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Pricing of and Access to Essential Medicines in Mongolia

Gereltuya Dorj (PhD)[1,2]

[1]Research Fellow, Faculty of Health Sciences, Curtin University of Technology, Perth, Western Australia;
[2]School of Pharmacy and Biomedicine, Mongolian National University of Medical Sciences, Ulaanbaatar, Mongolia

A recent United Nation (UN)'s Millennium Development Goals progress report has recognized a problem with the unaffordability and insufficient availability of essential medicines in low-income countries [1]. In spite of efforts to coordinate coherent national policies that are aligned with the global agreements, these problems have not been solved by the target date of 2015 [2]. To ensure access to essential drugs, it is critical that they are within in the financial reach of health care providers and individuals in need.

The Mongolian government is responsible to ensure that all Mongolian citizens have access to affordable health care and medicines. One way to ensure such access is by controlling the different stages of the pharmaceutical supply chain [3]. The World Health Organization (WHO) has introduced guidelines on implementing effective pharmaceutical pricing policies for low- and middle-income countries [4]. Policies include the regulation of mark-ups in the pharmaceutical supply and distribution chain; tax exemptions or reductions for pharmaceutical products; the application of cost-plus pricing formulae for pharmaceutical price setting; the use of external reference pricing; the promotion of use of generic medicines; and the use of health technology assessment [4].

A majority of drugs (95%) from the essential medicines list, developed and recommended by the WHO, have no patents attributed to them [5]. Furthermore, it is assumed that the vast majority (approximately 340) of essential off-patent medicines can be produced locally, which would be advantageous especially in developing countries [6]. Patents are not what prevents access to medicines, but rather, the real barrier is a lack of basic health care infrastructure that is required to distribute existing medicines to people. The former UN Secretary General, Kofi Annan, identified poverty and the lack of basic health care infrastructure as the two greatest barriers to the accessibility of medicines in the developing world [7].

Medicines account for 10-12% of the health spending in Mongolia, compared with 20-60% in low- and middle-income counties and 18% in countries of the Organisation for Economic Cooperation and Development (OECD) [8-10]. Consumers International and Health Action International (HAI) conducted a survey on retail prices of 16 drugs in 36 countries [11]. The most remarkable feature of the survey was the high price difference of proprietary drugs in some of the developing countries of Africa, Asia, and Latin America, compared to the prices in ten OECD countries. Similar findings can be found in Mongolia, with variations in retail prices of generic equivalents range from 0.79 for cephalexin to 55.06 for mebendazole [12]. In a recent study conducted by the WHO, the highest procurement prices of medicines were found in Mongolia and Nigeria [13].

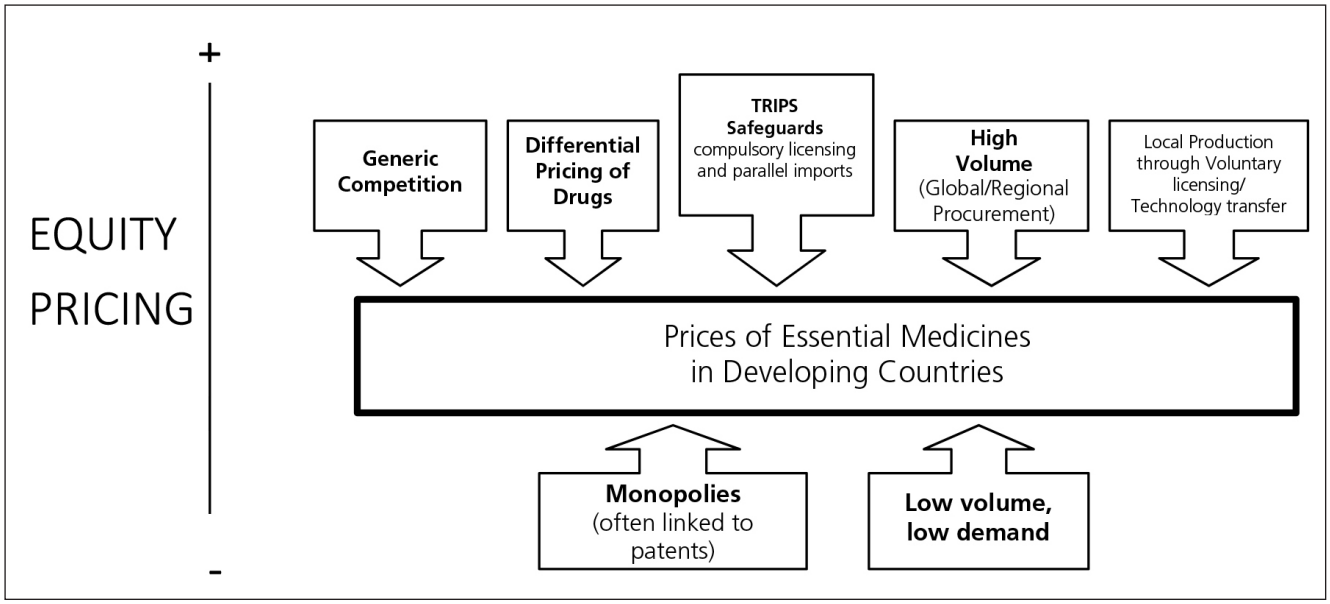

Figure 1. Strategy to implement equity pricing of essential medicines

Until 2014, there were no price control mechanisms in Mongolia specific to generic drugs, however, the latest revision of the National Drug Policy of Mongolia has indicated that the maximum price of essential medicines will be regulated by the government [3]. Therefore, the only price control mechanism in Mongolia is on reimbursable essential medicines. The access and effectiveness of this price control mechanism in Mongolia has not be evaluated due to insufficient data and the lack of transparent policy [14]. In Mongolia, registration fees do not differ between originator brands and generic equivalents, however, to encourage local production, registration fees are lower for locally produced medicines than it is for imported medicines.

It is well-known that the availability of generic products has a major influence on the price of medicines in developing markets. According to Médecins Sans Frontières (MSF), a medical aid charity organization, generic competition has lowered the price of antiretrovirals from more than US$10,000 per patient per year in 2000 to US$67 per patient per year today, which has galvanized the fight against human-immunodeficiency-virus (HIV) in countries with high HIV prevalence [15].

Another way to lower the cost of certain medicines is through voluntary licensing, a pricing mechanism used to increase the affordability for those who are poor and in need. Gilead Science, a company based in the United States, agreed to voluntarily license two hepatitis C antivirals, sofosvubir and ledipasvir, to seven Indian manufacturers [16]. As a result, the combination therapy of antivirals has been available at much lower prices in 91 developing countries, including Mongolia. Currently, a patient in Mongolia pays US$900 for a 12 week course of sofosvubir, whereas the nominal price of this medicine is US$42,017 in OECD countries, with prices ranging from US$37,729 in Japan to US$64,680 in the United States [17]. As a part of agreement, Gilead Science receives 7% of royalty on all sales [17].

As shown from experiences across many countries, no single strategy is sufficient to achieve and sustain equitable pricing. Rather, a comprehensive system of mutually supportive strategies is necessary. Possible strategies include encouraging generic competition, differential pricing of drugs, adopting Trade-Related Aspects of Intellectual Property Rights (TRIPS) safeguards into national legislation, creating high volume/high demand through global/regional procurement, and encouraging local production through voluntary licensing and technology transfer (Figure 1).

Successfully implemented pricing programs in Australia, South Korea, Thailand, Canada and United Kingdom have included evaluations of efficacy, comparative cost-effectiveness analyses of medical interventions, and published clinical guidelines [18-20].

The Mongolian Government should align with international organizations, including pharmaceutical companies, to ensure that the protection of intellectual property is not placed above public

health. International communities can invest in improving the health care capabilities in Mongolia, but more must also be done locally to reduce drug prices, such as enabling generic competition.

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