Policy Document

Access to Essential Medicines Policy

Background

The Australian Medical Students' Association (AMSA) is the peak representative body of Australia's 17,000 medical students. AMSA believes that all communities have the right to the best attainable health and actively seeks to advocate on issues that may impact health outcomes.

A major issue contributing to health outcomes is the fair access to medicines and medical services deemed essential, as pharmaceuticals are integral to humanity's efforts to prevent and treat the vast majority of common diseases. The World Health Organization (WHO) defines essential medicines as "those that satisfy the priority health care needs of the population", and has developed a list of over 350 medicines that are regarded as such.[1] Advocacy around this topic has evolved over the past twenty years to also include diagnostic testing, vaccines, and medical devices in addition to pharmaceuticals.

The global response

It is estimated that one-third of the world's population lacks access to essential medicines.[2] As a result, preventable or easily treatable diseases claim millions of lives each year.[3] A range of factors compromise access to essential medicines, including company monopolies on high-cost pharmaceuticals as a result of long-term patent protection, the dependence on market-driven research and development agendas that may not target population-specific medical needs,[4] and insufficient health care systems in underdeveloped nations that result in a failure in delivery potential.[5]

The "90/10 Gap" is a significant barrier to access to essential medicines, with less than 10% of world research going towards improving health in developing countries that account for over 90% of the world's preventable years of life lost.[6] Médecins Sans Frontières (MSF) highlighted the need for government support on the issue, with trade agreements often acting as a barrier to maintaining affordable essential medicines.[7] In response, the Doha Declaration on Trade-Related Aspects of Intellectual Property (TRIPS) and Public Health allows World Trade Organisation (WTO) member states to circumvent patents when it is in the interest of increasing access to essential medicines, but only when it is a 'public health emergency'.[8]

On 6 December 2005, the TRIPS Protocol was amended to enable pharmaceutical products to be exported under compulsory license. This provided the legislation for public health problems in developing and least-developed countries to be addressed by gaining access to products that are needed. Australia became a signatory of the TRIPS Protocol in 2007. In 2014, the Intellectual Property Laws Amendment Bill reiterated the Australian Parliament's intent for distribution of essential medicines to less developed countries, and to 'encourage innovation, investment and international competitiveness'.[9]

On 9 February 2015, the Intellectual Property Laws Amendment Bill was passed, resulting in the implementation of the amended TRIPS Protocol in Australia.[10] This will permit Australian pharmaceutical manufacturers to export patented medicines to countries with health crises under compulsory license beginning 25 August 2015. However, concerns have

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been expressed by groups such as MSF about the implications of regional trade agreements such as the Trans-Pacific Partnership (TPP), which call for stronger intellectual property laws that may limit access to essential medicines.[11] Similar provisions are also included Asia–Pacific-based Regional Comprehensive Economic Partnership.[12]

Leaked drafts of the TPP have included an Investor-State Dispute Settlement (ISDS) process amongst their provisions. ISDS allows foreign investors to sue national governments over actions, including public health policies and interventions, which they believe cause a reduction in the value of their investment. This compromises the ability of nation states to retain autonomy to enact healthy public policy; they should not be beholden to pharmaceutical companies and their profits. Litigation has already been initiated against Australia on the basis of the ISDS mechanism in a separate bilateral investment agreement with Hong Kong over Australia's *Tobacco Plain Packaging Act 2011 (Cth)*.[13] Furthermore, in 2013, Eli Lilly launched a case against the Canadian government over a decision to invalidate two of their pharmaceutical patents which did not meet patenting standards.[6] ISDS mechanisms, and the threat of their implementation, could jeopardise not only access to essential medicines both in Australia and further afield, but also the government's ability to legislate in the public interest.

The most recent leaked draft of the TPP intellectual property chapter shows that countries are continuing to consider provisions that will expand and extend monopoly rights for pharmaceutical companies in most TPP countries.[14] TPP provisions will also entrench, at the regional level, an intellectual property regime that has failed to deliver both affordable access to medicines and real innovation benefiting those in developing countries. However, further provisions are being negotiated that could also place limits around pharmaceutical regulation intended to contain costs and promote affordable access.

In 2012, the Asia–Pacific Conference held in Sydney focused on the National Medicines Policy, and Australia was a delegate in attendance. Its efforts were focused on actively implementing a national medicines policy to promote universal access to, and rational use of, essential medicines. This was held in follow-up to the 1995 conference of the same name, where discussions around this topic were first put forward to low and high income countries in the Asia Pacific region. The four themes of the Australian National Medicines Policy included affordable access, safe and efficacious medicines of appropriate quality, a viable and responsible pharmaceutical industry, and the rational use of medicines. The issues brought about in this conference were the production of poor-quality medicines internationally, causing death through counterfeit and contaminated materials.[15]

Australia's Response to Access to Essential Medicines

Australia supports universal access to essential medicines on a domestic level, with the National Medicines Policy representing a cooperative state and government commitment to promoting "timely access to the medicines that Australians need, at a cost individuals and the community can afford".[16] This is primarily accomplished via the Pharmaceutical Benefits Scheme, which subsidises the cost of medicines such that expenses for consumers are capped. However, the list of drugs subsidised by the PBS represents those that are cost-effective, rather than essential, due to economic concerns.[17]

Australia has an important part to play in supporting developing countries in the region in ensuring access to medicines. Despite the 2012–2013 Australian Government recommendation that patents be reduced, leaks from the TPP suggest that Australia currently supports some of the US proposals to extend them.[14] Australia has sought to undermine the WHO's authority to advise member states on health implications of the trade agreements, aiming to augment pharmaceutical intellectual property's mandate by introducing agencies that regulate essential medicines. One such way such undermining has been achieved is by Australia's contribution to reducing the monetary donations to the WHO

by member states, essentially freezing their capacity to continue resolution discussions and the use of TRIPS flexibilities.[18]

Universities play a key part in funding and providing the areas for research on medicinal products, vaccines, tools, and procedures that ultimately are licensed for public use. One student-led organisation advocating for equal access to health care is the Universities Allied for Essential Medicines (UAEM), which has developed a 'Global Access Licensing Framework' that universities around the world may elect to sign. Instead of universities selling new medical discoveries to pharmaceutical companies, whereby the companies can patent medications developed through these discoveries for twenty years preventing others from producing the medication, signatory universities state that they agree to sell their research in a more socially responsible way. This enables the production of generic versions that can be sold in resource-limited countries earlier.[19]

Medical students are in a unique position both as future medical professionals and as students within universities that contribute to medical research.[20] Tthrough international medical electives and other educational activities, medical students bear witness to the health outcomes caused by insufficient access to essential medications. In addition, pharmaceutical companies direct advertising towards medical students. Thus, an awareness of the broader context of issues surrounding the pharmaceutical industry is essential. As members of an increasingly global medical community, medical students must demand the equal access to medicines, in order to properly care for all peoples without monetary or political restriction. It is a moral imperative and a professional expectation that we advocate for the needs of our patients and, as such, stay locally responsive and globally connected.

Position Statement

AMSA believes that:

1. Access to essential medicines is a necessary step towards realising the human right to health;
2. The conditions of the current global pharmaceutical industry create certain barriers to the access of essential medicines, and stakeholders in high income countries have a responsibility to allocate resources, pass legislation, and negotiate trade agreements that minimise these barriers.
3. Health systems in all countries should be supported in their capacity to provide access to essential medicines.

Policy

AMSA calls upon:

1. Medical students and healthcare professionals to:
    a. Acknowledge that health professionals, medical, nursing and allied health students, university researchers and academic staff, are well placed to become leaders and supporters of practical initiatives that promote humanitarian licensing provisions for drugs, diagnostics, vaccines, and devices and research on neglected disease outlined in this policy, and consider:
        i. Engaging in personal, peer-to-peer and public education of access to essential medicines and neglected disease issues, and use this knowledge to initiate innovative responses to overcome challenges in the discovery, development, production, licensing and distribution of medications;

ii. Advocating for the inclusion of access to essential medicines and neglected disease in aspects of current and future medical and health sciences curricula;
iii. Partnering with existing organisations to promote awareness within the student body, staff and public arenas of the issues surrounding access to essential medicines;
iv. Encouraging policy reform within universities to make publicly-funded research publicly available; and
v. Supporting and contributing to AMSA-led initiatives and campaigns to advocate for greater access to essential medicines.

b. Be mindful of opportunities to promote humanitarian licensing provisions for drugs, diagnostics, vaccines, and devices and research on neglected disease:
i. Incorporate practices that promote rational use of medicines, where they are available, into the core activities of health professionals and patients;
ii. Uphold ideals of equity and justice in the prescription and provision of medications, and avoid the unnecessary waste of inappropriate medications; and
iii. 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.

2. Universities and other publicly funded health research institutions to:
a. Acknowledge that research universities are largely publicly funded and have an imperative to develop and adopt a global access strategy to ensure humanitarian licensing provisions for drugs, diagnostics, vaccines, and devices and research on neglected diseases. Such a strategy might include:
i. Incentives and systems to promote research and development to address neglected diseases;
ii. Incorporating licensing provisions that allow exemption of intellectual property use where appropriate to facilitate low-cost access to data and materials for generic production of essential medicines in majority world nations such as those outlined in Universities Allied for Essential Medicines' Global Access Licensing Framework; and
iii. Partnering with third-party organisations in research, development and distribution, which share the goal of improving access in majority world nations.

3. The pharmaceutical industry to:
a. Acknowledge their considerable influence on access to essential medicines by increasing attention towards the actions and considerations that can be taken in order to improve global access to essential medicines;
i. Act 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. Take action to enable generic production of affordable drugs, which is essential to maintain a minimum of healthcare service for the world's poorest and most vulnerable populations;
iii. Participate in programs/partnerships, such as innovative financing arrangements and global patent pools that have been developed to incentivise research and development of medicines to address diseases that predominantly affect the world's poor;

iv. Redistribute their research and development budget and resources to more closely reflect the morbidity and mortality of the global burden of disease; and
v. Cooperate with governments and international trade organisations to further develop tiered pricing systems to overcome financial barriers to access to essential medicines in majority world nations.

b. Improve health literacy and consumer knowledge about medicines; by understanding product contents, consumers can make more informed purchases. For example, via television advertisements, information leaflets in general practice waiting rooms, radio advertisements and discussion forums.

4. The Australian Commonwealth Government to:
   a. Acknowledge the potential for excessive intellectual property (IP) regulations to create significant barriers to humanitarian licensing provisions for drugs, diagnostics, vaccines, and devices;
      i. Resist increasing monopoly protections through new or existing bilateral or regional free trade agreements (FTAs) such as the Trans-Pacific Partnership (TPP). In particular avoid legal and intellectual property clauses that may decrease access to essential medicines or services or limit any sovereign government's ability to legislate to protect public health including, but not limited to, investor state-dispute settlements, "evergreening", data exclusivity, patent lengthening and removal of pre-patent challenges.
      ii. Maintain and facilitate usage of flexibilities in the Trade Related Intellectual Property Rights (TRIPS) legislation as reaffirmed in the Doha Declaration; and
      iii. Increase transparency of FTA negotiations, particularly the Trans-Pacific Partnership (TPP), that may erode the flexibility of TRIPS; to facilitate scrutiny by experts and the Australian public;
   b. Share information regionally about manufacturing quality of pharmaceuticals produced within Australia, and gain information from the USA, Asia and neighbouring countries about imported pharmaceutical quality and packaging;
   c. Ensure chemical analysis for all medicines by regulatory authorities;
   d. Promote the use of generic medicines and increase health literacy through media campaigns, including reducing the inappropriate use of antibiotics, in an effort to reduce antibiotic resistance and thus future use of higher-cost, new medicines;
   e. Include access to essential medicines, Medicare and related healthcare services to foreign peoples visiting or working within Australia, including but not limited to asylum seekers, foreign aid workers, refugees, and those waiting for permanent Australian citizenship; and
   f. Fulfil Australia's commitment to the Millennium Development Goals, including Target 8e to cooperate with pharmaceutical companies to provide access to affordable essential drugs in majority-world nations.

5. The AMSA Executive to:
   a. Publicly support and collaborate with organisations and initiatives that promote humanitarian licensing provisions for drugs, diagnostics, vaccines, and devices and research in neglected diseases through direct statements, projects and campaigns;
   b. Actively advocate for institutional and curricular reforms by Australian medical schools to include content related to improving global medicines access and research in neglected disease per the above points;

c. Encourage all Universities to sign the Global Access Licensing Framework for equal distribution and production of new health care discoveries in lower income countries;
d. Where appropriate, lobby State and non-State actors to pursue the recommendations of this policy document per points 3.a and 4.a and include medicines access as a key component of foreign aid efforts;
e. Encourage and support educational and service activities pertaining to access to essential medicines among AMSA ThinkTanks, local Global Health Groups, Medical Students' Societies and individual members-at-large;
f. Actively advocate for the patients who are denied their right to health because of poor access to essential medicines; and
g. Actively support medical students to initiate UAEM chapters at their universities.

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