

# Efficacy of international approaches to medicine price regulation and control: A scoping review

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## ABSTRACT

**Background:** The access to affordable medicines is counted as a challenge, despite international measures taken towards cost containment and price regulation.

**Objective:** To identify and review the literature on international approaches related to medicine price regulation, control, and its effectiveness.

**Methods:** In this scoping review, peer-reviewed research and review articles, discussion papers, public documents relating to medicine pricing policies were reviewed. The search strategy was structured according to STARLITE principles. The key search terms and phrases were “medicine prices”, “causes of high medicine prices”, “approaches towards medicine prices control”, “national medicine policies”, “international approaches towards medicine price control”, “containment policies”, and “effects of pricing policy on medicine”.

**Results:** Medicine pricing and price regulation policies were drafted and implemented with no optimal results and things don't seem to have improved much and remain as the distant goal. These policies were either less comprehensive, outdated and fell short in implementation especially in low and middle-income countries (LMICs) due to lack of funding, infrastructure or trained professional task force. Overall, none of the policy options was preferred. Multi-pronged policy options crafted in local context are required to tackle the issue.

**Conclusion:** The authors identify gaps in the literature and propose advanced research in the area to strengthen the healthcare system by improving medicine pricing system in each country.

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## INTRODUCTION

Medicines are essential to sustainable health care systems and reduce morbidity and mortality rates and enhance quality of life (Kohler *et al.*, 2012). The medicine prices could play a crucial role in prescription decisions which ultimately affects pharmaceutical expenditures. The high medicine prices are budgetary burden on the individuals and governments, therefore, the public and nongovernmental organizations (NGOs) have been lobbying for decades for its regulation and control. Since, like past, the medicine prices are now a global issue, not just mostly for LMICs, according to Suzanne Hill. In addition,

the price is manipulated by a single supplier, even when a product goes off patent.

The issue has been discussed with member states and seen increasing frustration with the failure of the market to manage prices. The problem is much convoluted when the essential products disappear from the market due its lack of commercial viability, so manufacturers have a lack of interest, for example US, South Africa, and Europe (Ed Silverman, 2016). The pharmaceutical manufacturers' behaviour on their new branded medicines has resulted in many distinguished economists commenting that the medical profession constitutes a monopoly (Gelfand, 2000). Despite monopolizing the medicines, however the fair price competition among the competitive medicines facilitates to reduce the medicine prices. Markets work well in the interest of the society when there is price competition, comprehensive,

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accurate, unbiased medicine information and on adequate supply of drugs, where consumers are able to make informed unpressured choices between competing products and when there are few barriers for entry to the market (Kremer, 2002). The price competition should not be limited to generic medicines only since it is important to reduce the high prices of patented medicines as well. The market competition can benefit consumers through increased branded and generic competition and lower prices with higher availability (Berndt *et al.*, 2007). In non-competitive markets, suppliers have freedom to choose the level of profit they intend to take (Schüklenk and Ashcroft, 2002) but in such case there will be no regulation for medicine pricing and the possibility of availability of affordable medicines will be less.

The medicine price discrimination plays role in increment of medicine prices, for example the price discrimination by health practitioners by scaling fees to the income of patients (Szymanski and Valletti, 2005, Szende and Culyer, 2006). The price discrimination and irregularities are not the only factors of the high medicine prices in developing economies; even in the United States, the prescription drug prices are highly unregulated. This differs from most other countries, where drug prices are regulated either directly through price control, (e.g. France and Italy), or indirectly through limits on reimbursement under social insurance schemes, (e.g. Germany and Japan), or indirectly through profit controls, e.g. United Kingdom.

A common political belief exists in Europe is that governments should ensure that, medicines are made available to everyone. Each European Union (EU) member state has its own legislation and set of measures to reach this objective. While the governments and NGOs are pointed to be responsible to regulate the medicine prices, the world continues to grapple with this problem with high medicine prices (Huttin, 1999 and Simoens, 2007). In addition, the WHO also plans to work with the governments, patient groups, and drug makers to explore the true balance between access to affordable medicines and inviting the pharmaceutical companies to produce new and improved medicines, while also ensuring lower-cost generics remain available (Ed Silverman, 2016).

Hence, this scoping review aims to evaluate and discuss the medicine prices and its causes, drawbacks of high medicine prices, approaches towards its regulation and control, policy options and international approaches and their effects.

## MATERIAL AND METHODS

A scoping review of peer reviewed and gray literature regarding pharmaceutical pricing policies, national medicine/ drug policies, pricing models, qualitative and quantitative descriptive studies were reviewed, where the policies instigated by governments, NGOs, private institutions and policy makers were included. Additionally, peer-reviewed articles, research papers, discussion papers, and reviews, published in medical and pharmacy journals, related to medicine pricing policies; and documents from World Health Organization (WHO), Health

Action International (HAI), Médecins Sans Frontières (MSF) and World Bank were reviewed. The scope of this review was to ensure that all components of pharmaceutical pricing policies and measures were covered.

Complete search strategy is presented in Table 1 and structured according to STARLITE principles (Noyes *et al.*, 2011). The acronym STARLITE stands for (Sampling strategy, Type of study, Approaches, Range years, Limits, Inclusion and exclusions, Terms used, and Electronic sources).

**Table 1:** STARLITE Principles.

STARLITE principles	
S	Selective <b>sampling strategy</b> : Articles selected from health, pharmaceutical, trade organization, national medicine policies, international policies, health sciences databases
T	All <b>types of studies</b> were included (pricing policies, national medicine/ drug policies, pricing models, qualitative and quantitative descriptive studies, peer-reviewed articles, research papers, discussion papers, and guidelines)
A	<b>Approaches</b> : Keyword searching, hand-searching, reference searching, and internet searching
R	<b>Range</b> (No restrictions): The search ended in August, 2016
L	No <b>Limits</b>
I	<b>Inclusion</b> : Medicine pricing studies, regulatory affairs, cost-containment policies, national and international policies; <b>Exclusion</b> : Studies describing herbal medicines, vaccine prices, veterinary medicines, cosmeceuticals, nutraceuticals and homeopathic medicines. In addition, surgical instruments and medical supplies used for surgery.
T	<b>Terms</b> (See below in search methods)
E	<b>Electronic sources</b> : World Health Organization (WHO) library, Health Action International (HAI), Médecins Sans Frontières (MSF) and World Bank articles, PubMed, SciELO and Google Scholar.

## Search methods

The search methods included entering key words and phrases “medicine prices”, “causes of high medicine prices”, “drawbacks of high medicine prices”, approaches towards medicine prices control”, “national medicine policies”, “national medicine law”, “International approaches towards medicine price control”, “supply and demand side approaches of medicine price control”, “containment policies”, “effects of pricing policy on medicine” into relevant databases, the WHO essential medicine (EM) document library and Google scholar. The title, abstract and/or full articles were reviewed for relevance and included in the review.

## RESULTS AND DISCUSSION

The present study contributes to the literature about the causes of soaring medicine prices and the effectiveness of international approaches towards medicine price regulation and control.

The results showed that pharmaceutical prices consist of components such as the manufacturers' price, wholesalers' price and retailers' price. At each of these stages there are mark ups and

possible tax components and pricing policies can be targeted at one or more of these (Aaserud *et al.*, 2006). Additional factors affecting pharmaceutical products include price discrimination by suppliers of patented products according to market conditions in different countries or the presence of a domestic pharmaceutical industry with the capacity to produce generic substitutes (Oclay and Laing, 2005).

It was observed that countries have routinely increased the price of medicines to consumers through import tariffs, other duties and sales tax by 20 to 40%. The price of medicines can be significantly increased by additional non-tariff barriers, such as lengthy registration periods for medicines and onerous requirements to clear customs. The hidden costs can be more than double of the manufacturer's price (Pérez - Casas *et al.*, 2001), for instance, evidence indicates that in Pakistan has substantial hidden cost on medicines at public sector facilities and thus the mean out-of-pocket spending per prescription was USD 4.2 at private sector facilities compared to USD 3.3 at public sector facilities. There are additional factors which contribute to medicine prices, such as:

#### **Research and Development (R&D)**

According to our findings, despite of thirty years of research in this area, no published estimate of the cost of developing a drug can be considered a gold standard (Morgan *et al.*, 2011). But, estimated new drug development takes about 12 years with an estimated cost of US\$500–600 million to be developed (Henry and Lexchin, 2002). According DiMasi and others the average cost of new drug development to be \$802m per new drug (2003) and even the cost of drug development is over \$1 billion (Adams and Brantner, 2010).

#### **TRIPS**

In 14<sup>th</sup> century some European countries started issuing patents as an incentive for inventing (Strand, 2014). With passage of the time, the “exclusivity of production has been protected through World Trade Organization (WTO) agreements on trade-related intellectual property (TRIPS) (Pecoul *et al.*, 1999)”. Based on these agreements, the patent rights avoid the potential competitors from selling products covered by the patent during 20 years of patent duration, thus the patent holders enjoy a period of significant “monopoly power”.

It was noted that, much of the problem was attributed to the prices of patented medications, for instance, “150 Mg of the HIV drug Flucanazole costs USD 55 in India (where the drug is not patented), as compared to \$USD 697 in the Philippines, USD 703 in Indonesia and \$USD 817 in the Philippines, where the drug is patented. Similarly, the HIV treatment known as AZT (Zidovudine, Retrovir) costs USD 48 per month in India, as compared to USD 239 in the US where patent protection exists (Sykes, 2002).” Even though the medicine prices are high around the globe, but still the pharmaceutical industry justifies its research decisions.

The higher prices of patented medicines have been criticized by the developing economies for their inability to afford treatments against epidemics and premature deaths (Pogge, 2005) thus, these criticisms have resulted in alterations made to TRIPS commonly referred to as the “Doha Declaration” which permitted for the issue of compulsory licenses for medicines refused to be supplied at a reasonable price by the patent holders, or in cases of national emergencies (Strand, 2014) and the deadline for adherence with WTO conditions for least-developed economies was extended from 2006 to 2016 (Beall and Kuhn, 2012). The Doha declaration eased the pressure of high prices of patented medicines, and hence the developing economies benefited from the lower medicine prices when they do not create pharmaceutical patents. To find the impact of Doha declaration, a study was conducted in 65 developing economies where it was found that patents and patent applications existed for EM 1.4 percent of the time, and there were no patent barriers to accessing generic EM in 98.6 percent (Attaran, 2004). Overall, the pledges made in Doha “Doha Declaration” have not been met and as successful as expected (Grover *et al.*, 2012). However, still we are hopeful, since the Human Rights Council (HRC) approved a comprehensive declaration on access to medicines which provides the HRC authorization to observe the connection between international trade agreements, intellectual property rights obligations and their implications on access to medicines (SAEZ C, 2016).

#### **Price components**

Results showed that the major obstacle toward access to medicine was the cost. The pill received by a patient goes through a winding supply chain, e.g. when the medicines originate in manufacturing sites, imported or exported; quality control; transferred to wholesale distributors; stocked at retail; subject to price negotiations; dispensed by pharmacies; and finally delivered to and taken by patients. These structures vary from country to country since many actors and factors are involved in the supply chain (Kaiser Family Foundation, 2005). The final price paid for a medicine is the sum of the above and the price borne by the consumer includes additional charges, which can more than double the manufacturer's price (Pérez - Casas, 2001). Thus the reason behind high prices of medicines were the combination of manufacturer's price and hidden costs (Oclay and Laing, 2005).

The scenario of tariffs, mark-ups, retail-ups and other duties levied on medicines in LMICs is less systematically documented. A 2003 study from 57 LMICs showed that customs duties accounted for a third of total taxes levied on medicines and found VAT rates on medicines varying over 20%. In addition, the (WHO/HAI, 2008) database on medicine prices showed that in 23 LMICs the medicines were taxed in a range between 2.9% to 34%. Ten other countries in the dataset reported zero VAT or sales tax rates on medicines (Creese, 2011). The hidden cost varied from 48% in Nepal to 88% in Armenia (Levison and Laing, 2003).

In Afghanistan due to multiplicity of pharmaceutical products, the medicines prices in the country vary. The government charges fixed tax on all pharmaceuticals. There is no document / database to record the tax, tariff or mark ups on each item. As in Afghanistan large percentage of the medicines are imported, therefore the medicines are subject to extra charges, e.g. for imported medicines, the pricing starts with the cost, insurance, freight (CIF) price, which is whatever the manufacturer charges for the medicine, plus extra charges for the shipment/transportation of medicine inside country's borders. After CIF, there are additional payments charged by the directorate of revenue; ministry of finance and agents for getting medicines through the port. There may also be import taxes, and/or fees charged by the importing agencies. Once entered inside the country, additional mark-ups are there for each step in the distribution chain with other tariffs imposed throughout the way. Thus the final price to the patient is significantly higher than the mere CIF price (MOPH, 2011).

A study conducted in Shandong province of China illustrated, that price components, cumulative mark-ups were 25-35% and 10-33% in the public and private sectors respectively. The analysis demonstrated that in the public sector the hospital mark-ups of 26% were the greatest contributor, while in contrast only 3% wholesaler's mark-up was observed in the private sector for both originator brands and generic equivalent. In the public sector the mark-ups were different, for originator brand it was 13% and 10% for generics. In the private retail outlets (pharmacy) mark-ups varied from 4% - 25% with 3% sales tax and 17% VAT on imported medicines (Qiang, 2005). The price components study from India revealed that in the private sector, trade schemes were varied and limited between manufacturer, wholesaler and retailer. The retail mark-ups were found higher than range defined. Taxes of VAT 4%, excise tax, 2% education fund, 4% city sales tax were imposed on medicines both during manufacturing and distribution (Kotwani and Levison, 2007). According to Gelders and others, there were many variations across the countries, for instance in Pakistan the wholesale mark-ups were found to be 2% in Pakistan, cumulative taxes were found 380% in EL Salvador and retail mark-ups were 10% in Mongolia (2006).

In Sudan, the wholesale mark-ups varied from the retail mark-ups. The wholesale mark-ups in the public sector ranged from 125% and 240% in Central Medical Supplies (CMS) and Revolving Drug Fund (RDF) respectively. In the private sector mark-ups of wholesalers were fixed at 15%, in contrast the retail mark up ranged from 11% in CMS to 50% in RDF in the public sector, while it was 20% in the private sector. Overall, the final prices patient paid were highly raised by adding cost to manufacturer's selling price (MSP.), for example insurance and freight were added as 48.8% and 66.16% , and retailer mark-ups as 33.3% and 16.67% in public and private sectors respectively (Kheder and Ali, 2014). Results from China, Ethiopia, Mali, Mongolia and Uganda showed, that wholesale or retail mark-ups were also applied in the public sector, suggesting the use of

medicine sales as a revenue-generating mechanism (Olcay and Laing, 2005).

The result in 30 European countries showed that the VAT charged was between 15-25%, and among these countries five of them did not apply any VAT rate to some or all medicines. Similarly, 21 countries applied a lower tax rate ranging from 2.1-11% to some or all medicines. Where countries apply lower or zero rates only to some medicines, this is usually for prescription medicines or publicly reimbursed medicines, while over-the-counter (OTC) or non-reimbursable medicines are taxed at the standard rate (Creese, 2011).

### **Need for controlling high medicines prices to improve access**

Two billion people do not have regular access to life-saving drugs (Lee and Kohler, 2010). The market price frequently rises for medicines and they are not affordable and at the time treatment the patients pay the greatest share of a medicine's price out of their own pockets (Dávila, 2011). To tackle with the high medicine prices and to improve its access, different survey tools were developed and being used to study and assess medicine prices and pharmaceutical situations. Additionally, multidimensional approaches have been undertaken to control high medicine prices globally. These tools and approaches are discussed in details with its results.

### **Tools to study and assess medicine prices and pharmaceutical situations**

Many tools, instruments and guidelines have been designed and implemented to regulate and control the medicine prices and ensure its access in the world. These examine the equal and equitable access to medicines and other specific health care services (Susser, 1993). The main reason behind these tools development is that the patient "[enjoy] the highest attainable standard of health as a fundamental right" (WHO, 2007).

### **Medicine pricing studies using the WHO/HAI methodology**

Prior to 2000, there was no such standard methodology to measure, evaluate or assess the medicine prices and its availability around the world. The World Health Assembly (WHA) in 2001, passed a resolution (No 54.11) in which the WHO Director-General requested to explore the feasibility and effectiveness of implementing, in collaboration with NGOs and other concerned partners, systems for voluntary monitoring drug prices and reporting global drug prices with a view to improve equity in access to EM in health systems. (WHO/HAI, 2008).

According to WHO/HAI, more than 70 surveys have been conducted around the globe, so far using this methodology. The methodology is designed in a way that is adaptable in any situation, and has synthesized evidence based facts regarding medicine prices, availability and affordability. With the passage of time, the interest has grown among the countries regarding measurement of medicines prices, availability and affordability and price components using the WHO/HAI methodology directly or adapting (WHO/HAI, 2008).

### ***National medicine price and availability monitoring system***

The data revealed that most countries have some mechanisms in place for monitoring and evaluating their health care system to assess the performance and appropriateness of government's health care policies. For example, in developed economies the pharmaceutical policy monitoring often includes monitoring of price trends of medicines, medicine utilization, cost per treatment for various diseases, and clinical outcomes (Mossialos and Oliver, 2005).

Even though it has been known that medicine prices are a significant barrier to access to effective and safe medicines in developing economies, there is a scarcity of data on what people/governments disburse for medicines and how prices change with time in these countries. Data collected by industry and market research agencies in various countries are not publicly available in developing countries, and may not include all types of data. According to MSF, the price for medicine is not the only cause, but is a major barrier and in many life threatening conditions, the high cost of medicines deprives patients from getting the treatment and leads to death (Hoen, 2001).

Therefore, for effective policy-making to influence the medicine prices, it requires the use of evidence that is based on accurate monitoring and assessment of medicine price data, and for designing appropriate interventions to lower prices the accurate medicine price monitoring is vital. Due to lack of medicine prices data and price regulation policies, perhaps the worst options may include irregularities and variation in medicine prices in public and private sector, corruption in supply chain and uninformed decision-making based on anecdotes.

The ideal national or international medicine price monitoring system's objectives usually fall into one or both of the following : A reporting system that provide a measure of the current price of individual medicines of interest and the medicine price trend monitoring systems to generate a medicine price index for a basket of selected medicines, to measure average inflation or fluctuation of prices (HAI, 2008).

### ***Assessing governance of the health system in developing economies***

The advanced and self-reliant health system is a key determinant of economic development and help in the attainment of Sustainable Development Goals (SDGs). The health system with good governance has particular specification and "characterized by responsiveness and accountability; an open and transparent policy process; participatory engagement of citizens; and operational capacity of government to plan, manage, and regulate policy and service delivery" (Siddiqi et al., 2009).

In Rwanda, in 2009, the U.S. Agency for International Development's (USAID's) "Decentralization and Health Program" known as "Twubakane" provided financial and technical assistance to Rwanda's health system. After reviewing Twubakane's efforts toward decentralization of Rwanda's health system, it was found that health care programs and health governance benefitted with health service delivery enhancement

(Brinkerhoff et al., 2009). Several frameworks for measuring health system performance have been developed to assess the good governance in health sector in developed and developing countries, such as "A WHO framework for health system performance assessment" (Murray and Frenk, 1999) and "Health outcome measurement in OECD countries: toward outcome-oriented policy making. Paris, Organization for Economic Co-operation and Development, 1999" (Jee and Or, 1999).

### ***Service availability and readiness assessment (SARA)***

Monitoring healthcare infrastructure, human resources, capacity of health care providers basic medical and diagnostic equipment, EM and preparedness of healthcare facilities to provide services is important and integral part of the public health and the information derived from SARA could be used to scale up the health services to all those who need care (O'Neill et al., 2013). The WHO designed health facility assessment tool SARA to assess and monitor the service availability and readiness of the health sector and to generate evidence to support the planning and managing of a health system. The SARA has several advantages, such as; it encourages the maintenance of a coordinated national health services monitoring system, which promotes country ownership and transparency. Further it provides a comprehensive analysis of health system to address deficiencies and bridge the gaps to ensure universal health coverage (O'Neill, 2013).

According to O'Neill et al the SARA has been conducted in many of the low income countries, like Burkina Faso [2008], Cambodia [2008], Haiti [2008], United Republic of Tanzania [2009–2010] Sierra Leone 2011 (WHO, 2011) and Zambia [2008] (2013). The findings from the assessments of these six countries highlight important gaps in service delivery that are barrier to universal access to health services. Likewise, substantial disparities were observed in the distribution of health facility infrastructure and human resources in these. The problem which were observed in common included weaknesses in laboratory diagnostic capacities, access to EM and commodities within the health care facilities.

### ***Assessment of country pharmaceutical situations***

A package of core indicators was developed by WHO to monitor and evaluate the country pharmaceutical situation. WHO member states were requested to use this cost-efficient and easily repeated assessment on a regular basis. The country pharmaceutical situation report can support the Ministries of Health in many ways, such as tracking the progress, assessing their program effectiveness and fund raising. These core indicators have been divided into three levels of assessment. This standard assessment methodology is designed to track progress on periodic basis to evaluate situations in different health facilities (WHO, 2014).

Level I, indicator measures the structures and processes at strategic level, including assessment of health policies, quality assurance and quality control protocols, procurement and supply chain management, health financing and insurance schemes,

pharmaceutical manufacturing, EML, rational use of medicines (RUM) and issues around intellectual property rights (IPR). The measurement of (Level I) indicator uses the standardized questionnaire on structures and processes of country pharmaceutical situation, which is distributed every four years to all member states by WHO.

Level II, indicator uses to assess the outcomes of these structures at operational level, such as safety effectiveness and quality control. Along with RUM the access to medicine is also been considered to ensure availability and affordability of EM at household, health facilities and hospital levels. The information will be used for prioritizing health programs, tracking progress and fundraising.

Level III, indicator uses the in-depth analysis to assesses specific characteristics of pharmaceutical sector, national medicine policy, medicine prices, availability and affordability. The information collected from three levels of assessment is used by the countries to track the progress toward their predefined goals. The indicators will further assist to assess the availability, affordability and RUM. Along with other objectives, it supports the coordination among donors and advocates for fundraising (WHO, 2014).

The data collection in 193 members' states has been conducted by using the electronic questionnaire. The questionnaire is used by all WHO regions such as WHO African Region (AFRO), WHO Region of the Americas (AMRO/PAHO), WHO Eastern Mediterranean Region (EMRO), WHO European Region (EURO), WHO South-East Region, and WHO Western Pacific Region. The document contains information on existing socio-economic and health related trends, as well as on regulatory structures, processes and outcomes relating to the pharmaceutical sector (WHO, 2014).

#### **WHO access framework**

The perception and attitude toward access to medicines is different and it is defined and measured in different ways (Tuan, 2011). According to WHO "access to medicines as the percentage of the population who have access to a minimum of 20 of the most EM, that are continuously available and affordable at a health facility or medicine outlet, within one hour's walk from the patient's home (UN Millennium Project, 2005)". However, most of the people especially in LMICs have limited access to medicines due to many reasons, such as but not limited to either poor access or because patients must pay out-of-pocket for their prescriptions. The pharmaceutical spending is forecasted to reach ~ \$1.2 trillion (Brands \$615-645 billion and Generics \$400-430 billion) of which the spending per person in developed country is \$609, but still large proportion of people in LMIC have insufficient access to EM since availability and affordability are not assured (IMS Institute, 2012).

The access to medicine is not only the presence of medicine, there are many factors which define the level of access, such as financing, prices, distribution systems, appropriate dispensing and use of EM. To clearly define, guide and coordinate

collective action on access to EM the WHO has designed a four-part framework [rational selection, affordable prices, sustainable financing and reliable health and supply system]. The framework will act as a tool to evaluate and improve access to EM. To improve access to EM, all four inter-connected and determining factors must be taken into account. Overall the main purpose of the WHO access framework is to ensure the availability of EM for everyone, since EM plays pivotal role in the healthcare and acts as a foundation for every public health program.

#### **Basic Package of Health Services (BPHS) and Essential Package of Hospital Services (EPHS)**

The BPHS and EPHS provide standard clinical and administrative guidelines for the provision of basic primary health care services that address the major disease burden for maternal and child health in peripheral clinics and disease management and surgical standards for referral and tertiary hospital care. Service delivery is primarily through contractual agreements with NGOs (Siddiqi *et al.*, 2006). The BPHS has been seen in post-conflict settings viz. Afghanistan, Liberia, South Sudan, Somalia, the Democratic Republic of Congo, and Cambodia. The BPHS delivered at primary and secondary health care levels, addressed the country's major health problems with a confined list of cost-effective priority health services (Petit *et al.*, 2013). The studies from Liberia show that progress of BPHS has been slowed down. It found that health workers had a limited understanding of the BPHS and associated it with low salaries, difficult working conditions, and limited support from policy makers (Petit; Sondorp, 2013). While in Afghanistan, the BPHS expanded at national level which resulted in access to primary health care services and supply of EM increased (Newbrander *et al.*, 2014).

#### **National Medicine Policies (NMPs)**

Globally the mounting concerns towards access to affordable medicines have pushed the governments especially in developing economies to develop national policies in order to increase the affordability, supply, safety, and RUM (Ratanawijitrasin *et al.*, 2001). Among nine components of NMP indicated by WHO, two clearly emphasize on affordability and drug financing. Little is known regarding the anticipated and unanticipated effects of these social experiments on access to affordable medicine. The synthesis does not provide valid data to determine whether NMP can help on controlling the medicine prices. To ensure that health conditions are improved and cost is reduced, it is equally important to improve the objectives of the NMP (Nikfar *et al.*, 2005). A medicine policy without an effective implementation plan is a dead document.

#### **Internationally used approaches to control high medicine prices to improve access**

The price of medicines, their availability and affordability, are major determinants of access to treatment and it is a matter of concern for both patients and governments who are accountable with the duty to offer healthcare for their citizens

(Ewen and Dey, 2005). The pharmaceutical expenditure is rising globally, and LMICs, have less regulated pharmaceutical markets and often lack feasible pricing or purchasing strategies, and most pharmaceutical expenditure is out-of-pocket which creates a different dynamics for policy enforcement (Nguyen *et al.*, 2014). Effective pricing policies are needed to tackle with high medicine prices, poor affordability and low availability. The success of pricing policies relies on evidence, investigations to establish causality, effective policy implementation, enforcement, and regular monitoring of prices, availability and affordability (Ewen and Dey, 2005, Aaserud, 2006).

The medicine pricing is most hotly debated issue internationally among policy makers, and advocacy groups and thus pressure has increased on pharmaceutical industry to decrease the prices of newly produced medicines, especially the EM (Gregson *et al.*, 2005). If the medicines are affordable, only then can these offer a simple, cost-effective solution to many health problems (Pecoul;Chirac, 1999) and can decrease the expenditure on medicines (Gray, 2009).

The unaffordable EM for the poor are one example of conflicting social costs (Khor, 2002) and can negatively impact patient outcomes (Allan *et al.*, 2007). Looking into this situation, cutting pharmaceutical prices will assist in the reduction of health care expenditure and will decrease the out-of-pocket payments by patient (Ess *et al.*, 2003, Weinstein and Skinner, 2010).

The high prices of medicine and lack of availability can't be affordable for long time, (Giuliani *et al.*, 1998) since, its regulation and control is one of the prime objectives for health policy makers (Bloor and Freemantle, 1996, Maynard and Bloor, 2003, Docteur and Oxley, 2003). Looking into the rising cost of medical pharmaceutical expenditures, globally numbers of approaches have been designed to control the pharmaceutical expenditures. These approaches have been divided into two categories: the first category is the supply side and the second category is the demand side (Gross *et al.*, 1996, Ess, 2003, Meng *et al.*, 2005).

### Supply side approaches

The supply side approaches to regulate medicine prices hold the government responsible to remove all the trade barriers and international variation, which otherwise escalates the medicine prices. Removing trade barriers will allow the countries in equalizing prices of drugs of the same brand, manufacturer and dosage form. In doing so, effective policies are necessary to allow market competition at wholesale and retail levels. The supply side approaches focus to control the medicine prices at multiple points.

### Direct price control

The key reasons behind high medicine prices are the domination of mark-ups and impact of TRIPS, and to deal with these, the direct price regulation can bring the medicine prices closer to the average cost for treatment. In this case the government must subsidize the suppliers to be prevented from bankruptcy (Solon and Banzon, 1999). The direct pricing policies

include negotiated prices, maximum fixed prices, international price comparisons and price cuts or freezes (Aaserud, 2006).

### Indirect price control

The indirect price control methods consist of profit regulation and reference or index pricing where the government sets references prices to regulate the medicine procurement sold at national and local public health facilities or for reimbursements by public health insurance programs. New Zealand was successful in control of medicine prices by introducing reference pricing system (Braae *et al.*, 1999).

Introducing direct and indirect price regulation may offer a short-term solution to monopolistic pricing of medicines. The more sustainable solution however is the generic medicine policy enforcement and generic competition between pharmaceutical companies.

### Generic medicines strategy

During formulation of generic medicine strategies and prior to its implementation, consider the supply-side and the demand-side requirements. Supply-side interventions related to market entry and penetration of generic medicines, as well as issues around pharmaceutical pricing, setting a reimbursement price and determining pharmaceuticals available in a reimbursement list. Demand-side interventions are linked mostly with actions at prescribing and dispensing levels and, less so, purchasing by consumers (King and Kanavos, 2002), therefore, the true importance of generic drugs is seen by their effect on prices (Henry and Lexchin, 2002).

The notion behind development and implementation of effective generic medicine strategies is to improve affordability, reduce healthcare expenditure, and assist to rationalize selection and utilization of pharmaceuticals (Madrid *et al.*, 1998). Generic medicines provide the same therapeutic outcomes, and lead to substantial savings for healthcare systems (Hassali *et al.*, 2014). Execution of these strategies has the potential to make the market more competitive and improve the equity, quality, and efficiency in healthcare system.

The generic medicine strategies are based on two key features: The use of non-proprietary or generic names for pharmaceuticals, and the availability of a selection of equivalent products (generics) which can be identified as substitutes for each other and compete based on price (Madrid, 1998). Therefore, to explore the issue around generic medicine for better policy making, it is imperative to know that there are two types of generics; the "branded generics" and "unbranded generics". The branded generics are these off-patent medicines made by companies other than the originator company, and may be marketed under a trade name [branded generic] (Bhargava and Kalantri, 2013). Also, it could be produced by the same manufacturer that makes the originator brand medicine, and are then known as "fighting generics," "pseudo-generics" or "authorized generics" (Anis *et al.*, 2003, Berndt, 2007) or are the "unbranded generics" refers to those products which are sold

exclusively by generic name and are equal in safety and effectiveness to brand-name drugs while being marketed at a lower price, and can significantly reduce costs to consumers (Madrid, 1998, Generic Pharmaceutical Association, 2008, Anis *et al.*, 2011).

In India, the term “generic” is in line with its global usage to represent medicines which are off patent. In India, the basic division is therefore not between medicines under patent and off-patent medicines, but between unbranded medicines (generic in the Indian sense) and branded medicines (Bhargava and Kalantri, 2013).

Branded drugs in India are actually “branded generics” which are often misunderstood by patients and the media, as “patented” medicines (Mani, 2009), which they are not. Therefore, a generics strategy optimally promotes the use of unbranded generics since branded generics have drawbacks of 1) marketing costs are typically higher, thus increasing price, 2) brand loyalty may limit substitution, resulting in higher prices, 3) proliferation of brand names on the market can cause confusion, promote irrational drug use, and limit price competition. In contrast, the unbranded generics can be considerably cheaper than their brand equivalents offering affordability (Baltas and Argouslidis, 2007). For instance in 2008, the Indian government had launched the ‘Jan Aushadhi Campaign’ in each district to provide quality generic medicines at lower prices (Singhal *et al.*, 2011).

Likewise to make the medicines affordable the Indian states like Rajasthan and Tamil Nadu have implemented a model in 2011 where they sell unbranded generics, which have brought down the prices by at least 30 % (Mukherjee, 2014). But still being one of the largest producers of generic medicines in the world, the low cost generic medicines remain inaccessible and unaffordable to many Indians and based on WHO World Medicine Situation Report 2011, 65% of all Indians lack access to essential medicines (Hogerzeil and Mirza, 2011, Gupta, 2016).

### **Promoting culture of generic medicine among health practitioners**

Physicians are expected to be more knowledgeable about generic medicine prescription for controlling the medicine prices. But health practitioners have a poor understanding of medicine cost, instead to be sensitive to costs in their prescribing decision (Allan, 2007). Health practitioners’ ignorance of costs, combined with their inclination to underrate the price of medicines could have significant implications for overall drug expenditure (Allan, 2007).

Therefore, the culture of generic prescriptions requires promotion among physicians and other healthcare providers with a medical training rooted in social and economic realities so that health workers become oriented towards it. The schools, mass media, and community organizations should be used to challenge people's dependence on drugs (Degenhardt and Hall, 2012). Otherwise, the prescription of branded medicine, over-prescription and high free market price would lead to socially excessive healthcare expenditure in the absence of generic

medicine prescription and substitution (Bloom and Refenen, 1998).

### **Brand substitution**

The generic substitution is encouraged as an approach for containing the escalating cost of healthcare expenditure by rapid increase in medicines cost (Hassali *et al.*, 2010, Hassali *et al.*, 2014). Along with other options, the generic substitution could be one mechanism for limiting drug expenditure by reducing prescription medicine cost (Haas *et al.*, 2005) but it cannot guarantee the medicine price control. For example, the UK is unique in achieving a high level of generic drug use despite not employing a policy of generic substitution (King and Kanavos, 2002).

To ensure wider prescription and decrease in healthcare expenditure, the generic substitution should be politically and administratively supported, although in most countries, the generic substitution is not mandated (Suh, 1999, Mott and Cline, 2002), for instance, in South Africa, a pharmacist may not legally substitute any medicine on a prescription, without the physician's authorization. While in the private sector the generic substitution is encouraged in the private sector, in contrast in the public sector (Patel *et al.*, 2009).

The generic medicine prescription is the only cost-effective approach toward promoting the lowest priced medicines. The generic drugs, which contain the same therapeutic substance as the original formulation, become available once the patent protection granted to the brand name drug has expired, leading to greater market competition and lower prices.

In most countries like in France, control of pharmaceutical expenditure has been a policy priority for many years and generic policies have featured prominently on the policy agenda (Drummond *et al.*, 1997).

In Sweden in 2002 the generic substitution was made mandatory to reduce the pharmaceutical expenditure and decrease the medicine cost for both for the patients as well as the society (Andersson *et al.*, 2007). Appropriate and cost-effective prescribing is a major goal for all participants in the health care system (Shrank *et al.*, 2009) and the use of generic drugs can substantially reduce costs without compromising quality (Kesselheim *et al.*, 2008).

Likewise, in UK hospitals the generic substitution by pharmacists is a standard practice, and proposed for implementation in primary care. Although most prescriptions are already generic (83% in the community in England in 2008), there are still cost savings that could be made if generic medicines are substituted against prescriptions written in branded name or by getting prescribers to adhere to advice to prescribe generically (Duerden and Hughes, 2010).

In Switzerland, since 2001, pharmacists are authorized to substitute branded medicines with generics by notifying the prescribing physician and by 2003, the overall generics' substitution rate for 173,212 dispensed prescriptions was 31% (Decollogny *et al.*, 2011).



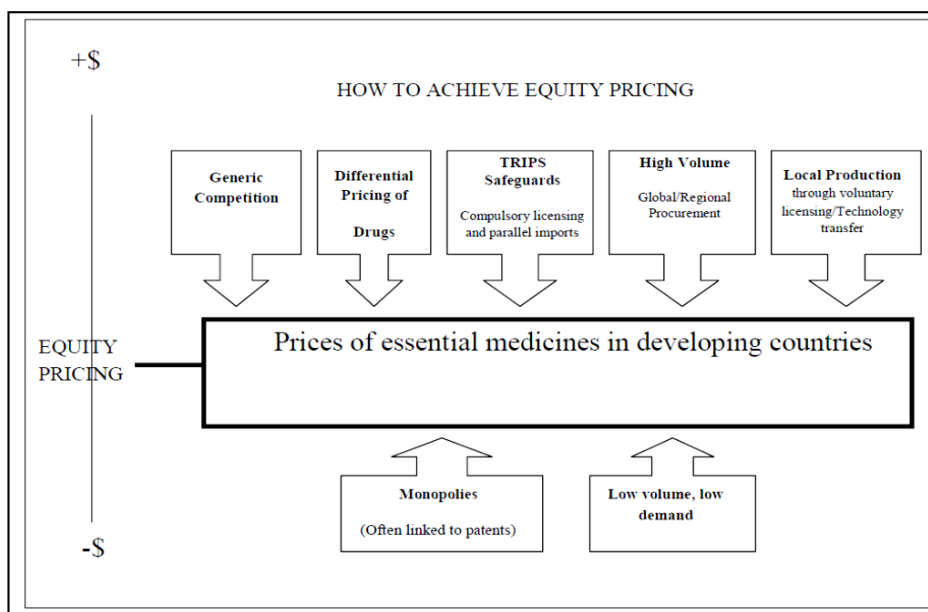


Fig. 1: How to Achieve Equity Pricing, Source: (MSF, 2005).

### Reference based pricing (RBP)/ reference price (RP)

This is one of the options employed to decrease the medicine related costs. “The RP involves grouping together similar products and defining a relative price that will be reimbursed by health insurance funds. Thus, if a pharmaceutical product is priced above the reference price, the insured is required to pay the difference in price” (Giuliani, 1998). The goal of the RP is to control and reduce the third party expenditure on prescription medicine either through (i) a relative decrease in the demand for highly priced products [a demand-side approach] or (ii) cutting drug prices by encouraging self imposed [a supply side approach] (López-Casasnovas and Junoy, 2000). It should be noted that, the reference pricing is not a form of price regulation, but is an effective tool for price control (Giuliani, 1998) and according to Dukes, the reference price “is a mean of limiting expenditure on the reimbursement for group of drugs which are considered to be interchangeable” (2003). Since its introduction in Germany in 1989, RP schemes have been applied in Netherlands, Sweden, Denmark, New Zealand, Poland, Slovenia, Spain, US, British Columbia (Canada), Italy and Australia and this scheme brought significant changes (López-Casasnovas and Junoy, 2000). In Germany, the prices of drugs declined (Giuliani, 1998) and in Sweden in 1993 RP had savings (Ljungkvist *et al.*, 1997). The European experience indicates that the generic medicines industry delivers competitive prices under a RP system if demand-side policies are in place that encourages physicians, pharmacists and patients to use generic medicines (Simoens, 2008).

### Equity pricing

From the perspective of MSF, the term equity pricing means that EM should be priced in developing economies based on the principle of “equity” and the poor should pay less for, and have access to EM. Comprehensive and supportive strategies such

as, generic competition, differential pricing, adopting TRIPS safeguards, bulk procurement and, encouraging local production are required to ensure sufficient gains through implementing equity pricing (Pérez - Casas, 2001, MSF, 2005) in healthcare systems.

### Generic competition

It is important to know about the determinants of pharmaceutical pricing and their effects on prices, availability and affordability. High prices of medicines and lack of access has turned the attention of policy makers and regulatory authorities to analyze the determinants of pharmaceutical pricing strategies. It is believed, that the use of less expensive generic medicines will improve further competition within the pharmaceutical industry (Culbert *et al.*, 2007).

In the early 1990s, a number of studies suggested that generic competition affects brand prices and generic producers often capture a relatively large market share very soon after patent expiration (Grabowski *et al.*, 2002). But still the price competition is challenging, since innovative manufacturers have a monopoly on their products and can charge high product prices to recover their R&D costs. However, if the governments impose regulations to foster competition among manufacturers (Aronsson *et al.*, 2001) and set incentives for patients, pharmacists and prescribing physicians, the pharmaceutical costs can be substantially decreased.

Generic competition is a powerful tool that policymakers have to lower drug prices in a sustainable way (Porter, 2008). Lessons learned from Brazil shows, that the price of AIDS drugs fell by 82% over 5 years because of generic competition. The prices of drugs that had no generic competitor remained stable, falling only 9% over the same period. Even more dramatic results can be seen in the price of AIDS triple-therapy for developing

countries, which fell from US\$10,000 per patient per year to as low as US\$350 in one year due to generic competition (Coriat *et al.*, 2006).

We found that generics offer a simple key solution to soaring healthcare expenditures, since high medicine prices and unaffordable treatments are considered a main barrier (King and Kanavos, 2002, Hassali *et al.*, 2009). Saving by promoting and prescribing generics medicines couldn't be underestimated because of its potential effects on controlling health expenditures (Haas, 2005). For instance, in Canada the availability, prescription, dispensing and use of generic medicines approximately saved \$44-billion over the past five years. The generic prescription and use play significant role in controlling costs (Hassali *et al.*, 2009). According to Canadian Generic Pharmaceutical Association, in Canada generic prescription medicines are used to fill 66 percent of all prescriptions, which account for only 23.5 percent of the \$22.2-billion dollars spent annually on prescription drugs in Canada (Canadian Generic Pharmaceutical Association, 2013).

### Differential pricing strategy

It refers to the voluntary lowering of prices by pharmaceutical manufacturers for lower-income markets. This strategy is named "market segmentation," (Hoen, 2011), "tiered pricing (Moon *et al.*, 2011)," "preferential pricing (Goemaere *et al.*, 2002)," or "discounted pricing," (Hoen, 2001). Despite many weaknesses of differential pricing, one of the potential aspects is to increase affordability of on-patent drugs in developing economies while protecting incentives for innovation. Differential pricing, based on Ramsey pricing principles (Wedig, 1993), is the second best way of paying for the costs of pharmaceutical R&D (Danzon and Towse, 2003).

Several factors can positively influence the differential pricing strategy during its design and implementation phases. During the design phase, the system should be designed for developing, middle-income and least developed countries. The system should set transparent prices, rules, and regulations for all EM and offer the lowest possible prices, using the marginal cost of production both in public, private and NGO sectors (Sethuraman and Cole, 1999).

There are many success stories of implementing the differential pricing such as, differential pricing implemented for oral contraceptives, with medicines costing 200 times less for poor countries. Through this process millions of people got access to medicines while manufacturers were able to increase their sales (Simoens and De Coster, 2006).

### TRIPS safeguards

TRIPS is a major determinant of medicine prices. The TRIPS related monopoly by pharmaceutical industries results in increasing medicine prices. In addition, it negatively affects the manufacturing ability of developing economies in producing affordable generic substitutions and it threatens the overall health sector by monopolizing on medicines for 20 years. Further to Doha declaration, the developing economies

have a right to raise their voice and advocate against the rising drug prices by "building TRIPS-compliant safeguards" into their national medicine policies and importation laws (Love, 2001).

There are many approaches to ensure TRIPS safeguards, such as granting compulsory licenses for manufacturing or import of generic versions of branded medicines. Secondly, encouraging the generic competition among pharmaceutical industries and parallel import among traders will help decrease the medicine prices.

Finally, the governments should accelerate the introduction of more affordable generics through the use of a "Bolar provision" (Sharma *et al.*, 2009) which allows a generic producer to conduct all tests required for marketing approval in advance, so that a generic can be put on the market as soon as the patent expires (De Joncheere *et al.*, 2002).

### High Volume

The MSF under "equity pricing" emphasizes over the global procurement and distribution of medicines, which can assist in decreasing medicine prices by balancing between high demand and supply of large quantities of medicines (Gray *et al.*, 2001). The other option to ensure "equity pricing" is the bulk procurement, which makes it easier to negotiate and purchase lower prices medicines; especially UNICEF where they possess extensive experience in bulk procurement.

This can support the developing economies in addressing quality issues. Despite these mechanisms of bulk procurement, patents are a barrier to transport the generic medicines across the globe. For instance, the lowest priced antiretroviral medicines, which are generically manufactured in India, cannot be used in countries where similar products are under patent. This issue could be addressed by permitting for patent exceptions for globally purchased medicines (Vasan *et al.*, 2006).

### Encouraging local production

Improving local pharmaceutical production is one of the long-term and sustainable strategies of governments, which will directly affect the economic development of developing economies. Therefore, promoting domestic production of generic medicines is an integral part of this strategy in helping in lowering the medicine prices. For improving the local production in least-developed economies, high technology is required, and the developed economies are compelled to provide technology under TRIPS agreement. Additionally, this strategy can assist the developing economies to become regional suppliers. For instance in China, the government started to develop the domestic pharmaceutical industry and has also initiated subsidizing the public hospitals (Sun *et al.*, 2008).

### Demand side approaches

The demand-side interventional approach such as RUM and better quality information, value-based pricing and co-payments are crucial in decreasing medicine related expenditures.

## RUM

The RUM and improved communication programs assist to address the irrational drug use and control high medicine related expenditure. The irrational use of medicine is widespread and approximately half of all medicines globally are inappropriately prescribed, dispensed or sold, commonly in Eastern Mediterranean and South Asian countries (Hogerzeil, 1995, Rashidian, 2011). In China, the irrational use and utilization of medicine and prescribing expensive medicines contributed to increasing hospital drug expenditures (Meng, 2005).

### Value based pricing (VBP) of medicines

Introducing VBP can reduce medicine prices in manufacturing companies. The VBP is a process of reengineering the firm's operations to produce low-cost medicines without compromising quality, to attract value-conscious customers by analyzing how product benefits the customer in economic and emotional terms (Singh, 2014). The VBP could reduce the risk of paying high price and improve the access.

### Medicine prices and third party payment (co-payments)

Providing direct subsidies via social insurance or co-payment system can efficiently address high medicine prices and can improve access to medicines that arise due to affordability constraints. In addition to the literature review of international

approaches toward medicine prices control, we also reviewed the approaches MSF took to decrease the high mounting prices. The MSF uses the term "equity pricing" to describe policies that ensure that, from the point of view of the community and the individual, the price of a drug is fair, equitable and affordable, even for a poor population and/or the health system that serves them.

### Policy options for improving medicine affordability and availability: WHO recommended

The prices for medicines are higher, unaffordable, compounded with variable availability, in many LMICs. The low medicines availability ratio has direct correlation with poor disease control and makes the patients to go without the treatment they need (Cameron *et al.*, 2011). It has been stated by WHO, that "national policy-makers" are obliged to know thoroughly about the contributing factors toward high medicine prices and the national priorities, before launching any policy reforms for improving accessibility (Cameron, 2011). In this connection, the governments are open to consider suitable policy options, in order to reduce the medicine prices (Watal, 2000). All these policies are recommended by WHO (Table 2) having objective for closing the gaps around medicine prices and affordability by keeping patient prices closer to the manufacturers' prices as possible (Scherer, 2004).

**Table 2:** Policy options for improving medicine affordability and availability

Component of medicine policy	Specific actions to influence price, availability and/or affordability
Selection of EM	<ul style="list-style-type: none"> <li>• Formulation/updating of EML and institutional formularies</li> <li>• Development and use of Standard Treatment Guidelines</li> <li>• Development of a therapeutic substitution policy</li> </ul>
Procurement/purchasing	<ul style="list-style-type: none"> <li>• Limit to EML by international nonproprietary name (INN)</li> <li>• Base quantities on reliable estimates of actual need</li> <li>• Base on formal written procedures and explicit, predetermined criteria to award contracts (i.e. ensure transparency of the process)</li> <li>• Plan properly and monitor performance (results should be made public)</li> <li>• Base on competitive procurement from prequalified suppliers</li> <li>• Pool procurements at the national level</li> <li>• Use pharmacoeconomics or external reference pricing (international price comparisons) as a guideline for setting prices of new medicines (single-source)</li> <li>• For high-priced products, apply pressure for differential prices and consider use of TRIPS flexibilities for medicines under patent</li> </ul>
Distribution system	<ul style="list-style-type: none"> <li>• Maximize efficiency and transparency</li> <li>• Control mark-ups with regressive margins and with effective enforcement</li> </ul>
Generic competition	<ul style="list-style-type: none"> <li>• Establish an effective quality assurance capacity</li> <li>• Reduce regulatory barriers to market entry of generic equivalents (e.g. early-working, fast-tracking applications, reduce the application fee)</li> <li>• Permit and promote generic substitution</li> </ul>
Prescribing and dispensing	<ul style="list-style-type: none"> <li>• Introduce incentives to prescribe and dispense generic medicines</li> <li>• Improve health professional and public confidence in generics</li> <li>• Provide unbiased consumer medicine information</li> <li>• Strictly regulate promotion of products by pharmaceutical companies according to WHO's Ethical Criteria for Medicinal Drug Promotion and ban direct-to-consumer advertising of prescription medicines</li> <li>• Separate prescribing and dispensing functions; develop and monitor good prescribing and good dispensing practices</li> <li>• Empower patients through the publishing of prices and availability</li> <li>• Establish regular monitoring of prices and availability</li> </ul>
Financing	<ul style="list-style-type: none"> <li>• Encourage pooled and prepaid financing of medicines (e.g. through employment-based or social insurance schemes)</li> <li>• Support community-based insurance initiatives that focus on improving access to essential medicines</li> <li>• Establish a social health insurance system covering the whole population</li> <li>• Ensure that social health insurance benefits are comprehensive, using limited formularies based on cost-effective therapeutic guidelines, and that patients are not required to seek reimbursements</li> <li>• Abolish taxes and duties on essential medicines</li> <li>• Introduce minimal or no patient co-payments in the public sector or health insurance systems</li> </ul>

Adopted from: WHO, the World Medicines Situation 2011: Medicines prices, availability and affordability, 3<sup>rd</sup> Edition

### Effect of pricing policy on the cost of medicines

Many policies have been implemented with varied outputs or remained as a static document due to lack of enforcement, as a result, none of the specific policies have not been very successful and things don't seem to have improved much and medicine prices still remain as a problem as in the past (Ed Silverman, 2016). According to the draft Human Rights Council (HRC) resolution globally, for millions of people the highest attainable standard of physical and mental health remains a distant goal (SAEZ C, 2016). For example in Egypt the pricing policy change resulted in both price decreases and increases without substantive implications on affordability (Mohamed and Kreling, 2016).

The main reason is the lack of technical capacity to link price data to local policy processes, scarcity of published evidence on the effectiveness of different policies (Mendis *et al.*, 2007). Thus, the medicine laws, policies and procedures are less comprehensive, outdated and falling short in their implementation due to lack of funding, infrastructure, professional task force, corruption and communication gap.

Although medicines' availability is optimal in the private sector, however it is not accessible widely due to its high prices, even in rich countries (Henry and Lexchin, 2002). Despite improvements, treatment affordability still remains a cause of concern for low income countries. R&D cost and TRIPS agreement still act as the major contributor to the high medicine prices globally, especially in LMICs. Therefore, the R&D process to be examined, if the R&D is funding through public funding, there shouldn't be a full commercialization process. However it is required to work out ways to control the final commercialization price and do not charge a fully commercial price for a product that has been publicly developed (Ed Silverman, 2016). To that end, the governments and health-care organizations should aim at finding ways of keeping down costs without reducing the effectiveness of the health care they provide and everyone should attain the highest level of health as a global social right (Allan, 2007). In this context, multipronged policy reforms should be undertaken with rigorous enforcement by governments, for example, price regulation in one country affects entry into other countries, and may affect the strategies of domestic firms (Kyle, 2007). There will be different solutions for different systems (Ed Silverman, 2016). Thus, single policy will be less effective to combat with the convoluted pharmaceutical situation and even the response is unlikely to be sufficient (Cameron, 2011). The effective pricing policies can have positive implications on price regulation and can certainly decrease the medicine prices and ensure accessibility (Mendis, 2007, Vian, 2008).

### CONCLUSION

The results observed in the review on the impact of cost containment policies, each of the policy prescription is valid for implementation and could tackle high medicine prices. Since lack of access to medicine is a result of complex problems, particularly

price drivers such as taxes, fees, duties paid for imported medicine in addition to multiple price mark-ups. Therefore, it needs multi-layered steps directed at global, regional and national level with the involvement of economic, political, and perceptual intervention. Comprehensive response to health system strengthening in a crisis-affected fragile state demands coherent action by all national actors. The problems such as lack of professional technocrats, narrow lines of authorities, parallel healthcare providers and uncoordinated health financing mechanisms need to be addressed. Time has reached, that the governments and policy makers should lobby for access to affordable medicine in HRC's 34<sup>th</sup> session going to be held in March 2017.

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