6TH MEETING ON ACCESS TO MEDICINES UNDER UNIVERSAL HEALTH COVERAGE IN THE ASIA PACIFIC REGION

24–25 September 2019
Manila, Philippines
MEETING REPORT

SIXTH MEETING ON ACCESS TO MEDICINES
UNDER UNIVERSAL HEALTH COVERAGE IN THE ASIA PACIFIC REGION

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NOTE

The views expressed in this report are those of the participants of the Sixth Meeting on Access to Medicines under Universal Health Coverage in the Asia Pacific Region and do not necessarily reflect the policies of the conveners.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for Member States in the Region and for those who participated in the Sixth Meeting on Access to Medicines under Universal Health Coverage in the Asia Pacific Region from 24 to 25 September 2019.
CONTENTS

SUMMARY ............................................................................................................................................1

1. INTRODUCTION ................................................................................................................................2

1.1 Meeting organization .........................................................................................................................2
1.2 Meeting objectives ...............................................................................................................................2

2. PROCEEDINGS ..................................................................................................................................2

2.1 Opening session .................................................................................................................................2
2.2 Keynote presentation: Implication of population ageing for pharmaceuticals policy ..........3
2.3 Access to medicines: A changing agenda regionally and globally ..............................................3

2.3.1 Recent progress in the South-East Asia Region on improving access to medicines and moving towards UHC.................................................................3
2.3.2 Recent progress in the Western Pacific Region on improving access to medicines and moving towards UHC..................................................................................4
2.3.3 Global updates on WHO’s work on improving access to medicines in the context of SDGs: Road Map for Access, 2019–2023 .................................................................5
2.3.4 Updates on OECD’s work ..............................................................................................................5
2.3.5 Discussion ....................................................................................................................................6

2.4 Tools and indicators to measure access to medicines and the components of a national pharmaceutical system .........................................................................................6

2.4.1 Monitoring the components and predictors of access to medicines: Outcome of the international experts’ consultation ..................................................................................6
2.4.2 A tool to measure the availability and prices of medicines and medical products ................7
2.4.3 Panel discussion ............................................................................................................................7
2.4.4 Group work ..................................................................................................................................8

2.5 Improving price transparency: Taking stock and moving forward ................................................8

2.5.1 Improving transparency of markets for medicines, vaccines and other health medical products ....8
2.5.2 Panel discussion: Can transparency contribute to lower prices and improve access to pharmaceuticals? Views from the field .................................................................9
2.5.3 The impact of federalization on the availability of essential medicines, Nepal ..........................9
SUMMARY

Improving access to essential medicines is fundamental to achieving universal health coverage (UHC) and attaining the Sustainable Development Goals (SDGs). Low- and middle-income countries in the Western Pacific and South-East Asia regions face similar challenges in ensuring access to good-quality and affordable medicines.

The Asia Pacific Network for Access to Medicines under UHC was established in 2014. The Network was set up through a joint initiative of the World Health Organization (WHO) Regional Office for the Western Pacific and the Organisation for Economic Co-operation and Development (OECD) Korea Policy Centre, with the WHO Collaborating Centre for Health Systems and Financing at Seoul National University acting as the Secretariat. Over the years, the Network was expanded to be a biregional mechanism, with countries in the WHO South-East Asia Region joining as members.

The Network serves as a mechanism to support the formulation of policies and strategies, generation of evidence, capacity-building and information exchange, joint surveys and research across member countries. The Network has also served as a platform for national capacity-building in areas such as health technology assessment and price negotiations.

The annual meetings serve as a forum for presenting challenges, policies and programmes, as well as the results of studies and research pertaining to access to medicines. The Sixth Meeting on Access to Medicines under Universal Health Coverage in the Asia Pacific Region was held at the WHO Regional Office for the Western Pacific from 24 to 25 September 2019. Meeting attendees included participants from Bangladesh, Bhutan, Brunei Darussalam, Cambodia, China, India, Indonesia, the Lao People’s Democratic Republic, Malaysia, Maldives, Myanmar, Mongolia, Nepal, Papua New Guinea, the Philippines, the Republic of Korea, Singapore, Sri Lanka, Thailand, Timor-Leste and Viet Nam; observers from the Asian Development Bank (ADB) and Seoul National University; Secretariat members from OECD, OECD/Korea Policy Centre, WHO Regional Office for the Western Pacific and WHO Regional Office for South-East Asia; and several experts as advisers. Annex 2 provides a full list of participants, temporary advisers, observers and Secretariat members.

Access to medicines depends on the interaction and performance of complex systems within regulation, selection (HTAi), procurement, reimbursement, pricing, utilization (rational use) and information systems. A clear framework of what needs to be monitored and shared to support policy decision-making is needed.

The challenges, needs and capacities of countries vary widely depending on their stage of development. Despite the challenges, there are opportunities for intercountry learning, intercountry collaboration and regional solutions.

The meeting concluded with specific recommendations on pricing, collaboration, research and evidence, and availability of medicines, and suggestions for agenda items for the next meeting, which will include patient care consideration and more detailed discussion on pooled procurement.
1. INTRODUCTION

1.1 Meeting organization

A two-day meeting on access to medicines under universal health coverage (UHC) in the Asia Pacific region was convened from 24 to 25 September 2019. Day one was designed to provide global and regional updates and to review Asia Pacific pharmaceutical policies to improve access to medicines. Day two provided an opportunity for participants to discuss country updates and for experts to share advice on how to advance access to medicines in the light of the World Health Assembly resolution WHA 72.8 on improving the transparency of markets for medicines, vaccines, and other health products.

1.2 Meeting objectives

The objectives of the meeting were:

1) to discuss emerging challenges in access to medicines, including its implications on ageing;
2) to report on challenges and progress of implementation on medicines policies and share results of joint studies and research around medicines pricing; and
3) to discuss mechanisms for the adoption and implementation of the new indicators for assessing access to medicines under UHC.

2. PROCEEDINGS

2.1 Opening session

Dr Liu Yunguo, Director, Programme Management, WHO Regional Office for the Western Pacific Region, warmly welcomed the participants by acknowledging that access to medicines is important for the achievement of UHC in the Asia Pacific region and that the Access to Medicines Network has been instrumental in enabling an exchange of information as well as in building capacities across countries in the Asia Pacific region. He reaffirmed that WHO will continue to work with countries and partners such as OECD, OECD/Korea Policy Centre and Seoul National University to improve access to medicines. Support from WHO will be directed to strengthening pharmaceutical and regulatory systems to ensure availability of quality-assured and safe medicines; strengthening governance and evidence-based selection; intervening on pricing issues; and supporting countries to strengthen procurement systems. WHO is hoping that the Network will continue to support the formulation of country policies and strategies, while generating evidence and strengthening capacity and information exchange across countries.

Mr Seunghyun Hwang, Director-General, OECD/Korea Policy Centre, delivered his opening remarks on behalf of OECD. He noted the importance of health-care services but stressed that medical expenditure has been rising faster and has accounted for the majority of the countries’ total expenditures, especially for low- and middle-income countries. He recognized the challenges faced by many countries in terms of access to medicines and recommended strengthening the capacity of regional networks to address these challenges. Mr Hwang expressed his hope that the
meeting would provide direction and an opportunity to look at pharmaceutical trends and find effective ways to improve access in the Region.

After the opening remarks, Dr Klara Tisocki introduced the meeting objectives, structure and expected outcomes.

Dr Yunguo nominated the office bearers: Dr Anna Melissa S Guerrero as chairperson, Mr M.R.H. Swarnathilake as vice-chairperson and Mr Mohamed Fazeen as rapporteur.

2.2 Keynote presentation: Implication of population ageing for pharmaceuticals policy

Professor Soonman Kwon, Seoul National University, shared the results of the research conducted by the WHO Collaborating Centre for Health System and Financing in Seoul, Republic of Korea, on population ageing and its implication on pharmaceuticals policy.

Many countries in Asia and the Pacific are facing challenges linked to population ageing and the availability and affordability of pharmaceuticals. These challenges have been brought about by inadequate funding in the health sector, high prices, low benefit coverage for essential medicines, ineffective policies on generic medicines, inefficient procurement processes and distribution systems, lack of incentives for managing stock-outs, and lack of technical capacity. In addition, many countries are facing challenges associated with medication errors, adverse drug reactions, medication non-adherence with low efficacy of drug. There are also gaps in policies for the rational use of medicines for non-communicable diseases including polypharmacy. Increasing adverse drug reactions with polypharmacy was related to an increased risk of inappropriate medication, outpatient visits and hospitalization.

In terms of medicine affordability, cost containment policies such as internal and external reference pricing are in place in selected countries. Tariffs in some countries also affect the availability of medicines. There are countries that impose zero per cent mark-up policy for medicines used in the public that led to the decrease in expenditure per outpatient. Government funding is tight, so the margin for services provided is tight as well. Professor Kwon advised that one way to change the game of pricing is to set a margin for medicines to zero in public health facilities. This could help alleviate expenditure. It is by adopting these policies that the impact on both the private and public sectors will be even.

2.3 Access to medicines: A changing agenda regionally and globally

This session aimed to review the progress and provide global and regional updates on the access to medicines agenda and how it links to the broader agenda of UHC and the Sustainable Development Goals (SDGs).

2.3.1 Recent progress in the South-East Asia Region on improving access to medicines and moving towards UHC

Dr Klara Tisocki, WHO Regional Office for South-East Asia, shared that the Region is focusing on strengthening access to medicines and health workforce in achieving UHC. Many countries are still facing low overall government expenditure on medicines and high out-of-pocket costs for households, pervasive irrational use, challenges with procurement and fair pricing, and challenges
with supply chain integrity, ensuring last-mile delivery and access at primary health care level. The Region struggles with the availability of essential medicines, with levels below 80%, and oftentimes, medicines are available in the private sector but not in the public sector. Basic diagnostic tests for communicable diseases are often limited to the private sector, where patients must pay to receive treatment and services, thereby contributing to the high out-of-pocket expenditure. Pharmaceutical country profiles are updated every two years and serve as a basis for monitoring access to medicines.

Policies to increase access to medicines have been put in place:

1) Supply side – In most countries, free access to the list of essential medicines is offered by the government.
2) Demand side – A medicines reimbursement scheme is in place in a few countries.
3) Market-based solutions – Price regulation is making medicines more affordable, but poor populations cannot afford them, even at low prices.
4) Health financing solutions exist, but they may not be enough to manage the overconsumption of medicines.

Strategies to improve access to medical products in the South-East Region focus on 1) efficiency of selection and procurement, 2) strengthening regulatory systems, 3) financing and pricing policies, 4) transparency in pricing, 5) access-oriented approaches to international patent rules, 6) intercountry collaboration, 7) monitoring medicines demand, and 8) re-aligning incentives for research and development.

2.3.2 Recent progress in the Western Pacific Region on improving access to medicines and moving towards UHC

Dr Socorro Escalante provided an overview of challenges faced by countries and areas in the Western Pacific Region. Depending on the country’s stage of development, support should cater to priorities in terms of financial protection, medicine cost, availability, quality and safety, and regulatory systems. The Universal Health Coverage: Moving Towards Better Health is an action framework for the western pacific region that includes comprehensive approach for policy intervention of the whole pharmaceutical system, from the production of medicines to the evaluation of expenditures.

WHO has identified three key areas where it can principally intervene. The first area is strengthening national regulatory systems. The Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce provides guidance for countries on 1) strengthening national regulatory systems in a stepwise approach that is targeted and based on the country-specific context; and 2) engaging in regulatory cooperation between mature and less-mature regulatory authorities, which is supported by the Regional Alliance of National Regulatory Authorities in the Western Pacific Region. These strategies helped achieve the following: 1) registration system was set up in Cambodia; 2) registration systems and quality assurance laboratory was set up in Papua New Guinea; 3) assessment of national regulatory authorities was conducted in China, Viet Nam, Lao Peoples Democratic Republic and Philippines and 4). The Pacific island countries have endorsed the sub-regional regulatory platform for medicines that will provide technical support and undertake regulatory functions.
The second area is strengthening pharmaceutical systems. This area of support focuses on evidence-based medicines selection, financing coverage, pricing and access to high-cost medicines, and procurement systems. Two websites currently serving as information-sharing platforms – Price Information Exchange for Medicines (PIEMEDS, www.piemeds.com) and Medicines Quality Assurance (MEDQUAL) for laboratory testing results – are being revamped and updated. One key achievement in terms of pricing, which was a follow-up activity from the fifth meeting on access to medicines, is the training on negotiation conducted for eight countries in February 2019.

The third area is combating antimicrobial resistance (AMR). A regional framework for accelerating action to fight AMR is being developed as a new mechanism of working.

2.3.3 Global updates on WHO's work on improving access to medicines in the context of SDGs: Road Map for Access, 2019–2023

Ms Claudia Nannei and Ms Swathi Iyengar presented the WHO draft Road Map for Access to Medicines, Vaccines and Other Health Products, 2019–2023, endorsed by the World Health Assembly in 2019. The road map aims to transition into a more comprehensive health systems approach. The government-wide approach must ensure that strategies are streamlined in financing, governance, health workforce and information for decision-making.

The two main strategic areas and activities are 1) ensuring quality, safety and efficacy of health products that oversee all activities pertaining to regulations advocating the use of the global benchmarking tool, developing WHO-listed authorities, emergency preparedness, prequalification and global surveillance and monitoring system; and 2) improving equitable access to medicines that focuses on research and development (R&D), management of intellectual property, evidence selection and fair and affordable pricing, procurement and supply chain and appropriate prescribing, dispensing and rational use.

The strategies under the WHO road map for access to medicines are linked with the SDGs and the Thirteenth General Programme of Work 2019–2023, which is promoting good health and well-being by ensuring the quality of medicines, protecting the population from financial risk and protecting a bigger population from illnesses.

2.3.4 Updates on OECD’s work

Mr Martin Wenzl provided an overview of the role and function of OECD through its health committee composed of policy-makers who meet twice a year to exchange experiences and conduct significant analytical work and data collection.

Several challenges have been identified in OECD countries. They include increasing prices of therapeutic medicines for oncology and rare diseases, on-patent medicines and even off-patent medicines; unmet medical needs not being adequately addressed by current investments in R&D; and uncertainty around the clinical benefits of medicines with early regulatory approval.

OECD countries have identified five policy options for pharmaceutical innovation and access to medicines, namely: 1) reduce R&D costs and encourage harmonization and mutual recognition; 2) improve spending efficiencies, such as cooperation in health technology assessment (HTA), joint negotiation, contracting and procurement and market competition; 3) determine willingness
to pay for new treatments and for health benefits; 4) develop new push-and-pull incentives; and 5) strengthen the information base to inform policy. OECD countries call for greater transparency to increase bargaining power.

Mr Wenzl shared examples of OECD’s work since 2018, including a published report on the use of routine data to assess the performance of medicines in clinical practice and a published report on improving forecasting of pharmaceutical expenditures. There are ongoing activities on policy options for coverage and pricing of oncology medicines and capacity-building for negotiations and improving the use of managed entry agreements. Additional work is being done on developing strategies to improve the reporting of pharmaceutical expenditure.

2.3.5 Discussion

Certain countries in the South-East Asia Region requested more information sharing and capacity-building on price negotiation. The WHO Regional Office for South-East Asia will facilitate capacity-building through study tours, in-country training and regional workshops.

On the quality of medical products, especially active pharmaceutical ingredients (APIs), countries should ensure manufacturer compliance with good manufacturing practices. WHO has published a list of prequalified APIs for countries. Harmonization and convergence are in place, and South-East Asia and Western Pacific Region countries need to coordinate with the regulatory authorities.

Some countries also requested information on the electronic systems for registration and procurement. Countries should discuss further collaboration.

2.4 Tools and indicators to measure access to medicines and the components of a national pharmaceutical system

This session informed participants about the outcome of an international experts' consultation on monitoring the components of a predictor of access to medicines held in Delhi, India from 26 to 27 February 2019. Participants discussed a set of tracer indicators that will allow monitoring if enablers are to move available and affordable safe, effective and quality-assured medicines.

2.4.1 Monitoring the components and predictors of access to medicines: Outcome of the international experts’ consultation

Ms Claudia Nannei presented on monitoring access to medicines. She explained two main concepts: 1) availability, in terms of medicines available in a facility during data collection; and 2) affordability, in relation to medicines prices afforded by the lowest-paid unskilled government sector worker. The formula for affordability is the national poverty line plus the price per daily dose of treatment over the daily wage of the lowest-paid government worker.

Information available in the medicine database of countries is scattered and time consuming to collect. Furthermore, the data are rarely used to implement policies. In lieu of this, WHO is working with Member States to determine what information would be useful in outlining policies.

Since 2001, the main sources of information on availability and price of medicines have been the Health Action International (HAI) project, which has been updated and is now called the WHO Essential Medicines and Health Products Price and Availability Monitoring Mobile Application.
(MedMon), and the Service Availability and Readiness Assessment Survey (SARA). Ms Nannei explained the selected high-level reference list of indicators for global monitoring and shared how countries contextualized the global monitoring indicators in the South-East Asia Region.

2.4.2 A tool to measure the availability and prices of medicines and medical products

Ms Swathi Iyengar provided an overview of the features of MedMon, which is a software application introduced by WHO that aims to collect and monitor information on the availability and prices of medicines locally in both private and public facilities, the supply chain status and the regulatory status. MedMon represents a significant breakthrough in the monitoring of availability and prices of medicines. She demonstrated how to navigate the software application and how to generate data for decision-making. She also provided an example of countries that successfully used the data collected to improve their systems.

2.4.3 Panel discussion

Panellists: Indonesia, Mongolia, the Philippines, Thailand and Timor-Leste
Moderator: Ms Claudia Nannei

The session aimed to learn from and understand countries’ experiences and opinions regarding the indicators for access to medicines. The panellists were asked questions on three topics: 1) What are the currently used key indicators in your country to measure progress regarding access to medicines? How regularly are these indicators measured and reported? 2) In which areas do you think it is most important to collect data regularly and report results to decision-makers using key performance indicators? 3) What are your major successes and/or challenges regarding collecting national-level data? What tools and support should WHO provide to improve the monitoring of pharmaceutical system performance in your country?

Indonesia has implemented a scheme called Jaminan Kesehatan Nasional (JKN) to implement UHC. It sets the indicators to measure progress in improving access to medicines. An e-catalogue is used to monitor prices and availability of medicines in primary health care. The logistics system uses 20 indicators, and the data are updated yearly. Challenges include lack of infrastructure, accuracy in quantification, high prices and lack of negotiation on single-source medicines.

Thailand has four strategies to ensure access to medicines: 1) availability of quality medicines and management of shortages; 2) monitoring of percentage of patients with high-cost care; 3) antibiotic use; and 4) measuring the price and quantity of procurement based on the data approved by the Ministry of Health and national regulatory authority.

The Philippines is mandated by the Cheaper Medicines Act to lower medicines prices. An existing indicator is government spending on total pharmaceutical expenditure. Challenges include lack of patient-level data for reimbursement. For availability, only medicines procured centrally by the Department of Health (DOH) are being monitored monthly. For pricing, all drug establishments are required to submit price data to the DOH, thereby allowing the Department to track quantitative pricing.
Timor-Leste determines the total management of the supply chain and coordinates the budgeting with the Finance Department of the Ministry of Health. The current challenges are infrastructure programme and information system management in order to provide an efficient regulatory board to apprehend proper dissemination of information.

Mongolia has set up a health insurance system that is allowed to check the pharmaceutical budget. The government expenditure is roughly MNT 250 billion, 60% of which goes to tendering services, while 9% is for reimbursement. An efficient insurance system allows Mongolia to track the number of prescribed and non-prescribed medicines.

2.4.4 Group work

Working in small groups, participants were asked to share their opinions and perspectives on the access to medicines indicators previously identified by experts. The participants assessed and reviewed the indicators according to their country context, their country’s key priorities and relevance of the data. The outcome of the group work will provide direction for developing a proper system for access to medicines.

The results of the group work showed the relevant key performance indicators helpful in monitoring access to medicines in different areas, such as availability, financial protection, pricing, selection, rational use and regulation. For some countries, collecting and analysing data continue to be a challenge because they lack a proper information system. WHO can help these countries to identify and measure these indicators through a consolidated system (for presentation next year). It is imperative to note that these indicators, when evaluated, must not be treated in isolation but rather be integrated with the rest of the health information system.

2.5 Improving price transparency: Taking stock and moving forward

2.5.1 Improving transparency of markets for medicines, vaccines and other health medical products

Ms Swathi Iyengar and Ms Claudia Nannei presented the Seventy-Second World Health Assembly resolution that calls for price transparency. Ms Iyengar shared the trends and examples of a system-wide problem that will outstrip the rate of inflation. The WHO Technical Report on Pricing of Cancer Medicines and Its Impacts tackles the impact of growing differences in list prices and net prices of medicines on the effectiveness of external reference pricing. A lack of price transparency is not consistent with good governance and accountability, and without assurance that governments are acting in the best interest of taxpayers, purchasers cannot know if they are actually receiving a favourable deal. A price transparency tool developed by the Surescripts Network Alliance shows the prices of alternatives to help patients and carers make decisions.

Publication of the WHO technical report on pricing of cancer medicines helped to improve price transparency as a means of improving access. Resolution WHA72.8 laid out the specific action points for Member States and WHO to improve the transparency of markets for medicines, vaccines, and other health products.

To advance resolution WHA72.8, WHO urged the participants to contribute to global work on fair pricing, including participation in developing far pricing definition, forums and conferences and
establishment of working groups on issues affecting access. Updating PIEMEDS will also be an area of future work.

2.5.2 Panel discussion: Can transparency contribute to lower prices and improve access to pharmaceuticals? Views from the field

Panellists: Bhutan, Maldives, Malaysia, Republic of Korea and Singapore
Moderator: Professor Soonman Kwon

This session aimed to determine the perspective of countries on transparency as contributory to lowering prices and improving access to pharmaceuticals.

In terms of the feasibility of sharing information on the net prices of health products, all countries recognized the value of price transparency. Bhutan, Malaysia and Maldives publish the prices of registered medicines on the NRA website and the suggested retail prices of essential medicines on the health ministry’s website. However, prices from government procurement are not publicly available.

Malaysia, the Republic of Korea and Singapore have mechanisms to collect price information, but the information is not publicly shared because of confidentially agreements and lack of legal binding. India, Mongolia, the Philippines and Thailand have strict legal binding to enforce information sharing.

The types of information considered by countries to be a high priority for information sharing include high-cost medicines, single-source products and multisource products and oncology therapies. Certain countries shared that medicines for noncommunicable diseases and antibiotics should also be prioritized.

In terms of improving public reporting of patent status information and marketing of the approval status of health products, all countries refer to NRAs for marketing authorization and registration of medicines. NRAs are mandated to ensure the quality, safety and efficacy of medicines. However, the registration status usually does not provide information on the patent status; hence, most countries collaborate with their national Intellectual Property Office (IPO). Notably, the Republic of Korea discloses patent information through the Ministry of Food and Drug Safety’s website. When patent information is not available, technical evaluations are impacted, making it difficult to guide policy-makers on how to subsidize high-cost therapies.

It was noted that sharing of information should be taken with an in-depth analysis of the market and strategic response from the pharmaceutical industry. Strategies should not be totally dependent on legal binding, but there are several interventions that can be undertaken such as tapping the health insurance systems, allowing market competition and enforcing generic prescribing. It is also important to work with other ministries that might have a general mandate for price control that includes medicines.

2.5.3 The impact of federalization on the availability of essential medicines, Nepal

Ms Sangita Shah shared the journey of Nepal in transitioning to a unitary system with a three-tier federal government system in terms of availability of essential medicines. Before federalization,
public procurement was centralized. There was an international competitive bidding tender process that provided value for money through bulk purchasing. As Nepal transitioned to federalization, the management of basic health-care services including procurement of medicines moved to the local level. After federalization, significant work had to be done to strengthen local capacity in forecasting, technical evaluation and especially quality assurance for medical products.

In sectors like health, where resources are limited, studies have shown that centralized or partially centralized procurement offers a greater benefit because of the larger economies of scale. In order to address the current challenges, the Government came up with a framework agreement that: 1) allows centralized negotiation with decentralized purchasing; 2) establishes an autonomous procuring agency; 3) has appropriate legal provision and adequate technical capacity but should be flexible and responsive; and 4) analyses market prices and establishes standard market and institutional prices.

2.5.4 The effects of price controls on availability and affordability of targeted essential medicines and health products, Sri Lanka

Mr Dharmasiri Herath and Mr M.R.H. Swarnathilake shared that medicines in the public sector are freely given to the people, while medicines in the private sector are monitored and regulated by the Government. Sri Lanka faced major issues such as market monopoly, high costs, non-availability and poor quality of medicines, which led to the strategy of controlling medicines prices through a competitive bidding process and enforcing a maximum retail price.

All kinds of locally manufactured medicines are subjected to price control. The Government requires cost declarations and sets the profit margin. The prices are monitored by minor and major pricing committees.

Overall, the benefits of having a price control system include price competition and reduction, accessibility and price uniformity for both the private and public sectors. However, the price control strategy should not be taken as standalone; it needs to be combined with other interventions.

2.5.5 Current issues of medicines prices and price policies, Viet Nam

There are several laws and policies in Viet Nam to support access to medicines; however, more effort is needed to enforce inspections and penalties for violating regulations to control drug price margins. With the current strategy, the medicine market was stable between demand and supply from 2014 to 2018, and prices are lower than those of other Asian countries.

Centralized procurement and brand name controls have contributed significant savings and increased the trend of medicines utilization by the Government.

Moving forward, Viet Nam is considering expanding the list of medicines under centralized procurement, price negotiation and domestic drug production. The hospital pharmacies will be imposing price thresholds and printing them on the labels.
2.5.6 Actions to improve prices transparency and information sharing on health products in the Asia Pacific region

Panellists: Bangladesh, Brunei Darussalam, China, Sri Lanka and Viet Nam
Moderator: Dr Klara Tisocki

All of the countries on the panel have a similar approach to obtaining information on medicines prices, that is, referring to historical prices and exploring online prices from the websites of reference countries.

Countries have acknowledged that a regional source of information should be made available to share relevant price information (e.g. maximum retail price, net price and price paid by the patient) and to disclose product quality information.

In terms of medicine shortages, some countries such as Brunei Darussalam and China have a mechanism in place to report and gather information on stock levels, while other countries such as Sri Lanka have struggled to find alternate suppliers during shortages. A regional platform for notification of shortages is important to provide information on alternative medicines and suppliers.

2.6 Using health technology assessment (HTA), local price information and drugs consumption data and other international comparative work

2.6.1 Health technology development in China: How it has helped improve access so far

Professor Ying Yao Chen stated that older people are more susceptible to noncommunicable diseases and that high medicine prices make them vulnerable to limited medical options. China has a structured medicine information system under the UHC where there are primary medical schemes for three sectors: employees, rural farmers, and people residing in urban areas who are unemployed. All these schemes are publicly funded by the National Health Insurance System, and they come with generous benefits in terms of diagnosis and operation.

The reimbursement reform is undergoing negotiation exercises that are principally headed by the Chinese NMPA and National Medical Healthcare Security Authority, which was established in 2017. The national health reimbursement drug list is updated every four to five years. The central Government’s advocacy is to include innovative drugs with an expanded coverage rate including 15% Western medicines and 26% traditional Chinese medicines. Drugs are classified into two main types: Type A drugs are paid through government financing, while Type B drugs are paid in part by the patient.

The current challenges in terms of improving HTA includes drafting government-based policies on the efficiency and necessity of HTA, which must be done in consideration with policy-makers. The validity of medicine evaluations is also being assessed. The HTA agency must be more inclusive to stakeholders. The international HTA centres must conduct a comprehensive and integrated appraisal review to continuously expand knowledge on HTA efficiency.

In China, HTA activities are initiated by the central Government, National Health Commission and National Health Care Security Authority. The integrated HTA review appraisal and price
negotiation is shaping the emerging approach, and the structure of the HTA hierarchy is becoming clear.

2.6.2 Experiences of using HTA for drug reimbursement decisions in the Republic of Korea

Professor Seungjin Bae shared that the Republic of Korea has experienced a double increase in pharmaceutical expenditures since 2001, making 30% of the total expenditure. This triggered the Government to introduce the Drug Rationalization Program. Only medicines that were assessed based on pharmacoeconomic data will be included in the reimbursement system in the Health Insurance and Review Assessment (HIRA).

The HIRA programme had initial limitations because it was theoretical-based with no consolidated study for infrastructure and domestic feasibility. The programme has been revised to include scientific basis, budget impact, severity and rarity of disease. One of the challenges in implementing the HIRA programme is compromised accessibility of cancer drugs due to the lack of standard clinical data, making it difficult to justify its high price. The industry raised that it is very challenging to enter the market in the Republic of Korea; however, based on HIRA comparative studies with two countries, results showed that there were no significant differences between pricing mechanisms of drugs despite using similar methods. The HIRA guideline is being updated.

To complement economic evaluation as measures for reimbursement in the Republic of Korea, HIRA has introduced a benefit enhancement plan for four major disease categories: cancer, cardiovascular disease, cerebrovascular disease and rare diseases, and risk-sharing agreement and managed entry agreement for cancer and orphan drugs.

Overall, the economic evaluation deals with value for money but may not be helpful for medicines with no alternatives, such as cancer and orphan drugs. Countries should be considering compelling criteria in setting priorities.

2.6.3 Experiences with medicines price transparency and improving procurement efficiency in Thailand

Ms Netnapis Suchonwanich presented that Thailand sought to prioritize long-term goals in developing the national drug policy by evaluating the medicines framework. There have also been proposals to amend regulations to control availability and equitable access to medicine. The current priorities are strengthening local production for medical products and controlling prices.

Thailand employs a systematic means of identifying medicines that are deemed appropriate for screening and will be reviewed by different panels of experts before they are endorsed for price negotiation and later listed in the Essential Medicines List. The country also employs an objective approach that seeks to integrate HTA into the process by developing its own incremental cost-effectiveness ratio (ICER) that measures the outcome of new versus conventional interventions.

In developing a negotiation model, Thailand introduced a volume bargaining strategy, but it should not be used as standalone. Other strategies employed included value-based negotiation, compulsory licensing, strengthening local production, and bargaining for national and regional public hospitals and other organizations.
A price performance approach was also introduced for medical device as part of the bidding requirements. The lowest price possible must be considered with notes on quality assurance and existing certifications. Price transparency remains a challenge because most medicines have special contracts with manufacturers who demand that they remain confidential.

In terms of the health insurance bargaining system, Thailand uses a tracking system for high-cost medicines (e.g. oncology and orphan drugs) to ensure that products go directly to patients in hospitals or at home.

2.6.4 Group discussion

Participants were split into groups and asked to discuss the following questions: What issues do you think are needed to be addressed and escalated into a country-level discussion? and what are your expectations for WHO that can be integrated into the action plan next year?

Group 1: Price transparency and information sharing are crucial and must be given priority. Countries can review existing legislation that can facilitate information sharing, and, if necessary, amendments can be made. WHO is requested to provide support on the use of PIEMEDS as a platform to be consistently updated; facilitate coordination of NRAs for registration of medicines and quality assurance; facilitate pooling of procurement data and analyse total drug cost and availability with respect to economic evaluations; facilitate harmonization of HTA standards and methodology; provide technical assistance on data collection and analysis; and strengthen the capacity of countries and regional networks.

Group 2: At the country level, there is a need for sharing of information on pharmaceutical logistics and expenditure of public and private sectors alike to achieve price transparency, which covers costs from the manufacturer all the way down to the patient. Information should be for both branded and innovative generic drugs and relevant certifications regarding the quality, safety and efficacy of the products. Information systems should be in place to monitor drug shortages. Pooled procurement that initiates negotiations will help countries increase their negotiating power. In terms of research, collaboration on bioequivalence and clinical studies review is also needed to monitor the safety and efficacy of the products. WHO is requested to: 1) develop a standardized template on analysis of the data to assess monthly stock situations and quality management issues; 2) set up a platform for information sharing on medicines shortages; and 3) provide training and facilitate exchange programmes.

Group 3: At the national and regional levels, price sharing must be standardized for uniform implementation. Clear guidance on linkage of patent and registration is needed in some countries. An institutional development plan must be present in each country for access to medicines, and it needs to be shared publicly so all stakeholders are informed on their respective roles in the achievement of equitable access to medicines. WHO can assist by providing skills training, workshops and capacity-building on 1) price negotiation, 2) strengthening local production, and 3) review of pharmaceutical dossier and guidance on fast track mechanisms.

Group 4: At the country level, there is a need to 1) conduct proper market review and analysis; 2) strengthen methodology capacities of post-market control and pharmaceutical pricing; 3) strengthen coordination between all stakeholders; and 4) conduct quantification of essential medicines efficiently. WHO is requested to 1) support countries with the conduct of market
analysis; 2) support national and regional coordination in monitoring the implementation of access to medicines indicators; 3) provide capacity-building; and 4) establish a platform for information sharing on prices and other relevant information, such as technical guidance on reviewing HTA and clinical management.

2.6.5 Summary session

Dr Tisocki summarized the discussions and agreements of the two-day meeting, and Dr Escalante provided an overview of actions to be taken going forward.

2.7 Closing remarks

Mr Seunghyun Hwang, OECD/Korea Policy Centre, thanked the participants for their active cooperation in sharing their views and information on several matters that ultimately led to the success and productivity of the meeting. He acknowledged the need to review policies on a UHC perspective to improve and encourage collaboration between countries, and to pay keen attention to the policy portfolio that drives and dictates pricing. Major issues that directly impact consumers, such as out-of-pocket payments and expenditures, must also be re-evaluated for their implications to focus on the natural use of medication for the next meeting.

Separate sessions on issues of financial risk protection will be held at the next meeting, along with sessions on understanding barriers, feasibility and bringing in policy-makers when it comes to pricing and accessibility. Pharmaceutical policies will also be a priority agenda in the future.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

Rapid population ageing in Asian countries is increasing the demand for better quality and affordable health care, which leads to rapidly increasing consumption of medicines and health technologies. To achieve UHC with an ageing population, countries need to improve their pharmaceutical systems by identifying ways to deal with medication non-adherence, delayed treatment, inappropriate prescribing and use of medicines, polypharmacy, and adverse events including medication errors. Cost containment policies can help improve the allocation of resources. Furthermore, a more systematic approach is needed. There is also a need to consider determinants from both the supply and demand side.

Countries shared good practices in terms of pricing transparency and agreed that information should be publicly available. Some countries generously shared information on pricing (i.e. listed/maximum), how selection of medicines is supported in several countries on economic evaluation, pricing policies, and price negotiation practices (strategies and skills).

To improve price transparency, a World Health Assembly resolution (WHA72.8) provides specific recommendations for Member States. However, there are still many questions to consider, such as: Who needs what information? Different information is needed according to global needs and the needs of high-income countries and LMICs. The capacity to share can be very different with consideration to data availability, legal status at national level, and willingness of suppliers and
industry to provide. Transparency should look at other issues, including quality, supplier performance and shortages.

Several tools were discussed to measure access to medicine and the components of national pharmaceutical systems. Key performance indicators are needed to regularly monitor progress and performance of national pharmaceutical systems and implementation of national medicines policy in order to support policy decision-making.

The Road Map for Access, 2019–2030, developed by WHO in consultation with Member States, provides guidance on:

- ensuring quality, safety, and efficacy of health products by strengthening regulatory systems, assessment through prequalification and strengthening market surveillance; and
- improving equitable access by supporting research and development that meets public health needs and improves access to health products, application and management of intellectual property to contribute to innovation and promote public health, procurement and supply chain management and appropriate prescribing, dispensing and rational use.

Most of the performance indicators for regulation, supply chain, pricing, procurement and drug use are highly relevant or relevant in most countries, and most are doable, but some countries find it difficult to implement them. Most indicators are of high priority, with some to be measured less frequently. The most practical approach is to conduct a well-sampled, health/household survey only every three to four years.

There is a need to find suitable solutions in different contexts, especially when there is no complex and well-developed information yet in place. It is important to use existing services or other forms of data collection. The WHO MedMon application was introduced as a transitional tool to more comprehensive information on health systems that captures pharmaceutical data on affordability and availability such as pricing, registered medicines, procurement and prescription monitoring.

3.2 Recommendations

3.2.1 Recommendations for Member States

Member States are encouraged to consider a systematic approach in the achievement of UHC including all the determinants from both the supply and demand side in terms of the following areas:

1. **Pricing**
   - Explore existing policies to control prices (e.g. laws and regulations on financing, procurement, competition and insurance).
   - Focus on outcome-based interventions rather than pricing reduction alone, considering the treatment outcome of the larger population, as a whole but also developing policies to anticipate the needs of the ageing population.
   - In terms of legislation to facilitate information sharing, review existing policies to use as a mechanism to promote transparency.

2. **Collaboration**
• Work and collaborate more with national regulatory authorities in terms of registration and quality of the medicines and use existing regional networks such as the Regional Alliance for National Regulatory Authorities in the Western Pacific and the South-East Asia Regulatory Network in terms of sharing information.
• Review the suitability of pooled procurement according to country context.

(3) **Research and evidence**
• Consider a more comprehensive approach that extends beyond cost-effective evaluation to value-based frameworks that include political, ethical and equity issues across the population.

(4) **Availability of medicines**
• Assess the availability of medicines for chronic conditions and other conditions affecting the ageing populations.
• Strengthen stock-out monitoring and quantification of essential medicines at the primary health care level.

### 3.2.2 Recommendations for WHO

WHO was requested to support Member States in the following areas:

(1) **Pricing**
• Urgently improve the Price Information Exchange for Medicines (PIEMEDS) to better respond to the needs of countries and ensure timely price information sharing.
• Continuously support the improvement of negotiation skills.
• Review parallel product dossier evaluation.

(2) **Collaboration**
• Facilitate shared costs and availability of medicines through PIEMEDS.
• Provide technical assistance on pooled procurement and capacity-building of licensing and registration.
• Review setting up a network for product evaluation such as bioavailability and bioequivalence testing.

(3) **Research and evidence**
• Provide technical assistance on data collection and data analysis.
• Review setting up a collaborating centre for health technology assessment (HTA) at national and regional levels and updating treatment guidelines.

(4) **Availability of medicines**
• Support countries to support policies on increasing access and availability of essential medicines to chronic conditions and other essential medicines for the ageing population.
• Assist with the pooled procurement and development of benefit packages at the primary health care level to improve bargaining power.
• Provide continuous support for improving procurement systems in countries.
Annex 1:
List of participants, temporary advisers, observers and Secretariat

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## Annex 2: Agenda

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<tr>
<th>Day 1: Tuesday, 24 September</th>
<th>Day 2: Wednesday, 25 September</th>
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<tbody>
<tr>
<td><strong>8:30-9:00</strong> Registration</td>
<td><strong>8:30-8:40</strong> Recap from previous day's discussions</td>
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<tr>
<td><strong>9:00-9:30</strong> Opening session</td>
<td><strong>8:40-9:00</strong> Session 3: Improving price transparency: taking stock and moving forward</td>
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<tr>
<td>• Opening remarks – Dr Liu Yunguo, WPRO &amp; Mr Seunghyun Hwang, OKPC</td>
<td>• Improving transparency of markets for medicines, vaccines and other health medical products – 72nd World Health Assembly Resolution – Ms C. Nannei</td>
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<tr>
<td>• Introductions</td>
<td>• Panel discussion: Can transparency lower prices and improve access to pharmaceuticals? Views from the filed on the 72nd WHA – Bhutan, Malaysia, Maldives, Republic of Korea</td>
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<td>• Objectives of the meeting – Dr Klara Tisocki, SEARO</td>
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<td>• Appointment of officers of the meeting</td>
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<td>• Administrative announcements</td>
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<td>• Group photo (Conference Hall)</td>
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<td><strong>9:30-10:00</strong> Tea break (Lower lounge)</td>
<td><strong>10:00</strong> Country presentations</td>
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<td><strong>10:00-10:30</strong> Keynote presentation: Implication of population ageing for pharmaceuticals policy - Prof Soonman Kwon, SNU</td>
<td>• Nepal: The impact of federalization on the availability of essential medicines – the need for information on prices and quality of procured medicines</td>
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<tr>
<td><strong>10:30-11:10</strong> Session 1: Access to medicines: a changing agenda regionally and globally</td>
<td>• Sri Lanka: The effects of price controls on availability and affordability of targeted essential medicines and health products</td>
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<td>• Recent progress in the South East Asia and Western Pacific regions on access to medicines and moving towards UHC – Dr K. Tisocki &amp; Dr S. Escalante</td>
<td>• Viet Nam: Current issues of Medicines Prices and Price Policies Q&amp;A</td>
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<td>• Global update on WHO's work on improving access to medicines in the context of SDGs- Roadmap for access 2019-2023 – Ms Claudia Nannei, WHO HQ</td>
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<td>• Updates on OECD's work – Mr Martin Wenzl, OECD</td>
<td><strong>11:00-12:00</strong> Panel discussion: Actions to improve prices transparency and information sharing on health products in the Asia Pacific – Bangladesh, Brunei Darussalam, China, Sri Lanka, Viet Nam</td>
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<tr>
<td>Panel discussion</td>
<td>Moderator: Dr K. Tisocki</td>
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<td><strong>12:30-13:30</strong> Lunch (Cafeteria)</td>
<td><strong>12:00-13:00</strong> Lunch (Cafeteria)</td>
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<tr>
<td><strong>13:30 – 13:50</strong></td>
<td><strong>13:00-14:00</strong> Session 4. Using HTA, local price information and drugs consumption data and other international comparative work</td>
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<tr>
<td>• Monitoring the component and predictors of access to medicines: outcome of the international expert consultation – Ms C. Nannei</td>
<td>• Health technology assessment development in China: How it helped improve access so far? – Prof Yingyao Chen</td>
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<tr>
<td>• MEDMON: a tool to measure availability and prices of medicines and medical products – Ms Swathi Iyengar, WHO HQ</td>
<td>• Experiences of using HTA for drug reimbursement decisions in the Republic of Korea</td>
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<tr>
<td>• Panel discussion: Indicators – Indonesia, Mongolia, Philippines, Thailand, Timor Leste Moderator: Ms C. Nannei</td>
<td>- Prof Seungjin Bae</td>
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<tr>
<td>Group discussion</td>
<td>• Experiences with medicines price transparency and improving procurement efficiency in Thailand – Ms Netnaps Suchonwanich</td>
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<tr>
<td>Time</td>
<td>Event Description</td>
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<tr>
<td>15:30-16:00</td>
<td><strong>Tea break (Lower lounge)</strong></td>
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<tr>
<td>16:00-16:45</td>
<td>• <strong>Report back from group discussion</strong></td>
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<td>16:00-16:30</td>
<td><strong>Tea break</strong></td>
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<tr>
<td>16:00-16:45</td>
<td><strong>Summary session:</strong></td>
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<td>• Summary of what we have planned, including supporting research and evaluation</td>
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<td>• Support by the secretariat – Dr. Tisocki &amp; Dr. S. Escalante</td>
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