REVIEW

Policy options for pharmaceutical pricing and purchasing: issues for low- and middle-income countries

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Pharmaceutical expenditure is rising globally. Most high-income countries have exercised pricing or purchasing strategies to address this pressure. Low- and middle-income countries (LMICs), however, usually have less regulated pharmaceutical markets and often lack feasible pricing or purchasing strategies, notwithstanding their wish to effectively manage medicine budgets. In high-income countries, most medicines payments are made by the state or health insurance institutions. In LMICs, most pharmaceutical expenditure is out-of-pocket which creates a different dynamic for policy enforcement. The paucity of rigorous studies on the effectiveness of pharmaceutical pricing and purchasing strategies makes it especially difficult for policy makers in LMICs to decide on a course of action. This article reviews published articles on pharmaceutical pricing and purchasing policies. Many policy options for medicine pricing and purchasing have been found to work but they also have attendant risks. No one option is decisively preferred; rather a mix of options may be required based on country-specific context. Empirical studies in LMICs are lacking. However, risks from any one policy option can reasonably be argued to be greater in LMICs which often lack strong legal systems, purchasing and state institutions to underpin the healthcare system. Key factors are identified to assist LMICs improve their medicine pricing and purchasing systems.

Keywords Pharmaceutical pricing, pharmaceutical purchasing, value-based pricing, pharmaceutical expenditure, developing countries

KEY MESSAGES

- While there is extensive experience with pharmaceutical pricing and purchasing strategies in high-income countries, empirical studies in low- and middle-income countries are lacking.
- Successful pharmaceutical policies and pricing mechanisms have to be locally tailored, transparent, stable and predictable.
- Strengthening and enforcing the legal systems, including pharmaceutical sector regulation, competition and anti-corruption law to create a level playing field to ensure a healthy competitive generic market, together with policies that align pro-generic medicine incentives for prescribers, dispensers and patients may be the way forward in low- and middle-income countries.
**Introduction**

Pharmaceutical expenditure is increasing worldwide. Between 1995 and 2006 per capita spending on pharmaceuticals increased by ~50% (Lu et al. 2011). The average annual growth rate of pharmaceutical expenditure significantly surpassed that of total health expenditure and of Gross Domestic Product (GDP) in a number of different countries worldwide (WHO 2004; OECD 2008). This has resulted in increasing pressure on governments and individuals to be able to afford essential medicines.

In dealing with the problem, most high-income countries have policies directed at pricing or purchasing (Rietveld and Haaijer-Ruskamp 2002). The USA is the only major high-income country without a national pricing or purchasing strategy (Critchley 2006). However, organizational and institutional policies are common (Rietveld and Haaijer-Ruskamp 2002). Low- and middle-income countries (LMICs) usually have less regulated pharmaceutical markets than high-income countries (De Joncheere et al. 2002), and some LMICs are price acceptors, meaning they pay whatever price the pharmaceutical company specifies (Sengupta et al. 2008).

We sought to review some of the existing pharmaceutical pricing and purchasing strategies used across the world to illustrate how governments or insurers establish a fair price and manage pharmaceutical budgets to identify issues for LMICs to improve their pharmaceutical pricing and purchasing systems. Initially, the nature of pharmaceutical expenditure and market classifications is discussed including different demands in submarkets and different reimbursement structures. Various pharmaceutical pricing and purchasing policies are then reviewed with special reference to LMICs.

**Methods**

Descriptive and evaluation studies on pharmaceutical pricing and purchasing policies, the policies that determine or are intended to influence the prices that are paid for medicines were reviewed. In this review, policies were defined as laws, rules, financial and administrative orders made by governments, non-government organizations or private insurers. A broad range of sources was drawn upon which included: the academic peer-reviewed literature; the so called ‘grey’ policy literature on medicine pricing and purchasing policies; as well as authoritative research studies and seminal documents from influential international organizations, such as the World Health Organization (WHO) and the Organization for Economic Co-operation and Development (OECD). The scope of this review is intentionally wide and ostensibly all-inclusive, to reflect the multi-dimensional nature of the pharmaceutical pricing and purchasing mechanisms. This approach also provides a broad platform of ideas and research upon which appropriate policy recommendations can be formulated to improve pharmaceutical pricing and purchasing in LMICs. The following databases were initially searched for related studies with limitation to English language and in the period up to January 2011: MEDLINE, EMBASE, PubMed, International Network for Rational Use of Drugs (INRUD), OECD Publications and Documents, SourceOECD, WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, WHO Medicines Documentation system, WHO Western Pacific Region Price Information Exchange (PIE), WHO library database (WHOLIS), Pharmaceutical Pricing and Reimbursement Information (PPRI), Health Action International (HAI), World Bank e-Library and World Bank Publications and Documents. Updated searches were undertaken in January 2013. The key words used were medicine prices, pricing, purchasing, procurement, reimbursement, price control and cost containment policies. References in the review papers were cross-checked to avoid missing any important papers.

**Results**

**Pharmaceutical expenditure and the pharmaceutical market**

High-income countries remain the major market for the pharmaceutical industry. These countries accounted for 16% of the world’s population in 2006, but had a 78.5% share of the world’s pharmaceutical expenditure (Lu et al. 2011). In contrast, 84% of the world’s population living in LMICs consumed only 21.5% of the world’s total expenditure on pharmaceuticals. This resulted in a significant disparity with per capita pharmaceutical expenditures ranging from United States Dollar (USD) 7.61 in low-income countries to USD 431.6 in high-income countries (Lu et al. 2011). Nevertheless, LMICs are becoming an increasingly important market given that pharmaceutical expenditures increase faster in LMICs than in high-income countries (Lu et al. 2011).

Pharmaceutical expenditure is a function of medicine price, volume of medicines consumed and the interaction between these two variables (Gerdtham et al. 1998; Chen and Schweitzer 2008). Factors causing rises in global pharmaceutical expenditure vary but fall into two main groups: changes in consumption and prices (De Joncheere et al. 2002; NIHCM 2002; Lu et al. 2011). Therefore, when considering pharmaceutical budgets, pharmaceutical policies need to be designed to address both pricing and the level of consumption expected to arise within budget forecasts.

The pharmaceutical market comprises three main submarkets: community-based over-the-counter (OTC) medicines, hospital medicines for inpatients and prescription medicines for outpatients (Jönsson 1994). In most countries regardless of high or low and middle income, the OTC submarket is a relatively free market, which is largely self-regulated. It is characterized by well-known medicines that have been on the market for a relatively long time (Ess et al. 2003). Demand for OTC medicines is patient-determined, with or without prescriber influence. OTC medicines are often non-reimbursable and financed through patients’ out-of-pocket expenses, potentially making patient decisions price sensitive. Governments usually leave the pricing of non-reimbursable OTC medicines to market forces. Nevertheless, by regulating the classification of OTC medicines, governments may indirectly impact on the price of these medicines.

Expenditure on medicines in the hospital submarket is generally subsumed within the total hospital budget. Typically, the range and type of medicines used in hospitals are subject to the policies of hospital drug and therapeutic...
committees. Medicines may be purchased either through direct negotiation with manufacturers or by tender, often resulting in a discounted price or rebates. In most high-income countries, medicine prices in hospitals are frequently not subject to government purchasing or pricing policies (Jacobzone 2000). However, in some jurisdictions including many LMICs, governments fund hospitals and thus policies may impact on purchasing.

The prescription medicine outpatient submarket often accounts for the largest proportion of a nation’s total pharmaceutical expenditure and is often financed within the national budget in high-income countries. In most European and OECD countries, for example, outpatient medicines represent 75–84% of total pharmaceutical expenditure, of which 50–80% may be reimbursed by public health insurance or social security systems (Ess et al. 2003; OECD 2008). As the dominant purchaser, most European and OECD governments have pharmaceutical benefit arrangements in this submarket (GÖG/ÖBIG 2006; OECD 2008). In contrast, in LMICs, most payments are out-of-pocket (OOP). In 2006, private expenditures on medicines as a share of total pharmaceutical expenditure in per capita terms in LMICs ranged from 61.2 to 76.9% (Lu et al. 2011). This changes the power that can be wielded by the government from being the dominant purchaser to a weak regulator. The weak power wielded by LMICs’ governments is compounded by the fact that in poor resource settings of LMICs, laws and regulations may exist but are often poorly enforced and implemented (Nguyen et al. 2010). The lack of reliable healthcare information systems in LMICs also contribute to their poor implementation, monitoring and evaluation of health interventions in general and pharmaceutical pricing and purchasing policies in particular (Azubuike and Ehiri 1999; Tomasi et al. 2004; Nolen et al. 2005; Nguyen 2011). The following sections focus on the main policy strategies adopted for pharmaceutical pricing and purchasing in the prescription medicine outpatient submarket with special reference to LMICs.

Policy options for pharmaceutical pricing and purchasing

There is a wealth of literature on policy options for pharmaceutical pricing and purchasing, but very little is focused on LMICs. Most research has been undertaken in Europe and the OECD countries (Jacobzone 2000; Productivity Commission 2001; Rietveld and Haaijer-Ruskamp 2002; Ess et al. 2003; Mrazek and Mossialos 2004; GÖG/ÖBIG 2006; Mossialos et al. 2006; De Swael and Antonissen 2007; Kovács et al. 2007; Moïse and Docteur 2007a,b; Paris and Docteur 2007a,b, 2008; OECD 2008; Vogler et al. 2008). Only a few studies have been conducted in LMICs (Gray and Matseluba 2000; Liu et al. 2000; Zhen 2004; Meng et al. 2005; Chen and Schweitzer 2008; Sengupta et al. 2008; Sun et al. 2008; Jirawattanapisal et al. 2009; Thatte et al. 2009). Based on the results of 53 pricing surveys using WHO/HAI methodology, a number of policy options were recommended to improve medicine affordability and availability in LMICs, including pricing and purchasing policies (Cameron et al. 2011). A summary of medicine pricing, financing and public procurement in Western Pacific Region countries can be found at www.piemeds.com (WHO-WPRO 2009). Table 1 presents various pricing and purchasing strategies identified in this review, with examples of their use in LMICs.

Pharmaceutical pricing and purchasing policies are regulations or procedures used by government authorities or coverage decision makers to determine or influence the prices that are paid for medicines (Vogler et al. 2008). These policies can target manufacturers’ prices, wholesale prices, retail prices or reimbursement prices. Medicine prices may be determined directly (e.g. maximum fixed prices, price cuts or price freezes) or influence medicine prices indirectly (e.g. profit regulation) (Mrazek and Mossialos 2004; Aaserud et al. 2006). Prices may also be negotiated or set via a value-based mechanism or set competitively via tender arrangements.

Techniques used for defining price levels

Whatever approach is used, the most difficult task is establishing what is seen to be a reasonable, fair and appropriate price or a reasonable maximum price (Rietveld and Haaijer-Ruskamp 2002). Countries differ in their definition of a reasonable maximum price, depending on such factors as budget limits, prescribing behaviour, demography and the strategic importance of the industry to the national economy (Mossialos et al. 2006). Techniques used to calculate reasonable maximum prices also vary. Combinations of two or more of the following techniques are most commonly used: external reference pricing, internal reference pricing, economic evaluation, cost plus pricing and profit ceilings (Jacobzone 2000: Productivity Commission 2001; Rietveld and Haaijer-Ruskamp 2002; OECD 2008; Vogler et al. 2008).

External reference pricing. One of the most common pricing procedures, used also in combination with other strategies, is external reference pricing (Vogler et al. 2008), also known as international price benchmarking (Productivity Commission 2001) or international reference pricing (OECD 2008). In this system, prices of the product in various comparator countries are taken into account to determine a limit for the product’s market entry price or reimbursement price. It may also be used to determine price increases in the domestic market or simply to determine a benchmark in the negotiation process (Rietveld and Haaijer-Ruskamp 2002; OECD 2008).

The precise methodology adopted varies according to the perspective of regulators, purchasers and payers but the process is usually undertaken in three key stages. First is the selection of reference countries, which is often based on geographic proximity, economic similarity, historical links, the availability of price information, public health status, level of public health insurance, level of investment in the pharmaceutical industry and the relative economic importance of domestic pharmaceutical production (Critchley 2006; OECD 2008; Vogler et al. 2008; Espin et al. 2011). The reference countries usually number around five (Vogler et al. 2008). Given the difference in the availability of medicines across countries, some experts recommend that 10 reference countries should be included (Critchley 2006).

Second is to determine the level at which prices are compared and the ‘price date’ in the reference country (e.g. current price vs price at launch). Most European countries have used ex-factory price for comparison, as this approach eliminates the price differences caused by differences in distribution mark-ups.
Table 1 Pharmaceutical pricing and purchasing policies and examples of their use in LMICs

<table>
<thead>
<tr>
<th>Specific strategy</th>
<th>Examples of LMICs using the strategy</th>
<th>References</th>
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<tbody>
<tr>
<td>Pricing techniques</td>
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<tr>
<td>External reference pricing</td>
<td>Pakistan (for medicines in the third category: new molecules), Taiwan, Vietnam (in regulation only), Bulgaria, Hungary, Turkey</td>
<td>WHO-WPRO (2009), Nguyen et al. (2010), Nguyen (2011), Vogler et al. (2008), Sengupta et al. (2008) and Lee et al. (2006)</td>
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<tr>
<td>Internal reference pricing</td>
<td>Bulgaria, Hungary, Turkey, Philippines, Thailand (for setting up the price ceiling for medicines procured by public hospitals), Taiwan</td>
<td>Tam et al. (2008), Vogler et al. (2008), Thatte et al. (2009), Jirawattanapisal et al. (2009) and Lee et al. (2006)</td>
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<tr>
<td>Pharmacoeconomic evaluation for value based purchasing</td>
<td>Brazil, Bulgaria, Hungary, Turkey, Thailand, Taiwan, Philippines</td>
<td>Yang (2009), Augustovski et al. (2009), Kaló et al. (2013), Thatte et al. (2009), Ngorsuraches et al. (2012) and Vogler et al. (2008)</td>
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<tr>
<td>Profit ceilings</td>
<td>Not identified</td>
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<tr>
<td>Implementing pricing policies</td>
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<tr>
<td>Fixing price at retail/pharmacy level: Maximum Retail Prices (MRP)</td>
<td>China, India, Philippines, Sri Lanka, South Africa</td>
<td>WHO-WPRO (2009), Pillay (2010), Gray (2009), Picazo (2012), Chen and Schweitzer (2008), Sun (2013), Meng et al. (2005) and Sengupta et al. (2008)</td>
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<tr>
<td>Fixing price at wholesale level: maximum wholesale price</td>
<td>Sri Lanka</td>
<td>Sengupta et al. (2008)</td>
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<tr>
<td>Limiting price increases, price freezes</td>
<td>Hungary, India (price freeze in 1963, prior approval of the government for price increase from 1966), Taiwan, Vietnam</td>
<td>Nguyen et al. (2010), Nguyen (2011), Vogler et al. (2008), OECD (2008) and Lee et al. (2006)</td>
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<tr>
<td>Price cuts</td>
<td>China, Pakistan, Philippines</td>
<td>Picazo (2012), Chen and Schweitzer (2008), Sun (2013), Sengupta et al. (2008) and Liu et al. (2009)</td>
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<tr>
<td>Margin cuts</td>
<td>Hungary</td>
<td>Vogler et al. (2008)</td>
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<td>Fixed mark-ups</td>
<td>Bangladesh, China (fixed mark-ups between 1980 and 2000 and currently zero mark-up in public health facilities), Sri Lanka</td>
<td>Sun (2013), Meng et al. (2005) and Sengupta et al. (2008)</td>
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<tr>
<td>Capped mark-ups</td>
<td>India (before 2012)</td>
<td>Sengupta et al. (2008)</td>
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<tr>
<td>Regressive mark-ups</td>
<td>Vietnam (Public hospital pharmacies only), Bulgaria, Hungary, Turkey, South Africa</td>
<td>Gray (2009), Nguyen (2011) and Vogler et al. (2008)</td>
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<tr>
<td>Fixed dispensing fees</td>
<td>South Africa, Sri Lanka</td>
<td>Gray (2009) and Sengupta et al. (2008)</td>
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<td>Prohibition of discounts</td>
<td>South Africa</td>
<td>Gray (2009)</td>
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<th>Specific strategy</th>
<th>Examples of LMICs using the strategy</th>
<th>References</th>
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<tr>
<td><strong>Purchasing policies</strong></td>
<td>China (National basic medical insurance drug formulary list for Western medicines and traditional Chinese medicines), Philippines (Philippines national drug formulary—PNDF and a separate positive list of non-PNDF), Thailand (National list of essential drugs), Taiwan, Bulgaria, Hungary, Turkey</td>
<td>Yang (2009), Vogler et al. (2008), Meng et al. (2005), Hu et al. (2001), Thatte et al. (2009), Ngorsuraches et al. (2012) and Lee et al. (2006)</td>
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<tr>
<td>Negative list</td>
<td>China (National basic medical insurance drug formulary list for Chinese herbal pieces), Hungary</td>
<td>Vogler et al. (2008) and Ngorsuraches et al. (2012)</td>
</tr>
<tr>
<td>Price volume agreement</td>
<td>Not identified</td>
<td>WHO-WPRO (2009), Iglesias et al. (2005), Nguyen et al. (2010) and Sengupta et al. (2008)</td>
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<tr>
<td>Health outcome guarantee</td>
<td>Not identified</td>
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<tr>
<td>Tender</td>
<td>India, most LMICs in the Western Pacific Region including China, Fiji, Lao People’s Democratic Republic (PDR), Malaysia and Vietnam use a national competitive tender system in combination with one of the following: international competitive tender or negotiation/direct purchasing strategy. Public tenders are also the primary approach for medicine procurement in many LMICs in Latin America</td>
<td>WHO-WPRO (2009), Iglesias et al. (2005), Nguyen et al. (2010) and Sengupta et al. (2008)</td>
</tr>
<tr>
<td>Pooled procurement</td>
<td>Angola, Botswana, Democratic Republic of the Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, South Africa</td>
<td>WHO (2007)</td>
</tr>
<tr>
<td>Others</td>
<td>Co-payments Bulgaria, Hungary, Turkey, China (non-essential drugs in class B), Malaysia, Taiwan</td>
<td>Tarn et al. (2008), Vogler et al. (2008), Chen and Schweitzer (2008), Meng et al. (2005), Ngorsuraches et al. (2012), Jirawattanapisal et al. (2009), Lee et al. (2006) and Yoongthong et al. (2012)</td>
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<tr>
<td>Safety net</td>
<td>China</td>
<td>Yoongthong et al. (2012)</td>
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<tr>
<td>Brand premium</td>
<td>China (known as independent pricing policy)</td>
<td>Liu et al. (2009)</td>
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LMICs defined by World Bank income classification in 2012.
The third consideration is the method used to calculate the benchmark price. One common approach is to take a price average (Vogler et al. 2008). The benchmark price can also be a fixed percentage of the average price in comparator countries (e.g. 85% for patented, locally produced medicines and 96% for locally produced generics in Slovenia) (Vogler et al. 2008). In some countries, the benchmark is the lowest price, or the average of the three lowest prices (Vogler et al. 2008) or an average of the three lowest prices plus 10% (OECD 2008).

Irrespective of the approach used external reference pricing system need to be predictable and transparent, including transparent reference countries, price sources and the pricing procedure (Espin et al. 2011). The scope of external reference pricing is often limited to originator products (Leopold et al. 2012). An extensive account of the design of an external reference pricing system can be found in Espin et al. (2011).

LMICs wanting to develop an external reference pricing system need to consider the resources and expertise (human and material) required to collect and analyse data. There are technical difficulties in undertaking price comparisons for the same medicine across countries due to differences in commercial names, dosage forms, strength and packaging, distributors’ profit margins, local taxes and lack of price transparency (Productivity Commission 2001; Rietveld and Haaijer-Ruskamp 2002). Selecting reference countries at similar stages of development (i.e. other LMICs) increases the difficulty in collecting reference price data since LMICs often lack a reliable historical and systemic data source on medicine prices (Nguyen et al. 2010). Current mechanisms that are publicly available and commonly used include the Management Sciences for Health (MSH) International Drug Price Indicator Guide (http://erc.msh.org/mainpage.cfm?file=1.0.htm#module=dmp&language=English) or WHO’s Global Price Reporting Mechanism (http://www.who.int/hiv/amds/gprm/en). These provide an indication of pharmaceutical prices on the international market (Management Sciences for Health 2012) and may be used as an alternative to price data from reference countries.

Internal reference pricing. Another common pricing strategy is internal reference pricing involving price comparison among therapeutic equivalents within a country (Vogler et al. 2008). Internal reference pricing is often used by pricing authorities as a guide to pricing original products at market entry where therapeutic comparators are already available. In these instances, a medicine which is deemed to have no added therapeutic value over existing therapy is priced equivalent to its therapeutic comparators. In contrast, if it is considered superior to existing therapies, within an internal reference pricing system a premium is applied that represents a percentage increase. For example, in Japan, depending on the level of innovation, a medicine may be graded as: Innovativeness Premium (very innovative), Usefulness Premium I (less innovative) and Usefulness Premium II (minor therapeutic improvement) with a premium price of 70–120%, 35–60% and 5–30%, respectively, greater than the comparator price (OECD 2008).

Internal reference pricing may also be used for pricing generic medicines when they are listed for reimbursement, and in these instances a percentage price reduction from originator brand price is often applied (Vogler 2012). For example, in France, generic medicines are required to be priced at <50% of the off-patent originator price to be listed for reimbursement (OECD 2008).

Internal reference pricing may be used to define a single reimbursement price of medicines within a therapeutic group. If companies do not agree to the reference price, they are free to charge the higher price, however, where the retail price is higher than the reference price; patients are usually required to pay the difference. This price signal can result in a loss of market share to cheaper products (Aaserud et al. 2006; Vogler et al. 2008).

Technically, one issue to consider in developing an internal reference price system is the construction of the therapeutic groups, which may be on the basis of active ingredients (generics) or therapeutic actions (Löfgren 2007; Vogler et al. 2008). For example, Germany groups medicines that are therapeutically similar, but not chemically or class equivalent, such as all medicines for hypertension, or all anti-depressants (Aaserud et al. 2006; Paris and Docteur 2008).

In some countries, therapeutic groups only include off-patent medicines (Productivity Commission 2001), usually generics or ‘me-too’ products. In other countries such as Australia, New Zealand, Canada (British Columbia) and Germany, both patented and off-patent medicines may be included (Productivity Commission 2001; Vogler et al. 2008).

Another technical issue is defining the reference price, which is similar to external reference pricing, where the reference price is fixed at the level of the lowest priced product in the group (Productivity Commission 2001; Moise and Docteur 2007b) or the average price of all medicines within the group (Burstall et al. 1999). Germany uses the median as the reference price level (López-Casasnovas and Puig-Junoy 2000).

LMICs need to keep in mind the two principal objectives of an internal reference pricing system. These are to price original products at market entry level where therapeutic comparators are already available, or alternatively, to define a single reimbursement price for medicines within a therapeutic group. Pharmaco-economic may be needed to assess the level of innovation of original products over existing therapies or to develop relevant therapeutic groups. Pharmaco-economic evaluation is a technique requiring significant technical expertise and within country capacity building that is usually lacking in LMICs (see ‘Pharmaco-economic evaluation for value-based purchasing’ section below).

To add pressure for pharmaceutical companies to agree on a single reference price in a reimbursement scheme, LMICs need to be a dominant monopsony purchaser. This is less likely to happen if LMICs fail to move towards universal health coverage and most medicine payments remain as OOP expenses paid by individuals.

Finally, reference price systems need to be regularly updated to include new medicines within the reference group. Although reference pricing systems have been shown to limit the use of expensive medicines (Aaserud et al. 2006), somewhat paradoxically, they may also provide an incentive for lower priced medicines to be adjusted upwards to the reference price. Accordingly, it is considered that reference pricing should be...
used in combination with other measures, such as the requirement for official approval of price increases only on ‘reasonable grounds’ (Rietveld and Haaijer-Ruskamp 2002), compulsory generic substitution (Vogler et al. 2008) or compulsory price reductions (Löfgren 2007).

A variation on reference price systems is index pricing systems which provides a price signal to pharmacists and manufacturers. Within index pricing, the reimbursement price paid to pharmacists is calculated on the volume weighted average price of each medicine within the group (Brekke 2003 cited in Aaerud et al. 2006). Index pricing provides an economic incentive to pharmacists to dispense the lowest priced medicine in the index group as pharmacists are allowed to keep the difference between the index price and the retail price of the dispensed medicine. The calculated prices are regularly updated, which leads to a lower index price in the next regular update. An increase in the dispensing of cheaper medicines also creates incentives for manufacturers to lower their prices so as not to lose market share. When appropriately managed, the index pricing system has the potential to drive down group prices to a minimum economic floor level. Index pricing only works if therapeutic or generic substitution is allowed.

Pharmaco-economic evaluation for value-based purchasing. Pharmaco-economic evaluation is also used to establish fair price in addition to other common strategies such as external and internal reference pricing. It compares two or more therapies in terms of their costs and outcomes, whether expressed by monetary value, efficacy or enhanced quality of life (Productivity Commission 2001). The ultimate question posed in a pharmaco-economic evaluation is whether the cost to achieve the benefit that the new medicine offers compared with existing therapy represents value (Robertson et al. 2003). Four main types of pharmaco-economic evaluation are applied in the assessment of medicine pricing: cost-minimization analysis, cost-benefit analysis, cost-effectiveness analysis and cost-utility analysis (Drummond et al. 2005b).

In cost-minimization analysis, the costs of two or more therapies with identical outcomes are compared to select the least costly treatment. In cost-effectiveness analysis, the costs per unit of therapeutic outcome, measured in ‘natural units’, are compared, such as ‘mm Hg’ or ‘symptom-free days’. In cost-benefit analysis, cost and outcomes are compared in monetary terms, to select the therapy that provides the largest net monetary benefit. In cost-utility analysis, outcomes are measured in non-monetary terms, such as improvements in health status, often quantified as quality adjusted life years (QALYs) gained. Cost-utility analysis is used to select the therapy that minimizes cost per QALY gained (Drummond et al. 2005b).

Most European and OECD countries have used pharmaco-economic evaluation to some extent in their pricing and reimbursement decisions (Dickson et al. 2003; GÖG/ÖBIG 2006). Many have undertaken this technique on an ad hoc basis (Productivity Commission 2001), but it has also become mandatory in a number of countries. Although these methods are most needed where there is resource scarcity (Singer 2008), LMICs rarely conduct and use pharmaco-economic evaluation at a policy level (Augustovski et al. 2009). This is especially true for countries where private expenditure is a predominant form of health financing (Kulsomboon et al. 2012). 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 (Yang 2009).

Several barriers to the use of pharmaco-economic evaluation in LMICs have been identified. These relate to either to the production of economic information or to the decision to use the results at a policy level (Yang and Lee 2009; Yothasamut et al. 2009). The methodology employed is still a developing field (Yothasamut et al. 2009). Choosing an appropriate cost-effective threshold for decision rules that takes account of affordability issues in LMICs is still considered problematic (Shillcutt et al. 2009; Ngorsuraches et al. 2012). Limited capacity to conduct pharmaco-economic evaluation due to shortage of qualified researchers and reliable local healthcare data coupled with poor infrastructures is another major barrier to more widespread use of pharmaco-economic evaluations in LMICs (Babigumira et al. 2009; Tantivess et al. 2009; Yothasamut et al. 2009; Kulsomboon et al. 2012). Pharmaco-economic data are available from leading countries in the field such as Australia (see http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/public-summary-documents-by-product).

However, caution should be exercised in its application to LMICs. Published evidence suggests that not only is it difficult to apply pharmaco-economic results from high-income countries (Drummond et al. 2005a; Singer 2009), but extrapolation of the results from one LMIC to another can be problematic (Augustovski et al. 2009).

Cost plus pricing. Cost plus pricing is the application of negotiated additional costs to the basic production costs and Research and Development data as provided by the manufacturers. The additional cost normally takes the form of a fixed mark-up on the agreed base cost. Cost plus pricing is currently used for locally produced medicines in few European countries such as Cyprus, Greece and Slovakia (Vogler et al. 2008). Some Asian countries also use cost plus pricing, including China (Sun et al. 2008; Sun 2013) and Vietnam (Nguyen 2011). India once used this pricing mechanism (Sengupta et al. 2008) but their 2012 national pharmaceuticals pricing policy has given up this approach for a market-based pricing (Government of India National Pharmaceutical Pricing Authority 2012).

Although intuitively simplistic in its application, cost plus pricing has a number of limitations, which are often compounded by the lack of expertise and capacity in the poor resource settings of LMICs. The main problem lies in the setting of the initial cost parameters. It is difficult to verify company-supplied information on basic costs and profit margins (Rietveld and Haaijer-Ruskamp 2002). It is also difficult to assign overhead and research costs to individual medicines. Transfer pricing, a profit allocation method which refers to the setting, analysis, documentation and adjustment of charges between related parties, may be used to manipulate basic prices (Gray and Matsibula 2000). The cost plus pricing system also precludes regulators from making adjustments to prices in response to changes in market conditions (Rietveld and Haaijer-Ruskamp 2002). Cost plus pricing arrangements may fail to provide incentives for companies to improve efficiency.
and reduce costs, thus weakening their competitive position (Rietveld and Haaijer-Ruskamp 2002). A medicine with limited efficacy may be expensive to produce that can result in a high cost, low value product when a cost plus approach is used.

**Profit ceilings.** Profit ceilings are an alternative policy to fixing cost margins in cost plus pricing systems. The profit ceiling is based on the capital return of the company as a whole (Rietveld and Haaijer-Ruskamp 2002). This avoids the need to separate the costs of R&D and other costs for each product (Hutton et al. 1994). The setting of appropriate profit ceilings can be a challenging exercise in LMICs, where laws and regulations are often poorly enforced and administered. Profit ceilings work best where there is a comprehensive reimbursement system such as a national health service, an uncommon feature in many LMICs. A noticeable shortcoming of profit ceiling programmes is the incentive the system provides to increase prices to maintain profitability when sales are dramatically reduced for whatever reason (Bloor et al. 1996).

The Pharmaceutical Price Regulation Scheme (PPRS) in the UK is a profit ceiling system based on periodic negotiation between the Department of Health and the Association of the British Pharmaceutical Industry (UK Government Department of Health 2012). Companies within the scheme are free to set their market entry prices but their return on capital or the return on sale for those companies that do not have major capital investments in the UK is capped. If profits exceed specified levels, companies are required to repay the excess to the Department of Health or reduce prices (UK Government Department of Health 2012). Nevertheless, the PPRS is shifting towards a new system for pricing medicines, in which price will be determined by value (Webb 2011).

**Implementing pricing policies.** In implementing pricing policies, governments first need to decide what group of medicines in what submarket their pricing policies will target (i.e. the scope of price control). As discussed earlier, free pricing (i.e. pharmaceutical prices may be freely set by the manufacturers) is usually applied for non-reimbursable medicines, which often are the OTC products (GÖG/ÖBIG 2006). The prices of reimbursable medicines whose costs are at least partially covered by the national health services or social health insurance in the outpatient submarket are usually determined by competent authorities on a regulatory basis (statutory pricing) or through price negotiations with pharmaceutical companies (Vogler et al. 2008). In many LMICs, governments try to control prices for the benefit of consumers who pay OOP by defining maximum retail prices (MRP) or single exit prices as occurs in South Africa (Gray 2009; Pillay 2010) and China (WHO-WPRO 2009).

While the mechanisms discussed earlier identified methods for determining price, the price may be applied at various positions along the supply chain, from ex-manufacturer and importer level to wholesale or retail pharmacist level. Medicine prices are usually initially defined at the ex-manufacturer and importer level. Regulation at subsequent points along the supply chain may be implanted to minimize excessive mark-up by wholesalers and retailers. Alternatively, medicine prices may be defined at either the wholesale or retail level (Vogler et al. 2008). If the retail price is set, that price acts as a price ceiling and regulation of mark-ups further down the supply chain may not be necessary. In this case, manufacturers, importers, wholesalers and pharmacy retailers negotiate with each other on their charges and margins below the set retail price. However, if the price is defined at the wholesale level, regulation of retail mark-ups may be needed (Rietveld and Haaijer-Ruskamp 2002).

Different methods have been used to regulate distribution margins. Fixed or capped mark-ups on the ex-factory price and on the wholesale price are common methods used to regulate wholesale and retail margins (OECD 2008). In the fixed mark-up procedure, wholesale or retail mark-ups are regulated in the form of a fixed percentage added to the ex-factory price or wholesale price. In the capped mark-up method, mark-ups may vary provided that they do not exceed the cap. Another common approach to regulating distribution margins is regressive mark-ups where the percentage mark-up decreases when medicine prices increase (GÖG/ÖBIG 2006; Vogler et al. 2008).

An alternative mechanism is where, independent of medicine pricing, authorities elect to pay separate fees to remunerate pharmacists for their professional services (OECD 2008). Remuneration of dispensing pharmacists may be a fixed sum per patient per year or a fixed sum per prescription dispensed, making remuneration independent of the price of dispensed medicines. In South Africa, a combination of a fixed dispensing fee with a regressive margin was used (Gray 2009).

The difficulty in applying these mechanisms is that pharmacists may negotiate discounts on the wholesale price of a medicine (Rietveld and Haaijer-Ruskamp 2002). Pharmaceutical companies often offer discounts or rebates to preferred customers for their loyalty or for bulk purchases (Gray and Masebula 2000), resulting in the official mark-up rate differing from that determined by the market. This can happen in both high-income countries and LMICs, but is more likely in LMICs which either often lack regulation on pharmaceutical promotion or the regulation is inadequately enforced and administered. Africa has forbidden wholesalers and pharmacies from offering or accepting discounts (Pillay 2010). In response to discounts offered to pharmacists for generic medicine purchases, the Australian government requested compulsory price reductions (Löfgren 2007). Other countries, including the UK and the Netherlands, have introduced ‘claw back’ systems to pull back these discounts to their National Health Services or equivalent (Rietveld and Haaijer-Ruskamp 2002).

After market entry, some countries allow inflationary price increases, however, others limit price increases, enforce a price freeze or may instigate price cuts over time. In Switzerland and Vietnam, price increases are permitted post-entry but pharmaceutical companies are required to file an application providing a rationale for the increases (OECD 2008; Nguyen 2011). In Canada and Hungary, price increases are limited to the inflation rate (Critchley 2006; Vogler et al. 2008) while in Sweden and the Slovak Republic do not permit price increases, except under exceptional circumstances (OECD 2008). The UK launched a price freeze for generic medicines in 1999 and Ireland started a price freeze agreement in 2006 (Vogler et al. 2008). Germany has on occasions imposed price freezes and demanded across-the-board rebates to tackle deficits of the health insurance funds (Paris and Docteur 2008). Price cuts or
price freezes often occur following a price review by government. Some countries also use margin cut to limit the profits of the distributors (Vogler et al. 2008).

Purchasing policies
Medicine pricing is interdependent on the medicine purchasing system. In many LMICs, where individuals are the main purchasers, patients are basically price acceptors. This arises because as individuals, patients are in a very weak negotiating position in relation to suppliers. Meanwhile, medicine providers are in a very strong position by virtue of their monopoly over supply. In contrast to LMICs, most high-income countries have national purchasing systems as part of national health insurance where a government agency is essentially the single purchaser of medicines. Under these arrangements, the monopoly of medicine providers is matched by the monopsony position of the bulk purchaser. In such circumstances, the right of the single purchase agency to admit or exclude a particular medicine provides a government pricing agency with significant leverage in price negotiations (OECD 2008). Governments of these countries may use their market power in a number of ways to influence medicine pricing. To be able to make use of the following purchasing policies, LMICs need to enhance their economic power to become a dominant monopsony purchaser, with transition towards universal health coverage being a potential option.

Reimbursement schedules or formularies. A common approach is to construct a reimbursement schedule, either a positive list for medicines eligible for reimbursement or a negative list specifying products explicitly excluded from reimbursement (Rietveld and Haaijer-Ruskamp 2002; Vogler 2012). Inclusion criteria for the positive list may include cost effectiveness, medical need, therapeutic value and the estimated budget impact (Productivity Commission 2001; Vogler et al. 2011). Some countries include all medicines approved for marketing by regulatory authorities in the schedule once a decision about price and reimbursement level has been made (Paris and Docteur 2007b; Kaló et al. 2008). The positive list also may specify a particular clinical condition for use (OECD 2008). In case of the negative list, all medicines approved for marketing are automatically reimbursed unless assigned to the negative list.

Successful reimbursement schedules must have objective and transparent inclusion criteria which are consistently applied. De-listing should be considered when medicines become obsolete or over-priced. De-listing criteria need to be the same as those used for listing new medicines (Rietveld and Haaijer-Ruskamp 2002). Pharmaco-economic evaluation can be an important tool in listing or de-listing medicines from the formularies, but few LMICs have the capacity to conduct this evaluation.

Managed entry schemes. Price-volume agreement. Governments or insurers may also manage pharmaceutical budgets based on the total value of sales, rather than on a per-unit price basis, which is a form of risk sharing. In this situation, a set budget for reimbursement based on a sales forecast is negotiated as a condition of entry. The sales forecast is based on estimated country need. Any sales beyond the estimated need may indicate that the medicine has been used in populations less likely to benefit. In such cases, the company is required to pay a rebate. This approach, also known as a pay-back mechanism, is often applied in France to products with high sales potential (Mrazek and Mossialos 2004; Espin et al. 2011).

Health outcome guarantee. Health outcome guarantee schemes usually involve an arrangement where continued reimbursement is based on a health outcome being achieved. The arrangement may be patient based; where patients are first subsidized a product with the understanding that continued access is dependent on improvements in health measures. Failure to achieve the improved measure results in discontinuation of supply to the patient. Some programmes involve an agreement between governments or coverage decision makers and the pharmaceutical company on the expected outcomes from a medicine (e.g. only six supplies will be required for successful treatment). If the medicine fails to fulfill the expectation when used appropriately, the company is required to refund, in full or partly, the cost to the health service (Chapman et al. 2004).

Tendering. Where purchasing power is great and there are multiple potential sources for a medicine, competition from a tendering process can result in significant savings as payments may be reduced to the level of marginal production costs (OECD 2008). Tendering can be considered as a specific type of volume-price agreement as manufacturers set their bidding price conditional on a specified volume of sales. A tendering procedure is often used in case of public procurement (e.g. public hospitals and coverage schemes) (Vogler et al. 2008). A typical example of a country successful using tendering is New Zealand. An international competitive tendering system is used for prescription medicines that are distributed through private sector pharmaceutical supply chains but financed publicly, resulting in a price reduction of 15–20% beyond the already low prices achieved through internal reference pricing (Hawkins 2011). The success of tendering systems is heavily dependent on the existence of the so called ‘level playing field’ that enables like to be compared fairly with like. Such a field assumes the existence of appropriate laws and market infrastructures that encourage free and open competition in the tendering process as well as maintaining international pharmacopoeial standards. Core forms of regulation including general laws (e.g. competition and anti-corruption laws) as well as pharmaceutical sector regulation to foster healthy competition are often lacking or inadequately enforced in LMICs (Hawkins 2011; Nguyen et al. 2010; Nguyen 2011).

Pooled procurement. Pooled procurement is a form of cooperation between buyers to consolidate their purchasing power as a monopsony, a form of buyers’ cartel (Huff-Rousselle 2012). There are four models of pooled procurement which depend on the level of co-operation among the participating buyers. At the highest level, the purchasing is conducted collectively by ‘one procurement office on behalf of a group of facilities, health systems or countries’ and ‘group members agree to purchase certain drugs exclusively through the group’ as in a central contracting and procurement model (MSH 1997). At lower levels, actual purchasing is undertaken individually. Buyers may only share information on prices and suppliers (as in informed buying model and co-ordinated informed buying model) or negotiate prices collectively and select suppliers with
an agreement that procurement will be from the selected suppliers (Group contracting model) (WHO 2007). Although more empirical research is needed to validate the impact of pooled procurement on medicine prices (Waning et al. 2009), successful pooled procurement schemes have reported a number of benefits including reductions in unit prices of medicines purchased, improved quality assurance and reduction or elimination of corruption in pharmaceutical procurement (Huff-Rousselle 2012).

Pricing and purchasing related policies
In countries with subsidization of the purchase of medicines, the governments often influence the medicine demand to manage their pharmaceutical budgets. An extensive discussion of all government strategies using their subsidization power to influence medicine demand goes beyond the scope of this paper. Instead, the review focuses on the most commonly used pricing and purchasing related policies below.

Co-payments. Co-payments, also known as cost-sharing mechanisms, are the most commonly used approach to directly influence patient demand. In co-payment systems, patients are obliged to contribute directly to the cost of the reimbursable medicines they use (Rietveld and Haaijer-Ruskamp 2002; OECD 2008). Co-payments aim to increase consumer price sensitivity, thus moderating demand for medicines which are of little or marginal utility to the patient. Co-payments also reduce some of society’s financial burden by shifting part of medicine financing directly to the patients themselves (Doran and Robertson 2009).

Co-payments may be based on a fixed amount for each reimbursable medicine (called prescription fees) or a percentage of the medicine price. For example, in Australia, patients are required to pay a fixed initial amount and the government pays the remaining amount (Australian Government Department of Health and Ageing 2011a). The third type is deductible co-payments, also known as a graduated cost-sharing scheme (OECD 2008). Under this arrangement, a fixed amount is paid by the patient for a defined period with no reimbursement granted until total medicine costs are above the fixed amount. Sweden sets a threshold level for OOP spending for 1 year. Over the course of a year, patients pay the full cost of reimbursable medicines until the threshold is reached. Patients then have to pay a diminishing fraction of the cost as their cumulative spending increases, until a maximum amount is reached after which no co-payment is required (OECD 2008).

Co-payments add to patients’ financial burden. They may place a potential barrier to safe and timely use of prescription medicines (Doran et al. 2004), and in some cases may be high enough to impair medicine use (Paris and Docteur 2007a). Most European and OECD countries have introduced some mechanisms or safety nets to exempt, reduce or limit co-payments for some or all of their population. Hungary and Portugal have a 100% medicines’ reimbursement scheme for their poor or chronically ill. Belgium and Estonia provide the poor with higher reimbursement rates than the standard rate (Vogler et al. 2008). Variable co-payments may steer the use of medicines towards products with a lower co-payment. To avoid reduced use of important medicines, governments and third party payers may charge differential co-payments, with important medicines attracting lower co-payments. Belgium grades medicines into A, B, C, Cs and Cx categories with reduced levels of co-payment associated with greater significant therapeutic importance (De Swaef and Antonissen 2007).

Brand premiums. Reference price systems that enable companies to charge above the reference price and force consumers to pay the difference in price introduce an element of price sensitivity to patient demand. Governments or insurers pay up to the reference price. Any shortfall from the market price (called brand premium) is required to be paid by patients, thus encouraging patients to choose cheaper products (see ‘Internal reference pricing’ section).

Generic substitution. Usually, generic medicines with proven safety and efficacy represent a key strategy used by governments and third party payers to contain costs of health care and improve access to existing medicines (Nguyen et al. 2013). The availability of low-priced, quality-assured generic substitutes for off-patent medicines helps to reduce costs through competition (Hawkins 2011). To support generic use, reimbursement agencies may require prescribers to specify only generic names or they may authorize patients to choose equivalent generic items to branded products in return for a reduced price.

More often, generic substitution is regulated through generic dispensing policies that allow or require pharmacists to substitute the prescribed medicine with a generic product (OECD 2008).

Generic substitution varies across countries. Australia and Hungary allow generic substitution but do not make it compulsory (Kovács et al. 2007; Australian Government Department of Health and Ageing 2011b). Sweden and Germany require pharmacists to substitute a cheaper medicine whenever possible, unless the generic substitution indicated is not permitted by the prescribing clinician (Moïse and Docteur 2007b; Paris and Docteur 2008). Substitution is usually for the same substance, strength and form (Kovács et al. 2007) but may also be undertaken among therapeutically interchangeable products, as in therapeutic interchange programmes commonly used in the US Veterans Health Administration (Hoadley 2005).

Generic substitution, however, depends on more than just domestic reimbursement rates and substitution practices. Generic substitution only can achieve its goals if the quality of the respective generic medicines is assured in terms of therapeutic equivalence to the originator brand (Rietveld and Haaijer-Ruskamp 2002). Education for both health professionals and the public alike, based on objective scientific evidence, is necessary to counter possible mistrust regarding therapeutic equivalence. Financial incentives for prescribing doctors, dispensing pharmacies and patients may be needed to encourage the use of generic medicines (Kaplan et al. 2012).

Evidence on effectiveness of pricing and purchasing policies
Impact evaluation of pharmaceutical pricing and purchasing policies
Despite the limited number of quality studies evaluating the effectiveness of medicine pricing and reimbursement policies, there are some systematic reviews in this area but only a few relate to LMICs. A Cochrane systematic review (Aaserud et al. 2006) examined the effects of pharmaceutical pricing and
purchasing policies on medicine use, healthcare utilization, health outcomes and costs. Fifteen papers reporting 11 studies were included in the review and none involved LMICs. Fourteen papers were about reference pricing (i.e. reference price systems) and one evaluated index pricing; no studies other commonly used pricing policies, such as direct price controls. The review found that reference and index pricing systems tend to reduce both medicine prices and medicine expenditure through shifts in utilization towards less expensive medicines. However, no clear evidence was found for other outcomes such as adverse effects on health outcomes and increased healthcare utilization (Aaserud et al. 2006).

In 2008, another Cochrane systematic review examined the effects of caps and co-payments on medicine use (Austvoll-Dahlgren et al. 2008). Thirty evaluations in 21 studies were included, mainly from developed countries (e.g. the USA, Canada, Australia and Sweden) with one study from Nepal. Most evaluations were observational studies. Capped and co-payment policies were found to reduce medicine use and save third-party medicine expenditure. However, a substantial reduction in the use of medicines that may have adverse effects on health, thus increasing the use of healthcare services and overall expenditures was also noted. It was posited that these adverse effects might be overcome if exemptions were built in to systems to ensure that patients receive essential medical care.

Effectiveness of pharmaceutical pricing and purchasing policies in LMICs

In 2011, the WHO and Health Action International (WHO/HAI) commissioned a series of in-depth reviews on pharmaceutical pricing policies in LMICs as part of their project on medicine prices and availability (HAI 2011).

Espin et al. (2011) reviewed external reference pricing strategies and concluded that, due to the lack of monitoring reports or rigorous analytical studies, little was known about the effects of using this mechanism. In many LMICs, the reference price did not often become the actual national price. Moreover, there were some alleged undesirable consequences of using external reference pricing such as market launch delays in countries with low-price medicines and convergence in international pricing whereby low-income countries paid a higher price than in the past. Most importantly, companies reacted by reducing price transparency, with a resultant distortion of the external reference pricing mechanism, since decisions were made based on higher virtual prices rather than on actual transaction prices, creating opportunities for discrimination and corruption.

Faden et al. (2011) examined strategies whereby the health insurance system was used to improve cost-effective use of medicines by product selection (e.g. formularies, consumer cost-sharing, generic substitution); product purchasing (e.g. generic reference pricing, negotiated prices); reimbursement design and contractual arrangements (e.g. fee-for-service, capitation, case-based reimbursement, financial incentives, preferred providers) and utilization management (e.g. educational strategies, disease management). The authors found a paucity of published evidence on the impact of these strategies in improving the use of medicines in LMICs. It should be noted that this form of intervention is usually implemented by government agencies which often do not publish their work in academic journals.

In a review of the effects of mark-up regulation in the distribution chain in developing, no reliable information about the impact of mark-up regulation alone was found (Ball 2011). Nor was there any evidence that the regulation of discounts or rebates was effective in reducing medicine prices. Evidence about the effects of mark-up regulation on the viability of distribution operations at importer, wholesale or retail level was also very limited. Where available, published studies were either descriptive in nature or assessed the effects of mark-up regulations in combination with other policy interventions rather than as a sole measure. The author concluded that, to be effective in reducing medicine prices, mark-up regulation needs to be part of a comprehensive strategy, with regulation of either the manufacturer's selling price or the retail selling price implemented alongside adequate enforcement.

Hawkins (2011) reviewed the effects of competition policies on medicine prices and found good evidence, mostly in developed countries, that the competition and generic competition increased the availability of lower priced generic products. The competition was most effective with institutional purchasers, who are price conscious and have enough expert capacity to procure medicines. By implementing competition through tendering for off-patent, multisource essential medicines, institutional purchasers could obtain lower prices than by using price regulation. The author concluded that, to produce effective and efficient competition, core regulations including general laws (e.g. criminal law, contract law, competition law and anti-corruption law) and pharmaceutical sector regulation must be in place and adequately enforced. These regulations are often absent or not functioning effectively in many LMICs, thus making it difficult to ensure the quality and efficacy of medicines marketed and reducing potential to create effective competition.

Not directly funded by WHO/HAI, Kaplan et al. (2012) reviewed the impact of policies designed specifically to enhance the uptake of generic medicines in LMICs. They found that literature provided little insight into the impact of such policies on price and volume of generic medicines in LMICs. The authors suggested three principal prerequisites necessary for successful pro-generic medicine policies in LMICs namely: ‘a functioning medicines regulatory system in which all stakeholders have confidence, a competitive market for medicines, and an appropriate mix and alignment of financial incentives among prescribers, dispensers and consumers’.

Conclusion

This review demonstrates the variety of methods used internationally to support medicines pricing and purchasing. Each method is applied somewhat differently across countries, usually in combinations of strategies. While the information mostly comes from high-income countries, the implications for LMICs are clear. Choices exist but no one method is perfect and a range of strategies may be needed depending on the country-specific context. In developing effective pharmaceutical pricing and purchasing policies, governments from LMICs need to bear in mind the key question of who is paying for medicines. In the
long term, moving towards universal health coverage with most medicines being funded through public health insurance or social security systems will enable LMICs to enhance their economic power to become a dominant monopsony purchaser in the determination of reduced prices. Attainment of market dominance will open up new opportunities for governments to influence medicine pricing as an active economic player in price setting quite apart from their traditional regulatory and legalistic functions. Nevertheless, attendant risks from any of the available policy options are likely to be greater in LMICs if these countries still lack strong legal systems and supportive purchasing and administrative agencies to underpin their healthcare system. Maintaining, strengthening and enforcing the legal system are a necessary and ongoing adjunct to the development of pricing and purchasing policies. This needs to include pharmaceutical sector regulation, competition and anti-corruption law to create a level playing field to ensure a healthy competitive generic market given the clear advantages of pricing through competition over direct price regulation.

A comprehensive national generic medicine policy integrated within the broader framework of a national medicines policy including strategies that align pro-generic medicine incentives with prescribers, dispensers and patients would be the immediate option for LMICs. Co-development of reliable healthcare information systems is also needed to facilitate the implementation, monitoring and evaluation of pharmaceutical pricing and purchasing policies in LMICs.

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Contributors

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