MINISTRY OF HEALTH MALAYSIA
PHARMACEUTICAL SERVICES DIVISION

PHARMACOECONOMIC GUIDELINE FOR MALAYSIA

(MARCH 2012)

FOREWORD

The rising cost of healthcare delivery systems is a major concern to all patients, healthcare professionals, and the government. As the affordability of new medical technologies continues to be the subject of heated debate, attention is also increasingly focused on providing quality, cost-effective healthcare.

In this era of cost-conscious healthcare delivery, pharmacoeconomic research has evolved as a significant and important field of research. Pharmacoeconomic evaluation identifies measures and compares the costs and consequences of pharmaceutical products and services. The numerous stakeholders in the healthcare arena must understand the basics of pharmacoeconomic principles and how these may be applied to make rational therapeutic choices.

In an attempt to standardise the conduct of pharmacoeconomic studies in Malaysia for the purpose of preparing supporting economic documents, this guideline has been conceived and developed by an expert committee. I wish to congratulate all members of this committee for their hard work in developing this guideline. This document will serve as an invaluable tool for all stakeholders and researchers to produce relevant high quality pharmacoeconomic evaluations which will meet the needs of the clinicians and decision makers.

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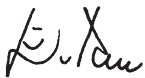Ministry of Health, Malaysia

PREFACE

Economic evaluation of pharmaceutical products, or pharmacoeconomics, is a rapidly growing area of research. Pharmacoeconomic evaluation is important in helping clinicians and decision makers to make choices about new pharmaceutical products and in helping patients obtain access to new medicines. Over the last few years, the scientific rigor of this field has increased greatly.

However, in Malaysia there is lack of local research done in the field of pharmacoeconomics. If we wish to make rational therapeutic choices, it is essential that all parties involved in healthcare profession know the basics of pharmacoeconomic principles as well as the need for pharmacoeconomic evaluations. Therefore, to address these shortfalls, the Pharmacoeconomic Guideline for Malaysia has been developed.

This guideline is intended to be used as a reference for the conduct of pharmacoeconomic studies in Malaysia. The development of this guideline is aimed to further promote relevant stakeholders and researchers so that more pharmacoeconomic studies are undertaken at various levels in healthcare settings to facilitate decision making. I hope this guideline will be utilised by relevant target groups.

Finally, I would like to express my gratitude to everyone involved in the development of this guideline especially the Technical Working Committee for their immense support and contribution towards making this guideline a reality.

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ABBREVIATIONS

ACER	Average Cost-Effectiveness Ratio
ATC	Anatomical Therapeutic Chemical
BIA	Budget Impact Analysis
CBA	Cost-Benefit Analysis
CEA	Cost-Effectiveness Analysis
CEAC	Cost-Effectiveness Acceptability Curve
CMA	Cost-Minimisation Analysis
CUA	Cost-Utility Analysis
DALY	Disability Adjusted Life Year
DCA	Drug Control Authority
DRG	Diagnosis-Related Group
EQ-5D	EuroQol 5D
HRQoL	Health-Related Quality of Life
HUI3	Health Utility Index 3
ICER	Incremental Cost-Effectiveness Ratio
MDC	Malaysia Drug Code
PSA	Probabilistic Sensitivity Analysis
QALY	Quality Adjusted Life Year
RCT	Randomised Controlled Trial
SF-6D	Short-Form 6D

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1. BACKGROUND AND PURPOSE

Pharmacoeconomics is a field within the broader health economics field that focuses mainly on the costs and benefits of pharmaceuticals. Pharmacoeconomic analysis concerns not only the efficacy and effectiveness of new health technologies but with the costs of these technologies weighed against their benefits.

Pharmacoeconomic analysis helps the decision makers of healthcare institution to optimise the limited resources in health. Healthcare providers and administrators must balance the needs of individual patients with the larger societal needs, recognising that limited resources cannot meet all needs and wishes. Therefore, pharmacoeconomic analysis is needed to assess both costs and benefits in order to bring the efficiency of the medical advances in an evidence-based manner.

This guideline shall serve as a standard to conduct pharmacoeconomic studies in Malaysia for the purpose of preparing economic supporting documents. This guideline will ensure the quality and standardisation of pharmacoeconomic analyses to enable more meaningful comparisons between similar health interventions. It will also encourage the generation of primary local data.

The guideline will also allow users of the pharmacoeconomic evaluation reports to assess the methodology of analyses and the report findings thus providing greater transparency and validity of analysis conducted, allowing replication of analysis if necessary.

The pharmacoeconomic reports shall be used as scientific tools to help decision makers in making informed and rational choices in striving to maximise total health benefits within the budget limitations.

2. OVERVIEW OF PHARMACOECONOMIC ANALYSIS

A. Types of Pharmacoeconomic Analysis

There are four main types of pharmacoeconomic evaluations:

- Cost-Minimisation Analysis (CMA)
- Cost-Effectiveness Analysis (CEA)
- Cost-Utility Analysis (CUA)
- Cost-Benefit Analysis (CBA)

Full economic evaluation has 2 major components – costs and outcomes of the compared alternatives. The cost component is always measured in monetary unit, while outcome component can be measured in various ways such as life years saved, case treated and utility terms.

CMA compares treatment alternatives that yield similar health consequences. Once the health consequences are established to be the same, a CMA would compare all cost between treatments to determine the option with the least cost.

CEA compares the relative difference of costs and consequences of different treatment strategies. In CEA, costs are measured in monetary terms and health consequences are measured in natural or physical units.

CUA has the same principle as a CEA, but includes measures of the impact on the quality of life. CUA is often used when quantity and quality of life are both important.

CBA compares treatment alternatives where both costs and benefits are expressed in monetary terms.

The difference between the types of pharmacoeconomic analysis is summarised in the following table.

Table 1: Difference Between Types of Pharmacoeconomic Analysis

Type of Analysis	Measurement of Costs	Measurement of Outcomes
Cost-Minimisation	Monetary	None (health consequences are assumed to be similar)
Cost-Effectiveness	Monetary	Natural/physical units (final, intermediate or surrogate outcomes)
Cost-Utility	Monetary	Multidimensional (DALY/QALY)
Cost-Benefit	Monetary	Monetary

B. Types of Costs in Pharmacoeconomic Analysis

Costs in health economic analyses are divided into three main groups:

- Direct cost
- Indirect cost
- Intangible cost

Direct cost mainly covers cost of resources used related to the illness and it consists of medical cost and non-medical cost. Direct medical cost is related to resources that are directly used in treating the patient such as the cost of medication, diagnostic, treatment, follow up, rehabilitation and hospital admission. It also includes the costs of treating side effects. Direct non-medical cost cover personal facilities, travel, food, lodging, paid personal care, etc.

Indirect cost refers to resources lost as a result of the treatment and illness that involve morbidity and mortality. This includes both paid and unpaid productivity loss such as temporary sickness absenteeism, permanent functional impairment, premature death, etc. Indirect cost can be measured by approaches such as the Human Capital or Frictional Methods.

Intangible cost represents costs as a consequence of the treatment not measurable in monetary terms. These costs can be pain, grief, and suffering. When intangible costs are quantified, this can be done using approved outcome-measurement techniques.

C. Measurements of Outcomes in Pharmacoeconomic Analysis

Health outcomes are consequences of a treatment/intervention or programme which results in changes of quantity and quality of life. Health consequences can be final, intermediate or surrogate outcomes.

Final outcomes are usually measured as life years or quality adjusted life years (QALYs). Intermediate outcomes are usually measured by clinical parameters that have evidence-based correlation with the final outcome. A surrogate outcome is an end point that substitutes and can be predictive of a final outcome.

Final outcomes are measured over a natural course of the disease whilst intermediate outcomes are measured over a short time horizon.

Changes in quality of life can be valued directly by several methods such as rating scale or time trade-off. It can also be valued indirectly by employing instruments such as EQ-5D, HUI3, or SF-6D.

D. Decision Analytic Model

Modelling is necessary in health economic analysis in order to inform decision-making. It consists of a series of health states, representing the expected health consequences of different treatments. Modelling provides an important framework for synthesising available evidence and generating estimates of clinical and cost-effectiveness. Modelling can be used to extrapolate short-term outcome data or surrogate measures to long-term outcomes using modelling techniques. It may also be used to generate data from clinical trial settings to routine practice and to estimate the relative effectiveness of the technologies where these have not been directly compared.

E. Discounting

The reason for the need to discount in an economic evaluation is 'time preference' which refers to the desire to enjoy benefits in the present while deferring any negative effects of doing so. Future costs are discounted to account for the time value of money, and future health benefits are discounted to account for the delay in satisfaction from these outcomes. The effect of discounting is to give future costs and health benefits less weight in an economic analysis.

F. Sensitivity Analysis

Uncertainty could arise in pharmacoeconomic studies from the natural variation in populations and also the heterogeneous external data source used. Sensitivity analysis is performed for all key parameters in an analysis, in order to test the validity and robustness of the conclusion.

G. Average Cost-Effectiveness Ratio (ACER) and Incremental Cost-Effectiveness Ratio (ICER)

ACER is the ratio of the cost to benefit of an intervention without reference to a comparator. It deals with a single intervention and evaluates that intervention. ACER is calculated by dividing the net cost of the intervention by the total number of health consequences prevented by the intervention. It is generally described as cost per unit of outcome.

ICER compares the difference between the costs and health consequences of two alternative interventions that compete for the same resources. It is generally described as the additional cost per additional health consequence.

H. Budget Impact Analysis (BIA)

BIA estimates the financial consequences of adopting a new health technology in a clearly specified setting. BIA complements the pharmacoeconomic evaluations by providing additional information for decision making as it addresses the issue of affordability and sustainability. BIA provides information on the overall impact of a new health technology to a budget.

3. THE METHODOLOGICAL GUIDELINE

This methodological guideline shall be used when conducting any pharmacoeconomic studies in Malaysia for the purpose of preparing economic supporting documents. The key features of this guideline are summarised in section 5.

A. Scope of the Analysis and Perspective of Study

i) Problem Statement

The problem statement that brought about the pharmacoeconomic analysis or study should be clearly stated. This includes information on the disease such as epidemiology, cost of illness and standard treatment options used in the applied setting.

ii) Description of Drug/Intervention and Its Use

The drug/intervention under study should be fully described. If the study involves drugs, it should include name of drug, Anatomical Therapeutic Chemical (ATC) classification or Malaysia Drug Code (MDC), strength, dosage form, indication(s) and drug registration number in Malaysia (if available).

iii) Target Population

The target population should be clearly described. It may be defined by describing type of patient in terms of age, gender, socioeconomic status with a specific disease, with or without other comorbidities or risk factors.

Subgroup analysis can be performed if there is evidence to support better results in a particular patient subgroup.

iv) Perspective of the Study

The study should be conducted from the perspective of the provider or funder in the applied setting. Patient and societal perspectives are encouraged. The perspective should be consistent for both cost and outcome components.

B. Evaluation Technique

The type of economic analysis selected should be indicated and the choice should be justified. The following types of evaluation can be carried out:

i)   CMA should be applied when two interventions have similar health consequences at different costs. In this case, only the costs of treatment are compared.

ii) CEA should be used to compare differential costs and differential outcomes of the alternatives. It should be chosen when clinical outcome parameter or improvement in life expectancy is the main objective of the treatments. Final outcome is preferred. When using intermediate or surrogate outcome, it should be justified.

iii) CUA should be used if the quality of life forms an important effect of the intervention assessed. It should also be used when the treatment assessed has multiple patient-related outcome parameters reported in different units.

iv) If it is feasible and acceptable to interpret the outcomes studied into monetary terms, CBA can be undertaken.

C. Selection of Comparator(s)

The health technologies to be assessed should be compared against the most relevant alternative(s) for the proposed indication in the applied setting.

The most relevant alternative should be the standard intervention based on the National Clinical Practice Guidelines and Standard Treatment Guidelines, if available. If standard treatment guideline does not exist, usual treatment can be used upon prior consultation with subject matter experts.

Comparator(s) should not be a placebo but non-drug therapy can be used. Multiple comparators can be included in the analysis. In case of add-on intervention, the current treatment without the added intervention can be used as comparator. In the case where replacement of intervention is necessary, the intervention most likely to be replaced can be used as the comparator.

The choice of comparator(s) should always be justified.

D. Source and Retrieval of Evidence

Data from local setting should be given precedence. In the absence of evidence from local setting, the pharmacoeconomic analysis shall be based on evidence of clinical effects and adverse reactions of treatment obtained via a comprehensive and systematic literature review. All available evidence should be sought and considered as part of the review process.

The most common source of clinical data for pharmacoeconomic studies are randomised controlled trials (RCTs). Whenever available, data from meta-analyses or systematic reviews of RCTs should be used.

In the absence of valid RCTs, evidence from the highest available level of study design should be considered with reference to the limitations of the study design. The methods used to analyse or combine data should be clearly outlined and justified.

E. Measuring Cost

i) Cost Perspective

Fundamentally, all costs relevant to the chosen perspective must be determined and included in the analysis and in this case the perspective of the provider or funder in the applied setting. The different costs should be reported in both disaggregated and aggregated forms.

If it is feasible, societal cost is preferred in any analysis.

ii) Cost Data Sources

Local cost data should be used if available in the applied setting. The source of cost data must be identified. These sources may include cost from observational studies, databases, Diagnosis-Related Group (DRG) list, patient records or local literatures. Where the local costs cannot be obtained, other sources such as expenses and charges can be used as substitute, but the reasons for this must be justified.

F. Measuring Health Outcome

The choice of outcome parameters will depend on indication of the drug, the research question(s) and also the type of pharmacoeconomic analysis selected. The outcome parameters selected should be made in advance and justified. Health consequences in natural form, and measured as intermediate or final outcome can be analysed using CEA. However, only final outcome valued by utility can be analysed using CUA whilst outcomes that are valued as monetary term can only be analysed using CBA.

The final outcome is usually measured as survival, and/or QALYs. QALYs is preferable for the following conditions: [1]

- When health-related quality of life (HRQoL) is the/an important outcome.

- When the intervention affects both morbidity & mortality and common unit of outcome is needed.

- When the interventions compared have a wide range of outcomes and a common unit of output is needed for comparison.

- When an intervention is compared to others that have already been evaluated using CUA.

- When dealing with a limited budget situation such that the decision maker must determine which programmes/services to reduce or eliminate to free up funding for new programme.

- When the objective is to allocate limited resources optimally by considering all alternatives and using constrained optimisation to maximise the health gain achieved.

Outcomes should be measured using validated tools or instruments. As utilities may be influenced by local cultural factors, preferences obtained directly from the target and local population is preferred. Where local preferences are not available, preferences from populations with greatest similarity to the local population should be employed.[2-3]

Beside valuation by preference, changes in health state can also be valued in monetary term using human capital approach, contingent valuation, revealed preference or discrete choice experiment.

G. Decision Analytic Model

Modelling can be used for the pharmacoeconomic evaluation in certain situations, for example to extend the time horizon to longer time span due to the nature of the disease or to model comparators which have become more relevant to practice.

When modelling is used, it is recommended to present the structure, rationale behind chosen model and as well as to present it in a graphical way (simple decision tree or Markov model). When choosing relevant clinical trials for a model, it is important to ensure that the trials are as similar as possible with respect to patients population, inclusion and exclusion criteria, the problem presented in the trial, and the duration of the treatment. This is to ensure that mutual consistency is achieved.

Models should be as transparent as possible with all assumptions explicitly stated. The simplest model type should be chosen providing it captures the essential features of the disease and interventions, and all relevant data are incorporated and referenced.

Non-Malaysian model analyses may be used, but they should principally be adjusted to Malaysian conditions regarding clinical practice, costs and possibly health consequences. Justification must be given for any adjustments made. In the absence of adjustments, the consequences which the lack of adjustment may have on the results must be stated.

H. Time Horizon

Time horizon chosen should be long enough to include or capture all changes in cost and outcomes of the intervention being analysed. The choice of time horizon depends on the natural history of the disease and should be justified clearly.

I. Discounting

In a study longer than a year, annual discount rate of 3% should be adopted for both costs and outcomes. Sensitivity analysis with higher and lower discount rates (for example 0% and 5%) should be used to verify the robustness of the results of the analysis.

J. Sensitivity Analysis

In the sensitivity analysis, critical component(s) in the calculation should be varied through a relevant range from worst case to best case, and the results recalculated. These ranges and the omission of any model input from the sensitivity analysis must be justified.

Although univariate sensitivity analysis is acceptable, a multivariate analysis is preferred where appropriate. A probabilistic sensitivity analysis (PSA) with presentation of cost-effectiveness acceptability curve (CEAC) can be used.

K. Presentation of Results and Discussion

Data and results of the analysis should be presented in the most transparent and clear way so that the quality, validity and relevance of the findings to local settings can be easily assessed.

The total costs and total health consequences of all alternatives being considered should be reported separately to provide clear view on economic and   health consequences of the alternatives. Base case results can be presented as a table of costs (itemised by the different types of cost) and outcomes of all the alternatives considered. Aggregate and disaggregate results on costs, outcomes and cost-effectiveness ratio should be presented to provide information about the new drug or intervention at individual and population level.

ACER and ICER for the CEA and CUA can be presented if deemed appropriate.

The ICER reflects the additional (incremental) cost per additional unit of outcome achieved. No formal cost-effectiveness threshold is adopted in this guideline. Graphical presentations such as in the form of cost-effectiveness planes can be used when it is deemed beneficial.

Justifications must be made on the transferability of trial results to the local clinical practice (efficacy vs. effectiveness). Sources of secondary data used and assumptions made in the analysis should be clearly stated and properly referenced to the 'references' list. Limitations of the analysis should also be discussed in the 'discussion' section. Comparison of findings with other pharmacoeconomic analysis should be discussed.

L. Budget Impact Analysis

BIA shall take the budget holder perspective i.e. of the healthcare provider or funder. The design of the BIA model must be clear and justified, incorporating real population data in Malaysia or specific local setting. It must consider the population, market share, growth rate and costs in two scenarios i.e. scenario with the new treatment and scenario without the new treatment. The reference scenario shall comprise of the current treatment mix of the healthcare setting being analysed.

M. Report Format for a Standard Pharmacoeconomic Analysis

- Summary

- Definition of issue

- Epidemiological/Prevalence data (Malaysia)

- Review of literature

- Analysis objectives

- Target audience

- Study perspective

- Time horizon

- Comparator(s)

- Study methodology

- Description of model

- Costs (units of used resources, unitary costs, source of data)

- Outcome(s)

- Discounting

- Sensitivity analysis

- Presentation of results (e.g. ACER, ICER, etc.)

- Budget Impact Analysis

- Discussion

- References

- Appendices (samples of questionnaires, quality of life measurement tools or instruments, source of data i.e. meta-analysis, RCTs)

- Declaration of a potential conflict of interest

N. Ethical Code of Practice While Conducting and Publishing Results of Pharmacoeconomic Analysis

Pharmacoeconomic analysis should be conducted in accordance to this guideline. Any financial support for the study should be revealed. The author(s) should also declare any relationship with the funders of the study or any other conflict of interest. Publication of the local pharmacoeconomic studies is encouraged.

O. Format for References

All references should be written according to Vancouver Style as shown in examples below.

1. Journal article, personal author(s):

   Rose ME, Huerbin MB, Melick J, et al. Regulation of interstitial excitatory amino acid concentrations after cortical contusion injury. Brain Res. 2002; 935(1-2):40-46.

2. Journal article, organisation as author:

   Diabetes Prevention Program Research Group. Hypertension, insulin and proinsulin in participants with impaired glucose tolerance. Hypertension. 2002; 40(5):679-686.

4. LIST OF REFERENCES

1. Drummond MF, Sculpher MJ, Torrance GW, et al. Methods for the economic evaluation of health care programmes. [Oxford medical publications].3rd ed. New York: Oxford University Press; 1997.

2. Dolan P. Modeling valuations for EuroQol health states. Med Care. 1997; 35(11):1095-1108.

3. Faridah AMY, Goh A, Soraya A. Estimating an EQ-5D value set for Malaysia using Time Trade-Off and Visual Analogue Scale Methods. Value in Health. 2012; 15:S85-S90.

5. LIST OF KEY FEATURES

List of Key Features of Pharmacoeconomic Guideline for Malaysia

KEY FEATURES	
Title and year of the document	Pharmacoeconomic Guideline For Malaysia 2012
Affiliation of members	PSD, MOH, MaHTAS, MySPOR, MPS, MUSC, UM, UKM, UKMMC, USM, UNU-IIGH, UiTM
Purpose of the document	A methodological guide to conduct pharmacoeconomic analysis in Malaysia.
Standard reporting format included	Yes
Disclosure	Yes
Target audience of funding/ author's interests	Both public and private payers, healthcare industries, clinicians, and research communities, accordingly.
Perspective	Provider or funder. Patient and societal perspective are encouraged.
Indication	Indication(s) must be approved by DCA/reference country.

KEY FEATURES	
Target population	Must be clearly stated.
Subgroup analysis	Yes, can be included when appropriate.
Choice of comparator	To be compared against the most relevant alternatives for the proposed indication in the applied setting. Comparator(s) should not be a placebo but non-drug therapy can be used. The choice of comparator(s) should always be justified.
Time horizon	Should be long enough to capture all changes in cost(s) and outcome(s) of the intervention.
Assumptions required	Yes. Should be clearly stated.
Preferred analytical technique	CEA and CUA. Technique chosen should be justified clearly.
Costs to be included	All costs relevant to the chosen perspective (provider/funder). Societal cost is preferred in any analysis.

KEY FEATURES	
Source of costs	Local cost data in the applied setting. The source of cost data must be identified.
Modelling	Yes. Clearly detailed with maximum transparency. All assumptions should be explicitly stated.
Systematic review of evidence	Yes. Meta-analysis is encouraged.
Preference for effectiveness over efficacy	N/A
Preferred outcome measure	Should justify the selection.
Preferred method to derive utility	Should justify the selection.

KEY FEATURES	
Equity issues stated	N/A
Discounting costs	3% (Sensitivity Analysis, 0 and 5%)
Discounting outcomes	3% (Sensitivity Analysis, 0 and 5%)
Sensitivity analysis-parameters and range	All key uncertain parameters. Best and worst case scenario presented.
Sensitivity analysis-methods	One-way, multivariate analysis as deemed appropriate.
Presenting results	Aggregated and disaggregated form for cost(s) and outcome(s).

KEY FEATURES	
Incremental analysis	Yes
Total C/E	Yes
Portability of results (Generalisability)	N/A
Budget impact analysis	Yes
Mandatory or recommended or voluntary	Voluntary for 2 years upon launch of the pharmacoeconomic guideline and mandatory thereafter.