Research Synthesis:
Price controls / Regulation

v1.0 researched and written by Elise Erickson, edited by Suerie Moon, last updated June 2018

Introduction

The literature on price controls/regulation is rich*, possibly because the topic covers a wide variety of pricing policies. That said, the literature seems to focus on developed countries, particularly those in the EU. There are limited studies that focus on developing countries.

Search terms

Price control, price regulation, reference pricing, product price control, price setting, price freeze, price cut, price fix, profit control, price negotiation, price ceiling, cost plus, generic substitution, external reference pricing, international reference pricing, reference-based pricing

Synthesis of the literature

Overviews
For a detailed overview of the issues and mechanisms for price regulation across a variety of countries, see Pharmaceutical Prices in the 21st Century (Z.-U.-D. Babar 2015). This book's chapters cover pharmaceutical pricing policies and strategies in: Australia, Canada, China, Egypt, Ethiopia, Finland, India, South Korea, Malaysia, New Zealand, Norway, Sweden, Qatar, South Africa, Turkey, the Gulf Countries' Council (GCC), the United Arab Emirates, US, Vietnam, Europe, and the UK (the UK chapter, however, focuses primarily on HTA). Additionally, Hassett (2004) offers a useful introduction (see pages 1-10) that groups price control interventions into three categories: price controls, volume controls, and spending controls—each of which with supply-side and demand-side interventions (e.g. direct price control via price ceilings as a supply-side price control intervention).

Ess et al. (2003) describe how price controls/regulation mechanisms typically fall into one of three categories: direct product price control, indirect product price control, and profit control. Finally, Appendix A on "The effect of regulation on pharmaceutical revenues: experience in nineteen countries" by Sood et al. (2009) provides a useful list of papers on pharmaceutical regulations in 18 different countries, organized by country.

The discussion on price control revolves primarily around five issues: the impact of price controls on R&D and innovation; the impact of price controls on total pharmaceutical expenditure; the impact of price controls on generics; reference pricing as a specific price control strategy; and the overlap between price control and health technology assessment.

1.   Price control & R&D/innovation: Pharmaceutical price control and price regulation emerges as a contentious issue in the literature with regards to R&D/innovation. While those in favor of price controls tend to argue that prices are excessive, and therefore need to be regulated to increase access to drugs, and to contain total pharmaceutical expenditure, those opposed to price controls argue that these mechanisms decrease pharmaceutical revenues (Sood et al. 2009), thereby hampering innovation and R&D (R. J. Vogel 2002). It has also been argued that price controls result in fewer drug launches and longer launch delays (Danzon, Wang, and Wang 2005; Kyle 2007).

2.   Price control & total pharmaceutical expenditure: Price controls can be implemented as a way to contain total pharmaceutical expenditure. Some studies, however, argue that pricing policies are a weak tool for curbing expenditures, since they do not monitor physicians' prescribing behavior (Lambrelli and O'Donnell 2011). There is a reoccurring concern over expenditures rather than prices for policy decision-making (Menon 2001; Lambrelli and O'Donnell 2011), and therefore the need for demand-side incentives to reduce unnecessary use and volume controls (in addition to the supply-side controls) to control overall expenditures (Mrazek 2002).

3.   Price control & generics: It is argued that pharmaceutical price control/regulation is necessary to safeguard access, particularly when price competition for a given product is weak or absent. It has also been claimed, however, that price competition between generic manufacturers is stronger in less or un-regulated regulated markets, and weaker in highly regulated markets, implying that price regulation may undercuts savings from generic drugs (Danzon and Chao 2000). When generics prices are regulated, evidence from Europe suggests that price caps on generics resulted in a price higher than without the regulation; the same study found that reference pricing reduced consumer prices, though to a greater extent for originator than for generic prices (Puig-Junoy2010).

4.   Price control & reference pricing: Reference pricing is a widely implemented price containment method. There are several different reference pricing designs including index pricing, international reference pricing, and external or internal reference pricing, etc. The methodologies behind these forms of reference pricing can differ, for example as with the external reference pricing methodology of different European countries (Leopold et al. 2012, see Table 1 for overview of external reference pricing methodology by country; Rémuzat et al. 2015). Several papers examined Norway's experience with reference pricing (specifically index pricing), which was introduced in 2003, and replaced their previous price cap regulation. These studies found that index pricing resulted in lower prices of both brand-name and generic drugs (Brekke, Holmas, and Straume 2011), and reduced competition from parallel imports without any firmly negative impact on producer profits (Brekke, Holmås, and Straume 2015). Furthermore, studies on the experience found that index pricing is more effective than price caps in decreasing drug prices (Brekke, Grasdal, and Holmås 2009). Others, however, found that direct price control (international reference pricing) was the most successful in Norway in bringing about price decreases (Håkonsen, Horn, and Toverud 2009). Data from Denmark illustrates that internal reference pricing was more successful than external reference pricing in lowering list prices, reference prices and patient co-payments (Kaiser et al. 2014).

Acosta et al. (2014) provide a thorough review of primarily reference-based pricing papers, and found that reference pricing tends to lead to an increase in 'reference medicine' prescriptions, and a decrease in the overall money spent by insurers on pharmaceuticals.

5. Price control & health technology assessment/pharmacoeconomics: Price control/regulation and HTA overlap in that HTA can be considered a mechanism for setting the maximum price at which a medicine would be considered cost-effective in a given health system. Theidel and von der Schulenburg (2016), however, find that negotiation strategy and other 'soft' factors appear to be more influential when negotiating reimbursement prices in Germany than 'hard' factors such as an HTA's benefit rating or size of target population.

The majority of the literature on price controls/regulation focuses on developed countries (Brekke, Holmas, and Straume 2011; Brekke, Grasdal, and Holmås 2009; Brekke, Holmås, and Straume 2015; Danzon, Wang, and Wang 2005; Ess, Schneeweiss, and Szucs 2003). Only a few studies examine price controls in LMICs. This is perhaps due to the lack of price control mechanisms and the challenges in regulating prices in contexts where legal systems may be weak, and where drug purchasing institutions may not exist (Nguyen et al. 2015). A paper examining Malaysia illustrates these issues (Hassali et al. 2015); and a study on Mozambique suggests price controls may not be effective in increasing access to medicines in LICs (Russo and McPake 2010). Some papers, however, examine price negotiation strategies by LMICs. For instance, two studies pointed to the success of Mexico's Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs (CCPNM) in reducing drug prices (Gómez-Dantés et al. 2012), including ARVs specifically (Adesina, Wirtz, and Dratler 2013). The evidence is not necessarily clear, however, as others argue that Mexico's CCPNM was unsuccessful in lowering ARV prices, and point to the lack of existing legal and structural options available to Mexico for ARV price control (Chaumont et al. 2015). Another study compared Brazil's ARV price negotiation experience with Thailand's compulsory licensing experience, and concluded that Brazil's price negotiation technique was insufficient, leaving ARVs unaffordable. This study underscored the role of civil society in raising the priority given to health vis-a-vis IP or trade considerations (Ford et al. 2007). There are few evaluations of pro-generic policies in LMICs on generics uptake (Kaplan et al. 2012).

Research gaps

• Impact of different price regulation policies on prices and availability of medicines
• Further research on efficacy of current or potential price control mechanisms in relatively small markets, e.g. LMICs or HICs with small populations.

Cited papers with abstracts

Acosta, Angela, Agustín Ciapponi, Morten Aaserud, Valeria Vietto, Astrid Austvoll-Dahlgren, Jan Peter Kösters, Claudia Vacca, Manuel Machado, Diana Hazbeydy Diaz Ayala, and Andrew D Oxman. 2014. "Pharmaceutical Policies: Effects of Reference Pricing, Other Pricing, and Purchasing Policies." Cochrane Database of Systematic Reviews 10 (Art. No. CD005979). https://doi.org/10.1002/14651858.CD005979.pub2.

Abstract:

Background: Pharmaceuticals are important interventions that could improve people's health. Pharmaceutical pricing and purchasing policies are used as cost-containment measures to determine or affect the prices that are paid for drugs. Internal reference pricing establishes a benchmark or reference price within a country which is the maximum level of reimbursement for a group of drugs. Other policies include price controls, maximum prices, index pricing, price negotiations and volume- based pricing.

Objectives: To determine the effects of pharmaceutical pricing and purchasing policies on health outcomes, healthcare utilisation, drug expenditures and drug use.

Search methods: We searched the Cochrane Central Register of Controlled Trials (CENTRAL), part of The Cochrane Library (including the Effective Practice and Organisation of Care Group Register) (searched 22/10/2012); MEDLINE In-Process & Other Non-Indexed Citations and MEDLINE, Ovid (searched 22/10/2012); EconLit, ProQuest (searched 22/10/2012); PAIS International, ProQuest (searched 22/10/2012); World Wide Political Science Abstracts, ProQuest (searched 22/10/2012); INRUD Bibliography (searched 22/10/2012); Embase, Ovid (searched 14/12/2010); NHSEED, part of The Cochrane Library (searched 08/12/2010); LILACS, VHL (searched 14/12/2010); International Political Science Abstracts (IPSA), Ebsco (searched (17/12/2010); OpenSIGLE (searched 21/12/10); WHOLIS, WHO (searched 17/12/2010); World Bank (Documents and Reports) (searched 21/12/2010); Jolis (searched 09/10/2011); Global Jolis (searched 09/10/2011) ; OECD (searched 30/08/2005); OECD iLibrary (searched 30/08/2005); World Bank eLibrary (searched 21/12/2010); WHO - The Essential Drugs and Medicines web site (browsed 21/12/2010).

Selection criteria: Policies in this review were defined as laws; rules; financial and administrative orders made by governments, non-government organisations or private insurers. To be included a study had to include an objective measure of at least one of the following outcomes: drug use, healthcare utilisation and health outcomes or costs (expenditures); the study had to be a randomised trial, non-randomised trial, interrupted time series (ITS), repeated measures (RM) study or a controlled before-after study of a pharmaceutical pricing or purchasing policy for a large jurisdiction or system of care.

Data collection and analysis: Two review authors independently extracted data and assessed the risk of bias. Results were summarised in tables. There were too few comparisons with similar outcomes across studies to allow for meta-analysis or meaningful exploration of heterogeneity.

Main results: We included 18 studies (seven identified in the update): 17 of reference pricing, one of which also assessed maximum prices, and one of index pricing. None of the studies were trials. All included studies used ITS or RM analyses. The quality of the evidence was low or very low for all outcomes. Three reference pricing studies reported cumulative drug expenditures at one year after the transition period. Two studies reported the median relative insurer's cumulative expenditures, on both reference drugs and cost share drugs, of -18%, ranging from -36% to 3%. The third study reported relative insurer's cumulative expenditures on total market of -1.5%. Four reference pricing studies reported median relative insurer's expenditures on both reference drugs and cost share drugs of -10%, ranging from -53% to 4% at one year after the transition period. Four reference pricing studies reported a median relative change of 15% in reference drugs prescriptions at one year (range -14% to 166%). Three reference pricing studies reported a

median relative change of -39% in cost share drugs prescriptions at one year (range -87% to -17%). One study of index pricing reported a relative change of 55% (95% CI 11% to 98%) in the use of generic drugs and -43% relative change (95% CI -67% to -18%) in brand drugs at six months after the transition period. The same study reported a price change of -5.3% and -1.1% for generic and brand drugs respectively six months after the start of the policy. One study of maximum prices reported a relative change in monthly sales volume of all statins of 21% (95% CI 19% to 24%) after one year of the introduction of this policy. Four studies reported effects on mortality and healthcare utilisation, however they were excluded because of study design limitations.

Authors' conclusions: The majority of the studies of pricing and purchasing policies that met our inclusion criteria evaluated reference pricing. We found that internal reference pricing may reduce expenditures in the short term by shifting drug use from cost share drugs to reference drugs. Reference pricing may reduce related expenditures with effects on reference drugs but the effect on expenditures of cost share drugs is uncertain. Reference pricing may increase the use of reference drugs and may reduce the use of cost share drugs. The analysis and reporting of the effects on patients' drug expenditures were limited in the included studies and administration costs were not reported. Reference pricing effects on health are uncertain due to lack of evidence. The effects of other purchasing and pricing policies are until now uncertain due to sparse evidence. However, index pricing may reduce the use of brand drugs, increase the use of generic drugs, and may also slightly reduce the price of the generic drug when compared with no intervention.

Link: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005979.pub2/full

Adesina, Adebiyi, Veronika J. Wirtz, and Sandra Dratler. 2013. "Reforming Antiretroviral Price Negotiations and Public Procurement: The Mexican Experience." Health Policy and Planning 28 (1): 1–10. https://doi.org/10.1093/heapol/czs015.

Abstract: Since antiretroviral (ARV) medicines represent one of the most costly components of therapy for HIV in middle-income countries, ensuring their efficient procurement is highly relevant. In 2008, Mexico created a national commission for the negotiation of ARV prices to achieve price reductions for their public HIV treatment programmes. The objective of this study is to assess the immediate impact of the creation of the Mexican Commission for Price Negotiation on ARV prices and expenditures. A longitudinal retrospective analysis of procurement prices, volumes and type of the most commonly prescribed ARVs procured by the two largest providers of HIV/AIDS care in Mexico between 2004 and 2009 was carried out. These analyses were combined with 26 semi-structured key informant interviews to identify changes in the procurement process. Prices for ARVs dropped by an average of 38% after the first round of negotiations, indicating that the Commission was successful in price negotiations. However, when compared with other upper-middle-income countries, Mexico continues to pay an average of six times more for ARVs. The Commission's negotiations were successful in achieving lower ARV prices. However, price reduction in upper-middle-income countries suggests that the price decrease in Mexico cannot be entirely attributed to the Commission's first round of negotiations. In addition, key informants identified inefficiencies in the forecasting and procurement processes possibly affecting the efficiency of the negotiation process. A comprehensive approach to improving efficiency in the purchasing and delivery of ARVs is necessary, including a better clarification in the roles and responsibilities of the Commission,

improving supply data collection and integration in forecasting and procurement, and the creation of a support system to monitor and provide feedback on patient ARV use.

Link: https://academic.oup.com/heapol/article/28/1/1/643825

Babar, Zaheer-Ud-Din, ed. 2015. Pharmaceutical Prices in the 21st Century. ADIS. www.springer.com/de/book/9783319121680.

Abstract: This book provides an overview of the global pharmaceutical pricing policies. Medicines use is increasing globally with the increase in resistant microbes, emergence of new treatments, and because of awareness among consumers. This has resulted in increased drug expenditures globally. As the pharmaceutical market is expanding, a variety of pharmaceutical pricing strategies and policies have been employed by drug companies, state organizations and pharmaceutical pricing authorities.

Link: http://www.springer.com/de/book/9783319121680

Brekke, Kurt R., Astrid L. Grasdal, and Tor Helge Holmås. 2009. "Regulation and Pricing of Pharmaceuticals: Reference Pricing or Price Cap Regulation?" European Economic Review 53 (2): 170–85. https://doi.org/10.1016/j.euroecorev.2008.03.004.

Abstract: We study the relationship between regulatory regimes and pharmaceutical firms' pricing strategies using a unique policy experiment in Norway, which in 2003 introduced a reference price (RP) system called "index pricing" for a sub-sample of off-patent pharmaceuticals, replacing the existing price cap (PC) regulation. We estimate the effect of the reform using a product level panel dataset, covering the drugs exposed to RP and a large number of drugs still under PC regulation in the time before and after the policy change. Our results show that RP significantly reduces both brand-name and generic prices within the reference group, with the effect being stronger for brand- names. We also identify a negative cross-price effect on therapeutic substitutes not included in the RP system. In terms of policy implications, the results suggest that RP is more effective than PC regulation in lowering drug prices, while the cross-price effect raises a concern about patent protection.

Link: https://www.sciencedirect.com/science/article/pii/S001429210800024X

Brekke, Kurt R., Tor Helge Holmas, and Odd Rune Straume. 2011. "Reference Pricing, Competition, and Pharmaceutical Expenditures: Theory and Evidence from a Natural Experiment." Journal of Public Economics 95 (7): 624–38. https://doi.org/10.1016/j.jpubeco.2010.11.015.

Abstract: We study the impact of regulation on competition between brand-names and generics and pharmaceutical expenditures using a unique policy experiment in Norway, where reference pricing (RP) replaced price cap regulation in 2003 for a sub-sample of off-patent products. First, we construct a vertical differentiation model to analyze the impact of regulation on prices and market shares of brand-names and generics. Then, we exploit a detailed panel data set at product level covering several off-patent molecules before and after the policy reform. Off-patent drugs not subject to RP serve as our control group. We find that RP

significantly reduces both brand-name and generic prices, and results in significantly lower brand-name market shares. Finally, we show that RP has a strong negative effect on average molecule prices, suggesting significant cost-savings, and that patients' copayments decrease despite the extra surcharges under RP.

Link: https://www.sciencedirect.com/science/article/pii/S0047272710001751

Brekke, Kurt R., Tor Helge Holmås, and Odd Rune Straume. 2015. "Price Regulation and Parallel Imports of Pharmaceuticals." Journal of Public Economics 129 (September): 92–105. https://doi.org/10.1016/j.jpubeco.2015.08.002.

Abstract: This paper studies the effects of price regulation and parallel imports in the on-patent pharmaceutical market. In a theory model where the producer price is subject to bargaining between the brand-name producer and a distributor, we show that the effects of stricter price regulation crucially depend on whether the producer faces competition from parallel imports. While parallel imports improve the bargaining position of the distributor, price regulation counteracts this effect and may even be profitable for the producer. We test the implications of our model on a unique dataset with information on sales and prices at both producer and retail level for 165 substances over 4 years (2004–2007). We show that stricter price regulation reduces competition from parallel imports, and has no (strictly negative) effect on producer profits in the presence (absence) of parallel imports. Our results suggest that price regulation might improve static efficiency without being harmful for dynamic efficiency in the presence of parallel imports.

Link: https://www.sciencedirect.com/science/article/pii/S0047272715001371

Chaumont, Claire, Sergio Bautista-Arredondo, Juan José Calva, Roberto Isaac Bahena-González, Gerda Hitz Sánchez-Juárez, Arturo González de Araujo-Muriel, Carlos Magis-Rodríguez, and Mauricio Hernández-Ávila. 2015. "Antiretroviral Purchasing and Prescription Practices in Mexico: Constraints, Challenges and Opportunities." Salud Pública de México 57: s171–82.

Abstract: OBJECTIVE: This study examines the antiretroviral (ARV) market characteristics for drugs procured and prescribed to Mexico's Social Protection System in Health beneficiaries between 2008 and 2013, and compares them with international data.

MATERIALS AND METHODS: Procurement information from the National Center for the Prevention and the Control of HIV/AIDS was analyzed to estimate volumes and prices of key ARV. Annual costs were compared with data from the World Health Organization's Global Price Reporting Mechanism for similar countries. Finally, regimens reported in the ARV Drug Management, Logistics and Surveillance System database were reviewed to identify prescription trends and model ARV expenditures until 2018.

RESULTS: Results show that the first-line ARV market is concentrated among a small number of patented treatments, in which prescription is clinically adequate, but which prices are higher than those paid by similar countries. The current set of legal and structural options available to policy makers to bring prices down is extremely limited.

CONCLUSIONS: Different negotiation policies were not successful to decrease ARV high prices in the public health market. The closed list approach had a good impact on prescription quality but was ineffective in reducing prices. The Coordinating Commission for Negotiating the Price of Medicines and other Health Supplies also failed to obtain adequate prices. To maximize purchase efficiency, policy makers should focus on finding long-term legal and political safeguards to counter the high prices imposed by pharmaceutical companies.

Link: https://scielosp.org/pdf/spm/2015.v57suppl2/s171-s182/en

Danzon, Patricia M., and Li-Wei Chao. 2000. "Does Regulation Drive out Competition in Pharmaceutical Markets?" The Journal of Law and Economics 43 (2): 311–58. https://doi.org/10.1086/467458.

Abstract: Most countries regulate pharmaceutical prices, either directly or indirectly, on the assumption that competition is at best weak in this industry. This paper tests the hypothesis that regulation of manufacturer prices and retail pharmacy margins undermines price competition. We use data from seven countries for 1992 to examine price competition between generic competitors (different manufacturers of the same compound) and therapeutic substitutes (similar compounds) under different regulatory regimes. We find that price competition between generic competitors is significant in unregulated or less regulated markets (United States, United Kingdom, Canada, and Germany) but that regulation undermines generic competition in strict regulatory systems (France, Italy, and Japan). Regulation of retail pharmacy further constrains competition in France, Germany, and Italy. Regulation thus undermines the potential for significant savings on off-patent drugs, which account for a large and growing share of drug expenditures. Evidence of competition between therapeutic substitutes is less conclusive owing to data limitations.

Link: http://www.journals.uchicago.edu/doi/abs/10.1086/467458

Danzon, Patricia M., Y. Richard Wang, and Liang Wang. 2005. "The Impact of Price Regulation on the Launch Delay of New Drugs—evidence from Twenty-Five Major Markets in the 1990s." Health Economics 14 (3): 269–92. https://doi.org/10.1002/hec.931.

Abstract: We analyze the effect of price regulation on delays in launch of new drugs. Because a low price in one market may 'spill-over' to other markets, through parallel trade and external referencing, manufacturers may rationally prefer longer delay or non-launch to accepting a relatively low price. We analyze the launch in 25 major markets, including 14 EU countries, of 85 new chemical entities (NCEs) launched between 1994 and 1998. Each NCE's expected price and market size in a country are estimated using lagged average price and market size of other drugs in the same (or related) therapeutic class. We estimate a Cox proportional hazard model of launch in each country, relative to first global launch. Only 55% of the potential launches occur. The US leads with 73 launches, followed by Germany (66) and the UK (64). Only 13 NCEs are launched in Japan, 26 in Portugal and 28 in New Zealand. The results indicate that countries with lower expected prices or smaller expected market size have fewer launches and longer launch delays, controlling for per capita income and other country and firm characteristics. Controlling for expected price and volume, country effects for the likely parallel export countries are significantly negative.

Link: http://onlinelibrary.wiley.com/doi/10.1002/hec.931/abstract

Ess, Silvia M., Sebastian Schneeweiss, and Thomas D. Szucs. 2003. "European Healthcare Policies for Controlling Drug Expenditure." PharmacoEconomics 21 (2): 89–103. https://doi.org/10.2165/00019053-200321020-00002.

Abstract: In the last 20 years, expenditures on pharmaceuticals — as well as total health expenditures — have grown faster than the gross national product in all European countries. The aim of this paper was to review policies that European governments apply to reduce or at least slow down public expenditure on pharmaceutical products. Such policies can target the industry, the wholesalers and retailers, prescribers, and patients. The objectives of pharmaceutical policies are multidimensional and must take into account issues relating to public health, public expenditure and industrial incentives. Both price levels and consumption patterns determine the level of total drug expenditure in a particular country, and both factors vary greatly across countries. Licensing and pricing policies intend to influence the supply side. Three types of pricing policies can be recognised: product price control, reference pricing and profit control. Profit control is mainly used in the UK. Reference pricing systems were first used in Germany and The Netherlands and are being considered in other countries. Product price control is still the most common method for establishing the price of drugs. For the aim of fiscal consolidation, price-freeze and price-cut measures have been frequently used in the 1980s and 1990s. They have affected all types of schemes. For drug wholesalers and retailers, most governments have defined profit margins. The differences in price levels as well as the introduction of a Single European Pharmaceutical Market has led to the phenomenon of parallel imports among member countries of the European Union. This may be facilitated by larger and more powerful wholesalers and the vertical integration between wholesalers and retailers. To control costs, the use of generic drugs is encouraged in most countries, but only few countries allow pharmacists to substitute generic drugs for proprietary brands. Various interventions are used to reduce the patients' demand for drugs by either denying or limiting reimbursement of products and providing an incentive for patients to reduce their consumption of drugs. These interventions include defining a list either of drugs reimbursed (positive list) or one of drugs not reimbursed (negative list), and patient co-payments, which require patients to pay a proportion of the cost of a prescribed product or a fixed charge. Policies intended to affect physicians' prescribing behaviour include guidelines, information (about price and less expensive alternatives) and feedback, and the use of budgetary restrictions.

Link: https://link.springer.com/article/10.2165/00019053-200321020-00002

Ford, Nathan, David Wilson, Gabriela Costa Chaves, Michel Lotrowska, and Kannikar Kijtiwatchakul. 2007. "Sustaining Access to Antiretroviral Therapy in the Less-Developed World: Lessons from Brazil and Thailand." AIDS 21 (July): S21. https://doi.org/10.1097/01.aids.0000279703.78685.a6.

Abstract: ANTIRETROVIRAL ROLLOUT IN BRAZIL AND THAILAND: Brazil and Thailand are among few developing countries to achieve universal access to antiretroviral therapy. Three factors were critical to this success: legislation for free access to treatment; public sector capacity to manufacture medicines; and strong civil society action to support government initiatives to improve access.

LOCAL PRODUCTION OF AFFORDABLE, NON-PATENTED DRUGS: Many older antiretroviral drugs are not patented in either country and affordable generic versions are manufactured by local pharmaceutical institutes.

EFFORTS TO ENSURE ACCESS TO EXPENSIVE, PATENTED DRUGS: Developing countries were not required to grant patents on medicines until 2005, but under US government threats of trade sanctions, Thailand and Brazil began doing so at least ten years prior to this date. Brazil has used price negotiations with multi-national pharmaceutical companies to lower the price of newer patented antiretrovirals. However, the prices obtained by this approach remain unaffordable. Thailand recently employed compulsory licensing for two antiretrovirals, obtaining substantial price reductions, both for generic and brand products. Following Thailand's example, Brazil has issued its first compulsory license.

LESSONS LEARNED: Middle-income countries are unable to pay the high prices of multinational pharmaceutical companies. By relying on negotiations with companies, Brazil pays up to four times more for some drugs compared with prices available internationally. Compulsory licensing has brought treatment with newer antiretrovirals within reach in Thailand, but has resulted in pressure from industry and the US government. An informed and engaged civil society is essential to support governments in putting health before trade.

Link:https://journals.lww.com/aidsonline/fulltext/2007/07004/Sustaining_access_to_antiretroviral_therapy_i n_the.4.aspx

Gómez-Dantés, Octavio, Veronika J Wirtz, Michael R Reich, Paulina Terrazas, and Maki Ortiz. 2012. "A New Entity for the Negotiation of Public Procurement Prices for Patented Medicines in Mexico." Bulletin of the World Health Organization 90 (10): 788–92. https://doi.org/10.2471/BLT.12.106633.

Abstract: Problem As countries expand health insurance coverage, their expenditures on medicines increase. To address this problem, WHO has recommended that every country draw up a list of essential medicines. Although most medicines on the list are generics, in many countries patented medicines represent a substantial portion of pharmaceutical expenditure.

Approach To help control expenditure on patented medicines, in 2008 the Mexican Government created the Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs (CCPNM), whose role, as the name suggests, is to enter into price negotiations with drug manufacturers for patented drugs on Mexico's list of essential medicines.

Local setting Mexico's public expenditure on pharmaceuticals has increased substantially in the past decade owing to government efforts to achieve universal health-care coverage through Seguro Popular, an insurance programme introduced in 2004 that guarantees access to a comprehensive package of health services and medicines.

Relevant changes Since 2008, the CCPNM has improved procurement practices in Mexico's public health institutions and has achieved significant price reductions resulting in substantial savings in public pharmaceutical expenditure.

Lessons learnt The CCPNM has successfully changed the landscape of price negotiation for patented medicines in Mexico. However, it is also facing challenges, including a lack of explicit indicators to assess CCPNM performance; a shortage of permanent staff with sufficient technical expertise; poor coordination among institutions in preparing background materials for the annual negotiation process in a timely manner; insufficient communication among committees and institutions; and a lack of political support to ensure the sustainability of the CCPNM.

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3471060/

Håkonsen, Helle, Anne Marie Horn, and Else-Lydia Toverud. 2009. "Price Control as a Strategy for Pharmaceutical Cost containment—What Has Been Achieved in Norway in the Period 1994–2004?" Health Policy 90 (2): 277–85. https://doi.org/10.1016/j.healthpol.2008.09.018.

Abstract: Objectives: To describe and evaluate the different price control strategies implemented in Norway after its accession to the European Economic Area (1994–2004).

Methods: Interviews with ten key persons who had broad insight into the field in question were held. All the available literature was reviewed.

Results: Direct price control involving international reference pricing of prescription drugs, and the subsequent price revisions, that occurred from the year 2000 onwards, resulted in predictable and substantial price reductions. With respect to the indirect methods which targeted the off-patent market, the price reductions resulting from reference-based pricing (1993–2000) were only marginal and the achieved savings derived mainly from increased patients' charges. The introduction of generic substitution in 2001 led to increased market shares for non-branded products, but discounts from the manufacturers were not reflected in retail prices. An index price system (2003–2004) was therefore created; but as it entailed negative economical incentives for the pharmacy chains, the price changes did not meet the expectations.

Conclusion: The direct pricing strategy, i.e. the international reference pricing, was considered to be the most successful method. In contrast, due to the unpredictability of the market situation, the resulting effects of the indirect methods, i.e. reference-based pricing, generic substitution, and index pricing, were more limited.

Link: http://www.healthpolicyjrnl.com/article/S0168-8510(08)00220-0/abstract

Hassali, Mohamed Azmi, Ching Siang Tan, Zhi Yen Wong, Fahad Saleem, and Alian A. Alrasheedy. 2015. "Pharmaceutical Pricing in Malaysia." In Pharmaceutical Prices in the 21st Century, 171–88. Adis, Cham. https://doi.org/10.1007/978-3-319-12169-7_10.

Abstract: Malaysia's healthcare system consists of two sectors namely public and private sector. Ministry of Health (MOH) is the main agency providing healthcare services in public sector. Malaysia pharmaceutical market is dominated by prescription drugs that account for approximately 60 % of the pharmaceutical market share by value. There is no price control mechanism for pharmaceuticals in Malaysia. In fact, drug prices are not regulated in Malaysia and it is left to market forces to foster competition. However, in public sector, few price control

strategies are employed by MOH to ensure fair, reasonable, affordable and stable prices of drugs. Despite various strategies formulated, there are challenges that need to be addressed. In public sector, the main challenges include escalating cost of pharmaceuticals as a result of privatization of Government Medical Store, lack of implementation of pro-generics policies and overlapping role of Malaysian Health Technology Assessment (MaHTAS) and Pharmacoeconomic Unit at Pharmaceutical Service Division (PSD) in cost-effectiveness evaluation of drugs. Similarly, in private sector, majority of the private health care providers would not follow the recommended retail price in selling medicines. In conclusion, there are several challenges that need be addressed in order to have a good pharmaceutical pricing strategy in Malaysia.

Link: https://link.springer.com/chapter/10.1007/978-3-319-12169-7_10

Hassett, Kevin A. 2004. "Price Controls and the Evolution of Pharmaceutical Markets (Preliminary)." http://www.who.int/intellectualproperty/news/en/Submission-Hassett.pdf.

Abstract: Many countries have essentially nationalized their health care systems. One byproduct of this is that pharmaceutical prices and volumes (utilization) are the subjects of explicit government directives and decisions, rather than the outcome of a market process. This paper synthesizes the substantial economic literature that has emerged that has studied the impact of these factors. Evidence suggests that drug prices and volumes are significantly lower outside the U.S. than they are inside the U.S. There is also evidence that these lower volumes are associated with trade factors. Domestic generic manufacturers often control a large share of the domestic generic market, often leading to an inefficient use of limited healthcare resources by governments with price controlled markets. The paper provides commentary on the literature that tracks the impact of lower revenue pharmaceutical research. That literature suggests that revenue reductions lead to reduced research and development activity and less drug discovery. The final section evaluates the impact of reduced drug discovery on health costs and outcomes, highlighting key evidence that the foreign price controls have significant human and economic costs associated with them.

Link: http://www.who.int/intellectualproperty/news/en/Submission-Hassett.pdf

Kaiser, Ulrich, Susan J. Mendez, Thomas Rønde, and Hannes Ullrich. 2014. "Regulation of Pharmaceutical Prices: Evidence from a Reference Price Reform in Denmark." Journal of Health Economics 36 (July): 174–87. https://doi.org/10.1016/j.jhealeco.2014.04.003.

Abstract: Reference price systems for prescription drugs constitute widely adopted cost containment tools. Under these regimes, patients co-pay a fraction of the difference between a drug's pharmacy retail price and a reference price that is set by the government. Reference prices are either externally (based on drug prices in other countries) or internally (based on domestic drug prices) determined. We study the effects of a change from external to internal reference pricing in Denmark in 2005. We find that the reform led to substantial reductions in retail prices, reference prices and patient co- payments as well as to sizable decreases in overall producer revenues and health care expenditures. The reform induced consumers to substitute away from branded drugs for which we estimate strong preferences. The increase in consumer welfare due to the reform therefore depends on whether or not we take perceived quality differences into account in its calculation.

Link: https://www.sciencedirect.com/science/article/pii/S0167629614000460

Kaplan, Warren A., Lindsay Sarah Ritz, Marie Vitello, and Veronika J. Wirtz. 2012. "Policies to Promote Use of Generic Medicines in Low and Middle Income Countries: A Review of Published Literature, 2000–2010." Health Policy 106 (3): 211–24. https://doi.org/10.1016/j.healthpol.2012.04.015.

Abstract: Objective: Review the literature on the impact of policies designed to enhance uptake of generic medicines in low and middle income countries (LMICs).

Methods: We searched for publications related to generic medicines policies (January 2000–March 2010) and did a bibliometric, descriptive analysis of the dataset in addition to an analysis of studies evaluating the impact of pro-generic policies. We repeated a subset of this larger search in January 2012.

Results: Of the 4994 articles screened, 315 (6.3%) full-text publications were related to generic medicines policies. Of these 315, 236 (75%) dealt with generic medicine policies in high-income countries, and 79 (25%) with policies in LMICs. In total, we found only 10 evaluation studies looking at the impact of competition, trade, pricing and prescribing policies on generic medicine price and/or volume. Key barriers to implementing generic medicine policies in LMICs are negative perceptions of stakeholders (e.g., generics are of lower quality) plus perverse private sector financial incentives to sell products with the highest profit margin. Other relevant barriers are legal/regulatory, such as the absence of generic substitution regulations. There also exists a general difficulty in promoting generics due to a lack of transparency in the pharmaceutical supply and distribution system, for example, a lack of price information provided by health care provider organizations to physicians.

Conclusion: There is little policy evaluation to determine which pro-generic policies increase generic medicines utilization in LMICs. Ensuring a functioning medicines regulation authority, creating a reasonably robust market of generic medicines and aligning incentives for physicians, consumers and drug sellers are necessary prerequisites for increasing the uptake and use of generic medicines.

Link: http://www.healthpolicyjrnl.com/article/S0168-8510(12)00132-7/abstract

Kyle, Margaret K. 2007. "Pharmaceutical Price Controls and Entry Strategies." The Review of Economics and Statistics 89 (1): 88–99. https://doi.org/10.1162/rest.89.1.88.

Abstract: This paper finds that the use of price controls has a statistically and quantitatively important effect on the extent and timing of the launch of new drugs. Firms headquartered in countries that regulate price reach fewer markets than those in countries without price controls. Companies avoid price-controlled markets, and are less likely to introduce products in additional markets after entering a price-controlled country. Launches into low-price European countries are further delayed following legalization of parallel imports. The results suggest that price regulation in one country affects entry into other countries, and may affect the strategies of domestic firms.

Link: https://www.mitpressjournals.org/doi/10.1162/rest.89.1.88

Lambrelli, Dimitra, and Owen O'Donnell. 2011. "The Impotence of Price Controls: Failed Attempts to Constrain Pharmaceutical Expenditures in Greece." Health Policy 101 (2): 162–71. https://doi.org/10.1016/j.healthpol.2010.08.023.

Abstract: Background: While the prices of pharmaceuticals are relatively low in Greece, expenditure on them is growing more rapidly than almost anywhere else in the European Union.

Objective: To describe and explain the rise in drug expenditures through decomposition of the increase into the contribution of changes in prices, in volumes and a product-mix effect.

Methods: The decomposition of the growth in pharmaceutical expenditures in Greece over the period 1991–2006 was conducted using data from the largest social insurance fund (IKA) that covers more than 50% of the population.

Results: Real drug spending increased by 285%, despite a 58% decrease in the relative price of pharmaceuticals. The increase in expenditure is mainly attributable to a switch to more innovative, but more expensive, pharmaceuticals, indicated by a product-mix residual of 493% in the decomposition. A rising volume of drugs also plays a role, and this is due to an increase in the number of prescriptions issued per doctor visit, rather than an increase in the number of visits or the population size.

Conclusions: Rising pharmaceutical expenditures are strongly determined by physicians' prescribing behaviour, which is not subject to any monitoring and for which there are no incentives to be cost conscious.

Link: http://www.healthpolicyjrnl.com/article/S0168-8510(10)00257-5/abstract

Leopold, Christine, Sabine Vogler, A. K. Mantel-Teeuwisse, Kees de Joncheere, H. G. M. Leufkens, and Richard Laing. 2012. "Differences in External Price Referencing in Europe—A Descriptive Overview." Health Policy 104 (1): 50–60. https://doi.org/10.1016/j.healthpol.2011.09.008.

Abstract: Objective: This study aimed to provide an up-to-date description as well as comparative analysis of the national characteristics of pharmaceutical external price referencing (EPR) in Europe.

Methods: Review of the country-specific PPRI (Pharmaceutical Pricing and Reimbursement Information) Pharma Profiles written by representatives of the PPRI Network. The Profiles were analysed according to predefined criteria.

Results: Of 28 analysed European countries 24 applied EPR in 2010. The majority of countries have statutory rules to implement EPR. Most countries had less than 10 countries in their reference baskets. Higher income countries tend to include higher income countries in their basket, whereas lower income countries refer to lower income countries. Taking the average price of all countries in the basket as the basis to calculate the national price was the most

common strategy (n = 8). The methodology of EPR has changed in most European countries over the past 10 years (n = 19).

Conclusions: EPR is a widely used pricing policy in Europe and is still actively used as well as adjusted by national authorities. However, we still see room for improvement by implementing more detailed legislations in terms of the revision of prices and by identifying alternative countries in case a product is not on the market. We also see the need for formal information sharing (e.g. congresses dedicated to pricing strategies and systems) with other public pricing authorities to learn about the different EPR methodologies as well as the national experiences. These congresses might also give room to better understand national pricing methods including discussions on possible limitations of these pricing methods.

Link: https://www.sciencedirect.com/science/article/pii/S0168851011001953?via%3Dihub

Menon, Devidas. 2001. "Pharmaceutical Cost Control In Canada: Does It Work?" Health Affairs 20 (3): 92–103. https://doi.org/10.1377/hlthaff.20.3.92.

Abstract: Governments in Canada have instituted mechanisms intended to control drug prices. These include the establishment of a semi-judicial body by the federal government to control factory-gate prices and of various measures at the provincial level, such as formulary management, use of generics, reference-based pricing, price freezes, and limits on markups. To a large extent, these measures have been effective in price control. Total drug spending in the country continues to rise, however; clearly, mechanisms other than price controls will need to be developed if drug spending is to be better managed.

Link: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.20.3.92

Mrazek, Monique F. 2002. "Comparative Approaches to Pharmaceutical Price Regulation in the European Union." Croatian Medical Journal 43 (4): 453–61.

Abstract: AIM: To review pharmaceutical price regulation methods in countries of the European Union (EU), in terms of the anticipated impact of regulation on pharmaceutical expenditures and evidence of actual outcomes.

METHOD: An extensive search was performed of medical and economic studies on regulatory interventions specifically targeting pharmaceutical prices in EU countries, published between January 1990 and April 2002. Both peer-reviewed and "gray" literature were systematically reviewed.

RESULTS: Four principle approaches to pharmaceutical price regulation with some methodological differences were identified in EU countries, as follows: fixed pricing, cost-effectiveness pricing, profit controls, and reference pricing. Actual evidence of the impact of price regulation was limited in many of these countries. Cross-country comparisons suggested that limiting the rise of pharmaceutical prices did not equate to controlling the rise of pharmaceutical expenditures because of the volume effect of utilization.

CONCLUSIONS: Supply-side regulation without the simultaneous use of demand-side incentives and volume controls does little to control the rise in pharmaceutical expenditures. The types of needed demand-side controls depend on the context of the individual country, on political priorities, and on the type of supply-side regulation in place.

Link: https://www.ncbi.nlm.nih.gov/pubmed/12187524

Nguyen, Tuan Anh, Rosemary Knight, Elizabeth Ellen Roughead, Geoffrey Brooks, and Andrea Mant. 2015. "Policy Options for Pharmaceutical Pricing and Purchasing: Issues for Low- and Middle-Income Countries." Health Policy and Planning 30 (2): 267–80. https://doi.org/10.1093/heapol/czt105.

Abstract: 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.

Link: https://academic.oup.com/heapol/article/30/2/267/618341

Puig-Junoy, Jaume. 2010. "Impact of European Pharmaceutical Price Regulation on Generic Price Competition." PharmacoEconomics 28 (8): 649–63. https://doi.org/10.2165/11535360-000000000-00000.

Abstract: Although economic theory indicates that it should not be necessary to intervene in the generic drug market through price regulation, most EU countries intervene in this market, both by regulating the maximum sale price of generics (price cap) and by setting the maximum reimbursement rate, especially by means of reference pricing systems.

We analyse current knowledge of the impact of direct price-cap regulation of generic drugs and the implementation of systems regulating the reimbursement rate, particularly through reference pricing and similar tools, on dynamic price competition between generic competitors in Europe.

A literature search was carried out in the EconLit and PubMed databases, and on Google Scholar. The search included papers published in English or Spanish between January 2000 and July 2009. Inclusion criteria included that studies had to present empirical results of a quantitative nature for EU countries of the impact of price capping and/or regulation of the reimbursement rate (reference pricing or similar systems) on price dynamics, corresponding to pharmacy sales, in the generic drug market.

The available evidence indicates that price-cap regulation leads to a levelling off of generic prices at a higher level than would occur in the absence of this regulation. Reference pricing systems cause an obvious and almost compulsory reduction in the consumer price of all pharmaceuticals subject to this system, to a varying degree in different countries and periods, the reduction being greater for originator-branded drugs than for generics. In several countries with a reference pricing system, it was observed that generics with a consumer price lower than the reference price do not undergo price reductions until the reference price is reduced, even when there are other lower-priced generics on the market (absence of price competition below the reference price). Beyond the price reduction forced by the price-cap and/or reference pricing regulation itself, the entry of new generic competitors is useful for lowering the real transaction price of purchases made by pharmacies (dynamic price competition at ex-factory level), although this effect is weaker or non-significant for official ex-factory prices and consumer prices in some countries. When maximum reimbursement systems such as reference pricing or similar types are applied, pharmacies are seen to receive large discounts on the price they pay for the pharmaceuticals, although these discounts are not transferred to the consumer price. The percentage discount offered to pharmacies in a country that uses a price-cap system combined with reference pricing is positively and significantly related to the number of generic competitors in the market for the pharmaceutical (dynamic price competition at ex-factory level).

Link: https://link.springer.com/article/10.2165%2F11535360-000000000-00000

Rémuzat, Cécile, Duccio Urbinati, Olfa Mzoughi, Emna El Hammi, Wael Belgaied, and Mondher Toumi. 2015. "Overview of External Reference Pricing Systems in Europe." Journal of Market Access & Health Policy 3 (September). https://doi.org/10.3402/jmahp.v3.27675.

Abstract: Background and objectives: External reference pricing (ERP) is a price regulation tool widely used by policy makers in the European Union (EU) Member States (MS) to contain drug cost, although in theory, it may contribute to modulate prices up and down. The objective of this article was to summarise and discuss the main findings of part of a large project conducted for the European Commission ('External reference pricing of medicinal products: simulation-based considerations for cross-country coordination'; see www.ec.europa.eu/health/healthcare/docs/erp_reimbursement_medicinal_products_en.pdf) that aimed to provide an overview of ERP systems, both on processes and potential issues in 31 European countries (28 EU MS, Iceland, Norway, and Switzerland).

Methods: A systematic structured literature review was conducted to identify and characterise the use of ERP in the selected countries, to describe its impact on the prices of pharmaceuticals, and to discuss the possible cross-country coordination issues in EU MS. This research was complemented with a consultation of competent authorities' and international organisations'

representatives to address the main issues or uncertainties identified through the literature review.

Results: All selected countries applied ERP, except the United Kingdom and Sweden. Twenty-three countries used ERP as the main systematic criterion for pricing. In the majority of European countries, ERP was based on legislated pricing rules with different levels of accuracy. ERP was applied either for all marketed drugs or for specific categories of medicines; it was mainly used for publicly reimbursed medicines. The number of reference countries included in the basket varied from 1 to 31. There was a great variation in the calculation methods used to compute the price; 15 countries used the average price, 7 countries used the lowest price, and 7 countries used other calculation methods. Reported limitations of ERP application included the lack of reliable sources of price information, price heterogeneity, exchange rate volatility, and hidden discounts. Spill-over effect and downward price convergence have often been mentioned as ERP's consequences leading to pricing strategies from pharmaceutical companies.

Conclusion: While ERP is widely used in Europe, processes and availability of price information vary from one country to another, thus limiting ERP implementation. Furthermore, ERP spill-over effect is a major concern of pharmaceutical firms leading to implementation of the so-called 'launch sequence strategies'.

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4802694/

Russo, Giuliano, and Barbara McPake. 2010. "Medicine Prices in Urban Mozambique: A Public Health and Economic Study of Pharmaceutical Markets and Price Determinants in Low-Income Settings." Health Policy and Planning 25 (1): 70–84. https://doi.org/10.1093/heapol/czp042.

Abstract: It has been suggested that medicines are unaffordable in low-income countries and that world manufacturing and trade policies are responsible for high prices. This research investigates medicine prices in urban Mozambique with the objective of understanding how prices are formed and with what public health implications. The study adopts an economic framework and uses a combination of quantitative and qualitative methods to analyse local pharmaceutical prices and markets. The research findings suggest that: (a) local mark-ups are responsible for up to two-thirds of drugs' final prices in private pharmacies; (b) statutory profit and cost ceilings are applied unevenly, due to lack of government control and collusion among suppliers; and (c) the local market appears to respond effectively to the urban population's diverse needs through its low-cost and high-cost segments, although uncertainty around the quality of generics may be inducing consumers to purchase less affordable drugs. We conclude that local markets play a larger than expected role in the determination of prices in Mozambique, and that more research is needed to address the complex issue of affordability of medicines in low-income countries. We also argue that price controls may not be the most effective way to influence access to medicines in low-income countries, and managing demand and supply towards cheaper effective drugs appears a more suitable policy option.

Link: https://academic.oup.com/heapol/article/25/1/70/625932

ABOUT US

The Knowledge Network on Innovation and Access to Medicines is a project of the Global Health Centre at the Graduate Institute, Geneva. The project seeks to maximize the contributions of research and analysis to producing public health needs-driven innovation and globally-equitable access to medicines.

CONTACT

globalhealthresearch@graduateinstitute.ch

Sood, Neeraj, Han De Vries, Italo Gutierrez, Darius Lakdawalla, and Dana Goldman. 2009. "The Effect of Regulation on Pharmaceutical Revenues: Experience in Nineteen Countries." Health Affairs (Project Hope) 28 (1). https://doi.org/10.1377/hlthaff.28.1.w125.

Abstract: This paper describes the pharmaceutical regulatory environment in 19 developed countries from 1992 to 2004 and examines how changes in regulatory policies affect pharmaceutical revenues. Several important findings emerge from our analysis. First, we document a trend towards increasing pharmaceutical regulation over this 13-year period. Second, we find that a majority of regulations reduce pharmaceutical revenues significantly. Third, we find that most countries that adopted new regulations since 1994 already had some regulations in place for controlling costs. We find that such additional regulation had a smaller impact on further controlling costs. However, we find that introducing new regulations in a largely unregulated market, for example the US, could reduce pharmaceutical revenues significantly. Finally, we show that the effects of price controls increase over time.

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3829766/

Theidel, Ulrike, and J.-Matthias Graf von der Schulenburg. 2016. "Benefit Assessment in Germany: Implications for Price Discounts." Health Economics Review 6 (1): 33. https://doi.org/10.1186/s13561-016-0109-3.

Abstract: Background: The AMNOG regulation, introduced in 2011 in Germany, changed the game for new drugs. Now, the industry is required to submit a dossier to the GBA (the central decision body in the German sickness fund system) to show additional benefit. After granting the magnitude of the additional benefit by the GBA, the manufacturer is entitled to negotiate the reimbursement price with the GKV-SV (National Association of Statutory Health Insurance Funds). The reimbursement price is defined as a discount on the drug price at launch. As the price or discount negotiations between the manufacturers and the GKV-SV takes place behind closed doors, the factors influencing the results of the negotiation are not known.

Objectives: The aim of this evaluation is to identify factors influencing the results of the AMNOG price negotiation process.

Methods: The analysis was based on a dataset containing detailed information on all assessments until the end of 2015. A descriptive analysis was followed by an econometric analysis of various potential factors (benefit rating, size of target population, deviating from appropriate comparative therapy and incorporation of HRQoL-data).

Results: Until December 2015, manufacturers and the GKV-SV finalized 96 negotiations in 193 therapeutic areas, based on assessment conducted by the GBA. The GBA has granted an additional benefit to 100/193 drug innovations. Negotiated discount was significantly higher for those drugs without additional benefit (p= 0.030) and non-orphan drugs (p= 0.015). Smaller population size, no deviation from recommended appropriate comparative therapy and the incorporation of HRQoL-data were associated with a lower discount on the price at launch. However, neither a uni- nor the multivariate linear regression showed enough power to predict the final discount.

Conclusions: Although the AMNOG regulation implemented binding and strict rules for the benefit assessment itself, the outcome of the discount negotiations are still unpredictable. Obviously, negotiation tactics, the current political situation and soft factors seem to play a more influential role for the outcome of the negotiations than the five hard and known factors analyzed in this study. Further research is needed to evaluate additional factors.

Link: https://healtheconomicsreview.springeropen.com/articles/10.1186/s13561-016-0109-3

For the purposes of this review, we have established three categories to describe the state of the literature: thin, considerable, and rich.
- *Thin: There are relatively few papers and/or there are not many recent papers and/or there are clear gaps*
- *Considerable: There are several papers and/or there are a handful of recent papers and/or there are some clear gaps*
- *Rich: There is a wealth of papers on the topic and/or papers continue to be published that address this issue area and/or there are less obvious gaps*

Scope: While many of these issues can touch a variety of sectors, this review focuses on medicines. The term medicines is used to cover the category of health technologies, including drugs, biologics (including vaccines), and diagnostic devices.

Disclaimer: The research syntheses aim to provide a concise, comprehensive overview of the current state of research on a specific topic. They seek to cover the main studies in the academic and grey literature, but are not systematic reviews capturing all published studies on a topic. As with any research synthesis, they also reflect the judgments of the researchers. The length and detail vary by topic. Each synthesis will undergo open peer review, and be updated periodically based on feedback received on important missing studies and/or new research. Selected topics focus on national and international-level policies, while recognizing that other determinants of access operate at sub-national level. Work is ongoing on additional topics. We welcome suggestions on the current syntheses and/or on new topics to cover.