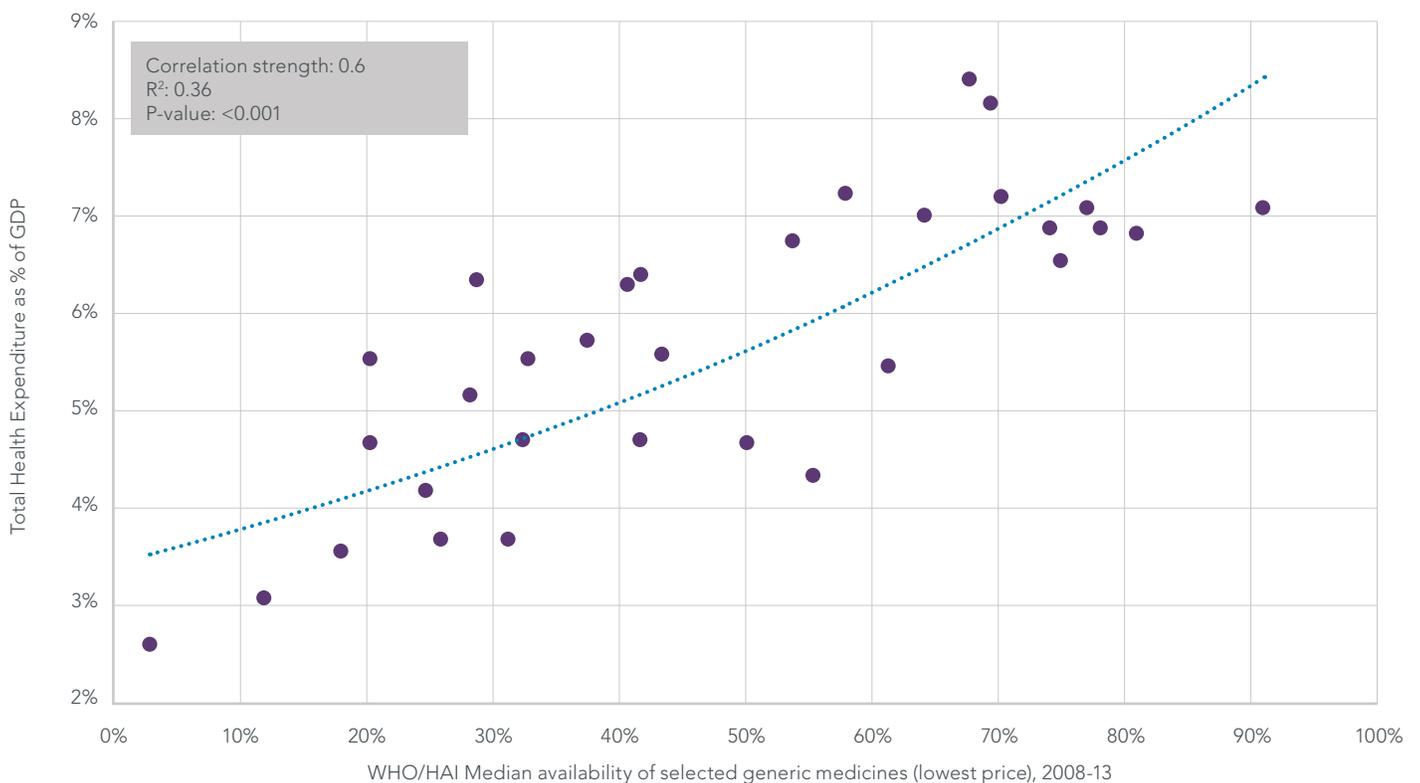
(including for medicines) in order provide their citizens with adequate access to basic medicines.

As seen in Figure 5, here too a clear linear relationship exists between the two variables, where countries whose total health spending accounts for ~7% or more of the GDP tend to experience substantially better rates, of 60% and more, of availability of essential medicines, compared with countries whose total health spending accounts for 6% of the GDP and less, which provide their populations with only 20%-40% of availability of essential medicines.

Additional barriers to availability of essential medicines

Although the study indicates that the five factors discussed above represent the most substantial barriers to availability of essential medicines, this is not to say that the other sampled factors are

FIGURE 5 Association between availability of essential medicines and total expenditure on health (as a share of GDP)



Source: The World Bank, 2017; analysis: Pugatch Consilium



not also important to address. In fact, as Table 2 outlines a number of indicators display moderately strong relationships with availability of essential medicines.

Volume of physicians, correlation strength: 0.55

A statistically significant relationship, just below the threshold of ‘strong’, and with an R-square value of 0.3, suggesting that the lack of physicians and other health care providers, who are crucial conduits for medical consultation and drug prescription as well as raising patient awareness to needed treatment, is an additional barrier to availability of essential medicines.

Burden of government regulation, correlation strength: 0.45

Burdensome requirements of the public administration (such as compliance with non safety related regulations, permits and reporting) can add substantial costs to the supply of medicines, and have an indirect effect on prices.

Effectiveness of anti-competition/antitrust policy, correlation strength: 0.44

Countries lacking a framework that provides for fair competition in the pharmaceutical value chain and in the health care system (and in turn, may see unethical business practices and high rates of corruption) tend to experience lower rates of availability of essential medicines.

Burden of customs procedures, correlation strength: 0.43

In addition to the added costs incurred from tariffs, duties and taxes, the burden of red tape around customs procedures, delays in clearance and overall inefficiency of the customs system (and associated costs) display a negative relationship with actual availability of medicines in pharmaceutical outlets.⁶⁶

2.2 Results of the multivariate regression tests: Measuring the amassed effect of wider policy areas on availability of essential medicines

In order to confirm these results and, given that the factors showing the strongest relationship with availability of essential medicines fall within two wider policy areas – namely 1) taxes and tariffs; and 2) healthcare and medicines financing – the second tier of this analysis uses multivariate regression to measure their amassed effect on access. Specifically, these tests were performed on policy areas (based on the categories in Table 1) with variables showing moderate to strong correlation to availability of essential medicines.

Table 5 describes the results of the multivariate regression tests for each category, including the variables tested in aggregate, the P-value (statistical significance), and the coefficient of determination (expressed as the R²).

TABLE 5 Results of multivariate regression tests on correlated policy areas

Category	Variables included	R ²	p-value
Healthcare and medicines funding	<ul style="list-style-type: none"> Public health expenditure (% of government expenditure) Total health spending as % of GDP Out-of-pocket expenditure as % of total health expenditure 	0.62	<0.001
Trade and supply chain (cost-related)	<ul style="list-style-type: none"> Tariffs on medicinal products Trade-weighted average applied tariff rate VAT and other duties on medicines Prevalence of non-tariff barriers Burden of customs procedures 	0.52	<0.002
Healthcare workforce	<ul style="list-style-type: none"> Physicians per 1,000 population Pharmaceutical personnel per 1,000 population 	0.4	<0.005
Regulatory system	<ul style="list-style-type: none"> Burden of government regulation Wastefulness of government spending Effectiveness of anti-corruption/antitrust policy 	0.35	<0.01
Distribution infrastructure	<ul style="list-style-type: none"> Quality of airport infrastructure Quality of road infrastructure Quality of seaport infrastructure 	0.3	<0.022

Source: Pugatch Consilium analysis

These results reinforce the results from the correlation analysis and provide a number of insights into the wider policy implications in relation to access to essential medicines:

1. Underdeveloped or under-funded health care and medicines systems are a top barrier to availability of essential medicines

The level of healthcare and medicines financing shows the strongest relationship with access to medicines, explaining approximately 60% of the variance in availability of essential medicines in public sector outlets across LMICs. This result suggests that the most significant barrier to access to essential medicines is inadequate financing from governments for, at a minimum, basic health care and drug coverage, and lack of a private sector to fill in this gap. This then shifts the burden of costs to patients, significantly limiting access and driving further poverty, which contributes to perpetuating the cycle of low availability and access.

It goes without saying that these results can mean different things for different countries. For example, for middle-income countries with the means and platforms in place to channel greater resources into health and drug coverage these

results underscore the urgent need to prioritize financing for universal health care or another type of safety net that reaches to currently neglected populations and covers essential medicines. One often cited example (which will be developed further in the next section) is India: health care and medicines account for a relatively small share of India's economy, with a total health expenditure of only 4.7% of its GDP. In addition, the share of OOP spending on healthcare in India is among the highest in the world (62.4%), with about 75% of OOP spending used to purchase medicines.⁶⁷ This does not reflect instances where people opted to not purchase medicines due to lack of funds. In this context, despite being among the world's largest manufacturers of generic drugs, an estimated 50-80% of people in India lack access to essential medicines on a regular basis.⁶⁸

At the same time, for low-income countries, particularly least developed countries, these results point to the value of committing resources to establishing a tangible and effective basic health care and medicines coverage, potentially with international or philanthropic support. Funds are no doubt limited but what these results suggest is that directing available efforts and financing, including from the government, specifically to

country-wide platforms enabling free or low-cost coverage of a set of essential medicines should be top of the list for countries seeking to improve access to and availability of medicines.

2. Added costs through taxation, trade barriers and excessive red tape weigh heavily on essential medicines availability

The second policy area that was found to have the most significant impact on availability of essential medicines is the supply chain, which includes various tariffs and duties applicable to medicines, burden of customs procedures and additional national and sub-national taxation. A coefficient of determination of 0.52 indicates that under that model at least 50% of access to essential medicines is explained by the amassed effect of these policy-related barriers. The actual impact may even be higher, considering the fact that other costs that are added to drug prices (such as insurance and freight, banking fees, importers' mark-up, clearing charges, quality assurance, transportation and more)⁶⁹ were not included in the regression analysis.

Although a number of factors contribute to cost and affordability of medicines, these results provide interesting insight into factors that appear to be contributing heavily to high costs (or lack of affordability) of generic and other essential drugs in many LMICs. They shed light on where governments can focus their efforts, on top of dedicating resources to health and medicines coverage, when seeking to improve availability of essential medicines.

3. There is no silver bullet for improving availability of essential medicines; other areas remain important, particularly improving personnel and infrastructure for distribution/delivery and regulatory frameworks, where resources are available

Interestingly, while many of the variables tested showed weak to moderate relationships to availability of essential medicines when tested individually, when analyzing their aggregated impact – such as the total regulatory system or capacity for health care delivery – a strong and statistically significant relationship is visible. Above all, this finding suggests that, there is no “silver bullet” for improving availability of essential medicines, and while the areas discussed in the first two points display the closest link to availability of medicines, this does not mean that other factors are not empirically associated with availability of medicines. In fact, the results indicate that availability of healthcare providers and the effectiveness and efficiency of the regulatory system both can explain around or nearly 40% of essential medicines available – a very substantial portion. As a result, where additional resources are available, these areas should also be addressed in policy reform.

Patent protection and access to essential medicines: What it is and what it isn't

IP rights and patent protection have been and remain at the core of heated debates over their potentially detrimental effect on access to medicines and drug prices. For instance, the 2016 final report of the UN High-Level Panel on Access to Medicines makes the link between access to essential medicines and patents as a potential obstacle:

...[E]nsuring access to medicines, and particularly to essential medicines, is a fundamental elements of [State] obligations... On the one hand, governments seek the economic benefits of increased trade. On the other, the imperative to respect patents on health technologies could, in certain instances, create obstacles to the public health objectives of WTO Members.”⁷⁰

In addition, among the recommendations of the Panel is a call for all WTO members to “make full use of TRIPS flexibilities...to promote access to health technologies when necessary”.⁷¹

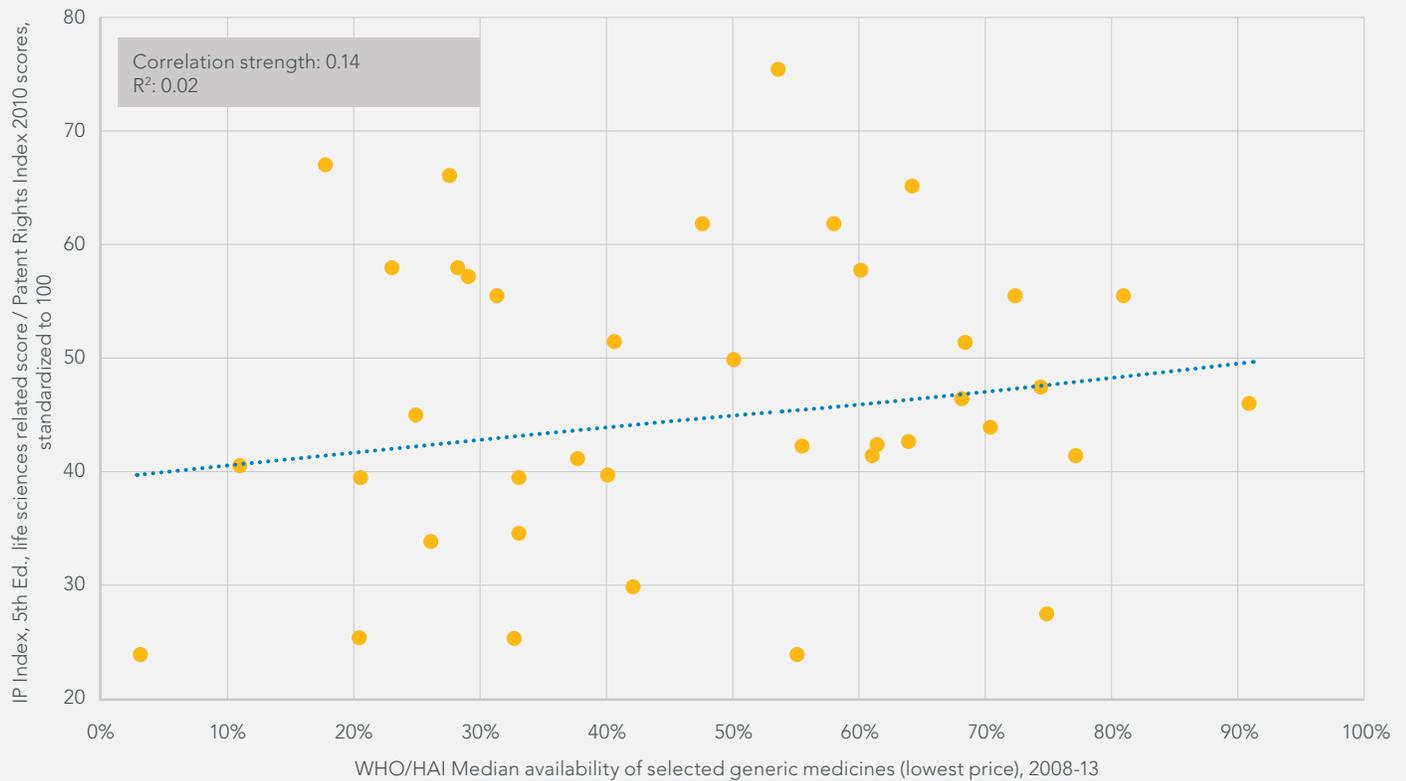
Given that, as mentioned, essential medicines lists – and particularly the WHO’s Model List of Essential Medicines⁷² – are comprised of medicines the majority of which are off-patent (up to 95% by WIPO estimates) it does not seem likely that patents are a main barrier to access to essential medicines today or have a significant impact on prices of most essential medicines. Indeed, the study has empirically identified other factors that are strongly statistically related to availability of essential medicines.

Still, it is worthwhile to examine whether there is a statistical relationship between the level of intellectual property (IP) protection (especially, where possible, of existing IP rights aimed specifically at life sciences) and availability of essential medicines globally. Do countries with less stringent levels of IP protection, including the use of so-called “TRIPS flexibilities” such as use of

compulsory licensing, tend to experience greater levels of availability of essential medicines?

Figure 6 displays the relationship between IP protection (as measured by the Patent Rights Index and the US Chamber’s International IP Index, where available)⁷³ and availability of essential medicines. As is clearly evident, IP protection displays nearly no relationship to availability of essential medicines, with a correlation of 0.13 and a coefficient of determination of nearly 0, indicating that patent and other IP protection do not explain the variance in availability of medicines. Indeed, a closer look at a sample of different LMICs with high variance in terms of rates of availability of essential medicines (depicted in Figure 7) also shows that the level of IP protection remains very low across these countries.

FIGURE 6 Association between availability of essential medicines and the level of IP protection

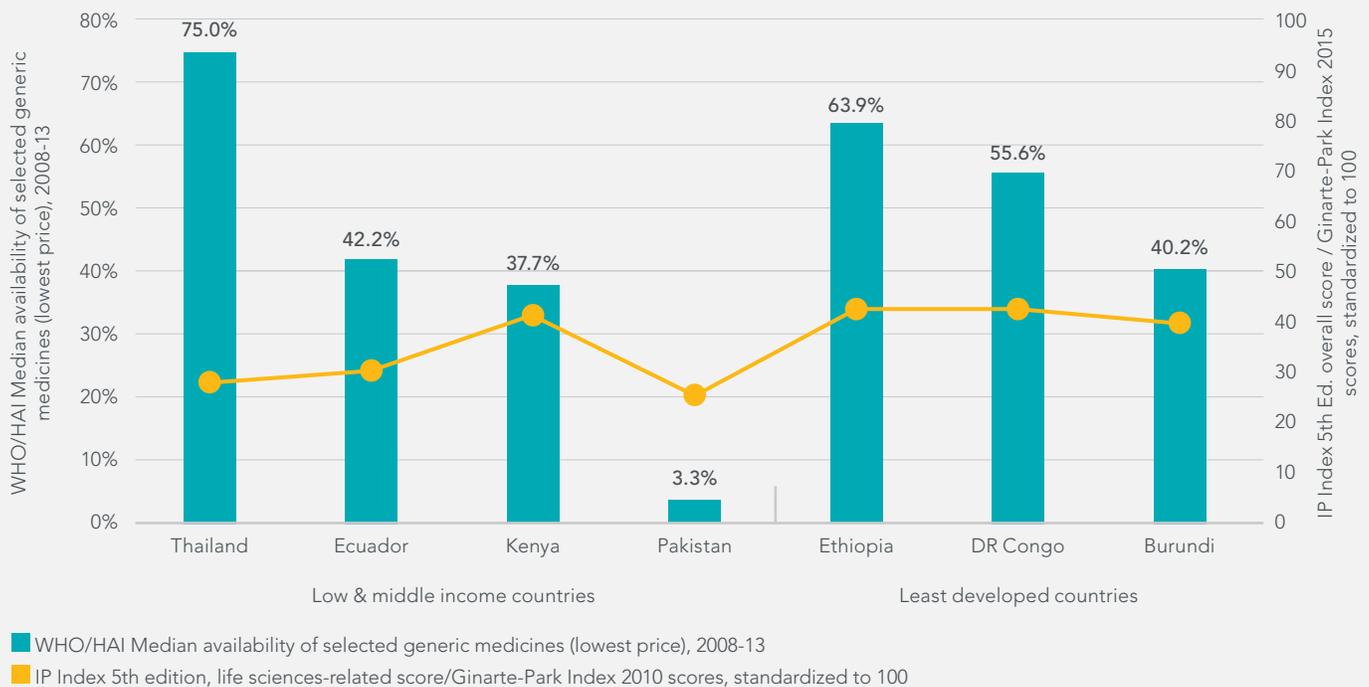


Source: US Chamber (2017); Park (2008/2010); analysis: Pugatch Consilium



Hence, relaxing patent protection and IP rights for life sciences more generally does not appear to have a statistical effect on or bear a relationship with availability of essential medicines empirically. Rather, these results and the wider results of the study suggest that the issue of IP protection is not relevant – or at least, not a top priority – for discussions on how to lower prices of essential medicines and truly strengthen availability and access to them in LMICs.

FIGURE 7 Association between availability of essential medicines and the level of IP protection, selected countries



Source: US Chamber (2017); Park (2008/2010); analysis: Pugatch Consilium



3 EVALUATING BARRIERS TO ESSENTIAL MEDICINES AVAILABILITY ON THE GROUND: CASE STUDIES OF SELECT LMICS

The previous section identified five factors that are most closely related to availability of essential medicines that fall under the umbrella of either lack of universal health and medicines coverage or high taxes and tariffs on medicines. This section will explore the real and practical challenge that inadequate financing for medicines and added costs in the supply chain pose for availability of, and more widely access to, essential medicines by looking at a number of case studies of LMICs that face these challenges. The countries examined reflect a sample of representative LMICs, including major middle-income countries and least developed countries.

3.1 Middle-income countries



Brazil

In Brazil, years of economic hardship and political turmoil have put a strain on the federal budget including funding for the healthcare system. Indeed, just in 2016 the budget for the country's Universal Health System (SUS) was cut by 10% and the Healthcare Minister himself acknowledged that the Government cannot fulfil its duty – enshrined in article 196 of the Constitution – to ensure health for the entire population.⁷⁴ This in itself has a major impact on medicines coverage, as medicines constitute the main item on Brazilians' health bill,⁷⁵ reaching close to 75% of the monthly healthcare expenditure for low-income patients.⁷⁶ In 2017 budget cuts have resulted in the closure of the national pharmacy program and its 393 federal pharmacies.⁷⁷

On top of ongoing cuts to the health and medicines budget, Brazil also has one of the highest and most complex tax regimes for medicines worldwide.⁷⁸ The average tax burden for drugs across all states is around 34%, which only rose further in 2016 following the decision by 12 states to increase the Tax on Sales and Services.⁷⁹ Recently, social contributions levied on the import of medicines were also raised by 4%.⁸⁰ This has had a strong negative effect on medicines prices in

Brazil, with more than a third of the price of drugs sold in pharmacies earmarked for or attributed to taxation. In comparison, the tax burden on veterinary products is only 13%.⁸¹ Although waivers on some taxes are available for the majority of drugs, their application is fragmented and delayed.⁸² The result is a highly complex and costly system, with more than 50 taxes, fees and contributions levied on drugs.⁸³

The lack of adequate resources for health and medicines coverage and delivery and the costs of the punitive tax environment – which has only heightened in the past several years – along with other factors⁸⁴ pose serious obstacles to the ability to supply and access essential medicines in Brazil. In primary health care facilities, local studies suggest that, on average, 40% of the medicines prescribed are not available when needed.⁸⁵ Another survey found that basic medicines like insulin were missing from half of public hospitals visited.⁸⁶ In state pharmacies, drug shortages are registered frequently for many diseases. In the Rio de Janeiro state, roughly 70,000 people have reportedly been affected by lack of treatments for chronic (as well as rare) diseases,⁸⁷ and nearly one in five listed drugs was noted as unavailable in recent surveys.⁸⁸ Similarly, in the state of São Paulo, 21,000 people fell short of key drugs to treat Hepatitis C, Alzheimers and cancer.⁸⁹ Faced with widespread shortages of essential medicines, patients have increasingly resorted to judicial measures to receive drugs through the National Health System.⁹⁰



India

As mentioned, India faces major gaps in access to essential medicines, particularly among poor and rural populations, despite having been known for many years as the “pharmacy of the developing world” for its world leading generics industry. Recent studies point to the chronically low level of government spending on health and the wider lack of resources dedicated to ensuring drugs produced in India are actually made available in public medicines outlets.⁹¹

The healthcare system is plagued by under-financing, with public spending on health at only 1.4% of GDP and per capita spending more than five times less than China.⁹² The Indian government covers only one third of healthcare costs, and the share further decreases when looking specifically at pharmaceuticals, where the government accounts for 7.2% of total spending.⁹³ Spending dedicated to essential medicines is therefore also limited, despite announced desire to improve availability of low-cost drugs. In addition, health insurance plans are currently limited to less than 20% of the population.⁹⁴ This is reflected in the high rate of OOP spending on medicines (at over 60%), one of the highest globally.⁹⁵ In addition, large variation in public spending on drugs is registered among states.⁹⁶

Gaps in drug funding are borne out on the ground. For instance, from 2011 to 2015 India provided only slightly more than half of the money committed for its tuberculosis program.⁹⁷ Without a practical safety net, the number of Indians falling into poverty because of healthcare costs remains stunningly high (around 7% of total population).⁹⁸ Roughly one in five Indians relies on borrowing to fund medical treatment.⁹⁹

In this context, any price increase is directly relayed to patients and further reduces their capacity to access treatment, including through the Indian taxation and tariff system for pharmaceuticals. Drugs in India are subject to 5% VAT and a 3% education tax, which add to state taxes ranging from 5% to 16%.¹⁰⁰ As a result, between 13 to 24%

of the retail price of drugs is attributable to taxes.¹⁰¹ With the unfolding of the Goods and Services Tax regime – a single-tax system across India to be implemented in 2017 – the total tax rate applicable to pharmaceuticals is expected to increase and result in prices rising by at least 4%.¹⁰² Furthermore, India’s import tariffs on medicines – with a levy of 10% across the board – are among the highest globally, including on vaccines.¹⁰³ Only five countries (including Nepal, Pakistan, DR Congo and Russia) are on record as applying a higher rate.¹⁰⁴

In spite of this already high charge for taxes and tariffs on medicines, in 2016 the Indian government increased the number of products subject to tariffs to 76 additional drugs – 47 of which are on India’s National List of Essential Medicines – including life-saving oncology and HIV treatments.¹⁰⁵ The measures, intended to protect local manufacturers and boost the “Make in India” initiative¹⁰⁶ could result in a further 10-25% increase of final prices.¹⁰⁷

This environment (compounded by other challenges like lack of infrastructure and a complex procurement system) completely undermines the potential India uniquely possesses to supply essential medicines across the country. Indeed, despite its substantial local pharmaceutical industry, shortages of essential drugs are registered regularly, including in public facilities responsible for supplying treatments to the poorest.¹⁰⁸ A recent study in the state of Chhattisgarh showed that only 58% of the generic medicines prescribed in public health facilities there were provided by the same public outlets, although the government committed to free provision of essential drugs.¹⁰⁹ Another survey carried out in districts of Maharashtra found that essential drugs like paracetamol and common antibiotics were insufficiently supplied in 75% of the primary health centers surveyed, and were not available in 13% of them.¹¹⁰ Similarly, in private pharmacies drug shortages are the norm. A recent study showed that availability of human insulin in Delhi’s private pharmacies was 44%, compared to a reported WHO availability target of 80%.¹¹¹ The more expensive, analogue insulin was available only in 13% of outlets.

Lack of drug availability hampers the effectiveness of the country’s free treatment programs, notably for HIV/AIDS.¹¹² Supply of anti-retroviral (ARV)



Indonesia

Similar to India, Indonesia is faced with a large population and under-budgeting for health care and medicines. The Indonesian government spends only 1.1% of the country's GDP on health care, less than India and among the lowest level worldwide.¹¹⁸ Indonesia is eager to expand its healthcare and insurance system to reach all of its citizens through the "Jaminan Kesehatan Nasional" (JKN) program, which set as a target for achieving universal healthcare by 2019 through its single payer health insurance system.¹¹⁹ Nevertheless, plagued by continued under-budgeting the Healthcare and Social Security Agency (BPJS) faces a soaring deficit that is expected to result in higher premiums and lower reimbursement levels than targeted.¹²⁰

In addition, although decreasing, out-of-pocket spending remains high, slightly less than half of total expenditure on health.¹²¹ Spending on medicines is reportedly the biggest driver of expenditure, even among the currently insured, partly linked to their lack of availability in the standard distribution network (see below discussion).¹²²

Moreover, despite a growing focus on developing the local generic sector, the Indonesian pharmaceutical market displays comparatively high drug prices.¹²³ Including generics, drug prices stand at above WHO modeling of international reference prices.¹²⁴ In a bid to offset high local drug prices, the Indonesian government is also encouraging the import of low-cost pharmaceutical products from other neighboring countries with potentially weaker quality controls, such as Bangladesh.¹²⁵

Notwithstanding the government's efforts, the lack of effective universal health care along with other factors (such as poor infrastructure and distribution channels) means that essential medicines supply remains inadequate in Indonesia. Only about half of the drugs on the WHO Model Essential Drug List are estimated to be readily available throughout the country (also due in part to the fact that the Indonesia EDL is smaller than the WHO

drugs by government-run hospitals has reportedly been patchy since 2013, even more so since 2015.¹¹³ In spite of the fact that free ARVs have been provided for since 2004, only 44% of eligible patients received ARV treatment in 2015.¹¹⁴ A recent IHS study mentions delays in approving tenders, inefficiency of the supply chain and late payment to manufacturers as the main problems affecting ARV availability.¹¹⁵

The just-launched National Health Policy contains ambitious plans to raise public health expenditure to 2.5% of GDP by 2025 and increase the spread of health insurance plans.¹¹⁶ In addition, recognizing the growing role of health costs in generating poverty, the Indian government has set a target for reducing incidence of catastrophic expenditure by 25%.¹¹⁷ Achieving the objectives of the National Health Policy and reconciling them with industrial ambitions will require a coherent approach across policies, recognizing for instance the punitive role of high taxes on drug access and availability, and the advantages of better drug availability for the local pharmaceutical sector.

list).¹²⁶ Even just considering the domestic EDL, a survey of 9,000 health centers found that 85% had less than 80% of the medicines on the national list in stock.¹²⁷ In addition, the country has the lowest coverage of malaria control interventions for at-risk persons (except Nepal) and the lowest estimated coverage of ARV therapy among people living with HIV (nearly 10% of the population), except Pakistan.¹²⁸ National coverage also rates below the global average with regard to vaccines.

3.2 Low-income countries

According to the WHO, inadequate availability of treatment and lack of medical personnel are the main reasons behind the persistently high mortality rate for diseases particularly affecting low-income countries such as HIV, malaria and tuberculosis.¹²⁹ At the same time, low spending on health and related challenges of high out-of-

pocket spending, limited infrastructure and trained medical staff are common across low-income countries. Furthermore, paradoxically, generic medicines are sold in LDCs at largely above international reference prices. A 2012 WHO study found that in the public sector generic medicines cost on average 250% more than the international reference price, and were available in less than only 40% of facilities.¹³⁰ Tariffs and multiple taxes along the supply chain are key factors attributed to these price discrepancies, for instance in Sub-Saharan Africa.¹³¹

The Democratic Republic of Congo is one least developed country that exhibits the challenges and implications of inadequate prioritization of health spending and draconian mark-ups in the supply chain quite poignantly. DR Congo has a very small healthcare budget (just about 3% of GDP on average over the past 15 years), and



this translates into few health facilities, faulty equipment and little to no health coverage for its citizens.¹³² Close to 50% of household expenditure is on health, with the majority of this devoted to medicines.¹³³ Moreover, high tariffs affecting medicines particularly inflate drug prices. DR Congo applies the highest average tariffs for pharmaceutical products worldwide, along with Nepal and Pakistan, and is one of few countries imposing tariffs on vaccines (and at a high rate of 10% at that).¹³⁴

In turn, and despite guidelines promoting access to essential medicines published in 2015 by the Ministry of Health,¹³⁵ severe gaps in availability remain in DR Congo. For instance, at present, less than 25% of those in need are reported to have access to ARV therapies.¹³⁶ Reportedly, hospitalized patients have to bring their own drugs and pay for essential materials such as syringes, gloves and needles.¹³⁷ In addition, the country remains particularly vulnerable to epidemics, with the international organization GAVI reporting that at least a third of healthcare centers have had to interrupt vaccination programs due to inadequate supplies and equipment.¹³⁸

Lack of funding and faulty infrastructure also undermine availability of medicines in Chad. Currently, no safety net is available for patients (though the government is considering creating universal health insurance).¹³⁹ According to a 2011 survey of medical facilities, lack of funding was the main reason behind the insufficient stock of essential pediatric medicines.¹⁴⁰ Only 43% of facilities had pediatric ARVs and just 21% had tuberculosis treatments. Also when available, drugs often do not reach patients due to lack of proper and timely distribution and affordability. Somewhat similar to DR Congo, Chad applies relatively high tariffs to pharmaceuticals, and notably also to vaccines (though, at 5% for both products, not as high as the rate applied in DR Congo).¹⁴¹

At the same time, there are also examples among low-income countries of governments taking steps towards committing greater resources to health care and medicines, introducing public health insurance systems, reducing out-of-pocket payments, and improving the drug supply chain. Burkina Faso, one of the poorest countries in

the world and one that continues to face many challenges in health care delivery and in securing better health outcomes, is nevertheless one illustrative case of how small steps can have visible impact on availability of essential medicines. Between 1990 and 2000 the country engaged in a lengthy reform of the health and pharmaceutical system amid wider economic reform. Among other steps, the government began redirecting increasing funds to health care and medicines and prioritizing these sectors, with the share of government spending on health of total public spending doubling between 1995 and 2005 from 9% to around 18% and leveling off around 15% (some of the highest rates among LDCs in Africa),¹⁴² which was then complemented by donor funding. In parallel to this process, a platform for centralized procurement of generic medicines, the Central Procurement Agency for Generic Essential Medicines, was created and endowed (it later became an independent, non-profit organization that is still funded by the Ministry of Health but aids in ensuring the funding stream is continuous).¹⁴³ This period also saw greater coverage for and establishing of basic health centers across the country, growth of health care providers and better availability of essential medicines and interventions.¹⁴⁴ According to one study from 2010, public sector pharmacies displayed on average a 73% rate of availability of 50 essential medicines, compared to a figure of about 40% on average across Africa.¹⁴⁵

Having said this, government funding for health and medicines has not necessarily been maintained over the past five years in Burkina Faso, with for instance the level of public spending on health falling down closer to 10% of government spending since 2012-13.¹⁴⁶ This trend is compounded by other factors, including mark-ups in the supply chain that mean that the actual price of medicines is often beyond the reach of patients and out-of-pocket spending remains relatively high at around 40% of total health expenditure.¹⁴⁷ Today, Burkina Faso again faces the challenge of committing greater resources to health and essential medicines, especially as part of implementation of its recently adopted Universal Health Insurance.¹⁴⁸



4

CONCLUSIONS AND STRATEGIES FOR IMPROVING ESSENTIAL MEDICINES AVAILABILITY

The key question this report has sought to address is: from a global perspective, which policy-related barriers to accessing essential medicines are most closely linked to access? What does statistical and case study analysis of the relationship between different barriers and one measure of access – availability of essential medicines – tell us about which areas of policy reform countries may want to prioritize when seeking to improve access?

Today, major efforts are underway globally to improve conditions among LMICs for achieving a basic level of access to, and as part of that availability of, medicines. Countries and regional organizations also invest in local initiatives and agendas aimed at specific areas of health care and pharmaceutical policy reform. It is widely recognized that there are a number of challenges and policy areas affecting availability of essential medicines in LMICs today. Indeed, a significant body of empirical literature identifies a wide range of policy, structural and environmental factors. Existing efforts often attempt to target a number of these factors or, alternatively, highly specific areas that are perceived as “low hanging fruit”.

What is often missing from these efforts globally is an empirical understanding of the relative importance or impact of different barriers on the availability of access essential medicines, including factors of supply and price. It goes without saying that a number of factors feed into the supply, affordability and actual accessibility of medicines, but for governments facing the real and urgent challenge of securing better access to basic medicines, addressing which of these factors is likely to yield the greatest and most tangible returns in terms of access?

This purpose of this report has been to help fill in this gap by using a combination of statistical and case study analysis of around 50 LMICs to identify the top barriers to one critical component of access – availability of essential medicines – from a universal perspective. Of over 20 barriers analyzed the most substantial barriers to availability of essential medicines surround two main areas:

- inadequate healthcare financing, as a proxy for the level of financial coverage of health services and interventions, including medicines; and
- imposing additional costs in the supply chain including tariffs and taxes on medicines (which are relayed to patients and medicines outlets).

One of the factors tested that displays a very low correlation and R^2 in relation to availability of essential medicines is the level of IP protection (as measured by the Patent Rights Index and the US Chamber’s International IP Index). A correlation of 0.13 and a R^2 of nearly 0 indicate that the strength of IP rights does not explain the variance in availability of medicines in LMICs and that relaxing IP protection for medicines does not appear to have a statistical effect on the availability of essential medicines.

In addition to the statistical tests, case study analysis from several LMICs suggests that countries facing some of the most striking gaps in availability of essential medicines (each in their own way) are also characterized by an ongoing lack of prioritizing adequate resources for health and medicines and high tariffs, taxes and other mark-ups in the supply chain. While each country faces its own unique set of circumstances, these areas remain insufficiently addressed or overlooked altogether, despite efforts to resolve other perceived factors of access taking place. At the same time, where countries, even LDCs, have taken steps, however small, to build practical initiatives addressing these specific areas they have seen results in terms of better health provision and wider availability of basic interventions.

TABLE 6 International targets and best practices for addressing key barriers to availability of essential medicines: Guide for action

Recommended quantitative targets for LMICs	Recommended best practices
Health and medicines financing	
<p>Total expenditure on health At least 4-5% of GDP¹⁴⁹</p> <p>Public expenditure on health</p> <ul style="list-style-type: none"> • 8-15% of total government expenditure (WHO¹⁵⁰, Abuja Declaration¹⁵¹) • At least 5-6% of GDP (WHO¹⁵²) • US\$86 per capita (in 2012 terms)¹⁵³ <p>Out-of-pocket expenditure Less than 15-20% of total health expenditure¹⁵⁴</p>	<p>Dedicate/secure a sufficient level of funding in line with international targets with the aim of establishing basic universal health coverage</p> <ul style="list-style-type: none"> • Should involve creation of a type of pool of funds (prepaid for LICs, with small amount of user fees for MICs) covering primary health services and medicines¹⁵⁵ • Sources and mechanisms may vary (e.g. government revenues, social contributions, private insurance, philanthropic, etc) but government should play an important role in LMICs in order to minimize reliance on OOP spending¹⁵⁶ <p>Allocate funding efficiently in the management and delivery of health services and interventions (including medicines)</p> <ul style="list-style-type: none"> • In LMICs the onus is on governments to put in place an effective system and infrastructure • Payments should be structured to different levels of care and providers in line with domestic needs and should incentivize efficient use of resources¹⁵⁷ • Exact health care delivery mechanisms (whether public, private or philanthropic health and medicines outlets) inherently vary by domestic needs and capacity • Aim is to secure effective coverage and minimize household financial risk <p>Within the wider health system, establish a dedicated system, infrastructure and technical capacity for funding and delivery of medicines, including:</p> <ul style="list-style-type: none"> • Clear and up-to-date framework for identifying essential medicines as a guide for procurement, stocking and use of medicines¹⁵⁸ • Ensure application by all relevant institutional actors
Trade and supply chain barriers	
<p>Tariffs on medicines None (medicines exempted)¹⁵⁹</p> <p>VAT and other duties on medicines Minimal to none (medicines exempted)¹⁶⁰</p>	<p>Tariffs and taxes on medicines should be minimized or eliminated altogether, particularly for essential medicines¹⁶¹</p> <ul style="list-style-type: none"> • Evidence suggests that both tariffs and taxes on medicines are inefficient (representing a tax on the poor and reducing productivity) and raise the price of medicines¹⁶² • Medicines-based tariff revenues should not merely be substituted by medicines-based taxes <p>Taxes on medicines may be minimized through, for instance:</p> <ul style="list-style-type: none"> • Shifting burden of taxation to other areas of the economy (such as unhealthy habits or areas that are more efficient over the long-term)¹⁶³ • Balancing the tax regime such that medicines face a more equal tax burden compared to other sectors <p>Refrain from using trade and tax policies to boost domestic companies by levying high duties on, e.g., imported finished pharmaceutical products</p>
Healthcare workforce	
<p>Density of physicians, nurses & midwives 4.5 per 1,000 population¹⁶⁴</p> <p>Density of pharmaceutical personnel ~0.85/1,000 population (estimated OECD average based on available data¹⁶⁵)</p>	<p>Strengthen and intensify recruitment and training of local health care personnel through inter alia accreditation systems in line with international standards and ensuring course completion¹⁶⁶</p> <p>Enhance the distribution of healthcare personnel in line with current and future country-specific needs¹⁶⁷</p> <p>Ensure healthcare workforce supply covers a diverse range of relevant skills (including up-to-date medicines delivery) within the wider umbrella of primary and preventative care¹⁶⁸</p>
Regulatory system	
<p>NA</p>	<p>Harmonize regulatory standards governing the quality, safety and efficacy of medicines in line with international norms including ICH and WHO good practices¹⁶⁹</p> <p>Ensure regulatory frameworks governing medicines are clear, consistent and efficient and that decision-making takes place in a transparent manner and on a sound legal basis¹⁷⁰</p> <p>Enhance international cooperation in order to promote the timely entry of drug and vaccine products to the market</p>

Global Lessons and Proposed Strategies for Improving Access to Essential Medicines

Recognizing that every country faces its own unique set of conditions – macroeconomic, geographical, cultural, or other – what do the above findings suggest for LMICs, organizations and other partners at the front line of efforts to improve access to and as part of that availability of, essential medicines? In a context of limited resources and acute needs, what should be countries' strategic approach to moving the needle in the availability of essential medicines? While this system will inherently and necessarily vary by country and situation, the following table outlines a number of international targets and best practices based on empirical literature and institutional guidance that policymakers and other partners may refer to when considering reforms.

It is also important to reiterate that there is no “silver bullet” for improving availability of essential medicines. The study results imply that where additional resources are available, areas such as improving infrastructure as well as distribution and delivery of medicines should be addressed in policy reform in partnership with international and philanthropic organizations and the private sector.

It is hoped that the findings of this study can further illuminate and aid in targeting the extensive efforts that are already taking place to improve access to essential medicines in LMICs. International, government and civil society discussions about access to essential medicines should explore how to integrate these findings into existing work on introducing universal health coverage and reducing duties for medicines in LMICs, both at an international and national level. There is also need for further understanding how these priorities can be applied in a given country and what they mean for decision-making concerning allocation of resources, problem-solving and generation of additional country-specific data and insights.

A Note on Need for Further Empirical Research

This analysis seeks to build on the wider existing analysis about barriers to access to medicines as well as serve as a platform for further research and knowledge acquisition about which factors matter most for improving access to essential medicines, in what manner and how these lessons can be applied in different countries. It is hoped that future research could aid in addressing, among others, the following areas (this list is by no means exhaustive):

Data on availability of essential medicines

- There is a need for deeper, wider and more up-to-date data on availability of essential medicines. Specifically, the WHO/HAI dataset is an excellent one and the data should be collected (and the survey conducted) on a more consistent basis in a wider number of countries. This would aid both in country-specific analysis as well as further honing global analysis of essential medicines availability.
- In addition, particularly for low-income countries, to our knowledge cross-country data on availability of essential medicines does not currently account for the share of medicines or resources available from donors/philanthropic sources. Including this figure, where possible, would be helpful for generating a clearer picture of the full availability of essential medicines in different countries and delivery by different segments.
- Finally it also worth exploring alternative datasets to surveys in order to complement existing data and potentially capture a more dynamic picture of rates of availability.

Data on potential factors of/barriers to essential medicines availability

- As with rates of availability of essential medicines, it is important to ensure that indicators of factors of access are also kept current in terms of coverage of countries and years.
- Due to lack of quantitative measures with sufficient and relevant cross-country datasets it was not possible to capture the relationship between essential medicines availability and several identified barriers to access. These include other supply chain barriers such as scope and quality of pharmaceutical distribution systems; level of healthcare infrastructure (including comparing rural versus urban conditions); quality of the medicines regulatory system; and cultural and political barriers to access.
- Were greater indicators of barriers to access to be available, this could affect the relative importance of a given policy area or even raise to the fore a policy area that did not display a very strong relationship with medicines availability in our current analysis. For example, if a measure of the quality and effectiveness of the medicines regulatory system were available for a sufficient amount of LMICs it may be that, when tested, this area would exhibit an even stronger link to essential medicines availability than it does in the current study.







ANNEX: FURTHER DETAILS ON THE STATISTICAL ANALYSIS IN THE STUDY

This Annex outlines in brief the methodological approach taken in the statistical analysis discussed in sections 1 and 2 of this report. The study employs two layers of statistical analysis – Pearson correlation and multivariate linear regression – to examine the strength of the relationship between an established measure of essential medicines availability in around 50 LMICs and a set of 20+ indicators identified in the empirical literature as key barriers to availability of essential medicines.

In order to identify the most substantial barriers to availability of essential medicines, this study uses two tiers or statistical methods of analysis:

1. A Pearson Correlation test for assessing the existence and relative strength of the relationship between availability of essential medicines (the dependent variable) and each of the 20 potential barriers (the independent variables); and
2. A Multivariate Linear Regression test for assessing the amassed effect of a combination of two or more related independent variables on the dependent variable.

Tier 1: The Pearson Correlation test

Simply put, the Pearson Correlation Coefficient is a widely-used statistical method of establishing whether two variables are related to each other, or correlated. This statistical test provides a value between -1 and 1, which represents the strength of this correlation. Thus, the Pearson Correlation Coefficient tells us whether a linear relationship exists between two variables and if it is positive or negative.¹⁷¹

In this study, the strength of a given positive correlation follows this legend:

- .00-.19 - “very weak”
- .20-.39 - “weak”
- .40-.59 - “moderate”
- .60-.79 - “strong”
- .80-1.0 - “very strong”

In addition, a Pearson Correlation also enables us to determine the “goodness of fit” of the data, also referred to as the *coefficient of determination* – a measurement of the alignment of the distribution of the data of the independent variable with the fitted line of regression. Expressed as the R-squared (R^2), this value provides a statistical measurement of the proportion of the variance in the data of the dependent variable that is explained by the independent variable, or how much a change in the dependent variable may be explained by a given factor.

Each individual test of the correlation between two variables was performed in this study under a confidence level of 0.95 (reported as the P value being less than 0.05). A confidence level of 0.95 means that if this procedure would be repeated on multiple samples, the calculated confidence interval (i.e. a range estimation which is calculated from the observation, and therefore would be different for each sample) would encompass the true parameter of 95% of the time. In other words, the confidence interval represents values for the parameter, for which the difference between the parameter and the observed estimate is not statistically significant at the 5% level.

However, it is important to note that correlation does not imply causation. The fact that two variables are very strongly correlated does not mean that one has caused the other. That said, a strong correlation does mean that a linear relationship exists between the two variables, the nature of which depends on the variables.

Tier 2: The Multivariate Linear Regression test

As a second layer of analysis, the study also utilizes the Multivariate Regression test, which enables one to measure the nature of a relationship between two or more independent variables taken together and the dependent variable – in this case between each of the eight categories and access to essential medicines. In this study, the Multivariate Regression test serves two purposes: 1) as a distinct analysis to test and confirm the results of the Pearson Correlation exercise; and 2) to test the impact of a wider policy area or theme on availability of essential medicines – such as the overall level of financing of medicines or supply chain barriers. The Multivariate Regression test looks at amalgamated effect on essential medicines availability of groups of indicators from Table 1 in five categories:

- Healthcare and medicines financing
- Supply chain
- Healthcare delivery (providers)
- Regulatory system
- Import and production

Similar to the Pearson Correlation test, the Multivariate Regression test produces a Coefficient of Multiple Correlation, which in this test identifies whether a linear relationship exists between the group of measured independent variables (e.g. within one of the five categories) and the dependent variable, and if it is positive or negative. When raised by the power of 2, the R^2 value provides a statistical measurement, expressed as a percentage, of the proportion of the variance in the data of the dependent variable that is explained by the independent variable.

It is worth noting that in the regression tests performed the proportion of variance in the dependent variable explained by a given group of independent variables does not affect the explanatory power of other groups of independent variables tested within the regression analysis. The relative strength of different groups of variables is

comparable by the size of the explanatory power of each out of 1 (or 100%). As a result, the ability of each variable to express variation in the dependent variable will overlap and will not add up to 1 (or 100%).

In order to run a Multivariate Linear Regression test a set of assumptions must be met, such as the existence of a linear relationship, normal distribution of the residuals and constant variance. In this study all of the Multivariate Regression tests were validated.¹⁷²

A note on the WHO/HAI measure of availability of essential medicines

As mentioned the study uses the WHO/HAI measure of availability of essential medicines, looking specifically at lowest price generics (based on prices face by patients). The data is drawn from national or sub-national surveys (of major urban zones or regions) of public sector pharmacies and other medicines outlets concerning the share of a selection of medicines (usually between 30 and 50) from the WHO's Essential Medicines List that are in stock in the outlets at the time of the survey.¹⁷³ The study relies on survey results for the latest available year (data for most countries is within the range of 2008-2013).¹⁷⁴ Though data is also available on availability in private sector outlets for some countries, we focus on public sector outlets based on the assumption that these are the primary or minimum points of access for essential medicines in most LMICs (or should be, if basic health care and medicines coverage were available).

NOTES

- ⁱ Availability of essential medicines, measured here as the median percent availability of selected generic medicines in a sample of public medicines outlets, is one measure identified by the WHO reflecting access to medicines. (WHO Global Health Observatory, "Median availability of selected generic medicines (%)", Indicator Metadata)
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- ¹ Jowett, M. & Kutzin, J. (2015), "Raising revenues for health in support of UHC: strategic issues for policy makers", Health Financing Policy Brief No.1, WHO, 2015
- ² UN Sustainable Development Goals, Target 3.8; see, for instance, UN, "Goal 3: Ensure health lives and promote well-being for all at all ages", <http://www.un.org/sustainabledevelopment/health/>
- ³ World Health Organization (WHO) (2009), Health financing strategy for the Asia Pacific region (2010-2015), Geneva, p.27
- ⁴ WHO (2010), Strategic directions to improve health care financing in the Eastern Mediterranean Region: moving towards universal coverage 2011-2015, WHO Regional Office for the Eastern Mediterranean
- ⁵ Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases. April 2001
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- ⁷ Mcintyre, D.M. (2014), "Shared Responsibilities for Health: A Coherent Global Framework for Health Financing", in Final Report of the Centre on Global Health Security Working Group on Health Financing, Chatham House: London, UK; see also: World Health Organization (High-level Taskforce on Innovative International Financing for Health Systems) (2009), More money for health and more health for the money
- ⁸ WHO (2010), "Health systems financing: the path to universal coverage", in World Health Report; see also: Xu, K.S., P. Jowett, M. Indikadahena, C. Kutzin, J. Evans, D.B. (2010), Exploring the thresholds of health expenditure for protection against financial risk, WHO: Geneva
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- ¹² WHO (2015), Essential medicines and basic health technologies for noncommunicable diseases: towards a set of actions to improve equitable access in Member States, WHO Discussion Paper, July 2015; Arney, L & Yadav, P. (2014), "Improving Procurement Practices in Developing Country Health Programs", Final Report, January 2014; WHO (2010), Options for financing...
- ¹³ WHO (2010), Options for financing and optimizing medicines in resource-poor countries, Discussion Paper No.7, 2010
- ¹⁴ WHO (2015), WHO Guideline on Country Pharmaceutical Pricing Policies, 2015, pp.9-11
- ¹⁵ WHO / HAI Global (2014). "Sales Taxes on Medicines", Pharmaceutical Pricing Policies and Interventions, Policy brief number 5, February 2014, http://haiweb.org/wp-content/uploads/2015/08/5_WHOHAI_Policy-Brief_Taxes_2015.pdf; WHO, (2015). WHO Guideline on Country Pharmaceutical Pricing Policies, Geneva, Switzerland, <http://apps.who.int/medicinedocs/documents/s21016en/s21016en.pdf>; Bate, R., Tren, R. and Urbach, J. (2006). Still Taxed to Death: An Analysis of Taxes and Tariffs on Medicines, Vaccines and Medical Devices, AEI-Brookings Joint Center for Regulatory Studies
- ¹⁶ Ibid.
- ¹⁷ See for instance, WHO (2015), WHO Guideline on Country Pharmaceutical Pricing Policies, 2015, pp.68
- ¹⁸ WHO (2016), Global strategy on human resources for health: Workforce 2030, p.42
- ¹⁹ WHO Global Health Observatory, "Pharmaceutical personnel density (per 1,000 population)", 2014 (calculated as average of available OECD countries)
- ²⁰ WHO (2016), Global strategy on human resources for health: Workforce 2030, p.15-22
- ²¹ Ibid., pp.23-28
- ²² WHO (2016), "Health Workforce Requirements for Universal Health Coverage and the Sustainable Development Goals", Human Resources for Health Observer Status Series, No.17, p.7
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- ²⁷ See, for instance: Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R (2009) Medicine prices, availability, and affordability in 36 developing and middle-income countries: A secondary analysis. *Lancet* 373: 240–249; Cameron A, Roubos I, Ewen M, Mantel-Teeuwisse AK, Leufkens HG, et al. (2011) Differences in the availability of medicines for chronic and acute conditions in the public and private sectors of developing countries. *Bull World Health Organ* 89: 412–421
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- ²⁹ Availability refers to the supply of essential medicines in medicinal outlets in a given country; it is one factor affecting ability to actually access medicines, though not the only one (other factors include cost of medicines to patients and awareness of available medicines).
- ³⁰ See: WHO Global Health Observatory, "Median availability of selected generic medicines, Data by country", <http://apps.who.int/gho/data/node.main.488?lang=en>; and Health Action International, "Medicine Prices, Availability, Affordability & Price Components Database", <http://haiweb.org/what-we-do/price-availability-affordability/price-availability-data/>.

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- ³² See, for example: IMS Institute for Healthcare Informatics, Understanding the Role and Use of Essential Medicines Lists, April 2015
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- ¹⁷⁴ See Table 1 in the Annex for a summary of the data on availability of generic medicines in public sector outlines in the 50 sampled countries.



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