

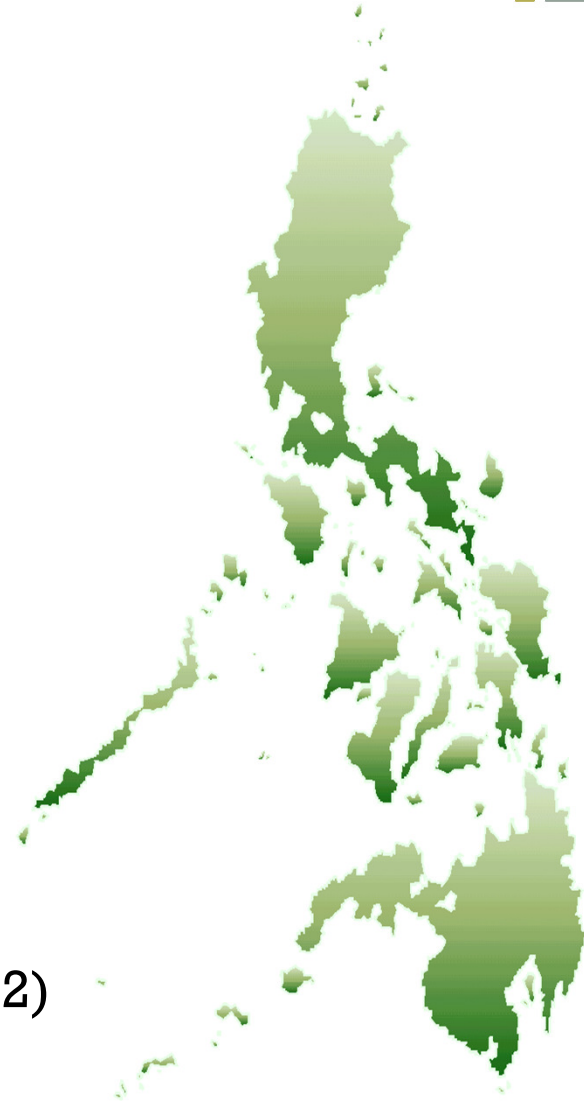
Health Technology Assessment in the Philippines



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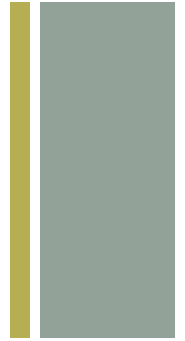
+ Philippines

- *Archipelagic*: 7,107 islands
- Population of 94.01 M as of 2010
- Healthcare:
 - GDP spending for health : **4.4%**
 - High OOP spending: 63%
 - Government share: 27%
 - SHI (Philhealth): 9.9%
 - Devolved system, largely private
 - Total expenditure on health per capita:\$ 223
- Pharmaceuticals account for 70% of household out-of-pocket payments
 - Php 131 billion market (IMS Health, 2012)
 - 60% branded products
 - 40% generics





The need for HTA in the Philippines



- Large population, limited resources
- Multiple disease burdens – rise of NCDs
- High cost of drugs
- Irrational prescribing
- Variations in access, quality, and costs of health care
- Uncontrolled large private system of care



Rapid diffusion of new technologies

“In the Philippines, there is observed proliferation of ‘centers’ offering stem cell treatments for medical and aesthetic purposes. Although this technology holds promise, stem cell therapy is not yet part of standard of care and is considered an investigative procedure for compassionate use,”

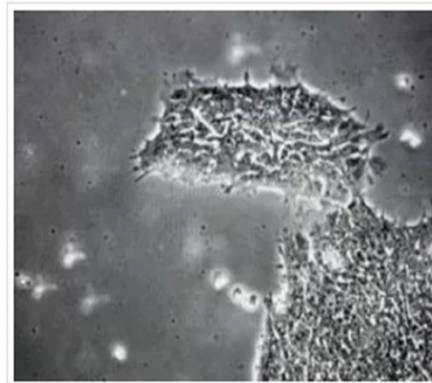
– Health Secretary Enrique Ona

DOH issues stem cell guidelines

By Philip C. Tubeza
Philippine Daily Inquirer

10:49 pm | Wednesday, March 20th, 2013

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Human embryonic stem cells can become any cell in the body. AFP FILE PHOTO

very complex nature of this therapy,” Ona said.

MANILA, Philippines—The Department of Health on Wednesday released the implementing rules and regulations that will cover stem cell and cell-based therapy to prevent abuses and dubious practices.

Health Secretary Enrique Ona said the regulations contained in DOH Administrative Order 2013-0012 aimed to ensure that human stem cell and cell-based therapies in the country would be safe and effective for their intended use.

“Our efforts at regulating the practice of stem cell therapy in this country are aimed at safeguarding the welfare of our patients and the general public by making safe, effective and ethical stem cell modalities and practices are within emerging international and global standards considering the

Many technologies are adopted before they are even assessed for potential impact and value in the Philippines.



Unaffordable new drugs

Drug / Indication	Cost per patient
Imatinib for CML and GIST	Php 1,733,760 per year
Trastuzumab for Her2+ breast cancer	Php 1,500,000 per 6-month course
Erythropoietin for anemia in CKD (dialysis patients)	Php 360,000 per year*
Imiglucerase for Gaucher's disease	Php 5,000,000 per year (lifetime)
Dabigatran for the prevention of ischemic strokes in AF patients	Php 120,000 per year

+ Institutions conducting technology assessments in the Philippines



MARKETING APPROVAL

- Pharmaceuticals
- Food
- Medical devices
- Biological agents
- Cosmetics

Safety, efficacy and quality

FORMULARY LISTING

- Pharmaceuticals
- Comparative cost-effectiveness
- Budget impact
- Health service impact
- Equity/ethical/social implications

PURCHASING /ACCREDITATION

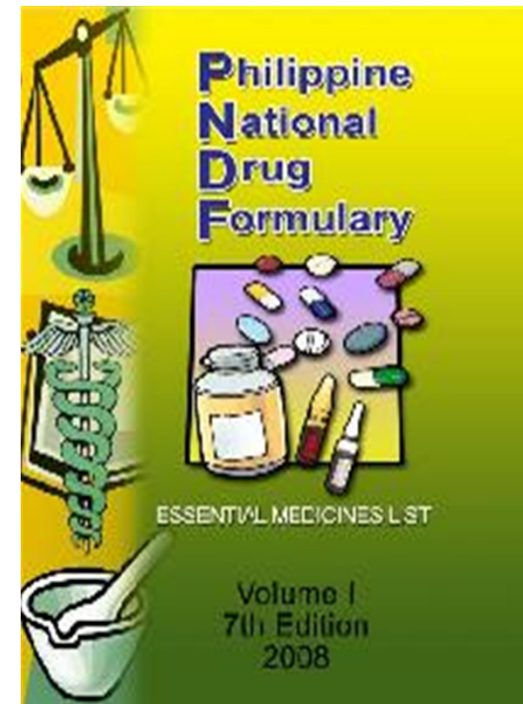
- Pharmaceuticals
- Diagnostics
- Medical /Surgical procedures
- Professional services
- Sustainability
- Equity
- Affordability

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The Philippine National Formulary

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





PNF Legal Framework



Law /Policy	
<i>Republic Act # 6675 (Generics Act of 1988)</i>	Use of generic names/INN in labeling, advertising, prescribing and dispensing Development of the National Essential Drugs List
<i>Executive Order #49 (1993)</i>	Mandatory use of the Philippine National Formulary as the basis for drug procurement by the government
<i>Philippine Health Insurance Corporation Board Resolution #265 (1999)</i>	The PNF became the basis for claim reimbursements for drugs by Philhealth
<i>RA # 9502 – (Universally Accessible Cheaper and Quality Medicines Act of 2008)</i>	Reinforcement of the Philippine generics Act and enhancement of the national formulary Price regulation and TRIPS flexibilities



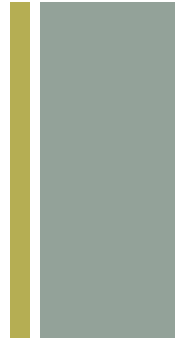
Formal HTA systems to assess other technologies beyond drugs began in the 1990's

- HTA was identified by Philhealth as a tool to guide the development of reimbursement policies on medical claims based on the cost-effectiveness of tests and treatments
- In 1999, the **Philhealth HTA Committee** was created to guide Philhealth in the selection of health technologies for insurance coverage.





HTA and the National Health Insurance Act of 1995



SEC. 37. *Quality Assurance.* – Under the guidelines approved by the Corporation and in collaboration with their respective Offices, health care providers shall take part in programs of quality assurance, utilization review, and technology assessment that have the following objectives:

a) to ensure that the quality of personal health services delivered, measured in terms of inputs, process, and outcomes, are of reasonable quality in the context of the Philippines over time;

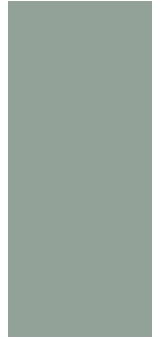
b) to ensure that the health care standards are uniform within the Office's jurisdiction and eventually throughout the nation; and

c) to see to it that the acquisition and use of scarce and expensive medical technologies and equipment are consistent with actual needs and standards of medical practice, and that:

- 1) the performance of medical procedures and the administration of drugs are appropriate, necessary and unquestionably consistent with accepted standards of medical practice and ethics. Drugs for which payments will be made shall be those included in the Philippine National Drug Formulary, unless explicit exception is granted by the Corporation.
- 2) the performance of medical procedures and the administration of drugs are appropriate, consistent with accepted standards of medical practice and ethics, and respectful of the local culture.



Health Technology Assessment Unit- PhilHealth



- established in March 1999
- tasked to develop reimbursement policies on medical claims based on the cost effectiveness of tests and treatments.

Composition of HTA Unit



1. Department Representatives:
 - a. Standards and Monitoring Department
 - b. Accreditation Department
 - c. Benefits Development and Research Dept.
 - d. Protest and Appeal Review Department

Roles:

- Identify policy gaps and issues on claims evaluation & where policy development could be focused
- Determine which problems regarding use of medical technologies by providers needs immediate assessment
- Assist on drafting of policies for presentation to the PhilHealth Board for its final approval

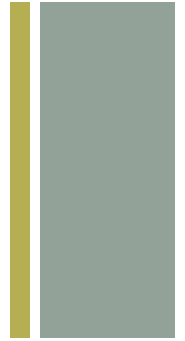


The Philhealth HTA Committee

- Clinical Epidemiologists
- Pharmacologist & Toxicologist
- Expert in Health Policy and Economics
- Expert in Procedures/Medical Devices
- Expert in Health Economics
- Expert in Quality Assurance and Improvement
- Expert in Evidence Base Medicine
- Expert in Health Management, Planning and Policy



Functions of the Philhealth HTA Committee



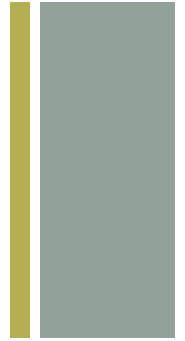
- Create a positive list of drugs to complement the national formulary
- Appraise and disseminate clinical practice guidelines
- Evaluate the effectiveness and safety of medical and surgical procedures



***Its ten years of
existence has been
marked by several
important activities.***

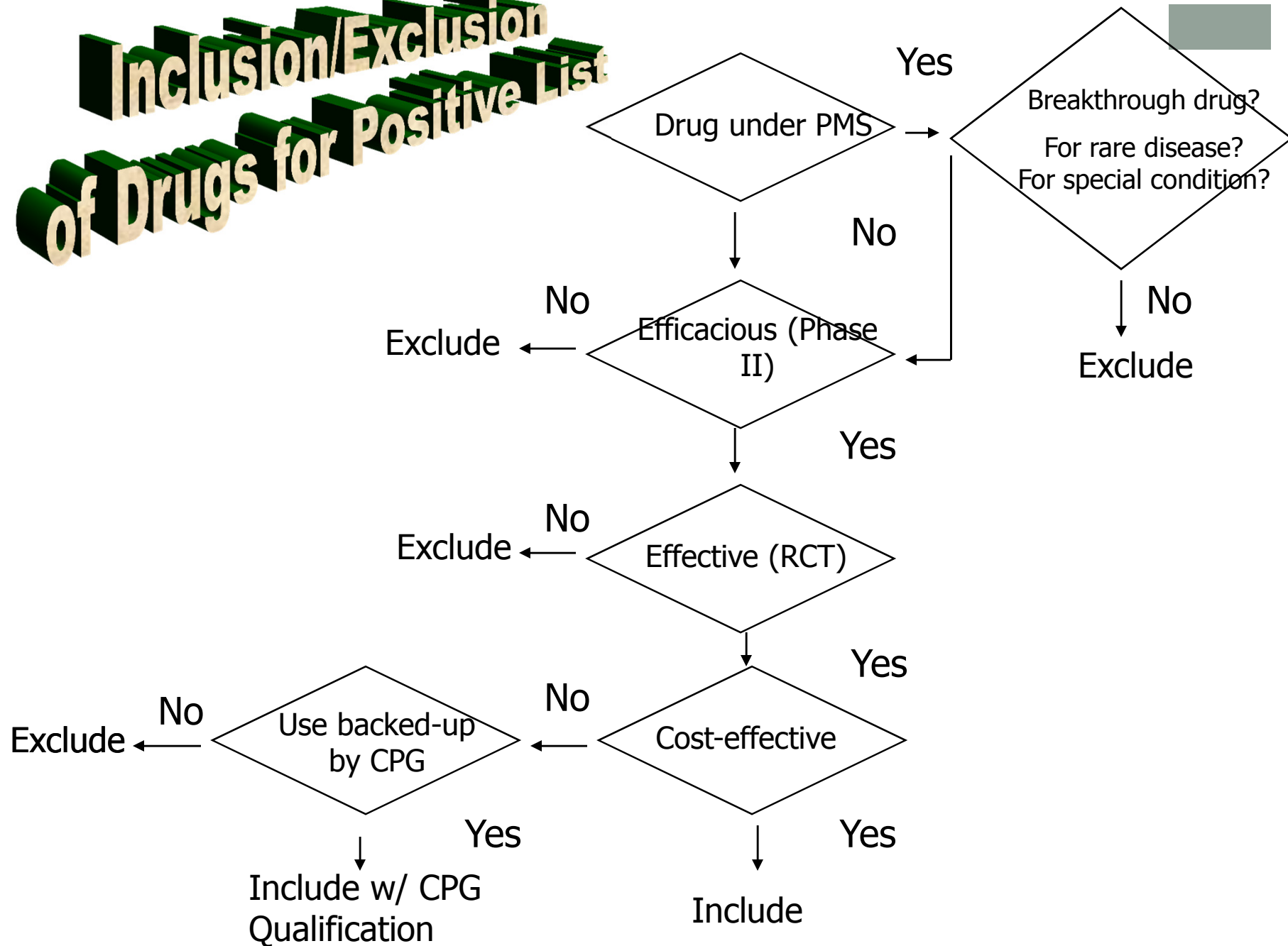


HTA to guide drug reimbursements: The Philhealth Positive List



- Drugs assessed to be effective, safe, and cost-effective are temporarily included in the PhilHealth positive list;
- Upon inclusion of the Positive List in the National Formulary, the temporary list will cease to exist;
- When the PNDF was revised in 2004, drugs in the positive list have expired; and since then, PhilHealth has not yet conducted HTA of drugs for the purpose of inclusion in the Positive List

Inclusion/Exclusion of Drugs for Positive List



+ **Generics Act Implementation/ Rational Drug Use Promotion**

- **Strict implementation of the Philippine Generics Law disallows reimbursements of claims for drugs not in the Philippine National Drug Formulary (PNDF) and not written generically**

It authorized the HTA unit to arbitrate on appeals and questions on the effectiveness of drugs introduced in the market after publication of the PNDF





HTA as a tool to drive quality: The Philhealth CPGs

- Community Acquired Pneumonia
- Acute Appendicitis
- Hypertension
- Dyspepsia
- Acute Bronchitis
- Adult Asthma
- Urinary Tract Infection
- Acute Gastroenteritis
- Maternity Care



Measures of compliance to Philhealth CPGs are linked to claims payment.



Evaluation Tools Used for the appraisal and adoption of CPGs

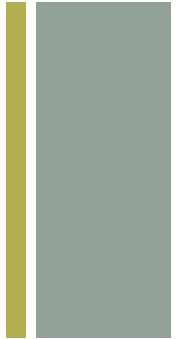
Critical appraisal checklist from “Users Guides to the Medical Literature” series of JAMA by Hayward

AGREE Instrument

PhilHealth Appraisal Tool



CPG-based Policy Statements



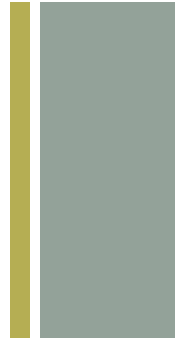
- PhilHealth has identified and converted ten (10) clinical practice guidelines for the most commonly claimed illnesses into **policy statements** which can serve as basis for quality care.
- The policy statements are based on key CPG recommendations and provide guidance to doctors, hospitals and patients as to what tests, medicines and procedures are strongly recommended (when their benefits clearly outweigh the harms)



HTA to inform clinical practice:

The effectiveness and safety of medical and surgical procedures

- *Goal of HTAC:* support providers' efforts in adhering to the law, which states that accredited providers are required to use only effective and appropriate medical and surgical interventions;
- *Examples:* Evaluation of outpatient cataract surgery and antenatal and postnatal care for low-risk pregnancy
 - became inputs into the development of the benefit packages for these 2 health services



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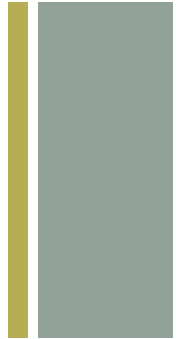
Methods involved:

- Systematic review
- Cost-effectiveness analysis
- Policy Analysis





HTA and Universal Health Care



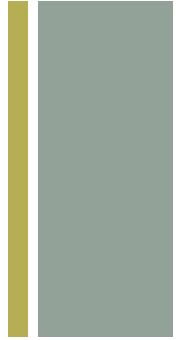
- Need to embrace HTA for better prioritization given resource constraints
 - *“Every Filipino covered”*
 - *“No balance billing for the poor,” limited co-pay for others*
 - *Expansion of benefits to costly catastrophic diseases*

- Currently no structured and well-coordinated HTA under one identified Unit or Organization within or outside DOH/PHIC
 - *Philhealth HTAC inactive since 2011*

- Key to sustainability is building institutional and technical capacity and a culture of evidence-based healthcare



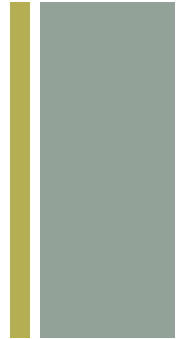
Challenges of HTA in the Philippines



- Changing attitudes/culture of policymakers toward evidence-based decision-making
- Building sustainable HTA systems and capacity
- Strengthening the research infrastructure fit for HTA
 - e.g. lack of access to good local and international databases, support for researchers
- Tensions with political, commercial, professional, donor interests
- Issue of context: forming a HTA system appropriate and responsive to local situation and needs



Ways forward



- **Creation of *Health Research Hub* to execute the health system research agenda**
 - allocation and pooling of 2% of MOOE funds (Php 150 M)
 - harmonization of efforts across national research institutes
 - dedicated pool of research fellows
 - long-term research capacity-building

- **Institutionalizing HTA through a *whole-of-government* approach**
 - FDA, DOH and Philhealth as key drivers

- **Forging national, regional and global networks to strengthen the national HTA system**
 - work with NICE International, HITAP and HTAsiaLink



Current developments in HTA

[REPUBLIC ACT NO. 10606]

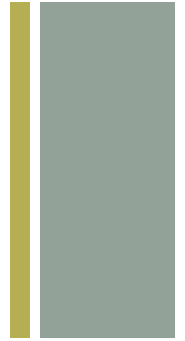
AN ACT AMENDING REPUBLIC ACT NO. 7875, OTHERWISE
KNOWN AS THE “NATIONAL HEALTH INSURANCE ACT OF 1995”,
AS AMENDED, AND FOR OTHER PURPOSES

“SEC. 11. *Excluded Personal Health Services.* – The Corporation shall not cover expenses for health services which the Corporation and the DOH consider cost-ineffective through health technology assessment.

President Benigno “Noynoy” Aquino III recently signed the Universal Health Care Act of 2013. HTA is identified as a tool to inform coverage decisions by Philhealth.



Current developments in HTA

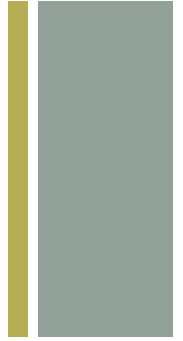


- Beginning 2013, DOH through the *Formulary Executive Council (FEC)* will incorporate formal methods on pharmaco-economic evaluation as part of the decision-making process
- A country specific threshold of 1 GDP capita per QALY was recently adopted by the FEC to guide the drug approval process



Current developments in HTA

- National guidelines for conducting HTA and economic evaluation will be drafted to guide sponsors and researchers tasked to deliver HTA output to the DOH
- Ongoing partnership with NICE International and HITAP on HTA capacity-building, peer review of methods, clinical guideline development and evaluation of new vaccines (i.e. PCV and HPV)
- *A Medicines Price Board* will be created to approve and set prices of drugs in the national formulary and negotiate with suppliers on pharmaceutical prices deemed cost-effective by DOH/Philhealth for financing



Thank you!