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Ministerial Roundtable: Improving access to essential medical products in the Region and beyond

To make progress towards universal health coverage (UHC), more equitable access to essential medical products (medicines, vaccines, diagnostics and medical devices) is needed. Despite some progress in the past 10 years, it has not been uniform and challenges remain in availability, quality and affordability. The markets for medical products have changed in recent years. Demand has expanded, with new health care needs from noncommunicable diseases and ageing populations, and as effective new therapies have become available. The SEA Region is now a major manufacturer of medical products worldwide, primarily generic medicines and vaccines. This means there are new opportunities for improving access – through both individual and collective country action – with benefits within the Region and beyond. Progress will involve a wide range of stakeholders within and beyond ministries of health.

It is proposed that the Ministerial Roundtable is invited to discuss steps – individual and collective – being taken by Member States to improve access to essential medical products in the Region and beyond, and consider ways to accelerate progress. Member States have also participated in the preparation of a Ministerial Declaration on increasing access to essential medical products in the Region and beyond, which will be submitted for endorsement during the Roundtable.

The attached working paper was submitted to the High-Level Preparatory (HLP) Meeting for its review and recommendations. The HLP reviewed the working paper and made the following recommendations for consideration by the Seventy-first Session of the Regional Committee:

Actions by Member States

- Continue, in collaboration with the Regional Office, to take action on the challenges identified during the discussions at the HLP Meeting.
- Broaden the scope of the Ministerial Roundtable discussions from a focus on essential medicines to include the perspective of medical products, including medicines, vaccines, diagnostics and devices.

- Share the draft of the Ministerial Declaration, discussed during the HLP Meeting, between Member States immediately after the meeting for finalization before the Regional Committee Session. The final draft of the Ministerial Declaration should be ready by 17 August 2018.

The final Ministerial Declaration on “Improving access to essential medical products in the Region and beyond” and the associated draft resolution are submitted to the Seventy-first Session of the WHO Regional Committee for South-East Asia for its consideration and decision.

Introduction

1. To make progress towards universal health coverage (UHC), more equitable access to essential medical products (medicines, vaccines, diagnostics and medical devices) is needed. Despite some progress in the past 10 years, it has not been uniform. Challenges remain in availability, quality and affordability. Medical products are the major cause of out-of-pocket (OOP) spending on health care by households, which has pushed 65 million people into poverty in the WHO South-East Asia (SEA) Region.
2. The markets for medical products have changed in recent years. WHO's Model Essential Medicines List, which guides country demand, has expanded. The first edition of WHO Model List of Essential In Vitro Diagnostics (IVD) was published in May 2018 and recommends IVDs for use at various levels of national health care system. WHO also recommends, through various Lists for priority medical devices, the proper and cost-effective selection of medical devices appropriate to the needs of the population.
3. While over 95% of products on the WHO Model Essential Medicines list can be procured as low-cost generics, new products have been added to address changing health needs such as cancer or hepatitis C. Some newer products are under patent and are expensive. Supply has also changed: the SEA Region is now a major manufacturer of medicines worldwide, primarily generics. Generic competition has helped to reduce prices of some medicines and vaccines by up to 90%. One characteristic of the market in this Region is the combination of very large and very small countries that purchase in relatively small quantities and find it hard to negotiate equivalent prices and oversee quality compared with their larger neighbours.
4. SEA Region Member States have long committed to improving access. All have national essential medicines policies and programmes. The Regional Committee has endorsed ten medicines-related resolutions since 2002, of which four are current.¹ Since 2014, access to essential medicines has been a priority in the Regional Flagship on UHC. In 2017, the South-East Asia Regional Committee endorsed decision SEA/RC70(3) on access to medicines, covering collaboration in procurement, regulation, better use of intellectual property and trade rules and TRIPS flexibilities, increased equitable access to and use of antimicrobials, and improved monitoring of access to medicines.
5. Global attention on access to medical products is currently high. In 2016, the report of the UN Secretary-General's High-Level Panel on Access to Medicines targeted incoherencies between trade and public health objectives regarding promotion of innovation and access to health technologies, while acknowledging the need to tackle other bottlenecks in low- and middle-income countries at the same time. At this year's World Health Assembly, the WHO Secretariat was tasked with developing a roadmap on access to medicines and vaccines, in time for the next Executive Board.

¹ International trade and health (SEA/RC59/R9); Measures to ensure access to safe, efficacious and affordable medical products (SEA/RC62/R6); National essential drug policy including the rational use of medicines (SEA/RC64/R5); Effective management of medicines (SEA/RC66/R7).

6. These changes mean new thinking about solutions to the problem of access is possible, at the same time as needing to continue with older, proven strategies.

7. This Roundtable is an opportunity to take stock on steps to improve access in the Region and beyond, and consider where more individual and collective action to accelerate improved access is possible and desirable.

Current situation: progress, challenges and responses

8. *Improvement in the availability of medical products has not been uniform.* Significant improvements have been made in access to medicines and vaccines for communicable diseases and vaccines, less so in medical products for noncommunicable diseases (NCDs) and common illnesses. Availability tends to be lower in health centres than in hospitals, and lower in the public sector compared with the private sector.

9. *There are many reasons.* Even for low-cost medical products, access will not improve if production is low because of low demand and weak incentives for producers; if there is inefficient public procurement and supply chain management, and if there is low public spending on essential medical products. All these challenges have been faced by Member States at different times. For newer on-patent medical products, there are examples where costs are being kept high by manufacturers through strategies to retain monopoly and delay generic entry and competition.

10. *To improve access, action is needed on several fronts:* on procurement and pricing, regulation, financing, delivery and use of medical products. There are examples of both progress and continuing challenges in all these areas across the Region.

11. *Procurement and pricing.* Several countries have introduced more efficient public procurement processes. Intercountry collaboration is also beginning, through sharing information on medicines and vaccines procurement prices, and first steps taken towards regional pooled procurement, starting with antidotes. Member States also benefit from existing global procurement mechanisms for selected products.

12. Price controls such as setting maximum retail prices for medical products are being used by some countries to contain costs – both for government purchasers and individuals. More research is needed to identify the mix of pricing and financing policies that reduce out-of-pocket expenditure and inequities in access to essential medical products.

13. *Regulation and quality assurance are important aspects of access.* National regulatory capacity has improved, especially in large countries that manufacture medical products (primarily medicines and vaccines). All Member States have joined the South-East Asia Regulatory Network (SEARN), which was established in 2016 to increase information exchange, reliance on each other's regulatory decisions, and regulatory capacity development. There are working groups on regulatory information-sharing, implementation of good regulatory practices, work-sharing between quality control laboratories, development of medical device regulatory systems and enhanced vigilance of medical products.

14. *Effective use of intellectual property and trade rules, and TRIPS flexibilities can help.* Investment in research for new products, especially for health conditions prevalent in low- and

middle-income countries, is essential. At the same time, public health needs must be protected. In practice, greater capacity to work within intellectual property and competition rules, and use TRIPs flexibilities² would help improve access to new therapies included in national essential medicines lists. The first World Conference on Access to Medical Products and International Laws for Trade and Health, in the Context of the 2030 Agenda for Sustainable Development in New Delhi, 2017 focused substantially on ways to address these challenges.³

15. *Increased physical access, and more appropriate use, should not be forgotten.* Improved physical access to free essential medical products, e.g. through better distribution and supply chain management to ensure access at points of care, are valuable strategies that need to be complemented by trained staff and by strategies to stop inappropriate use, which itself reduces access – the rise in antimicrobial resistance being a good example. A range of strategies are already being used to reduce inappropriate antibiotic use, such as eliminating over-the-counter purchase, Antibiotic Smart Use programmes, and red-line labelling of antibiotic packages. Their effectiveness needs to be documented.

16. *Financing.* Low public spending on medical products, especially essential medicines leads to high out-of-pocket spending by people when they are sick. Over 65 million people in the Region are impoverished because of health-care spending,⁴ and data show this is mainly on medicines, and often on common medicines that are considered “low-cost”.⁵ Poorer households tend to spend proportionally more on medical products. Several countries have recently increased government spending on medical products.

17. Data on access to medical products is scarce. In 2017, only two Member States in the Region were able to report on the medicines target of the Sustainable Development Goals (SDGs). More reliable and regular information on availability is needed, so that the effectiveness of policies and strategies can be monitored.

The way forward

18. What is outlined below builds on the decision of the Seventieth Regional Committee SEA/RC70(3), and recent global agreements on improving access to essential medicines and other medical products.

19. *Renew commitment to achieve universal access to essential medical products by 2030,* reinforced by national policies that encourage the production, distribution and use of low-cost , appropriate medical products.

20. *Encourage more strategic procurement of medical products,* and therefore greater value for money, through increased transparency on procurement prices and product quality, and greater capacity to negotiate. Seek further opportunities for collective negotiation in the Region where

² The 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) focused on patent protection. The 2001 Doha Declaration introduced “TRIPs flexibilities” to address public health crises.

³ <http://www.worldsdg2030.org/>

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).

⁵ Financial protection in the South-East Asia Region: determinants and policy implications. Working paper, 2017 (http://apps.who.int/iris/bitstream/handle/10665/259639/financial_protection_wp.pdf?sequence=1&isAllowed=y, accessed 5 June 2018).

appropriate; for example, for small countries' procurement, or for new high-cost, low-volume medicines.

21. *Make greater use of the Region's role as a major manufacturer of generic medicines to improve access within Member States and beyond. Continue to shape market demand, for example through including new products in national essential medical products lists; more strategic forecasting and procurement, and be vigilant in ensuring that public health needs are taken into account in trade policies.*

22. *Progressively strengthen regulatory collaboration to improve the quality and safety of medical products through priority actions identified by SEARN. This will have benefits within the Region and also beyond. SEARN's medium-term strategic plan is being developed, outlining steps to promote information sharing and regulatory convergence and reliance, where appropriate, within the Region.*

23. *Facilitate enhanced use of TRIPS flexibilities for improving access to essential medical products and innovative health technologies.*

24. *Take urgent action to improve antimicrobial use in the community and in health facilities, and thereby reduce antimicrobial resistance, including through revised education and training of health-care professionals.*

25. *Allocate financial resources for essential medical products as part of an overall national health financing strategy to support UHC, including actions to reduce out-of-pocket payments.*

26. *Monitor trends in access to medical products, as agreed in the SDG monitoring framework, using new tools developed by WHO. This includes increased monitoring of the availability, quality and use of essential medical products. Report every two years to the Regional Committee.*

27. *Improve the evidence base on effective strategies to improve access to essential medical products by supporting local research institutions to analyse the effectiveness of targeted national policies and strategies.*

28. *Help stimulate research and development (R&D) for neglected health problems in the Region, and in other low- and middle-income countries, by participating in R&D discussions in the Region and at the global level.*

Conclusion

29. To make progress towards UHC, more equitable access to essential medical products is needed. Despite some progress in the past 10 years, it has not been uniform and challenges remain in availability, quality and affordability.

30. Medical products markets have changed in recent years, and there are new opportunities for improving access – through both individual and collective country action – with benefits within the Region and beyond.

31. Progress will involve a wide range of stakeholders within and beyond ministries of health, including national and subnational governments, the pharmaceutical industry, academia, health professional bodies, civil society organizations and development partners.

32. The Ministerial Roundtable will be invited to discuss steps – individual and collective – being taken by Member States to improve access to essential medical products in the Region and beyond, and consider ways to accelerate progress.

- Take stock of progress to date on improving access to essential medical products. What are the greatest remaining challenges?
- Look forward, acknowledging the opportunities that exist to accelerate progress within the Region and beyond. Are there new and so far untapped opportunities to improve access to essential medical products, which can be tailored to different country situations? What additional steps can be taken, individually and collectively, by Member States of the SEA Region?

33. Member States are invited to actively participate in the preparation of a Ministerial Declaration on increasing access to essential medical products in the Region and beyond.