



REGIONAL COMMITTEE

Provisional Agenda item 8.3

*Seventieth Session
Maldives
6–10 September 2017*

SEA/RC70/9

21 August 2017

Access to medicines

Access to medicines is at the core of universal health coverage and the Sustainable Development Goals. Despite progress over the past decade in improving access to essential medicines in the Region, this has not been uniform. As health needs in the Region evolve, Member States face increasing challenges in ensuring equitable access to a growing range of quality essential medicines at affordable prices. Access to medicines has been a Flagship Priority for the WHO South-East Asia Region since 2014.

An earlier version of the attached working paper was presented to the High-Level Preparatory (HLP) Meeting for its review and recommendations. It reviewed the current situation, progress and challenges; outlined some emerging messages and suggested a way forward. The HLP Meeting discussed these, and recommended that the paper should be revised after the Regional Consultation on access to medicines for universal health coverage (16–18 August 2017), so that recommendations from the consultation could be included for consideration by the Seventieth Session of the Regional Committee.

The Regional Consultation recommended four areas for inter-country collaboration to advance the medicines agenda. These are: a) information sharing on medicines prices, building on existing platforms; b) information sharing on medicines quality, through the South-East Asia Regulators Network (SEARN); c) taking small but concrete steps in multicounty collaboration on procurement by starting with antidotes (which are lifesaving, and often hard to obtain rapidly); and d) supporting more systematic approaches to bilateral collaboration in procurement. Additional regional actions to strengthen regulatory systems for medical products through SEARN will focus on making greater use by Member States of reliance on each other's regulatory decisions, to improve regulatory performance.

The results of the HLP Meeting deliberations and recommendations from the Regional Consultation are presented below.

Actions by Member States

- (1) Individual country actions, which include:
 - a) Maintain national medicines policies and essential medicines lists as the backbone of action to improve access, supported by sufficient resources for implementation;
 - b) Action to strengthen procurement, pricing and regulation of medical products, and make appropriate use of TRIPS flexibilities;
 - c) Action to encourage more appropriate medicines use, especially of antimicrobials;
 - d) Better monitoring of access to medicines.
- (2) Greater inter-country cooperation, beginning with four priorities:
 - a) Information sharing on price, building on an existing platform.
 - b) Information sharing on medicines quality, through SEARN.
 - c) Initiate small but concrete collaboration in procurement, starting with antidotes.
 - d) Bilateral cooperation agreements: development of more systematic approaches.

Actions by WHO

- (1) Foster inter-country and regional cooperation in procurement, pricing and regulation of medical products, focused on the four agreed priorities, with short- and medium-term deliverables,
- (2) Technical support to build capacity as needed,
- (3) Support improved data on access to and use of medicines, with a focus on antimicrobials.

This working paper and the recommendations from the HLP Meeting and the Regional Consultation on access to medicines for universal health coverage are submitted to the Seventieth Session of the WHO Regional Committee for South-East Asia for its consideration and decision.

Introduction

1. Ensuring access to safe, efficacious, quality and affordable medical products is a challenge for all Member States of the South-East Asia (SEA) Region.

2. SEA Region Member States have long been committed to improving access: since 2002, the Regional Committee has endorsed ten resolutions that include reference to improved access to medical products. Four (SEA/RC55/R4; SEA/RC62/R6; SEA/RC64/R5; SEA/RC66/R7) have focused specifically on medicines policy and management (Annexure). The Sixty-ninth Regional Committee reviewed all regional resolutions, and sunset one resolution on medicines (RC55/R4). The three remaining active medicines resolutions cover: national essential drug policies and strategies for their implementation, including promoting and monitoring the rational use of medicines (SEA/RC64/R5); a resolution on measures to ensure access to safe, efficacious and affordable medical products, part of which focuses on incorporating public health safeguards in domestic intellectual property legislation, to promote medicines access (SEA/RC62/R6); and effective management of medicines (SEA/RC66/R7). This last resolution urges Member States to invest in a comprehensive approach to promoting rational use and more effective management of medicines, including accelerated implementation of SEA/RC64/R5, and endorsing periodic reviews of the medicines situation in Member States. In 2014, access to essential medicines was made a focus area in the Regional Flagship for Universal Health Coverage (UHC).

3. Global attention on access to medicines has also considerably increased recently. Since 2014, four World Health Assembly resolutions, highlighted in the Annexure, have re-emphasized the need for greater availability of essential medicines. SDG 3 for health has an explicit target for medicines: “Achieve UHC, including ... access to quality medicines and vaccines for all.”¹ In 2016, the report of the UN Secretary-General’s High-Level Panel on Access to Health Technologies highlighted the need for “bold new approaches to both health technology innovation and ensuring access so that all people can benefit”.² Access to medicines, and ways to address shortages, was a major topic of discussion at the Seventieth World Health Assembly, and it will be discussed again at the 142nd Executive Board in January 2018. In 2017, WHO published its new global medicines framework “Towards Access 2030”.³

4. In the SEA Region, many challenges remain in providing the right medicines at the right time to those in need. The rise in noncommunicable diseases, ageing populations, and effective but often costly new medical products all put additional pressure on government budgets, at the same time as governments have committed to reducing out-of-pocket (OOP) expenditure on medicines. Additional action to tackle the availability, quality and affordability of medicines is needed.

¹ Sustainable Development Goal 3: Ensure healthy lives and promote well-being for all at all ages. In: Sustainable Development Goals [website] (<http://www.un.org/sustainabledevelopment/health/>, accessed 12 June 2017).

² The United Nations Secretary-General’s High-Level Panel on Access to Medicines Report. Promoting innovation and access to health technologies (<http://www.unsgaccessmeds.org/final-report>, accessed 12 June 2017).

³ Towards access 2030: WHO Essential Medicines and Health Products Programme Strategic Framework 2016–2030. Geneva: World Health Organization; 2017 (WHO/EMP/2017.01). (http://www.who.int/medicines/publications/Towards_Access_2030_for_web.pdf?ua=1, accessed 12 June 2017).

5. There are some unique characteristics in the market for medicines in the Region, which could be used to advantage. Several countries are significant manufacturers and exporters of medical products, especially generic medicines. The biggest is India, exporting to over 170 economies, but so do Bangladesh, Indonesia and Thailand. Smaller countries with little local production have few alternatives to importing medicines and often have little influence over price. More could be done to explore the potential of these unique market characteristics to improve access to essential medicines.

Current situation: progress and challenges

6. In the SEA Region, there has been progress on access to quality essential medicines over the past ten years, but it has not been uniform. Significant improvements have been made in access to medicines for HIV/AIDS, TB and malaria, and in the coverage of vaccines; less progress has been made in access to medicines for noncommunicable diseases and other essential medicines for common illnesses. Availability of essential medicines is also not uniform: it tends to be lower in health centres than in hospitals, and lower in the public sector compared with the private sector. Moreover, the latest estimates suggest that at least 65 million people in the Region are pushed into poverty due to OOP health-care payments, with the cost of medicines being one of the main causes.⁴

7. Many interventions contribute to improving access to quality medicines, including action to improve procurement and pricing, regulation, financing, delivery and use of medicines. There are examples of both progress and continuing challenges across the Region.

Procurement and pricing

8. Procurement remains a real challenge in the Region. National systems for medicines procurement aim to secure needed supplies at an affordable cost, and reduce shortages and stock-outs. Some countries such as Bhutan, Indonesia, Sri Lanka, and several states in India have strengthened their public supply chain management systems and reduced stock-outs. Others need to introduce more efficient logistics management information systems that can cope with current needs.

9. Efficient procurement of medicines requires timely information on needs, quality assurance, larger or longer-term tenders, and negotiation skills. Several countries, including India, Indonesia and Thailand, have introduced more strategic public procurement practices such as longer-term contracts, central bargaining and e-procurement. These have contributed to lower prices and fewer stock-outs.

10. The increasing cost of medicines, especially of new therapies (including biologicals and vaccines), is a growing concern for all countries. The impact of pharmaceutical patents, designed to encourage research, on access to medicines through their effects on prices, is much debated.

⁴ Health in the Sustainable Development Goals: Where are we now in the South-East Region? What next? New Delhi: World Health Organization; 2016 (<http://apps.who.int/iris/bitstream/10665/249536/6/9789290225218-Eng.pdf>, accessed 12 June 2017)

In practice, countries could make greater use of the provisions already contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including the flexibilities recognized by the Doha Ministerial Declaration on TRIPS. To date, only a few countries in the Region have done so – either through ensuring that their domestic patent legislation takes public health needs into account, or by actively using provisions such as compulsory licensing or parallel imports.

11. Evidence helps when negotiating price and rules on reimbursement, which in turn affect access. Health technology assessment is a routine part of the decision-making process for adding medicines to the national benefit package in Thailand, and other countries such as Indonesia and India are introducing this approach.

12. Price regulation and controls such as maximum retail price are used in several countries, with mixed success.

13. National medicines policies and essential medicines lists remain valuable guides to public procurement. Most Member States have national medicines policies and all have essential medicines lists. WHO recommends that essential medicines lists be updated every two to three years to reflect changing needs and new developments. Recent revisions within the SEA Region range from 2009 to 2017.⁵

Regulation

14. The number and complexity of medical products are increasing. This puts increased demands on already stretched national regulatory authorities (NRAs), who are responsible for ensuring the quality, efficacy and safety of medicines. The globalization of pharmaceutical supplies such as through Internet sales means that NRAs need to be increasingly vigilant in detecting substandard and falsified medical products.

15. A number of NRAs, especially those in countries with large domestic vaccine and pharmaceutical manufacturing capacity such as India, Indonesia and Thailand, have already made significant progress in strengthening their regulatory capacity and have been recognized as functional NRAs for vaccine regulation by WHO. Other countries are also taking steps to strengthen their regulatory systems.

16. Regulators in all Member States have recognized the importance of working together to tackle these challenges and use their existing capacities more effectively. They established the South-East Asia Regulatory Network (SEARN) in 2016, with support of the WHO Regional Office for South-East Asia. The Network has set clear goals to increase regulatory collaboration, information exchange, and reliance on each other's regulatory decisions, and support regulatory capacity development.

⁵ Improving access to medicines in the South-East Asia Region: progress; challenges; priorities (2017, *forthcoming*)

Improved access to medicines through more appropriate use

17. Inappropriate use of medicines remains a common problem, despite many decades of effort to improve rational use. This is particularly problematic with antimicrobial agents, given the scale of antimicrobial resistance in the SEA Region. Attention to more rational antibiotic use is growing. Examples include Bhutan's success in eliminating over-the-counter purchase of antibiotics; Thailand's Antibiotics Smart Use programme, and India's introduction of red-line labelling to promote appropriate use. This is a key part of the antimicrobial resistance (AMR) response, reported under RC70 Agenda item 9.4. Actions to improve physical access to medicines, such as by increasing the number of pharmacy outlets across the Maldives, need to be complemented by staff able to advise on appropriate use of medicines.

Financing

18. Access to medicines is also affected by who pays for them. An analysis of pharmaceutical expenditures in the Region shows that governments' share of total pharmaceutical expenditure in Member States ranges from 5% to 91%. The reality is that medicines are a major component of out-of-pocket (OOP) spending. Several countries, such as Myanmar and Indonesia, have increased government spending on medicines in recent years, but there is still a long way to go to achieve more equitable financing. National financing strategies to advance UHC should include ways to reduce OOP expenditure on medicines.

Emerging messages and the way forward

19. There are many opportunities for improving access to quality essential medicines – through action by individual countries and through new forms of collaboration. Member States and WHO can usefully work together in five clear areas.

Collaboration on procurement to reduce price and improve quality

20. The Regional Consultation in August 2017 discussed options for intercountry and regional collaboration on public procurement and pricing. The consultation involved procurement managers and regulators from national medicines regulatory authorities in all 11 countries of the South-East Asia Region; UN agencies and other international partners including the Global Fund and the United States Pharmacopeia. Member States agreed on some key principles for moving forward: build on what exists; start with small but concrete steps; keep collaboration voluntary; and build trust. They identified feasible collaboration in four priority areas, with short- and medium-term deliverables and benefits.

Information sharing on medicines prices. Member States confirmed the need to share medicines procurement price information to improve price negotiation capacity of public procurement agencies. Two immediate actions were agreed. First, SEARO will develop a "one-stop" web portal to facilitate access to existing public information on

medicines prices, quality and supplier performance. Second, the practical steps required to share more detailed regional price information, using an existing platform which will be adapted as needed for SEA Region countries, will be agreed at an experts' workshop before the end of 2017. Countries can then voluntarily start to share price information through the agreed platform in early 2018.

Improved access to information on product quality through the South-East Asia Regulators Network (SEARN). This is already a priority for SEARN, and its planned information working group will be discussing a minimum set of information on quality of medical products to be made available on national regulatory authority websites later this year. The ideas from the regional medicines consultation in August will be shared with SEARN.

Initiating small but concrete collaboration on procurement, starting with antidotes. An initial collaborative procurement activity was identified, focused on improving availability of lifesaving antidotes, including snake anti-venom and other antisera, building on existing experience in the Region. Interested countries will discuss operational and logistics arrangements for this in the first quarter of 2018. The initial small-scale cooperation can serve as a useful first step before broadening regional collaboration for procurement of other essential medicines.

Bilateral cooperation agreements. A "checklist" of critical issues to be considered in order to set up effective bilateral cooperation agreements for procurement of essential medicines will be prepared by WHO in 2017. Case studies of country experience will be synthesized during 2018.

Other collaboration in regulation: more focus, less duplication

21. Regulatory agency collaboration in medical product regulation through SEARN will help amplify the use of scarce NRA capacities and aim to reduce duplication. It will promote regulatory convergence, and support capacity-building of individual NRAs.

Working within intellectual property and trade rules, and using TRIPS flexibilities

22. There is great potential for increased use of regionally produced, quality generic products. There is a need to increase working within intellectual property and trade rules, and use of TRIPS flexibilities to expand access to new therapies. Using affordable generic versions and biosimilar products that advance treatment for hepatitis, HIV/AIDS, cancer and other diseases can improve access. WHO added several such "high-cost" medicines to its Model Essential Medicines List, and will support their inclusion in national lists. WHO will also work with Member States to increase their capacity to use TRIPS flexibilities to get better prices, especially for high-cost therapies.

Increased access to effective antimicrobials through improved antimicrobial stewardship

23. Rational use of medicines is particularly important for antimicrobials in this Region. Member States have committed to improving stewardship in their national antimicrobial resistance (AMR) action plans. WHO will support three critical components of antimicrobial stewardship: (a) improved capacity for monitoring antimicrobial use; (b) strengthening antimicrobial policies and regulations to control use and preserve their effectiveness; (c) increased education and advocacy on how to optimize antibiotic use. WHO will support adoption of its new recommendations⁶ to improve stewardship by applying ACCESS, WATCH and RESERVE categories of antibiotics, and improve monitoring of their use, especially for reserve antibiotics.

Improved monitoring of access to medicines

24. There is an urgent need for improved data on trends in access to medicines. This Region is not alone – all other regions face the same problem. Good data enable decision-makers to know how many people cannot access the medicines they need and where medicines are not available; whether unsafe or ineffective products are on sale, and the scale of misuse or wastage of medicines. WHO will support the development and use of practical indicators, methods and systems for monitoring access to medicines, and use of these data to improve policies and practice. This will also help reporting on the medicines indicator in the SDGs.

Conclusion

25. Continued high-level political attention, resources, collective action with a wide range of stakeholders, and regular oversight are needed to take this agenda forward. National medicines policies provide the framework for organizing, financing and regulating the pharmaceutical sector, and for coordinating stakeholders to achieve the agreed objectives.

26. The Sustainable Development Agenda 2030, and recent global and regional developments in access to medicines, have given renewed urgency to this agenda. In light of the developments outlined above, and the fact that there are multiple regional resolutions on medicines, further guidance is required from the Regional Committee on the proposed way forward, which emphasizes both national action and increased collaboration within the Region, facilitated by WHO. This will help foster an integrated and sustained approach to improving access to medicines as part of the Sustainable Development Agenda.

⁶ WHO Model List of Essential Medicines 20th List (March 2017) (http://www.who.int/entity/medicines/publications/essentialmedicines/20th_EML2017.pdf?ua=1, accessed 12 June 2017).

Annexure

List of relevant resolutions

Current resolutions related to access to medicines in the South-East Asia Region

- SEA/RC59/R7 Public health, innovation, essential health research and intellectual property rights
- SEA/RC59/R9 International trade and health
- SEA/RC62/R6 Measures to ensure access to safe, efficacious, quality and affordable medical products
- SEA/RC64/R5 National essential drug policy including the rational use of medicines
- SEA/RC65/R3 Consultative Expert Working Group on Research and Development: financing and coordination
- SEA/RC65/R6 Regional strategy for universal health coverage
- SEA/RC66/R4 Health intervention and technology assessment in support of universal health coverage
- SEA/RC66/R7 Effective management of medicines
- SEA/RC68/R3 Antimicrobial resistance

World Health Assembly resolutions related to access to medicines

- WHA54.11 WHO Medicines Strategy
- WHA55.14 Ensuring accessibility of essential medicines
- WHA58.27 Improving the containment of antimicrobial resistance
- WHA59.26 International trade and health
- WHA60.16 Progress in the rational use of medicines
- WHA60.20 Better medicines for children
- WHA60.30 Public health, innovation and intellectual property
- WHA61.21 Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
- WHA64.9 Sustainable health financing structures and universal coverage
- WHA66.10 Follow-up to the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases
- WHA66.22 Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination
- WHA67.19 Strengthening of palliative care as a component of comprehensive care throughout the life course

- WHA67.21 Access to biotherapeutic products including similar biotherapeutic products and ensuring their quality, safety and efficacy
- WHA67.22 Access to essential medicines
- WHA67.23 Health intervention and technology assessment in support of universal health coverage
- WHA68.7 Global Action Plan on Antimicrobial Resistance
- WHA69.11 Health in the 2030 Agenda for Sustainable Development
- WHA69.20 Promoting innovation and access to quality, safe, efficacious and affordable medicines for children
- WHA69.25 Addressing the global shortage of medicines and vaccines