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REVIEW ARTICLE

How the West Controls Pharmaceutical Prices: Lessons for Malaysia

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ABSTRAK

Harga ubatan di Malaysia telah naik mendadak sejak beberapa tahun lalu. Pembuat polisi di Malaysia boleh belajar dari negara-negara Barat tentang cara untuk mengawal kenaikan perbelanjaan farmaseutikal. Kami melakukan satu kajian untuk menilai strategi yang dilaksanakan di negara-negara Barat bagi mengawal harga ubatan dan membandingkannya dengan strategi di Malaysia. Kajian ini mendapati bahawa negara-negara Eropah mengamalkan pasaran terkawal bagi industri farmaseutikal. Melalui pasaran terkawal ini, harga ubatan ditentukan oleh harga rujukan luar. Harga ubatan ditentukan berdasarkan beberapa panduan berbanding penilaian secara rawak. Selain itu, penilaian teknologi kesihatan di Eropah menggunakan sistem penilaian bagi mengkategorikan manfaat tambahan ubat-ubatan. Sistem penilaian ini akan memberi lebih maklumat dalam perundingan antara kerajaan dan syarikat farmaseutikal. Tambahan pula, kajian keberkesanan kos diambil kira dalam membuat keputusan bagi memastikan sumber kesihatan yang terhad digunakan secara optimum. Sistem perolehan terkumpul digunakan untuk memanfaatkan harga yang lebih murah dari jumlah yang banyak. Langkah-langkah ini dapat membantu Malaysia memastikan perbelanjaan farmaseutikal kekal lestari dan rakyat Malaysia dapat terus memperoleh sistem kesihatan yang berkualiti tinggi dan berpatutan pada masa akan datang.

Kata kunci: harga ubatan, liputan kesihatan sejagat, polisi kesihatan

ABSTRACT

Drug price in Malaysia has increased substantially over the years. Malaysian policymakers may learn from the Western countries on how to control pharmaceutical spending. We conducted a review to assess the pharmaceutical strategies adopted in Western countries to curb pharmaceutical pricing and compared it with the

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current Malaysian system. The study found that the European countries adopted a regulated pharmaceutical market. In this regulated market, the price of the drugs will be determined using external reference pricing. The reimbursement and pricing of the drugs are also based on a set of guidelines rather than arbitrary nature. Additionally, the health technology assessment in the European countries utilised rating systems to categorise the added therapeutic benefit of the drugs. This rating system will add more information for price negotiation between the government and pharmaceutical manufacturers. Furthermore, cost-effectiveness analysis is also being incorporated into the decision-making process to ascertain the optimal use of scarce health resources. On top of that, pooled procurement system has been established in order to benefit from the higher volume purchasing. These measures may help Malaysia to ensure that the pharmaceutical spending remain sustainable and that Malaysians, will continue to have access toward a high-quality and affordable healthcare in the future.

Keywords: drug industry, health equity, health policy, health services, pharmaceutical policy

INTRODUCTION

The healthcare system in Malaysia, consist of two sectors, the public and the private sectors. The public sector, is controlled by Ministry of Health (MOH), and is mainly financed through general taxation. Whereas the private sector, are funded by commercial health insurance, out-of-pocket (OOP) payments by consumers, and nonprofit and private institutions (Malaysia Competition Commission 2017). Malaysia is an upper-middle income country with a world-class healthcare system. However, the cost of drug prices in Malaysia has been increasing substantially over the years. Drug prices in Malaysia in the private sector is unregulated and is left entirely to market forces. Hence, the manufacturer may hike the price at will, as long as the market can bear it.

The pharmaceutical industry in Malaysia rose at an annualised rate of 8.3% from RM3.4 billion in 2006 to RM8.6 billion in 2016, owing to higher wages, changing demographics, and an increase in non-communicable diseases. Between 2006 and 2016, spending on prescription pharmaceuticals increased by almost 75%, while spending on over-the-counter (OTC) drugs decreased by 21% (Malaysia Competition Commission 2017).

In 2017, MOH spent the most on health care, accounting for 43% of total expenditures, followed by OOP spending at 38%, and private insurance at 7% (Figure 1). From 1997 to 2017, OOP spending accounted for between 29 and 38% of total health spending (Ministry of Health Malaysia 2019). According to the World Health Organisation (WHO), OOP of 30 to

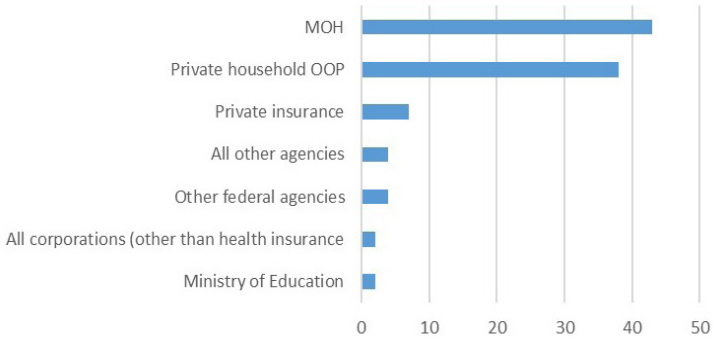

Figure 1: Total Expenditure on Health by Sources of Financing 2017. (Adopted from Ministry of Health Malaysia, 2019)

40% of total spending indicates that people are not adequately covered. In practice, an OOP of 15-20% of overall health expenditures greatly decreases a country's financial disaster (World Health Organisation 2017). From 1997 to 2017, OOP remained the largest source of private sector financing in Malaysia, accounting for roughly 77% of total financing. Furthermore, between 1997 and 2017, pharmaceutical spending surged by almost ninefold from RM325 million in 1997 to RM2.9 billion in 2017. In 1997, pharmaceutical spending accounted for 10% of OOP spending and increased to 14.94% in 2015 before decreasing to 13.55% in 2017 (Ministry of Health Malaysia, 2019). Therefore, this article draws lessons from several Western countries on how to keep the drug price sustainable.

MATERIALS & METHODS

A systematic literature review was conducted to address the objective of the study. The review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.

Search Strategy

We examined for studies that describe pharmaceutical policies and strategies in United States, United Kingdom, Germany, France and Canada (Figure 2). We identified the relevant literatures from the scientific databases which included PubMed, Cochrane Library and ScienceDirect for English-language peer reviewed article, from 2016 to 2021. Keywords such as "drug price", "pharmaceutical pricing", "drug reimbursement", "health technology assessment", and related queries were used. Studies that evaluate the pharmaceutical pricing process and strategies in these three countries were included in this review. Studies were excluded if they were not conducted in these countries. Other excluded studies were secondary research articles such as systematic reviews, economic analysis, reimbursement system, posters and abstracts without full text article.

The findings were imported into Mendeley and duplicates were deleted.

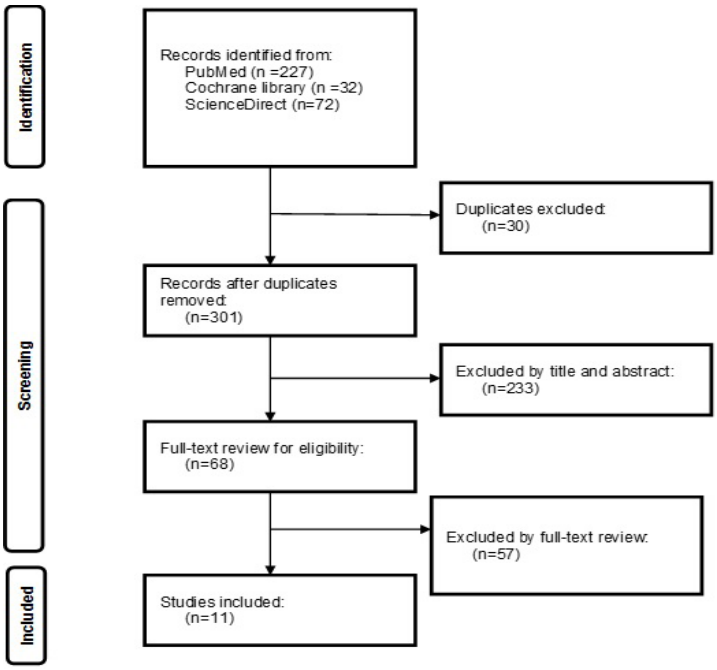

Figure 2: Search strategy

Following that, the data was uploaded to Rayyan (Ouzzani et al. 2016) for title and abstract screening. 20 studies were selected in the final review.

RESULTS AND DISCUSSIONS

After full-text screening,11 studies were included. Table 1 shows the overview of the included studies. Seven themes were selected, namely free market ideology, cost analysis, rating system, arbitration board, reference pricing and purchasing committee (Table 2).

In Malaysia, three distinct drug procurement procedures are used i.e. i) a national concession arrangement with a single designated supplier; ii) national tenders; and iii) direct procurement by healthcare facilities. Pharmaniaga Logistics Sdn Bhd presently has the national concession deal, which allows it to deliver medications to public institutions at a price agreed by the MOH. In the second method, medications with an annual purchase value greater than MYR500,000 shall be procured via tenders conducted by the Procurement Division. The third procedure enables health institutions to acquire medicines directly from suppliers if the purchase amount is between MYR50,000 and MYR500,000 (Pharmaceutical Services Division 2017).

MOH publishes the Consumer Price Guide (CPG) on its website in an effort to control prices in the private sector. The project began in 2011 when the MOH encouraged pharmaceutical businesses to self-disclose their wholesale and recommended retail prices (RRPs) to the Pharmaceutical Service Division (PSD). The CPG gives

Table 1: Overview of the included studies

	Year	Countries	Strategies
Gaffney & Lexchin	2018	United States Canada	Drug price negotiation policies: -Government must negotiate drug prices with the drug firms -If the patent holder refuse to offer reasonable prices, license must be given to generic manufacturer -If negotiation fails, non-profit drug production must be initiated -New government division is needed to produced non-patented drugs
Fischer et al. 2016	2016	Germany United Kingdom Australia	Comparison of health benefit assessment process in terms of: -Final choice should include comparative effectiveness into account -Cost effectiveness is taken into account while making a final choice -Process of evaluation/appraisal -Criteria for selecting appraisers
Dintsios et al. 2019	2019	Germany	Comparison of early benefit assessment between HTA body and decision-maker
Ludwig & Dintsios 2016	2016	Germany	Arbitration board algorithmic approach: -Number of prescriptions -Contract period -Redemption of manufacturers' discount -Application of statutory discount
Gandjour et al. 2020	2020	Germany	Predictors of negotiated prices for new drugs: -Extent of added benefit -Treatment cost of new medicine and its comparators -Target population -Adverse events' frequency
Worm & Dintsios 2020	2020	Germany	Factors that affect orphan drug prices: -Therapeutic area -Target population -Comparators price -Price in other European countries
Berdud et al. 2020	2020	United Kingdom	A framework for orphan drug pricing based in the idea that rates of return for investments in developing orphan drugs should not be greater than the industry average.
Grimm et al. 2017	2017	United Kingdom	Development of HTA risk analysis chart: -Payer uncertainty burden -Payer strategy burden
Woods et al. 2021	2021	United Kingdom	Estimating the shares of the value of branded pharmaceuticals accruing to manufacturers and to patients served by health systems -Total potential net health effect generated by new branded medicine -Realised net health effect -Health forgone due to payment to manufacturer
Armoiry et al. 2019	2019	United Kingdom France	Comparison of HTA process in United Kingdom and France
Berdud et al. 2020	2020	United Kingdom	Establishing a reasonable price for an orphan drug

Table 2: Strategies employed in pharmaceutical pricing

		United States	United Kingdom	Germany	Malaysia
Strategy	Free market	X			X
	Cost analysis	X	X	X	X
	Rating system			X	
	Arbitration board			X	
	External Reference Pricing (ERP)		X	X	
	Central purchasing committee	X	X	X	

market pricing recommendations to assist customers in making informed purchasing decisions. In the CPG, only RRP was published. The PSD utilised the disclosed wholesale prices solely for monitoring purposes and did not make them public. PSD also conducted the Medicine Price Monitoring Survey (MPMS), which collected data on medication prices from institutional counters, invoices, or both. The MPMS assessed the costs of widely used medications for acute and chronic disorders (25 core and 32 supplementary drugs) as reported by the World Health Organisation (WHO) (Pharmaceutical Services Division 2012).

Free Market

The free market is an economic system based on supply and demand with little or no government control (Symanska 2019). Proponents of unregulated drug price in Malaysia argued that it is best to let market force to determine the price of the drug. Competition between drug companies and manufacturers will let the price to be optimised, in tandem with the supply and demand. The biggest example for free market in pharmaceutical industry is United States (US). The US does not have any regulation or framework to control the drug price. As a result, drug price in US is higher than other OECD countries (Mulcahy et al. 2021). In 2015, Martin Shkreli rose to notoriety when his company, Turing Pharmaceuticals bought a cheap generic drug called Daraprim (Pyrimethamine) and increased the price from USD13.50 to USD750 overnight. Shkreli was sentenced to seven years' prison term for two counts of securities fraud, unrelated to Daraprim. Meanwhile the USD750 price for Daraprim remain in effect (Pollack 2015). This is not an isolated case. There have been several examples of similar outrageous price gouging. Rodelis Theraupetic, acquired a tuberculosis drug called cycloserine, and promptly increases the price from USD500 to USD108000 (Brunker 2015). Doxycycline price rose from USD20 to USD1849 between October 2013 and May 2014 according to lawmakers (Pollack 2015).

Proponents of regulated market argued that pharmaceutical market is not identical to normal market. In

normal market, the users have the option to choose other alternative if a product does not suit to their interests. However, in pharmaceutical market, the users cannot simply switch to other drugs if the drug does not align to their interest. The patient will have to pay for the drug no matter how expensive it is. The demand for the drug is insensitive to the cost, which is different from the normal market (Marcelle Arak 2017). In the pharmaceutical market, the users also do not choose the drugs. The drugs were chosen by the physician who prescribes them (Mwachofi & Al-Assaf 2011). In addition, physicians may also be unaware of the differences in the drug prices and prescribe an expensive drug although a cheaper alternative is available (Schutte et al. 2017). In some countries where prescription and dispensing is not separated, this add to further complexity as the physician may have financial interest in prescribing certain drugs (Goldacre et al. 2019). Pharmaceutical market in some countries is also intertwined with various schemes, insurance fund and limitation which reduce the ability of the users to choose the drugs.

Meanwhile, those who support the free market argue that the reason drug price is high is that, the pharmaceutical market is not free in the first place, mainly due to over-regulation from the government (Coburn 2018). In a free market, the sellers cannot increase price without receiving reaction from the buyers. The price signal and the competition between the sellers will help drive down the price and improve healthcare quality (Kerpen 2019). However, as the pharmaceutical sector is highly regulated, the competition between the sellers is stifled. They also argued that the existence of extensive regulatory agencies has greatly increased the cost of bringing the drugs into the market, and these costs need to be absorbed by the users (Rich 2020). The regulation which incentivise the users to adopt health insurance has also been criticised as it reduces users' option to select the drugs or healthcare plans according to their needs (Schulman & Dabora 2018).

The reality on the ground shows that US has one of the most expensive pharmaceutical market in the world. When we compared this to other countries with some form of price regulation, these countries have substantially lower drug price. Therefore, a regulated pharmaceutical pricing system is needed. However, Malaysia also should encourage competition as much as possible. Any regulation that may reduce competition should be removed. Bureaucratic procedures that may slow down the application process should be improved and revamped. Transparency in the private sector is much needed as it would encourage better competition among the industry players, hence drive down the price for the consumers (Morgan et al. 2020). Malaysia should adopt a balanced mix of free market and regulated market in order to ensure that Malaysian will continue to have access to an affordable and high-quality healthcare system.

Health Technology Assessment

In Malaysia, health technology assessment (HTA) is done by the Malaysia Health Technology Assessment Section (MaHTAS) which is responsible for the assessment of cost and safety of the drugs, medical devices and technologies. Meanwhile, the Formulary Management Branch of Pharmacy Practice & Development Division (PPDD), is responsible in overseeing the incorporation of the drugs into the Ministry of Health Medicine Formulary (MOHMF) (Roza et al. 2019). The MOH has published two pharmacoeconomic guidelines since 2012 describing the requirements of pharmacoeconomic studies needed to be fulfilled by pharmaceutical companies when submitting new drug application. The guideline generally follows The Professional Society for Health Economics and Outcomes Research (ISPOR) recommendation. However, cost-effectiveness analysis (CEA) is currently not mandatory to be submitted during new drug application. Only budget impact analysis (BIA) is mandatory. The goal of CEA was to ascertain the optimal use of scarce health resources. This was accomplished by aggregating the costs of health-care treatments with varying outcomes into a single measurement unit, i.e. the incremental cost-effectiveness ratio (ICER), which was then compared to a threshold value of willingness-to-pay (WTP) in a particular country. Meanwhile, BIA evaluates the intervention's financial impact from the payer's perspective using a set of assumptions. The CEA and BIA results may differ, since the former may demonstrate if an intervention is cost-effective from a payer's viewpoint based on the country's WTP. By integrating both methodologies, policymakers may more effectively decide on incorporating only efficient programmes in the health system. (Yagudina et al. 2017). In United Kingdom (UK), The National Institute for Health and Care Excellence (NICE) is responsible in evaluating the safety and cost-effectiveness of the drugs, new technologies and procedures. In UK, CEA is mandatory and served as an important factor for reimbursement decision (Serra-Sastre et al. 2021). Meanwhile in Germany, CEA is not required as it is deemed to violate the citizens constitutional right to health as guaranteed by the German Basic Law (Grundgesetz, GG). The differences of any drugs above the CEA threshold will need to be paid by the citizens (Caro et al. 2010). In Germany, CEA served mainly as the guidance to determine the amount of rebates or discounts provided by the insurance fund, which is contrary to UK in which CEA was used to determine whether the drug should be reimbursed or not. In Germany, The German Institute for Quality and Efficiency in Health Care (IQWIG) plays a similar role as NICE in UK where they evaluate safety and pharmacoeconomic analysis on the drugs, medical devices and procedures (Dintsios et al. 2019). Under The Act on the Reform of the Market for Medical Products (Arzneimittelmarkt-Neuordnungsgesetz, AMNOG) legislation, the manufacturer is free to set up the drug price for a maximum of 12 months. This price is fully reimbursed by the National Association

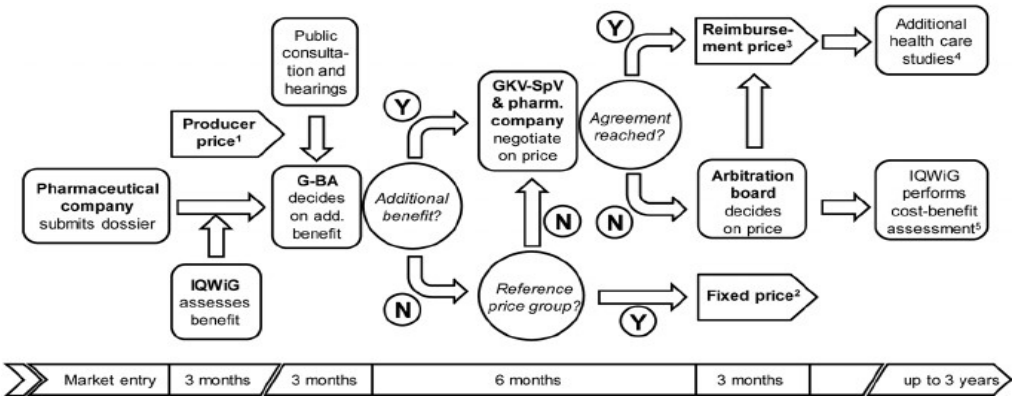

Figure 3: Early benefit assessment in Germany. Adopted from (Ivandic 2014)

of Statutory Health Insurance Funds (Spitzenverband Bund der Krankenkassen, GKV-SV). At the time of listing, the manufacturer need to submit a benefit dossier to the Federal Joint Committee (Gemeinsamer Bundesausschuss, GBA) which will commission IQWIG to conduct a benefit assessment analysis (Figure 3). This analysis only includes BIA while the CEA is optional. After benefit assessment is completed, the GBA will publish their final report. If the drug was found to have no additional benefit, the drug price will be allocated to a reference pricing group. If the drug has additional benefit, an arbitration board will be set up in order to negotiate the price. At this point, CEA will play a role in order to negotiate the price (Lauenroth et al. 2020).

Rating System

Canada, Germany and France have a rating system to determine the therapeutic benefit for the drugs; the Commission de Transparence (Transparency Commission) in France, the Patented Medicine Prices Review Board (PMPRB) in Canada, and the GBA in Germany. This rating system will guide the pricing and reimbursement decision. The German system categorise the clinical benefit into 6 categories: major, considerable, minor, non-quantifiable benefit, none, and less. In France, the French National Authority for Health (Haute Autorité de Santé, or HAS) is a HTA agency which conduct similar activities such as NICE in UK and MaHTAS in Malaysia. The Transparency Commission (TC) under HAS will assess the new products dossier to evaluate its actual medical benefit (service médical rendu or SMR). The purpose of SMR is to determine whether the drugs should be reimbursed or not. There are 4 categories of SMR: 'Insufficient medical benefit' (not recommended for reimbursement); 'Low medical benefit'; 'Moderate medical benefit'; and 'Substantial medical benefit'). The SMR rating considers several criteria such as the severity of the disease, safety of the medicine and the impact of the drugs on public health. These categories will determine the reimbursement rate eligible for the

Table 3: Reimbursement rate

Category	Reimbursement rate
Important	65%
Moderate	30%
Mild	15%
Insufficient	Not included

drugs (Table 3).

If the drug was recommended to be reimbursed, the improvement of medical benefit (amélioration du service médical rendu, or ASMR) rating will be assigned. The ASMR rating determines the added therapeutic benefit offered by a drug relative to the current comparators or treatments. There are 5 categories of ASMR i.e. major, important, moderate, minor, and none (Table 4). This rating will be used by The Comité Economique des Produits de Santé (CEPS) to negotiate the price with the manufacturers. If a medicine gets an ASMR V rating, it can only be listed if its prices are lower than those of the comparative drugs. For drugs with ASMR IV, it depends on the target population. The price can be higher if the drug offers better result in specific population. For drugs with ASMR I, II and III, these drugs will have faster access with price notification instead of negotiations – as long as pricing is consistent with European counterparts (Haute Autorité de Santé 2014).

Meanwhile, Canada has 4 categories i.e. breakthrough, substantial, moderate, and slight/none (DiStefano et al. 2021). However, Malaysia does not have similar measure or agency to do that. Therefore, it is hard for the government to negotiate the price as they do not have a benchmark to start with. The rating system will also help Malaysia to assess whether the expenditure for a certain drug is appropriate with its additional benefit. If a drug does not provide sufficient benefit and yet, the expenditure for that drug keep increasing, the government will have the information to regulate the usage of the drug. In addition, Malaysia also does not have a specific guideline or criteria to determine how much a drug should be subsidised or reimbursed as in France. Hence the manufacturer will able to decide and demand a higher price, especially for patented drugs. The rating system will help the government to determine the price based on principled form rather than arbitrary nature. Malaysia should adopt similar rating system as this will help ensure that the pricing will be fair and align with the benefits incentivising the manufacturers to develop better drugs.

Table 4: Level of ASMR in France

Level of ASMR	Criteria
I	Major therapeutic advancement
II	Important advancement in terms of therapeutic efficacy and/or adverse effect reduction
III	Moderate advancement in terms of therapeutic efficacy and/or adverse effect reduction
IV	Minor advancement in terms of therapeutic efficacy and/or reducing side effects
V	No therapeutic progress over existing options

Arbitration Board

In Malaysia, the drug formulary consists of all heavily subsidised drugs approved by the MOH Drug List Review Panel. The drugs listed here will be available in all MOH facilities. The review panel is chaired by the Director General (DG) of Health, and includes the Deputy DG of medical services, the Director of Pharmaceutical Services, eight public-sector consultants, and three public-sector pharmacists (Hassali et al. 2014). The price for the drugs in the formulary will remain constant for at least 1 year, and any subsequent increments, must be justified (Hassali et al. 2014).

In Germany, the drug price which shows additional benefits, will be negotiated between the manufacturers and the GKV-SV. This period of negotiation is confidential and is not open to the public. The negotiations will be held within 6 months of GBA resolution and if a conclusion is reached, the price will be valid from the second year onwards. If no conclusion is reached on the price, an arbitration board will be set up. This board is made up of an impartial Chairman and two other neutral members, as well as two members selected by both parties to the discussions (the GKV-SV and the pharmaceutical company). Patient organisation and the Federal Ministry of Health (BMG) may attend this meeting and the decision on the drug price will be reached through a simple majority vote. The price will be valid until a new agreement is negotiated (Ludwig & Dintsios 2016).

The involvement of patient organisation in the arbitration process is a unique thing as this will lead to more transparency. The final negotiated price will also be published. Therefore, Malaysia can follow similar example. The price negotiation between MOH and pharmaceutical companies must involve patient organisations as they are directly impacted by the result of the negotiation. MOH also need the recommendations and suggestions from these organisations in order to determine a fair price for the drugs. The final negotiated price must also be made transparent. A transparent pricing system, will lead to more competition and thus, driving down the price.

External Reference Pricing (ERP)

External Reference Pricing is an approach where a country takes the price from other country as their reference to set the price in their own country. The country that applies ERP usually choose a country to be referenced based on several criteria such as the similarity between socioeconomic status, size of gross domestic product (GDP) and also the countries proximity (Kanavos et al. 2020). This method has been adopted by many European countries (Rémuzat et al. 2015). External Reference Pricing appeals to the policymakers due to their simplicity and flexibility. Many low- and middle income countries have also begin experimenting with this approach including Malaysia.

MOH has proposed for ERP adoption in 2019. Our research found that ERP has a better possibility of being adopted due to substantial political backing from both the administration

and the opposition. External Reference Pricing was also well-received by the general public and consumer advocacy groups (Ashraf & Ong 2021). One concern for ERP implementation is the delayed entry of the drugs. This happened because pharmaceutical companies will then prioritise countries that have higher price level. The companies avoid introducing drugs to lower income countries for fear that the price in these countries will be referenced by other higher income countries, and therefore reduced their profit. To mitigate this issue, Malaysia can learn from Germany whereby the drug manufacturers were allowed to set their own price for the maximum of 12 months while benefit assessment is being conducted. By following this example, MOH can obtain a real-world evidence on the safety and efficacy of the drug in a Malaysian setting. This evidence can be used to negotiate the price in the formulary.

Central Purchasing Committee

Pooled drug procurement is a system whereby a group of institutions or countries consolidate their purchases. This system is useful to reduce the price of the medicine as they can leverage the economies of scale to reduce drug prices.

Since the 1980s, the Eastern Caribbean Drug Service (ECDS), which comprises nine small island nations (Huff-Rouselle & Burnett 1996), the Gulf Cooperation Council group-purchasing programme (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates), and the Pan American Health Organisation (PAHO) Strategic Fund, which groups seventeen countries for the purchase of vaccines, have all used pooled drug procurement mechanisms (DeRoeck et al. 2006). Other mechanisms have been employed, such as the United States President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund) (Pierre et al. 2019).

The Association of Southeast Asian Nations (ASEAN) does not have a similar system and therefore ASEAN countries should embark together and establish a similar committee. If this is proved to be difficult and take a long time, Malaysia should establish a pooled procurement system within the country first. In 2019, the government announced during the tabling of Budget 2020 that MOH, the Defence Ministry, and the Education Ministry would engage in pool procurement for half a billion-ringgit worth of medicines, however this plan was later cancelled (CodeBlue 2020). Malaysia should resume the pool procurement plan as this will generate substantial saving, and subsequently pioneering the introduction of pool procurement committee on ASEAN level.

CONCLUSION

Malaysia need to improve its current approach towards drug pricing. If the continuous increasing of pharmaceutical expenditure persists, it will become unsustainable in the near future and jeopardise Malaysian's access towards a high-quality and

affordable healthcare. Malaysia may draw insights from other countries which may help them to reevaluate their system and quickly adapted it in order to avoid any drastic and catastrophic consequences in the future.

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