Perspective

Approaches to improving access to essential cancer medicines in the WHO South-East Asia Region

Meenakshi V Chivukula¹, Klara Tisocki²

¹Independent consultant, New Delhi, India, ²World Health Organization Regional Office for South-East Asia, New Delhi, India

Correspondence to: Dr Klara Tisocki (tisockik@who.int)

Abstract

The high cancer burden in the World Health Organization (WHO) South-East Asia Region represents not only a significant cause of death, disability and suffering but also a major threat to development. In 2015, the need for equitable access to cancer treatments was underscored by the addition of 16 cancer drugs to the 19th WHO model list of essential medicines, including three high-cost medicines. This paper explores strategies to improve access, including – but not limited to – managing costs through regional cooperation; coordinated procurement mechanisms; price controls; differential pricing; and licensing agreements. The composition of the region, with small and large pharmaceutical markets with a range of manufacturing capacities and supply-chain issues, offers a unique frame of comparison and consideration for access issues. Different approaches are needed that are tailored to specific country situations. However, in the absence of global collaborative funding mechanisms, the region can advocate now, with one voice, for regional action to improve the affordability and availability of essential cancer medicines and align national cancer-control strategies to leverage regional strengths. Delays will lead to more premature cancer deaths and more households in the WHO South-East Asia Region being impoverished through out-of-pocket payments for cancer medicines.

Keywords: access to health care, antineoplastic drugs, national health policy, South-East Asia, World Health Organization

Background

The cancer burden in the World Health Organization (WHO) South-East Asia Region is high, with 1.1 million cancer-related deaths and 1.7 million new cancer cases in 2012.¹ The annual number of new cancer cases globally is projected to increase from 14.1 million in 2012 to 21.6 million by 2030, yet barriers in access to safe, quality, effective and affordable options for prevention, detection and treatment continue to exist, especially in low- and middle-income countries, where patients often present with advanced disease, further limiting treatment options and benefits.² Management of cancer is complex and can be expensive. In high-income settings, cancer is a major economic burden and political inability to ensure fair access to affordable cancer treatment is criticized.³ In lower-income settings, such as the countries of the WHO South-East Asia Region, the challenge is therefore multiplied, since access to cancer medicines and other aspects of cancer care is severely limited.

In 2014, one initiative to improve access to cancer medicines in lower-resource settings was undertaken by the Union for International Cancer Control (UICC).⁴ At the invitation of WHO, UICC undertook the first comprehensive review in 15 years of the cancer medicines included in the WHO model list of essential medicines (WHO EML). A new, disease-based methodology was used that started by identifying the cancer types that would most benefit from systemic treatment and/or that cause the largest burden on the population.⁴ The UICC review resulted in significant changes to the 19th revision of the WHO EML in 2015,⁵ with 16 cancer drugs – including three high-cost medicines – being added.

This issue of the WHO South-East Asia Journal of Public Health reports the results of an investigation to quantify the extent to which the expanded WHO EML influenced inclusion of cancer medicines in the most recent national lists of essential medicines of the countries of the WHO South-East Asia Region, and an assessment of the availability and affordability of selected cancer medicines in countries in the region.⁶ The results indicated that there has been no significant shift in recent years in increasing the inclusion of essential cancer medicines in national lists of essential medicines, despite some lists in the study being dated post 2015.⁶ With respect to the availability and affordability of cancer medicines in the region, the picture is mixed but concerning, with a significant proportion of countries requiring patients and their families to bear full out-of-pocket costs.⁶ Clearly, there is an urgent need for different approaches to improve access to essential cancer medicines for countries in the region.
Reviewing cancer medicines on lists of essential medicines

The WHO EML aims to identify the medicines necessary for a basic health system to function. Time will tell whether the 19th WHO EML of 2015 marks a tipping point for access to essential cancer medicines in low- and middle-income countries, and propels a dramatic shift in strategy and global commitment analogous to strides in improving access to essential antiretroviral medicines for HIV/AIDS. In practice, countries of the WHO South-East Asia Region may use the 19th WHO EML as a tool to guide the rational selection of medicines and identify ways to improve public procurement and supply through targeted policies and programmes.

Prioritizing actions to improve access to cancer medicines in low- and middle-income countries

In individual countries, updated national lists of essential medicines can help shape the market and increase generic production of selected medicines, especially when linked to policies for universal health coverage targeting populations and diseases. However, inclusion of essential cancer medicines in national lists is only indicative of the government’s commitment to ensuring access. Policies and initiatives are needed to promote action.

Table 1 details initiatives in the four areas of access to care, new payment methods, cooperation among stakeholders, and research for improving access to cancer medicines in low- and middle-income countries, with examples from the WHO South-East Asia Region. This table expands upon the work of Lopes Jr. et al. in 2013, and identifies quality-assured generic and biosimilar drugs; pricing policies; tiered pricing; health technology assessments; and value-based insurance as priority actions for countries of the region.

Governments have the greatest responsibility in ensuring access to essential cancer medicines, and need policy strategies to improve access. For example, to ensure access to new, patented and expensive medicines for noncommunicable diseases, governments should make full use of the flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and explore the use of compulsory licences for essential cancer medicines. Well-known cases are documented from India and Thailand, of decreasing prices of cancer drugs through compulsory licensing. Ways to counter intimidation from pharmaceutical companies and threats of trade barriers by importing countries should also be documented and shared by countries using TRIPS flexibilities. Importantly, in the WHO South-East Asia Region, there are five countries that meet the United Nations criteria of being a “least developed country”: Bangladesh, Bhutan, Myanmar, Nepal and Timor-Leste. Under the Doha Declaration, these countries can import lower-cost generic medicines produced with compulsory licences. There is an opportunity for these countries to come together to develop pathways to improve procurement under the Doha Declaration, with support from within the region.

Pharmaceutical companies also have a role to play in improving access to essential cancer medicines. In 2017, the Access to Medicine Foundation studied the inclusion of essential cancer medicines in access initiatives by major pharmaceutical companies in low- and middle-income countries, and found that there were access strategies for only 11 of the 56 products that matched the list of essential cancer medicines on the WHO EML. Also, despite the visibility of many such access programmes, they remain poorly evaluated, with limited evidence of meaningful impact.

Adapting health policies to improve access and ensure quality standards

To meet the increasing burden of noncommunicable diseases like cancers, countries need to create an enabling policy environment that engages stakeholders to work together to strengthen medicines management systems for cancer. Priority attention is needed for pricing of cancer medicines; reducing out-of-pocket payments for cancer care; strengthening local pharmaceutical companies that are capable of producing low-cost quality cancer medicines; and rational selection of products for use in public health systems. Special attention should be given to identifying candidates for compulsory licences based on health needs.

Countries can learn from the policies and programmes that contributed to improved access to antiretroviral medicines for HIV/AIDS globally. These include improving price transparency; stimulating production of low-cost generic medicines; and ensuring sustainable differential pricing, with specific licensed-originator, branded-generic and generic products for low- and middle-income countries. Countries in the WHO South-East Asia Region are already taking steps to share price information for medicines and improve price transparency. Additionally, it is also important to keep in mind ground realities, among other barriers to overcome, that reveal the need, for example, for strengthened regulatory capacity and timely support from federal regulatory authorities and WHO. One such case is biosimilar medicines. As with generic medicines, lower-cost biosimilar medicines could help to increase access to treatment in lower-resourced countries, once the patents of innovator biotherapeutic products have expired. WHO launched a pilot of prequalification of rituximab and trastuzumab in 2017 and will also review its 2009 guidelines on the evaluation of similar biotherapeutic products, to ensure that guidance to national regulatory authorities reflects recent evidence and experience. While complex to implement, these innovations are important to making systems work. Ideally, health authorities can take practical actions to review national cancer policy and standard treatment guidelines, strengthen supply chains with quality-assured WHO prequalified products, and advocate for collaborative funding mechanisms. Suggested actions are detailed next.

- Update national cancer policy for the prevention, diagnosis, and treatment of cancer: there are examples of national cancer policy and national cancer-control plans in the WHO South-East Asia Region. Strengthening the implementation of these plans will play a role in improving access to essential cancer medicines. For example, strengthening partnerships can help facilitate resource mobilization; promote shared learning on specific areas like...
### Table 1. Approaches to improving access to cancer medicines in countries of the WHO South-East Asia Region

<table>
<thead>
<tr>
<th>Initiatives</th>
<th>Description</th>
<th>Benefits</th>
<th>Challenges</th>
<th>Example(s) from the WHO South-East Asia Region</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Access to care</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government-initiated access programmes for selected high-cost medicines (through national health insurance)</td>
<td>• Free access to selected very high-cost medicines, including selected essential cancer medicines, to patients meeting strictly defined criteria</td>
<td>• Transparent and equitable health-care rationing, using the national list of essential medicines to define a special category of medicines for insurance coverage</td>
<td>• Challenge to implement</td>
<td>Thailand: selected &quot;high-cost medicines for specific conditions&quot; listed in a subcategory (E2) of the national list of essential medicines are provided free of cost to patients meeting prior authorization requirements</td>
</tr>
<tr>
<td><strong>Universal health coverage</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Government-provided health insurance coverage for the entire population</td>
<td>• Pooling of resources</td>
<td>• Rising costs</td>
<td></td>
</tr>
<tr>
<td><strong>Quality-assured generic and biosimilar drugs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Produced without a licence once patents or exclusive rights expire</td>
<td>• Lower costs to the payer, through increased competition</td>
<td>• Without regulatory oversight, there is a risk to safety and efficacy</td>
<td>Regional generic manufacturing in Bangladesh, India, Indonesia and Thailand</td>
</tr>
<tr>
<td><strong>Pricing policies – compulsory licensing:</strong></td>
<td>• Using the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for government to issue volunteer or compulsory licences, on grounds of public interest, to produce generic drugs while they are still within intellectual property rights</td>
<td>• Early introduction of generic drug competition</td>
<td>• Pressure from pharmaceutical companies (including lawsuits)</td>
<td>Notable examples of use of compulsory licensing from India and Thailand</td>
</tr>
<tr>
<td></td>
<td>• The Doha Declaration allows import of low-priced generic medicines produced with compulsory licences in least developed countries</td>
<td>• Lower costs to the payer</td>
<td>• Pressure from outside governments (trade sanctions)</td>
<td></td>
</tr>
<tr>
<td><strong>New payment methods</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tiered pricing (price discrimination)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Different prices for the same product in different markets, based on ability to pay and elasticity of demand</td>
<td>• Increased affordability</td>
<td>• Risk of parallel imports (illegal import of lower-priced drugs to higher-paying markets)</td>
<td>India: government-owned retail outlet with discounted cancer and cardiovascular medicines (Affordable Medicines and Reliable Implants for Treatment [AMRIT] shops)</td>
</tr>
<tr>
<td><strong>Price ceiling</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Government intervention on the maximum retail price</td>
<td>• Lower prices for selected products distributed</td>
<td>• Industry backlash</td>
<td></td>
</tr>
<tr>
<td><strong>Industry-led access programmes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Industry-led tiered pricing in the form of rebates/discounts/extra products</td>
<td>• Companies expand their customer base</td>
<td>• Limited evidence of actual improvements to access</td>
<td></td>
</tr>
<tr>
<td><strong>Risk-sharing agreements</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The provider company gets paid only when conditions are met (i.e. clinical benefit)</td>
<td>• Decreases payer costs</td>
<td>• Risk of parallel import</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Lack of agreement on the definition of benefit</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
cancer-control costing; and advance a research agenda through cancer registries that monitor screening and early detection for prevention, and link early detection, diagnosis and treatment, as well as access to pain relief and palliative care services and survivor care.21,22

- **Review standard treatment guidelines**: national health authorities can prioritize the development and dissemination of standard treatment guidelines for cancers. Standard treatment guidelines support doctors in selecting the right tools to make the best diagnosis and develop an appropriate treatment plan. An illustrative example is breast cancer, where 20% of patients may require the targeted and expensive treatment of trastuzumab, and 80% of patients may be treated with older, less costly medicines.17

- **Establish WHO prequalification**: WHO prequalification of medicines is a service provided by WHO to assess the quality, safety and efficacy of medicinal products.22 National procurement agencies, especially in low-income countries, may use the WHO list of prequalified medicines to guide procurement. As of 2017, WHO is piloting prequalification of biosimilar products for targeted cancer therapies.19

- **Advocate for collaborative funding mechanisms**: despite calls to action, noncommunicable diseases have not yet been the target of global funding mechanisms. A coordinated global approach is needed to develop sustainable financing mechanisms for governments in low- and middle-income countries.24

### Conclusion

There is no single strategy to improve access to essential cancer medicines for countries in the WHO South-East Asia Region, especially unaffordable high-cost therapies. Different approaches are needed that are tailored to specific country situations and progress towards universal health coverage. Understanding what is included in national lists of essential medicines can be a first step to analysing a nation’s health priorities and capacities. Also, in the absence of global collaborative funding mechanisms, the region can advocate now, with one voice, for regional mechanisms to promote actions to improve the affordability and availability of essential cancer medicines and align national cancer-control strategies to leverage regional strengths. Regional strengths include experience in using compulsory licences to manufacture low-cost generic medicines and using health technology assessments to provide free cancer medicines via national health insurance.

To meet the global goals for the prevention and control of noncommunicable diseases in the context of universal health coverage, actions to improve access to essential cancer medicines are a priority. Time lost in rallying action will lead to more premature cancer deaths and more households in the WHO South-East Asia Region being pushed into poverty by out-of-pocket payments for cancer medicines.
Chivukula & Tisocki: Improving access to essential cancer medicines in the WHO South-East Asia Region

Source of support: The work contributing to this paper was supported by the World Health Organization Regional Office for South-East Asia, New Delhi, India.

Conflict of interest: None declared.

Authorship: MVC completed the data analysis and developed the manuscript. KT designed the study and reviewed the manuscript.

How to cite this paper: Chivukula MV, Tisocki K. Approaches to improving access to essential cancer medicines in the WHO South-East Asia Region. WHO South-East Asia J Public Health. 2018;7(2):62–66. doi:10.4103/2224-3151.239415.

References


