Pharmacoeconomics Guidelines in Malaysia: An Update

Professor Dr Syed Mohamed Aljunid

MD (UKM) MPH (Singapore) PhD (London); DLSHTM (London); FAMM, FPHMM

Professor of Health Policy and Management

Faculty of Public Health

Kuwait University

&

Professor of Health Economics & Public Health Medicine

National University of Malaysia

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Outline

- Current Pharmacoeconomic Issues in Malaysia
- Types and Role of PE Guidelines
- Contents of PE Guidelines
- Updates on Submission Guidelines
- Major Gaps in Submission Guidelines
- Conclusion

Current PE Issues in Malaysia

- Increasing overall health expenditure
- High OOP Expenditure
- Access to Essential Drugs
- Plan For Voluntary Health Insurance
- Move for Separation of Dispensing
- Cost of NCDs
- UHC in Malaysia

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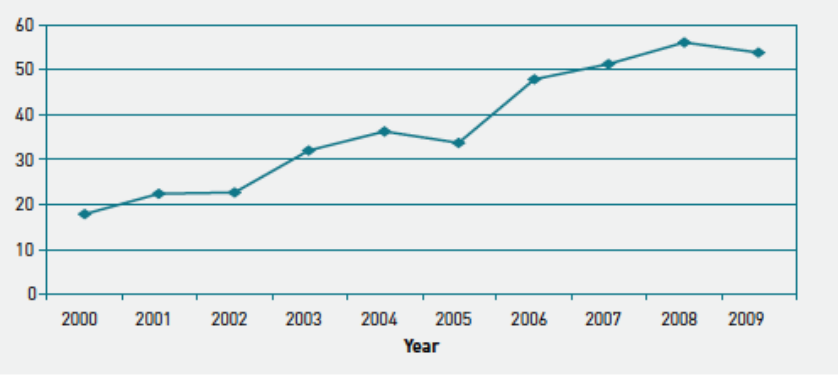
Percapita Expenditure on Pharmaceuticals



rce: Malaysia National Health Accounts (MOH Sub-accounts Database), 2011

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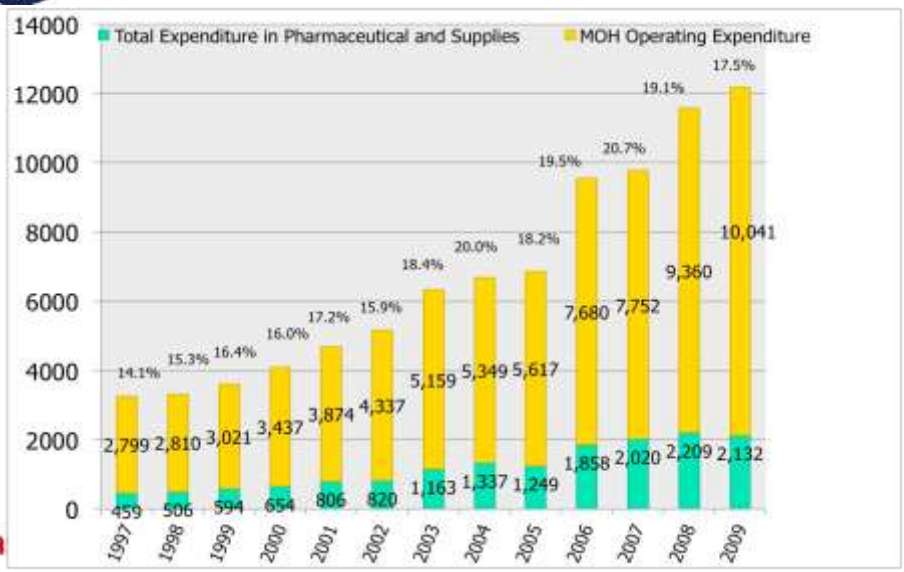
MOH Malaysia Pharmaceutical Supplies and Operating Expenditures 1997-2009 (RM Million)



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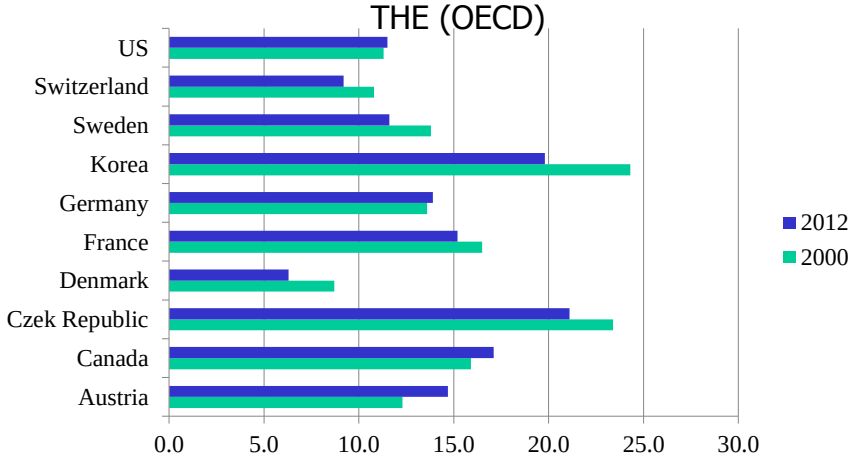
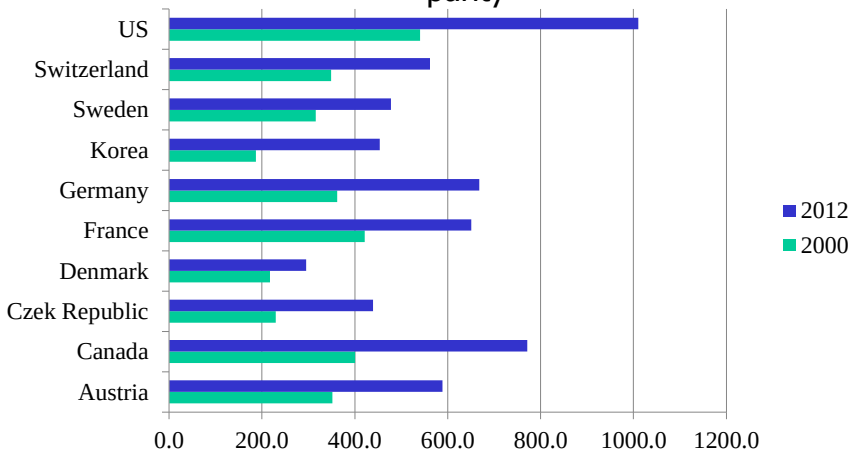
Total expenditure on pharmaceuticals and other medical non-durables, % total expenditure on health, THE (OECD)



Total expenditure on pharmaceuticals and other medical non-durables, /capita, US$ purchasing power parity



What is Pharmacoeconomics Guidelines?

- Technical document to guide economic evaluation of pharmaceuticals
- Developed by authorities with participation of stakeholders
- Assist/Guide in preparing supporting documents for drug listing/submission

Three types of Guidelines:

- PE Guidelines
- Submission Guidelines
- Published PE Recommendations

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Pharmocoeconomics Guidelines

- Country-specific "official" guidelines or policies concerning economic evaluation that are recognized or required by the healthcare decision making bodies/entities in this country/region for reimbursement.

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Submission Guidelines

- Country-specific "official" guidelines or policies concerning drug submission requirements with an economic evaluation part/section and are required by the healthcare decision making bodies/entities in this country/region for reimbursement.

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Published PE Recommendations

- Country-specific economic evaluation guidelines or recommendations published by experts in the field but are not "officially" recognized or required by the healthcare decision making bodies/entities in this country/region for reimbursement.

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PE Guidelines in Malaysia

- Launched in 2012
- Purpose:
  - Service as a standard to conduct PE studies
  - Guide for preparation of PE Supporting Document for Submission
  - Encourage local PE studies
  - Appraisal of PE Documents submitted for drug approval
  - Support Decision Making Process

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PE Guidelines: Major Contents

- Type of Economic Evaluation
- Costing Approach
- Outcome Measurement
- Discounting
- Sensitivity Analysis
- Time Horizon
- CE Ratio (ICER/ACER)
- Budget Impact Analysis

Benefits of PE Guidelines

- Standardized methods/approach of Economic Evaluation
- Enhanced quality of PE data for drug submission
- Promote use of local data in economic evaluation studies
- Improved decision making process – Evidence-Based Policy Decision

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Challenges in Implementing PE Guidelines

- Lack of technical capacity to conduct and evaluate PE studies
- Limited funding for good quality research
- Limited sharing of information
- Transparency in decision making on drug evaluation
- Limited role of HTA Agency

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Implementation Issues

- Lack of Data
- Limited Data Sharing
- Slow approval of research project
- Lack of technical capacity
- Governance/Corruptions
- Monitoring and Evaluation
- Use of Drugs outside MOH Formulary
- Long term impact

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MOH DRUG SUBMISSION GUIDELINE IN MALAYSIA (2012)

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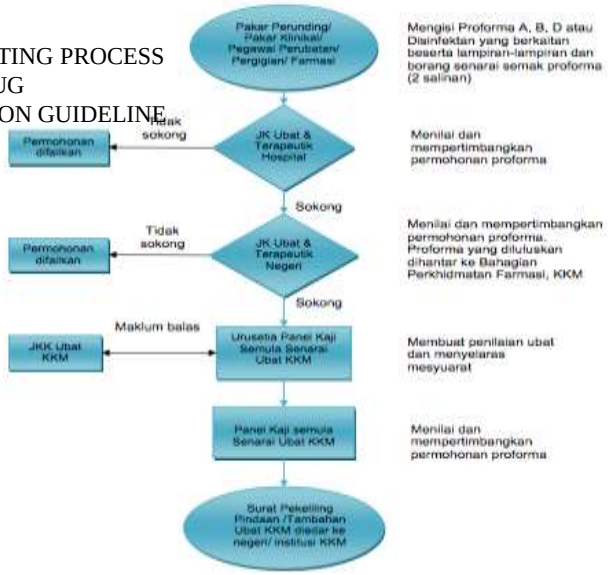
CARTA ALIRAN PERMOHONAN MEMANSUH/ MEMINDA/ MENYENARAI UBAT-UBAT KE DALAM FORMULARI UBAT KKM

A) Hospital

DRUG LISTING PROCESS (MOH DRUG SUBMISSION GUIDELINE 2012)



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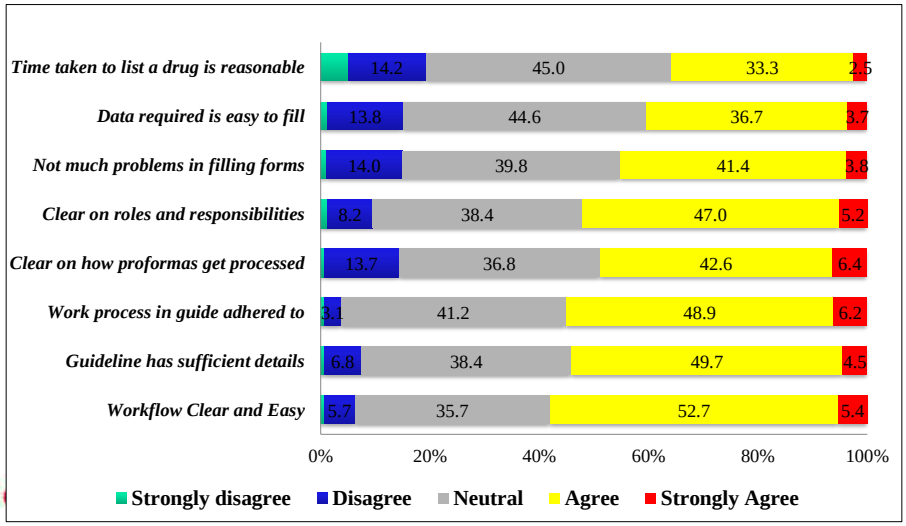
STEPS LISTING MEDICINES INTO MOH MOH FORMULARY (MOH Drug Submission Guideline 2012):

- STEP 1: Submission of application by proposers (MOH Clinicians)
- STEP 2: Review of applications (and decisions) by the Hospital or State Drug and Therapeutics Committee (D&TC).
- STEP 3: Drug Evaluation by evaluators at Pharmaceutical Services Division and Expert Opinions from Therapeutic Drug Working Committee (TDWC)
- STEP 4: Deliberations leading to drug listing decisions by the MOH Drug List Review panel members
- STEP 5: Dissemination of drug listing results to the proposers and facilities.

Issues in Submission Procedures (N=362)



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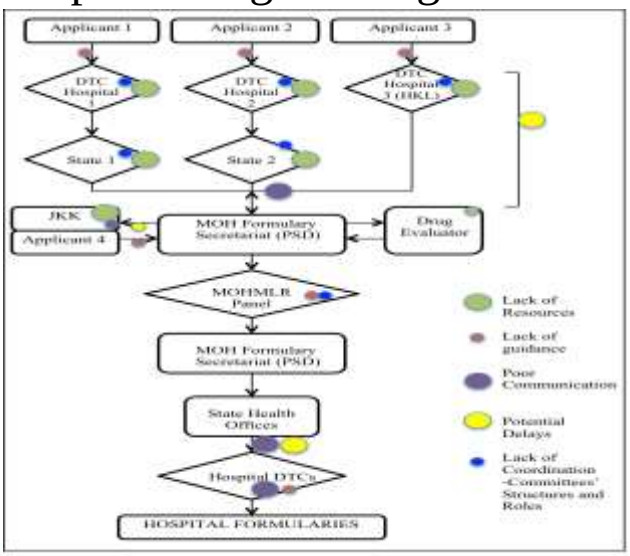
Gaps in Drugs Listing Process



The New Submission Guideline

- Launched in 2015. Start to receive dossiers with new requirements Jan 2016.
- Main Change: Direct submission by Pharmaceutical Companies.
- Purpose:
  - To guide applicants in producing a standardized and complete dossiers to support applications for listing medicines into the MOHMF.
  - To ensure medicines listed in the MOHMF are safe, of good quality, efficacious, cost-effective and affordable.

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The New Submission Guideline

- Objectives
  - To assist applicants to present the values of their products.
  - To ensure quality dossiers are submitted.
  - To standardize the requirements and presentations of evidence in the dossier.
  - To streamline process of listing medicines into MOHMF.

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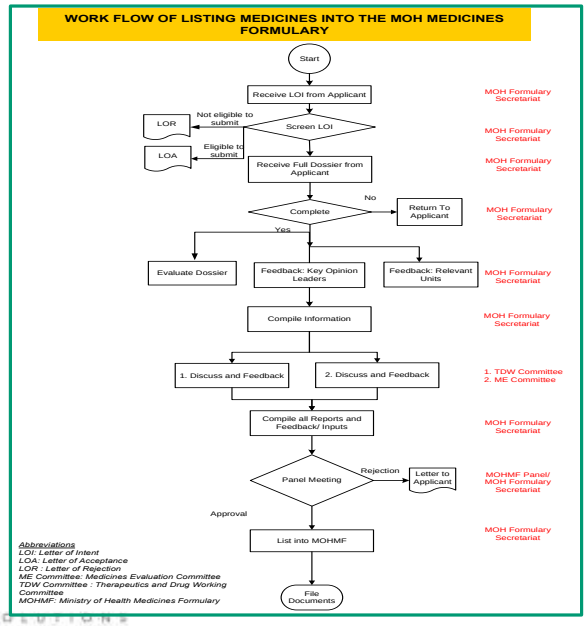

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Type of Dossiers

- D1
  - New Drugs
- D2
  - Add/Amend Formulation/ Dosage/Strength
- D3
  - Change Category of Prescriber
- D4
  - Add into Local (hospitals) Formulary
- D5
  - Delisting of Drugs

Information Required

- Medicine Information
  - Drug particulars, Clinical Info, Pharmacological Info, Cost
- Rationale for Application and Comparators
- Clinical Evidence
  - Efficacy, Effectiveness & Safety
- Pharmacoeconomics Evidence
  - Economic Evaluation & BIA

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Evidence Required for Each Dossier

Type of Dossier	*Recommended number of journal articles/ written evidence	Types of evidence
D1	5	Efficacy/ effectiveness and safety
	1	Economic evaluation and/or budget impact analysis
D2	3	Efficacy/ effectiveness, and safety
	1	Economic evaluation and/or budget impact analysis
D3	1	Safety aspects must be included.
	1	Economic evaluation and/or budget impact analysis
D4	As per institution's requirement	As relevant
D5	1	As relevant

*Not applicable for resubmissions

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Budget Impact Analysis

- Mandatory. (CE Analysis is optional)
- To estimate the financial consequences of adoption and diffusion of a new health-care intervention within a specific health-care setting or system context given inevitable resource constraints.
- Predicts how a change in the mix of drugs and other therapies used to treat a particular health condition will impact health spending.

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Budget Impact Analysis

- Use Malaysian data is highly encouraged
  - (e.g. prevalence of disease states, projected market shares from the MOH)
- MOH perspective or payer perspective should be used
- Five-year time horizon on MOH is required for all projections
- Full disclosure of methodology
  - Calculation and uncertainty should be provided in an Excel format. Calculation should be accessible to the user and allow replication of analysis.

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BIA: Six Steps (ISPOR Recommended)

- Estimating the target population.
- Selecting a time horizon.
- Identifying current and projected treatment mix.
- Estimating current and future drug costs.
- Estimating changes in disease related costs.
- Estimating and presenting changes in annual budget impact (Both static and dynamic methods)

Conclusion

- Pharmaceuticals is a significant component that contributes to raise in healthcare cost
- PE Guidelines can help to standardize economic evaluation studies for drugs assessment
- Lack of data, human resource capacity and information sharing are among the main challenges of implementing PE and Submission Guidelines
- The New Submissions Guidelines that has recently being launched is an important step to efficiently support decision making process and improve access to pharmaceuticals
- Continuous review of the Submissions Guidelines to ensure major gaps have been addressed by policy makers

Thank You

syed.aljunid@hsc.edu.kw
saljunid@gmail.com

www.casemix.com.my