

**EVALUATION OF GENERIC MEDICINES  
SUBSTITUTION PRACTICES AMONG  
COMMUNITY PHARMACISTS IN MALAYSIA  
AND AUSTRALIA**

**By**

**CHONG CHEE PING**

**Thesis submitted in fulfillment of the requirements  
for the degree of  
Doctor of Philosophy**

**UNIVERSITI SAINS MALAYSIA**

**November 2010**

## **STATEMENT OF ORIGINALITY**

I declared that the work presented in this thesis contains no material which has been accepted for the reward of any other degree or diploma in any university or other institution. To the best of my knowledge, the thesis contains no material previously published or written by another person, except where due reference is made in the text.

Chong Chee Ping

## ACKNOWLEDGEMENTS

I wish to express my deepest appreciation to all the people that have contributed to the completion of this thesis.

Firstly, I would like to thank Universiti Sains Malaysia (USM) for providing me with the scholarship to undertake my PhD studies at School of Pharmaceutical Sciences, USM and a research affiliation at Quality Use of Medicines and Pharmacy Research Centre (QUMPRC), Sansom Institute, School of Pharmacy and Medical Sciences, University of South Australia. Upon completion of my master degree study, I remember talking with my supervisor Assoc Prof Mohd Baidi Bahari one day in his office about my frustration with the role of community pharmacists in Malaysia. We talked about how we could improve the pharmacy profession and Malaysia health system. That conversation set the seed for my interest in this research. Later, Dr Mohamed Azmi Ahmad Hassali joined in supervising me just after the completion of his PhD study at Victoria College of Pharmacy. I am extremely grateful for his patience, guidance and perceptiveness in assisting me in this research.

I had the great fortune to conduct the Australian arm study under the supervision of Prof Andrew Gilbert and Dr Geoff March. Their profound knowledge of different perspective of health system and generic medicines policy provided me with the opportunity to broaden my knowledge and to make significant progress. I am also indebted to their friendly support and enthusiasm. I would also like to thank Dr Alice Clark for her fruitful comments and suggestions during the initial phase of the Australian arm study. Special thanks to Dr Lisa Kalisch, Joseph Whitehouse and Adam Phillips for their comments and suggestions regarding the data collection tools. Many thank to John Barratt who assisting me in conducting the web-based survey. I also owe many thanks to Prof Adrian Esterman who provided statistical advice and alternatives for the analysis of my research data. I cannot forget to thank Noordin Othman and Teresa Duncan for their valuable assistance in the data collection. I am sincerely acknowledged Dr Libby

Roughead, Dr Manya Anglely, Dr Susan Semple, Kathy Mott and other members of the QUMPRC for their moral and social support.

A special appreciation goes to my parents and family members for their support throughout my education years. Last, but not least, I would personally like to thank my wife Lee Sau Yong for her patient, support and love that has got me through this journey.

## TABLE OF CONTENTS

	<b>Page</b>
Statement of Originality	ii
Acknowledgement	iii
Table of contents	v
List of Tables	xi
List of Figures	xvi
List of Abbreviations	xvii
List of Appendices	xix
List of Publications and Communications	xx
Abstrak	xxi
Abstract	xxiii
<b>Chapter 1: General Introduction</b>	
1.1 Introduction	1
1.2 Generic medicines use in Australia and Malaysia: A brief overview	4
1.3 Justification for this study	5
1.4 Objectives of this study	6
1.5 Overview of thesis	7
<b>Chapter 2: Literature Review</b>	
2.1 The ideal healthcare system	9
2.1.1 Goals of an ideal healthcare system	10
2.1.2 Performance indicators for an ideal health system	11
2.1.3 A comparison of the performance of Australian and Malaysian healthcare system	13
2.1.3(a) Health status	15
2.1.3(b) Responsiveness	15
2.1.3(c) Fair financing and affordability	15
2.1.3(d) Overall measure of attainment	19
2.1.3(e) Efficiency	20
2.1.3(f) Conclusions	20
2.2 Australian healthcare system	20
2.2.1 Administration and funding of health services in Australia	20
2.2.1(a) Medicare	22
2.2.1(b) Private health insurance	24
2.2.1(c) Public hospital sector	24
2.2.1(d) Private health sector	25
2.2.2 National Medicine Policy (NMP) and the Quality Use of Medicines (QUM) Framework	26
2.2.2(a) Introduction	26
2.2.2(b) The Australian National Medicines Policy (NMP) 2000	27
2.2.2(c) The Australian National Strategy for Quality Use of Medicines	28

2.2.3	Pharmaceutical Benefits Scheme (PBS)	29
2.2.3(a)	History and development of PBS	29
2.2.3(b)	Policies, procedures & method used in the listing of pharmaceuticals	35
2.2.3(c)	Policies, procedures & method used in the pricing of pharmaceuticals	38
2.2.3(d)	Outcome of controls on the PBS - medicine prices in Australia	41
2.2.4	Generic medicines policies in Australia	44
2.2.4(a)	Minimum Pricing Policy, MMP (or Brand Premium Policy, BPP)	45
2.2.4(b)	Brand (Generic) Substitution Policy	46
2.2.4(c)	Therapeutic Group Premium (TGP) Policy	47
2.2.4(d)	PBS Reform	48
2.2.5	The Australian medicines regulatory system	53
2.2.5(a)	Regulation requirements for generic medicines in Australia	55
2.2.6	Pharmaceutical industry in Australia	58
2.2.7	Pharmaceutical wholesaler and distributor in Australia	60
2.2.8	Pharmacy profession in Australia	61
2.2.8(a)	History and development of pharmacy profession	61
2.2.8(b)	Pharmacy workforce	63
2.2.8(c)	Roles of community pharmacy in Australia	65
2.2.8(d)	Operation of community pharmacy	67
2.2.8(e)	Challenges and future directions of community pharmacy	68
2.3	Malaysian healthcare system	70
2.3.1	Administration and funding of health services in Malaysia	70
2.3.1(a)	Public health sector	71
2.3.1(b)	Private health sector	72
2.3.1(c)	Development of National Health Financing Scheme	74
2.3.1(d)	Privatization in the Malaysian healthcare system	78
2.3.2	Vision and mission of Malaysian healthcare system	80
2.3.3	Malaysian National Medicines Policy (MNMP)	81
2.3.3(a)	Generic Medicines Policy under the MNMP	82
2.3.3(b)	Drug Pricing Policy under the MNMP	83
2.3.3(c)	Medicine financing under the MNMP	83
2.3.3(d)	Prescribing and dispensing practices under the MNMP	84
2.3.4	Pharmaceutical situation in Malaysia	84
2.3.4(a)	The Malaysian pharmaceutical market	84
2.3.4(b)	Medicine prices, affordability and generic medicines use in Malaysia	84
2.3.4(c)	Pharmaceutical regulatory system	87
2.3.4(d)	Bioequivalence requirement for generic medicines	88
2.3.4(e)	Malaysian pharmaceutical industry	89
2.3.5	Pharmacy profession in Malaysia	91
2.3.5(a)	History and development of pharmacy profession	91
2.3.5(b)	Pharmacy workforce	94
2.3.5(c)	Dispensing separation, generic medicines use and medicines affordability	96
2.3.5(d)	Role of community pharmacist in Malaysia	98
2.3.5(e)	Operation of Malaysian community pharmacy	100
2.3.5(f)	Challenges and future direction of community pharmacists	102
2.3.6	Factors influencing generic medicines utilization	103

2.3.6(a) Impact of generic medicines policy	104
2.3.6(b) Physicians' perception, knowledge and acceptance of generic medicines	105
2.3.6(c) Pharmacists' perception and knowledge of generic medicines and substitution practices	108
2.3.6(d) Consumers' perceptions and acceptance towards generic medicines and substitution	113
2.3.6(e) Communication between pharmacist and physician	117
2.3.6(f) Cost-saving from generic substitution	118
2.3.6(g) Statement of the problem	120
 Chapter 3: Methodology	
3.1 Introduction	123
3.2 Objectives and research questions	123
3.3 Independent and dependent variables	124
3.4 Study design	125
3.5 Study participants and sampling method	126
3.6 Inclusion criteria	126
3.7 Exclusion criteria	126
3.8 Data collection	127
3.9 Data analysis	127
3.10 Ethical approval	127
 Chapter 4: A national survey of Malaysian community pharmacists' perceptions knowledge and practices of generic substitution (Part I - Malaysian Arm Study)	
4.1 Introduction	128
4.2 Objectives	128
4.3 Methods	128
4.3.1 Development of the survey questionnaire	129
4.3.2 Study participants and sample size	131
4.3.3 Survey administration and time frame	131
4.3.4 Data analysis	132
4.4 Results	133
4.4.1 Demographics and practice characteristics	133
4.4.2 Non-response bias analysis	134
4.4.3 Perceptions of generic medicines and substitution	135
4.4.3(a) Factors significantly influence pharmacists' perceptions	135
4.4.3(b) Differences between perception groups	137
4.4.3(c) Differences between demographics and practice characteristics	139
4.4.4 Opinion on generic substitution	141
4.4.5 Knowledge about efficacy, safety, quality and regulatory standards of generic medicines	143
4.4.5(a) Differences between perceptions groups	144
4.4.5(b) Differences between demographic and practice characteristics	146
4.4.5(c) Knowledge of allowable bioequivalence limit and bioequivalency	148
4.4.5(d) Ratings of therapeutic index and comfort in substitution level	150
4.4.6 Perception of future implementation of generic substitution policy	150
4.4.7 Current generic substitution practices	151

4.4.7(a) Communication with the physician	151
4.4.7(b) Information provided when performing generic substitution	153
4.4.8 Documentation and follow-up	155
4.5 Discussion	157
4.6 Study limitations	167
4.7 Suggestions for future studies	167
4.8 Conclusions	168
Chapter 5: A web-based survey of Australian community pharmacists' perceptions, knowledge and practices of generic substitution (Part I - Australian Arm Study)	
5.1 Introduction	169
5.2 Objectives	169
5.3 Methods	169
5.4 Results	172
5.4.1 Demographic and practice characteristics	172
5.4.2 Perceptions of generic medicines and substitution	174
5.4.2(a) Factors significantly influence pharmacists' perceptions	174
5.4.2(b) Differences between perceptions groups	176
5.4.2(c) Differences between demographic and practice characteristics	177
5.4.3 Opinion on generic substitution	179
5.4.4 Generic substitution practices	181
5.4.5 Knowledge about efficacy, safety, quality and regulatory standards of generic medicines	182
5.4.5(a) Differences between perceptions groups	183
5.4.5(b) Differences between demographic and practice characteristics	184
5.4.5(c) Comparison between registered pharmacists and pharmacy pre-registrants	187
5.4.6 Knowledge of allowable bioequivalence limits	188
5.4.7 Ratings of therapeutic index and confidence in substitution level	189
5.5 Discussion	190
5.6 Study limitations	196
5.7 Suggestions for future studies	196
5.8 Conclusions	197
Chapter 6: Community pharmacists' perceptions and knowledge of generic medicines and substitution: A comparison between Malaysia and Australia (Part I)	
6.1 Introduction	198
6.2 Objectives	198
6.3 Methods	198
6.4 Results	199
6.4.1 Perceptions of generic medicines and substitution	199
6.4.2 Opinion on generic substitution	201
6.4.3 Knowledge about efficacy, safety, quality and regulatory standards of generic medicines	202
6.4.4 Opinion of allowable bioequivalence limit	204
6.4.5 Rating of therapeutic index and comfort/confident in substitution	204
6.5 Discussion	206



6.6	Conclusions	211
Chapter 7: A national survey on generic medicines substitution practices among Malaysian community pharmacists (Part II – Malaysian Arm Study)		
7.1	Introduction	212
7.2	Objectives	212
7.3	Methods	212
	7.3.1 Data analysis	214
7.4	Results	216
	7.4.1 Demographic and practice characteristics	216
	7.4.2 Non-response bias analysis	218
	7.4.3 Brand name medicines requests	218
	7.4.4 Generic substitution recommendations	224
	7.4.5 Patients' acceptance	225
	7.4.6 Generic products involved in generic substitution practices	226
	7.4.7 Extent of communication between pharmacists and physicians	230
	7.4.8 Physicians' acceptance	230
	7.4.9 Pharmacists and physicians' influences on the patients' acceptance toward generic substitution	234
	7.4.10 Cost-saving through generic substitution	234
	7.4.10(a) Pharmacists' cost-saving in purchasing the stocks	235
	7.4.10(b) Patients' cost-saving through generic substitution	236
	7.4.10(c) Cost-saving according to disease, poison and therapeutic classification	236
	7.4.11 Follow-up on patients who received generic substitution therapy	239
7.5	Discussion	242
7.6	Study limitation	245
7.7	Conclusions	245
Chapter 8: A national survey on generic medicines substitution practices among Australian community pharmacists (Part II – Australian Arm Study)		
8.1	Introduction	246
8.2	Objectives	246
8.3	Method	246
	8.3.1 Study participants and sampling method	248
	8.3.2 Data collection	249
	8.3.3 Ethical approval	249
	8.3.4 Data analysis	249
8.4	Results	252
	8.4.1 Demographic and practice characteristics of the respondents	253
	8.4.2 Non-response bias analysis	254
	8.4.3 Brand name medicines requests	254
	8.4.4 Generic substitution recommendation by the pharmacists	261
	8.4.5 Patient acceptance	262
	8.4.6 Generic products involved in generic substitution practices	264
	8.4.7 Brand substitution involved identical alternatives (pseudo-generics)	269
	8.4.8 Cost-saving achieved for the patient through generic substitution	273
8.5	Discussion	276
8.6	Study limitations	279
8.7	Conclusions	280

Chapter 9: Generic medicines substitution among community pharmacists: a comparison between Malaysia and Australia (Part II)	
9.1 Introduction	281
9.2 Objectives	281
9.3 Methods	281
9.4 Results	282
9.4.1 Opportunity for generic substitution	282
9.4.1(a) Generic substitution recommendation rate	282
9.4.1(b) Patients' acceptance	283
9.4.1(c) Generic products involved in generic substitution practices	283
9.4.1(d) Cost-saving from generic substitution	284
9.4.2 Comparable brand name medicines requests	284
9.4.2(a) Generic substitution recommendation	286
9.4.2(b) Patients' acceptance	287
9.4.2(c) Average cost-saving from generic substitution	291
9.5 Discussion	294
9.6 Conclusions	295
Chapter 10: Thesis Conclusions and Recommendations	
10.1 Introduction	296
10.2 Conclusions of literature review	296
10.3 Conclusions of Part I study	297
10.4 Conclusions of Part II study	302
References	305
Appendices	

## LIST OF TABLES

<b>Table No.</b>	<b>Title</b>	<b>Page</b>
2.1	Expenditure on Pharmaceutical Benefits Scheme, constant price (expressed in terms of 2004-05 prices), by source of funds, and annual growth rates, 1999-00 to 2005-06	34
2.2	The pharmacist's dispensing fee, the wholesaler mark-up and the pharmacist mark-up, based on the Fourth Community Pharmacy Agreement between The Commonwealth of Australia and The Pharmacy Guild of Australia	40
2.3	International comparison between prices of medicines in Australia and other countries using Fisher Pharmaceutical Price Indexes	43
2.4	Schedule of medicine and poisons category in Australia	55
4.1	Numbers of enrolled pharmacy outlets, response rate & distribution of respondents according to state and region in Malaysia (Part I study)	134
4.2	Demographics and practice characteristics of surveyed respondents in Malaysia (Part I study)	135
4.3	Malaysian Pharmacists' perceptions of generic medicines and substitution	136
4.4	Differences in Malaysian pharmacists' perceptions of generic substitution among the three perception groups	138
4.5	Demographic and practice characteristics of Malaysian pharmacists with significant differences in their willingness to offer generic substitution (Part I study)	141
4.6	Malaysian pharmacists' responses to question exploring the factors which influence the pharmacists' decision to dispense a brand name medicine rather than a generic	143
4.7	Percentage of Malaysian pharmacists among different perception groups who answered "somewhat" or "a great deal" to question exploring the factors which influence the pharmacists' decision to dispense a brand name medicine rather than a generic	143
4.8	Malaysian pharmacists' understanding of issues around the use of generic medicines and generic substitution	145
4.9	Differences in Malaysian pharmacists' understanding of generic medicines and substitution among the three perception groups	146
4.10	Differences in Malaysian pharmacists' understanding of generic medicines and substitution among the ethnic groups	147
4.11	Differences in Malaysian pharmacists' understanding of generic medicines and substitution among regions where pharmacy located	148
4.12	Malaysian pharmacists' professional judgment of the acceptable variation in bioavailability	148

<b>Table No.</b>	<b>Title</b>	<b>Page</b>
4.13	Frequency and percentage of Malaysian pharmacist who correctly identified medicines listed in the Malaysia DCA's bioequivalence list	149
4.14	Frequency and percentage of Malaysian pharmacist among different perceptions groups who correctly identified medicines listed in the Malaysia DCA's bioequivalence list	149
4.15	Malaysian pharmacists' perceived therapeutic index and comfort in substitution for five brand name products	150
4.16	Reasons for not consulting the physician when performing generic substitution	152
4.17	Information provided to the physician by the Malaysian pharmacist when performing generic substitution	154
4.18	Information provided to the patient by the Malaysian pharmacist when performing generic substitution	154
4.19	Reasons for not keeping the patients' record	156
4.20	Reasons for not follow up the patient	157
5.1	Distribution of respondents according to state and area in Australia (Part I study)	172
5.2	Demographics and practice characteristics of survey respondents in Australia (Part I study)	173
5.3	Banner groups and companies (chain pharmacies) which involved in the Part I Australian arm study	174
5.4	Australian pharmacists' perceptions of generic medicines and substitution	175
5.5	Differences in Australian pharmacists' perceptions of generic medicines and substitution among the three perceptions groups	177
5.6	Demographic and practice characteristics of Australian pharmacists with significant differences in their willingness to offer generic substitution (Part I study)	179
5.7	Australian Pharmacists' responses to question exploring the factors which influence the pharmacists' decision to dispense a brand name medicine rather than a generic	180
5.8	Percentage of Australian pharmacists among different perception groups who answered "somewhat" or "a great deal" to question exploring the factors which influence the pharmacists' decision to dispense a brand name medicine rather than a generic	180
5.9	Information provided to the patient by the Australian pharmacists regarding generic medicines	181
5.10	Australian pharmacists' understanding of issues around the use of generic medicines and substitution	183

<b>Table No.</b>	<b>Title</b>	<b>Page</b>
5.11	Differences in Australian pharmacists' understanding of generic medicines and substitution among the three perceptions groups	184
5.12	Differences between the scores for questions relating to quality (Question 21F) and safety (Question 21G) of generic medicines across states where the Australian pharmacists practising and their graduating university	186
5.13	Differences between the scores for questions relating to therapeutic failure (Question 21C) and quality (Question 21F) of generic medicines across Australian pharmacists' employment position characteristics	187
5.14	Australian pharmacists' knowledge of the maximum variation in bioavailability allowed by the TGA for a generic equivalent medicine	188
5.15	Percentage of Australian pharmacists who correctly indicated the bioavailability variation allowed by the TGA Australia for generic medicines	188
5.16	Australian pharmacists' opinions of the acceptable variation in bioavailability	189
5.17	Australian pharmacists' perceived therapeutic index and confident in substitution for five brand name products	190
6.1	A comparison between Malaysian and Australian pharmacists' perceptions of generic substitution	200
6.2	A comparison between Malaysian and Australian pharmacists' responses to question exploring the factors which influence the pharmacists' decision to dispense a brand name medicine rather than a generic	201
6.3	A comparison between Malaysian and Australian pharmacists' knowledge of generic medicines and substitution	203
6.4	Malaysian and Australian pharmacists' opinion of the acceptable variation in bioavailability of generic medicines	204
6.5	Malaysian and Australian pharmacists' perceived therapeutic index and comfort/confident in substitution for three brand name products	205
7.1	Numbers of enrolled pharmacy outlets, response rate & distribution of respondents according to state and region in Malaysia (Part II study)	216
7.2	Demographics and practice characteristics of surveyed respondents in Malaysia (Part II study)	217
7.3	Multi-source brand name medicines requests, generic substitution recommendations and patient acceptance toward generic substitution among the Malaysian community pharmacies	220
7.4	Brand name medicines requests and generic substitution among the Malaysian pharmacists	227

<b>Table No.</b>	<b>Title</b>	<b>Page</b>
7.5	Most common generic products involved in generic substitution practices among the Malaysian pharmacists	228
7.6	Manufacturers of generic products which involved in generic substitution practices among the Malaysian pharmacists	229
7.7	Manufacturer's country of origin of the generic products which involved in generic substitution practices among the Malaysian pharmacists	229
7.8	Manufacturer's country of origin of the generic products which involved in generic substitution practices among the Malaysian pharmacists	229
7.9	Consultation between Malaysian pharmacists and physicians and physicians' acceptance toward generic substitution	231
7.10	Malaysian physicians and patients' acceptance toward generic substitution	234
7.11	Malaysian pharmacists' cost-saving in purchasing the stocks	235
7.12	Malaysian pharmacists' monthly cost-saving (per 30 days) for chronic cases	235
7.13	Malaysian patients' cost-saving through generic substitution	236
7.14	Malaysian patients' monthly cost-saving (per 30 days) for chronic cases	236
7.15	Percentage of cost-saving through generic substitution according to disease, poison and therapeutic classification (Malaysian arm study)	237
7.16	Follow-up on patients who received generic substitution	240
8.1	Population of community pharmacies, minimum responses required and numbers of enrolled pharmacy outlets according to area in Australia (Part II study)	249
8.2.1	Calculation of cost-saving from generic substitution (Example 1: General patient not under Safety Net Scheme)	250
8.2.2	Calculation of cost-saving from generic substitution (Example 2: General patient under Safety Net Scheme)	250
8.2.3	Calculation of cost-saving from generic substitution (Example 3: Concessional patient not under Safety Net Scheme)	251
8.2.4	Calculation of cost-saving from generic substitution (Example 4: Concessional patient under Safety Net Scheme)	251
8.2.5	Calculation of cost-saving from generic substitution (Example 5: General patient not under Safety Net Scheme)	251
8.2.6	Calculation of cost-saving from generic substitution (Example 6: General patient under Safety Net Scheme)	251
8.2.7	Calculation of cost-saving from generic substitution (Example 7: Concessional patient not under Safety Net Scheme)	252

<b>Table No.</b>	<b>Title</b>	<b>Page</b>
8.2.8	Calculation of cost-saving from generic substitution (Example 8: Concessional patient under Safety Net Scheme)	252
8.3	Numbers of enrolled pharmacy outlets, response rate & distribution of respondents according to area in Australia (Part II study)	252
8.4	Demographic and practice characteristics of survey respondents in Australia (Part II study)	253
8.5	Therapeutic class of the brand name medicines request items which disallowed to be substituted by the prescriber	255
8.6	Brand name medicines request items which disallowed to be substituted by the prescriber	255
8.7	Multi-source brand name medicines request, generic substitution recommendations and patient acceptance toward generic substitution among the Australian community pharmacies	257
8.8	Brand name medicines and generic substitution among the Australian pharmacists	265
8.9	Most common generic products involved in generic substitution among the Australian pharmacists	267
8.10	Manufacturers of generic products which involved in generic substitution among the Australian pharmacists	268
8.11	Manufacturer's country of origin of the generic products which involved in generic substitution among the Australian pharmacists	268
8.12	Brand substitution which involved identical alternatives (pseudo-generics)	270
8.13	Status of the patients who received generic substitution and determination of cost-saving achieved from substitution (Australian arm study)	273
8.14	Status of the chronic patients who received generic substitution and determination of cost-saving achieved from substitution (Australian arm study)	274
8.15	Amount of cost-saving through generic substitution according to disease, therapeutic class and therapeutic sub-class (Australian arm study)	275
9.1	Lists of comparable brand name medicines requests which allowed opportunity for generic substitution among the Malaysian and Australian community pharmacies	285
9.2	Brand name medicines requests, pharmacists' generic substitution recommendation and patients' acceptance: a comparison between Malaysia and Australia	288
9.3	Patient's cost-saving per substitution case according to disease, therapeutic class and therapeutic sub-class: a comparison between Malaysia and Australia	292

## LIST OF FIGURES

<b>Figure No.</b>	<b>Title</b>	<b>Page</b>
2.1	Framework for measuring health systems performance	13
2.2	Flow of funding in Australian Health System	22
2.3	Process of medicines subsidy under the PBS	37
2.4	Comparison of plasma concentration-time profiles following administration of the innovator brand (Product A) and generic formulation (Product B) of an oral medicine	57
2.5	Flow of Funding in Malaysian Health System	74
2.6	Medicines affordability problem in Malaysia	121
3.1	Relationship between independent and dependent variables	124
4.1	Malaysian pharmacists' general opinion on generic substitution	142
4.2	Group of medicines which the Malaysian pharmacists prefer to consult the physicians when performing generic substitution	151
4.3	Consultation between Malaysian pharmacist and physician when performing generic substitution	152
4.4	Percentage of Malaysian pharmacists who documented and provided follow-up services for patients who received generic substitution	155
4.5	Malaysian pharmacists' preferable model of generic substitution practice	163
4.6	Suggested framework for future Malaysian generic substitution policy	165
7.1	Conceptual model of generic substitution practices (Malaysian arm study)	214
8.1	Conceptual model of generic substitution practices (Australian arm study)	247



## LIST OF ABBREVIATIONS

AACP	Australian Association of Consultant Pharmacy
AD\$	Australian Dollar
ADEC	Australian Drug Evaluation Committee
AACP	Australian Association of Consultant Pharmacy
DP	Drugs Payment
DPIs	Dry Powder Inhalers
EMEA	European Agency for the Evaluation of Medicinal Product
EPF	Employee Provident Fund
FDA	Food Drug Association
FDS	Flying Doctors Services
GDP	Gross Domestic Product
GMiA	Generic Medicines Industry Association
GMP	Good Manufacturing Practice
GMS	General medical Services
GP	General practitioner
GS	Generic substitution
HMRs	Home Medicines Reviews
ICC	Intra-class Correlation Coefficient
IRP	International Reference Price
MBS	Medicare Benefits Scheme
MMA	Malaysian Medical Association
MNMP	Malaysian National Medicines Policy
MOH	Ministry of Health Malaysia
MPP	Minimum Pricing Policy
MPR	Median price ratio
MPS	Malaysian Pharmaceutical Society
NGOs	Non-governmental organizations
NHFA	National Health Financing Authority
NHFS	National Health Financing Scheme
NHS	National Health Service
NHSF	National Health Security Fund
NMP	National Medicine Policy
NPS	National Prescribing Service

## LIST OF ABBREVIATIONS

NSAIDs	Non-steroidal anti-inflammatory drugs
NTI	Narrow therapeutic index
NZ	New Zealand
OECD	Organization for Economic Co-operation and Development
OTC	Over the counter
PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme
PGA	The Pharmacy Guild of Australia
PhARIA	Pharmacy Access/Remoteness Index of Australia
PHARM	Commonwealth Pharmaceutical Health and Rational Use of Medicines
Pharmac	Pharmaceutical Management Agency for New Zealand
PharmD	Doctor of Pharmacy
PhC	Pharmaceutical Chemist
PIC	Pharmaceutical Inspection Convention
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PSA	Pharmaceutical Society of Australia
QUM	Quality Use of Medicines
R&D	Research and Development
RPBS	Repatriation Pharmaceutical Benefits Scheme
Socso	The Social Security Organisation
SSRIs	Selective serotonin re-uptake inhibitors
TCM	Traditional complementary medicine
TGA	Therapeutic Goods Administration of Australia
TGP	Therapeutic Group Premium
TRIPs	Trade-Related Aspects of Intellectual Property Rights
WAMTC	Weighted Average Monthly Treatment Cost
WAP	Weighted average disclosed price
WHO	World Health Organization
WTO	World Trade Organization

## LIST OF APPENDICES

<b>Appendix No.</b>	<b>Title</b>
1.	Preliminary version of questionnaire (Part 1- Malaysian arm study)
2.	Final questionnaire (Part I - Malaysian arm study)
3.	Recruitment materials for Malaysian arm study
4.	Scatter plot for the linear regression analysis result (Part I – Malaysian arm study)
5.	Preliminary version of questionnaire (Part I - Australian arm study)
6.	Final questionnaire (Part I - Australian arm study)
7.	Recruitment materials for Part I – Australian arm study
8.	Ethical approval for Australian arm study
9.	Scatter plot for the linear regression analysis result (Part I – Australian arm study)
10.	Data collection form (Part II - Malaysian arm study)
11.	Data collection form (Part II - Australian arm study)
12.	Recruitment materials for Part II - Australian arm study
13.	Endorsement from the Pharmacy Guild of Australia (Australian arm study)

## LIST OF PUBLICATIONS AND COMMUNICATIONS

Communications arising from the thesis:

### Journal Publications

#### Published/ In Press

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#### Conference Presentation

1. **Chong, C. P.**, Hassali, M. A., & Bahari, M. B. (2009, October 23-25). A nationwide study on generic medicines substitution practices among Malaysian community pharmacists. Paper presented at the The 4th Asian Conference on Pharmacoepidemiology, Tainan, Taiwan.

# **PENILAIAN AMALAN PENUKARGANTIAN UBAT-UBATAN GENERIK DALAM KALANGAN AHLI-AHLI FARMASI KOMUNITI DI MALAYSIA DAN AUSTRALIA**

## **ABSTRAK**

Banyak negara termasuk Australia telah menggubalkan dasar penukargantian ubat-ubatan generik untuk mengurangkan beban perbelanjaan ubat. Malaysia juga mengalami cabaran yang sama dalam menangani peningkatan dalam kos ubat. Namun demikian, tidak seperti Australia, Malaysia masih belum melaksanakan strategi penukargantian ubat-ubatan generik untuk menangani masalah ini. Jadi, kajian dalam tesis ini bertujuan menghasilkan data dan garis-panduan yang dapat membantu pembangunan dasar ubat-ubatan generik di Malaysia. Objektif kajian ini termasuk menilai dan membanding tanggapan, pengetahuan dan amalan penukargantian ubat-ubatan generik dalam kalangan ahli-ahli farmasi komuniti di Malaysia dan Australia. Selain itu, penerimaan pengguna terhadap penukargantian ubat-ubatan generik dan jumlah penjimatan wang yang terhasil daripada amalan ini juga dibandingkan di antara dua negara.

Kajian ini merupakan kajian keratan rentas diskriptif nasional. Bahagian I mengkaji tanggapan dan pengetahuan ahli-ahli farmasi terhadap ubat-ubatan generik melalui borang soal selidik. Bahagian II mengkaji amalan penukargantian ubat-ubatan generik oleh ahli-ahli farmasi berdasarkan permintaan terhadap ubat berjenama daripada pesakit. Seluruh populasi farmasi komuniti di Malaysia ( $n = 1419$ ) telah dijemput untuk menyertai kajian Bahagian I dan II menerusi surat. Manakala, kajian Bahagian I di Australia dijalankan menerusi laman web di mana sesiapa ahli farmasi komuniti yang terdedah kepada laman ini boleh menyertainya. Untuk kajian Bahagian II, sejumlah 500 buah farmasi komuniti yang mewakili seluruh populasi farmasi komuniti di Australia telah dipilih secara rawak dan dijemput menerusi surat.

Sejumlah 219 dan 157 ahli farmasi dari Malaysia dan Australia menyertai kajian dalam Bahagian I. Peratusan ahli farmasi Australia yang sudi mengamalkan penukargantian ubat-ubatan generik (93.7%) adalah nyata lebih tinggi daripada Malaysia (66.7%). Ahli-ahli farmasi Australia dengan nyatanya mempunyai tanggapan yang lebih positif dan lebih berpengetahuan daripada ahli-ahli farmasi Malaysia dalam isu efikasi, keselamatan, kualiti dan piawai pengawalan ubat-ubat generik. Kadar penyertaan dalam kajian Bahagian II adalah 11.1% (n = 157) dan 16.4% (n = 82) masing-masing bagi ahli-ahli farmasi Malaysia dan Australia. Ahli-ahli farmasi Australia dengan jelasnya mempunyai kadar amalan penukargantian ubat-ubatan generik (96.4%) yang lebih kerap daripada kumpulan ahli farmasi Malaysia (84.7%). Namun, rakyat Malaysia memaparkan kadar penerimaan terhadap penukargantian ubat-ubatan generik (88.9%) yang nyata lebih tinggi daripada rakyat Australia (78.5%). Menerusi penerimaan penukargantian ubat-ubatan generik, perbelanjaan dalam pembelian ubat bagi pengguna Malaysia telah berkurang sebanyak 57.4% berbanding dengan lebih kurang 21.0% bagi pengguna Australia.

Sebagai kesimpulan, ahli-ahli farmasi komuniti Malaysia perlu memperbaiki tanggapan dan pengetahuan mereka terhadap ubat-ubatan generik, supaya dapat menyumbang kepada pembangunan dan pelaksanaan dasar ubat-ubatan generik di masa depan.

# **EVALUATION OF GENERIC MEDICINES SUBSTITUTION PRACTICES AMONG COMMUNITY PHARMACISTS IN MALAYSIA AND AUSTRALIA**

## **ABSTRACT**

Many countries including Australia have developed a generic substitution policy designed to reduce medicines expenditure. In Malaysia, the government is facing a similar challenge of managing increasing medicines expenditure. However, unlike Australia, the Malaysian government has not yet implemented the generic substitution strategy. This thesis will provide some baseline data and guideline for the development of a generic substitution policy in Malaysia through direct comparison of issues around generic substitution among community pharmacists in both countries. The study aims to evaluate and compare the perceptions, knowledge and practices of generic substitution among the Malaysian and Australian community pharmacists. The patients' acceptance toward substitution and the resulting cost-saving were also evaluated and compared between the two countries.

This was a nationwide cross-sectional descriptive study. Part I of the study involved a questionnaire to assess the pharmacists' perceptions and knowledge of generic substitution. In the Part II study, data were progressively collected across the multi-sources brand name medicines requests encountered by the pharmacists. The entire populations of 1419 Malaysian community pharmacies were invited in both Part I and II studies via mail. In Australian scene, the recruitment of participants in Part I study was via self-selection using an anonymous web based survey. A national representative sample of 500 Australian community pharmacies were randomly selected and invited via mail in the Part II study.

Responses were received from 219 and 157 Malaysian and Australian pharmacist respectively in the Part I study. A higher proportion of Australian pharmacists (93.7%) than the Malaysian group (66.7%) indicated that they were willing to offer generic substitution. The Australian pharmacists significantly held more positive attitudes and better understandings of generic medicines than the Malaysian group, including issues around efficacy, safety, quality and regulatory standard of generic medicines. The response rate in Part II study was 11.1% (n = 157) and 16.4% (n = 82) respectively for both the Malaysian and Australian arm study. The Australian pharmacists significantly demonstrated higher generic substitution recommendation rate (96.4%) than the Malaysian group (84.7%). Nevertheless, Malaysian consumers' acceptance toward generic substitution (88.9%) was significantly greater than the Australian citizens (78.5%). Through acceptance of substitution, the Malaysian consumers' medicines expenditures reduced by 57.4%, as compared to around 21.0% among the Australian consumers.

In conclusion, the Malaysian pharmacists' perceptions, knowledge and practices of generic substitution need to be improved, if they are to play a future role in supporting the implementation of a generic medicines policy.



## **CHAPTER 1 GENERAL INTRODUCTION**

### **1.1 Introduction**

In an ideal healthcare system, every consumer should have timely and equal access to high quality health services at an affordable cost (Duckett, 2004a). Medicines are an accepted part of healthcare and there are high level of use of medicines in the community of Australia and Malaysia. In order to achieve equity and affordability in access to healthcare services including medicines, a developed country like Australia has implement a national health insurance scheme (Medicare) and a national medicines scheme (Pharmaceutical Benefits Scheme) to subsidize the medical expenses of the consumers in both public and private sector. Nevertheless, with the implementation of a government funded medicines subsidy scheme, the rising cost of expenditure on medicines has become a worldwide problem. The Australian Pharmaceutical Benefits Scheme (PBS) expenditure has escalated by an average of 8.4% annually from AD\$2,711 million in 1996-97 to AD\$6,227 million in 2006-07 (AIHW, 2008b) due to the increase in subsidizing expensive new medicines (ADHA, 2007a), pharmaceutical promotions (Dora & Henry, 2006) and population ageing (Duckett, 2004b; Harvey, 2002). The substantial increment in government's medicines expenses has threatened the sustainability of PBS and subsequently affects the equity and affordability in access to medicines.

The Australian government has reacted to this increasing cost of medicines by encouraging the uptake of generic medicines. Australia and other countries like US, Belgium and French have developed policies to encourage generic substitution (GS) (Allenet & Barry, 2003; McManus, Birkett, Dudley, & Stevens, 2001; Mott & Cline, 2002; Simoens, Bruyn, Bogaert, & Laekeman, 2005). In each of these countries, the community pharmacist is able to undertaken GS unless the physician does not indicate approval, therapeutic equivalence has not been demonstrated or the patient declines the substitution. The legislation of this GS policy has contributed to the slowing

growth rate of medicines expenditures in these countries (Allenet & Barry, 2003; Mott & Cline, 2002; Simoens, Bruyn, Bogaert, & Laekeman, 2005).

Malaysia is a developing country with the government highly subsidized the healthcare services in public sector. In 2006, 86% of funding in public health sector was provided by the government (WHO, 2008). The consumer can received their public health services at very low cost. For instance, charges for an outpatient visit in public hospital is RM1 per visit and this charge will include the consultation with doctor, any pathological tests and the medicines prescribed. However, the government subsidized cost for medicines in public hospital increased from RM 200 million in 1995 to RM 800 million in 2005 with an annual increment of 10-15% (Anonymous, 2004; Chua, 2005). The burden in medicines expenses has affected the government's ability to sustainably finance pharmaceutical in the public sector (Anonymous, 2004). In recent years, patients who visit a public hospital increasingly asked to buy their own medicines form private pharmacies and clinics due to the non-availability of medicines (Netto, 1999). A survey in 2003 showed 37% of the consumers obtain medicines from private hospital or clinic and 42% from community pharmacies. In fact, 56% of the consumers view medicines in private sector as expensive (Babar & Ibrahim, 2003). As there is no National Health Insurance Scheme in Malaysia, 74% of source of funding in private sector is from consumers' out-of-pocket money (WHO, 2008). As the result, the medicine's price has become the major determination of access to affordable medicines in the private health sector.

The Australian government sets medicines pricing control policies towards the medicines listed on the PBS (PBPA, 2007b). The government as the sole purchaser of medicines from drug companies has great power in negotiating the price of medicines. If the government does not accept a price, then the drug is not listed on the PBS. Prescriptions subsidized by the PBS accounts for around 90% of total prescriptions dispensed in the community and the private medicine market is rarely commercial viable (AIHW, 2008a). Consequently, the prices of PBS medicines are controlled at the affordable level for both government and consumers.

Meanwhile, the Malaysian government does not implement a policy to control the price of medicines. The manufacturers, distributors and retailers set prices without government control, thus allowing prices to be determined by market force (PSD, 2007). In the public sector, the government as the sole purchaser of medicines has significant negotiation power to lower the medicines prices. Meanwhile, without a National Health Insurance Scheme, the medicines prices in private sector are out of control of government's negotiation power. Subsequently, the wholesale prices of the medicines sold by the drug companies to the public sector are 60% cheaper than the private sector (PSD, 2007). The branded and generic medicines prices in private sector were 15-16 times and 6.6-7.0 times higher than the International Reference Prices (IRPs) which is the median of recent procurement or tender prices for multi-source product offered by non-profit suppliers to developing countries (Babar, Ibrahim, Singh, Bukahri, & Creese, 2007). As a result, uncontrolled high medicines prices in private sector have generate affordability problems among Malaysian consumers (Babar et al., 2007; Saleh & Ibrahim, 2005). In fact, the affordability problem directly reduced the equity in access among the consumers as the lower income groups have less ability to purchase medicines.

The encouragement to increase the utilization of generic medicines is one strategy to reduce Malaysian government and consumers' medicines expenses. In year 2007, the use of generic medicines in Malaysia is encouraged by the Malaysian government with the publication of the National Medicines Policy (MOH, 2007a). However, there are no generic medicines or substitution policies being implemented to driven the generic prescribing and substitution practices in both public and private sectors. Consequently, the availability of generic medicines in both public and private sectors was low (Babar et al., 2007) and the problem of increasing countries' medicines expenditures remain unsolved.

In conclusion, implementing a Generic Medicines Policy, a National Health Financing Scheme and a Medicines Pricing Control Policy are the key elements to improve the equity and

affordability of Malaysian healthcare services. Malaysian government can consider adopted these policies from countries which have good performance in their healthcare system.

## **1.2 Generic medicines use in Australia and Malaysia: A brief overview**

The Australian situation demonstrates the role of government and the development of national policies in introducing change in the health system. In the early 1990s, the Australian government started to legislate policies to encourage the use of generic medicines under the PBS (McManus, Birkett, Dudley, & Stevens, 2001). The competition between brand-name medicines and generic medicines under the PBS began with the introduction of Minimum Pricing Policy (or Brand Premium Policy) in December 1990 (McManus et al., 2001). This policy allowed different brands of the same medicine to be listed in the PBS at different prices. The government only subsidized up to the price of the “benchmark” brand which is the brand with the lowest price. Later, the pharmacists were permitted GS right with the introduction of legislation allowing brand (generic) substitution in December 1994 (Lofgren, 2004; McManus et al., 2001). The introduction of Therapeutic Group Premium (TGP) policy in February 1998 (Lofgren, 2004) also enhanced the utilization of generic medicines. The TGP policy is an extension of Brand Premium Policy which applies to medicines in a defined therapeutic subgroup which are similar efficacy and safety. The recent PBS reform which released on 16 November 2006 (ADHA, 2007b; Buckmaster & Spooner, 2007) requires the generic company to disclose the price of medicines sold to the pharmacy. The generic medicines’ price will be reduced periodically based on the disclosed price. This reform is aimed to further improve the generic medicines utilization. The details of these policies will be reviewed thoroughly in chapter 2.

In Malaysia, currently there is no generic medicines policy covering generic prescribing and substitution. In year 2007, the Malaysian National Medicines Policy documented that legislation of generic medicines policy is in the government’s future planning (MOH, 2007a). However, there is no documented time frame, framework and strategies for the legislation of generic

medicines policy. The uptake of generic medicines in Malaysia without a driving force of a generic medicine policy will be discussed in the next chapter.

### **1.3 Justification for this study**

In Australia, although GS has been allowed for Pharmaceutical Benefit Scheme medicines since 1994, the utilization of generics remain low partly due to historical legacy of small price differentials between branded and generic medicines (Lofgren, 2004). In 2001, the Australian market share of generic medicines only accounted for around 20% as compared to around 45% in US and 50% in UK (Lofgren, 2004). Over this period of time, the cost and sustainability of PBS have been a major concern for the Australian government due to high rate of increment in PBS expenditure (Buckmaster & Spooner, 2007). A recent PBS reform (2006-2008) significantly reduces the generic medicines' price and incentive will be given to pharmacist to further promote the routine use of generic medicines (ADHA, 2007b). Given the government's GS policy to encourage the use of generic medicines to reduce the PBS expenditure (McManus et al., 2001), it is important to ascertain the factors contribute to the initial low level of generic utilization in Australia and the effect of recent announced reforms. With the National Health Insurance Scheme and separation function of prescribing and dispensing between doctors and community pharmacies, the Australian pharmacists play a major role in helping government to implement pharmaceutical policies. The success of PBS reform in reducing government and consumers' medicines cost rely heavily on the community pharmacists' GS practices and their willingness to offer generic medicines to the consumer.

In Malaysia scene, there is a strong need to implement generic medicines policy in both the public and private sector to reduce government and consumers' medicines cost and subsequently improve the equity and affordability aspect. To date, there is limited documentation on GS practices in Malaysia which provide data to guide the development of generic medicines policies. The Malaysian community pharmacists are lacking opportunities to provide GS due to a lack of dispensing separation policy in Malaysia. However, there are annual

increment in the number of community pharmacies and number of patients who consult the community pharmacists regarding their choice of medicines treatment (Babar & Ibrahim, 2003). In fact, recently the Malaysian government has attempted to implement separation of prescribing and dispensing under the National Medicines Policy of Malaysia (Anonymous, 2008b; MOH, 2007a). Within this context, the pharmacists will have greater role in generic medicines use process. Therefore, studies are needed to evaluate the community pharmacists' contribution towards equity and affordability in health through their GS practices. Furthermore, as both the physicians and consumers are important stake holders in the medication distribution chain, studies are needed to evaluate their acceptance toward generic medicines.

Through the direct comparison between GS practices among Malaysian and Australian community pharmacists, this study will provide baseline data to guide the implementation of GS policy in Malaysia. This study will also indirectly provide guidance for implementing a National Health Insurance Scheme, a Medicines Pricing Control system and a Dispensing Separation policy in Malaysia through an evaluation on the Australian community pharmacists' practices.

#### **1.4 Objectives of this study**

The objectives of this comparative study were:

- 1) To evaluate and compare the GS practices among community pharmacists in Malaysia and Australia.
- 2) To evaluate and compare the perceptions and knowledge of generic medicines and substitution among community pharmacists in Malaysia and Australia.
- 3) To evaluate and compare the patients' acceptance towards GS in Malaysia and Australia.
- 4) To evaluate and compare the cost-saving achieved for the patients from GS between community pharmacies in Malaysia and Australia.
- 5) To give recommendations for future action and research based on the results of this study.

## **1.5 Overview of thesis**

Chapter 2, the literature review, starts with an overview of elements in an ideal healthcare system. A brief discussion of the performance of Australian and Malaysian healthcare systems is carried out to evaluate whether these two countries' healthcare systems have reach the ideal standard. The chapter continues with overview of Australian healthcare system starting from administration and funding of healthcare delivery system to development of pharmaceutical policies and finishes with a consideration of how the practice of pharmacists is influenced by various government policies. The examples of relevant Australian government policies, the Pharmaceutical Benefits Scheme and the generic medicines policy are discussed in depth.

The chapter continues with overview of Malaysian healthcare system. The overview starts with administration and funding of health services, followed by pharmaceutical situation in Malaysia and finally the practices of pharmacists driven by the pharmaceutical conditions in Malaysia. All the missing elements in Malaysian healthcare system in order to achieve the level of ideal health system are discussed in depth. Issues related to the use of generic medicines in Malaysia are also discussed.

Further discussion in this chapter includes the outcome of implementing GS policy from a worldwide perspective. This discussion is followed by a thorough literature review on the perception and knowledge of physicians, pharmacists and consumers towards the use and substitution of generic medicines and cost-saving achieved from GS practices in worldwide including Malaysia and Australia.

Chapter 3 details the methodology used for the studies in this thesis. Chapter 4, 5 and 6 are consolidated as Part I of the thesis which consists of the methodology, results and discussion of the first study which is a national survey designed to assess and compare the perception and knowledge of generic medicines and substitution practices among the Malaysian and Australian community pharmacists. Chapter 4 presents the findings from survey conducted with Malaysian

community pharmacists and discussion based on the findings. Meanwhile, chapter 5 details the findings from survey conducted with Australian community pharmacists and subsequent discussion based on the findings. Chapters 6 compare and discuss the findings from the Malaysian and Australian arms of the survey and draw conclusions from the findings.

Chapter 7, 8 and 9 are grouped as Part II of the thesis. Part II details the methodology, results and discussion of the second study which is a nationwide study involving community pharmacy across Malaysia and Australia to assess and compare the GS rate, patient acceptance and cost-saving achieved from substitution. Chapter 7 presents the findings from the Malaysian arm of the study and the findings are discussed. Chapter 8 describes the findings of the Australian arm study and related discussion. Finally, in chapters 9 the results from the both Malaysian and Australian arms study are compared and discussed.

In Chapter 10, conclusions from the discussion from the two studies are presented. A summary and a set of recommendations to improve the health system in both countries and for future research are provided.



## **CHAPTER 2 LITERATURE REVIEW**

### **2.1 The ideal healthcare system**

According to World Health Organization (WHO), health system is described as “all the activities whose primary purpose is to enhance, restore, or maintain health” (WHO, 2000). The WHO defined the characteristics of a well performing health system as one that should achieve three fundamental goals, which are: (i) it should be able to achieve good health, (ii) be responsiveness to the expectations of the population, and (iii) be affordable and equitable in distributing the costs of the health system across the population (termed “fair financing”) (WHO, 2000).

To achieve “good health” means to maximize the health status of the population over people’s whole life cycle. Meanwhile, “responsiveness” is measure of how the system responds to non-health aspects, and whether it meets the population’s expectations of how people should be treated by healthcare providers or non-personal services. It is an assessment of people’s satisfaction with the purely medical care they receive, such as waiting times for treatments and respect for the dignity of the person. Finally, “fair financing” means that the risks each household faces due to the expenses of the health system are distributed based on affordability to pay rather than to the risk of illness. The system should be based on fair finance to protect individuals from catastrophic healthcare cost. Nobody will be forced into poverty because of healthcare expenses (WHO, 2000).

Loewy has also attempted to define an “ideal” healthcare system. He defines it as one unencumbered by economic considerations and provide an ample supply of well-paid healthcare professionals who would supply culturally appropriate optimal healthcare to the level defined by patients (Loewy, 1998). This “ideal” health system only can exist in a society with unlimited resources for all social goods, but in reality such an ideal society hardly exists. It is more

rational to achieve a well perform healthcare system within the limits of what is possible and would optimize but not maximize the desired goals (Loewy, 1998).

### **2.1.1 Goals of an ideal healthcare system**

Apart from WHO's three overall goals of health system, others have suggested other goals for a health system. The United Nations' Committee on Economic Social and Cultural Rights set availability, accessibility, acceptability and quality of health services as goals of health system (UN, 2000). Hall and Griner proposed that an "ideal" health system must fulfill the goals of access, quality, affordability and professional satisfaction (W. J. Hall & Griner, 1993). Duckett suggested that a healthcare system can be evaluated with a two dimensional approach: quality, efficiency and acceptability on one dimension and equity on another (Duckett, 2004a). However, the WHO views the above elements like affordable, equitable, accessible, sustainable, good quality and efficiency as instrumental goals that will leads to final goals of health system (WHO, 2000). For instance, a health system which achieved instrumental goal of high accessibility will increase the number of peoples who utilize it and leads to final goal of improvement in health (WHO, 2000).

There are links between the "accessibility to healthcare" and others instrumental goals in the healthcare system (ABS, 2007, 2008b; WHO, 2007). Penchansky & Thomas define "access" as a general concept that summarizes a set of more specific dimensions which are availability, accessibility, accommodation, affordability and acceptability which describing the fit between the patient and the healthcare system (Penchansky & Thomas, 1981). Meanwhile, Gulliford and colleagues suggested that "access to healthcare" should be measured on at least four dimension which are affordability, physical accessibility, acceptability of services and equity of access (Gulliford et al., 2002). The deviations in point of views between experts and overlapping of context in the elements of health systems goals lead to difficulty in standardizing the assessment of health system performance.

### **2.1.2 Performance indicators for an ideal health system**

It is important to evaluate the performance of a health system in order to identify any weakness and subsequently developed strategies to improve the system. Recently, Kruk & Freedman have developed a framework for health system performance measures based on a systematic review of 305 research articles on indicators used in measuring health system performance (Kruk & Freedman, 2008). The starting points of the framework are the input of policies, funding and arrangement of health organization which aims to generate an effective, equitable and efficient health system. The framework groups together all the contributions of the instrumental goals (termed “output”) of health system into three major outcome measures which are “effectiveness”, “equity” and “efficiency” (see Figure 2.1).

This framework define an “effective” health system as one that is able to provide timely access to all of the components required of a health services, and ensures efficacious and safe care leading to improvement in health. The component of “effectiveness” in the healthcare system includes the outputs of “access” and “quality of care” which will lead to outcomes of “health status” and “patient satisfaction”. The “access” to healthcare further divided into three components of measurements; “availability” of healthcare services, “utilization” of services and “timeliness” in access to services. The last component of “effectiveness” is “quality of care” which stress on “efficacy” of treatment, “safety” of treatment and “continuity” in access to care (Kruk & Freedman, 2008).

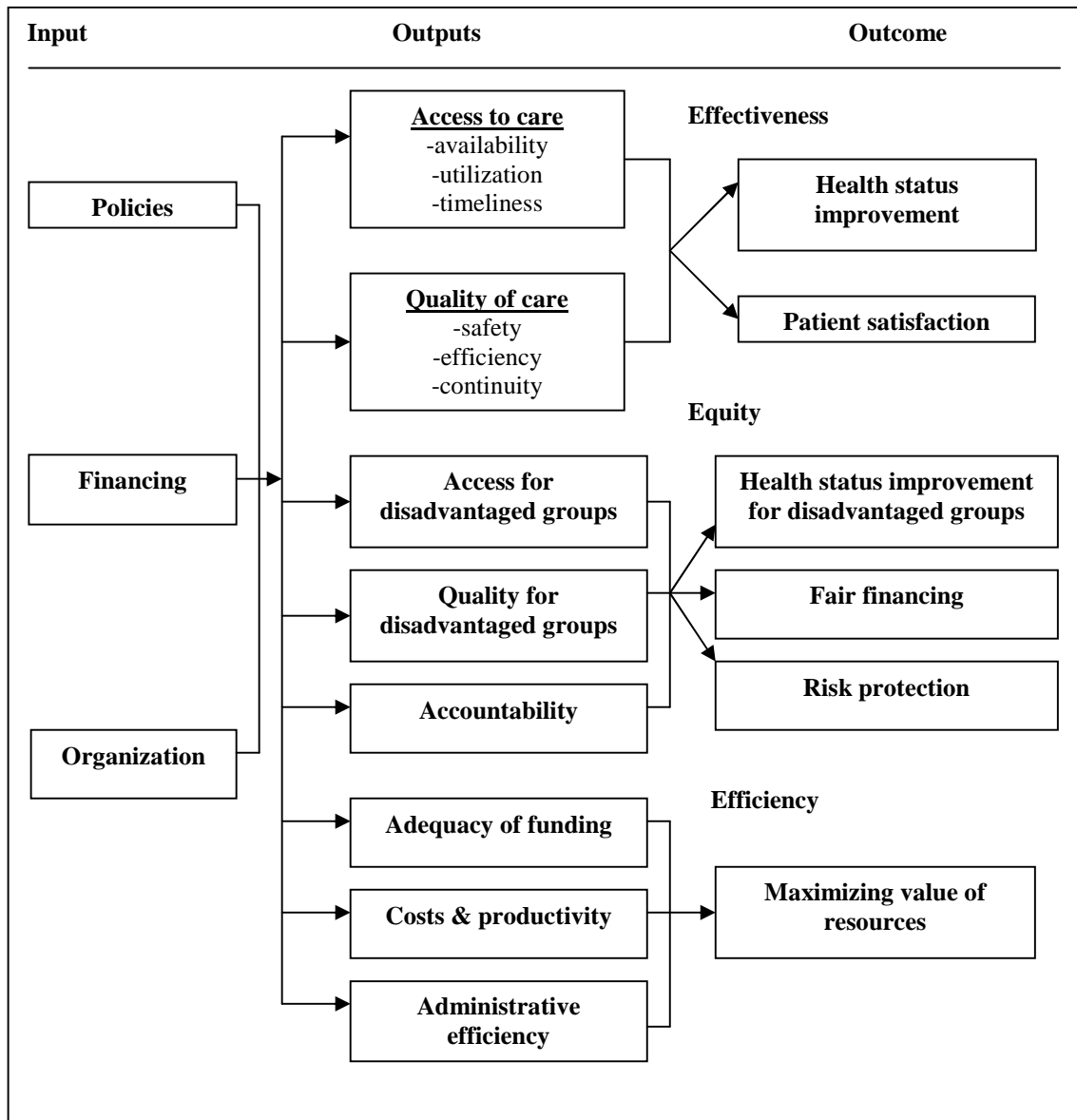
To achieve “equity” in health, all the health disparities which are unfair such as those due to poor access to services, unhealthy living or working conditions, or downward social mobility caused by ill health must be addressed. These disparities commonly related to social advantage or disadvantage such as wealth, gender, race or ethnicity. Therefore, the measurements of “equity” in healthcare system include “equitable access to care” which will result in “equitable health status”, “fair financing” and “risk protection” from financial ruin due to catastrophic health expenditures, which means the health services must be “affordable” for the whole

population. Equity in access to care is measure by analyzing the markers of effectiveness (access, quality and patient satisfaction) by income quintile, ethnicity, gender and geographic location. Meanwhile, “equitable health status” involves measuring mortality rates for lowest income quintile, women, immigrants, members of ethnic groups and populations in remote area. Measures of “equitable financing” can be performed by analysis of the distribution of government health financing to different parts of the country and different social groups, progressivity of financing methods (tax, out-of-pocket) and extent of out-of-pocket payments, indirect payments and informal fees for essential services. The component of “risk protection” can be measured by proportional of population with catastrophic health expenditures and incidence of impoverishment as a result of health payments (Kruk & Freedman, 2008).

“Efficiency” in health systems means to extract the maximum health gains from inputs of policies, funding and arrangement of organization. To achieve efficiency, the first requirement is the “adequacy of health funding”. “Cost and productivity”, and “administrative efficiency” are another two dimensions of efficiency in health system. “Adequacy of funding” can be measured by per capita healthcare spending. “Cost and productivity” involves measurements of cost per case treated (per hospital day, per out patient visit) and cost-effectiveness ratios for specific services as compared to alternative services. Lastly, “administrative efficiency” evaluates the ability of health system to maximize the value of health workers and the value of the patients’ time. The indicators for administrative efficiency include health worker attrition rates, health worker morale, frequency of supervision and training and availability of skilled worker when needed (Kruk & Freedman, 2008).

The components of “health status improvement”, “patient satisfaction” and “fair financing and risk protection” in the Kruk & Freedman framework (Kruk & Freedman, 2008) are equivalent to the three major goals of “good health”, “responsiveness to people’s expectation” and “fair financing” in the WHO’s framework (WHO, 2000). However, the WHO’s framework excludes health system’s instrumental goals of accessibility and efficiency (WHO, 2000). Both

frameworks are useful for policy makers & researchers to evaluate the performance of health systems and impact of changes in policies, funding or organization structure and subsequently develop appropriate strategies to improve the health system. The frameworks also allowed the comparison between different health systems become easier.



**Figure 2.1: Framework for measuring health systems performance** (Kruk & Freedman, 2008)

### 2.1.3 A comparison of the performance of Australian and Malaysian healthcare system

Australia is a high-income developed country with a land area of 7,692,000 square kilometer (WHO, 2007). The population is just over 21 million in 2008 (ABS, 2008b) with an annual

growth rate of 1.5% in 2007 (ABS, 2007). The population is ageing with the percentage of elderly population (over 65 years) was 13.3% whereas 19.4% of the population was below 14 years in 2006 (WHO, 2007). In 2005-06, the per capita GDP was US\$36,759.00 with the growth rate of 7.8% and the government spend 9.0% of GDP in the healthcare (AIHW, 2007; WHO, 2007). Meanwhile, Malaysia is a middle-income developing country with a size of 330,000 square kilometer (WHO, 2008). The population in 2008 is 27 million and annually growth at 1.9% as of 2006 (DSM, 2008b; WHO, 2008). The Malaysian population is relatively young with 32.4% below 14 years and only 4.3% were elderly in 2006. The per capita GDP was US\$5227.50 with the growth rate of 8.4% in year 2005. At the same year, the total expenditure on health was 3.5% of GDP (WHO, 2008).

A dual health system with both the public and private health services co-exists in Australia and Malaysia. Both the Australian and Malaysia governments highly subsidized the medical and medicines expenditure in public sector with limited contribution from the consumers. The Australian government implement national health insurance scheme to cover the medical and pharmaceutical expenditure in private sector. Conversely, there is no universal financing scheme in Malaysia and the expenditure in private health sector mainly funded through consumers' out-of-pocket money.

In year 2000, the WHO has assess the performance of healthcare system in 191 countries based on their ability to achieve the goals of "good health", "responsiveness" and "fair financing" (WHO, 2000). On the other hand, there are various studies on different dimension of health system performance being carried out in Australia and Malaysia. The aims of the following sections are to compare the performance of Australian and Malaysian health system and identified areas which needed to be improved.

### **2.1.3(a) Health status**

The WHO used “disability-adjusted life expectancy at birth (DALE)” as the indicator to assess the overall population health status and to evaluate how far the objective of good health is being achieved (WHO, 2000). DALE is a measurement of life expectancy adjusted to take account of time lived with a disability. A population with good health status is indicated by higher DALE. Australia rank number two in the WHO World Health Report 2000 with the total population’s DALE of 73.2 years (70.8 years for male; 75.5 years for female) as compared to Malaysia (ranked 89) with the DALE of 61.4 years (61.3 years for male; 61.6 years for female) (WHO, 2000). Another indicator for population’s health status is life expectancy at birth which does not adjust for the time lived with a disability. The different between these two countries were 79 years for males and 84 years for females in Australia (ABS, 2009) as compared to 72 years for males and 77 years for females in Malaysia in 2007 (DSM, 2009).

### **2.1.3(b) Responsiveness**

The WHO used two criteria to assess the responsiveness of a healthcare system. The first criteria is associated to respect for human beings like (i) respect for the dignity of the person; (ii) confidentiality on personals health information and (iii) autonomy to participate in choices about one’s own health. The second criteria is client orientation which include (i) prompt attention, (ii) amenities of sufficient quality, (iii) access to social support network and (iv) freedom in choice of provider. The overall responsiveness in Australian heath care system was ranked 12-13 whereas Malaysia was ranked 31 among 191 countries (WHO, 2000). Another survey in 2001 showed majority (63%) of Australian rated the medical care services in Australia as excellent or very good (Blendon et al., 2002).

### **2.1.3(c) Fair financing and affordability**

The WHO measured the fairness of the distribution of financial burden with an index which range from zero (extreme inequality) to 1 (perfect equality). Australia ranked 26-29 with the

index value of 0.971. However, the fair financing in Malaysia healthcare system is far behind Australia with the ranking of 122-123 (index value = 0.917) (WHO, 2000).

The health system is perfectly fair financed if the ratio of total health expenditure to total non-food expenditure is identical for all households, independently of their income, health status or use of health system. The funding would be unfair either if the poor spent a larger share than the high income groups or the high income groups spent more, as their higher capacity to pay. By paying the equal fraction, the high incomes would be subsidizing the poor. Overall, countries with universal health insurance scheme have the index value close to 1. In contrast, inequality happen in countries with high out-of-pocket health spending and the index value is far from 1. The Malaysian's out-of-pocket expenditure as percentage of total expenditure was 42.4% as compared to only 16.6% in Australia (WHO, 2000). The high out-of-pocket health expenditure in Malaysia is mainly due to the absence of social health insurance. Malaysia faces difficulty in implementing national health financing scheme due to the low general taxation which account for only 10.4% of GDP (2007 data) (DSM, 2008a; MOF, 2008). The low taxation is unable to generate a funding pool with high capacity to cover the health expenses of whole population. This problem generally happens in developing country with general taxation on average account for less than 20% of GDP (WHO, 2000). The high general taxation in Australia which account for 30.5% of GDP in 2006-07 (ABS, 2008a) enable the existence of national health insurance coverage.

There are studies particularly looking at affordability of medicines in private sectors of Malaysia which can be a barrier to access to adequate treatment. Affordability is not an issue in public sector because the medicines supply to the patients is almost free (Chua, 2005). The Malaysian government has no policy to control the prices of medicines and believes that market competition between drug companies is capable to generate fair and reasonable price (Babar et al., 2007). However study showed Malaysia has higher medicines prices as compared to other countries. For instance, in 2004, the median price ratio (MPR) of generic amitriptyline was 6.89,



which was higher than India (3.89 to 4.99), Indonesia (2.23), Kazakhstan (4.42) and Uganda (3.44) (WHO, 2006). The MPR is the comparison of the local median unit price of the medicine with the International Reference Price (IRP). In fact, a recent study showed the branded and generic medicines prices were 15-16 times and 6.6-7.0 times higher than the International Reference Prices (Babar et al., 2007). Under this circumstances, the affordability of medicines become a raised concern because unaffordable to medicines can causing prescription non-compliance (Kennedy, Coyne, & Sclar, 2004). A survey in 2003 showed majority (79%) of consumers purchased medicines from private sector (37% from private hospitals/clinics; 42% from pharmacies) as compared to 13% obtain from government hospitals. Among the respondents, 56% perceived medicines as expensive and 68% urged that government should control the prices (Babar & Ibrahim, 2003). Meanwhile, a study to measure affordability of medicines in community pharmacies showed that average 3.7 weeks of lowest government wage (US\$46.05 per week) was needed for treating moderate pneumonia (Saleh & Ibrahim, 2005). Another study was conducted to measure affordability of branded and generic medicines in private sectors. A one month treatment of Losec<sup>®</sup> (omeprazole 20mg daily) cost two weeks of lowest government wage while treatment using lowest-price generics cost about 3-4days' wage (Babar et al., 2007). Both studies concluded that medicine prices were hardly affordable for lowest income families. However, the generic medicines are more affordable than branded medicines. A survey in 2007 showed the branded medicines were about twice (114%) more expensive than generics in private sector (PSD, 2007). Nevertheless, without a generic medicines policy in Malaysia, the availability of generic medicines in private sector was low. The median availability for lowest-price generic was only 45% in private clinics and 43% in community pharmacies (Babar et al., 2007). The low availability may reduce the utilization of generic medicine which is more affordable for the lower-income groups.

Australia on the other hand supports a national subsidized medicines scheme (The PBS) with patient sharing a proportional of the costs, and the taxpayer paying for the larger portion. This is a deliberate policy initiative designed to contain the cost of medicines to the advantage of the

Australian taxpayer. This is a two stage process; the first is the focus on cost effectiveness when listing a new pharmaceutical (or brand) onto the PBS, and the second is a cost sharing mechanism whereby the public pay a co-payment system. As of 1st July 2008, when purchasing a medication under the PBS, the maximum a general patient and a concessional patient (low-income citizens and welfare recipients) paid is the patient co-payment of AD\$31.30 and AD\$5.00 respectively and the balance is subsidized by the scheme (ADHA, 2008b). Nonetheless, in the past decade, the rapid increment in PBS expenditure has force the government to release the burden of PBS expenditure through increased in patients' cost-sharing (Harvey, 2002, 2005). The PBS patients' co-payment were only AD\$20.00 for a general patient and AD\$3.20 for a concessional patient in year 1997 and the amount increased to AD\$30.70 and AD\$4.90 respectively in 2007 (Sweeny, 2007b). The increment in patient co-payment will have negative impact in both affordability and accessibility particularly among the financial disadvantage groups (Harvey, 2002). Data from the 1998 and 2001 Commonwealth Fund International Health Policy survey found that inequity in access to healthcare and medicines still existed between lower and higher income-groups in Australia due to a financial barrier (Blendon et al., 2002; Donelan, Blendon, Schoen, Davis, & Binns, 1999; Schoen et al., 2000; Schoen & Doty, 2004). Twenty one percent of lower income-groups reported a time when they did not fill a prescription due to cost as compared to 18% of higher income-groups. Conversely, United Kingdom with limited use of patient co-payment only have 7% of both lower and higher income citizens reported a time when they were noncompliance to prescription due to its cost (Blendon et al., 2002). Apart from rapid increase in PBS co-payment, another reason for inequity in access to healthcare in Australia could be that the higher income-groups were more likely than lower income-groups to purchase supplemental insurance coverage for their medical and medicines expenses. Therefore, the lower-income citizens are more exposed to financial burden due to lack of private insurance coverage (Schoen & Doty, 2004).

A few strategies have been carried out by the Australian government to ameliorate the financial barriers of access to medicines. Firstly, there are Safety Net provisions for a reduction in the

patient contribution once a family has exceeded a certain amount on PBS subsidized medicines in a calendar year. The general patients pay only AD\$5.00 per PBS prescription while the concession patient receives free PBS medicines for the rest of the calendar year. This strategy protects patients and families who needed large quantity of PBS medicines (ADHA, 2008b; Harvey, 2002). The second attempt is to control the PBS medicine prices to limit the PBS cost. The medicines prices are set by referring to the lowest-priced brand for the same medicine (Minimum Pricing Policy or Brand Premium Policy) or the medicines within a defined therapeutic sub-group with similar health outcome (Therapeutic Group Premium Policy) (Lofgren, 2004; McManus et al., 2001). The government only subsidizes up to the price of the lowest-priced brands and the consumers are required to pay the balance above the base price. As the result of these policies, the average price differences between a branded and a generic medicine was only AD\$3.03 in year 2008 (PBPA, 2008). In year 2005, the government mandated a 12.5% price-cut on the launch of the first generic brand of drug for an already PBS-listed drug (Abbott, 2005). The recent PBS reform in November 2006 required the generic companies to disclose the actual market price of the drug as a condition to be listed in the PBS. Staged price cuts will apply until the price of the medicines is based on the disclosed price (ADHA, 2007b; Faunce & Lofgren, 2007). The implementation of GS policy in 1994 is another strategy to improve affordability of medicines and reduced the government's PBS cost through increasing the utilization of generic medicines (McManus et al., 2001). The recent PBS reform further encourages the use of generics by giving pharmacy owner an incentive of AD\$1.50 to dispense a lowest-priced generic medicine (ADHA, 2007b; Faunce & Lofgren, 2007).

#### **2.1.3(d) Overall measure of attainment**

In the World Health Report 2000, the achievement in “health status”, “responsiveness” and “fair financing” have been combined into a single overall measure of attainment by an index value. Australia ranked 12 (index value = 91.3) in the overall goal attainment whereas Malaysia ranked 55 with the index value of 80.8. Japan is the top country with the index of 93.4; meanwhile Sierra Leone has the lowest index score of 35.7 (WHO, 2000).

### **2.1.3(e) Efficiency**

The efficiency of Australian and Malaysian healthcare system were ranked 32 and 49 respectively in the WHO report. The measurement was done by relating the overall measure of attainment to the resource use and human capital in the healthcare system (WHO, 2000).

### **2.1.3(f) Conclusions**

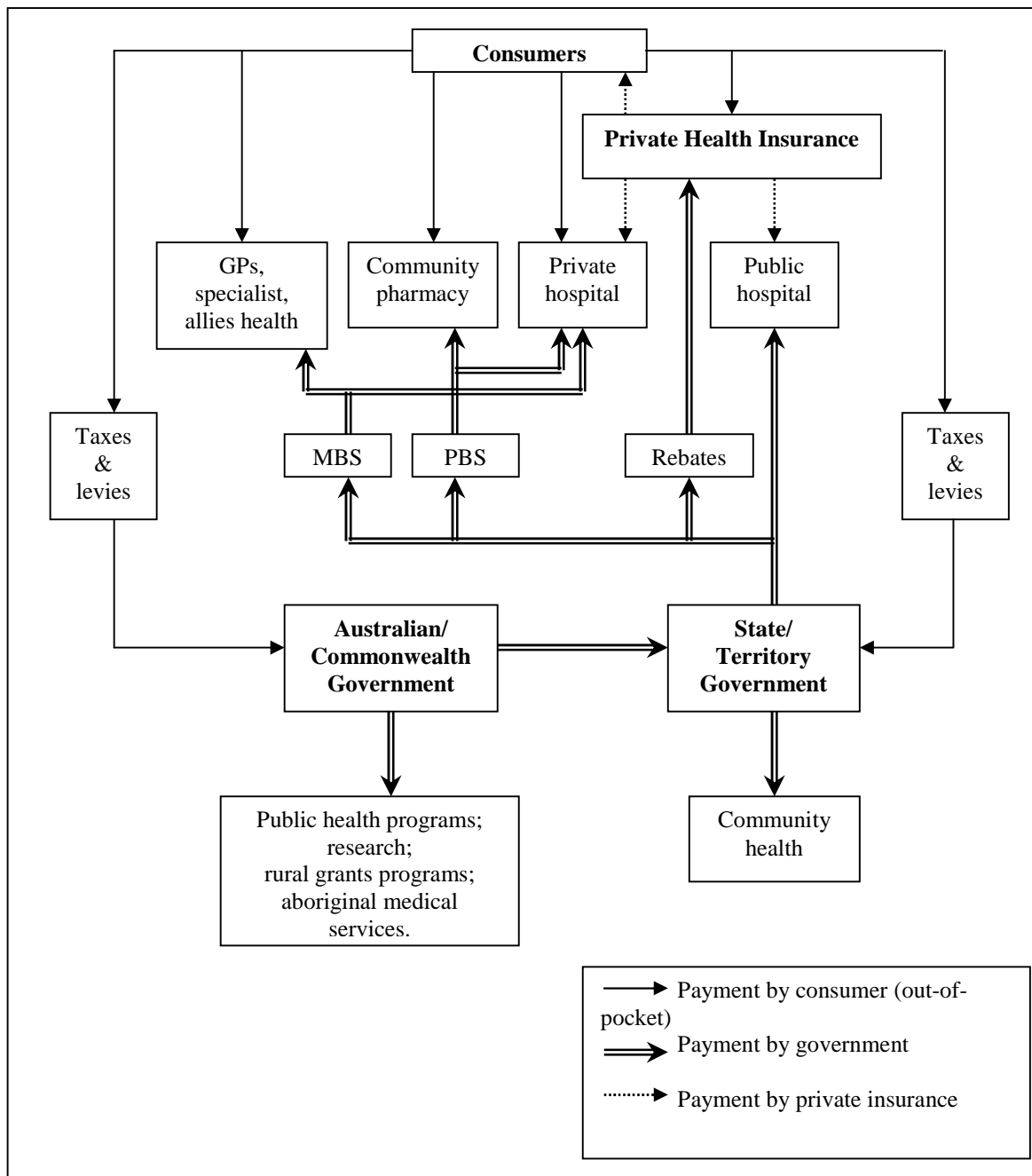
Generally Australia has better performed in regards to the performance indicators described above than Malaysia. The performance of Malaysia healthcare system in “health status”, “responsiveness” and “efficiency” are relatively high among the 191 countries in the WHO World Health Report (WHO, 2000). However, Malaysia performed unsatisfactory in “fair-financing”, particularly in affordability of medicines which will directly affect the equity and overall health outcome. In short, the Malaysian government can consider adapting the successful policies in the Australian health system to achieve fair financing and affordability in relation to medicines for its citizens. The high performance of “fair financing” in Australian health system is due to the existence of national subsidized health scheme which reduces the out-of-pocket medical and medicines expenditure. In addition, the Minimum Pricing Policy which controls the medicine prices at affordable level and cost-containment mechanisms like generic medicines policy further reduced the consumers’ medicine expenditure.

## **2.2 Australian healthcare system**

### **2.2.1 Administration and funding of health services in Australia**

Australia is a federation consisting of a national government (the Australian or Commonwealth government) and eight State and Territory governments. In addition, there are local councils in each State that have responsibility for a limited range of services delivered to the local community (for example, sanitation, local roads, planning and some public health services such as immunization) (Pink, 2008).

The majority of taxes are collected by the Commonwealth government which funds an increasing proportion of programs and services throughout Australia. The States and Territories have a range of clearly defined constitutional activities. The Australian health system is administered and funded by all three levels of government (Commonwealth, state/territory and local) and between the public and private sectors (AIHW, 2008a; Pink, 2008). The Commonwealth government is responsible for most of health service funding, operates a universal health insurance scheme (Medicare) and a subsidized medication scheme (the Pharmaceutical Benefits Scheme), regulation and licensing therapeutic products, a range of services and associated workforce and national health policy leadership.



**Figure 2.2: Flow of funding in Australian Health System** (AIHW, 2008a; Pink, 2008)

### 2.2.1(a) Medicare

Introduced in 1975 (known then as Medibank), the Medicare scheme was established by the Commonwealth government to provide and oversee Australia's tax-funded, universal public health insurance scheme (Parry, 1994; Scotton, 2000). Medicare covers all Australian citizens, permanent residents, and visitors from countries which have reciprocal arrangements with Australia who incur medical expenses for selected health services. It is funded by general

taxation and a 1.5% income tax levy (with exceptions for low-income groups). The high-income earners without private health insurance is imposed an additional levy of 1% (Pink, 2008).

Medicare administers two programs relevant to the studies conducted in this thesis:

i) Medicare Benefits Scheme (MBS) - component of Medicare which provides rebates to patients for health services provided by privately practicing doctors (GPs), specialists, optometrists and other allied health practitioners. For instance, for a GP visit, the doctor can send a bill directly to Medicare and must accept the government payment (rebate) as full settlement of the account. Conversely, the GP can bill the patient and there is no limit on that can be changed. The patient can claim the Commonwealth set rebate from Medicare for the GP's fee later (Pink, 2008). MBS does not cover people attending a public hospital which falls in the States' responsibilities.

ii) The Pharmaceutical Benefits Scheme (PBS) - component of Medicare which provides rebates to patients for a wide range of necessary and cost-effective prescription medicines obtain from community pharmacy (Graham, 1995; Sansom, 2004). The Medicare eligible patients are categorized into general and concessional patients (pensioners, low-income earners and welfare recipients). When purchasing a PBS medicine, the maximum price a general patient pay is the patient co-payment contribution which, as of 2008 is AD\$31.30. Meanwhile, a concessional patient only pays AD\$5.00 per prescription item. The PBS pays the pharmacist the balance between the co-payment and the dispensed price of the medicine as listed in the PBS. The PBS protects the patients and families who required large amount of PBS medicines from the cumulative effect of patient co-payment through a Safety Net Scheme with an annual threshold. In 2008, the Safety Net Thresholds are AD\$1141.80 (general patient) and AD\$290.00 (concession patient). When a patient incurs cumulative costs singly or as a family above the safety threshold amount during the course of a year, the general patients are entitled to PBS medicines at the concession price while concession patient can obtain PBS medicines free of charged for the remainder of the year (ADHA, 2008c).

In certain circumstances, patients may pay an extra fee in addition to the co-payment. This extra patient contribution is known as either a “brand premium” or “therapeutic premium” and has resulted where there is disagreement between the manufacturer and the government over the dispensed price for that benefit item (ADHA, 2008c). A further explanation of brand and therapeutic premium will be in Section 2.2.4(a) of this chapter.

In 2005-06, Australia’s estimated total pharmaceutical expenditure was AD\$10,551 million which mostly funded by the government (83.0%) and the remaining 17% was covered by individual out-of-pocket expenses. The majority of this pharmaceutical expenditure was for benefit-paid pharmaceuticals (69.1% or AD\$7,286 million), which also mostly funded by the government (80.6%) and 16.1% was due to patient co-payment (AIHW, 2007).

#### **2.2.1(b) Private health insurance**

The private health insurance co-exists with and supplements the Medicare system. It covers part or all of private treatment charges to private patients, in either a public or private hospital. It also helps to fund some ancillary services such as dentistry and physiotherapy (J. Hall, 1999; Pink, 2008). In 1999, the Australian government started to subsidized private health insurance premium through a 30% rebate, with higher rebates for elderly (35% for aged 65-69 years and 40% for aged 70 years and over) (Pink, 2008). Since then, the population with private hospital insurance coverage increased drastically from 31% in 1999 to 44% in 2007 and the governments increased their share of public and private hospital funding by 5.6% due to the effect of this private insurance rebate scheme (AIHW, 2007; Pink, 2008).

#### **2.2.1(c) Public hospital sector**

The public hospital is the responsibility of the State or Territory governments but is jointly funded by the Commonwealth (J. Hall, 1999; Pink, 2008). Patients who admitted to public hospital can choose to be treated as public or private patients. Public patients receive treatment from doctors and specialists nominated by the hospital and are free of charged for the treatment.



Private patients can select their personal healthcare providers, but charges are applied for all of the services. Medicare subsidizes the fees charged by doctors and private health insurance covers medical fees and the hospital costs. The public hospitals have their own pharmacies which provide free access to medicines for admitted Medicare eligible patients. The State and Territory governments are responsible for the cost of drugs used in public hospitals. However, a recent initiative is changing this when a state or territory government enters into a reform agreement with the Australian government, in which medicines provided to non-admitted patient may be charged to the PBS (Pink, 2008). In 2005-06, there were 755 public hospitals, including 19 psychiatric hospitals. The public hospital beds representing 68% of all beds in the hospital sector with the ratio of 2.7 beds per 1,000 populations (Pink, 2008).

#### **2.2.1(d) Private health sector**

The private health sector funds around one third of all healthcare, with 19% of total health expenditure was funded by consumers' out-of-pocket expenses and the rest was funded by government and private health insurance (Pink, 2008). The private health services include:

- i) Medical and allied health practitioners.
- ii) Community pharmacists who dispensed most prescribed pharmaceuticals.
- iii) Private age-care facilities which provide high-level residential aged-care beds.
- iv) Private health insurers provide rebates for ancillary health services and hospital treatment as a private patient.
- v) Injury compensation insurers providing worker's compensation.
- vi) Third-party motor vehicle insurance.
- vii) Private hospital which provide one-third of all hospital beds in Australia. There were 547 private hospitals in operations in 2005-06.