Policy Document

Access to Essential Medicines (2023)

Position Statement

AMSA believes that:

1. Access to essential medicines is central in providing a universal right to access to healthcare.
2. Current conditions of intellectual property rights ascertaining to the global pharmaceutical industry creates barriers to the access of essential medicines globally especially in times of medical crisis such as global pandemics.
3. Countries have a shared and individual responsibility to allocate resources, enact legislation, and negotiate trade agreements that improve access to essential medicines.
4. Additional support and initiatives are required to ensure equitable access to essential medicines for rural, remote, and Aboriginal and Torres Strait Islander communities in Australia.

Policy Points

AMSA calls upon:

1. The Australian Commonwealth Government and state governments to:
    a. Acknowledge the potential for Trade-Related Aspects of Intellectual Property Rights (TRIPS-plus) provisions to create significant barriers in the access of essential medicines by Low Income Countries (LICs) and Low and Middle Income Countries (LMICs) by:
        i. Maintaining and facilitating usage of flexibilities in the TRIPS legislation;
        ii. Advocating against TRIPS-plus provisions outlined in the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) that expand patentability standards of the pharmaceutical industry;
        iii. Avoiding legal and intellectual property clauses that may decrease access to essential medicines, or limit any sovereign government's ability to legislate to protect public health;
        iv. Increasing flexibility and openness to compulsory licence negotiations in compliance with the 2014 Intellectual Property Laws Amendment Bill;
        v. Discouraging trade barriers enacted against sovereign states for the use of compulsory licences for essential medicines;

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vi. Implementing more effective legislation to ensure that pharmaceutical companies consider public benefit whilst maintaining business viability;

b. Use public awareness campaigns, collaboration with foreign governments and non-government organisations to promote the choice of generic medicines over branded equivalents and assist in providing aid in order to combat the delayed distribution of generic medications;

c. Strengthen the governance and oversight of access to essential medicines by:
    i. Active monitoring of current medicine supply in the Australian and global supply chains to project future shortages and develop strategies to mitigate the impact on Australian
    ii. Negotiating and implementing agreements with pharmaceutical companies to ensure adequate medicine supply in Australia when the global supply chain is disrupted;
    iii. Strengthening local medication manufacturing, especially with regards to essential medicines;
    iv. Expanding the PBS Minimum Stockholding Requirements to include all medications under the essential medicines list;

d. Fulfil Australia's commitment to the Sustainable Development Goals, including Target 3b to support research, development and universal access to affordable essential medicines and vaccines;

e. Advocate for Aboriginal and Torres Strait Islander people's equitable access to essential medications through:
    i. Promoting cultural safety in practice with the aim of engaging higher utilisation of the PBS in Aboriginal and Torres Strait Islander peoples;
    ii. Further implementation of the S100 scheme, allowing practitioners to prescribe and dispense medication in rural and remote areas, particularly those in state and territory operated Aboriginal Health Services.

2. The global and national pharmaceutical industry to:
    a. Acknowledge their influence on the distribution of essential medicines by increasing attention towards actions that can be taken to improve global access to essential medicines by:
        i. Acting in a manner consistent with the knowledge that a significant role of pharmaceutical patents is to stimulate innovation for new medicines, and not solely to maximise profits;

ii. Taking action, within the limits of specific business strategy, to enable generic production of affordable medicines;
iii. Redistributing their research and development budget and resources to more closely reflect the morbidity and mortality of the global burden of disease;
iv. Collaborating with and assisting local governments and/ or administrations during a natural disaster, epidemic, or public tragedy by donating pharmaceuticals in line with World Health Organisation's (WHO's) key principles for good medical product donation;
v. Cooperating with governments and international trade organisations to further develop tiered pricing systems to overcome financial barriers to access to essential medicines globally;
vi. Assisting in the equal distribution of essential medications to ensure a constant supply chain is present and uninterrupted;

b. Adopt transparent and objective reporting on their commitments to access to essential medicines and public services by:
i. Incorporating external validation and/ or independent auditing;
ii. Promoting fair competition and collaboration.

3. Non-governmental and intergovernmental organisations to:
a. Focus efforts on overcoming barriers to access of affordable pharmaceuticals;
b. Increase transparency regarding procurement of essential medicines to create market competition.

4. International governments to:
a. Ensure affordable medication prices by adhering to the WHO guidelines on country pharmaceutical pricing policies;
b. Ensure the quality, safety and efficacy of health products, in alignment with the WHOs Access to Medicines, Vaccines and Other Health products eight-step action plan;
c. Contribute to the global accountability framework of the monitoring of essential medicines by:
i. Strategic generation, analysis and usage of data for decision making;
ii. Supporting innovative technologies to aid in data collection;
d. Promote the practice of culturally safe, and socially acceptable primary health care, to ensure access and adherence to essential medicines regimes, especially within minority groups.

5. Universities and medical schools to:

a. Include information about access to essential medicines, associated global policy, barriers to accessing essential medicines, and how medical students can be empowered to tackle these global issues in global health class curriculum;
b. Innovate strategies to overcome challenges in the development, licensing and distribution of key medications.

6. The Australian Medical Association, doctors, medical students, and other health professionals to:
    a. Advocate for the inclusion of access to essential medicines and neglected disease in medical and health sciences curricula to promote awareness of these issues, including the CPTPP, within the student body, staff and public arenas;
    b. Support and contribute to AMSA initiatives and campaigns, including but not limited to AMSA MedEd, AMSA Think Tanks and AMSA Global Health, to advocate for greater access to essential medicines;
    c. Become leaders and supporters of innovative and novel research to address neglected diseases and allow access to their discoveries to ensure affordable and appropriate medications are available to patients globally.

Background

Introduction

The Australian Medical Students' Association (AMSA) is the peak representative body of Australia's 18,000 medical students. AMSA believes that all individuals have the right to the best attainable health and actively seeks to advocate on issues pertaining to health outcomes. We recognise that universal access to essential medicines is an integral part of the right to health and Universal Health Coverage (UHC), which is reflected in the United Nations (UN) Sustainable Development Goal number 3 (SDG3) - Good Health and Well-being [1]. SDG3 Target 3.8 highlights the importance of UHC, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality, and affordable essential medicines and vaccines for all [1].

In 1977, the first essential medicine list (EML) was published by the World Health Organisation (WHO). It included 208 medications which were deemed of "utmost importance, and are basic, indispensable, and necessary for the health needs of the population". Other criteria relating to efficacy, safety, quality, and cost were also taken into consideration [2]. Since then, the EML has been revised biennially and in 2021, the WHO published its 22nd list [3]. In 2007, the WHO published its first EML for children (EMLc) which is intended for use for children up to 12 years of age [4].

Similar to the EML, the EMLc is revised biennially and is currently in its 8th edition (2021) [4].

The structure of the EML and EMLc has remained largely unchanged with medications being divided into two categories: core, defined as efficacious, safe and cost-effective medicines for priority conditions; and complementary, defined as medicines for priority disease, for which specialised diagnostic or monitoring facilities, and/ or specialist medical care, and/ or specialist training are needed [5]. The WHO EML and EMLc are often used by countries to develop their own lists. Country specific EML and EMLc are typically modified to reflect local and regional morbidity [6].

Factors affecting access to essential medicines falls into Penchansky and Thomas' five dimensions of access [7]:

1. Availability: the relationship between the volume and type of existing services (and resources) and the clients' volume and types of needs.
2. Accessibility: the relationship between the location of supply and the location of clients, taking account of client transportation resources and travel time, distance and cost.
3. Accommodation: the relationship between the manner in which the supply resources are organised to accept clients (including appointment systems, hours of operation, walk-in facilities, telephone services) and the clients' ability to accommodate these factors.
4. Affordability: the relationship between the prices of services and providers' insurance or deposit requirements and the client's income, ability to pay and existing health insurance.
5. Acceptability: the relationship between clients' attitudes about personal and practice characteristics of existing providers as well as provider attitudes about acceptable personal characteristics of clients.

Trade and Patents Rules - TRIPS and CPTPP

The World Trade Organisation (WTO) introduced the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement in 1995 to set the minimum standards for intellectual property regulations [8]. To date, this is the most comprehensive multilateral agreement on intellectual property. TRIPS required WTO member countries (including Australia) to ensure patented products such as essential medicines are produced, imported, sold, or used under the permission of the patent holder.

Consequently, TRIPS plays a crucial role in the accessibility of essential medicines as pharmaceutical companies may maintain a monopoly on their product without any competition from an affordable generic medicine producer. This situation

disproportionately impacts low and middle income countries (LMICs) that are constrained by limited health budgets and cannot afford certain essential medicines. However, TRIPS allows for the issuing of a compulsory licence to a manufacturer of generic products to produce copies of essential medicines without the consent of a patent owner. Under Article 31b of TRIPS, this is reserved for "national emergencies," "other circumstances of extreme urgency," or "public non-commercial use."

Despite the rights of WTO members to issue compulsory licences, LMIC countries continue to opt out of issuing a licence due to threats of economical and political retaliation from other major governments and corporations [9]. Governments are also pressured to accept stronger (TRIPS-plus) Intellectual Property Rights protection that have negative net effects on essential medicine accessibility and health status in order to obtain trade advantages (e.g. tariff reductions on agricultural exports) in other sectors [10]. This includes data exclusivity, requiring generic medicine manufacturers to conduct clinical trials despite producing the same medicine; patent term restoration, restoring lost patent terms whilst waiting for approval of a medicine product; and denial of parallel importing, preventing countries from importing medicines sold in a different country at a lower price.

In response to widespread criticism of the TRIPS agreement and its consequences for treatments of AIDS, the WTO adopted a ministerial declaration on public health in Doha, Qatar, in 2001 [11]. The declaration confirmed the right of WTO member countries to issue compulsory licences and recognised that members with insufficient or no manufacturing capacities could face "difficulties in making effective use of compulsory licensing." This led to expanded flexibilities for the TRIPS agreement to allow for the exportation of compulsory licensing products. This addition to TRIPS has only been used once in 2007, when Canadian generic pharmaceutical manufacturer, Apotex, exported three batches of antiretroviral medicine to Rwanda [12].

The declaration was far from accommodating the interests of low income countries or LMICs where pharmaceutical companies are still likely to influence trade agendas and influence tariffs from other countries. Thailand's decision in 2006 to import generic versions of antiretroviral medicine Efavirenz from India under the compulsory licence resulted in hostility from the manufacturer, Merck. The United States Special 301 Report which is used to report global sanctions impacting LMICs placed Thailand on the Priority Watch List [9]. In the same year, the United States issued compulsory licences on reverse genetics used to manufacture vaccines for avian flu, computer memory chips, and TV components [13].

In 2014, Australia passed the Intellectual Property Laws Amendment Bill that reiterated an intent to distribute essential medicines to less developed countries [14]. The bill allows Australian pharmaceutical manufacturers to export patented medicines to countries with health crises under compulsory licence. Despite legislation, a compulsory licence has never been granted in Australia with only a small number of applications made. Despite the TRIPS Agreement and Australia's national Intellectual Property Laws, Australia inherently supports TRIPS-plus propositions as a signatory of the Comprehensive and Progressive Agreement for Trans Pacific Partnership (CPTPP) [15]. These TRIPS-plus provisions throughout CPTPP fall under four categories [16]:

1. Provisions weakening patentability standards
2. Provisions that extend the patent term in compensation for delays in granting patent or marketing registration approval
3. Provisions that introduce rights relating to undisclosed test data
4. Provisions that link registration of generic products to validity of a patent

Such provisions increase the enforceability of patents and restrict accessibility of essential medicines for LMICs. Low and middle income countries in the Comprehensive and Progressive Agreement for Trans Pacific Partnership such as Brunei, Malaysia, Mexico, Peru, and Vietnam are impacted by these provisions in return for the international trade benefits provided.

The Global Response

Availability

The availability of essential medicines does not always meet the needs of populations where shortages and stock-outs are not uncommon. Procurement issues, especially in LMICs, can arise due to inadequate funding, lack of governance structure, and poor forecasting of demands [17]. This leads to low availability of essential medicines, such as in an Eastern Ethiopian survey it was found that only 16% of the surveyed medicines surpassed the WHO cut-off point of 80% availability [18]. Likewise, essential treatments for asthma and chronic obstructive pulmonary disease were largely unavailable and unaffordable in LMICs, with most medicines not meeting WHO's Global Action Plan target (80% availability) and costing over 1 day's wage of the lowest paid government worker [19]. These essential medicines can be bought by governments, the private sector or donated. However, due to issues arising when pharmaceutical companies have donated medicines, such as medicines being inappropriate for the country's needs or of poor quality, WHO stipulated guidelines that streamline the process for donating pharmaceuticals [20]. The four core principles include [20]:

1. Maximum benefit to the recipient.
2. Respect the wishes and authority of the recipient.

3. No double standards of quality.
4. Effective communication between donor and recipient.

The supply and demand of essential medicines are not always met and need to be improved in order to improve access to essential medicines. One such group that could improve access to essential medicines are non-governmental organisations (NGOs). NGOs are well known for their role in providing humanitarian aid. However, there are several NGOs which are responsible for facilitating national and international trade [21]. These trade NGOs can help counter the lack of availability of essential medicines, especially in countries without effective governmental activity and regulation [22]. NGOs can influence the availability of essential medicines in two ways: by directly improving price and accessibility of medication, and by influencing the behaviour of other market participants [22].

Tanzania is an example where trade NGOs have improved access to medicines. In Tanzania, Action Medeor Tanzania, a non-profit wholesaler with German support; and Mission for Essential Medical Supplies complement the Medical Stores Department [23]. The Medical Stores Department is an autonomous department under the Tanzanian Ministry of Health that is involved with managing an efficient and cost effective system of production, procurement, storage, and distribution of medicines by all public health facilities [24]. For 24 tracer medicines, the NGOs were buying them at significantly lower prices than private wholesalers in 2006. These savings were passed on in the form of lower prices to NGO facilities [22].

Accessibility

In 2017, WHO estimated 2 million people globally were not able to access essential medicines [25]. Accessibility can be correlated to the relationship between the supply of medication, and the location of patients in need [25]. Inequity in health care provision, when considering access to essential medication, is amplified when considering the resources, travel time, distance, and cost of providing those in developing countries with essential medicines [25]. This becomes more prevalent in isolated, rural areas of the developing world, where Primary Health Care (PHC) is scarce.

The COVID-19 pandemic provides a recent example of inequitable global distribution of resources. The WHO COVAX utility, a part of the Access to COVID-19 Tools (ACT) Accelerator, was developed in response to the delay that was seen during the 2009 H1N1 pandemic in vaccinating those in LMICs [26]. This helped to mitigate inequitable access, however, the measures could not keep up with the intense global demand, and the financial resources of high income countries. Vaccine inequity generally follows the pattern of developed countries purchasing and stockpiling as much of the vaccine as possible, before the UN and WHO have to intervene to ensure

LMICs have access [26]. Apart from widespread illness and the loss of life, inequitable access to essential medicines and vaccines causes collateral effects on the economy of countries, which further displaces already at-risk communities and intensifies the need for more financial aid [27].

Neglected Tropical Diseases (NTDs) are a group of 20 conditions that are more prevalent in tropical areas and disproportionately affect women and children especially in impoverished communities [28]. NTDs pose a large public health challenge as they are mostly vector borne, complex lifestyles, and are maintained by animal reservoirs [28]. A lack of access to medication is a challenge in the treatment and management of NTDs. This is recognised by the WHO who have a longstanding collaboration with German pharmaceutical company Bayer AG [29]. A 5 year agreement between Bayer AG and WHO was renewed in 2021 and provides access to medicines in the treatment of Chagas disease and human African trypanosomiasis (sleeping sickness) [29]. This is all part of the WHO roadmap for NTDs 2021-2030, which comprises 3 pillars: to accelerate programmatic action, to intensify cross-cutting approaches, and to change operating models and culture to facilitate country ownership [30]. It is essential that collaboration with major pharmaceutical companies continue to ensure that the 2030 goals can be achieved. One of the goals is to eradicate three NTDs by 2030: trachoma; the three major soil transmitted helminths - roundworm, whipworm, and hookworm; and schistosomiasis. All of these NTDs have available treatment options that are effective and usually curative, but are often limited [31]. Due to the limited accessibility, there is significant risk of resistance developing within affected populations [31]. As such, it is critical that research and medication development continue for NTDs. Continued treatment development allows for new possibilities to eradicate other NTDs and a reduced risk of resistance, especially for NTDs like schistosomiasis where there is currently reliance on a single treatment [31].

Accommodation

Accommodation on the global scale largely comes down to the relationship between pharmaceutical companies and countries. Pharmaceutical companies often control the supply and access of medications to countries. As such, pharmaceutical companies play an important role in ensuring equitable access to essential medicine. It is not uncommon for pharmaceutical companies to have opposing views to EMLs, and efforts to increase essential medicine accessibility. In 1987, the International Federation of the Pharmaceutical Manufacturers Associations (IFPMA) called the medical and economic arguments for the EML “fallacious” and claimed that its introduction “could result in sub-optimal medical care and might reduce health standards [6].” Over the decades, this view has not changed

significantly and was reiterated in the latest IFPMA Paper on Essential Medicine published in 1990 [32].

Contributing to the inequitable access are global trade and patent regulations as discussed above. These serve as a mechanism for pharmaceuticals to maintain a monopoly and often present as a massive obstacle for countries in their efforts to obtain essential medicines. In the 2019 IFPMA Position Statement on Essential Medicines, this issue was brought to the forefront; "In recent years there have been proposals, such as automatic compulsory licensing, for all medicines on the EML. Proposals like these weaken the incentive to invest in the development of products that address global health priorities [32]."

It is acknowledged that pharmaceutical companies function based on a sustainable business model that ensures the continuity of the company. However, there are still several roles to be played by pharmaceutical companies without compromising their commitment to their business strategies. These roles include but are not limited to [33,34]:

1. Licensing generic firms to manufacture affordable versions of their patented medicines.
2. Adjusting the prices of their medicines based on the purchasing power of low-income markets.
3. Conducting Research and Development in developing nations with high prevalence of neglected diseases.
4. Collaborating with local governments during a natural disaster, epidemic, or public tragedy.
5. Adopting self-regulation and transparency to provide essential public services.
6. Promoting competition and collaboration to encourage scientific progress in pharmaceutics.
7. Objective reporting on their access to medicines commitments by external validation and/or independent auditing.

Affordability

The affordability of essential medicines is a large factor in determining accessibility. Higher cost of these medicines is generally correlated with lower accessibility. This crisis is especially observed in LMICs, where people have to spend a greater proportion of their health budgets on pharmaceuticals, and up to 90% of those in

developing countries purchase medicines out-of-pocket, making it the largest expense after food [35]. In Eastern Ethiopia, almost one third of the medicines in the private sector were over four times more expensive compared to the international reference prices [18]. Similarly, in Uganda, where malaria is the single largest cause of illness, effective antimalarial medicines such as first-line treatment of artemisinin combination therapies (ACTs) were considerably more expensive than chloroquine and sulfadoxine which are widely available, but have become ineffective against malaria parasites over time [36]. The Global Fund subsidised ACTs in the private sector which improved from 4 days' wages in 2008 to half-a-day's wages in 2018 [36]. Despite the immediate benefit from involvement of not-for-profits, once donor funding termination occurs, there is a major supply disruption as well as lack of pathways for business continuity [36].

Three main themes emerged from the 2021 WHO Fair Pricing Forum on reaching fairer prices for medicines: transparency of pricing, improving government pricing policies and regulations, improving selection and effective use of medicines [37]. In 2020, WHO also published several pricing policy guidelines to improve affordable access to medicines. When setting prices for essential medicines, countries should consider the following guidelines as possible approaches to ensure affordability [38]:

1. **External reference pricing**, where prices are set by using the benchmark of prices for the same medicines in other comparable countries.

2. **Internal reference pricing**, where prices are benchmarked against the price of products with the same medicine or therapeutically similar medicines within the same country.

3. **Value-based pricing**, where prices are set after considering how much the medicine is 'worth' compared to existing available treatments for the same conditions. This includes assessing factors such as how many years of life a treatment can save, how much a treatment can improve the quality of life of the patient, and if a treatment can save the system resources by avoiding hospitalisation or longer-term care.

4. **Regulation of mark-ups across the pharmaceutical supply and distribution chain**, where governments set rates for how much suppliers can add to the costs of medicines as they sell the medicine along the supply chain and eventually to patients.

5. **Promoting price transparency** to make sure that the prices of medicines and how such prices are set are known to all relevant stakeholders.

6. **Tendering and negotiation**, where prices are set according to the best offer from suppliers.

7. **Promoting the use of quality assured generic and biosimilar medicines**, to encourage the use of versions of brand-name products that have exactly the same or similar characteristics as the original product.

8. **Pooled procurement**, where financial and non-financial resources are pooled to create greater purchasing power and improve efficiency.

9. **Cost-plus pricing**, where prices are set by assessing the costs of producing the medicine, plus a profit margin.

10. **Tax exemptions or tax reductions**, where taxes on pharmaceutical products are removed or reduced.

Acceptability

Social and cultural expectations of patients can often be overlooked as an important factor in determining accessibility and adherence to medication regimens. This is especially true in LMICs, where there has been limited research conducted on the acceptability of all health services. Studies in Bangladesh and India have suggested that patients' perceptions of quality of the medication can be a more important determinant of medication adherence than price [39,40]. In LMICs, studies show that village doctors are more popular among the residents due to fewer social barriers, helpful attitudes, and longstanding relationships [41]. At-risk minorities, such as poor women, are more likely to face health services that are not culturally safe or acceptable and are therefore far less likely to seek treatment for illness [41]. When there is a lack of acceptable PHC, access to essential medicines becomes compromised, and minority groups are the most adversely affected by this [41].

Improper pain treatment in LMICs brings to the foreground the inequity in access to essential medication surrounding a medication's acceptability [42]. The opioid epidemic in high income countries, particularly the United States, Canada, and Australia, has led to high levels of addiction and overdose related deaths [43]. This has had a negative impact on pain management globally [42]. It has created a strong reluctance to treat pain with opioid analgesics, especially in LMICs, therefore creating unnecessary suffering for those in end-of-life care with terminal illnesses [42]. It is estimated that 50% of the world's poorest populations live in countries that receive only 1% of the opioid analgesics distributed worldwide [44]. Physicians' attitudes towards pain management have been identified as one of the main factors negatively affecting opioid use [45]. The United Arab Emirates has high incomes and Human Development Index, but one of the lowest estimates of opioid analgesic consumption worldwide. This example highlights the impact cultural and religious

principles have in restricting opioid analgesic use in pain management practice [45]. Western Europe provides balanced and rational regulation on opioid prescription for pain management, where limited nonmedical use is reported [44]. Access to essential pain medication should be equitable globally. LMICs need more support in accessing opioid analgesics for pain management and creating a culturally and socially acceptable framework for pain management. Acceptability of medications essential to pain management of populations should not be restricted due to the negative stigma associated with their historical nonmedical use in high income countries.

The Australian Response

Context of Medicine Dispensing in Australia

In Australia, most medicines are dispensed at community pharmacies [46]. There are some prescription medicines which are sourced from the patient's General Practitioner, and others that are readily available over-the-counter without requiring a prescription. There are also both public and private hospital pharmacies that supply emergency departments, outpatient clinics, and inpatients upon discharge [46]. Other medicine dispensing methods are within Aboriginal Health Services; doctors' surgeries, ambulances, and remote farms having medicines for emergencies [46].

The Pharmaceutical Benefits Scheme (PBS) in Australia reimburses the cost of selected medications [46]. These prescriptions can only be written by a doctor, dentist, optometrist, midwife or nurse practitioner but not pharmacists [46]. A PBS prescription may also be written by a registered nurse or Aboriginal health worker in some locations, such as parts of the Northern Territory [46].

Section 100 of the National Health Act (1953) allows for special access arrangements where medicines cannot otherwise be supplied [47]. In the late 1990s, a study found that if equal access to the PBS was to be achieved between Aboriginal and Torres Strait Islanders and non-Indigenous Australians there needed to be an extension to Section 100 (S100) to expand access to medication in rural and remote areas [47]. The S100 scheme started in 1999, and by 2004, included 47 Aboriginal Controlled Community Health Services and 128 state and territory operated Aboriginal Health Services [47]. S100 allows patients in remote area Aboriginal health services to receive medications at the time of consultation, without a prescription and without charge [47]. Multiple reviews have found that this scheme has redefined the accessibility and adherence of medication in rural and remote Australia [47].

Availability and Affordability of Medicines

Australia is vulnerable to medicine shortages due to the decline in local medicine manufacturing and complex global supply chains, with >90% of medicine being imported [48]. Since Australia only controls 2% of the global pharmaceutical market, larger markets are given precedence when the global supply chain is disrupted [49]. To inform healthcare providers about ongoing shortages, the Therapeutic Goods Administration (TGA) established the Medicines Shortage Information Initiative (MSII) in 2014. The MSII was a voluntary reporting scheme that allowed sponsors to inform the TGA of existing shortages. The TGA relayed that information to healthcare providers on a website. This policy has been heavily critiqued because many sponsors did not inform the TGA of critical shortages and there was low awareness of this resource within the healthcare field [50,51]. A survey from the Society of Hospital Pharmacists of Australia membership revealed that 100% of respondents experienced a medication shortage between 2016 and 2017 [52]. To address ongoing supply chain issues, the TGA mandated medicine companies to publicly report medication shortages in 2019 [51].

Existing medicine shortages were further exacerbated by the COVID-19 pandemic as many generic medications are produced within China and India [53]. These countries were adversely affected by the COVID-19 pandemic, this caused issues in the supply chain, due to Australia not having the capacity to manufacture essential medicines. More than 300 medicines are currently in short supply in Australia, including the most prescribed antibiotics (amoxicillin, cefalexin, and metronidazole) [54]. To address critical shortages, the TGA announced the new Minimum Stockholding Requirements policy [55]. Commencing July 1st, 2023, this policy requires manufacturers of specific medications under the PBS to hold 4-6 months of stock in Australia [55]. Stockholding data is to be disclosed every 6 months to the Price Disclosure Data Administrator (PDDA), breaches to stockholding are also to be disclosed to the PDDA [49].

Australia supports universal access to essential medicines on a domestic level, with the National Medicines Policy representing a cooperative state and government commitment to promote “equitable, timely, safe and affordable access to a high-quality and reliable supply of medicines and medicines-related services for all Australians” [56]. This is primarily accomplished by the PBS, which caps the cost of medicines for Australians. This is evident through the addition of Trikafta, a cystic fibrosis medication, to the PBS heavily reducing costs from $250,000 per year to $360 [57]. In an effort to enhance affordability of medication, the PBS co-payment was reduced January 1st, 2023 for the first time in 75 years with general patients now paying $30.00, compared to the previous $42.50 [58].

To further reduce the burden of cost, the PBS also offers a concessional scheme for those holding one of the following cards: Pensioner Concession Card; Commonwealth Seniors Health Card; Health Care Card; or DVA White, Gold, or Orange Card. Under the concession scheme, individuals are eligible for a reduced co-payment of $7.30 [59].

There is also the PBS Safety Net scheme which aims to protect patients and their families who require a large number of PBS items. When a patient reaches the Safety Net threshold within a calendar year, they qualify to receive PBS items at an even cheaper price or free of charge for the remainder of the calendar year. From 1 January 2023, the general patient Safety Net threshold is $1,563.50. When reached, the individual may apply for a Safety Net concession card and pay the concessional co-payment amount of $7.30. The concessional Safety Net threshold is $262.80. When reached, the individual may apply for a Safety Net entitlement card and may receive medications and treatments free of charge [60].

However, the list of medicines subsidised by the PBS represents those that are cost effective, rather than essential, with consideration of economic cost-benefit of these patients receiving the pharmaceutical treatment at a subsidised price [61]. As a result, some medications listed on the WHO's essential medicines list are not included in the PBS.

There are also instances of medications being on both the EML and the PBS, for certain conditions but not others. This introduces the possibility of medications being prescribed for uses beyond the PBS listing. Gonadotropin-releasing hormone antagonists such as goserelin, leuprorelin, and triptorelin, are listed on both the EML and PBS for the treatment of malignant neoplasms of breast and prostate, central precocious puberty, endometriosis, and anticipated premature ovarian failure [62,63]. In addition to this, they are also an extremely effective and safe way to reduce testosterone levels through the downregulation of gonadotropin-releasing hormone receptors in the pituitary gland [64]. However, despite being commonly used for puberty suppression in transgender teenagers, they are not subsidised for this use and expensive to acquire [64].

Rural, Regional, and Remote Communities

For around 7 million Australians who live in rural and remote areas, geographical isolation presents significant challenges to accessing essential medicines [65]. Rural Australians are particularly vulnerable to medicine shortages, with disruptions to the supply chain underscored by transportation issues and extreme weather conditions. Medicine shortages have vast implications for patients, with timely access to medicines crucial to clinical and economic outcomes [66].

Access to essential medicines in rural and remote areas is further challenged by unprecedented shortages in prescribers and community pharmacies [67]. Whilst medication is primarily prescribed by medical practitioners, pharmacists play a critical role in dispensing medication, educating patients and ensuring patient safety. As such, with a significant under-representation of rural general practitioners and only 7.8% of Australian pharmacists working outside major cities or inner regional areas, the maldistribution of the medical workforce further limits access [68]. These issues were exacerbated by COVID-19, whereby the delivery of vaccinations through pharmacies and unprecedented demand for medications placed additional strain on an already struggling workforce [69].

Aboriginal and Torres Strait Islander Communities

Access to essential medicines is critical to Aboriginal and Torres Strait Islander peoples, who experience overrepresentation of morbidity and mortality due to illnesses when compared to non-Indigenous Australians [70]. Strategies have been undertaken by the Australian Government to address barriers to Aboriginal and Torres Strait Islanders access to medicines on the PBS by the Remote Area Aboriginal Health Services (RAAHS) Program and the Closing the GAP (CTG) PBS co-payment measure. However, there is a difference between Aboriginal and Torres Strait Islander PBS expenditure when compared to their non-Aboriginal and Torres Strait Islander counterparts. In 2016-2017, the average PBS expenditure per Aboriginal and Torres Strait Islander person was 29% of a non-Indigenous Australian, while the rate of Aboriginal and Torres Strait Islander people experiencing burden of disease and injury is 2.3 times of non-Indigenous Australians [71]. The Australian Government must be held accountable for the higher burden of disease but lower PBS medication access among Aboriginal and Torres Strait Islander peoples. This concerning statistic highlights the need for stronger, more culturally safe public health campaigns to increase PBS usage and reduce the burden of disease. The systemic issues surrounding access to essential medicines for Aboriginal and Torres Strait Islanders is an important issue the Australian Government should continue to consider as a contributing factor to the overall health of Aboriginal and Torres Strait Islander peoples. Notably, interventions must be designed and led by Aboriginal and Torres Strait Islander communities.

As the “Commonwealth Closing the Gap Annual Report 2022” discloses, the life expectancy between Aboriginal and Torres Strait Islander peoples and non-Indigenous Australians continues to differ, with 7.8 years for males and 8.6 years for females [72]. The largest gap in mortality rates between Aboriginal and Torres Strait Islander peoples and non-Indigenous Australians is attributed to circulatory diseases in 2015 to 2019, this could imply that a lack of suitable cardiac care in

conjunction with difficulty accessing medication and treatment increases the risk of Aboriginal and Torres Strait Islanders to suffer from circulatory diseases [73].

Affordability remains a major barrier for Aboriginal and Torres Strait Islanders to access essential medicine. Results from the 2018–19 National Aboriginal and Torres Strait Islander Health Survey showed that cost was the most common reason for not filling a prescription in the last 12 months, which was reported by 36% of participants [71].

Cultural appropriateness of health services is also an important determinant where barriers to access to essential medicines may occur if dispensing health services fail to acknowledge differences in concepts of health between Aboriginal and Torres Strait Islanders and non-Indigenous Australians. Due to ongoing colonial violence, and institutionalised racism, cultural safety may not be achieved, leading to reluctance to engage and therefore not being properly aware of the services available. This can continue to impede communications leading to inequitable access [74].

Role of Medical Students

Medical students are in a unique position both as future medical professionals and as students within universities that contribute to medical research [75]. Through international medical electives, and rural placements in Australia, medical students become aware of the lowered health outcomes caused by insufficient access to essential medications. Thus, an awareness of the broader context of issues surrounding the pharmaceutical industry and delivery of medication is integral to medical students' understanding of equitable access to healthcare and medicines. As members of an increasingly global community, medical students must demand equitable access to medicines through ensuring their research and medical discoveries are beneficial for resource limited countries, in order to properly care for all peoples without monetary or political restriction. It is a social responsibility and professional duty to advocate on behalf of our patients and, as such, stay locally responsive and globally connected.

Potential Solutions

The WHO has identified that access to essential medicines is a multi-dimensional problem which requires comprehensive national policies and strategies. Such strategies should align public health needs with economic and social development objectives and promote collaboration with other sectors, partners and stakeholders [76]. The 71st World Health Assembly gave rise to an Access to Medicines, Vaccines and Other Health products eight-step action plan for 2019 to 2023. It is centred around two key strategic areas: ensuring the quality, safety and efficacy of health products; and improving equitable access to health products [76].

There are 3 steps for ensuring the quality, safety and efficacy of health products:

1. Regulatory system strengthening.
2. Assessment of the quality, safety and efficacy/performance of health products through prequalification.
3. Market surveillance of quality, safety and performance.

The 5 steps for improving equitable access to health products are:

1. Research and development that meets public health needs and improves access to health products.

2. Application and management of intellectual property to contribute to innovation and promote public health.

3. Evidence-based selection and fair and affordable pricing.

4. Procurement and supply chain management.

5. Appropriate prescribing, dispensing and rational use.

The Lancet Commission, WHO and other UN agencies have collaboratively identified a global accountability framework that aims to create a more robust monitoring system of essential medicines, echoing the success of such frameworks in other initiatives, as shown by UNAIDS' HIV progress reports [77]. In this framework, there are four priorities:

1. High-level political support.

2. Strategic generation, analysis and usage of data for decision making.

3. Support from innovative technologies to aid in data collection.

4. Global advocacy to ensure engagement of all stakeholders at national and international levels.

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