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How much do life-saving drugs and essential medicines cost in South and Southeast Asia

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Abstract

A crucial subset of priceless treatments, life-saving medications have a special non-market value that makes them more significant than buying and selling. Drugs cannot be regarded as ordinary goods since they save lives and are necessary to monitor country-level progress toward Universal Health Coverage. Yet medicines account for one-fourth of all health spending worldwide.Drug manufacturers are frequently under pressure to prudently (i.e., low) price these medications. Drug accessibility, availability, and affordability are all impacted by drug costs. Runaway healthcare expenses are mostly attributed to rising prescription drug prices. The price of essential and life-saving drugs, the country's National Essential medicine lists, and how readily available they are in South and South East Asia are the topics of this paper.

Keywords: Life-saving drugs; Essential Medicines; South Asia; South-East Asia

1. Introduction

Access to affordability, effectiveness & quality medicines is part of Sustainable Development Goals 3.8 and underpinned by Universal Health Care. World Health Organization introduced the concept of essential medicines in 1977. One of the eight primary care essentials stated in the Alma Ata Declaration of 1978 is the provision of high-quality, reasonably priced essential medicines. Added to this quality of drugs is another issue in South and Southeast Asian countries. (Kar et al., 2010) (World Health Organization, 2013). The World Health Organization Global Action Plan 2013-2020 for Non-communicable diseases includes a target of availability and affordability of 80% of essential medicines, including generic ones, to non-communicable diseases patients. Medication is a public product, and thus it is funded partially or entirely by the Government (Rohra et al., 2020). Prices fluctuate because of variations in retail prices from the manufacturer or pharmacy. According to a study

by Lichtengerb, hospital expenses rise by 3.65 USD for every 1 USD increase in drug spending. Companies are free to charge whatever the market will bear, or they demand that they set medicine prices with restriction, depending on a number of variables. It is difficult for consumers—both individuals and health systems—to make informed judgements about buying drugs due to a lack of information regarding the prices of medications (Das & Horton, 2017).

2. World Health Organization Essential Medicines List and the National Essential Medicine Lists

It began in 1977 when the World Health Organisation published its first model list of essential medicines, a list of affordable and secure medications required for a fundamental healthcare system to operate effectively and where they can satisfy the global priority healthcare needs healthcare needs (World Health Organization, 2020). On the other hand, a national medicines list is a set of drugs the Government approves. It serves as a guide for public and commercial procurement, production of drugs, treatment guidelines, and reimbursement procedures. (Peacocke et al., 2022). But the question lies in the accessibility of these medicines to the population. Thus, the work of an essential medicine list is complex regarding accessibility, availability, and affordability.

The World Health Organisation published its first model list for children in 2007. The most latest versions in essential medicine lists, updated in September 2021, are the 8th Essential Medicines List for Children (EMLc) and the 22nd Essential Medicines List (EML).In addition, the choice of essential medicines is based on the availability of clinical data on drug safety and efficacy, the availability of treatment options for a given disease, demographic factors, shifting therapeutic needs, the shelf life of drugs, storage options, etc. (Bandameedi & Mohammed, 2016). Essential Lists mainly contain one specific compound and rarely fixed

dose combinations if they have a proven efficacy rate and advantage. Countries add to their national lists using WHO's model list as their guide or as a blueprint for medicines subgroups like that cancer, anti-infectives, cardiac, psychiatric, and anesthesia, etc. are there. Countries can infer the best options for their people and communities by seeing the list. The WHO EML's median availability rate for diverse medicines is 62%, significantly higher than the availability percentage of drugs not on the list (27%) (Kishore et al., 2018). In countries where governments do not directly procure medicines, the model list is a focal point for prioritizing reimbursement for government procurers and private and public insurers. (World Health Organization) Access and reimbursement issues arise when a medication is added to the model list. In the most recent WHO report for 2021, 479 medications are listed as necessary, and 350 are listed as essential for children (Publichealthupdate, 2021). A recent study published in the BMJ reveals a wide gap while the selection of medicines at the country level compared with those listed in WHO's model list (Piggott et al., 2022). Around 70.6% of the WHO member states globally have a formal model list for essential medicines. However, there are several reasons why MLEM and National EMLs are not aligned. First, it's possible that the WHO does not choose at the appropriate moment or delays recommendations for medicines when nations haven't thought through or have already made their choices. Second, the proper justification for choosing those essential medicines may not have been effectively communicated to all nations.

Further is not yet a repository of all the decisions of the WHO committee group for EMLs, which makes it the member states harder to retrieve the evidence (Persaud N, 2019). Some countries have fewer or more restrictions while developing the National Essential Medicine List. At the same time, some are caught up in the market pressure for selecting and putting additional items on the medicine list.

Table 1: Number of registered Essential Medicine List of WHO (MEML) in South & South-East Asian region's National Essential Medicine List (NEML)		
Countries	National Essential Medicine List	WHO Model Medicine List (from)
India	367	239
Bangladesh	187	170
Bhutan	291	202
Iran	886	342
Maldives	535	243
Nepal	300	242
Pakistan	373	347
Srilanka	318	230
Brunie	No data	No data
Cambodia	44	35
Timor Leste	239	203
Indonesia	275	222
Laos	No data	No data
Malaysia	308	220
Myanmar	315	249
Philippines	519	291
Singapore	No data	No data
Thailand	547	303
Vietnam	743	282

Source: Global Essential Medicine Database, World Health Organization

A recent PLOS paper in 2022 emphasises the problem of only providing for what the WHO EML defines as an individual's minimal health needs and not always providing all necessary

and effective medications (Peacocke et al., 2022). For example, medicines like Anti snake serum, available in most of South-South-east Asia, are not on the WHO list (Global essential medicines, Database). Another drug category, Insulin long-acting, is used for maintaining healthy blood glucose levels throughout the day; for example, glargine and detemir, are not included in the WHO list (Chouhan R, et al., 2017).

3. New Essential Medicines and their Pricing Dilemma

Globally, 284 million people are infected with the hepatitis C virus. Due to this, the WHO added four direct acting antiviral medications (DAAs) in 2015, namely daclatasvir, dasabuvir, simeprevir, and sofosbuvir, to the WHO Model List of Essential Medicines. In an effort to increase access, national governments are likewise making every effort to include these medications on their national lists. But there is one issue that is quite important: price. A big obstacle is affordability. For instance, sofosbuvir costs $87340 in Malaysia for a 24-week course, but it costs $500 in India. Due to the local manufacturing of the the same medicine, it is priced at $300 in Egypt. Thus there is a strong price variation and a huge difference in production cost of medicines. As for Sofosbuvir, production cost is somewhere around $68 and $136 for a 12 week treatment course (Das & Horton, 2017).

4. Availability & affordability of Essential Medicines in South and South East Asia

Fifty percent of those who pass away from medication non-fulfillment live in Africa and Asia, killing about 10 million individuals worldwide(Thanh Nguyen et al., 2020). Medications are considered essential for public health, effectiveness, safety, and cost-efficiency in any nation and worldwide. Therefore, they should always be available in sufficient quantities in health centers (Kar et al., 2010). The World Health Organisation released its initial list of essential medications in 1977. A new revision to the list of required drugs was released in 2022.

However, most countries believe medicines should be available based on their need rather than their ability to pay. Price Control can also sometimes create shortages as they take away incentives to invest in producing more of an existing good. It is important to understand the vitality of essential medicines by knowing their availability in the retail market and national distribution list.

Around 25-70% of health expenditures in developing countries go towards purchasing drugs, which can cost up to 15 times the average daily wage, as opposed to less than 10% in developed nations. The high cost of drugs is caused by factors like distribution costs, taxes, import duties, and markup of the price of drugs (Ari Kristina et al., 2020). The prices of 23 pharmaceuticals were examined in another research study by (Rohra et al., 2020), and it was discovered that there is a significant disparity in drug prices between different countries. For instance, the cost of the antipsychotic medicine Risperidone in Pakistan was seven times more than in Sri Lanka. Understanding why drugs are essential is important since nations have always had difficulty obtaining the correct medications when needed. Some governments have inadequate supply and procurement systems and many unregulated drug transactions. There are different pharma markets in Asian countries. There are some big nations with sizable domestic pharmaceutical manufacturing industries. Smaller nations with insufficient domestic pharmaceutical production have more challenges when purchasing medications on the international market because they have few other options and limited control over market prices (World Health Organization, 2017). According to Hadi M. A. et al. (2017), medications are a reliable indicator of adherence. Because of the high expense of medications, there is a substantial risk of non-adherence in lower-middle-income countries. Many governmental initiatives aim to reduce the price of these pharmaceuticals. Pharmaceutical policies and charges come in a wide variety.

Despite this, western medicines dominate in nations like India, Malaysia, Pakistan, Thailand, and Singapore (Tarn et al., 2008). In recent decades, total health spending in Asian nations has dramatically increased, rising from an average of 4.6 percent of GDP in 1970 to 8.8 percent by 2018.. In contrast to nations where they are primarily funded by the Government (Bhutan, Thailand, and Timor-Leste), most South and Southeast Asian countries, such as Bangladesh, India, Myanmar, and Nepal, rely mainly on out-of-pocket spending to meet their demands. How medicines are financed has a huge implication on policy development, implementation, and enforcement. When medicines are predominately funded by the household, ensuring the affordability of medicines in the retail sector is essential as it is the primary avenue for purchasing medicines. On the other hand, when medicines are financed by Government ensuring their affordability through a selection of medicines is also relevant as it will provide the route to accessing people'ssuitable needs. Countries with very low per capita spending on drugs will struggle to offer an essential basket of medicines required to satisfy the health need of the population. World Health Organization Southeast Asian regions differ largely in health & medicines expenditure per capita. User fees as mentioned by Hakim et al. in their article from 2022 as a means for the healthcare system to raise the standard of care and broaden the range of services offered. A Lancet study published in 2022 revealed that essential medicines for chronic diseases like asthma and COPD were largely unaffordable in Lower middle-income countries and were primarily available in private facilities or hospitals (Stolbrink M, et al, 2022). Providing free essential medicines is an important step in achieving UHC. In 2017, the Lancet Commission Report released five necessary elements of essential medicines policies: 1. Affordability, 2. Quality and safety, 3. Quality use of medicines, 4. Paying for the core set of essential medicines, and 5. Developing missing essential medicines. (WHO, 2020) However, these policies often fail to achieve the goal of providing drugs.

5. Challenges and Opportunities

The Southeast Asia Regulatory Network was established in 2017 to increase this region's accessibility to safe and high quality medical products. (Travis & Khetrapal Singh, 2018) Despite improvements in overall availability, medicines are still more challenging to obtain in the public sector than in the private sector, in health centres than hospitals, and for non-communicable diseases rather than infectious diseases. Some nations have weak supply chains and procurement, and many drug sales are unregulated. Further, Governments and the global public health community have historically ignored the private sector's contribution to providing drug supply. However, it is well known that private pharmacies and drug stores are typically patients' first point of contact with the healthcare system and the preferred channel to purchase medications in most low-and middle-income countries (LMIC) (Miller & Goodman, 2016). These essential medicine lists either influence the procurement policies and decisions or, in some cases, the country insurers use essential medicine lists for reimbursement decisions. (Piggott et al., 2022).

Let's outline what South and Southeast Asian nations comprehend and provide in terms of necessary and life-saving medications:

1. Bangladesh: Hakim S, et al, 2022 write that Bangladesh is among the top ten countries globally for diabetes patients, and 80% of all diabetic patients reside in lower-middle-income nations. According to a recent analysis of 30 surveys by Ewen et al., 16.7% of low-income countries and 20.8% of LMICs, respectively, have access to diabetes medications in the public sector. In the Private sector, it was 16.7& in low income & 20.8% in low-middle-income countries. There is poor availability of essential medicines for diabetes at publicly managed healthcare institutions compared to private facilities. The intended medicine hierarchization for public sector procurement may be

to blame for the shortage of necessary medications in the public sector; nevertheless, the private sector also appears to have been affected. Private facilities are less hesitant than public facilities to provide high-quality services and more effectively meet customers' healthcare needs because they are not financed and rely solely on client profits. Another factor might be that certain government employees illegally sell pharmaceuticals to private hospitals despite having an enormous supply of medications meant to be provided free of charge at government hospitals. Bangladeshi pharmacies and medications are governed by two organisations: The Pharmacy Council of Bangladesh (PCB) and the Directorate General of Drug Administration (DGDA) (Islam et al., 2018). Apart from that, there is also a huge rural-urban divide. (Kasonde et al., 2019) writes the availability of NCD medicines is a key concern. An increase in life expectancy and increased urbanisation are causing a demographic and epidemiological change in this lower middle-income country. Due to this demand for medication for chronic conditions like diabetes, and hypertension, public health care system medicines are free of charge to patients. However, drugs are less available, increasing out-of-pocket expenditure (OOPE). Essential medicines are less available than nonessential medicines in the public sector. Pharmaceutical sector in Bangladesh. (Islam et al., 2018) writes that the Government of Bangladesh restricts the importation of drugs from other nations to support domestic drug production like Insulin, Cancer, vaccines, Pertussis, etc. However, till the early 80s, 75% of the market was generally imported by various Multinational Companies. In 1982 Bangladesh developed its first National Drug Policy (Murshid & Haque, 2019). Their pharma companies meet 97% of the country's pharmaceutical demand. By 2024, the market size of pharma will reach about 3084353.25 USD. After the new National Drug Policy of 2005, the result of price relaxations on manufacturing drugs, pharmaceutical companies in Bangladesh got

the opportunity to increase prices. However, the Policy had no pricing instrustions for essential medicines and FDCs. Following the 2006 Drug Control Ordinance revisions, Bangladesh can now collaborate with any pharmaceutical business worldwide to create any medicine. The latest editions to the national drug policy of 2016 again discourage the production of combination drugs (Murshid & Haque, 2019). Bangladesh imports 80–90% of its active pharmaceutical components, the main factor driving up drug prices there.

2. India: Since the 1980's India had a strong pharma industry aiming towards generic medicines (medicines at low cost). The quality of most of the pharma products exported to other Asian countries is better than their counterparts (Srinakharinwirot University, 2016). Another point to make is India has generally low levels of cost of production (low-cost R and D, low manufacturing cost) than countries like the USA and European countries. There is also a growing scope of FDI by MNCs, technology, economy, and an increase in pharma outsourcing, making India a great pharmaceutical leader. The country has also found a niche in the growing generic medicine market (Ray et al., 2019). In India, the essential medicines drugs initiative aimed to provide essential medicine free of cost in the public sector. Tamil Nadu and Rajasthan have implemented free medicines for all public hospitals. In India, the National list of essential medicines forms a reference list from where price control of drugs is referred. But it does not reflect the drug prescription, production, and availability reality. Brookings India, 2020 writes that India's pharmaceutical expenditure contributes 43.16% of the total OOPE. It is the highest category of OOPE in health, followed by expenditure in private hospitals, medical diagnostics, Government hospitals, and general medical practitioners. The state of Bihar has the highest OOPE, 80% of the total health expenditure. In India, the share of medicine in OOPE was around 51% in 2013-14, reduced to 43% in 2015-16. In 2004 WHO estimated that 649 million Indians lacked regular access to essential medicines.

Drug Price Control Order (DPCO) has put medicines in NLEM under price control. The availability of affordable medicines saw reality with the opening of Jan Aushadi Kendras in 2008. India's healthcare services delivery, including the pharma sector, is largely privately bent (90% of the drugs are prescribed & distributed in the private sector) and ranks thirds in volume, and 50% of the total production is exported to other countries. Regulation of pharma in India is complex, with several governing bodies controlling cost and quality. India has emerged as a significant player of pharmacy of the global south. India-branded generic medicines are still unaffordable to many households (Health Systems Review, WHO, 2022). According to WHO's medical products profile of India, 2019 shows that 34.7% of the total healthcare cost was spent on medicines, and mostly 90% was an out-of-pocket expenditure. (WHO, 2019)

4. Sri Lanka: The State Pharmaceuticals Corporation (SPC) procures pharma products for the State. Sri Lanka does rely hugely on imports. In the year 2019, total imports in USD million were 504 (Stax, 2020). Free distribution of essential medicines in Sri Lanka at public health facilities. (WHO, 2019) The country also has free essential medicines in the public sector, but due to their unavailability, there is high OOPE. Sri Lanka's pharma market is US$400 million annually on essential medicines. In 2016, Sri Lanka transformed the pricing policies on essential medicines, making pricing drugs more affordable. (Rathish et al., 2017) write availability of generic medicines was fairly high according to many research published and surveys conducted in Sri Lanka; however, the number is not high for children. (Balasubramaniam et al., 2011)

5. Nepal: The Drugs Act of 1978 is responsible for the medicinal drugs in Nepal. National Drug Regulatory Authority (DDA) is responsible for drug production, distribution, export, and regulation. DDA also comes under the Ministry of Health (MOH). The Association of Pharmaceutical Producers of Nepal (APPON), established in 1990,

consists of 50 pharma companies providing 40% of the pharma market in Nepal (Ranjit, 2016). Distribution of free essential medicines is there only at the district level. However, the distribution is not timely and uniform. (Khanal et al., 2019) The rest is generally imported from other countries, mainly India. The Country's current pharma sector is focussed on building and manufacturing finished goods with the help of import of APIs from other countries. The first essential medicine list came in 1986, serving as a basis for procuring and distributing drugs through government outlets. Nepal is a low-income country in Southeast Asia challenged by the dual disease burden (i.e., communicable & non-communicable). Non-communicable diseases are on the rise, putting immense health pressure on people and the Government. There is a shortage of NCD medicines. The availability of medicines is higher in private hospitals, more than 60% of OOPE. There should be more strategies to ensure adequate funds to purchase essential Medicines in the public sector are financed through National and International sources and pooling procurement. National Health Policy 2019 also emphasized ensuring production and access to safe, effective & quality needs at an affordable price.

6. Cambodia: Cambodia has a very high OOPE on health (60%), and pharma constitutes 77% of total spending. People (Sengxeu et al., 2021) Drug distribution is centralized in Combodia's public sector. However, the public sector is experiencing a shortage of drugs. The country has several local manufacturing companies; however, they often do not comply with good manufacturing practices (GMP). The country has a dual burden of disease. Self-medication is yet another challenge in Cambodia (2020). Drug distribution in the public sector of Cambodia is centralised. However, there are still drug shortages in the public health system, and the storage conditions for medications at all stages of distribution need to be improved. There are numerous domestic manufacturers in Cambodia. Local producers continue to use production methods that do not adhere to

Good Manufacturing Practise. Cambodia also has some of the highest out-of-pocket expenditures (74% of Total Health Expenditure). (Ozawa S, et al, 2018). The country has a Health Equity Fund, wherein poor individuals can claim free medicines in the public sector. However, the coverage is pretty low. In 1991, Cambodia entered the market economy. It started the long process of liberalization (both public-private) of the pharma sector, i.e., an increase in pharma companies(308 in 2015) and an increase in medicines (12000 in 2015). Till date, Cambodia has the feel of French pharma style, like a monopoly given to pharmacists who look after the drug import, distribution, and sales. India is a significant exporter of medicines to Cambodia (Bureau-Point et al., 2020) (Tenni et al., 2023)

7. Singapore: (Pearce et al., 2019) write that Singapore has a robust healthcare system compared to other Asian countries. The Ministry of Health is the basic governing body. In the public sector, there are subsidies and financial assistance to those who need medical care, and they are provided drugs under standard drug lists & medication. It is reportedly the healthiest country in Asia, with universal access to health care. The public sector covers 80% of acute care and 20% of primary care, and the private sector provides the rest. There is no formal medicines policy. The country's public insurance system, MediShield Life (mandatory universal coverage plan), covers large hospital bills and some outpatient treatments but does not cover prescription drugs. However, people are also supported by other government subsidies. (Ong et al., 2018) The country has become the pharmaceutical hub regarding Foreign direct investments (high levels of MNCs). These MNCs can establish manufacturing operations in Singapore, catering generics to patented products. This has led to the country's label as a pharma trading base for the Southeast Asian region. Singapore is a small, high-income, and free-market economy.

The R and D are the strongest asset of the Singapore Pharma industry (MERCURIO & KIM, 2015).

8. Malaysia – Malaysia's healthcare system is both public and private, and the Ministry of Health is the apex body that provides health services. It follows a free market economy. Since there is no regulation of drug prices (apart from some control in the public sector), there is no price control. (Ahmad & Islahudin, 2018) In Malaysia, there is a lack of price control of drugs resulting in exorbitant amounts the private sector and high OOPE in the private sector. Here the price of generic medicines (lack of pro-generic policies) is also high (Babar et al., 2016). The importance of essential medicines is emphasised in Malaysian National Medicines Policy (MNMP – locally known as a blue book). Drugs are provided through Government funded public sector & self-sustaining private sector. However, these medicines were not addressed to maintain the stocks and procurement processes at central or major regional warehouse levels. In 2014, all drugs under the essential medicine list got exempted from taxation to ensure affordability. Also, there is a lack of essential medicines in public facilities. There is no structural price regulation policy on drugs in Malaysia. The impact of high-priced medicines on the sustainability of health care is a growing issue as the demographics of Malaysia is bent toward the population who prefer halal pharmaceutical. The Government is pushing this industry to the best. (Sadeeqa et al., 2013) Drug pricing is sometimes extremely high, up to 16 times that of international reference prices in private settings. This shows the low levels of public procurement policies. This is also can be the result of privatising the drug procurement process, and thus this monopoly has further increased the prices (Mohd-Tahir et al., 2015)
9. Thailand: Thailand has shown significant growth in the pharma market and is striving to become a leader of the medicab hub in the Asian region. They export pharma products

to Myanmar, Vietnam, and Cambodia and import API and other pharma products from the USA, Germany, France, and Switzerland. The leading multinational companies in Thailand include Pfizer, Novartis, GlaxoSmith, etc. However, more than 75% of pharma companies are local, namely Greater Pharma, Biolab, Siam Pharma, and Thai Meiji. For its citizen, Thailand has at least a basic level of care under its Universal healthcare system. The pharma industry is two folds in Thailand: govt and private enterprises. Thailand uses Health Technology assessment to support decisions for including new medicines in benefit packages. (Beran et al., 2019). Thailand shows how very few countries in LMIC prioritize medicines to include in their health package. Thailand's Universal Coverage Scheme (UCS) was successfully implemented in 2002, providing financial security for medical treatment to the whole population. (Tangcharoensathien et al., 2019) In Thailand, many patients in public health care seek various forms of traditional medical treatment, including herbal ones. Most of the Thai international pharma market (size and not value) is dominated by generic drugs (Srinakharinwirot University, 2016)

10. Vietnam: Only after the late 1980's (DoiMoi) Viet Vietnam's healthcare system shift from a pure public (centralised) to a private-public healthcare system. The pharma market is quite bent towards market-oriented measures like user fees in public centers, legalisation of private pharmacies, less focus on free medicines, etc. These measures, no wonder, led to high OOPE. However, to address the challenge, VietNam introduced Health Insurance in 1992 to curb the costing. The insurance, however, did not covered the medicines available at retail pharmacies. Thus, in 1996, The National Drug policy came into existence to maintain good GMP and storage practice and distribution practices, but no generic medicine policies were rooted in that. However, the first element of essential medicines was rooted in the 1996 policy, but EML is not used and reflected

well in procurement policies. There is an alternative expanded list of main medicines used in public facilities. The country's pharma market is generally dependent on imports as domestic manufacturing is bounded by limited resources, thus resulting in producing mainly therapeutic drugs. The Drug Administration of Vietnam (DAV) is the regulatory body of Vietnam at the state level. The supply chain of medicine is again very complex in Vietnam as there is a long chain of intermediaries between manufacturers and consumers. (Babar, 2018) In 2014, to improve the country's pharma sector of country there was a strong focus on investing more in generic medicines production in Vietnam. About 77% of health professionals work in Public Health Facilities, and 91% of the population is covered under social insurance in 2018. Vietnam's NLEM (latest) was released in 2018. By virtue of low cost and national policies in place, generic medicines are prioritised in the public sector. Its Pharmaceutical Industry development aim for 2016 to 2020, a vision to 2035, is an efficient supply of medicines in a timely and adequate manner. However, there is a regional disparity when getting medicines, and medicines available in districts like Binh Dinh, Dong Nai & Dong Thap have more availability than in Hanoi, Dien Bien, and Dak Lak. (Nguyen et al., 2021)

11. Pakistan: In 1994, Pakistan came up with its first essential medicine list, which mandates both public and private health instututions to follow. Pakistan has centralized and decentralized procurement systems (Babar, 2018). In a decentralized system, public hospitals contact registered pharma manufacturers to bid, whereas, in the centralized one, the provincial Government plays an important role in drug procuremnt based on the hospital's needs. In Pakistan, the local pharma market is proliferating. Till the 1990s, the reliance on multinational companies to address the demand for medicines was higher. After that, National Pharmaceutical compliance with the global standard of quality drugs came, and the share of national companies or manufacturers grew. (Ahmed & Chandani,

2020) However, there is a significant dependence on the foreign market for APIs from countries like Europe, North America, China, and India. In 2015, the Pharma industry grew to 2.6 Billion US$. Today the National share of the pharmaceutical market is 69%, and multinational companies are 31%, with companies like GloxoSmithKline& Getz Pharma Pakistan Pvt. Ltd (Ahmed & Batool, 2016). In Pakistan, Drug Regulatory Authority (DRAP) is responsible for the price control of drugs and is an essential division of the Ministry of National Health Services Regulation and Coordination (NHSRC). The price of patents and generic products is 2.36 and 2.26 times higher than the International Standards. (Saeed et al., 2019) in a recent research study, the availability of generic medicines in Public and Private is only 15% and 31%. The cost of treatment for diseases like hypertension, diabetes, depression, etc., is unaffordable. The availability of essential medicines is strictly followed only by public sector hospitals. (Babar, 2018). Patients receive partial free treatment in public hospitals; however, like in many Asian countries, this system is not uniform as patients need to buy medicines, resulting in high OOPE (64% of the total health expenditure). Doctor pharma nexus is also present in some parts of Pakistan. The country's OOPE on health is 64%and there is a persistent increase in the cost of medicines. It is the 10th largest pharma industry in the Asia-pacific region and has shown exponential growth in the last two decades (Ahmed & Batool, 2016). Pakistan imports drugs (to serve 20% of the local demand) from countries like Germany, Switzerland, Japan, the Netherlands, the US, the UK, and France. Major export partners of pharma products include countries like Afghanistan, Sri Lanka, Viet Nam, the Philippines, and Lithuania, with 94.7 (million US$) in 2013. Pakistan exported 13 & 30.3 (million US$) of inorganic and organic chemicals to India in 2012.

12. Bhutan: In Bhutan, the essential drug program began in 1987 with a good distribution of essential medicines in all public health facilities. Bhutan Health Trust fund is responsible

for purchasing essential medicines. There is a central procurement of drugs in Bhutan (WHO, Situation Analysis, 2015) Healthcare in Bhutan and the bulk of medicines are imported from generic companies in India after the no-objection letter from Bhutan's Drug Regulatory Authority to grant the import of small quantities of unregistered essential medication. The step was taken to ease the problem of importing essential drugs. It is a very small country, and health care is generally free of cost. Thus Government revenue is the major source of healthcare financing in Bhutan. (WHO, 2017) Also, the engagement of the private sector is limited to retail shops and some diagnostic centers. The Department of Medical Supplies and Infrastructure (DMSHI) is responsible for procuring and supplying all Drugs, Vaccines, and Equipment Drugs & medicines. Regulation & compliance is taken care of by the Drug Regulatory Authority (DRA). There is no local manufacturing unit to produce drugs. (Bhalla, 2018) Apart from India, Bhutan imports drugs from Bangladesh, Thailand, and other countries. The Medicine Regulations of 2012 (also the National Drug Policy) permit foreign and Bhutanese manufacturers to register pharmaceutical items in Bhutan. The latest edition of the essential medicines came out in 2018. Because of the difficult terrain and topography, health equity is a major concern in Bhutan. (Chejor et al., 2018)

13. Indonesia: Indonesia has one of the largest pharmaceutical market shares in ASEAN, accounting for 27% of the region's total market share, with domestic pharmaceutical companies holding a 73% majority. (Ari Kristina et al., 2020) Availability of Essential medicines is a challenge to developing countries like Indonesia compared to international standards. The availability of essential medicines was higher in public health care centers. There were little to no price control regulations in lower-income nations like Indonesia. As a result, drug companies frequently raise the cost of patients' essential medications. Out-of-pocket expenditures on medicines are common in the country (44.9% of the total

health expenditure in 2014). Presently the insurance system is developing in Indonesia (2005, Askeskin). Thus, private hospitals have a lesser number of generic medicines available with high prices. There is also a lack of restrictions on prices in private settings. There is a difference in patient prices in public and private hospitals and among public hospitals and private pharmacies. Thus there is an urgent need to regulate the procurement prices of drugs. In this regard, the country is also implemented the National Drug Policy, where generic drug standardization will be used for all public procurement. (Anggriani et al., 2020) Jaminan Kesehatan Nasional (JKN) is their social health insurance implemented in 2014 till 2019 Jan, covering 83% of the country's population. Before this, drug policies of 2005 and 2015 aimed to reduce essential medicines' prices, not branded generics. (Erlangga et al., 2020) In the early 1990s, the pharma industry shifted from traditional ways of selling drugs to a modern competitive style. Ministry of Health Food and Drug Supervisory Board manages the quality of pharma production, essential medicines, and price regulation. Although a large number of drugs are produced locally, 95% of the API are still imported. There are both public and private manufacturers. The concept of essential medicine got released in 1980, and the publication of its National Drug Policy got released in 1983. These essential medicines are free of charge to people with low incomes. The Directorate General of Pharma and Medical Equipment in the Ministry of Health is responsible for the public procurement of decentralised drugs (local govt. procures the drugs at a local level). And In the private sector, the system is self-owned and funded according to the market (Health Systems Review, 2017)

14. Iran: Food and Drug Administration (FDA) under the Ministry of Health (MOH) is responsible for managing and regulating the pharma sector in Iran. (Sajadi et al., 2020) (Minaei et al., 2019) Regarding accessibility, which calls for the Government to ensure

that essential medications are accessible in pharmacies and affordable for vulnerable groups, the study's findings show that Iran has the lowest prices for essential generic medicines in both the public and private sectors. Since the WHO states that key medications must be available at least 80% of the time, the rational use of medicines is one of the most challenging issues in Iran. A generic pharmaceutical market exists in Iran. For instance 2018, there were 185, 232, and 50 Iranian pharmaceutical manufacturing, import, and distribution companies. In Iran, there is considerable difficulty in exchanging finances, which creates problems in importing drugs. Thus, the reference pricing method is used to meet the challenge. Like Bangladesh, to increase their internal production of drugs, the internal Policy sometimes limits the patient's choices, low competition between companies, or even bans importing certain drugs (Ebadi Fardazar et al., 2019). Iran also lacks a plan to export its drugs to international markets.

15. Philipines: Philipines has a well-developed pharma sector with a straight focus on generic medicines and a decentralised planned healthcare system since the 1990s.However, given the history and geopolitics of the country, the system is quite complex. The first National Drug Policy came in 1987 with an aim to promote the selling of generic medicines. After that, in 2012, National Formulary System (PNFS) was established to select medicines based on efficacy, safety, and cost-effectiveness. Regarding the pricing of medicines, certain sections of society are exempted from paying for medicines. However, a question of the availability of medicines results in high OOPE. (Babar, 2018) Majorly, domestic pharma manufacturers are focussing on generic medicines (especially branded generics). Drugs and medical items are governed by the Food and Drug Administration. The Department of Health is the prime agency in Health Care. (Lambojon et al., 2020) writes that the nation lacks adequate access to the necessary medications for treating these major Non-communicable diseases. In both the public and

private sectors, the costs of originator brands were more than 30 times higher than the international reference price, while those of generic drugs were almost 10 times higher. The biggest access obstacle is high drug pricing. Affordable drug prices can be attained by implementing strategies including lowering margins and tariffs. While the Philippines has a 12% value-added tax (VAT), other countries' rates range from zero to 19% globally. However, lowering taxes does not always imply or guarantee lower prices. Access to medicines in both sectors is affected by low availability. The Philippines' decentralised procurement system may explain the low availability and varied supply of most medicines in public outlets across different regions. Both by DOH at the national level and by local Government in charge of purchasing and proving medicines not covered by DOH. Similar studies in developing nations show that Originator Bands are less readily available than generic substitutes in both the public and private sectors.

16. Myanmar: Health care services in Myanmar are provided mainly by the public sector, where drugs are also available free of charge. However, availability is again a question that prompts patients to buy medicines from private pharmacies. (Chauhan, 2017) writes Myanmar is the growing pharmaceutical market in Asia and globally. However, Myanmar's healthcare is still one of the least in the Association of Southeast Asian Nations (ASEAN) region. And the sector is open to foreign investments a lot. Imports feed local demands for medicines. OOPE is essentially paying most healthcare spending in Myanmar. Myanmar health systems offer traditional herb medicines alongside allopathic medicines. In 2014, drug procurement for the public hospital was decentralised. Before that, the drugs were procured and distributed by the central medical store depot (governed by the Department of Medical Services, Ministry of Health and Sports) going to the govt health facilities using a PUSH strategy (central level to town/district level). However, there were problems with the availability of generic drugs,

and stock-outs were common. However, after the decentralisation, which was fully functional in 2015-16, it focused on two ways of distributing and purchasing medicines. The first was based on the need for hospitals, and the second, a budget was allocated to a facility (hospital with more than 200 beds) to purchase medicines every six months (Pwint et al., 2021).

17. Maldives: Ministry of Health (MOH) delivers health services, and Maldives Food and Drug Authority (MFDA) is the National Regulatory Authority. Healthcare is mainly public. It is also dependent primarily on imports. State Trading Organization (STO) is the agency responsible for public procurement. (WHO, 2017)
18. Brunei, Laos: Brunei is a very small country with a large population clustered around the capital with a small medical industry. Ministry of Health is responsible for providing free health care services. However, with limited resources, citizens seek healthcare services by traveling to countries like Singapore, Malaysia, and Thailand (International Trade Administration) (Ali, 2022). The country was one of the early exponents of halal pharmaceuticals (2010), Malaysia being the first to manufacture halal medicinal products[1], traditional and health supplements. The USA is one of the leading exporters of Brunei. In Laos, there is both a public and private healthcare system. Before 1987, the health system was mainly centralised. During the 1987-1991 period, provinces got the power. The 2005 Healthcare law, revised in 2016, provides the healthcare regulatory framework. Since 2016, one single insurance scheme NHI has been introduced, which till 2017 had covered more than 90% of its population. The National Medicine Policy (revised) of 2003 demands consumer protection in the pharmaceutical area by providing all essential medicines in health facilities at all levels. However, till now, there has been a massive problem with access to essential medicines due to their high prices (World Health Organization, 2018) (Peabody et al., 2019). The National Drug Policy

first came into existence in 1993, followed by a health care law in 2005 to streamline the progress of health development. Until 1995, health care was free in Laos, but the problem of accessibility and shortage of medicines.

[1] https://www.halalwatchworld.org/everything-you-need-to-know-about-the-halal-pharmaceutical-industry Products must not contain any ingredient derived from pig, alcohol, blood, predatory animals, human parts, or insects

This led to the bloom of private pharmacies. Thus, the policy was endorsed to stop the frequent buying of medicines from the pharmacy and other issues in 1993. due to the complex topography, service delivery is a challenging task. Laos has one of the highest OOPE in the world. (Jönsson et al., 2014)

7. Conclusion

Essential medicines play an important role in any health system delivery and are also integral to Universal Health Coverage. Yet medicines account for one-fourth of all health spending worldwide. It is common practice in most South & Sea countries to rely heavily on out-of-pocket expenditures to finance their needs, for example, Bangladesh, India, Myanmar, and Nepal, compared to countries where the Government largely invests in them Bhutan, Thailand, and Timor Leste. Since there is a growing demand for pharmaceutical products and thus a growing market, some countries still rely on importing API and other pharma products, especially innovative medicines. In 2016, The Southeast Asia Regulatory Network came into existence to improve access to safe and high-quality medical products in this region. How medicines are financed has a huge implication for developing, implementing, and enforcing policies. When medicines are funded predominately by the household, ensuring the affordability of medicine in the

retail sector is essential as it is the primary avenue for purchasing medicines. On the other hand, when meds are financed by govt ensuring their affordability through a selection of medicines is also relevant as it will provide the route to accessing people's relevant needs. Countries with very low per capita spending on medicines will struggle to provide an essential basket of medicines required to satisfy the health need of the population. To understand better the pricing of life-saving medications in South and Southeast Asia, this working paper will go even deeper into the role that pharmacies and the private sector play in supplying essential medications and how its practice has changed in past years.

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1. Table 1: South & East Asia Total Health spending (current health expenditure – healthcare goods and services consumed during an year, more specifically total healthcare services, medical goods dispensed to outpateints, prevention and public health services, and health financing) as percent of GDP 2019 (The Global Economy, The World Bank)

Country Total Health Spending as % of GDP, 2019 Indonesia 2.9
Philippines 4.08
Singapore 4.08
Laos 2.6
Thailand 3.79
Cambodia 6.99
Brunei 2.16
Malaysia 3.83
Myanmar 3.83
Vietnam 5.25
India 3.01
Sri lanka 4.08
Bangladesh 2.48
Nepal 4.45
Afghanistan 13.24
Bhutan 3.61
Pakistan 3.38
Maldives 7.04

Source: The World Bank, World Health Organization Global health Expenditure database , 2022

Table 2 Out-of-pocket expenditure (% of current health expenditure) of South and Southeast Asia, 2019

Country Out-of-pocket expenditure (% of current health expenditure), 2019
Indonesia 34.76
Philippines 48.56
Singapore 30.15
Laos 41.83
Thailand 8.67
Cambodia 64.39
Timore Leste 8.15
Brunie 5.68
Malaysia 34.57
Myanmar 75.95
Vietnam 42.95
Afghanistan 79.30
Bangladesh 72.68
Bhutan 17.79

India 54.78

Maldives 16.45

Nepal 57.91

Pakistan 53.81

Sri Lanka 45.64

Source: The World Bank, World Health Organization Global health Expenditure database , 2022 Table 3: Pharmaceutical system flow chart of South Asian Countries

Pharmaceutical system flow chart/ Indicators	South Asian Countries									
	India	Sri lanka	Bangladesh	Nepal	Bhutan	Indonesia	Myanmar	Thailand	Maldives	Timor leste
National regulatory authority	Central Drugs Standard Control Organization (CDSCO) w	National Medicines Regulatory Authority (NMRA)	Directorate General of Drug Administration (DGDA)	Department of Drug Administration (DDA), Ministry of Health	Drug Regulatory Authority of Bhutan	Medicines and vaccines: National Agency of Drug and Food Control;18 Medical device: Minist	Department of Food and Drug Administration (DFDA)	Thai Food and Drug Administration (Thai FDA)	Maldives Food and Drug Authority (MFDA)	No official National Regulatory Authority . Directorate of Pharmacy and Medicines (DNFM) responsible for some regulatory functions

						ry of Heal th				
Number of products on essential medical list	376 (API)	3 6 1 (A PI)	285 (API) allopat hic drugs	359 (API)	33 2 (A PI)	321 (API)	34 1 (A PI)	68 1 (A PI)	3 2 6 (A PI)	274 (API)
Agency for public prodcur ement of drugs at public se ctor	Minist ry of Hea lth & Family Welf a re	Sta te Pha rm ace uti ca l Cor po rati on	Central Medical Stores Depot (CMSD)	Logistic Manage ment Division	M edi c al Su pp li e s Pr oc	Direct orate Gener al of P har m aceuti cal and	Cen tr al Me dic al Sup pli es De par	Nat ion al Me dici ne Sy st e m s Dev el	Sta te Tra di n g Og ani zati o n (ST O)	SAMES IP (Servi ce Autonom o de medi cam entos e Equipa m

					urem ent Divisi		tment	opme		

					on under Department of Medical Supplies and Health Infra	Medical Device	(CMSD) and some local procurement	nt Committee.		ents de Saude)

					structure (DMSHI), Ministry of Health					
Procurement of medicines done at	Central, state & facility levels	Central & Facility	Central and Facility levels	Central, State and Facility	Central	Central	Central, State & Facility	Facility	facility	Central & Facility

Price control Public level Private level	Yes National Pharmaceutical Pricing Authority National Pharmaceutical Pricing Authority, Minist	Yes Private: Ministry of Trade and Industry with Sri Lanka Manufacturers Association and Sri Lanka	Yes Public: DGDA Private: Price fixation committee (Manufacturer & retailer)	No data found Private: DDA and Drug Pricing Monitoring Committee	No At private level, Drug Regulatory Authority	Yes Private: Ministry of Health	Yes Private: Myanmar Pharmaceutical and Medical Equipment & Entrepreneur Association	NO Private: : Ministry of Trade/ Commerce (retailer)	No Private: : MFDA and Ministry of Economic Affairs	Yes Public: NO data Private: Not Controlled

	ry of Chemicals and Fertilizers	n Standards Institute.					in collaboration with Ministry of Comm			

							erce			
Price mechanism Public Private	Lowest procurement price considered Market based pricing (Manufacturer, Wholesale & Retailer)	Public: Tenders are scheduled according to ascending prices and evaluated technically Private (none)	(--) Market based pricing	Private: Using the mean median technique, get the Maximum Retail Price (manufacturer, wholesale & retailer)	Public-health insurance Private: Price structure to be submitted at th	Public - Lowest price bid accepted Private - Market based pricing (wholesale drugs)	Public -: Lowest priced quotation is chosen Private Retailer	Public: Prices at or below standard price as mentioned in the standard price list Private☹retailer)	Public☹no data) Private: under review	Public: : Bid evaluation based upon Lowest price criteria Private: NA

					e time of registration of product (retailer)					
Mark ups regulated at private sector	Yes	No	yes	no	Yes	NO data available	NO	No price cap	Under review	No policy
Free medicines in public sector	Yes (jan Aushadi Kendras)	Yes	yes	Yes(upto district level)	Yes	No data available	Yes	Yes	No	Yes

Number of local pharma	4900 for formu	12	814 pharma ceutical	130	2	174	9	Allopathic 186	0	0

manufacturers	lations and 1500 for active pharmaceutical ingredient		manufacturers including 266 allopathic, 202 ayurvedic, 272 Unani, 32 herbal & 42 homeopathic manufacturers					and Traditional 964		
Pharmacy education accreditation	yes	no	yes	yes	No	yes	No	Yes	Yes	Yes
Spending on medicines as share of total healthcare cost (2014)	34.7%	26.5%	44.6%	29.1%	9.7%	25.5%	28.8%	55.5%	9.7%	12.8%

Share of public and OOP spending on medines (2014)	Public – 10% OOP: 90%	No data	No data	Public: 12% OOP: 88%	Public – 67% OOP: 33%	Public: 21% OOP: 79%	Public – 5.5% OOP: 94.5%	Public – 91% OOP:9%	Public:48% OOP: 52%	Public 63% OOP: 37%

Source: Medical products profile

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