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
Health System Objectives

ACCESSIBILITY  QUALITY

HEALTH SYSTEM

EFFICIENCY  EQUITY

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
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
Table 2: Drug Discovery and Development Process

Boston Consulting Group, 2001

<table>
<thead>
<tr>
<th></th>
<th>Cost US$m</th>
<th>Cost %</th>
<th>Time years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Identification</td>
<td>165</td>
<td>18.8</td>
<td>1.0</td>
</tr>
<tr>
<td>Target Validation</td>
<td>205</td>
<td>23.3</td>
<td>2.0</td>
</tr>
<tr>
<td>Chemistry</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screening</td>
<td>40</td>
<td>4.5</td>
<td>0.4</td>
</tr>
<tr>
<td>Optimisation</td>
<td>120</td>
<td>13.6</td>
<td>2.7</td>
</tr>
<tr>
<td>Development</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preclinical</td>
<td>90</td>
<td>10.2</td>
<td>1.6</td>
</tr>
<tr>
<td>Clinical</td>
<td>260</td>
<td>29.5</td>
<td>7.0</td>
</tr>
<tr>
<td>Total</td>
<td>880</td>
<td>100.0</td>
<td>14.7</td>
</tr>
</tbody>
</table>

## Cost of Drug R&D

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

### Cost Components

(Medical Cases In UKMMC)

![Pie chart showing the distribution of cost components]

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THE CURRENT PROCESS OF LISTING MEDICINES INTO THE MOH FORMULARY
GARIS PANDUAN FORMULARI UBAT KEMENTERIAN KESIHATAN MALAYSIA
Edisi Ketiga (Ogos 2012)

- Pengenalan Formulasi Ubat Kementerian Kesihatan Malaysia (FUHKM)
- Prosedur Penyemakan Ubat Ke Dalam FUHKM
- Pengenalan Senarai Ubat Penting Kebangsaan/National Essential Drug List (NEDL)
- Prosedur Permohonan Ubat Khas Kedua Pengarah Kesihatan (UKR)/Pengarah Kasar Perkhidmatan Parduan (PKPP)

Sumber: Panduan Pemasangan Formulasi Ubat Kementerian Kesihatan Malaysia

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

1. Applications Filed
   - Not Supported
     - Hospital Health Drug Committee
     - State Drug Committee
   - Supported
     - Hospital Health Drug Committee
     - State Drug Committee
2. Applications Filled
   - Technical Working Committee for Drugs, MOH
   - Feedback
     - Not Approved
       - MOH Drug List Review Panel
       - MOH Drug Formulary Review Panel
     - Approved
       - MOH Drug List Review Panel
       - MOH Drug Formulary Review Panel
3. Management
   - Manage Drug Evaluations and MOH Panel Meetings
   - Make Decisions to Approve or Otherwise the Applications
   - Circulars to amend MOH Drug Formulary list sent to all States/ MoH institutions

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

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

1. **Drug Particulars**
   - **Generic Name**
     - [Please specify dosage form(s) & strength(s)]
   - **Trade Name**
   - **Manufacturer**
   - **DCA Registration No.**
   - **DCA Registration & Treatment**
     - [Such as dose, frequency, duration, details of monitoring required etc.]
   - **Please attach:**
     1. Approved product information
     2. DCA Approved Letter
   - **(Proposed Indication)**
     - [If different from DCA indication]

2. **Existing Drugs** in MDS 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: **YES/NO**
       - b) A replacement for what is already existing: **YES/NO**

3. **Cost Comparison** (please add more columns if there is more than one comparison)

<table>
<thead>
<tr>
<th>Proposed Drug</th>
<th>Current Drug/Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Cost per dosage unit</td>
<td>RM</td>
</tr>
<tr>
<td>b) Number of patients administered per dosage unit</td>
<td></td>
</tr>
<tr>
<td>c) Average duration of treatment in days</td>
<td></td>
</tr>
<tr>
<td>d) Total cost per patient per year</td>
<td>RM</td>
</tr>
<tr>
<td>e) Additonal cost per patient per year</td>
<td>RM</td>
</tr>
<tr>
<td>f) Expected number of patients per year</td>
<td></td>
</tr>
<tr>
<td>i) Institution</td>
<td></td>
</tr>
<tr>
<td>ii) State</td>
<td></td>
</tr>
<tr>
<td>iii) Country (MDS)</td>
<td></td>
</tr>
</tbody>
</table>

4. **Financial Implication**
   - a) Institution | | |
   - b) State | | |
   - c) Country (MDS) | | |

5. **Proposed & Declaration of Potential Conflict of Interest**
   - I declare a potential conflict of interest: **YES/NO**
   - 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)

<table>
<thead>
<tr>
<th>Age Category</th>
<th>N</th>
<th>%</th>
<th>DTC Type</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;30 Years</td>
<td>134</td>
<td>37.0</td>
<td>DTC in State Health Dept</td>
<td>49</td>
<td>13.5</td>
</tr>
<tr>
<td>31-40 Years</td>
<td>98</td>
<td>27.1</td>
<td>DTC in Tertiary/State Hospitals</td>
<td>97</td>
<td>26.8</td>
</tr>
<tr>
<td>41-50 years</td>
<td>64</td>
<td>17.7</td>
<td>DTC in District Hospitals</td>
<td>216</td>
<td>59.7</td>
</tr>
<tr>
<td>&gt;50 years</td>
<td>66</td>
<td>18.2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender</th>
<th>N</th>
<th>%</th>
<th>Membership Term</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>128</td>
<td>35.4</td>
<td>&lt; 1 year</td>
<td>96</td>
<td>26.5</td>
</tr>
<tr>
<td>Female</td>
<td>234</td>
<td>64.6</td>
<td>1-3 Years</td>
<td>164</td>
<td>45.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4-5 Years</td>
<td>102</td>
<td>28.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Profession</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant/ Specialists</td>
<td>95</td>
<td>26.2</td>
</tr>
<tr>
<td>Medical Officers</td>
<td>35</td>
<td>9.7</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>192</td>
<td>53.0</td>
</tr>
<tr>
<td>Nurse/ Medical Assistants</td>
<td>27</td>
<td>7.5</td>
</tr>
<tr>
<td>Administrator</td>
<td>13</td>
<td>3.6</td>
</tr>
</tbody>
</table>

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

- Time taken to list a drug is reasonable
- Data required is easy to obtain
- Not much problems in filling forms
- Work process in guide adhered to
- Clear on roles and responsibilities
- Clear on how proformas get processed
- Guideline has sufficient details
- Workflow Clear and Easy

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METHODOLOGY
• Qualitative Study
• Stakeholders views via 3 Focus Group Discussions (FGD) and 13 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

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
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

Three types of Guidelines:

- PE Guidelines
- Submission Guidelines
- Published PE Recommendations
Pharmacoconomics 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.

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.
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.

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

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
**Barriers to STI in health:**

- Insufficient researchers

**Full Time Equivalent (FTE) Researchers per ten thousand Populations / Workforce by Country**

<table>
<thead>
<tr>
<th>Country</th>
<th>FTE Researchers to 10,000 Workforce</th>
<th>FTE Researchers to 10,000 Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaysia</td>
<td>4.0</td>
<td>9.1</td>
</tr>
<tr>
<td>EU / UK</td>
<td>25.5</td>
<td>55.0</td>
</tr>
<tr>
<td>Russian Federation</td>
<td>33.3</td>
<td>66.6</td>
</tr>
<tr>
<td>South Korea</td>
<td>32.3</td>
<td>68.2</td>
</tr>
<tr>
<td>Canada</td>
<td>34.9</td>
<td>70.9</td>
</tr>
<tr>
<td>Taiwan</td>
<td>38.8</td>
<td>87.0</td>
</tr>
<tr>
<td>United States</td>
<td>45.4</td>
<td>91.1</td>
</tr>
<tr>
<td>Singapore</td>
<td>53.8</td>
<td>109.1</td>
</tr>
<tr>
<td>Japan</td>
<td>61.8</td>
<td>118.1</td>
</tr>
</tbody>
</table>

Notes: Malaysia: 2006 data; Singapore, Taiwan: 2005 data; the remaining countries are based on 2004 data.

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**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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