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Improving Access to Innovative Medicines in Emerging Markets: Evidence and Diplomacy as Alternatives to the Unsustainable Status Quo

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Improving Access to Innovative Medicines in Emerging Markets: Evidence and Diplomacy as Alternatives to the Unsustainable Status Quo

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Abstract

Introduction: Access to medicines is a substantial component of universal health coverage. However, the current dynamics between the innovative pharmaceuticals industry and governments in emerging markets are adversarial and may be counterproductive to sustainably increasing access to current and future patented medicines.

Methods: This work is a review of public sources including white papers, news and peer-reviewed literature with a focus on mainstream approaches used by the pharmaceutical industry (such as unaffordable price premiums for innovative medicines) and governments (such as denial of intellectual property rights) to support their interests. We assess the need for consensus-based approaches as alternatives to the above policies and review country cases with supporting evidence. We also explore the implications of possible approaches on pharmaceutical policy in the context of global health diplomacy. The latter is a requirement for universal health coverage given the increasing power of state and non-state actors in emerging markets.

Results: We conclude that evidence and due processes, through inclusive and transparent priority-setting mechanisms, offer a reconciliatory way forward for both parties. Value-based pricing, underpinned by Health Technology Assessment (HTA), could leverage global health diplomacy to set priorities and resolve the perhaps unsustainable status quo. HTA is itself a diplomatic, consensus building and evidence-based approach that can help diffuse the current tension, enhance mutual understanding and perhaps help strengthen (or even mend) the current model of product development.

Discussion: Value-based pricing and HTA offer a potential priority setting mechanism that can serve as a transparent, non-adversarial platform for governments and the pharmaceutical industry to engage with each other and work towards enhancing access to medicines. Further quantitative research, exploring the impact of different policy-setting approaches by governments on medicine access using HTA, would strengthen this discourse.

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Introduction

This work discusses trends in medicines policy across emerging economies with a view to assess whether the current relationship between governments and the pharmaceutical industry helps meet access goals and propose possible alternatives. It synthesizes existing evidence from secondary sources to demonstrate how the pharmaceutical industry and governments collide in their current approaches. The work reviews five primary tactics commonly used by both parties. The pharmaceutical industry tactics include unaffordable prices and aggressive patent policies. Government tactics include compulsory licensing and arbitrary price cuts and pricing formulas. We offer a perspective on the need for evidence-informed priority setting mechanisms in emerging governments working towards universal health coverage (UHC), while incentivizing innovation and we propose that value-based pricing informed by health technology assessment (HTAs) may be an alternative for governments to own priority setting and pharmaceutical policy processes while constructively engaging the pharmaceutical industry. In conclusion, we assert that science and due process owned by the government through inclusive and transparent priority setting mechanisms offer a reconciliatory way forward for both parties and can advance the UHC agenda.

a. Background: Access to medicines under the universal health coverage umbrella

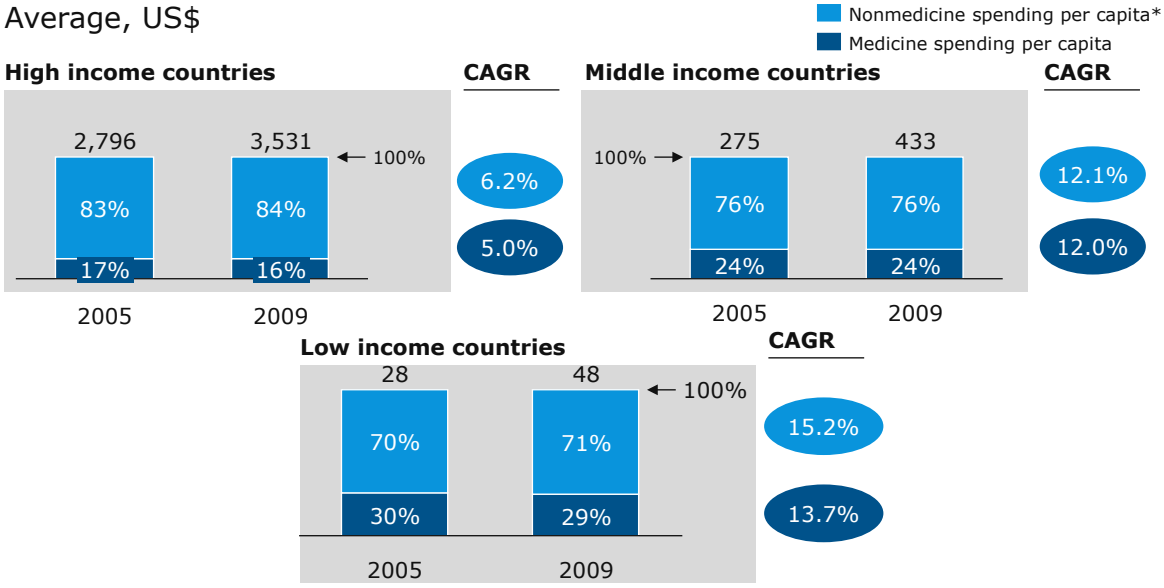
According to the World Health Organization (WHO), the goal of Universal Health Coverage (UHC) is to ensure that "all people obtain the health services they need without suffering financial hardship when paying for them" (WHO, 2012). Both the WHO and the United Nations (UN) stress that access to medicines is a critical component of UHC, defined as "…having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes of the population" (UN Development Group, 2003). At the global level, the UN General Assembly adopted a resolution in December 2012, on affordable universal healthcare, with wide support from countries representing different income levels and health systems (United Nations General Assembly, 2012). This global recognition prioritizes UHC on the post-Millennium Development Goal (MDG) agenda and is likely to influence priorities of global health donors and policy implementers (Tran, 2012; Horton, 2013). Rich and poorer country governments are now committing to UHC: in the US, health insurance reforms under the Affordable Care Act of 2010 guarantee coverage for almost all citizens, including those with pre-existing conditions (US Department of Health and Human Services, 2010). In China, a number of reform schemes over the last ten years resulted in 95 percent national coverage by 2011 (Liang & Langenbrunner, 2013). In Mexico, the Popular Health Insurance (PHI) programme now covers all intended citizens who are not currently covered by social security schemes (Bonilla-Chacín & Aguilera, 2013). Other countries such as Thailand, India, South Africa, Indonesia, Vietnam and the Philippines are following suit (see e.g. UHC Forward; Hughes & Leethongdee, 2007).

Achieving UHC has significant implications for policies on access to medicines. Medicines form a substantial component of health spending and can in principle increase health system efficiency through prevention and treatment. Figure A shows trends in medicine spending across high, middle and low income countries. While non-medicine spending is greater, medicine spending has consistently amounted to about one-third of the total health expenditure in low-income countries—much higher than the respective proportion in developed country systems.

Figure A

Across middle and high income countries, medicine spending is less than a quarter of total health spending while growth rates are comparable

NONMEDICINE SPENDING VS. MEDICINE SPENDING PER CAPITA
Average, US$

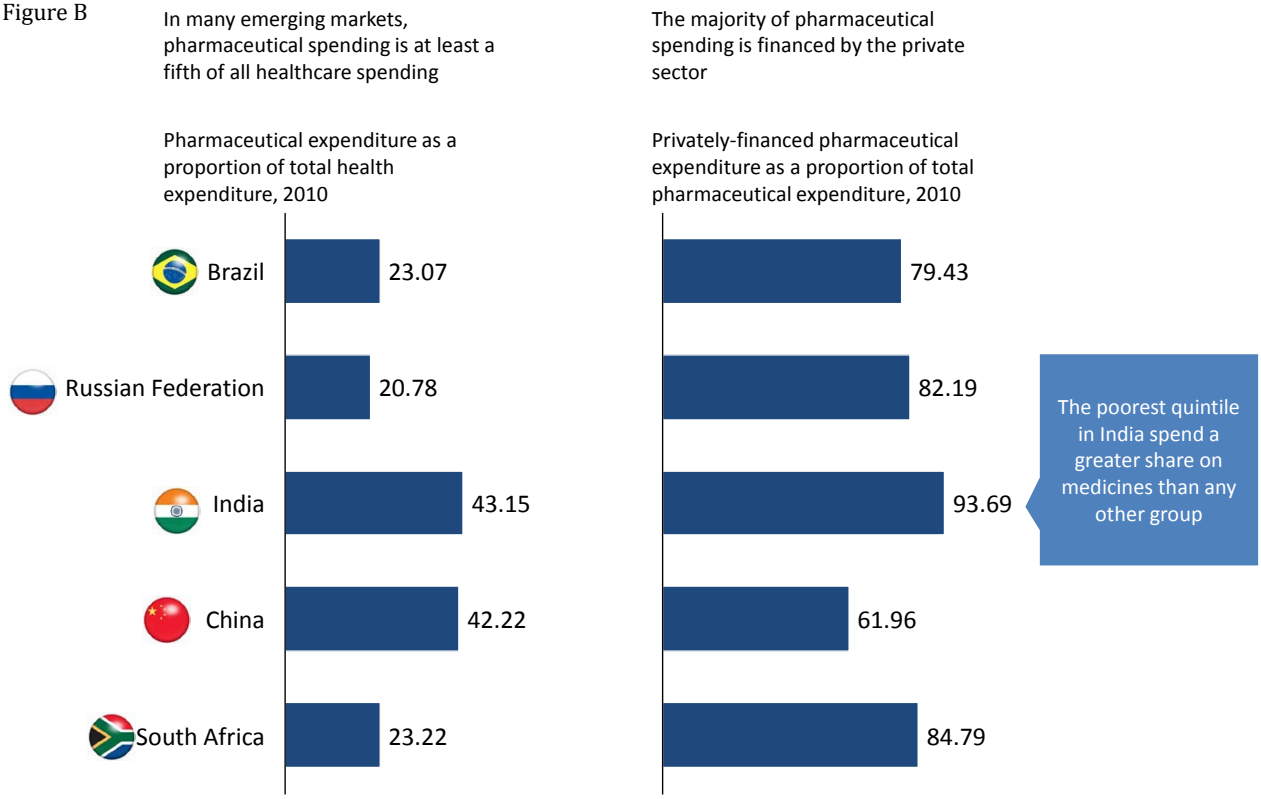


* Nonmedicine spending is calculated by subtracting pharmaceutical expenditure from total health expenditure per capita
Source: IMS Institute for Healthcare Informatics, 2012; World Bank; WHO (latest available data for a subset of countries representing over 50% of each income group based on World Bank income groupings)

Furthermore, over one-third of healthcare spending is out-of-pocket in middle and low-income countries, with a number of countries far beyond this average: in India and Vietnam, for example, this value is over 60 per cent (authors' analysis, based on World Bank Databank figures from 2010). Private, out-of-pocket (OOP) spending on medicines in many of these countries is substantial and often affects those who are in the poorest segments of society, resulting in a high cost burden for many individuals. Figure B, on the following page, shows pharmaceutical spending as a percentage of total health expenditure, and the percentage of pharmaceutical spending which is privately financed, for Brazil, the Russian Federation, India, China and South Africa.

The reasons for differences in pharmaceutical spending and financing between countries are outside the scope of this paper and are explored elsewhere (WHO, 2011). However, it is notable that the private spending burden of medicines disproportionately affects the poorest households. For example, in India, where the government has recently committed to UHC as set out its 12th Five-Year Plan, OOP spending on medicines is around 80 percent, and 80-90 percent of that spending goes towards pharmaceutical products for the bottom quintile of the poorest households (Alam & Tyagi, 2009). The concentration of poor people living in slum and rural areas makes OOP spending on medicines a major driver of impoverishment.

Figure B



Sources: World Health Organization (2013a); Alam et al. 2009

Given the non-negligible share of medicines in healthcare spending and the skewed impact of this spending on the poor, access to medicines has received attention in the first MDG agenda (especially MDG 8[1]) and more recently in the first health summit organized by Brazil, Russia, India, China and South Africa (the BRICS countries) in 2011, reflecting the fact that middle-income countries are prioritizing medicine access with a focus on both their availability and affordability, hence aiming to reduce OOP spending (BRICS Health Ministers, 2011). Indeed, emerging economies are now spending more of their own funds on health. With population needs and pressures from the pharmaceutical industry on the rise, most governments and insurance funds are seeking to apply tools and implement policies to prioritize health spending, including on pharmaceuticals (Glassman et al., 2012a). Traditionally, essential drug lists (EDLs) have been used to prioritize access to medicines. EDLs are national lists of medicines informed by WHO and selected by experts with due regard to disease prevalence, evidence on efficacy and safety and, oftentimes though not consistently or in a way that relates to the local context, comparative cost-effectiveness (WHO, 2013b) Increasingly, countries are using other, more complex and locally relevant tools to steward medicine access such as regional- or state-specific formularies and price lists. A comprehensive overview of how countries define health and medicine benefit plans is outside the scope of this paper and can be found elsewhere (Glassman, A. et al. 2012a).

[1] MDG 8 refers to Develop a global partnership for development. http://www.unmillenniumproject.org/goals/gti.htm

Existing tools and processes to ensure access to medicine must increasingly tackle challenges related to patented medicines—commonly known as 'innovative medicines'—claiming to offer benefits over existing ones (as opposed to generics) and hence commanding a price premium. Once the patent on a new innovative medicine expires, generic medicines, which are bioequivalent copies, enter the market. Generic medicines are cheaper than patented originals because their prices reflect the marginal production cost as opposed to upstream investment in research and development (which makers of generic medicines do not need to undertake). How governments respond to the challenge of ensuring access to and affordability of innovative, patented medicines is a key consideration in light of medicine access under UHC efforts and is the focus of our assessment. While access to generics is most relevant to UHC, perhaps even more so than innovative medicines, this is discussed elsewhere (IMS Institute for Healthcare Informatics, 2012; Responsible Use of Medicines report ref; Sheppard, 2010; Kaplan et al., 2012; Access to Medicine Foundation, 2012).

Governments in Emerging Markets and the 'Innovative' Pharmaceutical Industry are Currently in Gridlock

High prices and intellectual property challenges are especially contentious areas of misalignment between the pharmaceutical industry and governments. Priced at over ten times the gross domestic product (GDP) per capita, patented products for high-burden diseases such as cancer and hepatitis C have been unaffordable for the vast majority of people in emerging markets. For example, in India, Bayer's Nexavar for primary kidney cancer and advanced liver cancer was priced at around US$5000 per month, or 18 times India's monthly GDP per capita (Ahmed, 2013).[2] This is also the equivalent of eight times the monthly GDP in both Thailand and China. Novartis' Glivec for chronic myelogenous leukemia and other cancers, and Roche's Pegasys, cost around US$3000 and US$700 per month, respectively (Stainburn & Overdorf, 2013; India.com Health, 2012). These prices ensure that such drugs remain largely out of reach for the majority of the population, especially the poorest, in many emerging markets where most medicines are paid for out-of-pocket, as discussed earlier. While some companies have launched patient assistance programmes to provide access to poorer patients (e.g., Glivec International Patient Assistance Programme), this is not enough to address the access challenges (Experts in chronic myeloid leukemia, 2013).

The Pharmaceutical Industry's Mainstream Approach

The general consensus within the pharmaceutical industry is that compared to other challenges—such as weak health systems and infrastructure, poor regulations and inadequate financing—prices are not the main barrier to access (Mackay, 2009). When it comes to reducing prices in low income countries, the industry is concerned that lower prices will be referenced in richer markets, thereby negatively impacting sales in these markets (Yadav, 2010; Taylor, 2012). In addition, the industry fears parallel exports from lower-priced to higher-priced countries (Yadav, 2010; Towse et al., 2011). A number of solutions exist to mitigate leakage. For example, partnerships with major donors could leverage reputational risk since it is in their interest to prevent physical arbitrage and ensure drugs get to the intended patients. Contractual arrangements with distributors can ensure that products reach the intended market and there is transparency in the supply chain to counter diversion (Yadav, 2010; Towse et al., 2011). Clear separation between procurement, physical distribution and payment for different market segments is also needed in order to support differential pricing schemes. Howev-

[2] Using monthly GDP/capita at PPP, international $, 2011 from World Bank Databank 2013. Annual GDP/capita divided by 12 for a monthly average

er, such solutions require a functional health system and strong negotiation skills with regard to domestic (e.g., supply chain as well as pricing and reimbursement stakeholders) and global (e.g., donors and multilateral institutions such as the Global Fund and the World Bank) actors, to build consensus and align incentives. Perhaps as a result of a lack of meaningful engagement with governments, and in light of their weak systems, the pharmaceutical industry's mainstream response has instead been to maintain high prices for patented medicines in emerging markets focused on small segments that can afford these prices and with little regard to access and volume.

Nevertheless, many companies have started to recognize the importance of access and now offer new pricing structures that may satisfy both business and access goals through price tiers, increased volumes and risk sharing (Hirschler, 2012). For example, Roche negotiated a deal for its innovative drug Pegasys for Hepatitis C in Guangzhou, China whereby insurance companies pay for the first 6 months of treatment while Roche provides the rest for free—essentially a 50 percent discount (IMS Consulting Group, 2011). Roche also uses tiered pricing for Herceptin and other cancer drugs to reach poorer segments of the Indian market, working together with local manufacturers (Whalen, 2012). Novartis commonly uses tiered pricing most notably with Coartem, a fixed-dose combination malaria drug (Novartis, 2010). The public sector and non-governmental organizations (NGOs) funding patients' healthcare receive lower Coartem prices than the private, for-profit institutions (Yadav, 2010). According to the Access to Medicine Foundation, Pfizer leverages inter-country tiered pricing across all relevant countries where it operates, and does so to a greater extent than other manufacturers (Access to Medicine Foundation, 2012).

However, and despite these efforts, the mainstream response by industry has been to fiercely defend its price structure by mostly targeting developed markets, and to concentrate on the price rather than the volume factor of the revenue equation—where revenue equals price multiplied by volume—in developing markets.

In parallel, industry often adopts an aggressive approach to intellectual property, including through pay-for-delay deals with generics manufacturers, and lobbying as part of Free Trade Agreements (FTAs) (Interfaith Center on Corporate Responsibility, 2009; United States Federal Trade Commission, 2013; Médecins Sans Frontières, 2011). Pay-for-delay deals are settlements made between generic and innovative pharmaceutical companies to disrupt generic competition. These include promises by the innovators not to market their generic product that would compete with the generic company's product as well as payments to generic companies to stall generic entry (United States Federal Trade Commission, 2013). According to the US Federal Trade Commission, pay-for-delay deals cost Americans US$3.5 billion annually; there is no evidence regarding the cost of such deals in developing countries (United States Federal Trade Commission, 2013). Recently, in a wave of litigation in the USA and the European Union (EU), the pharmaceutical industry has been penalized for pay-for-delay deals (Bodoni, 2013; Wyatt, 2013; Schondelmeyer & Purvis, 2013).

FTAs occur between two or more countries, and usually eliminate taxes and other forms of restrictive commerce regulations in order to encourage trade (World Trade Organization, 2013). FTAs often include the pharmaceutical industry and allow for the negotiating power of multinational companies vis-à-vis payers and the local industry. For example, according to a leaked draft of a US position paper from the recent negotiations on the Trans-Pacific Partnership (TTP), pharmaceutical lobbying resulted in the USA supporting a position that allows patents to be available for "a new form, use, or

method of using a known product … even if such invention does not result in the enhancement of the known efficacy of that product" (United States Government, 2011). The US position on the TTP also includes patents for "new form, use or method of using" and "new formulations" of an existing product even if there is no increase in efficacy, a practice known as evergreening (United States Government, 2011; Médecins Sans Frontières, 2012) Evergreening extends the patent life of a product based on minor changes or other adjustments. These kinds of clauses could extend monopoly protection for existing medicines, thereby maintaining high prices and limiting affordability.

Governments' Mainstream Approaches

Among most governments, which are increasingly acting as payers for healthcare, the mind-set is different and concentrates on enhancing access while ensuring affordability, especially as emerging markets are transitioning to UHC. Not surprisingly, price is a critical barrier for payers, but is easily identifiable and controllable. At the same time, price targeting may be politically motivated or else advocated for by local and international NGOs keen to encourage aggressive government policies in order to broaden access (Palmer, 2013). As a result of increasing pressures to expand coverage, governments in emerging markets often respond by introducing complex price formulas or arbitrary cuts to companies' list prices, or else by challenging intellectual property rights through compulsory licensing and legal challenge.

Complex price formulas are exemplified in India, whereby pricing of patented medicines is proposed to be based on a Purchasing-Power-Parity (PPP) per capita GDP-based reference pricing method that, if implemented, would result in generic level prices for all patented medicines. The proposed formula is accompanied by further proposed reductions through negotiations, although the details remain unclear (India Department of Pharmaceuticals 2012). Arbitrary price cuts have occurred in a number of countries, including China and the Philippines. In China, a series of price cuts have been implemented since 2011, while in the Philippines, in 2009, the president imposed price controls, mandating that companies lower prices by at least 50 per cent (Burkitt, 2012; Reuters, 2009) Such practices are hardly limited to low and middle income country settings: Greece and Portugal, and even Germany, have introduced price cuts in light of the economic crisis (McKee, 2012; Reinaud, 2012).

Moreover, emerging markets have been using compulsory licensing or resorting to other forms of patent denial in order to bring down patented medicine prices. Compulsory licensing is rooted in the history of HIV medicine access, whereby price reductions were brought about through advocacy efforts by patient groups across the developed and developing world. Prices ranging from US$10,000 to US$15,000 per year were reduced by 99 percent due to aggressive mobilization by advocates in response to the crisis (Joint United Nations Programme on HIV/AIDS, 2000; 't Hoen et al., 2011). In 2001, the annual World Trade Organization (WTO) meeting on Trade-related Aspects of Intellectual Property Rights (TRIPS) in Doha passed a declaration with provisions for countries in public health emergencies, including HIV/AIDS. These include compulsory licenses, parallel importing, Bolar provisions (which expedite generic manufacturing of the product prior to patent expiry) and TRIPS exemption extensions for least developed countries (Joint United Nations Programme on HIV/AIDS, 2011). Since the Doha meeting, the UN has actively encouraged countries to leverage these provisions for access to medicines.

Between 2001 and 2013, primarily middle-income countries have exercised such provisions, particularly compulsory licensing. One recent analysis showed that since 2001, 30 compulsory licenses have been issued, of which 16 have been for HIV/AIDS in low- and middle-income countries (Shankar et al., 2013). Increasingly, some of these countries, particularly India, are using compulsory licenses and patent revocation for other therapy areas such as oncology (India Patent Controller, 2011; PMLive, 2013). Additionally, Thailand issued compulsory licenses for Tarceva, Femara and Taxotore, based on high disease prevalence of lung and breast cancer and the lack of accessibility to the treatment (Shankar et al., 2013). The Thai Health Intervention and Technology Assessment Agency (HITAP) carried out an evaluation of the compulsory licencing policy offering information on the policy background of the decisions and their impact on commerce (Health Intervention and Technology Assessment Program, 2011). The evaluation found that the implications were overall beneficial for Thai society and that such measures are effective at broadening access. Such use of compulsory licensing demonstrates that countries are using TRIPS provisions to address broader affordability and innovation challenges.

Pricing changes due to advocacy alongside compulsory licensing have expanded treatment access and in the case of HIV, reversed the spread of the epidemic (United States Department of Health and Human Services, 2013). However, neither is a sustainable resolution for medicine access. For example, second- and third-line anti-retroviral drugs (ARVs) are now being used increasingly in developing country settings, including Africa, at very high prices. These ARVs account for a fraction of overall volume (5 percent) but around 20 percent of total spend (Venkatesh et al., 2012; Soni & Gupta, 2009). Advocacy- or celebrity-driven price cuts are not based on explicit priority setting mechanisms owned by the countries, raising concerns both about their long term sustainability and their rationale for favouring certain conditions (e.g. HIV/AIDS) over others (e.g. diarrhoea or diabetes mellitus). A recent report by the Centre for Global Development notes that almost every disease or medication has been deemed a 'health priority' by advocates, researchers and policymakers (Glassman et al., 2012). However, advocacy alone cannot form the basis for a sound policy on access to medicine as it is inherently inequitable and easily manipulated by those with resources and a stronger voice. Consequently, advocacy-based approaches may contribute to arbitrary decisions on access, and to increased inequity and inefficiency in a health system (Rosen et al., 2005).

Protecting their price has been central to the policies of most multinationals, in developed and developing countries alike, the rationale being that industry sets prices for innovative medicines at levels that allow it to recoup its significant research and development (R&D) costs and invest in future R&D. However, the way in which prices are set by industry remains opaque, with the actual cost of development of innovative products deemed confidential information, generating controversy both within and outside industry (Hirschler, 2013; Light & Warburton, 2011). Rehashing the arguments for and against price premiums for innovative drugs is beyond the scope of this paper. However, industry's expectations that governments will pay premiums for innovation without requiring companies to disclose R&D costs, combined with doubts about the connection between true innovation and better health, have led to wide scepticism on the part of governments, researchers, patients and payers alike in both rich and poorer countries (Light & Lexchin, 2012; Claxton, K. et al., 2009; Experts in chronic myeloid leukemia, 2013). In developing countries, where budgets are tighter and the disease burden is different, this approach becomes even harder to defend. For example, findings from an extensive WHO review on the impact of intellectual property protection on innovations concluded that there is no evidence that WTO rules promote R&D for diseases affecting developing countries where innovation would carry the greatest value ('t Hoen, 2006). As a result, the system in which the pharmaceu-

tical industry currently operates makes it unlikely that emerging markets will allow unaffordable premium prices justified solely by recouping investment in R&D in areas prioritized by industry itself and often not addressing these countries' real needs.

Figure C synthesizes the main points of contention between the pharmaceutical industry and governments.

Figure C: Are governments and the pharmaceutical industry on a collision course?

Are governments and the pharmaceutical industry on a collision course?

Common points of adversarial relations	
Governments/payers	**Pharmaceutical industry**
Opaque price formulas and arbitrary price cuts	Opaque price setting, non-transparent cost basis (including research & development investment)
Little opportunity for formal industry engagement	Little appetite for meaningful engagement with payers
Compulsory licensing and intellectual property violations	Aggressive patent policies (e.g., pay-for-delay tactics, ever-greening)
Relying on manufacturers for evidence generation	Confusion of evidence generation with marketing
Protectionist policies for local pharmaceutical industries	Linking price to industrial policy through relocation threats and lobbying for FTAs with governments
Circular and counterproductive reference pricing	Failure to price discriminate and emphasis on price rather than volume and access
Burdensome regulation, inconsistent processes and delaying tactics	Rigid research and development, locking products with little evidence of incremental benefit

Value-Based Pricing and Health Technology Assessment as Diplomacy-Based Approaches for Pharmaceutical Policy in Emerging Markets

Global health diplomacy has been described as a series of 'multi-level, multi-actor negotiation processes that shape and manage the global policy environment for health' (Kickbusch et al., 2008). Global health diplomacy can include and is influenced by the actions of governments seeking to expand coverage to medicines, as well as the actions of pharmaceutical companies seeking sustainable businesses in emerging markets (Kickbusch et al., 2008). The rise of new superpowers such as India, China and Brazil necessitates a response in relation to access to medicines on the part of both multinational companies and developed country governments that is grounded in diplomacy (Lee & Smith, 2011). This is because in the changing landscape, multiple new actors now have a stake and a voice. Indeed, powerful domestic generic manufacturers and the rising middle class in the world's most populous countries are non-negligible influences with whom traditional players such as multinational pharmaceutical companies and Western governments need to engage.

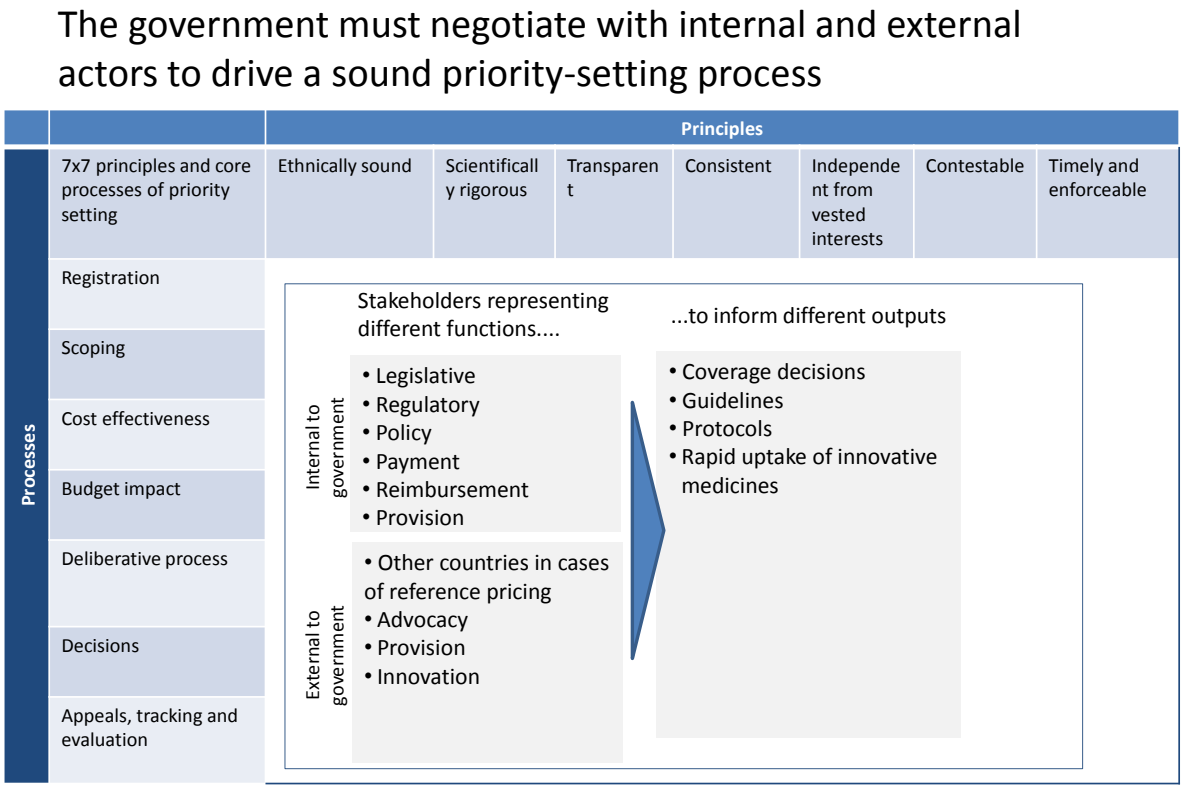
As part of this new diplomacy, governments, especially those in emerging economies, need institutional arrangements to move beyond reactive policymaking and take the lead in negotiations on price and on access. At the same time, they need to think about investment in R&D and a sustainable industry—regardless of whether or not that industry is domestic. It is important to realize and be explicit about the fact that no government could afford to provide access to every medicine for every citizen who may benefit from it. Indeed, limited resources dictate implicit (e.g., waiting times) or explicit (e.g. formularies and lists) priority setting (Glassman et al., 2012). Governments need an explicit and scientific priority setting process in order to optimally allocate limited resources and support price negotiations with pharmaceutical companies over economically justifiable prices.

Value based pricing (VBP), informed by health technology assessment (HTA) may be one option. In a functioning market economy prices are supposed to reflect people's valuing of what is being sold. However, this is not necessarily the case when it comes to the market for pharmaceutical products, where those who consume (patients) are usually neither those who pay (insurance funds) nor those who prescribe (doctors). In the context of the National Health Service (NHS) in the United Kingdom, and following an in-depth review of pharmaceutical pricing carried out by the British Office for Fair Trading (OFT), VBP is defined as a system whereby 'the prices the NHS pays for medicines reflects the therapeutic benefits they bring to patients,' hence helping 'to deliver better value for money from NHS drug spend and to focus business investment on drugs that have the greatest benefits for patients' (OFT, 2007). VBP is seen as a possible means for helping payers and industry converge in their definitions of value, as well as their views of how this value ought to be rewarded, and is currently being rolled out by the British Government (UK Department of Health, 2013).

VBP can be underpinned by HTA, which has been described as 'a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner.' Furthermore, the aim of HTA is to 'inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value' (EUnetHTA, 2013). When carried out properly, HTAs can inform resource allocation decisions. Regardless of policy goals, HTAs should be grounded in evidence and robust scientific methods. General principles, ethics and other key aspects of HTAs are extensively covered in existing literature (Drummond, et al., 2008; Facey et al., 2010; Rawlins & Culyer, 2004). They will not be discussed here, other than to emphasize that in order to implement an HTA process, governments and payers must develop and assign key functions, budgets and capacities to individuals and agencies within and outside of the government to carry out intended tasks, making the institutional and legal context most important in effective HTA implementation (Glassman et al., 2012). We assert that, as a well-tested and well-studied multi-dimensional engagement process, HTA exemplifies a platform for what we call a new health diplomacy for emerging economies committed to ensuring access to medicines for their populations but struggling in their interactions with the pharmaceutical industry, patients and healthcare professionals.

Research from Asia and Latin America suggests that a clear set of process principles and guidelines are needed to frame the conduct of HTAs for resource allocation decisions, stimulating discussion and policy dialogue among researchers, pharmaceutical industry and policymakers (Pichon-Riviere et al., 2010; Kamae, 2010). These discussions are an inherent component of HTA and of the local process a country decides to apply when prioritizing resources. To help describe the different stages in these discussions, the Centre for Global Development's Working Group on Priority Setting Institutions for Health developed a '7x7 framework' of principles and processes which highlights the multiple levels of necessary diplomacy throughout an HTA and emphasizes the not solely technocratic but also deeply institutional and process aspects of HTA (Glassman et al., 2012; Rosen et al. 2005). Figure D shows the framework conflated by the multiple stakeholders that must be involved in and outside the government.

Figure D: The government must negotiate with internal and external actors to drive a sound priority-setting process



Governments can use the 7 x 7 framework to set out rules of engagement, develop scientific methods, support uptake of decisions at the local level and help create an environment in which intellectual property is enforced and respected. To apply this framework locally, governments must be equipped to acknowledge and negotiate with a variety of stakeholders representing different and legitimate functions in healthcare, including the pharmaceutical industry. Additionally, the pharmaceutical industry must be willing to engage with governments and payers by generating and using evidence of value of their products as the basis for price negotiations; sharing information on the comparative value of technologies; and demonstrating an appreciation for the value-for-money payer perspective in light of limited budgets. The idea of diplomacy becomes most relevant as a result of the implementation of the 7 x 7 framework.

There will be many points of tension between stakeholders that need to be resolved. For example, donors supporting countries in developing their capacity for priority setting may find this process of country-owned priority setting to be in conflict with their own advocacy agenda for single diseases (e.g. HIV/AIDS) or technologies (e.g. vaccines). HTAs can help diffuse the tension emanating from a currently adversarial relationship between the demand and supply sides through a diplomatic, consensus-building and explicit approach. They can also enhance mutual understanding and perhaps strengthen (or even mend) the current model of product development. Because an HTA involves negotiation based on scientific evidence, while also taking account of explicit value judgements endorsed by society, it is a more predictable and less arbitrary process than the current norms of price setting or price cutting applied by manufacturers and payers, respectively.

Through the application of science and process that comprise HTAs, health system leaders, alongside other key stakeholders such as innovators and consumers, can help maximize health impact from limited budgets; accelerate access to new, high value technologies (hence enhancing static efficiency); and identify obsolete or unproven technologies that should no longer be invested in. In this way, HTA processes also signal payers' willingness and ability to pay—a clear definition of value—and, therefore, a value-based price that drives both public and private investment in research efforts towards greatest need, as seen by the payers' perspective (hence enhancing dynamic efficiency). Furthermore, HTAs may help encourage market entry of new innovative products, displacing low-value incumbents and hence fuelling investment and innovation. Finally, by making opportunity costs explicit, HTAs can help health systems appreciate the value of a technology across the continuum of care, and also assist innovators in making a better case for product value (Claxton et al., 2009).

Priority setting using HTAs is a relatively new concept. While a number of middle-income countries use some form of HTAs, processes are often still ad-hoc, leaving resource allocation decisions open to lobbying by pharmaceutical companies, clinical leaders and advocacy groups. Table 4, on the following page, provides a synthesis of HTA agencies in selected countries with a focus on how and why for product selection.

Few countries have an explicit process for allocating resources on pharmaceutical products. South Korea, Thailand and Taiwan employ HTA concepts in their decision making under the auspices of UHC goals and recognition for the need to allocate scarce resources (Kamae, 2010). All three countries leverage available HTA professionals and faculties through international networks to develop locally-relevant processes under government leadership. Brazil and Mexico have also developed HTA systems, while Colombia recently set up Institute of Health Technology and Evaluation or Instituto de Evalución Technológica en Salud (IETS) an HTA agency to help make hard decisions on drugs and other technologies (Rodrigues, 2012; Cenetec, 2013; IETS, 2012 Colombian Ministry of Health Colombian Ministry of Health, 2012). In Brazil, the Secretariat for Science and Technology under the Ministry of Health—which brings together state-funded R&D, industrial policy in health and the processes for making listing and delisting decisions for the country's national package of health services—is an example of a more integrated cross-government approach (Lee & Gómez, 2011; Grabois Gadelha et al., 2010). The role of networks such as HTAsiaLink and the Pan American Health Organization (PAHO), through its Health Technology Assessment Network of the Americas (RedETSA) or the is critical in supporting countries build the technical and institutional capacity required for HTA (HTAsiaLink 2013; Pan American Health Organization, 2011). Indeed, these networks can also serve as platforms for a controlled engagement with industry, both domestically and globally.

Table 4:

Health technology assessment agencies in selected middle-income countries—how and why topics are selected

Country/entity	Prioritization process for topic selection	Criteria for deciding high-priority topics
Brazil/ ANVISA/CITEC	No formal process. The definition of priorities has been made through an Annual Workshop on Priorities	Epidemiological relevance and the quality of health care program for patients, opportunity for the Brazilian market, and budgetary impact
Chile/CCA	No formal process. Topic selection is carried out by the CCA	Health status of the population, the effectiveness of interventions, their contribution to the extension or the quality of life and, where possible, their cost-effectiveness
Colombia/ CRES	No preestablished process for topic selection. In 2011 for the first time a more systematic process was used, but this has not been institutionalized Colombian law	As established by law: epidemiological profile, appropriate technology available in the country, and the financial conditions of the system. In practice, cost of technology to the system has been a main driver for topic selection
Uruguay/ FNR/MoH	There is no formal process for topic selection. Both the MoH and the FNR define the topics	Prevalence, burden of disease, uncertainty, health impact, and potential economic, organizational, ethical, social, or legal impact
Poland[a]/ AHTAPol	The process has been performed through consensus meetings run between the AHTAPol and the MoH authorities. The MoH has the final voice, as AHTAPol is subordinated to the MoH. So far, if deadlines were not stated, a first-in, first-out approach has been applied	No precisely defined criteria to select health technology assessment topics at the AHTAPol
Thailand[a]/ HITAP	Representatives of four groups of stakeholders—health professionals, academics, patient groups, and civil society organizations—are appointed to sit on a panel overseeing intervention prioritization. To undertake the task, the panel introduces six agreed criteria (see the right column). A scoring approach with well-defined parameters and thresholds was employed to address each criterion. However, the ranks of interventions could be adjusted through deliberation among the panelists, and those that are prioritized are recommended to the Benefit Package and Service Delivery for endorsement	Size of population affected, severity of disease, effectiveness of health intervention, variation in practice, economic impact on household expenditure, and equity/ethical and social implications

a. Poland and Thailand are included in the context of the Center for Global Development Working Group using the templates developed by the Inter-American Development Bank, information provided by Tomasz Bochenek (Poland) and Yot Teerawattananon (Thailand).

Note: See abbreviations in table 4.2. Gray rows indicate countries reviewed by Giedion, Munoz, and Avila (2012).

Source: Giedion, Munoz, and Avila (2012).

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Discussion

Innovative pharmaceutical companies are not in denial about the need to identify new business models as a prerequisite for viable and sustainable operation in emerging markets. More than 60 percent of companies have demonstrated some form of commitment to access to medicine through meaningful targets and statements by senior leadership (Access to Medicine Foundation, 2012). However, the multinational industry needs to embrace the idea of access as an explicit business objective and commit to designing and rolling out medicines programmes. It must also work in partnership with national and local governments and provide locally relevant evidence of comparative clinical and cost-effectiveness while offering economically justifiable prices.

On the other hand, governments and payers must reassess how they will expand medicine access and reward value under universal coverage by being explicit, objective and—more importantly—evidence-informed in their decision-making. Access to medicines is not just about increasing financing

but also ensuring responsible use, whereby the right medicines are available to patients who need them and patients use medicines appropriately. For example, challenges related to non-adherence, antibiotic misuse and drug shortages contribute to over US$500 billion in global avoidable healthcare costs (IMS Institute for Healthcare Informatics 2012). Governments and payers, and the pharmaceutical industry, must work together to build the capacity for ensuring (and demonstrating) medicines generate value in the broader health system, beyond the early stages of pricing and reimbursement negotiations.

This review suggests that governments in emerging markets have an increasing ability (because they are richer) and need (because they are committing to UHC), to prioritize amongst competing resources and external agendas. Funding for such priorities and the methods used to identify them need to be clear and transparently set. As alluded to by Hillary Rodham Clinton:

> 'country ownership in health is the end state where a nation's efforts are led, implemented, and eventually paid for by its government, communities, civil society and private sector. To get there, a country's political leaders must set priorities and develop national plans ... And these plans must be effectively carried out primarily by the country's own institutions ... country ownership is principally about building capacity to set priorities, manage resources, develop plans, and carry them out' (Clinton, 2012).

While not a panacea, health technology assessments and value-based pricing offer a locally-driven priority setting platform and can perhaps remove the need for reactive and punitive measures such as compulsory licensing and arbitrary price cuts when it comes to access to medicines.

This discourse could be advanced through additional research that quantifies the economic and social benefits of different priority-setting mechanisms, including HTAs, in the context of increasing medicine access—compared to, for example, arbitrary price cuts—from the perspective of both payers and industry. Furthermore, such an analysis could show the impact of different engagement mechanisms on the effectiveness of negotiations with the pharmaceutical industry, patient advocates and multilateral organizations. Additionally, as the post-MDG agenda crystallizes and non-communicable diseases demand a share of existing resources, it would be helpful to understand possible tactical and realistic processes countries can adapt to set their own priorities in response to expected pressure from patients and the pharmaceutical industry alike.

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