

## Pharmaceutical policy reforms to regulate drug prices in Asia Pacific Region: The case of Australia, China, India, Malaysia, New Zealand and South Korea

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## **Abstract**

Medicine price affects affordability and access to medicines directly particularly in countries where a major portion of pharmaceutical spending is through out-of-pocket payment, such as in the Asia Pacific region. We have undertaken a detailed appraisal of the pharmaceutical policy reforms to regulate drug prices in three developed (Australia, New Zealand and South Korea) and three emerging (China, India and Malaysia) economies of Asia-Pacific region. Despite continuous effort by the authorities in adopting a wide range of reformatory pharmaceutical pricing policies to ensure affordability of medicines, these policies may not be optimal where drug prices were not lowered as expected (e.g. in Korea). In contrary, considerable price reductions of various pharmaceuticals have been observed in New Zealand and India owing to the reform in pharmaceutical pricing policy. This review of pharmaceutical pricing reforms reinforces the need for constant monitoring by policymakers in the Asia-Pacific countries to regulate drug prices and to undertake reform in pharmaceutical pricing policies when necessary to ensure affordability and access to medicines.

**Keywords:** Access, affordability, Asia, Pacific, pharmaceutical, policy, pricing

## **Introduction**

Competition within the pharmaceutical market is limited due to information asymmetry and divided responsibility between the purchasing decision makers and patients who bear the cost. Therefore, revision and reform of pharmaceutical pricing policy are needed to contain the unfair pricing of medicines in view of inadequate competition. This is especially true in countries with inadequately regulated pharmaceutical systems and improper price regulation allowing pharmaceutical manufacturers to set high prices for their products benefiting from their monopolistic power and the relatively inelastic demand for medicine. Medicines' prices affect affordability and access directly particularly in health systems where a major portion of pharmaceutical spending is through out-of-pocket payment and the availability of medicines in publicly-funded healthcare facilities is relatively low.

The pharmaceutical markets in Asia-Pacific region demonstrate heterogeneity in pharmaceutical pricing mechanisms. The policymakers in the Asia-Pacific countries constantly monitor the pharmaceutical market and undertake reform in their pharmaceutical pricing policies when necessary to ensure affordability and access to medicines. We have undertaken a detailed appraisal of the pharmaceutical policy reforms to regulate drug prices in three developed (Australia, New Zealand and South Korea) and three emerging (China, India and Malaysia) economies of Asia-Pacific region.

## **Pharmaceutical pricing policy in developed economy**

### Australia

The Australian market of prescription drugs has undergone some transformation since 2001 with the entry of many generic medicines after patent protection expiry. A plethora of studies published in the following few years reported higher prices of Australian generic medicines relative to other similar countries, with prices almost reaching the corresponding originator brands [1,2]. As an example, a study aimed to compare the prices of nine medicines listed on the Pharmaceutical Benefits Scheme (PBS), in Australia, New Zealand, and the United Kingdom, revealed that all the nine medicines studied were more expensive in Australia compared with both New Zealand and the United Kingdom [1]. Moreover, a study comparing the prices (adjusted using Purchasing Power Parity ratios) of 34 medicines in Australia to those of New Zealand, that included 12 medicines with generic versions available, showed that the Australians paid higher prices for 11 generic medicines than the New Zealanders, which registered a total cost difference of more than AUD 460 million [2].

Rather than engaging in competitive discounting of drug prices to the government, the generics suppliers competed on offering low drug prices to the pharmacists. As a result, government reimbursed the pharmacists at prices higher than what is actually paid [3,4]. To rectify the loopholes, the Australian government undertook some major reforms in the administration of PBS in August 2007, with modifications of the compensation arrangements between pharmacies and pharmaceutical wholesaler as well as on the pricing of PBS-listed medicines. This pricing policy reform commanded the creation of two separate formularies for PBS medicines, namely F1 formulary and F2 formulary, as well as the introduction of price disclosure and statutory price reductions.

Second wave of the reforms was introduced by the Australian government in December 2010 with further price reductions for medicines listed on the F2 formulary and for first-time listing generic medicines [5]. Furthermore, the introduction of Expanded and Accelerated Price Disclosure policy, mandated price disclosure for every medicine listed on the F2 formulary, and reduced the cycle for price disclosure from 24 months to 18 months [5]. The cycle has been further reduced to 12 months following the implementation of Simplified Price Disclosure policy in October 2014.

While the reform has been focusing on the market of generic medicines, concerns were being raised regarding the high prices of several new medicines negotiated by the pharmaceutical industry. Therefore, managed entry agreements have been implemented to allow the access to some new medicines with specific cost-effective clinical indications, but with limited use outside of these clinical indications. Some agreements come are pricing arrangements where

price or volume discount is in place, while other agreements are performance- or outcome-based, which require achieving certain clinical outcomes for continued reimbursement. As of February 2013, at least 71 medicines had established managed entry arrangements [6]. These special pricing agreements are kept confidential to avoid price comparison [7].

### New Zealand

During the 1980s, the rise in drug prices was a major problem in New Zealand, where in some years, a growth rate as high as 20% was noted. This rise in drug prices crowded out other aspects of healthcare expenditure [8]. Pharmaceutical Management Agency (PHARMAC) was established in June 1993 to manage government's spending on medicines within the amount of available fund.

One of the PHARMAC's first task was to arrange the array of subsidised outpatient pharmaceuticals and cancer treatments into a comprehensive list, known as the Pharmaceutical Schedule. Since then, PHARMAC manages the listing (or de-listing) as well as the funding budget of pharmaceuticals on the Pharmaceutical Schedule. The decision to list (or de-list) follows a rigorous and well documented process, considering various factors including health needs, health benefit, features of the medicine, health-related costs and savings, as well as availability and suitability of existing medicines [9,10].

PHARMAC's creation encouraged price competition among pharmaceutical manufacturers to drive drug prices down [11]. Reference pricing method was a significant strategy in achieving price reductions, where the government reimbursement is fixed for all medicines within a therapeutic subgroup. This method compels the manufacturer to either match the reference price for a group of medicines or risk patients and prescribers selecting a different medicine as patients pay the additional cost if the actual price of a medicine is higher than the government reimbursement [12]. In addition, since 1997, PHARMAC has been tendering out sole supply contracts for generic medicines, for a limited period, to encourage the development of cheaper generic versions of off-patented medicines [12]. In fact, half of the total volume of reimbursed drugs is purchased by tender.

Next came innovations including price rebate and cross-product agreements (bundling) to keep drug prices low [13,14]. PHARMAC enters negotiations with pharmaceutical manufacturers where PHARMAC would receive a rebate on the initially negotiated price after a certain period from the pharmaceutical manufacturers for their scheduled pharmaceuticals, with the value kept confidential [15]. Expenditure cap is one of the PHARMAC's strategies for ensuring rebates where it acts as risk-sharing agreements to ensure that if the sales volume of a listed pharmaceutical exceeds an agreed-upon level, the pharmaceutical manufacturer is responsible for covering all or part of the additional costs [13]. With regards to cross-product

(bundling) agreements, PHARMAC would negotiate a discount on the price of one or more of the currently listed pharmaceuticals provided by the pharmaceutical manufacturer who applies for a listing of new pharmaceutical that is clinically effective but not cost-effective [9,13,16].

PHARMAC started to assume the role of operating the financial budget for inpatient pharmaceuticals within the District Health Boards (DHBs) after the introduction of the National Hospital Pharmaceutical Strategy in 2002, allowing each DHB to make its own inpatient pharmaceutical formulary decisions, and to administer its own budget for inpatient pharmaceuticals [47]. However, this change raised concerns regarding inequities in access based on where a patient lived (sometimes referred to as postcode lottery). In July 2013, PHARMAC replaced all DHB pharmaceutical formularies with a nationwide inpatient pharmaceutical formulary, named as Hospital Medicines List [47]. It contains pharmaceuticals and the conditions under which the pharmaceuticals may be prescribed for inpatient use. Although some DHBs still manage the funding of their inpatient pharmaceuticals, PHARMAC will eventually take over the responsibilities of managing the budget for all pharmaceuticals within DHB hospitals.

Considerable savings have been achieved for several medicines because of PHARMAC's reformatory efforts over the years, with statins, for instance, becoming about half the price that they were in Australia [17]. An analysis undertaken by the Canadian government also reported the price of generic drugs in New Zealand was less than a quarter of that in Canada [18]. In addition, the patented drugs were about 10% cheaper in New Zealand compared with Canada [19]. The trend of prices for fluoxetine over the years best illustrates the various strategies of PHARMAC to achieve price reductions [11]. In 1993, 20 mg of fluoxetine capsules cost PHARMAC \$1.93 per capsule. There was about 40% price reduction in fluoxetine attributed to reference pricing upon the introduction of paroxetine to the market, which brought the price down to \$1.12. The subsequent availability of a generic version of fluoxetine in 2000 produced a further 60% reduction in the price, which stood at \$0.45. Over the years, sole supply, price rebates, and reference pricing has led to a cumulative price reduction of more than 98%, where the price of fluoxetine stood at \$0.032 per capsule in 2012.

### South Korea

In South Korea, following the introduction of the National Health Insurance System in 2000 (NHIS), the prices of reimbursed drugs are being regulated. Drugs available only with prescriptions are mostly being reimbursed and, their prices are controlled by the Maximum Allowable Price (MAP) policy [20]. Nevertheless, for non-reimbursable drugs, pharmaceutical manufacturers and retail pharmacies could independently set their prices.

The MAP policy, which has come into effect along with the introduction of NHIS, sets an upper limit of remuneration or a ceiling price for pharmaceutical products that are being reimbursed. For newly introduced innovator medicines, their MAPs were determined based upon cross-country price comparison (external reference pricing), for which the average wholesale prices of the innovator medicines in seven industrialized countries, including the United Kingdom, the United States of America, Switzerland, Germany, France, Italy, and Japan, were considered as the international comparator. Nevertheless, this pricing mechanism was criticized to potentially contribute to escalating drug prices as all the seven comparator countries have larger and stronger economies than South Korea [21-23].

There were, however, some substantial changes in the pricing mechanisms followed the enactment of Pharmaceutical Expenditure Rationalization Plan (PERP) in 2006 and the Single Price System in 2012, in view of the mounting opinion pleading to drive the drug prices down to make them affordable for Korean consumers. With the Introduction of PERP, which is a comprehensive pharmaceutical regulation package, the application for drug reimbursement operates with a positive list system whereby Health Insurance Review and Assessment would compare the cost-effectiveness of the candidate innovator product with the most frequently used alternative, which could be a drug or a medical procedure, when pharmaceutical manufacturers file a listing application. During the pricing negotiation, the highest MAP for the candidate innovator product that can be accepted by NHIS for drug reimbursement is the price where Drug Reimbursement and Evaluation Committee has deemed as being cost-effective, and NHIS would negotiate further for setting lower MAP based on cross-country price comparison and the MAPs for the available listed alternatives [24]. For a newly developed candidate product without relevant comparators, negotiation for appropriate price with the applicants would be required, where the predicted utilisation and health expenditure would be taken into consideration. Nonetheless, MAP for a candidate product could be set without any form of agreement other than pricing adjustments by the Benefit Coordination Committee if the candidate product contains one or more of the essential medicines.

The drug pricing policy was being improvised further with the introduction of Single Price System in 2012, which aims to encourage market competition by taking advantage of low-cost generic medicines. The core principle of this new policy is based on internal reference pricing method, where the same MAP was set for both innovator brand and its generic versions of a particular medicine. It was envisaged that such measure would make the market competitive, as generic manufacturers would be able to freely compete in the pharmaceutical market with lower prices. With the promulgation of Single Price System, prices for the immediate off-patent innovator products would be reduced to 70% of the prices before the expiry of the patent. In addition, the Korean Linkage Price System for the pricing of generic products has been

abolished and instead, generic products would be priced at 85% of the prices of their corresponding immediate off-patent innovator products (equivalent to 59.5% of the prices before the expiry of the patent), irrespective of the order of market entry. One year after expiry of the patent, the off-patent innovator products and their generic counterparts would then be uniformly priced at 53.55% of the prices of innovator products before the expiry of the patent.

Nevertheless, when Kwon et al. examined if the aim of Single Price System to encourage market competition by setting the same MAP for both generic and innovator products was achieved. It was observed that despite a decrement in market shares of the innovator products, the decrement was only marginal, and their market shares remained high with innovator products being prescribed about 6 times more than the generic versions after the introduction of the new policy [25]. Moreover, price dispersion was narrowed rather than being broadened, indicating that the prices of generic products were not lowered as expected. The results suggest that there was no market competition, which could be due to a lack of coordination between demand- and supply-side policies as hypothesised by the authors, since demand-side measures to promote increased prescribing and dispensing of the low-cost generic products were not implemented along with supply-side price cutting policies.

## **Pharmaceutical pricing policy in emerging economy**

### China

Historically, in China, the Bureau of Pricing under the National Development and Reform Commission (NDRC), was responsible for pricing of all drugs and medical devices listed on the drug formulary for reimbursement under publicly funded medical insurance programs, at the national as well as provincial levels. There were two categories to the drug formulary, namely category A and category B. The maximum retail prices of category A drugs, which were definitive ceilings for retail pharmacies and public hospitals, were determined by the NDRC at the national level. Prices were set for each active ingredient and dosage form based both on declared costs by manufacturers multiplying by some mark-ups to account for profits as well as costs of research and development. For drugs in category B, while their guiding prices were set by NDRC at the national level, the price ceilings were determined by the governments at the provincial level, usually established through a local tendering system.

Over the years, there is a large body of evidence suggesting that price ceilings have been ineffective in containing drug prices. One study which determined the effect of four price ceilings on the antibiotic costs in twelve hospitals between 1996 and 2005 in Beijing, China reported more than a quadruple increase in the overall expenditure on antibiotics although the prices of targeted antibiotics were 47% less in 2005 than in 1996 [26]. The authors hypothesised that prescribers could evade price ceilings easily by substitution with more

expensive antibiotics or prescribing higher doses of antibiotics [26]. Similarly, in another study that considered macroeconomic data to determine the effects of price regulations, it was found that despite a small initial decrement in pharmaceutical price indicators, the regulations did not cut household spending on pharmaceuticals or the profitability of pharmaceutical firms [48]. In fact, price regulations indirectly caused an increase in the importation of more expensive foreign-manufactured medicinal products [48].

In 2015, China made a series of legislative and policy reforms to relax the administrative controls over drug prices in which the price ceiling policies have been formally abolished [27]. The reforms introduced to build a system whereby pharmaceutical prices are mainly determined as a result of orderly market competition rather than regulation by the authorities [27]. The core component of the reform is the abolishment of the classification system of drugs into category A and B and the introduction of new mechanisms of price control. With the newly announced policy, drug pricing control, formerly the primary responsibility of the NDRC, would be shared by the Ministry of Human Resources and Social Security and the National Health and Family Planning Commission [27,28]. The NDRC has introduced a reimbursement standard to function as a guide for the market prices of pharmaceuticals included in the formulary for which there is an existing market competition [27,28]. It is understood as a form of a reference price used in internal reference pricing systems [27,28]. Although NDRC's Academy of Macroeconomic Research suggests that drug quality, drug costs and winning tender prices could be incorporated into the definition of reimbursement standard, there was no conclusive guidance provided [28]. Therefore, Chinese local administrative divisions have the autonomy to employ their own methodology before the introduction of final regulations at the national level [29]. The formulary medicines with little or no market competition (i.e. in-patent drugs) are not included in reimbursement standard system. For these products, retail prices would be established by multilateral and transparent negotiation mechanism involving the pharmaceutical industry and other stakeholders [29].

### India

Pharmaceutical pricing policies have been introduced formally in India since 1963 with the promulgation of the Drugs (Display of Prices) Order of 1962 and the Drugs (Control of Prices) Order of 1963 under the Defence of India Rules, where the drug prices were frozen following the waging of war with China [49]. Thereafter, a series of price control regimes were notified through various Orders varied in the extent and the nature of control of drug prices [49].

When the Drugs (Prices Control) Order of 1966 came to effect, the government was not legitimized to reduce the prices of pharmaceuticals, although prior approval from the government was required for increasing the prices of certain drugs. The enactment of the



Drugs (Prices Control) Order of 1970 had legitimized the right for government to set the price ceilings of bulk drugs for the first time, for which the price ceilings of 18 bulk drugs were revised while the prices of other bulk drugs were frozen with no increment allowed without prior approval from the government [49]. Nevertheless, since the promulgation of Drugs (Prices Control) Order of 1979, a selective approach has been undertaken where only scheduled bulk drugs and their pharmaceutical formulations were brought under price control ambit. Drugs (Prices Control) Order of 1995 constituted a major departure from the previous policies on the selection of scheduled drugs for price control. Instead of taking the essentiality of the drug into account, it envisaged control over drug prices via the adoption of economic criteria based on market share, number of manufacturers, and turnover of drugs.

A new pharmaceutical pricing policy, announced in the year 2002, aimed to further relax the control over drug pricing with a proposal to liberalize the economic criteria for the listing of drugs under price control, including the market share and the limit of turnover of drugs [49]. The enactment of this new policy would reduce the number of scheduled drugs for price control to less than 35 [30]. Nevertheless, the new policy was challenged in the court, which eventually hindered its implementation and the government was ordered by the Supreme Court to devise relevant criteria in order to ensure the application of price control on essential, lifesaving drugs.

Taking court order into consideration, the National Pharmaceuticals Pricing Policy was introduced after much deliberations in the year 2012 [49], which proposed three key changes that constituted a radical departure from the then-existing drug price control policy: drugs come within the ambit of price control would be decided on their essentiality instead of economic criteria; bulk drugs would no longer come within the ambit of price control and; market-based pricing mechanism instead of cost-based pricing mechanism would be employed to determine and regulate the prices of finished pharmaceutical formulations. Drugs (Prices Control) Order of 2013 has been introduced to implement the 2012 National Pharmaceuticals Pricing Policy with some important provisions in line with the policy, including fixing of the ceiling price of every drug with finished pharmaceutical formulations specified in the National List of Essential Medicines based upon data obtained from market research. The ceiling price for a certain finished pharmaceutical formulation is the average of the prices of available brands with market share of at least 1%, and annual revision is allowed based on the variations in the Wholesale Price Index [31]. In addition, approval by the government is needed for the pricing of innovator drugs, new strengths of existing drugs, and combinations of existing drugs, considering the rational basis of experts' recommendations. Although the marketed non-scheduled finished pharmaceutical products would not come within the ambit of such price control mechanism, the government, through National Pharmaceutical Pricing Authority,

acquire the rights to revise the ceiling or retail price of any pharmaceutical formulation when extraordinary circumstances arise.

Since the introduction of Drugs (Prices Control) Order of 2013, prices for many drugs have declined dramatically, with price reductions of 84.2% for ofloxacin 200 mg tablets, 65.8% for omeprazole 20 mg capsules, 56.5% for azithromycin 500 mg tablets, 47.6% for amlodipine 2.5 mg tablets, 36% for atorvastatin 10 mg tablets, and 21.1% for sodium valproate 500 mg tablets [31]. In addition, the ceiling prices of over one hundred of finished pharmaceutical formulations of drugs not included in National List of Essential Medicines or the other strengths of drugs specified in National List of Essential Medicines, were revised by the National Pharmaceutical Pricing Authority of India in July 2014. The revision, covered 50 cardiovascular and anti-diabetic medicines, upon observing the hiking of prices for drugs not included in National List of Essential Medicines by more than 25% of the simple average [32].

### Malaysia

Ministry of Health of Malaysia, serves as the largest healthcare service provider within the Malaysian public healthcare sector, controls the medicines within the public healthcare sector at prices lower than those within the private healthcare sector by formulating and administering the Ministry of Health Medicines Formulary since 1983. The formulary includes every pharmaceutical formulation approved by Drug List Review Panel to be reimbursed by the government and made available for the healthcare facilities within public healthcare sector [33].

The private healthcare sector practices an open market economy concept and a price deregulation system where the medicine prices are wholly dependent on the prevailing market forces without an external control (i.e. pharmaceutical-free market) [34]. Over the years, owing to free pricing policy, escalation of drug prices has been observed in Malaysia within the published literature, Malaysia has been known as a “high price island” for pharmaceutical prices. A study conducted by Babar et al. between the year 2004 and 2005 reported that the generic brand and innovator brand medicines were on average priced 6 times and 16 times higher, respectively, than the International Reference Prices (IRP) in the community pharmacies [34]. In line with what has been observed earlier, in 2012, Hassali et al. who compared the mean retail prices of medicines in the state of Penang, Malaysia to the corresponding prices in Australia reported that the prices were 30.3% to 148.2 % higher in Malaysia [35].

In view of the observed high drug prices, the Pharmaceutical Service Division of Ministry of Health has undertaken few initiatives. The Medicine Price Unit has been set up by the Pharmaceutical Service Division tasked to monitor the trends of medicine prices in Malaysia,

and the unit operates in accordance with the concept outlined in Malaysian National Medicines Policy by Malaysian Government to “ensure equitable access and rational use of safe, effective and affordable essential medicines of good quality” [36,43]. A national database on the information of medicine prices has subsequently been developed by Medicine Price Unit to enhance the implementation of Malaysian National Medicines Policy with regards to containment of medicine price, ensuring accessibility and affordability of medicines, and provision of actual drug pricing scenario. In addition, Pharmaceutical Service Division directly involved in the monitoring of mark-ups of medicines to check the rising medicine prices [34]. Furthermore, guidelines on "Good Pharmaceutical Trade Practice (GPTP)" have been issued by the Pharmaceutical Service Division although without mandatory effect, which aim to encourage fair trade practices among different players in the private healthcare sector, namely private hospitals, community pharmacies, and general practitioner's clinics [43]. It is detailed within the GPTP that all pharmaceutical distribution channels in the private healthcare sector should be offered similar incentive schemes for the purchased pharmaceuticals [37]. Nevertheless, GPTP received opposition from some pharmaceutical industry stakeholders who would like to maintain the existing free market status [37].

## **Discussion**

We reviewed the reform in pharmaceutical pricing policy in three developed (Australia, New Zealand and South Korea) and three emerging (China, India and Malaysia) economies of Asia-Pacific region. It is worth noting that considerable price reductions of various pharmaceuticals have been observed in New Zealand owing to the pharmaceutical policy reforms. PHARMAC, which acts as a monopsony pharmaceutical purchaser in New Zealand, demonstrated that it is possible to manage drug spending within a capped public budget while improving access to subsidised medicines. As mentioned, PHARMAC sets national health priorities and contracts on behalf of all district health boards, giving it substantial bargaining power in price negotiations with pharmaceutical companies [9]. In fact, among the developed countries reviewed, New Zealand is the only country undertaking competitive tendering to obtain lower drug prices, while the others are utilising statutory legal processes to reduce the prices of pharmaceuticals. Nevertheless, it remains a concern that some of the pricing policies adopted by PHARMAC such as grouping patented medicines with generics within therapeutic subgroups discourages innovation [9]. Critics also argue that the reform in pharmaceutical pricing policies is at the expense of pharmaceutical research and investment in New Zealand where the government is more concerned with the efficiency with which its health budget is utilised than the economic performance of its pharmaceutical industry [9].

While New Zealand is able to achieve considerable savings owing to pricing reforms, the same is not observed in Australia. Australian drug prices remain high albeit the introduction of several pharmaceutical policy reforms. Indeed, drug prices in Australia was 3.6 times higher than those observed in New Zealand according to a recent report [38]. While the price disclosure policy which was introduced in Australia in a bid to cut the prices of generic drugs has worked, it has not gone far enough or fast enough to achieve considerable savings to the government [38]. It has been proposed that the price disclosure policy should be supplemented by a more effective policy of benchmarking Australian drug prices to the prices paid by comparable countries especially those of New Zealand [38]. A study revealed that Australia could have saved more than AUD 1.2 billion over the past four years had international benchmarking been in operation [38].

Despite that, credits must be given to the Australian government for the implementation of managed entry agreements to reimburse and subsequently allow wider patient access to new medicines which are frequently costly as detailed in the previous section. Indeed, Australia has the most experience in the arrangement of patient access schemes within Asia Pacific region [39]. It is possible that these risk-sharing agreements lead to better reimbursement of new medicines in Australia compared to New Zealand, where a study benchmarking Australia's access to new molecular entities saw that the new molecular entities reimbursed in Australia was more than double of those in New Zealand [40].

There is still much work to be done by the South Korean authorities despite constant revision of pricing policy. The Korean NHIS fails to achieve the potential savings from the availability of low cost medicines with the promulgation of Single Price System. As mentioned beforehand, reform in supply-side pricing policy should be complemented with demand-side measures to promote prescribing and dispensing of the lowest-priced generics. The reference pricing method adopted by PHARMAC can be considered in South Korea in which patients would be forced to pay out-of-pocket for prices higher than government reimbursement, thereby promoting the utilisation of lowest-priced generics. Other possible demand-side measures include mandatory substitution with the lowest cost generic equivalent or providing both prescribers and pharmacists with substitution targets.

In China, as described above, the authorities have been working to transition from centralised drug price regulation system and to a more indirect, market-driven drug pricing system. Nevertheless, several components of the new drug pricing reform, especially the reimbursement standard remain unspecified, although it is likely to involve internal reference pricing policies as adopted in the Organisation for Economic Co-operation and Development (OECD) countries [41]. The implementation of internal reference pricing policies has raised

some concerns as it promotes the use of cheap and low-quality drugs since a reliable quality control system is yet to be established. In addition, some elements have even been criticised by some as rather confusing since they seem not well-balanced, for instance, the introduction of the reimbursement standard while maintaining the local tendering system [39].

India is renowned for its strict price controls, especially those of essential medicines. Hard-line position and a non-restrictive attitude towards the development of generic drugs for the domestic market – sometimes before the expiry of patent protection period – has transformed India's generics industry into one of the world's foremost providers of low-cost medicines. Nevertheless, these policies have, to a certain extent, eroded the incentive of big pharmaceutical companies and international trade partners to invest in the Indian pharmaceutical market. It seems necessary to scrutinize the prices via administrative fiat currently since the majority of prescription drug costs in India are paid out-of-pocket, leading many into a medical poverty trap by the weight of healthcare costs. However, the Indian authorities should seek to transform the market into one where drug prices are kept low by competition among pharmaceutical manufacturers in the future; given that the vast majority of drugs in India have sufficient volumes or market shares and are facing intense competition. In addition, there has been criticism that the market-based formula employed currently to regulate the prices of drugs in India appears to be making the drugs more expensive compared to cost-based pricing method [42].

Malaysia has a relatively weak pharmaceutical system among the countries reviewed, whereby pharmaceutical manufacturers could easily seize upon the relatively inelastic demand and their monopolistic power to set drug prices at high levels. The huge differences between local and international reference prices in the different sectors and between patented medicines and generics suggest that prices can be brought down significantly [34,35]. Although few initiatives have been undertaken by the Pharmaceutical Service Division to tackle price hike as detailed previously, these cannot be considered as true reformative measures since they are without mandatory effects. The country should first empower Pharmaceutical Service Division or other relevant authorities to enforce all the proposed price control policies, especially on the regulation of distribution chain mark-ups and retail chain mark-ups and fees (community pharmacies, private hospitals, community pharmacies, and general practitioner's clinics), as they are always deemed as the contributor to the astronomical drug prices [43].

One of the common themes surrounding pharmaceutical pricing policies among emerging economies in Asia Pacific region, including the three countries we have reviewed (China, India, Malaysia), is the absence of a formal and rigorous health technology assessment (HTA)

program to inform the decision-making process about reimbursement of health technologies [44]. In contrast, HTA has found a firm footing in developed countries throughout the world, with variations in HTA and reimbursement processes among countries. The HTA system among all the developed economies in Asia Pacific region that we have reviewed (Australia, New Zealand, South Korea) is based on ex-ante cost effectiveness evaluation [45]. Available literature has highlighted that HTA, or a combination of tools including HTA, can have a profound influence on pharmaceutical prices in negotiations and pharmaceutical budget expenditure, as evidenced in New Zealand where PHARMAC has made significant progress to enhance the value of the government's expenditure on pharmaceuticals with a variety of tools that include HTA [46].

It is recommended that the next wave of pricing reforms among developing economies in Asia Pacific region encompasses the implementation of formal HTA programs particularly in countries where efficient allocation of limited health resources is needed. Besides pharmaceutical policy reforms, budget organisation, historical and economic factors should also be explored as these factors can influence drug prices or pricing mechanisms.

### **Conflict of interest**

None

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