



# HTA DEVELOPMENT ACTIVITIES IN INDONESIA

March 14-17, 2017

This visit covered the introduction of the Indonesia EQ-5D-5L instrument, the Guide to Health Economic Analysis and Research (GEAR) online resource launch, HTAC's plans for 2017, and the off-label medicines studies' stakeholder consultation.

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#### Disclaimer Page

This report is written as documentation for the Health Intervention and Technology Assessment Program's (HITAP) activities. The information may not be fully representative of all the discussions during the meetings. HITAP's activities in Indonesia is funded by the grant to the International Decision Support Initiative under the Bill and Melinda Gates Foundation as well as the grant from PATH under the Access and Delivery Partnership. The findings, results, and conclusions do not necessarily reflect the views of the funding agencies.



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## **List of Acronyms**

ADP Access and Delivery Partnership

Badan POM Indonesian National Agency of Food and Drug Control

BIA Budget impact analysis

BPJS Badan Penyelenggara Jamina Sosial (Agency for the Organization of

Social Insurance)

CEA Cost-effectiveness Analysis
CML Chronic Myeloid Leukemia

CRC Colorectal cancer EE Economic evaluation

DALY Disability Adjusted Life Years ESRD End-stage renal disease

GEAR Guide to Health Economics Analysis and Research Online Resource

GHD Global Health and Development Team

HePTA/HTA Health Technology Assessment Program in the Mahidol University HITAP Health Intervention and Technology Assessment Program, Thailand

HTA Health Technology Assessment

HTAC Health Technology Assessment Committee, Indonesia

IC Imperial College IDR Indonesian Rupiah

iDSI International Decision Support Initiative

JKN Jaminan Kesehatan Nasional, universal healthcare program

MoH Ministry of Health, Indonesia MoPH Ministry of Public Health, Thailand MoU Memorandum of Understanding PAH Pulmonary Arterial Hypertension

PEN Package of Non-Communicable Disease Interventions

PICs Persons in Charge

QALY Quality Adjusted Life Years

QoL Quality of Life

TNP2K National Program for Poverty Alleviation

UHC Universal Health Coverage

WB World Bank

WHO World Health Organization



## **Executive summary**

The HTA Committee was formally renewed and continues its work as a facilitator of national HTA studies as of 2016. Under their oversight, three HTA economic evaluation studies were completed from 2014-2016: the economic evaluation of sildenafil as a first line treatment for pulmonary arterial hypertension (PAH); the economic evaluation of the package of essential non-communicable disease interventions (PEN); and, the economic evaluation of the renal replacement therapy options for Indonesia.

Of the three, the economic evaluation of sildenafil as a first-line treatment for PAH has drawn much attention domestically. Sildenafil (Viagra) is registered for another indication, which means using it as a treatment for PAH is an off-label medicine use. Sildenafil has since then been registered into the national formulary to be used in the reimbursement list. During this process, however, to connect the study for policy, HITAP has supported the conduct of the review of laws, regulations, and use of off-label medicines in Indonesia locally as well as drawing from the experiences of other countries. The results were presented to stakeholders and potential ways of addressing off-label medicines, which still remains an issue in the country.

An Indonesian EQ-5D-5L value set, a measure of quality of life, was developed through the EuroQoL group, to be used as one of the HTA tools. This visit introduced the value set to relevant stakeholders, primarily the academics and researchers that would be using them, as well as to international partners such as HITAP and Imperial College's Global Health and Development Team (GHD). In addition to this, HITAP also launched and introduce the Guide to Health Economics Analysis and Research (GEAR) Online Resource for the researchers as a guide for conducting economic evaluations.

Given that the HTA Committee aims to conduct four HTA studies in the next year, two of which are economic evaluations, the GEAR will be helpful. HITAP will be providing technical assistance and support to the conduct of these four studies throughout the year, starting with the finalization of the proposals scheduled in the first week of August.

#### Objectives:

- 1. To support the conduct of the policy forum for the studies on off-label medicines; to facilitate the next steps for the two studies.
- 2. To support the development of HTA in Indonesia and conduct of the four new HTA studies for 2017.
- 3. To support the introduction of the EQ-5D-5L value set as a part of the HTA toolkit.
- 4. To explore opportunities and avenues to introduce HTA and collaborate with local and international partners on future activities.



## Introduction

At the beginning of 2014, Indonesia launched its universal healthcare program, the Jaminan Kesehatan Nasional (JKN), which will cover all Indonesians by 2019. By the end of the year, the Badan Penyelenggara Jamina Sosial (BPJS Health), became the administrator of the largest health insurance scheme in the world with over 133 million people enrolled<sup>1</sup>. In terms of financing, the JKN is a tiered premium-based system supplemented by government subsidies fully covering the poorest. The costs of the program are estimated to be around USD 13-16 billion per year until the JKN is fully rolled out<sup>2</sup>. The ambitious nature of the program, challenges for implementation and high costs associated with bringing healthcare to all brought priority setting to the fore and a Presidential Regulation in 2013 that called for the use of health technology assessment (HTA) in deciding the benefits covered by the scheme<sup>3</sup>.

The Health Technology Assessment Committee (HTAC) was set up in the Ministry of Health (MoH) to serve as the secretariat for HTA activities. It has received support from various international partners including the International Decision Support Initiative (iDSI) through which the Health Intervention and Technology Assessment Program (HITAP) has been providing technical assistance. To date, three HTA studies have been completed as part of this collaboration, one on the treatment of End Stage Renal Disease (ESRD), another on the use of sildenafil as treatment of Pulmonary Arterial Hypertension (PAH) and the third, an economic evaluation of the Package for Non-Communicable Disease Interventions (PEN) in Indonesia.

This visit is part of HITAP's ongoing efforts to assist the development of HTA in the country. Last year, HITAP visited the country in October 2016 to finalize the proposal and begin the two off-label medicines studies (Indonesia and international country experiences) as part of the support for the sildenafil study. The two studies have since been completed; HITAP supports the policy forum at the end of the trip which is the culmination of the two studies. It will introduce the two studies' results to Indonesian stakeholders and bring awareness to the issue of off-label medicines use in the country. Off-label medicine use can be beneficial or harmful. An appropriate mechanism needs to be in place to ensure that it is used appropriately.

HITAP also supported the showcasing of the new EQ-5D-5L value set for Indonesia, and introduced the Guide to Health Economic Analysis and Research (GEAR) online resource. These two tools will be useful, especially in the coming year with the HTAC aiming to conduct 4 HTAs. HITAP will provide intensive support to the researchers throughout the year. Details of these meetings as well as other related ones will be discussed in chronological order in the coming pages. Agendas of the meetings are in Appendix 1: Agendas.

<sup>&</sup>lt;sup>1</sup> "Indonesia Economic Quarterly In times of global volatility", The World Bank Group, October 2015. Available at: http://www.worldbank.org/en/news/feature/2015/10/22/indonesia-economic-quarterly-october-2015

<sup>&</sup>lt;sup>2</sup> "Indonesia's universal health care goals", Oxford Business Group, 2015, Available at: http://www.oxfordbusinessgroup.com/overview/indonesias-universal-health-care-goals

<sup>&</sup>lt;sup>3</sup> "Regulation Of President Of The Republic Of Indonesia No. 12 Year 2013 Concerning Health Care Benefits", Translation – Presidential Regulation No. 12/2013 Social Protection Team, The World Bank, Jakarta Office. Available at: www.social-protection.org



## **Main Meetings**

### **EQ-5D-5L Stakeholder Consultation**

Prof. Jan Van Bussbach introduced the EuroQoL group, a network of different academics (health economists, sociologists, psychologists, etc.) founded in 1986. He discussed the origins of the EQ-5D-5L tool, its characteristics, as well as its strengths and weaknesses as a measure of quality of life. The tool is measured through a survey given to the public wherein they value health states and conditions on a standard scale. These then measure societal values, which would be useful for decision-making. In the beginning, there were many versions of the EQ-5D-5L that were specific to different criteria. To resolve this, a short section was added to major questionnaires that would provide a standard measure for each aspect that the EQ-5D-5L without compromising the other questionnaires. Characteristics of the EQ-5D-5L are: the tool should be small enough not to cause too much burden on responders; it should give one value for QALY/DALY; and, it should be applicable to all diseases. A major critique of the tool is its lack of sensitivity; disease-specific instruments are more sensitive. However, because in health economics the measures needed are big effects, sensitivity is less of a priority. EQ-5D-5L measures should be included in studies for reimbursement claims because of its potential for high impact in this area.

Mr. Frederick D. Purba then introduced the Indonesian EQ-5D-5L value set, which was based on 1156 respondents selected through stratified quota sampling. Time trade off was chosen to limit the tendency for higher preference in standard gamble when responders are risk averse. Given Indonesia's huge variation in terms of demography, there may be differences in the results in different areas. The team is aiming to conduct a study comparing the East and West areas to understand these differences. They are also working on an EQ-5D-5L version for children, which is more complex than the current tool.

The Indonesian EQ-5D-5L tool is in the publication process of the PharmacoEconomics Journal and will be used in HTA studies in the country.

## **Indonesia HTA Development and HITAP Support**

The HITAP team, along with the IC GHD, met with the HTA Committee to discuss its plans for the coming year and the assistance that HITAP can provide.

HITAP and the PPJK have been processing a Memorandum of Understanding (MoU) in the past year. Capacity building and support for using evidence for policy are the main clauses in the MoU. HITAP's provision of scholarships to Indonesian researchers to attend the HePTA/HTA program in Mahidol University falls under this goal. Currently, the MoU is in the approval process in the Bureau of International Affairs; the Cabinet must review all documents for which the Health Minister will be the signatory. Indonesia may put their Secretary General or Health Minister as the corresponding signatory.



The HTAC informed HITAP that as of 2016, the HTAC has been renewed, keeping most of the original members as well as adding two new ones. This team is in place until 2018 (2-year contract) and they meet regularly, 2-3 times per month. In this time, they have completed the clinical and economic evaluation guidelines and completed the topic selection and prioritization process. The guidelines are in the approval process under the Legal Bureau of the MoH and was shared with HITAP earlier. They were also distributed to relevant stakeholders such as universities, hospitals, BPJS (Social Security Agency), research centers in a policy forum in February 2017. PATH, one of the international partners in Indonesia, will support the translation of the HTA methodological guidelines.

The HTAC facilitated and gathered topics from relevant stakeholders. From this process, they selected topics for which the four studies are planned for the coming year:

- 1. Assess the CE of bevacizumab as complementary therapy on chemotherapy for metastatic colorectal cancer compare with chemotherapy alone
- 2. Assess the cost effectiveness of cetuximab as complementary therapy on chemotherapy for metastase colorectal cancer
- 3. Assess the cost-effectiveness of nilotinib vs imatinib in chronic myeloid leukemia (CML)
- 4. Alternative therapy bupivacaine: lidodex, ropivacaine, levobupivacaine?

The PPJK (Centre for Healthcare Financing) Primary Investigators will handle two of these studies; the other two will be under the University of Indonesia and Gadjah Madah University Primary Investigators. For the first three topics, the proposal is now developed; however, the bupivacaine study was cancelled and may be replaced with a study on the treatment of diabetes through traditional vs. analog insulin. Regarding this, HITAP requested information on the policy relevance of the study. The HTAC responded that this is based on the BPJS claims data, and the studies selected represent some of the treatments that the BPJS spends the most on. A solid and evidence-informed justification for investment (and, potentially in these cases, disinvestment) must be provided. They also want to make this more sustainable in the future and ensure that other areas, such as provider payment, benefits from HTA and evidence.

The HTAC requested that HITAP provide technical oversight and assistance during all stages of the process: proposal development, data collection, analysis, write-up, and results dissemination. HITAP will join the team again on 5-7 April 2017, to assist in the first step of finalizing the proposal. The HTAC is plans to have a consultation for the proposals for HTA in 2017, with stakeholders including the HTAC, BPJS, national formularies, health professionals, and pharmaceutical companies.

## Guide to Health Economic Analysis and Research (GEAR) Launch

The GEAR is an online platform for low- and middle-income researchers use in case they have any methodological difficulties in conducting economic evaluations. The HITAP team introduced this tool to Indonesian partners (researchers from the PPJK and universities, e.g. University of Indonesia and Gadjah Madah) through a workshop. They began with an introduction to the basics of economic evaluations to provide the participants with a refresher and basis for the discussions. Then they showed the main features of the GEAR, which are: visualizing the methodological difficulties through a mind map; exploring guidelines; and, asking experts for possible solutions, in case they are not already in the website. Then the participants had the chance to use the website and work through an



exercise. They provided written feedback to feed into the next phase developments of the GEAR. Finally, they reviewed the event's effectiveness and whether they would use the GEAR for their activities.

Figure 1:

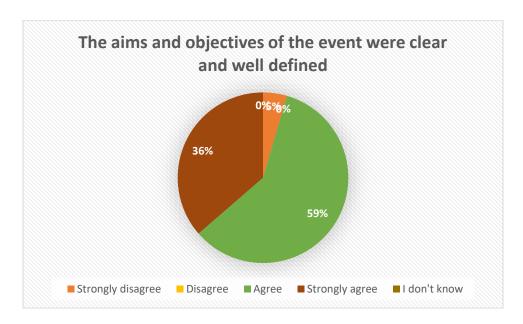


Figure 2:

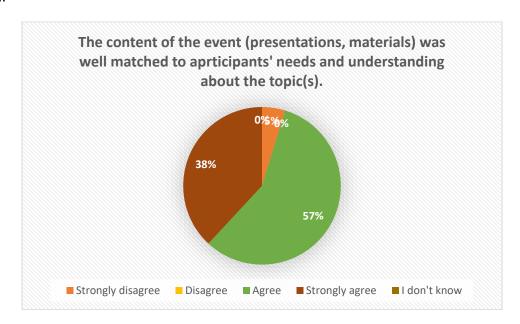


Figure 3:



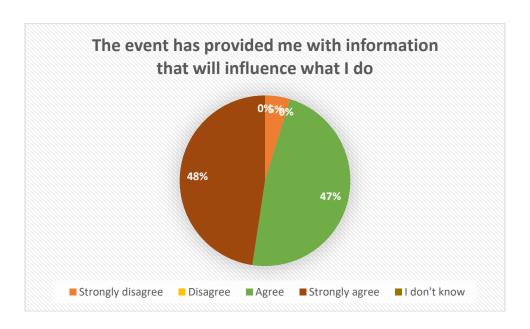
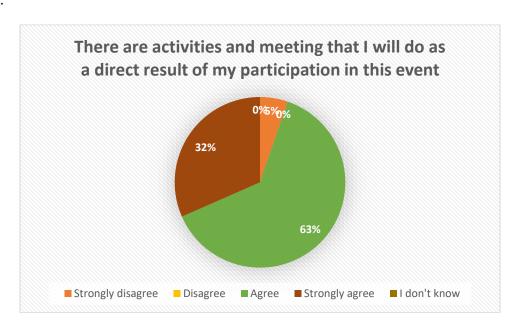


Figure 4:



Twenty-three respondents had favorable impressions of the event. Most felt that the objectives were clear and the content was presented well. They also mentioned that they will be using the GEAR in their future activities. In the qualitative section, the respondents cited the following: using the GEAR for pedagogical purposes (teaching economic evaluation); networking and exchanging information with other economic evaluation researchers; using the GEAR for conducting HTA; and, using the



GEAR to improve their knowledge. For improvements on the activity, the participants suggested longer time to explore the GEAR and exercises using real-world data.

### **Proposal Development**

HITAP met with the four research teams that will conduct the studies to discuss the context for the study, the research question, the methods/approach to be used, the timelines/major activities, and the major barriers.

- 1. Clinical effectiveness and EE of cetuximab on metastatic colorectal cancer (University of Indonesia)
  - a. Cetuximab is the fifth in terms of cost spending in the BPJS claims data. This medicine is currently under the Special Access Scheme.
  - b. The policy question is: how much is the threshold price for cetuximab? The cost is current 20 million IDR for each cycle and there are 12 cycles for this treatment.
  - c. It is the targeted therapy for CRC for KRAS negative wild type. One option is to compare between Cetuximab+chemotherapy and chemotherapy alone; chemotherapy is FOLFOX or FOLFIRI. However, chemotherapy is not used alone in most hospitals since it is provided as part of the targeted treatment with cetuximab.
  - d. For the analysis, use societal perspective, but for the BIA, it should be in the perspective of BPJS. Outcome is QALY.
  - e. The team is deciding between the choice of model (decision tree VS Markov) since patients' life won't last longer than a year.
  - f. They will gather data from hospitals and literature review.
  - g. HITAP recommended that the pattern of prescription/treatment be investigated as well. The question for the comparator is on the criteria for patients receiving either FOLFOX or FOLFIRI.
  - h. The pattern: if the patients still respond to basic chemotherapy, then they will continue to get it. If not responsive, then change to FOLFOX and FOLFIRI, respectively. If still non-responsive, then add cetuximab.
  - i. As for clinical effectiveness: retrospective and overall survival might not be feasible. HITAP recommended to do the completeness of treatment and find the survival through mapping between the completeness and the survival.
  - i. Comparators should be
    - i. Folfox
    - ii. Folfox+bevacizumab
    - iii. Folfox+cetuximab
    - iv. Folfiri
    - v. Folfiri+bevacizumab
    - vi. Folfiri+cetuximab
    - vii. Others
    - viii. Others+bevacizumab



#### ix. Others+cetuximab

- k. The team must create a table to outline this and review the model to be used. They should also conduct a quick systematic review of the clinical effectiveness of adding cetuximab to various treatments.
- l. They should also do a quick review of every patient in a hospital in Jakarta in the past 2 years to fill the number of patients.
- 2. Imatinib and nilotinib (PPJK PIC)
  - a. The team should use QFAST for systematic review appraisal.
  - b. They assume that the QoL is not dependent on the treatment received,
  - c. The cost of dasatinib is lower but it is not available here so it cannot be added to the study.
- 3. Alternative spinal anesthetic drugs for Bupivacaine: lidodex, ropivacaine and levobupivacaine (only lidodex can be reimbursed)
  - a. The team wants to conduct a CEA (societal perspective) and BIA based on a clinical effectiveness literature review. They want to use a decision tree.
  - b. They are unsure whether bupivacaine causes deaths in many patients (there were 12 cases in 2015).
  - c. HITAP recommended they conduct an international evidence review on safety of bupivacaine compared to other choices or do an analysis on the causal relationship between bupivacaine use and the deaths.

#### 4. Insulin

a. HITAP recommended they do a review of clinical outcome for insulin and a systematic review of economic evaluation of insulin.

The four studies teams' will meet again with HITAP from 5-7 April to discuss the proposals and present them to stakeholders.

#### Off-label Medicines Studies' Stakeholder Consultation

Attendees to the stakeholder consultation included the following (see Appendix 2: Attendees for the Off-Label Medicines Forum for the list): members of the HTA Committee; staff from the Directorate of Pharmaceuticals and Medical Devices; staff from the Director General; university HTA researchers; PPJK; BPJS; Badan POM (Indonesian National Agency of Food and Drug Control); and some pharmaceutical companies.

Dr. Yot Teerawattananon provided the basis for the discussions, defining what the off-label medicine use is, why they become off-label medicines, the risks vs. the benefits of using off-label medicines, the perspectives of stakeholders for off-label medicines, and the example of using sildenafil for pulmonary arterial hypertension or PAH (which is an off-label indication) in Indonesia (See Appendix 3: Presentations at the Off-Label Medicines Policy Forum for the presentation). He mentioned that these two studies were initiated in support of an economic evaluation for sildenafil that found it is a cost-effective option for PAH, though there are issues reimbursing it due to the law prohibiting use of off-label medications under the universal healthcare scheme.



Dr. Nattiya Kapol, from the Silapakorn University, then presented on the laws, regulations, and current situation of off-label medicines use in four countries: Australia, Singapore, Thailand, and the UK (see Appendix 3 for the presentation). They found that off-label medicine use is practiced in all countries and there is no law prohibiting their use. They are mostly used for pediatric patients, pregnant women, psychiatric patients, and the elderly – in other words, patient populations that may not commonly be involved in clinical trials. Often, they are also used because the current treatments are ineffective or they are already widely used such that companies no longer register them. Though there may be risks due to the lack of clinical trials, the balance needs to be made on accessibility to medicines as well as other factors such as non-registration by pharmaceutical companies. However, all countries studied have a mechanism for considering off-label medicines – whether through a formal process as in Australia and Singapore, or through HTA studies as in Thailand and the UK. The countries, however, prohibit the promotion of off-label drugs.

Dr. Prastuti Soewondo, from the National Program for Poverty Alleviation (TNP2K), presented on the laws, regulations, and current situation of off-label medicines use in Indonesia (see Appendix 3: Presentations at the Off-Label Medicines Policy Forum for the presentation). They found that the practice of prescribing off-label medicines is prevalent in Indonesia. Physicians may be unaware of the law prohibiting the use of off-label medicines; in addition, when they send the claims data, the information does not show whether it is an off-label medicine. They expect regulators to be the bridge for the use of off-label medicines and find the solution to address these issues. Pharmaceutical companies also do not promote off-label drugs but would be interested in a simpler system for registration. For example, in the case of sildenafil, once the evidence was available regarding its effectiveness and cost-effectiveness, they were able to expedite the registration process. Drug national formulary and the JKN can ensure that on-label drugs are prescribed or a better system is implemented.

During the discussion section, the following major points were raised. The clinical advisory (under the Ministry of Health, for which the PPJK is the secretariat), a committee under the Binfar that handles drug use, or a new committee can be tasked with creating the guidelines for off-label medicines consideration. HITAP recommended that there be an advisory statement: if there is more than one indication available, the companies should register the medicines for the indication, especially if there is evidence supporting their use. Given the prevalence of the practice, regulation may be difficult; therefore, it is important to focus on getting off-label drugs to be on-label or having a process (e.g. guidelines and/or conducting HTA studies) to support investment in or disinvestment from off-label drugs.



### **Policy Recommendations on Off-Label Medicines**



Photo 1: Discussion during the forum.

Off-label medicines use is an unexplored area in universal healthcare coverage.

HITAP presented the following framework for considering inclusion or exclusion of off-label medicines in the context of Indonesia:



	1							١.
Is this off-label	medicine	registered	ın	most	countries	tor 1	the indication:	?

is this on last mediane registered in most countries for the indication.				
	In the context of Indonesia	Yes	No	
		Group 1:	Group 2:	
Does this off- label medicine for this condition have	Yes	Sildenafil for pulmonary arterial hypertension (in Indonesia as of 2016)	Bevacizumab for macular disease	
strong scientific evidence of safety, efficacy, and effectiveness?	No	N/A	Group 3:  Anti-depressant bupropion for weight loss  Use of prophylaxis antibiotics for elective surgeries	

Figure 5: Framework for considering off-label medicines use, with examples from Indonesia

They suggested that medicines that fall under Group 1 and 2 should be considered for registration given that they have evidence of safety and efficacy. Medicines that fall in Group 3 should be monitored closely. With this framework, HITAP proposed the following policy recommendations for different stakeholder groups in order to ensure that they are used appropriately.

#### Policy Recommendations for Research Grant Agencies

- Provide resources for independent researchers to assess safety and clinical benefit of common or important (e.g. only choice for patients) off-label medicines use for particular indications.
- Provide resources for monitoring and assessing impact of off-label medicines use to set priority for research for their country.

#### Policy Recommendations for Healthcare Payers and Public Health Authorities

- Fund the use of off-label medicines with strong scientific evidence for the benefits package.
- Control the marketing and use of off-label medicines with no evidence of clinical benefit and safety, or, if there is clear evidence of harm.
- Provide financial and non-financial incentives for industry to register medicines for off-label medicine indications.
- Implement national guidelines on the use of off-label medicines at the policy level and for individual physicians.



#### Policy Recommendations for the HTA Agencies

• Conduct research on safety, clinical effectiveness, value-for-money, budget impact, affordability, and social and ethical effect of off-label medicines use to inform policy decisions of healthcare payers and public health authorities.

#### Policy Recommendations for Health Professionals

- Work with the government to develop codes of conduct or ethical guidelines regarding offlabel medicine use.
- Collaborate with HTA agencies to assess safety, clinical effectiveness, value-for-money, budget impact, affordability, and social and ethical effect of off-label medicines use.
- Inform and discuss with patients the non-routine use of off-label medicines. Informed consent should be given for these types of off-label medicine use.

#### Policy Recommendations for Industry

- Register products for off-label indications if the evidence is available.
- Develop evidence for off-label indications.
- No promotion of medicines for off-label indications.
- Monitor the use of medicines for off-label indications and inform stakeholders if these are identified.

#### Policy Recommendations for Civil Societies and Patients

- Be aware of the information and understand that the use of off-label medicines can have both benefits and risks.
- Monitor the use of off-label medicines, especially those with potential harms.
- Encourage patients to discuss the benefits and risks of their treatments with health professionals.
- Support the assessment of safety, clinical effectiveness, value for money, affordability, and social and ethical impact of off-label medicines use through participation – and encouraging others to participate – in good trials.



## **Miscellaneous Meetings**

### **BPJS (Indonesia Social Security Agency) Meeting**

The BPJS is now more involved in the HTA process and supporting studies in Indonesia, cosponsoring two alongside the PPJK. They may be more involved in the process in the future and provide more resources as well as the possibility of incorporating it into their systems. HITAP also proposed that they facilitate the process for one of the HITAP-sponsored Indonesia scholars to the HePTA/HTA Mahidol University program.

### World Bank (WB) Consultation

HITAP and the GHD met with the WB health team to discuss the possibility of collaborating on future activities. They introduced iDSI and its work in the country over the past four years, which primarily is on conducting HTAs and institutionalizing HTA in the Indonesian healthcare system. The WB informed iDSI that their work is focused on a broader level of looking at the efficiency of the entire health system, within which HTA and evidence-informed policymaking is one aspect. Their collaboration is within the context of the need for efficiency, the BPJS running a deficit, and the expansion of donor funding and transitioning of current funding to the Indonesian government's budget. The WB invited HITAP to join a workshop in the beginning of April that will present the possible areas of work to the country counterparts.

## **Access and Delivery Partnership Consultation Meeting**

HITAP met with PATH to discuss the off-label studies and the progress of their joint activities in Indonesia. PATH operates in Indonesia through the Access and Delivery Partnership (ADP). HITAP suggested that ADP consider including HITAP as a core partner in the next phase. Another point of discussion is the possibility of PATH joining HTAsiaLink and supporting Indonesian partners to attend the HTAsiaLink. Potential partners are Dr. Mardiati Nadjib, who is a part of the HTAC, and Dr. Maya Amiarny from the BPJS, as well as one researcher from the off-label medicines studies.



## **Appendices**





## **Appendix 1: Agendas**

### Meeting Agenda Harris Tebet Hotel Jl. Dr. Saharjo No 191 Jakarta

Tuesday, 14 March 2017					
Time	Activity	Speaker			
09.00-					
09.30	Registration	Organizing Committee			
09.30-	Report from the organizing				
09.45	Committee	Head Division of EEPK			
09.45-		Head of Center for Health Financing and Health			
10.00	Opening Remark	Insurance			
10.00-					
10.15	Foreword	HTA Committee Chairperson			
10.15-					
10.30		Coffee Break			
10.30-	EuroQol Group : Helping Policy				
10.45	maker and researcher	Prof. Jan Van Buschsbach			
10.45-					
11.00	Experience with Euroqol Group	Fredrick Dermawan Purba, Mpsi, MSc			
	The new Indonesian Euroqol EQ-				
11.00-	5D-5L : quality of life as part of				
11.30	health economics	Fredrick Dermawan Purba, Mpsi, MSc			
11.30-					
12.30	Discussion	Participants			
12.30-					
13.30	Lunch				
13.30-					
14.30	Indonesia HTA Development	HTA Committee Chairperson			
14.30-					
16.30	Discussion	Participants			
Wednesday, 15 March 2017					
08.00-	Registration	Organizing Committee			
08.30	veRiziration	Organizing Committee			
08.30-	Foreword	Hood Division of EEDV			
08.45	Tolewold	Head Division of EEPK			



08.45- 09.05	What is Economic Evaluation?	Dr. Yot Teerawatananon	Introduction of Economic Evaluation	
09.05- 09.35	Discussion: Challenges in conducting economic evaluation study in Indonesia	Ms. Alia Luz +	All participants	
09.35- 10.00	What is the GEAR online resource?	Ms. Waranya Rattanavipapong		
10.00-				
10.15	Coffee Break			
	GEAR website workshop:			
10.15-	Introduction to features			
10.40		Alia Luz		
10.40-	Individual and/or Group			
11.15	Exercise	Online Form		
11.15- 11.30	Feedback session			
11.30- 11.50	Discussion on exercises	All Participant	dr. Yot Teerawatananon	
11.50-	Feedback focus group	Ms. Waranya / Ms.	Focus Group based	
12.20	discussion	Alia Luz	on online form results	
12.20- 12.35	Closing	HTA Committee Chairperson		
12.35-	Lunch			

#### Policy Forum Agenda:

- 1. Opening
- 2. Background and introduction by Dr. Yot Teerawattananon
- 3. Presentation by Prof Nattiya about the result of literature study on off-label drugs
- 4. Presentation by Ibu Becky about the qualitative study on off-label in Indonesia
- 5. Presentation on the policy recommendations led by Dr. Ryan Li and Ms. Alia Luz
- 6. Discussion. led by Ibu Becky to explore several possibilities of policy type that can be developed in Indonesia.
- 7. Summary of discussions by Aziza Mwisongo
- 8. Closing remarks: WHO representative Dr. Salma Burton



### **Appendix 2: Attendees for the Off-Label Medicines Forum**

- 1. DG Health Services, MOH RI
- 2. DG-Binfar, MOH RI
- 3. Head of NIHRD, MOH (dan 2 staffs)
- 4. Head of Badan POM RI
- 5. Deputi I Monitoring Section on Therapeutic and Narcotic Products, Psychotropic& Addictive Substances BPOM RI
- 6. Director of Drug Assessment and Biological Products Badan POM RI
- 7. Director of Distribution Monitoring on Therapeutic Products Badan POM RI
- 8. Head of PPJK (and 2 staffs)
- 9. Director of Referral Health Services (and 2 staffs)
- 10. Director of Pharmaceutical Services, MOH (and 2 staffs)
- 11. Prof Dr. dr. Pradana Soewondo, SpPD-KEMD
- 12. Prof. Dr. dr. Sudigdo Sastroasmoro, Sp.A (K)
- 13. DR. Suharyono, MS, Apt. (Head of Master Program on Clinical Pharmacy, Universitas Airlangga)
- 14. Dr. drg. Mardiati Nadjib, M.Sc.
- 15. dr. Izhar M. Fihir, MOH, MPH
- 16. Head of Section Economic Evaluation and Health Financing PPJK
- 17. Head of Sub-Section Health Technology Assessment PPJK
- 18. Head of Sub-Section Efficiency and Effectiveness Analysis on Health Financing PPJK



- 19. Dean Faculty of Pharmacy Universitas Indonesia
- 20. Dean Faculty of Pharmacy Universitas Pancasila
- 21. Dean Faculty of Pharmacy UHAMKA
- 22. Vice Dean Academic Faculty of Public Health Universitas Indonesia
- 23. Head of Research Unit Faculty of Public Health Universitas Indonesia
- 24. Head of Department of Health Administration and Policy Faculty of Public Health Universitas Indonesia (and 1 lecturer)
- 25. Head of Center for Health Administration and Policy Studies Faculty of Public Health Universitas Indonesia (and 1 researcher)
- 26. Head of Center for Health Economics and Policy Studies Faculty of Public Health Universitas Indonesia (dan 1 researcher)
- 27. Health Intervention and Technology Assessment Program (HITAP): Dr. Yot Teerawattananon, Ms. Alia Luz, Ms. Benjarin Santatiwongchai, Mr. Rajibul Islam
- 29. Dr. Ryan Li, Global Health and Development (GHD) Team under the Imperial College (IC)
- 30. Prof. Nattiya Kapol, Silapakorn University
- 31. Aziza Mwisongo, PATH
- 32. Dr. Salma Burton, WHO
- 33. Dr. Prastuti Soewondo and Ms. Vetty Yulianty Permanasari, National Program for Poverty Alleviation (TNP2K)



### Appendix 3: Presentations at the Off-Label Medicines Policy Forum

See below the link for the policy forum presentations:

https://www.dropbox.com/sh/7ctcg1ktre62sef/AACfb0b8B LnF3cMTC4e7VIfa?dl=0

HITAP has also published a blog on the proceedings:

 $\frac{http://www.globalhitap.net/considering-the-inclusion-of-off-label-medicines-in-universal-health-coverage-uhc-packages/$