Second Meeting on Access to Medicines under Universal Health Coverage in the Asia Pacific Region

17–18 September 2015
Seoul, Republic of Korea
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MEETING REPORT

SECOND 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 Second 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 those who participated in the Second Meeting on Access to Medicines under Universal Health Coverage in the Asia Pacific Region in Seoul, Korea from 17 to 18 September 2015.
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Keywords: Pharmaceutical preparations/Delivery of health care/Universal coverage/Health services accessibility
ABBREVIATIONS

ADR    adverse drug reaction
ATC    anatomical therapeutic chemical classification
DDD    defined daily dose
ED     essential drugs
HTA    health technology Assessment
HIRA   Health Insurance Review and Assessment Service (Republic of Korea)
OECD   Organisation for Economic Co-operation and Development
PBAC   Pharmaceutical Benefits Advisory Committee (Australia)
PBS    Pharmaceutical Benefits Scheme (Australia)
PPRI   pharmaceutical pricing and reimbursement information
UHC    universal health coverage
SUMMARY

Medicines and health technologies are central to achieving equitable access to quality health services and risk protection goals of universal health coverage (UHC). The financing, pricing and reimbursement of medicines and health technologies have been major challenges for many countries. Medicines are often not covered or inadequately covered in benefit packages and health financing schemes, resulting in high out-of-pocket payments. Hence, efficient medicines management policies are crucial for the financial sustainability of health systems.

To assist the Member States to improve the efficiency of their medicines and health technology management system, the establishment of the Asia Pacific Network on Access to Medicines under Universal Health Coverage (UHC) was proposed at the first Meeting on Access to Medicines under UHC in the Asia Pacific Region held in 2014. The Network is a joint initiative by WHO Regional Office for the Western Pacific, the Organisation for Economic Co-operation and Development (OECD) Korea Policy Centre, and the WHO Collaborating Centre for Health Systems at Seoul National University. The first network meeting was held at the second Meeting on Access to Medicines under Universal Health Coverage in the Asia Pacific Region in Seoul, the Republic of Korea, from 17 to 18 September 2015.

The objectives of the meeting were:

1) to share information and results of studies initiated from the first meeting on Access to Medicines under Universal Health Coverage in the Asia Pacific Region to guide medicines and health technology policies and strategies to achieve Universal Health Coverage;

2) to identify good practices for decision-making that are appropriate to country contexts to develop financing schemes and comprehensive benefit packages for medicines and health technologies; and

3) to discuss the role and activities of the Asia Pacific Network on Access to Medicines and the options to participate and exchange information.

Participants shared information on global issues and regional initiatives on pharmaceutical policies for UHC and access to high-cost medicines (such as treatment for viral hepatitis) were highlighted. Australia and Mongolia shared experiences on sofosbuvir for hepatitis C. The results of brief country profiles on pharmaceutical system and policies were presented by all Member States. The Philippines and the Republic of Korea have completed the longer survey and they shared their results.

Participants in groups analysed issues and identified priority areas for collaboration. They acknowledged the importance of a regional network and confirmed interest and participation. The goals, objectives of the network, methods, membership, and secretariat roles were discussed and agreed. The network activities will enhance the capacity of policy-makers to identify good practices and to make decisions that are transparent, evidence-based and timely to develop national policies for medicines management as a key focus of sustainable UHC expansion.
1. INTRODUCTION

1.1 Meeting organization

The establishment of the Asia Pacific Network on Access to Medicines under Universal Health Coverage (UHC) was proposed at the first Meeting on Access to Medicines under UHC in the Asia Pacific Region held in 2014. The Network is a joint initiative by WHO Regional Office for the Western Pacific, the Organisation for Economic Co-operation and Development (OECD) Korea Policy Centre, and the WHO Collaborating Centre for Health Systems at Seoul National University.

The Second Meeting on Access to medicines Under Universal Health Coverage in the Asia Pacific Region was held in Seoul, the Republic of Korea, from 17 to 18 September 2015. This was the first network meeting for Member States to share information on how pharmaceutical systems are organized in each country, what medicines were covered by government procurement and national health insurance schemes, and the processes involved such as pharmacoeconomic evaluation. To achieve sustainable outcomes, the Network objectives, membership criteria, and governance structures were discussed and agreed upon. Policy-makers from 14 Member States participated (Australia, Brunei Darussalam, Cambodia, China, Indonesia, the Lao People's Democratic Republic, Malaysia, Mongolia, New Zealand, the Philippines, the Republic of Korea, Singapore, Thailand and Viet Nam).

1.2 Meeting objectives

The objectives of the meeting were:

1) to share information and results of studies initiated from the first meeting on Access to Medicines under Universal Health Coverage in the Asia Pacific Region to guide medicines and health technology policies and strategies to achieve Universal Health Coverage;

2) to identify good practices for decision-making that are appropriate to country contexts to develop financing schemes and comprehensive benefit packages for medicines and health technologies; and

3) to discuss the role and activities of the Asia Pacific Network on Access to Medicines and the options to participate and exchange information.

2. PROCEEDINGS

2.1 Opening session

Mr Lee, Suk Kyu, Director-General of OECD Korea Policy Centre, opened the meeting by welcoming participants to the Republic of Korea, and emphasized the mutual goal to achieve access to medicines under UHC. Dr Tisocki, Coordinator of Essential Medicines and Health Technologies at the WHO Regional Office for the Western Pacific, contributed on behalf of the WHO that the meeting is an ideal forum to collaborate and share ideas to facilitate best policy practices for medicines to benefit package design under UHC. Professor Tae-jin Lee from the WHO Collaborating Centre for Health System and Financing at Seoul National University also affirmed the benefits of establishing best practices in policy making between countries in the Asia Pacific. Mr Luca Lorenzoni of OECD, expressed his enthusiasm for the activities of the following two days, and the potential benefits it could have for the member states represented.

Following brief participant introduction, Ms Uhjin Kim, Technical Officer for Pharmaceuticals at the WHO Regional Office for the Western Pacific presented the meeting agenda. Ms Adriana Platona, Assistant Secretary of Pharmaceutical Evaluation at the Department of Health Australia was elected as Chairperson and Mdm Abida Syed M. HAQ, Director of Pharmacy Practice and Development, Pharmaceutical Services Division, Ministry of Health Malaysia was elected as Vice-Chairperson.
2.2 Pharmaceutical policies and the Regional Network on Access to Medicines under Universal Health Coverage

Dr Suzanne Hill presented on pharmaceutical policies for UHC – global perspectives. Dr Hill explained access to affordable medicines as an important element in achieving UHC. She presented data on several high cost medicines such as Hepatitis C and cancer medicines and their price differences across countries and over time. She has emphasized the importance of price control mechanisms and suggested several policy options. However, very low prices and donations may lead to reduction in market incentives, shortages, and poor quality.

Dr Zaheer-Ud-Din Babar presented the latest trends in pharmaceutical pricing policies and gaps in evidence by explaining the pharmaceutical pricing policies in Australia, New Zealand, China, Thailand, and Malaysia. These countries provide patient access to essential medicines through taxed-based system or social health insurance. Although many of these countries have almost 100% population coverage and low or no patient co-payment, they still face challenges in providing access to high cost medicines and controlling prices. Furthermore, the content, evidence, and impact of the Journal of Pharmaceutical Policy and Practice were discussed. Dr Babar emphasized that publishing research in an appropriate and high impact forum is crucial to initiate policy benefits.

Dr Tisocki presented on medicines access gaps and issues in Asia and the vision of the regional network. She outlined the challenges faced by countries in the Region and getting the medicines policies right on the scope and coverage of minimum benefit packages. To promote collaboration and share information on evidence-based policies, Dr Tisocki explained the rationale, goals, visions and desired outcomes of the Regional Network on Access to Medicine under UHC in the Asia Pacific Region.

2.3 Understanding country pharmaceutical systems

Ms Uhjin Kim presented the summary of pharmaceutical system country profiles. Two-page country profiles were developed to provide brief overview on how pharmaceutical systems are organized in member countries and how a drug enters the market, price set, and reaches a patient through procurement or reimbursement mechanisms. Once further refined and endorsed by the countries, the country profiles will be published online.

2.4 Poster walk on pharmaceutical system country profiles

Two-page country profiles were developed into poster presentations during the meeting. Countries were divided into three groups and each country explained their pharmaceutical system, key policies, and answered queries from other countries. The session enabled participants to gain deeper understanding of each other's' pharmaceutical system and exchange information and views on policy interventions.

2.5 Pharmaceutical pricing and reimbursement information survey

Professor Tae-jin Lee presented on adopting pharmaceutical pricing and reimbursement information (PPRI) survey for the Regional Network – purpose and methodology. Professor Lee expounded on the PPRI pharmaceutical survey that will be utilized as a common tool to systematically collect data on pharmaceutical policy, to provide in depth knowledge on country specific decision-making processes for selection, pricing, and reimbursement of medicines and health technology. Professor Lee projected the anticipated benefits as increased transparency on policy decisions and improved pharmaceutical system contributing to UHC.
2.6 PPRI longer survey presentations

Dr Francisco Soria presented the results of the PPRI survey in the Philippines. Dr Soria explained the results from the long survey outlining the major areas of concern in market authorization, pricing, procurement and reimbursement. Through this approach the Philippines has policies in place to ensure access to medicines, including: *The Philippine Medicines Policy 2011–2016*, The Philippine National Formulary, The Generics Act 1988, The Cheaper Medicines Act and the Drug Price Reference Index.

Dr Youn Jung presented the results of the PPRI survey in the Republic of Korea. Dr Jung explained the pharmaceutical system flow from marketing authorization to reimbursement and patient copayment. National Health Insurance Service (NHIS) covers the population and Health Insurance Review and Assessment Service (HIRA) recommends coverage based on pharmacoeconomic evaluation. Reimbursement is based on a national positive list from 2007. Pricing of medicines range from price-volume negotiation, generic price linkage, risk sharing agreements, and mark-up regulation.

Feedback on the PPRI survey was collected through a brief questionnaire which listed survey topics and asked if information is available in the country and if the participants found sharing information on the topic useful. Dr Klara Tisocki explained about the questionnaire and the participants handed in the completed forms during the meeting.

2.7 Access to high cost medicines

The purpose of the session was to raise awareness on access issues on high cost medicines, and for countries to exchange information on their plans on how to achieve equitable, affordable access to Sofosbuvir and other Direct Acting Antivirals for Hepatitis treatment.

Ms Tsetsgee Purejav presented the strategies to expand access to viral hepatitis treatment in Mongolia. Ms Purejav explained the high burden of liver cancer and viral hepatitis in Mongolia and the government efforts to tackle the issues. The draft National Program on Control of Viral Hepatitis 2016-2025 aims to reduce mortality due to chronic liver inflammatory diseases. Part of this endeavour includes an Access Program for expanded access to hepatitis B and C medicines. After almost two years of negotiation in June 2015 the Ministry of Health and Gilead signed a Memorandum of Understanding for the agreed prices for Sovaldi (US$ 300) and Harvoni (US$ 400).

Ms Adriana Platona presented on access to new Hepatitis C treatment in Australia. Ms Platona discussed how Australia, as a “rich” country, also has trouble with access to the high cost Hepatitis medicines. Australia has a high prevalence of Hepatitis C, projected to be 230,000 infected. Along with the high prevalence there is a high budget impact. To treat approximately 12,500 people per year, the initial asking price is AU$ 3.7 billion over five years. Based on the Pharmaceutical Benefits Advisory Committee (PBAC) framework the cost will be AU$ 1.3 billion over five years, this equates to AU$ 25,000 per cure. The negotiations to decrease the budget impact on Australia are ongoing.

Dr Peter Beyer presented on managing intellectual property for access to viral hepatitis medicines via Skype. He reviewed available options for lowering prices of new hepatitis drugs by comparing the price options between developed and developing countries, differential pricing and license agreements for Sofosbuvir. He also shared patent and price information for Hepatitis B drugs entecavir and tenofovir. Importantly, the WHO essential medicines list involves all new treatments for hepatitis C. On request, WHO can provide technical assistance to Member States to identify best options to access new treatments.

2.8 Pharmaceutical policies to address medicines access issues in the Asia Pacific region

Dr Libby Roughead presented on access to medicines for ageing population in the Asia Pacific. Medicines for chronic diseases are generally on Essential Medicines Lists in most countries, however, these medicines and their generic versions are not always available in the public sector and
procurement and patient prices are high. Ensuring access to medicines for older people involves strengthening pharmaceutical systems. However, while access to medicines is a key objective, provision alone does not address the issues of underuse and inappropriate use of medicines and poor health literacy. There is an opportunity to focus on whole patient management, rather than only a medicine focused approach.

Dr Kathy Holloway presented on the country situation analysis in South-East Asia Region countries. A rapid two-week “diagnostic” appraisal of medicine management was conducted which looks into medicines supply, selection, use, regulation and policy. Mandated by Regional Committee resolutions, appraisals were conducted in all 11 South-East Asia Region Member States. The rapid appraisal provided data that was accurate and acquired quickly (but required supervision), and was inexpensive, holistic and learning approach that can be replicated in other regions.

Ms Annalisa Belloni presented on a proposal for a framework to assess the impact of changes in policies on pharmaceutical spending and coverage trends. She shared the results from a survey on pharmaceutical expenditure data sources and methods in Asia/Pacific. Spending on retail pharmaceuticals has grown slower than overall health spending in OECD countries. In Asia and the Pacific, pharmaceutical expenditure has grown at 6% from 2000 to 2010. She also shared drivers and components of expenditure growth. However, challenges remain in analysing pharmaceutical spending due to limitations in availability, comparability, granularity and timeliness of pharmaceutical expenditure data.

2.9 Access to medicines under UHC Network

Dr Tisocki presented on the summary of key questions/issues raised on pharmaceutical policies for the network. The network's goal is to improve equitable, affordable access to households and health systems of appropriately used, high quality medicines as core components of sustainable UHC. The network's objectives and proposed outcomes were shared, along with priorities in information sharing, capacity development, collaboration, policy analysis and review.

2.10 Group discussions

Group work aimed to identify key activities that the network may conduct and support collectively on short (less than one year), medium (less than three years), long term, or on regular basis. Participants and experts were divided into three groups based on income groups (low-, middle-, and high-income countries).

Using a matrix, groups reviewed and identified challenges, high priority issues in the four areas of rational selection and use, affordable prices, sustainable financing and resilient supply system across network domain such as information sharing, policy analysis and review, and capacity-building and collaboration. Each group presented the results of the discussions as below.

Group A: Australia, New Zealand, the Republic of Korea, Singapore and Thailand

- Short-term activities
  - Adoption of a glossary of terms:
    - Review required;
  - Web-based resource of type and place of prices:
    - E.g. country, type of price (ex-manufacturer), web link of source, pharmacy mark-up;
    - Enable costs along the supply change to be determined;
  - Document outlining how to determine if price is hidden in each country (e.g. asterisk in PBS schedule);
  - Criteria for decision-making (for reimbursement, for inclusion on Essential Medicines List);
Comparative data analysis of one little thing (e.g. volume of use of class of medicines over time to cost of medicines over time, or percentage of patients who use percentage of medicines or cost (e.g. 16% use 80%); and
Identification of workshops and opportunities for participation across the Region.

- **Medium-term activities**
  - Case studies of biosimilar transitions:
    - E.g. transition to tacrolimus biosimilar;
  - Portfolio of case studies of clinician and consumer engagement in financing decisions; and
  - Quality use of medicines and demand side programs in place.

- **Longer-term activities:**
  - Push to transparency for prices; and
  - Push to transparency of hidden deals.

- **Activities yet to be timed**
  - Adaptive licensing, coverage with evidence development;
  - International reference pricing, group purchasing;
  - Intersection of health and industry policy:
    - Can work both ways, e.g. encouraging biotech companies to develop biosimilars;
  - Counterfeit and poor quality products;
  - Generic pricing policies and regulations;
  - Generic substitution transition:
    - Centrally or locally managed, quality assurance of transition;
  - IT systems, impact of systems on cost and use;
  - Process tracking and quality assurance of supply chain activities; and
  - Tender experiences.

**Group B: Brunei Darussalam, China, Indonesia, Malaysia and the Philippines**

- **High priority issues or challenges**
  - Data information on financing and pricing; and
  - Query system for the network.

**Group C: Cambodia, the Lao People's Democratic Republic, Mongolia and Viet Nam**

- **Rational selection and use**
  - Challenges:
    - Lack of data on drug use and adverse drug reaction (ADR);
    - Lack or poor use of health technology assessment in decision-making for selection and procurement of medicines; and
    - Poor implementation and use of standard treatment guidelines.
  - Priorities:
    - Collection and sharing of information on health technology assessment (HTA), ADR, indicators of drug use (short term);
    - Policy analysis and review (long term); and
    - Capacity development: data collection and analysis, HTA, pharmacovigilance, etc. (WHO’s facilitation) (long term).

- **Affordable prices**
  - Challenges:
    - Market information asymmetry; and
- Lack of information on prices.
  - Priorities:
    - Information sharing: unit prices, 20 top drugs, 20 key essential drugs (EDs) (short term);
    - Policy analysis and review (long term); and
    - Capacity-building (WHO’s facilitation) (medium term).

- Sustainable financing
  - Challenges:
    - Lack of clear priority setting in governance for health;
    - Insufficient public spending on medicines; and
    - Lack of information.
  - Priorities:
    - Information sharing: ABC analysis by value, pharmaceutical expenditure/capita (short term);
    - Policy analysis and review (long term); and
    - Capacity and development (medium term).

- Resilient supply system
  - Challenges:
    - Poor information sharing on availability of essential drugs, stock-out etc;
    - Weak supply chain information management systems; and
    - Shortage of skilled workers to manage supply chains.
  - Priorities:
    - Collection and sharing of information on availability of essential drugs, stock out (short term);
    - Policy analysis and review (long term); and
    - Capacity development (medium term).

**Summary of group work**

<table>
<thead>
<tr>
<th>Area of activity</th>
<th>Rational selection and use</th>
<th>Affordable prices</th>
<th>Sustainable financing</th>
<th>Resilient supply system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information Sharing</td>
<td><strong>Group A</strong> - Counterfeit, poor quality - Adoption of glossary</td>
<td><strong>Group A</strong> - Tender experiences - Reference pricing - Hidden prices - What price is reported - Definitions - What price-payer and consumer - Adjustment tools</td>
<td><strong>Group A</strong> - Look at the Republic of Korea's experiences - Criteria for decision-making</td>
<td><strong>Group A</strong> - What are the costs along the supply chain and what control are in place - Information management - Process tracking and quality assurance</td>
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<td><strong>Group B</strong> - Essential list and the criteria for selection (ST) - Utilization data (ST) - Experience on reimbursement scheme (claim data)</td>
<td><strong>Group B</strong> - Medicine prices (ST) - Identify information that can be shared (ST) - Maximum ceiling price - Production price - Legal requirements</td>
<td><strong>Group B</strong> - Co-payment implementation - Legal challenges - Stakeholder challenges - Human right issue on access to medicine</td>
<td><strong>Group B</strong> - Inventory management systems - Procurement system (who manages it) - Out-of-stock situation - Non-commercially viable medicine - Distribution barrier (geographical area, remote or rural)</td>
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<td><strong>Group C</strong> - HTA,</td>
<td><strong>Group C</strong> - Analysis of top</td>
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<td><strong>Group C</strong> - Strategies to address supply problem (MT)</td>
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<td>Group C</td>
<td>- Availability of EDs</td>
<td>- Stockout (ST)</td>
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<td><strong>Policy analysis and review</strong></td>
<td><strong>Group A</strong></td>
<td>- Generic substitution - Is it managed centrally or locally? - Brand loyalty? - Quality assurance</td>
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<td></td>
<td><strong>Group B</strong></td>
<td>- Country comparative analysis on the NEDL - Common medicines list - Country specific list (ST)</td>
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<td><strong>Group C</strong></td>
<td>Long Term</td>
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<tr>
<td><strong>Group A</strong></td>
<td>- Generic pricing policies and regulation - Hidden deals (rebates, additional others) - Outputs - What prices are public and where (e.g., in Australia, ex manufacturer, PBS schedule)</td>
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<tr>
<td><strong>Group B</strong></td>
<td>- Comparison of tax on medicine - Policy on pricing (rebate, bonuses, patient added services) - Price analysis on introduction of generic medicine</td>
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<td><strong>Group B</strong></td>
<td>- Bio similar transactions - Group purchasing - Adoptive licensing - Coverage with evidence development - Intersection of health and industrial policy - Can work both ways to develop biosimilar+ clinical consumers</td>
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<td><strong>Group B</strong></td>
<td>- Policy analysis on medicine for neglected diseases or orphan medicine</td>
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<thead>
<tr>
<th><strong>Capacity development, collaboration</strong></th>
<th><strong>Group A</strong></th>
<th>- IT system - Impact of system on costs and use</th>
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<tr>
<td></td>
<td><strong>Group B</strong></td>
<td>- anatomical therapeutic chemical classification define daily dose (DDD) capacity development (ST) - Analysis of ATC DDD (MT)</td>
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<td><strong>Group C</strong></td>
<td>WHO facilitation (MT)</td>
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<tr>
<td><strong>Group A</strong></td>
<td>- Output - What prices are public, where - Application of HTA</td>
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<td><strong>Group B</strong></td>
<td>- Negotiation skill - Price setting mechanism</td>
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<td><strong>Group C</strong></td>
<td>WHO facilitation (MT)</td>
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<tr>
<td><strong>Group B</strong></td>
<td>- Workshop on benefit package choice and management - Drug utilization review system</td>
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<td><strong>Group C</strong></td>
<td>WHO facilitation (MT)</td>
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<tr>
<th><strong>Others</strong></th>
<th><strong>Group A</strong></th>
<th>- Comparative analysis</th>
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<td></td>
<td><strong>Group C</strong></td>
<td>Monitoring (LT)</td>
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*Short term (ST), medium term (MT), long term (LT)*
2.11 Access to medicines under UHC Network – proposed governance

Participants discussed governance, including the name, goals, objectives, methods, membership, secretariat’s roles and support, and work plan. The name of the network was suggested to be the “UHC-AM Network” with the intention of operating as a regional network for countries including the WHO South-East Asia Region and Western Pacific regions. With the overall goal to “improve equitable, affordable access to households and health systems of appropriately used, quality-assured medicines as core component of sustainable universal health coverage.”

During the discussion it was decided that the network would focus on medicines rather than health technologies for the first several years to ensure realistic and achievable goals. A considerable portion of the methods discussion was devoted to disseminating research in the *Journal of Pharmaceutical Policy and Practice* that Dr Babar discussed on the first day of the meeting.

Primary objectives arising from the membership dialogue were that all members and organizations should confirm their interest to become a member and identify a named focal point as a contact for the network; to develop rules as the network evolves, and the mechanics of a confidentiality agreement. Sustainability of the secretariat functions was discussed, as was funding and placement of future meetings of the network. The concluding topic was regarding a monitoring and evaluation work plan to monitor the outcomes of the network.

2.12 Closing session

Participants shared what they had learned during the meeting and expressed their interest in continued collaboration. The meeting secretariat made remarks on the importance of the regional network and how to carry forward the recommendations of the meeting. Mr Lee, Suk Kyu, Director-General of OECD Korea Policy Centre thanked the participants and the meeting secretariat for their contributions. He extended his thanks to the chairperson and co-chairperson and closed the meeting.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

Participants shared information on global issues, regional initiatives on pharmaceutical policies for UHC and access to high-cost medicines (such as treatment for viral hepatitis) were highlighted. Australia and Mongolia shared experiences on sofosbuvir for hepatitis C. The results of brief country profiles on pharmaceutical system and policies were presented by all Member States. The Philippines and the Republic of Korea have completed the longer survey and they shared their results.

In the group discussions, countries by three income groups (high, middle, low) shared information on the challenges faced in selection and use of medicines, affordable prices, sustainable financing and resilient supply systems. There was a general lack of information on drug utilization and pricing, inadequate public financing and weak supply chain management in the low-income countries. The middle-income countries also faced challenges on evidence-based selection of medicines for procurement or reimbursement and were keen to know the Essential Medicines List and prices in other countries. However, even in high-income countries when price information is publicly available, it is difficult to know the real cost due to hidden costs. Hence, transparency in the medicines selection process and price information was discussed extensively.

As the groups analysed the issues, policy-makers expressed the need for more information exchange and close collaboration between countries.

1) Member States confirmed their interest in the regional network and future collaboration.
2) Information was exchanged regarding decision-making processes for medicine selection, pricing, procurement and reimbursement of medicines.

3) There was agreement among Member States that the draft short country profile (2 pages) is an effective tool for gathering and disseminating information about system structures and processes used for pharmaceutical policy decision-making in countries.

4) Goals, objectives of the network, methods, membership and secretariat roles were discussed and agreed.

3.2 Recommendations

3.2.1 Recommendations for Member States

1) To attend and contribute at regular network meetings and other activities of the network to exchange information on formulation and implementation of policies on medicines selection, pricing, procurement, reimbursement, cost containment strategies and financing of sustainable coverage via affordable benefit packages or procurement options;

2) To participate in workshops, conferences and inter-country visits to promote collaboration, information exchange and training to foster development of institutions and policy-makers responsible for pharmaceutical policies used to achieve UHC;

3) To generate regional and country level evidence-based policy and data analysis by use of relevant performance and other indicators measured across countries and to disseminate such evidence to support design and implementation of effective medicines policies in Member States; and

4) To carry out activities identified at group discussions among high-, middle-, and low-income countries to foster collaboration between similar health systems.

3.2.2 Recommendations for WHO

1) To assist Member States to attain their goals towards achieving UHC through transparent decision-making and technical expertise;

2) WHO in collaboration with Member States and OECD will complete and publish brief country profiles of pharmaceutical systems and comparative analysis of country profiles;

3) WHO in collaboration with Member States will carry out in-depth surveys and publish on pharmaceutical systems, pricing, procurement and reimbursement policies of selected countries;

4) WHO will make country Essential Medicines Lists accessible by providing the lists on the WHO Regional Office for the Western Pacific website; and

5) WHO will continue to collect information from countries on pricing, public sector financing, procurement and/or reimbursement under UHC to conduct comparative policy review and analysis to identify best practices and implementation across countries.

ANNEXES
Annex 1. List of participants

1. PARTICIPANTS

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## Annex 2. Meeting Timetable

<table>
<thead>
<tr>
<th>Time</th>
<th>Day 1 – Thursday 17 September 2015</th>
<th>Day 2 – Friday 18 September 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30–9:00</td>
<td>Registration</td>
<td>Pharmaceutical policies to address medicines access</td>
</tr>
<tr>
<td>9:00–10:00</td>
<td><strong>Opening and welcome address</strong>&lt;br&gt;Dr Lee, Suk Kyu, Director-General, OECD Korea Policy Centre&lt;br&gt;Dr Klara Tisocki, Coordinator, Essential Medicines and Technologies, WHO WPRO&lt;br&gt;Prof. Tae-jin Lee, WHOCC at Seoul National University&lt;br&gt;Luca Lorenzoni, OECD&lt;br&gt;Participant Introduction&lt;br&gt;Meeting agenda – Ms Uhjin Kim, Technical Officer, WHO WPRO&lt;br&gt;Nomination of Chair and Co-Chair&lt;br&gt;Group photo</td>
<td>Access to medicines for the ageing population in Asia Pacific – Dr Libby Roughead, University of South Australia&lt;br&gt;Country Situation Analysis in SEARO countries – Dr Kathy Holloway, Regional Advisor, Essential Drugs and other Medicines, WHO, SEARO&lt;br&gt;A proposal for a framework to assess the impact of changes in policies on pharmaceutical spending and coverage trends – Ms Annalisa Belloni, OECD&lt;br&gt;Pharmaceutical System Analysis, Gaps, and Opportunities Group Work Plenary</td>
</tr>
<tr>
<td>10:00–11:00</td>
<td><strong>Pharmaceutical Policies and the Regional Network on Access to Medicines under Universal Health Coverage</strong>&lt;br&gt;Pharmaceutical policies for UHC—Global Perspective – Dr Suzanne Hill, Senior Advisor, WHO HQ&lt;br&gt;Latest trends in pharmaceutical pricing policies and gaps in evidence – Dr Zaheer-Ud-Dun Babar, University Auckland&lt;br&gt;Medicines access issues in the Asia Pacific and the vision of the regional network - Dr Klara Tisocki, Coordinator, WHO WPRO</td>
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<tr>
<td>11:00–11:15</td>
<td>Morning Tea</td>
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<tr>
<td>11:15–13:00</td>
<td><strong>Understanding Country Pharmaceutical Systems</strong>&lt;br&gt;Summary of Brief Country Profiles – Ms Uhjin Kim, Technical Officer for Pharmaceuticals, WHO WPRO&lt;br&gt;Poster Walk on Brief Country Profiles</td>
<td>Access to Medicines under UHC Network—Proposed Activities&lt;br&gt;Summary of key questions/issues raised on pharmaceutical policies for the network – Dr Klara Tisocki, Coordinator, Essential Medicines and Technologies WHO, WPRO&lt;br&gt;Group discussions (topics on collaboration and network activities) Plenary</td>
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<tr>
<td>13:00–14:30</td>
<td>Lunch Break</td>
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<tr>
<td>15:00–15:15</td>
<td>Adopting PPRI survey for the regional network – purpose and methodology—Professor Tae-jin, WHOCC at Seoul National University&lt;br&gt;&lt;br&gt;<strong>PPRI longer survey presentations:</strong>&lt;br&gt;Philippines – Dr Francisco Soria, Vice President, Quality Assurance Group, Philippine Health Insurance Cooperation&lt;br&gt;The Republic of Korea – Dr Youn Jung, Post-doctoral fellow, Seoul National University&lt;br&gt;Collecting feedback on longer survey- Dr Klara Tisocki, WHO WPRO&lt;br&gt;Plenary</td>
<td>Access to Medicines under UHC Network—Proposed Governance&lt;br&gt;Plenary on proposed governance structures</td>
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<tr>
<td>15:00–15:15</td>
<td>Afternoon Tea</td>
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<tr>
<td>15:15–17:00</td>
<td><strong>Access to High Cost Medicines</strong>&lt;br&gt;Strategies to expand access to viral hepatitis treatment in Mongolia – Ms Tsetsgee Purejjav, Mongolia&lt;br&gt;Access to new Hepatitis C treatment in Australia – Ms Adriana Platona, Assistant Secretary, Pharmaceutical Evaluation, Department of Health&lt;br&gt;Managing intellectual property for access to viral hepatitis medication - Peter Beyer, Senior Advisor, WHO headquarters (Skype presentation)&lt;br&gt;Plenary</td>
<td>Conclusions and Closure&lt;br&gt;Meeting summary – Plenary Chair&lt;br&gt;Comments by the meeting organizers&lt;br&gt;Closing remarks: Lee, Suk kyu, Director-General, OECD Korea Policy Centre</td>
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<tr>
<td>18:30–19:30</td>
<td>Welcome reception</td>
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</table>
Annex 3: Presentations
Pharmaceutical policies for Universal Health Coverage – Global Perspectives

Dr Suzanne Hill
September 2015

Why a focus on medicines?
- Between 20% and 60% of the health budget in LMIC goes to medicines expenditures
- In LMIC countries, up to 80 to 90% of medicines are purchased out-of-pocket as opposed to being paid for by health insurance schemes
- In many LMIC out-of-pocket expenditures for health account for more than 50 per cent of total health spending
- Average availability of selected generic medicines in LMICs:
  - public sector less than 42%
  - private sector almost 72%

And for high income countries?

A global priority
- World Health Assembly resolutions
  - Access to medicines – 2014
  - Health technology assessment – 2014
  - Hepatitis C – 2014
- Sustainable development goals
  - ‘80% availability’

What determines access to medicines?

What is happening with market entry prices?

Figure 1: Comparison of nominal and PPP-adjusted prices of (a) Sovaldi™ and (b) Harvoni™

Figure 3: Financial impact of covering entire estimated population of people with HCV who require treatment for (a) Sovaldi™ and (b) Harvoni™

Price to buyer and supplier?

Vincristine 1mg

Methotrexate

Policy options (1)

- Move away from free market structure – price controls are necessary especially for UHC
- Price negotiation and price setting
  - What are the conditions for effective negotiation?
  - Fixed cost effectiveness thresholds are unwise
- Price rebates and discounts – to debate
- Supply chain controls

World Health Organization
Supply chain management

Policy options (2)

- External reference pricing may not be useful with hidden prices
- Efficient procurement – consolidated demand especially within national systems
- Control supply chain price!

What probably doesn’t work

- Donations
  - Reduce market incentives
  - Disrupt or by-pass supply chain
  - Unreliable supply leads to reduced demand
- Prices that are too low
  - Shortages
  - Poor quality

Is it time for a change?

"What do you mean, no?"
Latest trends in pharmaceutical pricing policies and gaps in evidence
The 2nd Meeting on Access to Medicines under Universal Health Coverage in the Asia Pacific Region, 17-18th September, Seoul

Zaheer-UD-Din Babar, PhD
Head of Pharmacy Practice
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Editor-in-Chief, Journal of Pharmaceutical Policy and Practice

Salient features
- Snapshot of pricing policies in the region (Australia, New Zealand, China, Thailand, Malaysia)
- Discussion on gaps identified and policy informed action
- Impact of Journal of Pharmaceutical Policy and Practice

Medicines New Zealand

Pharmaceutical Management Agency of New Zealand (PHARMAC)
- Established in 1993 by Government
- Single purchaser of pharmaceuticals (PHARMAC)
- PHARMAC’s key role is to decide whether a medicine will be subsidised or not
- It negotiate prices with pharmaceutical manufacturers
- Pharm uses rebates on list prices, reference pricing, tendering for generics and sole supply contracts, bundle agreements (where PHARMAC may list expensive new drugs in return for the manufacturer discounting the price of other products it supplies)

Impact of PHARMAC on drug expenditure

PHARMAC
Bundling agreement
- In the case of cross-product (“bundling”) agreements, PHARMAC may only agree to subsidise a new medicines in return for price reduction on one or more medicines already listed on the Pharmaceutical Schedule, produced by the same manufacturer (The Pharmaceutical Management Agency of New Zealand (PHARMAC) ; Morgan et al. 2007).
- The listed price in the Pharmaceutical Schedule for the new medicine will be the manufacturer’s international price, not including the overall discount obtained by PHARMAC for subsidising a bundle of medicines (The Pharmaceutical Management Agency of New Zealand (PHARMAC)2014 ; Morgan et al. 2007; Woodfield 2001).
Medicines prices in NZ: Issues and challenges

There was general appreciation shown towards PHARMAC’s strategy of creating competition in order to achieve a lower purchasing price. However, there are following issues:
  - Access to medicines being criticised
  - Access to high cost medicines
  - PHARMAC policy on reference pricing (only one member of a therapeutic class is funded) negatively impacts on GPs clinical decisions (58% agree)
  - TPPA


Medicines prices in Australia

- Australia has a comprehensive universal pharmaceutical funding programme
- Historically Prices for innovative medicines were similar to those in the other countries.
  - Australian Productivity Commission compared the prices for a basket of 150 widely used PBS medicines with seven other countries: Canada, France, Spain, Sweden, New Zealand, the United Kingdom (UK) and the United States of America (USA) in June 2000 (Australian Productivity Commission 2001).
  - It showed that Australian medicine prices were between 51 and 61% of the price paid by comparator countries, excluding New Zealand and Spain.


Medicines prices in Australia

- Reference pricing and value based pricing have been the main policies used for the pricing of subsidised medicines
  -Generic medicine price reforms have included mandatory price reductions and price disclosure cycles
    - The objective is to align PBS prices for generic medicines with pharmacy purchase prices.


Price Comparison between NZ and European Countries

- New Zealand prices were found in the lowest quartile for five medicines and in the highest quartile for seven other products.
- Price differences between the originator products and generic versions ranged from 0% to 90% depending on the medicine and the country.
- Medicine prices varied considerably between European countries and New Zealand as well as among the European countries.
- These differences are likely to result from national pricing and reimbursement policies.

Price Comparison between NZ and European Countries

• New Zealand’s prices ranked lowest in four cases
  – abacavir,
  – escitalopram generic version,
  – mycophenolate mofetil originator version,
  – pioglitazone generic version
• The medicines in the highest quartile in New Zealand were
  – darunavir ethanolate,
  – indinavir,
  – insulin lipro,
  – sunitinib,
  – venlafaxine, (the latter being both the originator and the comparable generic version)
• Forprasugrel (highest price in New Zealand), the New Zealand price is 25% higher than that of the highest-priced medicine in the European countries.

Price Comparison between NZ and European Countries

<table>
<thead>
<tr>
<th>No</th>
<th>NZ Lowest</th>
<th>NZ highest</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>abacavir</td>
<td>darunavir</td>
</tr>
<tr>
<td>2</td>
<td>escitalopram generic version</td>
<td>ethanolate</td>
</tr>
<tr>
<td>3</td>
<td>mycophenolate mofetil originator version</td>
<td>indinavir</td>
</tr>
<tr>
<td>4</td>
<td>pioglitazone generic version</td>
<td>insulin lipro</td>
</tr>
<tr>
<td>5</td>
<td>sunitinib, and venlafaxine</td>
<td></td>
</tr>
</tbody>
</table>

Vogler S, Vitry A, Babar ZU. Comparison of oncology medicine prices in European countries, Australia and New Zealand (Unpublished draft)

• The study aims to survey the prices of oncology medicines in European countries, Australia and New Zealand.
• Official list prices per unit at ex-factory price level of 31 originator oncology medicines in 16 European countries, Australia and New Zealand were surveyed as of June 2013.
• Medicine price data for the European countries were provided by the Pharma Price Information (PPI) service, Australian and New Zealand medicine price data were retrieved from the respective Pharmaceutical Schedules.

Vogler S, Vitry A, Babar ZU. Comparison of oncology medicine prices in European countries, Australia and New Zealand (Unpublished draft)

• Data availability was higher in the European countries compared with Australia and particularly New Zealand.
• Oncology medicines are highly priced.
  – None of the medicines surveyed had a unit price below €10 in the 18 surveyed countries.
  – Five medicines had an average unit ex-factory price between €250 and €1000, and seven medicines had an average unit price above €1000

Vogler S, Vitry A, Babar ZU. Comparison of oncology medicine prices in European countries, Australia and New Zealand (Unpublished draft)

• Medicine prices varied across European countries, Australia and New Zealand.
• No relevant price differences of Australia and New Zealand in comparison with European countries were found
• However, these official list prices do not include discounts and similar arrangements that are in place for several of the surveyed medicines in a number of countries.
  – Issues and impact ( If NZ prices are used as external reference prices in other countries, Brazil, South Africa etc)
Medicines pricing in China

WHO/HAI Medicine pricing surveys
- China, Shandong Province (October, 2004)
- China, Shanghai Province (September, 2004)
- China, Shaanxi Province, (March 2012)
- China, Shaanxi Province, (Sep 2010)
- Shanghai, 2012

Medicines pricing in China
- China plans to remove price caps for most medicines and give the market a larger role in setting prices (after criticism that its controls had caused shortages of a number of critical drugs (hyperthyroidism etc))
- It is argued that the change would encourage “reasonable” pricing of medicines and help control costs in the country’s state medical insurance schemes

http://www.reuters.com/article/2015/05/05/us-china-healthcare-idUSKBN0NQ07O20150505

Malaysia

Medicine prices in Malaysia: Issues and Challenges
- Free market economy, no control on drug prices in private sector
- Government purchasing is effective and it’s working
- High medicine prices and mark-ups (Babar et al, 2007)
- Price monitoring set-up
- Dispensing separation

Medicines pricing in Thailand

- WHO/HAI survey shows high drug prices and mark-ups
- Significantly varying prices for the same products at different sites
  - HIV drug manufactured by the Government Pharmaceutical Organisation is sold to hospitals at THB900 for 30 pills. In some private hospitals, the cost for the same pills can reach up to THB20,000.
- Thailand’s Drugs Bill. The bill includes draft legislation requiring pharmaceutical firms to reveal their pricing structures as part of the approval and registration process. This would, in theory, lead to direct drug price controls.


Medicines pricing in Thailand

Future price controls could be based on five factors:
- drug production costs,
- maximum profits,
- price comparisons with other countries at similar stages of economic development,
- price comparisons with similar treatments and drugs, and
- individual price negotiations between drug makers and hospital operators.

FDA and the Public Health Ministry agreed to require pharmaceutical firms and distributors to print the prices of medicines on their packaging.

Medicine prices in Fiji

- In the public sector all prescribed medicines (from registered doctors) are provided free to patients
- In the private sector prices vary.

In the national Strategic plan for implementation of National Medicines Policy there is an aim to:
- Collaborate with the Fiji Commerce Commission to support pricing policy for privately dispensed medicines.
  - In January 2015 a ‘Free Medicine’ initiative was introduced. This means that a list of medicines prescribed by private or public sector doctors according to the national treatment guidelines will be available free for certain accredited private pharmacies. These pharmacies will be reimbursed like the Australian PBS.

Source: Snell B, Sep 2015

Other countries in the region
- Vietnam
- Philippines
- Indonesia

Impact of Free Trade
McCall C. Trans-Pacific trade pact triggers fears over drug prices. The Lancet, 385 June 20, 2015

Its 12 members all belong to the wider Asia-Pacific Economic Cooperation forum (APEC).
- USA, Japan, Australia, Canada, Malaysia, Mexico, Peru, NZ, Vietnam (South Korea possibly)

Free trade negotiations would require other countries to change their domestic laws.
Already some governments have found free trade agreements exploited by multinational companies to challenge their laws, using clauses originally designed to prevent expropriation of property by foreign nations, for example through nationalisation.
The leaked proposals would require signatories to extend patents in line with the laws of other signatories.
Pharmaceutical companies can patent various uses of a drug. They can also seek data exclusivity.

Recap

Comparison of subsidised patient access across the Asia Pacific

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Subsidised patient access system</th>
<th>Coverage</th>
<th>Patient co-payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Pharmaceutical Benefit Scheme</td>
<td>Universal coverage of subsidised medicines for Australian residents</td>
<td>AUD 37.70 (adult)</td>
</tr>
<tr>
<td>China</td>
<td>Basic Health Insurance Scheme (BHIS)-urban and rural schemes</td>
<td>Coverage to 99% Korean citizens</td>
<td>30% (3% oncology medicines; 10% rare disease medicines)</td>
</tr>
<tr>
<td>South Korea</td>
<td>NHI Scheme</td>
<td>Coverage to 99% Korean citizens</td>
<td>Yes (amount depends on the subsurance system)</td>
</tr>
<tr>
<td>New Zealand</td>
<td>PHARMAC</td>
<td>Universal coverage of subsidised medicines for NZ residents</td>
<td>NZD5 Free for children</td>
</tr>
<tr>
<td>Thailand</td>
<td>National List of Essential Medicines</td>
<td>Coverage of generics and cost-effective patented medicines for Thai citizens</td>
<td>No co-payment</td>
</tr>
</tbody>
</table>

Medicines pricing issues in Asia Pacific

<table>
<thead>
<tr>
<th>Country</th>
<th>Evidence exists/what has worked</th>
<th>Challenges</th>
<th>Steps in Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>NZ</td>
<td>Low prices in government sector, Pharmac is monopoly purchaser</td>
<td>Access to high cost medications</td>
<td>Research regarding prices of drugs not covered by Pharmac, impact of TPPA on access prices</td>
</tr>
<tr>
<td>Australia</td>
<td>Generic medicine price reforms have included mandatory price reductions and price disclosure cycle</td>
<td>High prices of generics, high cost medications</td>
<td>Price agreement for new medicines</td>
</tr>
<tr>
<td>Thailand</td>
<td>Price variation, high prices for some drugs in public procurement sector, development of some generics were low</td>
<td>Central to drug prices</td>
<td>Research is needed regarding price regulation strategies</td>
</tr>
<tr>
<td>China</td>
<td>High prices for innovator brand in public and private sector, Government generic purchasing is effective in some cases</td>
<td>Large country medicine price control strategies</td>
<td>Detailed extended surveys, setting up of price monitoring system</td>
</tr>
<tr>
<td>Malaysia</td>
<td>High prices and mark-ups</td>
<td>Central to drug prices</td>
<td>Research is needed regarding price regulation strategies</td>
</tr>
</tbody>
</table>

Journal of Pharmaceutical Policy and Practice
www.joppp.org
The Journal

- Re-launched as Journal of Pharmaceutical Policy and Practice in June 2013
- Indexed in PubMed, PubMed Central, Scopus, etc.
- The journal is affiliated with The University of Auckland and Auckland UniServices Ltd.

http://www.joppp.org

Reason to launch JoPPP!

- Lack of platform for publication.
- Especially hard to find a ‘home’ for research papers focusing on pharmaceutical policy
  - Publishing research in an appropriate and high impact forum crucial to initiate policy benefits

Content, evidence and impact of the Journal

Vol 2 issue 2 2009 (Special issue on medicine pricing, policy and generics)

<table>
<thead>
<tr>
<th>No</th>
<th>Title (Articles)</th>
<th>Authors’ Background</th>
<th>Country Focus</th>
<th>Theme</th>
<th>Researcher Base</th>
</tr>
</thead>
</table>

Vol 2 issue 2 2009 (Special issue on medicine pricing, policy and generics)

Vol 3 issue 2 October 2010

<table>
<thead>
<tr>
<th>No</th>
<th>Title (Articles)</th>
<th>Authors’ Background</th>
<th>Theme</th>
<th>Country Focus</th>
<th>Researcher Base</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1 Steinhil SL, Baber ZU. Community pharmacy practice in high and low income countries: Commonalities, differences and the tension of being “retail” versus “primary health care provider”. Southern Med Review (2010) 3:1-21</td>
<td>Academic</td>
<td>Medicine policy</td>
<td>Middle and low income</td>
<td>New Zealand</td>
</tr>
</tbody>
</table>
Some more pricing evidence in JoPPP!


JoPPP supplement on PPRI conference

- 3rd International PPRI Conference – Pharmaceutical Pricing and Reimbursement Policies: Challenges beyond the Financial Crisis
- Supplement is appearing in Oct 2015

The journal and the media

- SCRIP- an international pharmaceutical news magazine has also published stories on the basis of articles being published in the journal.
- These articles were regarding medicines pricing policies in Vietnam and Thailand.

Sukkar E. The frustration of high medicine prices

A basic need becomes a luxury
Drug prices have always been a thorny issue in Vietnam. A Southern Med Review suggested that drug prices, including are too expensive for the majority of Vietnamese people.
WHO & the Journal

WHO & the Journal

The Journal has become well established within a short span of time and is fulfilling a global need in the area of essential medicines and pharmaceutical policy. In September, an article published in the journal has resulted in medicine pricing and policy changes in Vietnam.

Letter from WHO Essential Medicines and Policy Department

Ukraine

- Translation into Russian/Ukrainian of the following articles:
Medicines access gaps issues in Asia and vision of the regional network

Dr. Klara Tisocki
Coordinator, Essential Medicines & Health Technologies

The 2nd Meeting on Access to Medicines under Universal Health Coverage in the Asia Pacific Region
17-18 September 2015, Seoul, Republic of Korea

Outline

- Why medicines matter for UHC
- UHC aspirations
- Rationale, Goals, visions and desired outcomes of the network

Why medicines matter for achieving UHC?

- **Cost**
  - High Expenditures on medicines and other health technologies are a significant burden of health care budgets
- **Efficiency**
  - Medicines & health technologies can be a significant source of inefficiencies
- **Quality of care**
  - Quality of services highly dependent on availability and access to effective, affordable and quality health technologies

Attaining universal health coverage requires strong, efficient and well-managed health systems that ensure equitable access.

Dr. Shin Young-soo, WHO Regional Director for the Western Pacific, 2013

Articulation of UHC aspirations in WPR Member States

Cambodia
Health Sector Reform Framework to 2025:
"Reach UHC by 2035".

"A sector-wide/systemic approach to achieve a common goal - affordable, reliable, accessible health service to all Lao people."

Lao PDR

Mongolia
Mongolian Constitution, 1992

"The right to live in a safe and healthy environment and free access to primary health care."

The Health Sector Strategic Master Plan: 2005-2015
"Responsive and equitable, pro-poor, client-centered and quality services"

Articulation of UHC aspirations in WPR Member States

Malaysia
Country Health Plan, 2011-2015:
One of 3 Key Result Area:
"Health Sector Transformation Towards A More Efficient & Effective Health System in Ensuring UNIVERSAL Access to Healthcare"

Philippines
Universal Health Care Study Group, University of the Philippines
Provision to every Filipino of the highest possible quality of health care that is accessible, efficient, equitably distributed, adequately funded, fairly financed, and appropriately used by an informed and empowered public"

Vietnam
Law on Health Insurance (2009)

"UNIVERSAL Health insurance coverage by 2014"
5-year Health Sector Development Plan (2011-2015)
"Continue to develop a health care system towards equity, efficiency and development, improving quality of care, meeting the growing and diverse needs for health care."
**Articulation of UHC aspirations in WPR Member States**

**PNG**
- National Health Plan 2011-2020:
  - Key Goal: "Strengthened Primary Health Care for ALL and improved service delivery for the rural majority and urban disadvantaged."

**Fiji**
- MOH Strategic Plan 2011-2015:
  - "To provide high quality health care delivery services by a caring and committed workforce with strategic partners, facilitating a focus on patient safety and best health status for ALL of the citizens of Fiji."

**Samoa**
- Health Sector Plan, 2008-2018:
  - "Promotion of Appropriate and Affordable health services which enables EQUAL access by ALL the people of Samoa."

**Access to Medicines in Asia Pacific**

- Asia Pacific diverse set of countries containing 61% of world population
- Major health sector reforms ongoing or completed
- Medicines and health technology expenditures frequently rising faster than other health care costs
- Medicines and health technology expenditures cost often nearly half of total health care expenditures in many low and middle income countries
- Out-of-pocket payment for medicines often account for at least half of all payment made by patients and their carers.

**Key issues for national medicines policies for UHC**

- **Key issues**
  - Recognising health including access to medicines as a human right
  - Embedding medicines policies within national health system policy framework for UHC
  - Getting political will to introduce and implement legislation to support medicine policy implementation
  - Getting political will to provide adequate human and financial resources for policy implementation

**Importance of medicine financing policies**

- **Key issues**
  - Scope and coverage of minimum benefits, essential medicine must be defined
  - Prioritisation is needed and will raise ethical questions that must be addressed
  - Providing financing based on previous care practices may be inadequate
  - Clear linkages between benefit package design and epidemiology, STGs, health system capacity is needed
  - Information systems needed to monitor use, costs and expenditures – generate evidence for policy development
  - How to get medicines policies right?

**Brief history - Regional Network on Access to medicine coverage under UHC in Asia Pacific Region**

- 2013, Singapore - International Expert Consultation on Medicines as a Key Component of Universal Health Coverage
  - Priorities 1) sharing information for decision-making, 2) building institutional and human capacity, and 3) generating evidence about policy impacts 18 topics suggested for future work

- 2014, Seoul - the first Meeting on Access to Medicines under Universal Health Coverage in Asia Pacific Region
  - Agreed the establishment of Asia Pacific Network on Access to Medicines
  - Discussed tools and initiated country profile data collection – short and long survey tool

- 2015 – WPRO Note Verbale invited countries to nominate focal points and identify relevant national authorities/decision makers to become members

**Rationale**

- Comparison of pharmaceutical system performance across countries can be important to improve policies and systems
- World health Assembly Resolution (WHA67.22) called on to Members states
  - "to promote collaboration and strengthen the exchange of information on best practices in the development, implementation and evaluation of medicine policies and strategies, that enhance access to affordable, safe, effective and quality-assured essential medicines".
### Common System Needs

- A comprehensive framework of medicines in health systems (which includes the evaluation of ethical, legal and social implications of policy decisions);
- technical expertise to generate information for medicines policy decision making;
- evidence-informed policy and program options for improving medicines situations that take advantage of the levers of health insurance schemes; and
- innovative intercountry and multi-stakeholder collaborations.

### Goal and Vision of the network

**Improve equitable, affordable (to households and health systems) access to appropriately used, high-quality medicines as core component of Universal Health Coverage**

### Key objectives of the network

- to systematically collect and share information using common tools to guide medicines and health technology policies and strategies that can enhance medicine and health technology coverage to achieve Universal Health Coverage
- to conduct comparative policy review and analysis to identify good practices and their implementation across countries with development of indicators and where possible benchmarking on medicines/health technology selection (including use of tools like health technology assessment), pricing, public sector financing and/or reimbursement under UHC in the Members States
- to regularly exchange information through regular network meetings and/or through suitable virtual communication forum

### Proposed outcomes of the network

- in-depth knowledge and understanding of country-specific decision making process for selection, pricing and reimbursement of medicines and health technology through development of country profiles and exchange of information
- enhanced capacity of Member States to establish decision making processes that are transparent, evidence-based, and appropriate to country context to develop comprehensive benefit packages or financing schemes for medicines towards achieving Universal Health Coverage
Summary of Country Profiles

Uhjin Kim,
Technical Officer for Pharmaceuticals,
Essential Medicines and Health Technologies,
Division of Health Systems,
WHO Regional Office for the Western Pacific

Asia-Pacific Region
14 countries

Diverse region with different pharmaceutical systems

- Resource-limited countries
- Emerging middle income countries
- High income OECD member countries

Brief Country Profiles

2-page information on

- Socioeconomic and health expenditure data
- Pharmaceutical policies (pricing and procurement/reimbursement)
- Flowchart on pharmaceutical systems

Socioeconomic and Expenditure Data

- Population
- Life expectancy
- GDP/capita
- Human Resources for Health
- Expenditure on Health
  - Total Health Expenditure (public / private share)
  - Composition of Total Health Expenditure
    (Government / SHI / OOP etc)
- Pharmaceutical Expenditure (public / private share)
- Composition of OOP expenditure for health (OPT / INT / Medicines etc)

TPE/capita and GDP in Asia Pacific

Source: WHO QMR 2014, OECD Health Statistics
Pharmaceutical Policies

- Marketing Authorization
  Regulatory Authority
  No. of registered products

- Pricing
  Agency for price setting
  Pricing regulation in public/private sector
  Pricing control mechanisms

- Procurement/Reimbursement
  Agency for selection and reimbursement decisions
  Agency for HTA
  No. of products in EML, procurement/reimbursement list

Flowchart on Pharmaceutical Systems
Adopting PPRI survey for the regional network – Purpose and Methodology -

Conference on UHC & ATM
Sep 17-18, 2015

Tae-Jin Lee, Ph.D.
Professor
School of Public Health
Seoul National University, Korea

Road Map

• Background
• Purpose of country pharma survey
• Development of pharma profile template
• Contents of template
• Anticipated benefits: lessons learned from PPRI

Background

• Establishment of the Asia-Pacific Network on Access to Medicines under UHC
  - In Sep 2014, the 1st Meeting on Access to Medicines under UHC in the Asia-Pacific Region proposed to establish a network as a means to connect and strengthen collaboration between relevant national authorities and institutions
  • Evidence-based policy development
    - Importance of evidence-based policy development and decision-making in pharmaceutical systems for financing, resource allocation and service design to improve access to medicines

Purpose of country pharma survey

• To systematically collect and share information using a common tool to guide pharmaceutical policy and strategies that can enhance access to medicines to achieve UHC
• To give in-depth knowledge and understanding of country-specific decision making process for selection, pricing and reimbursement of medicines and health technology
• To conduct a comparative policy review and analysis to identify best practices and their implementation across countries

Development of pharma profile template

• Developed on the basis of two main sources
  ① Vogler, S., Zimmermann, N., Leopold, C.: PPRI/PHIS Pharma Profile Template (long version)
    (Accessible at: http://whocc.goeg.at/Literaturliste/Dokumente/MethodologyTemplate/PPRI_PHIS_Pharma_Profile_template_May_13.docx)
  ② World Health Organization, Global Fund
    Pharmaceutical Sector Country Profile Questionnaire
    (Accessible at: http://www.who.int/medicines/areas/coordination/Empty_English_Questionnaire.pdf)
• Further simplified and revised to meet the context of the Asia-Pacific region

Acknowledgement

• These slides were prepared with the help of Dr. Youn Jung, Ms. Ji-eun Park from SNU and Ms. Uhjin Kim from WPRO.
Key indicators of PPRI pharma profile

<table>
<thead>
<tr>
<th>Background</th>
<th>Pharmaceutical system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population age structure</td>
<td>Regulatory framework for pharmaceutical policy</td>
</tr>
<tr>
<td>GDP per capita</td>
<td>Key data on pharmaceutical industry</td>
</tr>
<tr>
<td>Public/private funding of health expenditure</td>
<td>Inhabitants per POM dispensary</td>
</tr>
<tr>
<td>Total health expenditure per capita</td>
<td>Total pharmaceutical expenditure as percentage of total health expenditure</td>
</tr>
<tr>
<td>Public/private funding of pharmaceutical expenditure</td>
<td></td>
</tr>
<tr>
<td>Pricing</td>
<td>Rational use of pharmaceuticals</td>
</tr>
<tr>
<td>Pricing policies at manufacturer level</td>
<td>Market share of generics</td>
</tr>
<tr>
<td>Pricing policies at distribution level</td>
<td>Prescription guidelines</td>
</tr>
<tr>
<td>Taxes on pharmaceuticals</td>
<td>Mandatory guidelines for decision makers/role of pharma-economics</td>
</tr>
<tr>
<td>Reimbursement</td>
<td>Information to patients</td>
</tr>
<tr>
<td>Positive/negative list</td>
<td>Monitoring of consumption</td>
</tr>
<tr>
<td>Reference price system</td>
<td>No. of prescriptions per capita</td>
</tr>
</tbody>
</table>

Mechanism for vulnerable groups

Contents of template

- **PART I. Pharmaceutical policy and financing**
  Qualitative questionnaire
- **PART II. General information and health**
- **PART III. Pharmaceutical system**
  Quantitative questionnaire

**PART I. Pharmaceutical policy and financing**

1. Organization of the pharmaceutical system
2. Market authorization
3. Quality assurance
4. Pricing
5. Reimbursement
6. Rational use of medicines
7. Intellectual property laws
PART I.
Pharmaceutical policy and financing (cont.)

1. Organization of the pharmaceutical system
   - Flowchart of the pharmaceutical system

2. Market authorization
   - Licensing and inspection

3. Quality assurance
   - Quality monitoring / combat for counterfeit medicines

4. Pricing
   - Pricing policies, Purchasing policies, Procurement, Pricing procedure, Discounts/rebates, Price composition

5. Reimbursement
   - Reimbursement policies/procedure, Reference pricing system, Risk-sharing schemes / Managed entry agreements, Decision making tools, Out-of-pocket (OOP) payments on medicines, Reimbursement policies in hospitals

6. Rational use of medicines
   - Monitoring and evaluation, Generic Promotion, Medicines advertising and promotion, Education and training, Pharmacovigilance

7. Intellectual property law
   - TRIPS flexibilities / data exclusivity / patent extension/ patent-marketing linkage

PART II.
General information and health

1. Population structure

2. Socioeconomic statistics

3. Health: Life expectancy, Fertility, Mortality

4. Health care delivery
   - Health care facilities and utilization
   - Human resource

5. Health care financing and expenditure
   - Total health expenditure (THE)
   - Structure of health expenditure (HE)

PART III.
Pharmaceutical system

1. Pharmaceutical financing and expenditure
   - Total pharmaceutical expenditure (TPE)
   - Structure of pharmaceutical expenditure (PE)

2. Availability and access: Market entry, Essential medicines

3. Pharmaceutical prescription and consumption
   - Separation of prescribing and dispensing
   - Pharmaceutical consumption
   - Generic market share

4. Pharmaceutical industry
   - Pharmaceutical manufacturers
   - Pharmaceutical distributors

Anticipated benefits: lessons learned from PPRI

- Exchange the information on pharmaceutical systems including pricing and reimbursement between countries
- Increase the transparency of each country's pharmaceutical systems
- Improve the pharmaceutical systems
- Contribute to ensuring access to medicine under UHC

The share of spending on pharmaceuticals within the health care budgets tends to be higher in lower income countries.
There are considerable differences in pharmaceutical consumption between PPRi countries.

The growth in public pharmaceutical expenditure has been higher than the increase in private pharmaceutical expenditure.

Thank you!
THE PHILIPPINE PHARMACEUTICAL COUNTRY PROFILE 2015

Dr. Francisco Soria
Philippine Health Insurance Corporation
Department of Health

PHILIPPINES

- Archipelagic: 7,107 islands, 17 regions
  81 provinces
- Health care system:
  - Devolved system, largely private
  - GDP spending for health: 4.6%  
    - High OOP spending: 56.3%
    - Government share: 18.9%
    - SHI (Philhealth): 11.5%
  - Total expenditure on health per capita: $287

SUMMARY PROFILE OF THE PHILIPPINES

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (000s)</td>
<td>102,965,300</td>
</tr>
<tr>
<td>Life expectancy at birth</td>
<td>69</td>
</tr>
<tr>
<td>Aged &lt; 15 years (%)</td>
<td>32</td>
</tr>
<tr>
<td>Life expectancy at age 60</td>
<td>17</td>
</tr>
<tr>
<td>Aged &gt; 60 years (%)</td>
<td>8</td>
</tr>
<tr>
<td>GDP/capita (PPP)</td>
<td>$6,915</td>
</tr>
</tbody>
</table>

Health care delivery

- No. of physicians (per 10,000 population) (2015): 3.56
- Doctor consultations (per capita): 3.56
- No. of pharmacists (per 1,000 population): 4.19
- Hospital beds (per 1,000 population): 1.2

Expenditure on health (2013)

- Total Health Expenditure (THE)/capita (PPP): $5,360
- General government (%): 18.9
- THE share of Gross Domestic Product (%): 4.6
- Social health insurance (%): 11.5
- Public share of THE (%): 30.4
- Private share of THE (%): 68.2
- Out-of-pocket (%): 56.3
- External resources share of THE (%): 1.4
- Other private (e.g. firms/corporations; NGOs) (%): 3.1

Out-of-pocket spending for medicines

- Family Expenditure on Health by Category (FIES, 2000)

- Medicines are the largest OOP expense for Filipino households.

Significance of medicines in the Philippines

- P146.8 total market (IMS Health, 2014)
  - 72% ethical, 30% OTC
  - Record high growth of BG at 6% since 2011
- Generization of the Philippine market
  - 65% generics (by, largely branded)
  - 3-5% true generics
  - 50% of out-of-pocket payments
  - No reimbursement of outpatient drugs
  - Limited inpatient drug coverage

Increasing market share of generics in recent years

<table>
<thead>
<tr>
<th>Year</th>
<th>Diagonists (3%)</th>
<th>Bxenics (4%)</th>
<th>Other (1%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>116</td>
<td>61</td>
<td>121</td>
</tr>
<tr>
<td>2011</td>
<td>117</td>
<td>64</td>
<td>112</td>
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<tr>
<td>2012</td>
<td>123</td>
<td>62</td>
<td>113</td>
</tr>
<tr>
<td>2013</td>
<td>123</td>
<td>65</td>
<td>114</td>
</tr>
<tr>
<td>2014</td>
<td>123</td>
<td>65</td>
<td>114</td>
</tr>
</tbody>
</table>

Source: IMS/MIDAS, MATCOR 2010-2014
The Universal Health Care Agenda in the Social Contract: Inclusive Growth

Societal Goal: Inclusive Growth and Poverty Reduction

Sector Outcome: Human Development Status Improved

Health Sub Sector:
- Health Status Protection
- Financial Risk
- Responsiveness

Access to quality education, training & culture
- Improved Health Status
- Access to quality social protection
- Access to asset reform

The Philippine Medicines Policy 2011-2016

- Overarching country plan and strategy to increase access to essential medicines and institute good governance reforms in medicines regulations (2011 – 2016)

To assure the safety, efficacy and quality of medicinal products in the market:
- To ensure the continuous availability of essential medicines in the health care system at prices that are within the reach of patients, consumers & the government
- To promote the rational use of medicines in the public and private sectors based on evidence-based and cost-effective treatments that will result in the best health outcomes for patients
- To institutionalize transparency, accountability and good governance along the registration, regulation, selection, procurement & management of medicines in the health sector

The Philippine Medicines Policy 2011-2016

A country strategy document providing the general directions and framework for improving access to essential medicines at all times and in all levels of health care (2011-2016)

Organisation of the Pharmaceutical System

- Pharmaceutical Marketing Authorization
- Pricing Regulator
- Procurement and Reimbursement

Pharmaceutical Regulatory Framework: Legal Bases

- Republic Act No. 3720 (as amended) – Foods, Drugs and Devices and Cosmetics Act
- Republic Act No. 9711 – Food and Drug Administration (FDA) Act of 2009
- Republic Act No. 7394 – Consumer Act of the Philippines
- RA 9502 (Cheaper Medicines Act)
REGULATORY FRAMEWORK ELEMENTS

1. Licensing/Accreditation of establishments
   • GMP, GDP, GSP, GCP and GLP

2. Pre-marketing assessment
   • Quality, safety and efficacy (for innovative medicines)
   • Quality+interchangeability (for generics)

3. Post-marketing surveillance
   • Safety (benefit/risk balance)
   • Quality (quality testing and compliance monitoring)

4. Communication

Number of Registered Medicines in the Philippines
(Market Entry)

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
<th>Notes</th>
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<tbody>
<tr>
<td>24,917</td>
<td>2015</td>
<td>CDRR Database</td>
</tr>
<tr>
<td>21,144</td>
<td>2015</td>
<td>CDRR Database</td>
</tr>
<tr>
<td>3,773</td>
<td>2015</td>
<td>CDRR Database</td>
</tr>
<tr>
<td>49</td>
<td>2015</td>
<td>CDRR Database</td>
</tr>
</tbody>
</table>

POST-MARKETING SURVEILLANCE

1. Pharmacovigilance
   • Safety monitoring of drugs on the market for unexpected health risks and informing the public of risks posed by specific drugs and other health products;

2. Monitoring, collecting, sampling and testing of drugs

3. Audits and inspection of manufacturers/distributors/retail outlets

4. Advertisements and claims monitoring

5. Consumer reporting of ADR

6. Product recall/Administrative sanctions

RATIONAL USE OF MEDICINES
THE PHILIPPINE NATIONAL FORMULARY

Created in the early 1990's under the first National Drug Policy
A government-approved selective list of medicines that guides:
The procurement and supply of medicines in the public sector
Schemes for drug reimbursement by Philhealth
Medicine donations
Local medicine production

VALUE FOR MONEY: AN IMPORTANT CONSIDERATION

In 2013, DOH through the Formulary Executive Council (FEC) began incorporating formal methods of pharmacoeconomic evaluation as part of the decision-making process
new costly therapies
likely high budget impact (> PhP500 million)
new therapies claiming modest to significant improvement in safety/efficacy
different additional benefits to specific subgroups of patients

A country specific threshold of 1 GDP capita per QALY (PhP 120,000) was recently adopted by the FEC to guide the drug approval process
RATIONAL USE OF MEDICINES: GENERICS PROMOTION

The Generics Act of 1988 (RA 6675)
- Mandatory generic labeling
- Generics prescription policy – strict generics-only prescribing in the public sector
- Generics dispensing and substitution in pharmacies (therapeutic substitution not allowed)
- Generics menu card

The Generics Month is celebrated every September during which the DOH launches campaigns in the quad-media on the use of generic drugs to commemorate the signing of the Philippines Generics Act.

Pricing of pharmaceuticals in the Philippines
- Freedom of pricing for both generic and innovator drugs based on what consumers are “willing to pay”
- Non-transparent and varied application of mark-ups
- Price-to-patient does not necessarily reflect cost of production or proof of additional clinical advantage over existing products (i.e. nature and size of the therapeutic benefit)
- Consumers and purchasing authorities are uninformed on fair prices of drugs

VARYING DRUG PROCUREMENT PRICES IN THE PUBLIC SECTOR AT DIFFERENT LEVELS

The Universally Accessible and Cheaper Quality Medicines Act

Enacted in 2008 and gave the government instruments to ensure the affordability of drugs to patients and consumers
- Power to set maximum retail prices of drugs sold in the Philippines as a consumer protection pillar
- Power to invoke TRIPS flexibilities particularly for public health emergencies and other situations as deemed necessary by the Secretary of Health

The Philippines: Cheaper Medicines Act (RA 9502)

The CMA has tools to improve access to medicines
- Improve Competition
  - Parallel Importation
  - Required Production of Generic Drugs
  - Promotion of quality generics
  - Enforcement of the Early working Provision for patented medicines
- Improve Availability
  - Compulsory Licensing
  - Special Compulsory Licensing for patented Medicines
  - Mandatory entry for patented parallel imports

Cost containment measures:
- PhilHealth reimbursements
- Government posted procurement
- Consignment

Rationalizing essential drug prices: The Drug Price Reference Index

- The Philippine Drug Price reference index (DPRI) was implemented in 2014 setting a ceiling price when procuring drugs listed in the national formulary
- Used by the FEC in evaluating incremental costs of new drugs with comparator drugs in the national formulary
- Referenced by PHIC in costing benefit packages
ELECTRONIC DRUG PRICE MONITORING SYSTEM (EDPMS)

- EDPMS is an online DOH system where drug retail outlets/manufacturers/distributors electronically report their prices and/or inventory of drugs on a regular basis.
- A price medicines report is generated and made available to the public to guide them on comparative drug prices and availability in major newspapers.
- An online searchable platform will be launched in September 2015 to provide access to more price information to the Filipino public.

Procurement

- The DOH carries out national procurement for public health programs (i.e. TB, EPI, malaria, neglected infectious diseases, HIV, reproductive health services).
- In 2011, a common tendering process was initiated by DOH for cancer drugs and medicines for hypertension and diabetes distributed in public health facilities.
- The Therapeutics Committees of each hospital determine drugs needed for common cases seen in the facility.
- The criteria of hospitals usually include disease burden, concordance with clinical guidelines and the national formulary, most commonly prescribed in the facility.

DOH PROCUREMENT OF ESSENTIAL MEDICINES

<table>
<thead>
<tr>
<th>PROGRAMS</th>
<th>FUNDS ALLOTTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXPANDED PROGRAM ON IMMUNIZATION</td>
<td>3,076,567,452.90</td>
</tr>
<tr>
<td>NATIONAL PHARMACEUTICAL POLICY</td>
<td>567,709,698.87</td>
</tr>
<tr>
<td>DEVELOPMENT INCLUDING PROVISIONS OF DRUGS AND MEDICINES</td>
<td>368,846,140.00</td>
</tr>
<tr>
<td>TUBERCULOSIS CONTROL PROGRAM</td>
<td>213,519,975.00</td>
</tr>
<tr>
<td>FAMILY PLANNING PROGRAM</td>
<td>345,095,513.24</td>
</tr>
<tr>
<td>ELIMINATION OF PUBLIC HEALTH THREATS (MALARIA, ETC.)</td>
<td>7,350,000.00</td>
</tr>
<tr>
<td>DANGEROUS DRUG ACCESS PROGRAM</td>
<td>11,491,496.40</td>
</tr>
<tr>
<td>RABIES CONTROL PROGRAM</td>
<td>17,280,720.72</td>
</tr>
<tr>
<td>HEALTH EMERGENCY PREPAREDNESS</td>
<td>36,429,510.50</td>
</tr>
<tr>
<td>OFFICE OF THE SECRETARY</td>
<td>12,491,496.40</td>
</tr>
<tr>
<td>TOTAL</td>
<td>4,867,349,727.63</td>
</tr>
</tbody>
</table>

WIDELY VARYING PRICES OF MEDICINES AT RETAIL

<table>
<thead>
<tr>
<th>Latin Name</th>
<th>Strength</th>
<th>Drug</th>
<th>Price</th>
<th>Price</th>
<th>Price</th>
<th>Price</th>
<th>Price</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paracetamol</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ibuprofen</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Codeine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diazepam</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

REIMBURSEMENT OF DRUGS

- The Philippine Health Insurance Corporation (PHIC) reimburses medicines on an inpatient basis.
- The "All Case-rates Policy" was implemented by PHIC in January 2014 understanding that essential drugs are part of the total package of care.
- The National Health Insurance Act mandates that hospitals use the Philippine National Formulary as basis for reimbursement.
- An outpatient drug benefit scheme is targeted to be implemented by 2016 among the poorest quintiles of the population.
KOREA PHARMACEUTICAL SYSTEM AND POLICY
- RESULTS FROM FULL SURVEY

YOUN JUNG Ph.D, R.Ph
Institute of Health and Environment
Seoul National University, Korea
17 Sep 2015

CONTENTS
Korea health care financing & expenditure
Overview of Korea pharmaceutical system
• Pharmaceutical financing and expenditure
• Availability
• Pharmaceutical industry
Korea pharmaceutical policy
• Market authorization
• Reimbursement
• Pricing
• Rational use of medicine

HEALTH CARE FINANCING AND EXPENDITURE
Major public financing mechanism for health care
• Social Health Insurance(SHI)
Total health expenditure
• 7.5% of GDP
• Public share of THE : 54.5% (2012)
• Private share of THE: 45.5%
General government expenditure on health
• 11.7% of total government expenditure (2012)

PHARMACEUTICAL FINANCING AND EXPENDITURE

<table>
<thead>
<tr>
<th>Year</th>
<th>2000</th>
<th>2005</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total pharmaceutical expenditure per capita (USD)</td>
<td>131.6</td>
<td>287</td>
<td>427</td>
<td>444.9</td>
<td>445</td>
</tr>
<tr>
<td>Total pharmaceutical expenditure (% of GDP)</td>
<td>1.02</td>
<td>1.34</td>
<td>1.58</td>
<td>1.58</td>
<td>1.51</td>
</tr>
<tr>
<td>Total pharmaceutical expenditure (% of THE)</td>
<td>26.8%</td>
<td>22.4</td>
<td>21.5</td>
<td>21.3</td>
<td>19.8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>2000</th>
<th>2005</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total pharmaceutical expenditure (TPE)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public share of TPE (%)</td>
<td>60</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private share of TPE (%)</td>
<td>40</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shares of prescription-only medicines in total market (%)</td>
<td>79.55</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shares of over-the-counter medicines in total market (%)</td>
<td>20.45</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CO-PAYMENT FOR MEDICINES

- Co-payment under National Health Insurance (NHI) scheme
  - Inpatient: 20% of cost (dispensing fee + drug cost)
  - Outpatient: 30% of cost (dispensing fee + drug cost)
  - 40 ~ 50% of cost for outpatient prescription issued by general/tertiary care hospitals for not severe cases such as cold, hypertension, diabetes etc.

- Safety mechanisms for vulnerable group or catastrophic cost
  - Age: Elderly (65 and over): 1,200 KRW (cost<10,000KRW)
    Children (under 6): 70% of adult copayment
  - Disease: Cancer (5%), Rare diseases (10%), Tuberculosis (10%)
    Heart/Cerebrovascular dx (5%), Severe burn (5%)
  - Ceiling of co-payment: Total seven sections for ceiling (1.2~5 million KRW per annum). Different according to the income level

AVAILABILITY OF MEDICINES

- No of authorized medicines

<table>
<thead>
<tr>
<th>Medicines</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No. of authorized (licensed) medicines</td>
<td>39,947</td>
</tr>
<tr>
<td>Prescription-only medicines</td>
<td>23,282</td>
</tr>
<tr>
<td>Over-the-counter medicines</td>
<td>16,565</td>
</tr>
<tr>
<td>New molecular entities (NMEs)</td>
<td>41</td>
</tr>
</tbody>
</table>

- Generic market share

<table>
<thead>
<tr>
<th>Generic shares (out-patient market)%</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>In volume</td>
<td>42.6</td>
</tr>
<tr>
<td>In value</td>
<td>41.7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Generic shares (in-patient market)%</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>In volume</td>
<td>44.3</td>
</tr>
<tr>
<td>In value</td>
<td>34.3</td>
</tr>
</tbody>
</table>

PHARMACEUTICAL INDUSTRY

- Pharmaceutical manufacturer

<table>
<thead>
<tr>
<th></th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of domestic pharmaceutical manufacturers</td>
<td>684</td>
</tr>
<tr>
<td>No. of active domestic pharmaceutical manufacturers in production</td>
<td>616</td>
</tr>
</tbody>
</table>

- Pharmaceutical distributor

<table>
<thead>
<tr>
<th></th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of wholesalers</td>
<td>2,393</td>
</tr>
<tr>
<td>No. of community pharmacies</td>
<td>20,886</td>
</tr>
</tbody>
</table>

KOREA PHARMACEUTICAL POLICY

MARKET AUTHORIZATION

- Marketing authorization(registration) is required regardless of whether the medicine is for reimbursement or not
- Primary criteria: safety, efficacy, bioequivalence (in the case of generics)
- No of registered medicines: 39,847 (POMs: 23,282, OTCs: 16,565)
REIMBURSEMENT

Korea operates national positive list system for the general reimbursement scheme from 2007

- Drugs that demonstrate cost-effectiveness can be included on the reimbursable (positive) list
- Negative listing before 2007: all drugs that obtained market authorization from the Korean FDA were automatically reimbursable
- A criteria of reimbursement: efficacy, safety, the result of economic evaluation, and the expected volume of sales
- 17,798 medicines are included in the list as of July, 2015

Procedure of reimbursement

- When a pharmaceutical company submits an application for a new drug to HIRA, the manufacturer performs an economic evaluation
- Then HIRA reviews submitted evidence and assesses the appropriateness of benefit inclusion of the drug
- Upon HIRA’s assessment results, the NHIS negotiates with the pharmaceutical company on pricing
- Finally, MOHW publishes the final price to the public after review by the NHI Policy Deliberative Committee

PRICING

Pricing of new medicines

- Based on price negotiation between manufacturers and the health insurer with price-volume consideration
- If the proposed price of new medicines is under the weighted price of alternative medicines, price negotiation is waived
- Price-volume agreement: At the time of price negotiation, pharmaceutical company and the NHIS sign an agreement on expected volume of sales. If the volumes are 30% greater than expected, then the price of the product should be lowered in proportion to the volume increase
- From the second year, products with consumption of 60% or greater than the preceding year are the target of re-pricing
- The agreement is based on the total expenditure of all products of a company within the same ingredient and same formulation

Over-the-counter medicine: free pricing

PRICING OF GENERIC DRUGS

Generic price linkage (from March 2012)

- First year after patent expiration: 30% reduction in the price of originator, 85% of which (59.5%) is the generic price
- From the second year after patent expiration: 53.5% of originator price (10% reduction from the year) for all generic medicines and original drug, regardless of the order of market entry

OTHER PRICING PROCEDURES

Risk-sharing agreement

- From 2014, NHIS funds the new treatment for diseases without other treatment (e.g., expensive cancer drug and the new treatment for rare disease) but will ask the company to refund if expected outcome is not gained.
- Pharmaceutical company can propose the method of risk-sharing agreement or select a method: conditional treatment continuation plus money back guarantee (based on health outcome), expenditure cap, refund or utilization cap/fixed cost per patient (based on budget impact)

Market-based actual pricing (or incentive system for purchasing low priced medicine):

- Introduced in Oct 2010 and reintroduced in Feb 2014 after suspended for 2 yrs.
- Providers are incentivized based on the difference of actual purchasing price and maximum reimbursable price.
- Maximum reimbursable price will be annually adjusted based on market-based actual price

Mark-up regulation

- For only reimbursable medicines, mark-up is regulated
- No mark-up policy for pharmacy/hospital
- 10% of VAT rate is applied for only OTC drugs
PURCHASING & PROCUREMENT

• No purchasing policy on national level
• Each hospital or pharmacy purchases directly. Sometimes they purchase medicines through private procurement agency
• Public hospitals or hospitals with more than 300 beds are recommended to purchase medicine through bidding process

RATIONAL USE OF MEDICINE

Generic promotion
• Generic substitution is allowed/voluntary
• Allowed either for the prescription with INN or brand name if it is bio-equivalent medicine
• If a pharmacist substitute prescribed medicines with lower priced medicines, financial incentive, whose amount is 30 percent of the price difference, is provided for the pharmacist.
• Generic substitution is still low

Pharmacovigilance
• ADRs are monitored in Korea
• Regional level: Regional Pharmacovigilance Center
• Central level: Korean Institute of Drug Safety

ACKNOWLEDGEMENT

Advisor
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Pf. Bae, Eunyoung (KNU)
Dr. Park, Sylvia (KIHASA)
Dr. Kim, Dongsook (HIRA)

Thank you
Access to Medicines under Universal Health Coverage in the Asia Pacific Region

New hepatitis antivirals: intellectual property challenges and mechanisms to achieve lower prices

September 2015
Dr. Peter Beyer

Hep C: WHO’s role in improving access

Pricing - Policy options

- Developed countries: ‘Value-based pricing’: price/volume agreements; pay for performance; risk-sharing agreement / patient access schemes; reference pricing schemes...
- Developing countries:
  - Differential pricing
  - Voluntary licensing agreements
  - Local production/import
  - TRIPS flexibilities, including compulsory licenses

Differential pricing

Sofosbuvir 12 weeks treatment course:
- US: US$84,000 (reductions since Abbvie came to market)
- UK: US$57,000
- Egypt: US$900 (public programme) (same price offered to public programme in Lao PDR; Mongolia, Pakistan)
- Pakistan: US$1,620 (private sector; distributor Ferozsons)

ombitasvir, paritaprevir/r; dasabuvir (Viekira Pak): US$80,000
Daclatasvir: ?

License Agreements

- Sofosbuvir, ledipasvir, GS5816:
  - 101 countries = around half of all middle-income countries
  - 11 Indian licensees; collaboration with companies in Egypt and Pakistan
  - Allows shipment under compulsory licenses
  - Shipments to non-patent territories prohibited (text unclear)
  - Allows combinations with “foreign” products (e.g. daclatasvir)
- Daclatasvir: announced for 90 countries, but no agreement signed
- Abbvie: ?

WHO Patent Landscapes
### Information on Patent Status in Asian Pacific Region

**Provision: only an indication and does not include secondary patents**

<table>
<thead>
<tr>
<th>Country</th>
<th>sofosbuvir</th>
<th>ledipasvir</th>
<th>daclatasvir</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Granted</td>
<td>Granted</td>
<td>Granted</td>
</tr>
<tr>
<td>Cambodia</td>
<td>Least developed country (LDC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>China</td>
<td>Pending</td>
<td>Granted</td>
<td>Granted</td>
</tr>
<tr>
<td>Indonesia</td>
<td>?</td>
<td>Pending</td>
<td>--</td>
</tr>
<tr>
<td>Japan</td>
<td>Granted</td>
<td>Granted</td>
<td>Granted</td>
</tr>
<tr>
<td>Lao PDR</td>
<td>LDC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malaysia</td>
<td>Granted</td>
<td>?</td>
<td>--</td>
</tr>
<tr>
<td>Mongolia</td>
<td>?</td>
<td>?</td>
<td>?</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Granted</td>
<td>Pending</td>
<td>Granted</td>
</tr>
</tbody>
</table>

Only main patents covered; dark blue shading = included in license agreement

*“-”patent not filed or granted

#### Generic manufacturers: sofosbuvir

<table>
<thead>
<tr>
<th>Company</th>
<th>Country</th>
<th>Gilead License?</th>
<th>Approx. Prices US$ (bottle of 28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hetero Labs</td>
<td>India</td>
<td>Yes</td>
<td>314 (printed on bottle) 193 (reported)</td>
</tr>
<tr>
<td>Natco Pharma</td>
<td>India</td>
<td>Yes</td>
<td>321 (printed on bottle) 313 (reported)</td>
</tr>
<tr>
<td>Biocon Ltd (selling Hetero product)</td>
<td>India</td>
<td>Yes</td>
<td>322 (printed on bottle) 226 (reported)</td>
</tr>
<tr>
<td>Zydus Cadila (selling Natco product)</td>
<td>India</td>
<td>Yes</td>
<td>321 (printed on bottle) 258 (reported)</td>
</tr>
<tr>
<td>Ranbaxy (selling Hetero product)</td>
<td>India</td>
<td>Yes</td>
<td>321 (printed on bottle) 258 (reported)</td>
</tr>
<tr>
<td>Cipla Ltd (selling Hetero Product)</td>
<td>India</td>
<td>Yes</td>
<td>321 (printed on bottle) 177 (reported)</td>
</tr>
<tr>
<td>Mylan Pharm (selling Natco product)</td>
<td>India</td>
<td>Yes</td>
<td>321 (printed on bottle) 322 (reported)</td>
</tr>
<tr>
<td>Abbott (selling Hetero product)</td>
<td>India</td>
<td>No</td>
<td>339 (printed on bottle) 226 (reported)</td>
</tr>
<tr>
<td>Dr Reddy's (selling Hetero product)</td>
<td>India</td>
<td>No</td>
<td>322 (printed on bottle) 226 (reported)</td>
</tr>
<tr>
<td>Pharma 5</td>
<td>Morocco</td>
<td>No</td>
<td>Not launched</td>
</tr>
<tr>
<td>Incepta Pharmaceuticals</td>
<td>Bangladesh</td>
<td>No</td>
<td>Approx. 302 - 350 for sof/ledipasvir</td>
</tr>
<tr>
<td>Beximco Pharmaceuticals</td>
<td>Bangladesh</td>
<td>No</td>
<td>Approx. 350 for sof/ledipasvir</td>
</tr>
<tr>
<td>Pharco Pharma</td>
<td>Egypt</td>
<td>No</td>
<td>187 public and 350 in private market</td>
</tr>
</tbody>
</table>

Source: Prices: TREAT Asia/amfAR – www.hepcasia.com; Pharco; Press; License agreement: Gilead

### Hepatitis B: Entecavir

**Patents:** expired or about to expire in many countries (2016-17); generic versions available from Canadian, Indian and other generic companies

**Prices:** Range from US$427 (Indian generics) to US$15,110 (US BMS) per 360 pills/0.5mg

Estimation that price could be as low as US$36/patient per year

Hill et al., Journal of Virus Eradication 2015; 1: 103–110

### Hepatitis B: tenofovir

**Patents:** Primary patents not granted in Vietnam, Philippines, Malaysia, Mongolia; China expiry: 2017/18

112 countries covered by Medicines Patent Pool license agreements

www.medicinespatentpool.org/patent-data/patent-status-of-arvs/

**Price:** Median cost /year (300mg) East Asia & Pacific:
- 2012: US$54
- 2013: US$43

WHO GRPM pricing database: www.who.int/hiv/amds/grpm/en/

### WHO Essential Medicines List(s)

Satisfy priority health care needs, should be available at all times in appropriate dosage forms, of assured quality at an affordable price; Price not an exclusion criterion; affordability as consequence

Contains 400+ medicines (19th EML). Median availability in developing countries:
- Public sector: 46%
- Private sector: 70.2%

Recent inclusions:
- All new treatments for hepatitis C
- MDR-TB (linezolid; terizodone, bedaquiline, delamanid)
- 16 new cancer medicines

---

*Department of Essential Medicines and Health Products*
**UN/WHO Prequalification**

**Vision:** Good quality medicines for everyone

**Call for Expressions of Interest Hepatitis C/B (2014)**
- sofosbuvir tablet, 400mg
- simeprevir capsule, 150mg
- ribavirin capsule, 200mg, 400mg, 600mg
- entecavir tablet, 0.5mg, 1mg scored

Currently work with a number of companies from different countries on sofosbuvir (finished product and API)

---

**Technical Assistance**

WHO, on request, provides technical assistance to Member States to identify best options to access new treatments

**Example Egypt:**
- joint mission of Dep. of HIV/Hepatitis & Dep of Essential Medicines & country office to advise Egypt on new treatments, including negotiations with companies
- 2-days training involving all relevant agencies and Ministries on public health and IP with WTO and WIPO, including WTO TRIPS flexibilities

---

**Promoting Access to Medical Technologies and Innovation**

[www.who.int/phi/promoting_access_medical_innovation/en/](http://www.who.int/phi/promoting_access_medical_innovation/en/)


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Tel. +41-22-791 25 07
Access to medicines for viral hepatitis in Mongolia

Purevjav Tsetsgee, MOHS, Mongolia

Presentation outline

- Background information
- Burden of viral hepatitis and liver cancer in Mongolia
- Actions and measures on viral hepatitis-’Access’ program on medicines
- Challenges

Background information

- Population of 3 million
- 19th largest country in the world

GDP per capita US$ 4,116 (2015 estimate)

In 2014, the average life expectancy at birth was 69.11 years, for females 75.01 years and 65.42 years in males.

Burden of viral hepatitis and liver cancer in Mongolia

- Hepatitis A (HAV): Common cause of acute jaundice until 2012 when HAV vaccination was introduced
- Hepatitis E (HEV): Moderately high. HEV IgG seroprevalence is high among Mongolian adults > 30 years estimated at 12%. Seroprevalence in children is very low (0.8%)
- Hepatitis B (HBV): HBsAg prevalence was 10.6% (2013), 11.8% (2005) in apparently healthy adult population
- Hepatitis C (HCV): HCVAb prevalence -11% (2013), 15.6% (2005) in apparently healthy adult population
- Hepatitis D (HDV): highly endemic among individuals with chronic HBV infection

Mongolia has the highest incidence of liver cancer (HCC) globally.

- According to National Cancer Research Center in Mongolia age-standardized liver cancer rate is 121.3 for men and 87.9 for women.
- The rates are 8 times higher than the global average estimated by WHO’s International Agency for Cancer Research which are 15.3 and 5.3 respectively.
Burden of viral hepatitis and liver cancer in Mongolia

Crude estimates of potential chronic hepatitis treatment burden in Mongolia

<table>
<thead>
<tr>
<th></th>
<th>Estimated population</th>
<th>% advanced liver disease</th>
<th>No. with advanced liver disease</th>
<th>No. indicated for treatment</th>
<th>No. indicated for treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic HBV</td>
<td>~200000</td>
<td>13 – 31%</td>
<td>26 000 – 62 000</td>
<td>41 800 – 71 400</td>
<td>56 614</td>
</tr>
<tr>
<td>Chronic HCV</td>
<td>~200000</td>
<td>31 – 37%</td>
<td>31 000 – 74 000</td>
<td>31 000 – 74 000</td>
<td>52 500</td>
</tr>
</tbody>
</table>

Source: Current situation and response to viral hepatitis in Mongolia, mission report

Actions and measures on viral hepatitis

- WPRO in collaboration with US-CDC conducted assessment on current situation and response to viral hepatitis in September 2014, January 2015
- Standing Committee on Social policy, education, culture and sciences discussed about viral hepatitis and decided and assigned the MOHS to develop costed National Programme on viral hepatitis
- TWG chaired by the Vice Minister of Health established
- Draft of the National programme on viral hepatitis prevention and control for 2016-2025 developed

National Program on control of viral hepatitis 2016-2025

- The goal of the National Program on viral hepatitis control is to reduce mortality due to chronic liver inflammatory diseases, liver cirrhosis and liver cancer by early screening and detection of viral hepatitis, reducing prevalence of hepatitis infection among general population and effective prevention interventions and by providing accessible and quality health services.

Expected outcomes of the Program

- By 2025 reduce case notification of acute viral hepatitis per 10,000 population to 5.5 (baseline is 24.08)
- Reduce prevalence of chronic hep B and C by 4% and 3%, respectively (baseline HBV-11.8, HCV – 10.0)
- 80% of targeted population screened for hep B and C.
- 95% of patients with HCV are enrolled in treatment.
**Actions and measures on viral hepatitis**

- Hepatitis C prevention, diagnosis and treatment national guidelines developed, approved by Health Minister’s order and 100 public and private health providers are trained
- Web-based information system development is in the progress
- Dialogue on financing options for hepatitis care and treatment
  - Standard package of services for hep C and B
  - Economic analysis of hep C and B care and treatment

**Actions and measures on viral hepatitis - Access program**

- Minister’s meeting with Gilead Sciences-2014, 2015
- Changes in the registration policy on medicines-2015
  - US FDA, EU, Japan, Canada, TGA-30 days, 3 countries
  - New medicines- after 3 years in the other countries market
- MOU 10th June 2015 between MOHS and Gilead Sciences and agreed price for:
  - Sovaldi 300 USD per bottle
  - Harvoni 400 USD per bottle
- Selected local importer & distributor “Ombol LLC”

**Access program**

- **Sovaldi**
  - 400mg 28 tab
  - June 2015
  - 30 patients
- **Tenofovir**
  - 300mg 30 tab
  - 30USD
- **Harvoni**
  - 90mg+400mg, 28 tab
  - November 2015

**RESEARCH PRIORITIES**

- Prevalence studies for hepatitis B, C, delta and other among general population,
- Studies among targeted populations
- Treatment of patients with co-infections
- Hepatitis screening among population aged 40-65
- Determine immune level after viral hepatitis B vaccination
- Efficacy of newly introduced antivirals and selection of treatment option
- Study on resistance to new HCV drugs, mechanisms

**Challenges**

- Great expectations from treatment - pressure from all sides
- Need for capacity building at all levels
- Need for start screening, identify priority patients
- Frequent changes in the government
- Reduction of government budget, tight government resources in 2015-2016
- Coordination between different players

**Thank you for your attention**
Access to new Hepatitis C treatments in Australia

Adriana Platona
Assistant Secretary
Pharmaceutical Evaluation Branch
Australian Department of Health

Interferon free drugs recommended by PBAC

<table>
<thead>
<tr>
<th>Drug name</th>
<th>Brand name</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>ombitasvir / paritaprevir / ritonavir / dasabuvir</td>
<td>VIEKIRA PAK</td>
<td>Abbvie Pty Ltd</td>
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<tr>
<td>ombitasvir / paritaprevir / ritonavir / dasabuvir / RBV</td>
<td>VIEKIRA PAK-RBV</td>
<td>Abbvie Pty Ltd</td>
</tr>
<tr>
<td>sofosbuvir / ledipasvir</td>
<td>Harvoni</td>
<td>Gilead Sciences Pty Ltd</td>
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<tr>
<td>daclatasvir dihydrochloride</td>
<td>Daklinza</td>
<td>Bristol-Myers Squibb Australia Pty Ltd</td>
</tr>
<tr>
<td>sofosbuvir</td>
<td>Sovaldi</td>
<td>Gilead Sciences Pty Ltd</td>
</tr>
</tbody>
</table>

PBAC advice to Minister for Health

- Large prevalent pool – 230 000 people infected
- Treatment in primary care setting needed not only in specialised liver clinics
- Treatment increase from current 2000-3000 people annually to 15 000 – 20 000 people
- Very large budget impact, large opportunity cost hence ICER needs to be low - $15 000 per QALY gained.
- Price per “cure” – regardless of which regimen and length of treatment

Post-PBAC price negotiations

- Informed by technical and allocative efficiency analyses
- Technical: large number of corrections to make the companies economic analyses more conservative – i.e. true ICER double than claimed by companies
- Allocative: low ICER, risk-sharing agreements with 100% rebate over agreed estimates

Budget impact

- To treat estimated 12 500 per year, at initial asking prices A$3.7 Billion over 5 years
- Based on PBAC’s framework A$1.3 Billion over 5 years – approx. A$25,000 per cure
- Alternative analysis - NPV (discounted, but not taking into account QOL, transmission rates and productivity) positive if treatment cost per cure about A$10 000.

Negotiations ongoing

- TO BE CONTINUED
Access to medicines and assistive devices for older people in the Western Pacific Region

Libby Roughead
University of South Australia

What are the implications for health?

- Chronic disease accounts for 80% of the disease burden in people 60 years and over
- In low, low middle and upper middle income countries
  - Ischaemic heart disease, stroke, chronic lung disease, osteoarthritis, dementia, diabetes, vision and hearing problems.
- Mobility challenges are also present
  - 20 – 30 % report moderate, severe or extreme difficulty moving around

Are we prepared for providing access to medicines and devices for older people?

Are medicines for chronic diseases on the essential medicines lists?

<table>
<thead>
<tr>
<th></th>
<th>Australia</th>
<th>Cambodia</th>
<th>China</th>
<th>Cook Islands</th>
<th>Fiji</th>
<th>Kiribati</th>
<th>Malaysia</th>
<th>Nauru</th>
<th>Philippines</th>
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<th>Tonga</th>
<th>Tuvalu</th>
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<th>Viet Nam</th>
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<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Cardiovascular: Antiplatelets, ACE inhibitors, Beta blockers, Ca channel blockers, diuretics
### Are the medicines for chronic diseases available? Public sector

<table>
<thead>
<tr>
<th>Country</th>
<th>Osteoporosis</th>
<th>Dementia</th>
<th>Macular degeneration</th>
</tr>
</thead>
<tbody>
<tr>
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<td>✓</td>
</tr>
<tr>
<td>Cambodia</td>
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<td>×</td>
<td>×</td>
</tr>
<tr>
<td>China (some provincial lists only)</td>
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</tr>
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<td>Nauru</td>
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<td>Papua New Guinea</td>
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<tr>
<td>Solomon Islands</td>
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<tr>
<td>Tonga</td>
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<td>Tuvalu</td>
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<tr>
<td>Vanuatu</td>
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</tr>
<tr>
<td>Viet Nam</td>
<td>×</td>
<td>×</td>
<td>×</td>
</tr>
</tbody>
</table>

**Overall median availability:** 40%

**Private Sector:** 70%

### Are generic medicines for chronic diseases available? Public sector

**Median availability brands versus generics: public sector**

**Overall median availability:** 33%

**Private sector:** 50%

### Are we purchasing medicines for chronic diseases at best prices? Generic medicines: public sector

**Median price (and range): ratio to international reference price for lowest price generic**

**Overall:** paying twice international best prices for generic medicines

### Are patients paying fair prices for medicines for chronic diseases? public sector

**Median price (and range): ratio to international reference price for lowest price branded products**

**Overall:** patients are paying twice the international standard for generics and nine times for branded medicines in the public sector.

**Four times for generics and 15 times for branded in the private sector**

### Are we purchasing medicines for chronic diseases at best prices? Branded medicines: public sector

**Median price (and range): ratio to international reference price for lowest price branded products**

**Overall:** paying twelve times international best prices for branded medicines
• Medicines for chronic diseases are listed on the essential medicines list in most countries in the region
• However,
  - Not always available
  - Generic version not always available
  - Procurement prices are high
  - Prices for patients are high
  - We don’t have much insight into how this relates to utilisation
Are we using medicines for chronic diseases well?

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Patients with a 20% or higher risk of cardiovascular disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antithrombotics</td>
<td>China (n=3070) 11, Malaysia (n=440) 11</td>
</tr>
<tr>
<td>Aspirin</td>
<td>China (n=3070) 14, Malaysia (n=440) 14</td>
</tr>
<tr>
<td>Blood pressure blockers</td>
<td>China (n=3070) 19, Malaysia (n=440) 19</td>
</tr>
<tr>
<td>Antihypertensives</td>
<td>China (n=3070) 24, Malaysia (n=440) 24</td>
</tr>
<tr>
<td>Diabetes control</td>
<td>China (n=3070) 33, Malaysia (n=440) 33</td>
</tr>
</tbody>
</table>

Not many published studies from the region. Collectively, studies suggest significant underuse of medicines for chronic diseases.

What about health literacy?

- 1500 from rural villages in China (80% > 50 years)
  - Half knew to take blood pressure medicines every day
  - Half knew blood pressure usually life long illness
  - Less than 40% knew consequences of blood pressure
- 3450 persons from Mongolia
  - 17% never heard of hypertension
  - Most did not think it a threat to health
- 3851 patients with diabetes in Malaysia
  - 30% didn’t understand their prescription labels

Collectively, studies suggest health literacy of both consumers and health professionals needs to be improved.

Schemes to improve access for older people to medicines for chronic diseases? An example

- **China**: New Cooperative Medical Scheme (covers rural population)
  - Provides free screening for cardiovascular disease and covers costs of 17 essential medicines for hypertension, diabetes, coronary heart disease and stroke
  - Evaluation showed 45% of participants screened and 85% of those screening positive had received free medicines

Strategies to improve use of medicines for chronic conditions: An example

- **Philippines**: First Line Diabetes Care Project to improve diabetes self-management
  - 32 hours of training for local government health unit staff and village health workers
  - Implemented in rural area where most services paid out of pocket
  - Participants visit clinic at least once every three months
  - Village health workers conducted home visits

- After one year
  - Knowledge and perceived control of diabetes improved
  - Adherence to medicines and exercise improved
  - Optimal glucose control rose from 42% to 51%
- New trial underway to see if smart phone messaging helps further

Conclusion

- Imperative to start building systems now to support older people and medicine use
- Opportunity to focus on whole of patient management, rather than a medicine focused approach
  - self management programs with access programs,
  - screening programs with access programs
- Opportunity to exploit technology developments
• Need to start developing or adapting resources now (Australia has some translated into Vietnamese, Chinese and Korean, but not contextualised to country) and trialling models of practice so we can learn from each other
• Important to understand utilisation of medicines to both inform procurement and pricing, as well as quality use of medicines.
• Evaluation of progress will be critical.
A new approach to reviewing & improving effective management of medicines:  
Country situational analyses in SEAR

Kathleen Holloway  
Regional Advisor in Essential Drugs and Other Medicines, WHO/SEARO  
September 2015

Need for a national coordinated health systems approach to Effective Management of Medicines

• Monitoring medicines mgmt. minimal, falling between different bodies:  
  – Medicines availability, use & policy implementation often suboptimal
• WHO monitoring  
  – Drug use database (from published articles), country pharma profiles  
    (from MOH questionnaires) – not enough for country policy action
• WHA resolutions WHAs 58.27, 60.16, 67.25:  
  – National programs needed to monitor & improve use & contain AMR
• RC resolutions:  
  – SEA/RC55/R4 & SEA/RC62/R6 call for measures to improve access to  
    essential medicines & to strengthen drug regulatory authorities  
  – SEA/RC64/R5 and SEA/RC66/R7 call for monitoring use & request  
    country situational analysis to be done 4-yearly to identify a country-  
    contextualized roadmap for action and monitor progress

Situational analyses in S. E. Asia:  
New rapid appraisal method over 2 weeks

• Negotiated with MOH & WHO Country Office about objectives & visit  
• Uses a workbook tool developed in WHO/HQ & adapted by SEARO  
• Work with a government team comprising at least one staff from supply,  
  regulation, health services and selection/use (pharmacologist)  
• Visit major MOH departments & agencies responsible for drug supply,  
  selection, regulation, insurance, academia, professional bodies  
• Visit at least 1 of each type of public facility (district, 2º, 3º hospitals,  
  PHCs) & 2 private pharmacies in 2 provinces/regions): 12 -16 facilities  
  – Enough facilities to identify problems, not get generalizable data  
• Conduct a 1-day workshop with national stakeholders to validate  
  findings & develop recommendations for a roadmap for future action  
• Publish a report on-line for use by MOH/partners in future planning  
• Costs approx. USD 20,000 per country including consultant fee

Data collected – not available elsewhere  
Used for: identifying problems, monitoring progress, institutional memory, advocacy, reality check.

• Drug supply - in public facilities & private shops  
  – Availability of ~30 key essential drugs, stock-out, expiry, price data,  
    storage conditions, procurement/distribution and LMIS systems
• Drug Selection – compliance with EML  
  – OPD Px survey (30/facility) & national/district consumption data
• Drug use  
  – OPD Px survey (INRUD indicators & % URTI cases treated with ABs)
• Drug Regulation  
  – Number of registered products, drug outlets, staff, samples tested  
    (with sampling & failure rate), ADRs, inspections, prosecutions, SOPs
• Drug Policies  
  – Policies in place and implementation

Situational analysis in Bangladesh Sept. 2014:  
Getting started

Briefing the government team  
Team talking to Dept. Health Services

Talking to stakeholders

National Regulatory Authority  
Academia  
Central Medical Supplies Depot
Collecting data on medicines use

OPD prescribing survey
Private pharmacy drug use survey

Inpatient ward & dispensing register

Collecting data on store management

Writing the report

Based on workbook tool
Info systematically recorded
Five sections
- Medicines supply
- Medicines selection
- Medicines use
- Medicines regulation
- Medicines policy
Recommendations
Agreed with government
Put on the web
- http://www.searo.who.int/entity/medicines/country_situational_analysis/en/

On the road in Bhutan, July 2015

Situational analysis: national workshop

1. Preparation with the team
2. Presenting the findings
3. Group work & development of recommendations

Situational analyses - some results:

Amazing achievements considering the low investment

Common findings
- Drug supply systems under-resourced & mostly manual
- Irrational use of medicines & little monitoring
- Drug regulation under-resourced & SOPs often not followed
- Drug policies poorly implemented, falling between different bodies & sometimes conflicting with each other
- All stakeholders had knowledge gaps on how medicines are managed & some were fearful to share info for fear of blame

Common recommendations
- Establish electronic LMIS & analyze data for better stock mgt.
- Invest in NRAs to ensure adequate human & financial resources
- Establish a high-level coordinating mechanism for policy discussion & an MOH unit to monitor drug use & coordinate policy implementation
Drug availability in public sector: - S. E. Asia

<table>
<thead>
<tr>
<th>Country</th>
<th>No. of Key Ess. drugs</th>
<th>% Avail. of key drugs</th>
<th>% DRA posts</th>
<th>% prescribable drugs dispensed</th>
<th>% prescribed drugs on file</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh 2014</td>
<td>61-100</td>
<td>95-2</td>
<td>85-97</td>
<td>66-96</td>
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<td>Bhutan 2011</td>
<td>97</td>
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<td>Maldives 2014</td>
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<td>6-21%</td>
<td>87-90</td>
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</table>

* Data from MOH; ** EML > 5 years old

Regulation: sector vs resources - S. E. Asia

<table>
<thead>
<tr>
<th>Country</th>
<th>% Ave. DRA posts</th>
<th>% prescribable drugs dispensed</th>
<th>% prescribed drugs on file</th>
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<tr>
<td>Bangladesh 2014</td>
<td>95-2</td>
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<td>2.2-2.9</td>
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</table>

Public PHC antibiotic use & stewardship – S. E. Asia

<table>
<thead>
<tr>
<th>Country</th>
<th>% OPD cases given AB</th>
<th>% URTI cases given AB</th>
<th>Nat AMR strategy</th>
<th>DTGs most nos.</th>
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</table>

Public sector health worker views

**Nepal Auxiliary Health Worker (1 year trained paramedic in HP)**

- "For children under 5 years with pneumonia I must give amoxycillin syrup according to IMCI guidelines. Since we are short of amoxycillin syrup & have short-dated chloramphenicol syrup, I am prescribing it to children of more than 5 years with pneumonia in order to use up the stock."

**Nepal Peon (untrained asst. in sub-HP)**

- "When doctor saab is not here I do dressings and give out cetamol. For young children I give cotrim." - Timor-Leste Hospital Senior Doctor

- "The Standard Treatment Guidelines marked for referral hospitals are not appropriate because the medicines are too simple."
- **Nepal Auxiliary Health Worker (1 year trained paramedic)**

- "When doctor saab is not here I do dressings and give out cetamol. For young children I give cotrim."

- **Timor-Leste Hospital Pharmacy technician**

- "Monitoring expired drugs on the ward is not my job, it is the nurses’ job."

Clarifying & solving complex problems

- Bhutan – stock-out due to simultaneous policy changes
  - Regulation on non-importation of unregistered drugs enforced.
  - Anti-corruption Task Force, Audit Commission, & Min. of Finance misunderstanding about higher prices for better supplier criteria
  - Trying to encourage local wholesalers by giving 3-year tenders and higher punitive rates for defaulting
  - For some products: no bids, no supplier & stock-out
  - Resolved after policy changes - after sit. analysis & 2nd policy meeting

- Sri Lanka stock-out due to quality problems
  - NRA registration process weak - few qual. staff, not following SOP
  - Registration with the NRA is the only quality criteria in govt. purchase
  - 800 samples tested last year with 30% failure rate leading to withdrawal of 12 products & stock-out

Learning about medicines in health care delivery together

**Private retail shops**

**Public sector health facilities**

Major outcome: less fear, more openness to sharing info & acting on it
Country situational analyses: summary

- 2-week rapid “diagnostic” appraisal of medicine management
  - Developed during a 1st round in all 11 countries during 2010-13
  - Approach revised during a 2nd round in 8-9 countries during 2014-15
- Mandated by RC resolutions 2011 & 2013
- Done by government team using workbook/survey tools
- Requires external facilitator with good knowledge/overview
  - Training team of regional facilitators, but facilitator guide needed
- Accurate data collected quickly – but requires supervision
- Facilitates a coordinated, holistic, learning approach, & cheap
- Future: analyse & publish SEAR findings & progress, discuss progress
A PROPOSAL FOR A FRAMEWORK TO ASSESS THE IMPACT OF CHANGES IN POLICIES ON PHARMACEUTICAL SPENDING AND COVERAGE TRENDS

Annalisa Belloni - OECD Health Division

2nd Meeting on Access to Medicines under Universal Health Coverage in the Asia Pacific Region
Seoul, 17-18 September 2015

Spending on Retail Pharmaceuticals has Grown More Slowly Than Overall Health Spending

Source: OECD Health Statistics 2015

Total Pharmaceutical Spending, Per Capita, 2013

Source: OECD Health Statistics 2015

Per Capita Spending On Retail Pharmaceuticals, 2013

Source: OECD Health Statistics 2015

Pharmaceutical Expenditure Growth 2009-2013

Source: OECD Health Statistics 2015
Pharmaceutical Expenditure has Grown at 6% from 2000-10 in Asia/Pacific Countries

![Graph showing pharmaceutical expenditure per capita and % growth](image)

**Main results:**
- Government expenses reports are the main source of data for retail pharmaceuticals expenditure
- Industry data on retail sales of pharmaceuticals are also used to estimate private spending in several countries

**Main issues:**
- Underestimation of total pharmaceutical expenditures as the share of pharmaceutical spending in hospital is not available
- Difficulty of collecting data from non-pharmacy stores (e.g. outlets, petrol stations)
- Lack of data to determine whether medicines were prescribed or not as required by health accounts standards

**ANALYSIS OF DRIVERS AND COMPONENTS OF SPENDING GROWTH**

- **What Drive Pharmaceutical Expenditure?**
  - Policies to improve efficiency
  - Market dynamics
  - Increased demand
  - Coverage expansion
  - Introduction of new drugs

<table>
<thead>
<tr>
<th>Demand for pharmaceuticals</th>
<th>Quantity</th>
<th>Prices (of existing drugs)</th>
<th>Therapeutic mix</th>
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<td>Population size and demographic composition</td>
<td>Changes in practice guidelines and/ or physicians’ practices</td>
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<tr>
<td>Emergence of new diseases</td>
<td>Changes in practice guidelines and/ or physicians’ practices</td>
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<td>Disease prevalence and severity</td>
<td>Changes in practice guidelines and/ or physicians’ practices</td>
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<tr>
<th>Pharmaceutical market dynamics</th>
<th>Introduction of new drugs</th>
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<th>Animal health</th>
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<td>Introduction of new drugs</td>
<td>Introduction of new drugs - if price competition</td>
<td>Introduction of new drugs</td>
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<tr>
<td>Patent expiries, generic competition</td>
<td>Patent expiries, if shift of prescription to off-patent products</td>
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<th>Pharmaceutical policies</th>
<th>Coverage expansion</th>
<th>Price cuts, changes in distribution mark-ups, in VAT</th>
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<tr>
<td>Reference price policies</td>
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Source: WHO GHO 2014, OECD Health Statistics 2014
Challenges on the Analysis of Pharmaceutical Spending

- Availability, comparability, granularity and timeliness of pharmaceutical expenditure data
- How to track changes in pharmaceutical policies and market dynamics

Thank you!

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