Pharmacoeconomics Guidelines in Malaysia: Development, Content and Applications

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Outline

- Introduction
- Development Process of PE
- Content of PE Guidelines
- Current Status & Challenges of PE Guidelines
- Future Directions
- Resources and References
- Conclusions

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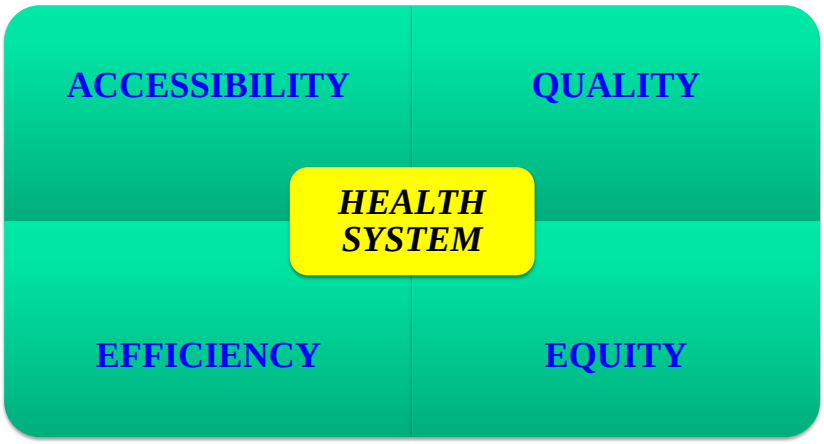
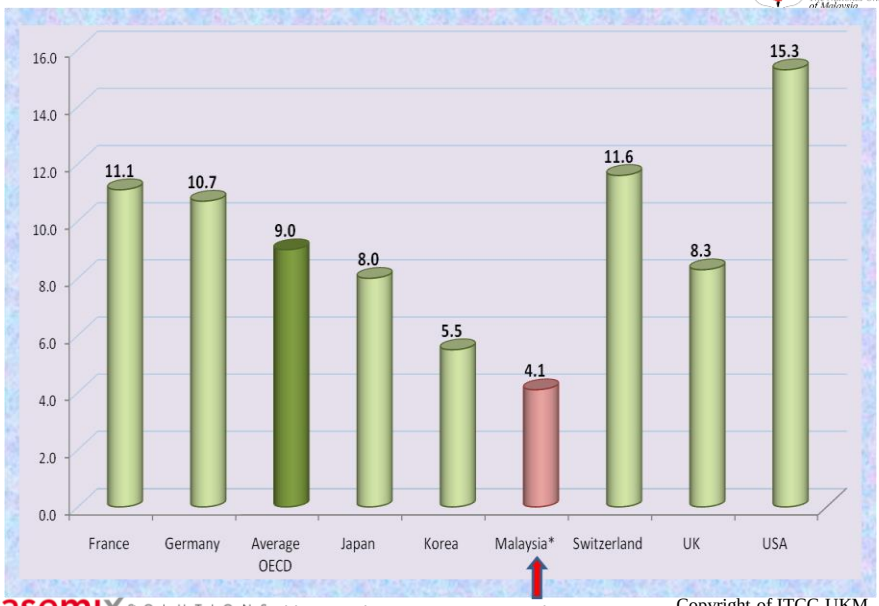
Health System Objectives



Current Challenges in Health System

- Efficiency
  - Raised in healthcare cost and provision of unnecessary services
  - Ageing population and raised in chronic NCDs
- Quality
  - Huge variation in quality of care affecting patient safety
- Accessibility
  - Limited access to healthcare services for significant number of people
- Equity
  - Poverty is major obstacle to access health services access to services

TOTAL HEALTH EXPENDITURE AS PERCENTAGE OF GDP IN SELECTED OECD COUNTIRES AND MALAYSIA, 2005



Source: MNHA Study 2003-2006, Health At A Glance 2007- OECD Indicators

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Why Focus on Pharmaceuticals?

- Significant amount of resources are spend on drugs/pharmaceuticals
- New drug discovery is costly
  - 12 years costing about USD 800 mill
  - Growth in costly pharmaceuticals
- A lot of wastages if drugs used are not used efficiently managed

Pharmaceutical Industry Annual Sales

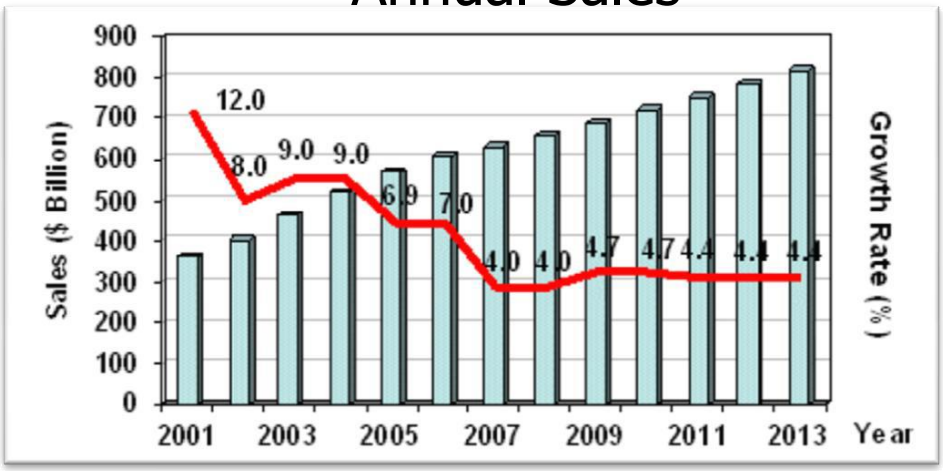

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Table 2 **Drug Discovery and Development Process**
Boston Consulting Group, 2001

	Cost US$m	Cost %	Time years
Biology			
Target Identification	165	18.8	1.0
Target Validation	205	23.3	2.0
Chemistry			
Screening	40	4.5	.4
Optimisation	120	13.6	2.7
Development			
Preclinical	90	10.2	1.6
Clinical	260	29.5	7.0
Total	880	100.0	14.7

Source: Boston Consulting Group, A Revolution in R&D, November 2001 p12.

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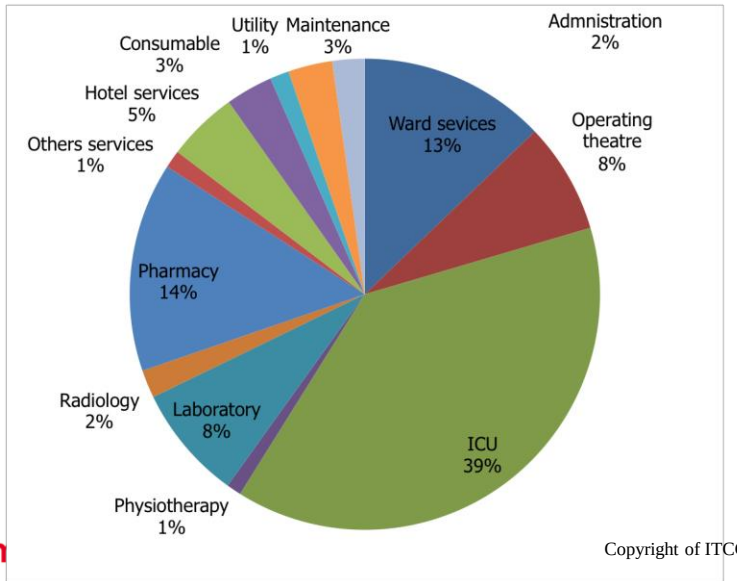
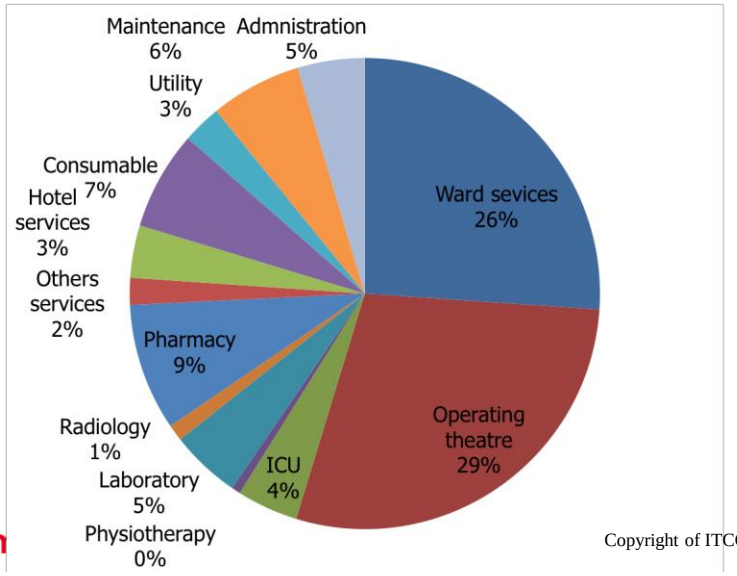
Cost of Drug R&D

R&D Function	%
Discovery/Basic Research	
Synthesis and Extraction	10.0
Biological Screening and Pharmacological Testing	14.2
Preclinical Testing	
Toxicology and Safety Testing	4.5
Pharmaceutical Dosage Formulation and Stability	7.3
Clinical Trials	
Clinical Evaluation Phases I, II and III	29.1
Clinical Evaluation Phase IV	11.7
Process Development for Manufacturing and Quality Control	8.3
Regulatory: IND and NDA	4.1
Bioavailability	1.8
Other	9.0
Total	100.0

Cost Components (Medical Cases In UKMMC)



Cost Components (Surgical Cases In UKMMC)



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THE CURRENT PROCESS OF LISTING MEDICINES INTO THE MOH FORMULARY

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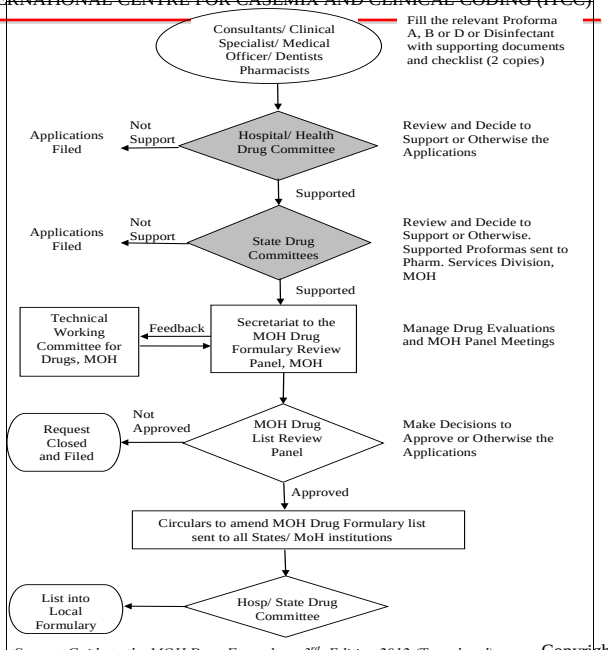
WORK FLOW PROCESS TO DELETE/ AMMEND/ LIST DRUGS INTO THE MOH DRUG FORMULARY (MOH Hospitals)



Source: Guide to the MOH Drug Formulary, 3rd. Edition 2012 (Translated)

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PROFORMA D

PROPOSAL TO INTRODUCE A NEW DRUG INTO THE MINISTRY OF HEALTH DRUG FORMULARY

1.Drug Particulars		
a	Generic Name *[Please specify dosage form(s) & strength(s)]*	
b	Trade Name	
c	Manufacturer	
d	Distributor/Registration holder	
e	DCA Registration No.	
f	i) DCA Indication & treatment details *[Such as dose, frequency, duration, details of monitoring required etc.]* Please attach: 1. Approved product Information 2. DCA Approval letter	
	ii)Proposed Indication *[if different from DCA indication]*	

2. Existing Drug(s) in MOH Drug Formulary *[please specify strength & dosage form]*		
Existing drugs for the same indication		
Would the drug be: a) An additional to what is already existing **OR**	**YES / NO**	If (b) applies/is choosen which drug can be deleted:
b) A replacement for what is already existing	**YES / NO**	

11. EVIDENCE TABLE (PHARMACOECONOMIC)
[Please fill up evidence table for each studies/trials with respect to drug cost pertaining to the proposed therapy as required in section 4]

Bibliography	
Study Design (eg. CMA, CUA, CEA)	
Level of Evidence	
Number of patients	
Patients Characteristic & Location of study	
Intervention	
Comparison/ control	
Time Horizon	
Model Inputs And Data Sources	
Results: Base Case, Sensitivity Analysis, Limitations, QALYs, Discounts, Perspective	
Sponsor	

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5. Cost Comparison *[please add more columns if there is more than one comparator]*

		Proposed Drug	**Current Drug/Comparator**
a	Cost per dosage unit *[nett price to MOH hospital, inclusive of agent fees]*	RM *(Source:……)*	RM *(Source:……)*
b	Number/average number of dosage units administered per day/cycle		
c	Average duration of treatment in days/ cycle *[if continuous write '365']*		
d	Total cost per patient per year **[d = a x b x c]**	RM	RM
e	Additional cost per patient per year, if it is possible to calculate *[e.g. cost of monitoring, drug administration cost, cost of additional equipment required, etc]*	RM	RM
f	Total annual cost per patient **[f = d + e]**	RM	RM
g	Expected number of patients per year :		
	i) Institution		
	ii) State		
	iii) Country [MOH]		

6. Financial Implication			
Annual cost (f x g)	**Proposed Drug [RM]**	**Current [RM]**	**Difference [RM]**
i) Institution			
ii) State			
iii) Country [MOH]			

7. Proposed & Declaration of Potential Conflict of Interest

I declare a potential conflict of Interest ☐ YES, please provide details below* ☐ NO

*Financial or other interest from contact with pharmaceutical companies, which may have bearing on this submission:

METHODOLOGY

- Nationwide Survey among members of Drugs and Therapeutics Committee in MOH Hospitals and State Health Departments.

RESULTS

- Respondents' Demographics (N=362)

	N	%		N	%
Age Category			**DTC Type**		
<30 Years	134	37.0	DTC in State Health Dept	49	13.5
31-40 Years	98	27.1	DTC in Tertiary/State Hospitals	97	26.8
41-50 years	64	17.7	DTC in District Hospitals	216	59.7
> 50 years	66	18.2	**Membership Term**		
Gender			< 1 year	96	26.5
Male	128	35.4	1-3 Years	164	45.3
Female	234	64.6	4-5 Years	102	28.2
Profession					
Consultant/ Specialists	95	26.2			
Medical Officers	35	9.7			
Pharmacist	192	53.0			
Nurse/ Medical Assistants	27	7.5			
Administrator	13	3.6			

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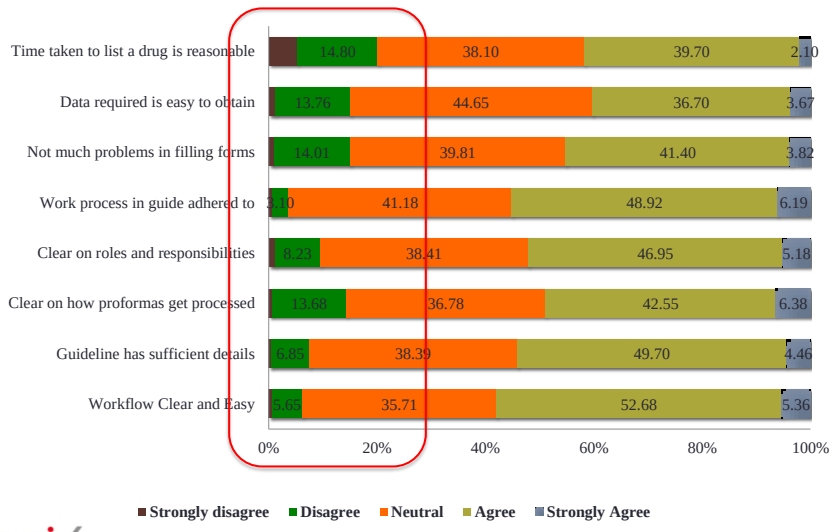
Respondents' Responses to Statements on the Current Process of Listing Medicines into the MOH Formulary



METHODOLOGY

- Qualitative Study
- Stakeholders views via 3 Focus Group Discussions (FGD) and13 In-Depth Interviews
  - FGD1: (Pharmacists working in hospitals or states jelath departments-involved in processing proformas)
  - FGD2: Pharmaceutical Company Representatives
  - FGD3: Senior Pharmacists in Pharm Services Division, tertiary hospitals, drug evaluators, Secretariat to the MOH Formulary.
  - In-Depth Interview Respondents: National Drug Review Panel members, Expert Group Members, Specialists, Chief Pharmacists, Hospital and State Pharmacists

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RESULTS (Qualitative Study)

(Gaps identified in the current drug listing process)

1. INEFFICIENT WORKFLOW
   - Lack of coordination on roles – repetitive process, work redundancy, duplicates: resulting in waste of resources.
   - Poor Communication: external and internal
2. LACK OF GUIDANCE
   - Submission Guideline (applicant)
   - Work Procedures/ Manuals (internal)
   - Goals
3. LACK OF RESOURCES
   - Mainly hospital and state levels: resource, time, skills
4. LACK OF TRANSPARENCY
5. PHARMACEUTICAL COMPANY INFLUENCES
6. UNPREDICTABLE TIMELINE/ DELAY
7. COMMITTEE COMPOSITIONS

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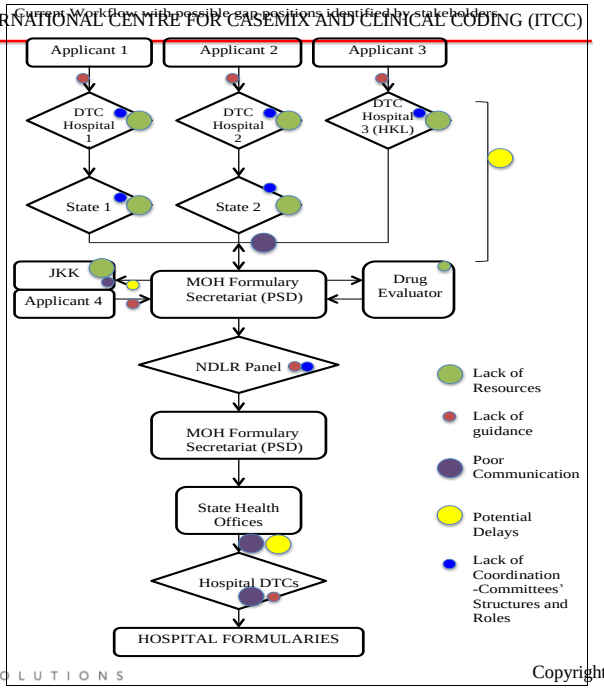
Current Workflow with possible gap positions identified by stakeholders



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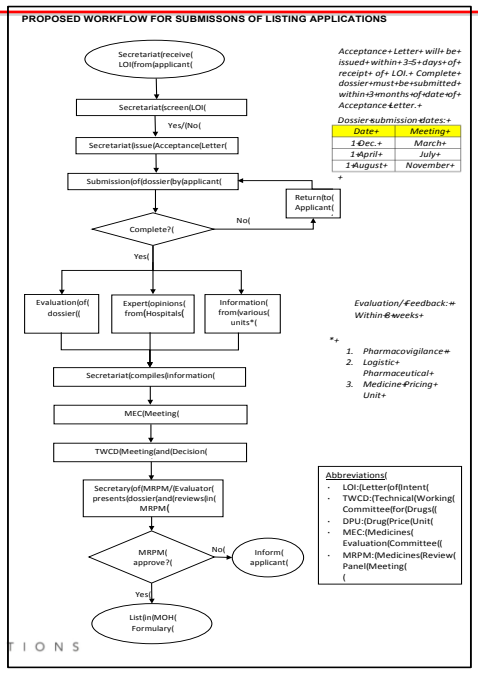
UNIVERSITI KEBANGSAAN MALAYSIA
The National University of Malaysia



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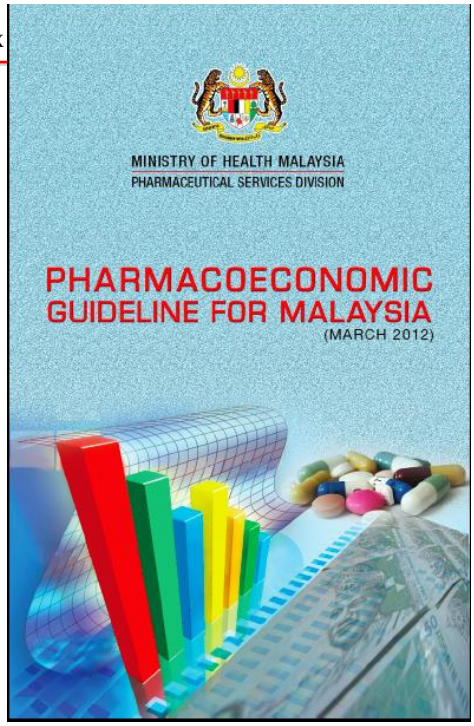
http://www.pharmacy.gov.my/v2/sites/default/files/document-upload/pharmacoeconomic-guideline-malaysia.pdf



- http://www.pharmacy.gov.my/v2/sites/default/files/document-upload/pharmacoeconomic-guideline-malaysia.pdf

What is Pharmacoeconomics Guidelines?

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

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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: Major Contents

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

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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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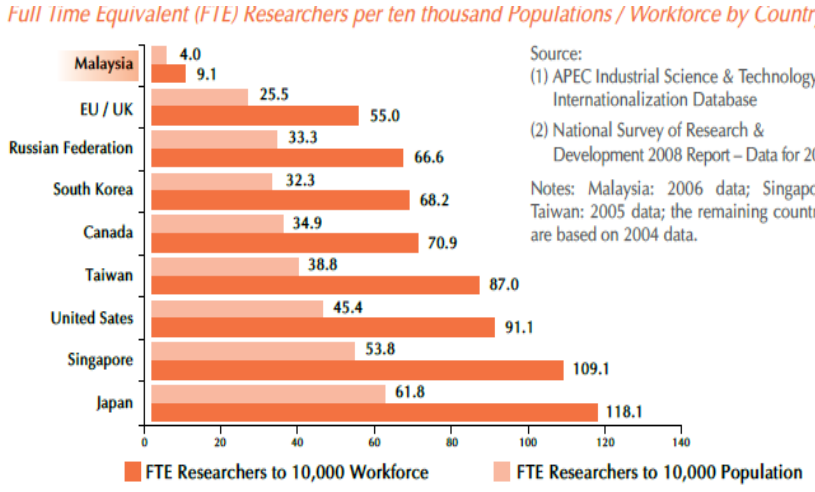
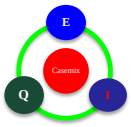
Barriers to STI in health: Insufficient researchers



Researchers in health sector: 0.7 per 10,000 workforce

Conclusion

- Raised in healthcare cost can be seen in most countries worldwide
- Pharmaceuticals is an important component that contributes to raise in healthcare cost
- Economic evaluation studies to assess Pharmaceuticals can provide good quality data for Evidence-Based Decision Making
- PE Guidelines can help to standardize economic evaluation studies for drugs assessment
- Lack of human resource capacity and sharing of data are among the main challenges of implementing PE Guidelines



Thank You

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