Template for summary record

Title session:

1. Launch of drug system papers, report
2. Essential medicines for universal health coverage
3. Situation on access to essential medicine in Thailand
4. TRIPs plus provision to ensure access to medicine: challenge or obstacle?

Q&A

Session Rapporteur Team

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Summary:

1. Key message of the session

Thailand had the first essential medicine list on 1974. Thailand had 3 version reports since 1994 (1st edition). This session was talking about how we need essential medicines and how we can get the access to the essential medicines. This topic will be the main concern because the medicines expenditure in Thai predicted to be more than 44% of healthcare expenditure based on the data that Thai had 22% medicines expenditure increment in 2000 then doubled up to 44% in 2016. Supporting the use of generic medicines and 100% NLEM availability in the public health care supposed to be done by both financial and policymakers. The relationship between the drug access and other components in Pharmaceutical system was illustrated by the Conceptual Framework of Thai Drug System 2020. The key challenges addressed by the Lancet Commission were highlighted: Paying for a basket of essential medicines – The medicine expenditure (97 USD per capita in 2016) in Thailand was higher than the threshold per capita in low- and middle- income countries. In terms of the SDG 3.8 UHC, Thailand was comparable to high income countries. Regarding the issue of making essential medicines affordable, we have implemented the UHC and several strategies, including the NLEM E (2) and compulsory licensing for ensuring sufficient access to essential medicines. TRIPS agreement can provide the countries to mitigate the access to expensive medicines. By supporting the local manufacturer of drugs and also the universities in providing the new drugs with big modification as well as its evidence to the policy maker, so hopefully these efforts can reduce the drug price and can cover all Thai people need of essential medicines.

2. Major problems & issues raised / discussed

How much we need to pay the essential medicine: Among the low- and middle-income countries (LMICs), researchers proposed a threshold of the appropriate pharmaceutical expenditure $13-25 per capita. Most of the LMICs didn't provide enough money for their Essential Medicine

(approximately 25% of the countries spent less than $13 per capita). The medicines expenditure has increased 21% in 2000 and 44% in 2016. So possibly, it can predict that will be more increasing medicine expenditure in 2020 and it supposed to be tackled by the policy maker in Thai.

How to make the affordable essential medicine: If the government paid too much for non-essential medicine, this will be harder to cover all people's need of medication. So, we need to find the best procurement for the substitution drug so we can reduce the price. We also force the use of generic drug and supported by the policy maker. We make sure that every public health care has every drug listed in Thai NLEM, if there is an out-stock condition, so it will be considered as major problem issues. NHSO reported there is available special list essential medicine for particular high price medicines which can be covered by the government. In terms of the SDG 3.8 UHC, Thailand was comparable to high income countries. Regarding the issue of making essential medicines affordable, we have implemented the UHC and several strategies, including the NLEM E(2) and compulsory licensing for ensuring sufficient access to essential medicines. Unfortunately, there is no countries reported their status in SDG 3.b.3 so this condition will be challenging for Thailand to evaluate our access to medicines and vaccines (Dr. Walaiporn).

How we ensure the quality of essential medicine: It is important to ensure that essential medicines possess good quality, safety, and efficacy properties. The problem is that prescribers and patients are not able to verify these properties by themselves which is an essential public function. We asked the WHO not only do the prequalification exam once for entire life of the drugs but also repeating the qualification test to make sure there is no counterfeit drug. The support to harmonize the International Standard of Drug's Quality Assurance is needed among the Drugs Manufacturer in the worldwide. The transparency and accountability of drug's manufacturing information should be prioritized and also checked continuously by the FDA.

How we promote the quality use of essential medicine: In Indonesia most of the DM patients use the Insulin Analogue due to the 3 monopoly pharmacy manufactures. But in Thailand we are trying to minimize the use of Insulin Analog and optimizing the use of Human Insulin.

How to develop the missing essential medicine: Currently, producing the antibiotics is not interesting anymore for the pharmaceutical industry. Some of the medicines are being abandoned due to less benefit which can be earned by the pharmaceutical industry even in the condition that Thai people still need those medicines. So, we are encouraging our local manufacturer to produce the drugs for the Thai people and also get the license for other needed drug (especially for biological drugs and high-cost drugs) so we can reduce the drug price.

The intellectual property should be recognized by all countries. It is a human right for every people to access in essential medicines. TRIPS agreement was started from our concerned about the copyright protection from the foreigners. The new drugs and gaining the profit are played by the developed countries. Most of the patent drugs has only small change part (not a big invention for the new drug) and it's used to derive more profit by the manufacturers. Manufacturers playing their role in patent protection by producing the established drug's polymorphism or its derivatives.

Currently, TRIPS have dramatically change to reduce the monopoly so recently the access to essential medicine can be more flexible. Inside the TRIPS agreement, it provided for countries to mitigate the access to expensive medicines. The users can be more flexible to determine the

appropriate method of implementing the provisions of the agreement within their own legal system and practice. TRIPS agreement regulates a condition that If the drug patented in Thai, but then there is a similar patented drug in other countries and it is cheaper, so Thailand can import that drug. Nowadays, The European Union countries and USA commission are planning to extend the patent period to more than 20 years, so the TRIPS agreement can ask the waive for this condition or to stop the extension planning as well as avoid for data exclusivity. Argentina is the good example for essential medicine access improvement while it only had few granted license.

3. Suggested solutions

We need to force the policy maker to support the use of generic medicines, to support the new drugs inventions, to support the negotiation for achieving the high-cost drugs to be affordable drugs for Thai people. TRIPS agreement can be one of ways to be applied to reduce the patented drug's price from either patent holder or patent drug's exporter.

Dr. Yot suggested the way for counteracting the five key challenges on essential medicines for UHC. For example,

1. Paying for a basket of essential medicines – The budget would be allocated to improve the per capital national drug expenditure to meet the threshold in some countries.

2. Making essential medicines affordable – Some effective measures to make the drug more affordable are procurement interventions, pro-generic policies, pricing interventions, quality use of medicines interventions, and Trade-Related Aspects of Intellectual Property Rights (TRIPs) flexibilities.

3. Assuring quality and safety of essential medicines – It would be improved by emphasising on international harmonization, regional collaboration, and WHO Prequalification Programme, promoting better quality assurance in procurement agencies, involving other stakeholders and the general public in quality assurance, promoting transparency of information etc.

4. Promoting quality use of medicines - We should ensure rationale drug use and control any strategies of pharmaceutical companies for manipulating the market. Additionally, independent pharmaceutical analytic unit is required to gather and generate information for promoting good quality medicines use and other issues.

5. Developing missing essential medicines – There is a current effort through new alternative incentives, regulatory incentives, public funding, patent pooling, and TRIP flexibilities (e.g., compulsory licensing).

The interventions and strategies should be cross-cutting implemented and their progress must be measured.

For the IP issue affecting the drug access, we should negotiate, particularly to block patent term extension and data exclusivity. The negotiation with the countries of patent owners should be done as a group of countries where to gain more power (e.g, Thailand and EU countries vs. the US). Evidence is also required to support the process.

4. Quotations

“We need to do negotiation all the time to get the access to all the medicines we need because an access to the essential medicines is a human right” Dr. Walaiporn

“Prescribers and patients cannot verify the quality, safety, and efficacy of a product themselves; that is an essential public function” Dr.Yot Teerawattananon

Dilemma: How can we respect intellectual property while ensure a human right to access to medicine in public health? Dr Carlos Maria Correa