

Procurement Approaches and Policies in Low- and Middle-Income Countries

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Disclaimer: This document was prepared by Roxanne Oroxom in July 2018 as input to the third meeting of the Working Group on the Future of Global Health Procurement.

This table summarizes the theoretical and realized effects of various approaches to procurement in low- and middle-income countries (LMICs).¹ Much of the peer-reviewed literature on procurement policies describes, rather than empirically evaluates, their application in LMICs. Overviews with similar aims, such as [Nguyen et al \(2013\)](#), have confronted the same issue and focused on lessons from European countries, or focused on pooled procurement, such as the review by [Seidman and Atun \(2017\)](#). The research covered by this table is a non-exhaustive list of assessments (mostly time series analyses) and modelling efforts focused on national or state-level procurement and published in journals, as working papers, and in systematic reviews in or after 2008. The table also includes references to research that describe risks associated with, consequences that resulted from, or terms of specific policies.

POLICY	ILLUSTRATIVE EXAMPLES	THEORETICAL BENEFITS & EVIDENCE OF EFFECTS
Stimulating the Market [Supply]		
Advance Market Commitment	GSK and Pfizer committed to supplying 30 million doses of their second-generation pneumococcal vaccines annually for 10 years, starting in 2013 for \$225 million each	<p>Theoretical Benefits:</p> <ul style="list-style-type: none"> ▶ Incentivizes manufacturers to conduct more R&D on diseases that exclusively affect people in LMICs ▶ Incentivizes manufacturers to accelerate the testing of products in later stages of development <p>Evidence of Effects:</p> <p>→ Snyder, Begor, and Berndt (2011) simulate the vaccine supply that would result from different designs of the GSK and Pfizer AMC, including more suppliers, a subsidy cap, changes in the fixed cost per dose, changes in the health benefit per dose, and increases in the tail price. Based on their preliminary analysis, the authors found that making the AMC's terms more generous would generally increase the supply of vaccines and net social benefit accrued. The authors also note a reduction in the time lag between when non-GAVI and GAVI countries introduced PCV-10 and PCV-13 (after the AMC) compared to PCV-7 (before the AMC).</p> <p>→ Hargreaves et al (2011) compare the GSK and Pfizer AMC to the Meningitis Vaccine Project, in which BMGF gave \$70 million to PATH and WHO to advance the development and testing of a vaccine for meningitis A. The authors provide descriptive comparisons of the two approaches in terms of public support, upfront price cutoff/commitment (people perceived the \$3.50 tail price of the AMC to be too high, donors had originally decided on a price of \$2), and technology transfer (PATH negotiated a non-exclusive license for MenAfriVac).</p> <p>→ Martin, Gupta, and Natarajan (2018) analyze the effectiveness of purchase guarantees in AMCs using game theory and show that a better alternative could be requiring minimum capacity investments by manufacturers.</p>
Domestic Manufacturing Promotion	Brazil; India; China; Indonesia; Thailand; Pakistan; Philippines; Bangladesh; Malaysia; Turkey; Singapore; Cuba (80 percent of pharmaceuticals consumed are locally made); Nigeria has applied pharmaceutical import bans	<ul style="list-style-type: none"> ▶ Creates local jobs ▶ Builds national capacity/technical skills ▶ Generates savings since raw materials are cheaper than finished products ▶ Produces more reliable supply (<i>note: anecdotal evidence suggests quality issues are a serious concern</i>) <p>→ Kaplan, Ritz, and Vitello (2011) conduct a systematic review of the literature on the benefits of domestic production and access to medicines. They note conflicting findings across multiple studies, including:</p> <ul style="list-style-type: none"> - A study on Vietnam found that “locally produced HIV/AIDS medicines (antiretrovirals: ARVs) are priced considerably lower than imported ARVs currently on the Vietnamese market, but they are five to seven times higher than the current best offer on the international market.”

		<ul style="list-style-type: none"> - A modelling study on various sub-Saharan African countries found that “domestic production of a variety of medicines may have a "modest" impact on medicine affordability. "Modest", defined as between a 1-26% reduction in ex works price. This price reduction was found to be very sensitive to increase in API prices or a loss of (or failure to reach) market share and this could "easily" negate price reductions.” - A study on Brazil found that “as of 2006, prices for Brazil's locally produced generics were generally much higher than corresponding global prices. These prices have risen in Brazil while declining globally. The estimated "excess" costs of Brazil's locally produced generics totaled US\$110 million from 2001 to 2005.” - A study on Uganda found that “Ugandan companies have upgraded by importing finished technologies and knowledge, not by learning production methods. Production is at a low level technologically and has not increased the companies’ technological capabilities.” - An assessment in 7 African countries of the quality of chloroquine syrup or tablets found that “there were quality failures of 56% (27/48) among locally made products, compared to 47.2% (17/36) for foreign products for CQT active ingredient content, and 28% (7/25) versus 13% (3/23) for CQS active ingredient content.” <p>→ WHO (2011) provided a literature review on local production and access to medicines. The review found little direct evidence for or against increased reliability of supply, improved quality standards, increased local innovation capacity, and development of export capacity in LMICs owing to local production.</p> <p>→ Wilson, Kohler, and Ovtcharenko (2012) suggest Tanzania’s ability to locally procure a first-line ARV is affected by a lack of political support, limited production capacity, and limited competitiveness across multiple markets due to its lack of WHO PQ and the availability of medicines at donor-procured prices.</p> <p>→ Russo and Banda (2015) outline policies implemented by Mozambique and Zimbabwe, such as a commitment to buy 75% of output, no import duties for API, AIDS levy (50% of the revenue generated from a 3% tax on all formally employed people must be used for purchasing medicines related to HIV/AIDS).</p>
Procurement Processes		
Enhancing demand forecasting capacity	UNICEF provides manufacturers with long term forecasting; the Global Fund, PEPFAR, and the Government of South Africa are taking a consolidated approach to demand forecasting for 10 products that will “prepare a product-specific quarterly forecast breakdown” that can be shared with suppliers and countries	<ul style="list-style-type: none"> ▶ Manufacturers allocate resources to develop, produce, and commercialize new products because they know demand exists ▶ Countries can improve and expand their supply chains in advance ▶ Donors and countries can use funds more efficiently because demand forecasting allows them to circumvent penalties for late orders ▶ The public health community can better identify bottlenecks <p>→ Levine et al. (2008) summarizes the Center for Global Development’s Global Health Forecasting Working Group’s findings. The Working Group recommends the use of a broader menu of contracting options (e.g., minimum purchase commitments, buyback contracts, revenue sharing, flexible quantity contracts); the creation of a global health infomediary that would serve as a neutral party for collecting information, cleaning data, and generating forecasts; and the universal adoption of 10 forecasting principles, including:</p> <ul style="list-style-type: none"> - Create a forecasting process that is independent of planning and target setting - Protect the forecasting process from political interference and ensure it is transparent - Create a dynamic forecasting process - Make forecast assumptions clear and explicit <p>→ Bam et al (2017) develop a model of the supply chain in South Africa for the second-line drug for tuberculosis amikacin. The authors highlight an inefficient excess of inventory, as well as long and fluctuating supplier lead times as two of the main challenges. The authors find that ordering safety stock when demand fluctuates is more optimal than setting and readjusting minimum and maximum levels to order. In addition, the authors find that, all else equal, issues with supplier lead times can be addressed by selecting suppliers with shorter and less variable lead times.</p>
E-procurement	Brazil (ComprasNet); Chile (CENABAST & ChileCompra); Indonesia (Lembaga Kebijakan Pengadaan Barang Jasa Pemerintah); Wambo.org	<ul style="list-style-type: none"> ▶ Drives competition between suppliers since they can monitor the bidding process online at any time ▶ Reduces paperwork and administrative burden, which leads to quicker disbursements since information flows faster between suppliers and procurers ▶ Reduces errors through automated checks ▶ Buyers cannot alter suppliers’ bids

		<p>► Facilitates the placement of collective orders, which results in price reductions</p> <p>→ Sigulem and Zucchi (2009) analyzed 9 group purchases of 37 pharmaceuticals in Brazil and found that “of 37 drugs included, 34 showed price reductions after implementation of e-procurement system, and 27 showed further decreases in price over the following 2 years.”</p> <p>→ Singer (2009) analyzed data from ChileCompra and determined that the use of e-procurement generated price reductions of 2.65% and administrative cost savings of 0.28%-0.38% between 2006 and 2007. The authors attributed most of the savings to price differences that resulted from attracting several bidders, rather than administrative savings.</p> <p>→ Barahona and Elizondo (2014) describe Costa Rica’s launch of two separate national e-procurement systems. In 2001, Costa Rica’s government launched a national e-procurement system, CompraRed, to provide a fix to the many organization-specific e-procurement systems in existence. Costa Rica’s state-owned energy and telecommunications company tried CompraRed, determined it could not fit their needs and had too many inefficiencies (too few bidders; too many processes; did not link to the Costa Rican government’s main financial system, creating duplicate work; poorly trained workers; system failures), and launched their own e-procurement system Mer-link in 2010. Mer-link faced its own criticisms (the press and public saw it as duplicative; CompraRed was free; national security concerns about a foreign system (developed by Samsung, Korean government, among others).</p> <p>→ Kohler et al (2015) found that the introduction of the price transparency portal BPS in Brazil was followed by a decrease in the unit price of 5 out of 19 medicines in Paraiba state while no decrease was seen for any of the 19 medicines in São Paulo.</p> <p>→ Berdud et al (2018) explores the difference between transparency around procurement processes and transparency around the prices obtained from that process.ⁱⁱ The authors argue that transparency around procurement processes increases efficiency by making it easier for suppliers to engage in the market, but that price-transparency for on-patent medicines reduces access to medicines and reduces the return on innovation. They recommend the creation of a database of ex-factor off-patent prices that suppliers cannot access.</p> <p><i>Note: Rachel Silverman published a CGD blog in November 2017 on the Global Fund’s audit of the Wambo.org platform. The three main takeaways are paraphrased below:</i></p> <ul style="list-style-type: none"> - <i>Estimates of the savings generated by Wambo.org should account for the savings concurrently generated by other initiatives</i> - <i>Wambo.org notifies buyers when a less expensive product becomes available, but the Global Fund and Wambo.org should consider cost-effectiveness and value over solely price</i> - <i>Projections of the savings Wambo.org could generate were based on bold assumptions that did not play out and highlight the need for impact evaluations that are transparent, rigorous, and directly measured based on actual data</i>
Contracts		
<p>Framework Contract</p>	<p>Chile; Mexico; Brazil; Global Fund framework agreements in year 3 of implementation in 2017-2018; UNFPA’s Access RH model negotiates framework contracts that include minimum volume guarantees; PEPFAR SCMS indefinite quantity contracts essentially framework contracts</p>	<p>► Reduces the cost of setting up a tender/auction every time a request arises</p> <p>► Reduces risk of administrative error/allows personnel to check tender documents more carefully</p> <p>► Obtains lower prices by centralizing the government’s bargaining/buying power and aggregating demand</p> <p>► Gives buyers the flexibility to buy when needed</p> <p>→ Alabano and Sparrow (2010) describe framework contracts, including design options (whether all, some, or only core conditions are established in the first stage and single award vs. multiple award). The authors note that if buyers have the option to purchase goods/services outside the framework contract, it may undermine the contract because demand may be lower than pre-award estimates. The authors also note some risk (in terms of higher prices) to “good” public agencies that stems from grouping their orders with “bad” public agencies.</p> <p>→ Barbosa and Fiuza (2011) analyze medicine and device procurement data from Brazil (which uses framework agreements). They determine that aggregating demand from several buyers results in lower prices and that buyers with reputations for paying on time face higher prices when their orders are joined with buyers that do not regularly pay on time. The study also finds that the reserve price (aka the maximum unit price or estimated price) marked by buyers is higher in pooled versus individual procurement.</p>

		<p>→ Advance Family Planning (2014) describes the Government of Tanzania’s reasons for using a framework contract to procure three types of contraception in 2013. The framework contract was selected as opposed to the Pledge Guarantee for Health since the pledge only covers family planning commodities and the Ministry of Health and Social Welfare felt the broader issue of inefficiencies required addressing. The final commodities selected – an injectable, implant, and male condoms – were selected because stocks of them were low, funding was available to purchase the needed supplies, and the Medical Stores Department declared them were eligible for procurement.</p> <p>→ Gur, Lu, and Weintraub (2016) develop a model that considers the uncertainty around production costs suppliers face over the timeline of a framework contract, which may lead them to submit higher bids (i.e., bids with a “charge”). The authors provide 3 design recommendations based on their analysis:</p> <ul style="list-style-type: none"> - Monitor the price charged in the outside market by the contract winner and use it to bound the buying price whenever it is lower than the winning bid - Invest in implementing price indexes for the random part of suppliers’ costs - Allow suppliers the flexibility to reduce their prices to compete with the open market throughout the selling period
Long-Term Agreement	UNICEF transitioned from a 1-year “invitation to bid” to 3-year LTAs with manufacturers; UNFPA uses LTAs to ensure price stability, while UNICEF has indicated that they use LTAs for products that are not considered “innovators” and have been on the market for a long time; PAHO Revolving Fund	<ul style="list-style-type: none"> ▶ Ensures price stability ▶ Provides manufacturers with evidence of future demand <p>→ Terzi and Flores Callejas (2013) reviewed the use of LTAs by the United Nations and found that proper planning and policies needed to be in place prior to the establishment of LTAs for benefits to materialize. The authors recommended using joint-LTAs more frequently to reduce duplication and increase volume leverage.</p>
Group Purchasing	2003 policy between Argentina, Bolivia, Colombia, Chile, Ecuador, Mexico, Paraguay, Peru, Uruguay, and Venezuela to conduct joint price negotiations on ARVs and diagnostics; the Central American Protocol for Drug Procurement and Quality Control Regional Public Good project; Gulf Cooperation Council; Southern African Development Community; Eastern Caribbean Drug Service; Organization of Eastern Caribbean States’ Pharmaceutical Procurement Scheme	<ul style="list-style-type: none"> ▶ Facilitates the placement of collective orders, which results in price reductions ▶ Depending on the mechanism, may involve information sharing and joint negotiation <p>→ Tres and Barbieri (2017) describe the Central American Protocol for Drug Procurement and Quality Control Regional Public Good project and lay out a potential framework for an empirical assessment of the project, including possible limitations. The project includes 5 steps in the first phase—(i) planning; (ii) event publicizing and tender reception; (iii) legal and technical assessment of tenders; (iv) price negotiation; and (v) allocation of medicines according to each country’s demand and needs”—and a second step where individual ministries of health submit bids as a collective “at prices and quality standards agreed on by the region.” Importantly, “winners are the companies that offer the highest-quality medications at the lowest cost. To be eligible for the auction, suppliers must meet several requirements and obtain a prequalification certificate from COMISCA that allows them to participate in negotiation events.” A COMISCA evaluation cited in the chapter suggests savings of around \$36 million between 2010 and 2015 through 5 “negotiation events.”</p> <p>→ Scott, Gardiner, and de Lucia (2015) examine the emergence of pediatric tuberculosis drugs and the role of the Global Drug Facility in facilitating access to such medicines. Out of 17 high tuberculosis burden countries eligible for UNITAID grants to cover pediatric treatments, 64 percent procured treatments from GDF at least once. Procurement from GDF was sporadic and the highest burden countries did not purchase via GDF (e.g., India). The 17 countries constituted 40 percent of the total number of estimated cases (as documented in each country’s National Treatment Plan). Countries that did not procure via GDF used adult drugs for pediatric treatments or procured drugs locally. There are several constraints on the pediatric TB drug market, including the length of time it takes to obtain approvals, frequent changes in treatment policies, and uncertain purchasing volumes, all of which drive the limited number of suppliers in the market.</p> <p>→ Kim and Skordis-Worrall (2017) use data from the WHO GPRM to estimate the effect of purchasing 600 mg generic Efavirenz through the Global Fund’s voluntary pooled procurement scheme. Specifically, this study applies a difference-in-difference analysis to examine the introduction (or non-introduction) of VPP in 25 treatment countries and 82 control countries, using incoterms and ex-works prices as dependent variables. The results showed that VPP reduced both the ex-works price and the incoterms price of Efavirenz by 16.2 percent and 19.1 percent, respectively, and that the price of Efavirenz decreased over</p>

		<p>time. The effects of other independent variables, such as HIV prevalence, transaction volume, and the number of generic manufacturers in the market were not statistically significant.</p> <p>→ Wirtz et al (2009) use data from the Global Price Reporting Mechanism and price per active pharmaceutical ingredient from other research, the authors analyzed differences in the median price per patient per year and whether the price of a drug was higher than the lowest and highest direct manufactured cost per patient per year (LDMC and HDMC, respectively). The results showed that despite the availability of pricing mechanisms meant to increase access, the prices of innovator products continue to be higher than that of generic products. Innovator status was strongly associated with price. Purchasing volume, on the other hand, is not consistently associated with price. Upper middle-income countries paid more than the lowest and highest direct manufactured costs giving weight to concerns about the purchasing capabilities of countries that are no longer eligible for price lowering mechanisms. Procuring through a third party, in this case CHAI, was not consistently associated with lower prices.</p> <p>→ Ewen et al (2014) compare the prices of medicines procured in 2010 by UNRWA to the prices obtained by various other procurers, including a national agency (Jordan's Joint Procurement Department), a regional organization (the Gulf Cooperation Council), and an international non-profit supplier (the IDA Foundation). In addition, the authors compare all those prices to the prices listed in Management Sciences for Health's International Drug Price Indicator Guide. The study found that prices were relatively similarly across procurers and the price guide in the aggregate, but UNRWA paid notably more or notably less for a handful of medicines. Disaggregating UNRWA's purchases by those procured centrally or those procured locally by field offices revealed that local procurement resulted in higher prices for Lebanon and the West Bank, but lower prices for Syria. Based on their findings, the authors recommend that:</p> <ul style="list-style-type: none"> - UNRWA should try to purchase 5 specific medicines at the prices obtained by one of the other procurers, either by joining their tenders or rethinking its own policy of not negotiating prices (UNRWA can, however, terminate a contract if it finds lower prices elsewhere). - UNRWA should expand its pool of potential suppliers to pre-qualified suppliers from outside Europe and the Middle East. <p><i>Note: A review of the literature returned many more studies on group purchasing. The full scope of this work is reflected in other CGD pieces.</i></p>
Legal Mechanisms (Buyers)		
Voluntary Licensing ⁱⁱⁱ	Medicines Patent Pool; Gilead and Tenofovir Disoproxil Fumarate; Aspen and Lamivudine and Nevirapine	<ul style="list-style-type: none"> ▶ Access to products will increase since generic companies can produce medicines without fearing legal recourse/need to await the outcome of legal challenges ▶ May result in a two-way transfer of technology if generic companies learn how to produce new medicines or if they improve on the manufacturer's original methods ▶ Non-exclusive VLs may encourage greater competition across license holders <p>→ Beall and Attaran (2017) compare procurement data for January 2014 - August 2015 from WHO's GPRM on 12 patented ARVs sold by a single supplier in the US or Canada to lists of legal flexibilities that facilitate access to generics to answer two questions: How often do countries that have granted patents on essential ARVs procure generic equivalents? Which legal policies (LDC waiver, non-assert policies, voluntary licenses, compulsory licenses, and other) facilitate such access? They find that voluntary licensing agreements between originator companies and generic-production companies correlate with the largest number of generic procurement observations.</p>
Compulsory Licensing	Argentina; Egypt; Ghana; India; Indonesia; Malaysia; Mozambique; Rwanda; South Africa; Taiwan; Thailand; Zambia; Zimbabwe in 2002 for a selection of ARVs (including stavudine, nevirapine, and zidovudine); Brazil in 2007 for efavirenz; Ecuador in 2010 for ritonavir	<ul style="list-style-type: none"> ▶ Allows countries to bypass pharmaceutical patents and produce domestically <p>→ Nunn (2009) (as cited in Cherian [2016]) suggests Brazil attained discounts between 40-70% using a combination of negotiation, local production, and the threat of deploying compulsory licenses, with savings of 1.2 billion on ARVs.</p> <p>→ Lybecker and Fowler (2009) describe Canada's and Thailand's experiences with compulsory licensing. Canada's Access to Medicine Regime (CAMR) provided Rwanda with quality, Canadian-made triple combination AIDS therapy drugs at low cost (but not on par with the prices of Indian generics). The complexity of CAMR's processes resulted in a multi-year delay of the first shipment. The Thai government's use of compulsory licensing failed to live up to expectations: the company given the sole license to produce an HIV/AIDS drug produced products that never met WHO's standards, creating additional demand for second-line treatment.</p>

		<p>→ Bond and Saggi (2014) note some cases in which the issuance of compulsory licenses did not proceed as planned:</p> <ul style="list-style-type: none"> - “Farmanguinhos – the leading government owned pharmaceutical manufacturer in Brazil – struggled to manufacture Efavirenz since it lacked the technological know-how to do so... It eventually took Farmanguinhos two years to be able to supply Efavirenz to the local market. In the meantime, Brazil had to resort to importing a generic version of the drug from India.” - In both Thailand and Brazil, there was essentially a single local producer that had the competence to produce the relevant drug... in both instances, the local producer's technological capability was inferior to that of the original patent-holder <p>→ Beall, Kuhn, & Attaran (2015) showed that compulsory licensing obtained prices that were lower by more than 25 percent in only 5 of out 30 cases. Restricting the sample to exclude licenses issued in 2003, exclude cases from Brazil and Thailand, and separate countries by Human Development Index showed international procurement resulted in better prices. Compulsory licensing obtained lower prices than international procurement when the median international procurement price was recalculated to only consider countries with an applicable patent. There was essentially no difference when compulsory licensing prices were compared to international procurement prices from the previous year.</p> <p>→ Guennif (2017) provides counter-arguments to three arguments against the use of compulsory licensing: its deleterious effects on innovation/R&D; how it affects the incentive of companies to offer tiered pricing; and that it overlooks the lack of technical capacity and regulatory requirements in developing countries needed to produce high-quality medicines. The author notes no empirical studies have shown a negative effect of compulsory licensing on innovation. The author also cites how Cipla setting a low price for a generic ARV therapy in the 2000s forced other firms to cut their prices (i.e., restoring competition). The author cites the inability of GPO to meet WHO PQ standards and how rates of resistance have risen since GPO's manufacture and distribution of an unpatented cocktail therapy.</p>
Compulsory Generic Substitution	South Africa; Indonesia; Iran; Brazil	<p>► Cost savings on medicines at the national level should trickle down to patients</p> <p>→ Nguyen et al (2013) reports on conversations from the Asia Pacific Conference on National Medicines Policies 2012 and highlights challenges for generics medicines policies, such as, “the lack of clear bioequivalence assessment systems as a regulatory requirement in generic medicines registration or lack of appropriately skilled inspectors and monitoring to ensure the quality of generic medicine products was reportedly attributable to this mistrust.”</p> <p>→ Gray, Santa-Anna-Tellez, and Wirtz (2016) used an interrupted time series analysis to determine that South Africa's mandatory switch to generics resulted in an increase in the utilization of several medicines for chronic conditions.</p> <p>→ El-Jardali et al. (2017) surveyed and interviewed community pharmacists in Lebanon following the Ministry of Public Health's August 2015 decision to introduce generic drug substitution. They confirmed that substantial challenges persist in getting pharmacists to switch to generics: “the majority of respondents (64%) were in favor of generic drug substitution; however, less than half (40%) indicated they have substituted brand drugs for generic equivalents.”</p>
Legal Mechanisms (Suppliers)		
Tiered Pricing	Abbott Laboratories for African countries and 16 non-African LDCs; Eli Lilly and capreomycin and cycloserine through UNITAID's Green Light Committee	<p>► Sets prices levels that account for countries' different abilities to pay</p> <p>→ Waning et al (2009) “found that the tiered prices for 15 of 18 antiretroviral (ARV) drugs were 23-498% higher than the generic price.”</p> <p>→ Moon et al (2011) explored the trend in prices for several antiretrovirals, artemisinin combination therapies, drug-resistant tuberculosis medicines, liposomal amphotericin B (for visceral leishmaniasis), and pneumococcal vaccines. The authors also noted several potential limitations to tiered pricing:</p> <ul style="list-style-type: none"> - Tiered pricing may set prices that are still too high for certain countries - Tiered pricing may set prices so low that it creates a disincentive for new competitors to join the market - Companies all use different thresholds, e.g., region or income group or Human Development Index category

		<p>→ Babar and Atif (2014) performed a bibliometric review of the literature available on differential/tiered pricing. They noted a lack of research articles devoted entirely to differential/tiered pricing; a plethora of reports, background papers, and opinion pieces; the lack of papers from the industry standpoint; and the lack of papers related to cancer or reproductive health. Moreover, they noted that tiered pricing has been applied in limited instances, mostly for HIV, TB, and in some cases, malaria.</p>
Approaches to Assessing Prices (Buyers)		
Value-Based Pricing/Health Technology Assessments	India; Brazil; Bulgaria; Hungary; Turkey; Thailand; Taiwan; Philippines	<p>► Reduces spending on products that do not contribute significant value for money</p> <p>→ Thatte et al (2009) describes the use of evidence-based assessments in the Philippines and Malaysia to determine purchase orders, e.g., in Malaysia “With the HTA unit recommendation, it is mandatory for medical devices costing more than RM200,000 (US\$57,000) to undergo Health Technology Assessment before it is purchased for MOH facilities.”</p> <p>→ Nguyen et al (2014) note that “LMICs rarely conduct and use pharmaco-economic evaluation at a policy level... Few LMICs formally use this method in pharmaceutical pricing and reimbursement decision making, and those that do have universal health coverage, such as Thailand and Taiwan. Nevertheless, their use of the method is still in its infancy.”</p> <p>→ Boswell Dean (2018) found “no study assessing the efficacy of health technology assessments on pricing and availability in LMICs.”^{ivv}</p> <p><i>Note: Empirical studies exclusively focus on efforts in high-income countries. Examples from a few high-income countries are listed below.</i></p> <p>Young, Soussi, and Toumi (2017) describe the BeNeLux:A agreement (Belgium, the Netherlands, Luxembourg, Austria, and Ireland), which includes four components to obtainment of medicines for rare diseases (or “orphan diseases”): “(1) horizon-scanning databases to detect potentially significant orphan drugs in development; (2) joint research on the market and products; (3) combinations of two or more countries conducting health technology (HTA) evaluations; and (4) collective bargaining for select high-cost medicines.”</p> <p>Remuzat et al (2015) note that Denmark and Sweden switched to value-based pricing and internal reference pricing from external reference pricing.</p>
Cost-Plus Pricing	India (before 2012); Vietnam; China; Sri Lanka; Bangladesh; Iran; Pakistan	<p>► Stabilize medicine prices in unregulated settings</p> <p>► Reduce out-of-pocket payments in an unregulated market</p> <p>→ WHO (2015) describes cost-plus pricing arrangements in several countries, including Pakistan (“the manufacturer’s retail price for non-sterile products is prime cost + 75% mark-up, while sterile products are priced at prime cost + 90% mark-up”) and China (“prices are set on the basis of declared costs submitted by manufacturers and are calculated as factory prices with duty/taxes and retail distribution profits incorporated. The prices submitted by manufacturers are not checked for accuracy”).</p> <p><i>Note: It is difficult to identify the true costs of production due to the shared nature of many production supplies and the secrecy around costs.</i></p>
External Reference-Pricing	Mexico; Brazil to on-patent products; Colombia; Iran; Jordan; South Africa	<p>► Prices should converge as more countries apply ERP</p> <p>→ Espin, Rovira, and de Labry (2011) describe ERP policies in various countries, including Mexico (“Mexico uses the weighted average of the ex-factory prices with respect to the previous quarter in the six countries with bigger sales. The reference prices are reviewed annually and verified by an external auditor. The ERP determines the...reference price for sales to the public...”). The authors also review ERP policies and identify a few obstacles to its use. In Europe, countries apply ERP differently: some use the lowest price out of a group or the average price across countries. Pharmaceutical companies have an incentive to target countries without price adjustments like ERP and then delay launching in countries that have significant price adjustments; ERP requires a regularly updated price database that has strict definitions for a drug; ERP does not reflect markup or confidential, second-stage adjustments to the initial price.</p> <p>→ Mehtap (2014) highlights a decline in pharmaceutical expenditure as a percent of total health spending in Turkey from 36% in 2004 to 27% in 2011, which coincides with when ERP replaced Turkey’s use of cost-plus pricing in 2004.</p>

		<p>→ Boswell Dean (2018) notes that Brazil “references the lowest price from the European Union to determine its prices in the private sector, but requires a 26% reduction for its public sector, which generally serves the low-income population.”^{viii}</p> <p><i>Note: Empirical studies exclusively focus on efforts in high-income countries.</i></p>
Managed Entry Agreements		<p>► Share risk with manufacturer if the product is not performing as agreed (x)</p> <p>► Managing uncertainty relating to clinical and/or cost-effectiveness (x)</p> <p>→ Klemp and Fronsdal (2011) identify several disadvantages to managed entry agreements, including: costs/bureaucracy required for implementation of agreement; payback/price reductions if pre-agreed outcomes are not met; limited access if budget cap is reached; managing multiple schemes across small providers; possible need to withdraw technologies at the end of the agreement/difficult to withdraw once in practice; risk that the product does not show the benefit that is expected</p> <p><i>Note: Empirical studies exclusively focus on efforts in high-income countries.</i></p>
Payment Arrangements		
Bridge Funding	<p>UNFPA Supplies Bridge Funding Mechanism; UNICEF’s Pledge Guarantee for Health; US Fund for UNICEF Bridge Fund</p>	<p>► Mitigates the effect of delayed disbursements on the processing on medicine/device orders</p> <p>→ Gallien et al (2014) use a discrete-event simulation model to answer, in part, what are the potential effects on stockouts of the Global Fund switching to a different disbursement model, such as:</p> <ul style="list-style-type: none"> - Instantaneous replenishment from an international or regional buffer stock of supplies - Bridge financing in the form of a loan from a third party equal in amount to the next anticipated disbursement when that disbursement is overdue - Synchronized financing where disbursements cover one and a half reporting periods <p>The authors use data from the Global Fund’s Price and Quality Reporting database for their analysis and find that synchronized financing is the only intervention to substantially reduce the likelihood of stockouts (13 percentage points in West & Central Africa and 16 percentage points in North Africa) though additional simulations revealed that any gains would be time limited and that instantaneous replenishment may be a better option.</p>

ⁱ Options not covered include product development partnerships (PDPs); transferable intellectual property rights (TIPRs); priority review vouchers (PRVs); patent pools; internal-reference pricing; and in-licensing.

ⁱⁱ Refers to “The Future of Global Health Procurement: Issues around Pricing Transparency” written by Mikel Berdud, Kalipso Chalkidou, Emma Dean, Jimena Ferraro, Lou Garrison, Cassandra Nemzoff, and Adrian Towse.

ⁱⁱⁱ The theoretical benefits section draws heavily on “Voluntary Licensing Practices in the Pharmaceutical Sector: An Acceptable Solution to Improving Access to Affordable Medicines?”

^{iv} Refers to “Literature Review on Pharmaceutical Price Controls and Reimbursement Regulation” Emma Boswell-Dean shared with CGD.

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