GENERIC MEDICINES: THE BIG PICTURE

Kami Memimpin *We Lead*

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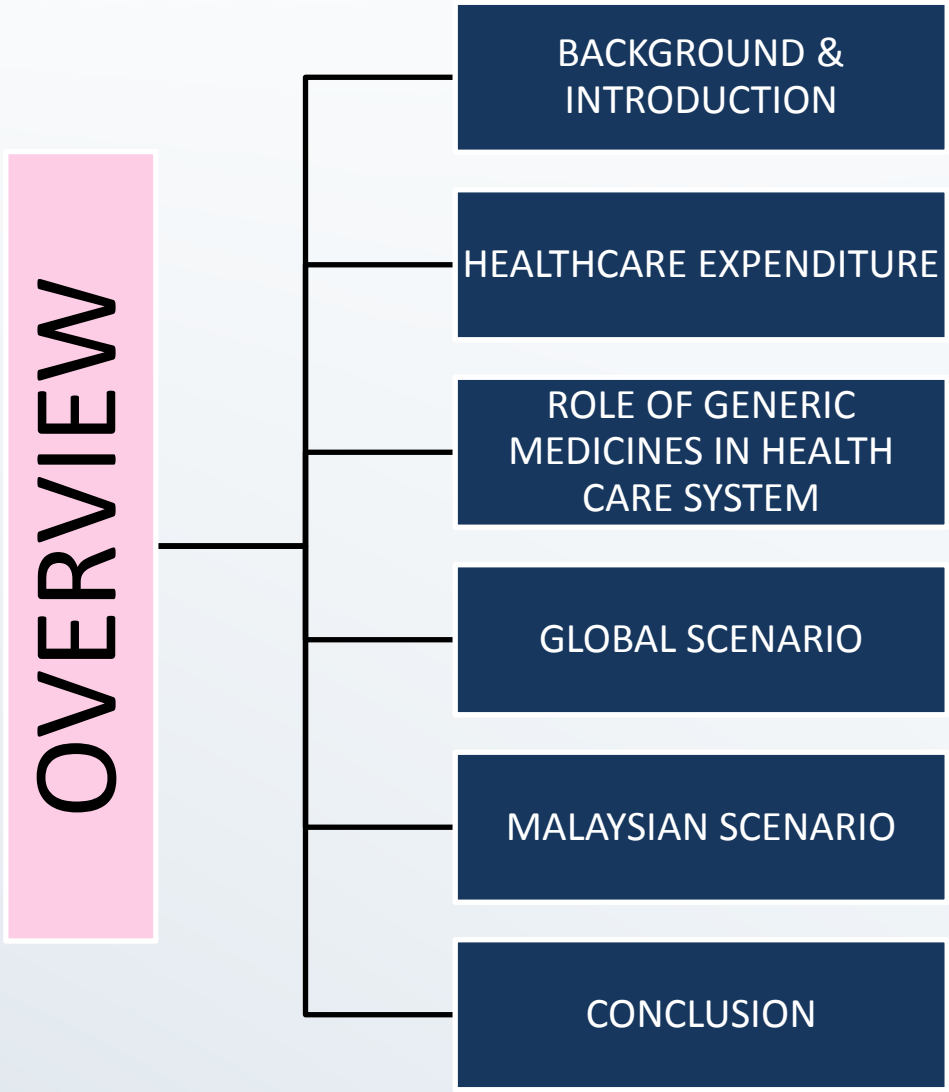
Disclosure of Conflict of Interest

Presenting Author Has No Relationships to Disclose


OVERVIEW
BACKGROUND & INTRODUCTION
HEALTHCARE EXPENDITURE
ROLE OF GENERIC MEDICINES IN HEALTH CARE SYSTEM
GLOBAL SCENARIO
MALAYSIAN SCENARIO
CONCLUSION

Introduction

- ✓ Most of countries around the globe are facing the challenges of growing healthcare demand with limited available resources
- ✓ Era of 'the best care that medicine can provide' is slowly being replaced by a new slogan, 'the best care we can afford' (Wettermark *et. al.* 2009)
- ✓ In middle and lower income countries, expenditure on pharmaceuticals ranges from 20 to 60% of total spending on health (Godman *et al.* 2010)
- ✓ Pressures to control pharmaceutical expenditure have led to increased prescribing and dispensing of low cost generic drugs (Araszkiewicz *et al.* 2008)

Leading Causes For Increase In Healthcare Costs

- Ageing population
- Increase in incidence of diseases
- Health technologies advancement
- Administrative cost

Need cost-effective approaches to ensure better use of limited health care dollars

Definition of 'Generic Medicine'

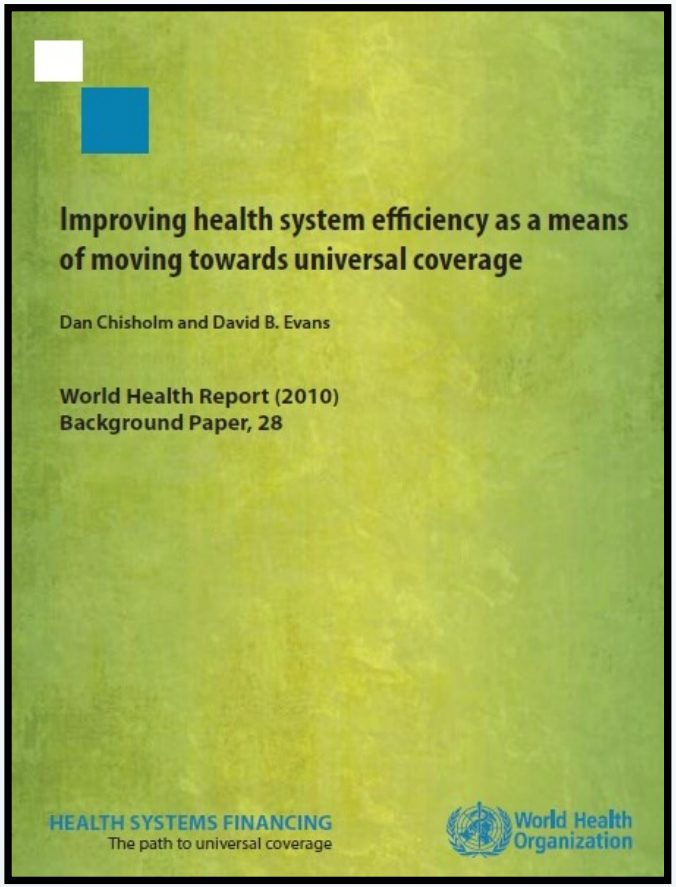
- In the USA, the FDA, which is responsible for registering and marketing authorization, defines generic medicine as 'a medicine that is identical, or bioequivalent, to a brand name medicine in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use'
- The EMA defines generic medicines as "a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bio-equivalence with the reference medicinal product has been demonstrated by appropriate bio-availability studies"*

** Definition adopted by the Malaysian NPRA*

The Importance of Generic Pharmaceuticals

The World Health Report (2010) identified the following ten leading cause for health systems inefficiency:

- **Medicines - use of sub standard and counterfeits**
- **Medicines - inappropriate and ineffective use**
- **Medicines - underuse of generics**
- **Health care products & services - overuse**
- **Health workers - inappropriate or costly staff mix**
- **Health care services - inappropriate hospital admission and length of stay**
- **Health care services - inappropriate hospital size**
- **Health care services - medical errors and suboptimal quality of care**
- **Health system leakages - waste, corruption & fraud**
- **Health interventions- inefficient mix/inappropriate strategies**



The Importance of Generic Pharmaceuticals

- Lower prices
- Competition and innovation
- Access to essential medicines.
- Supply continuity.
- Economic development and employment
- Savings for national healthcare systems

Original Paper

Generic Medicines

The expanding world market of generic pharmaceuticals

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SAGE

Yannik Brems[1,2], Jonathan Seville[1] and Jan Baeyens[1]

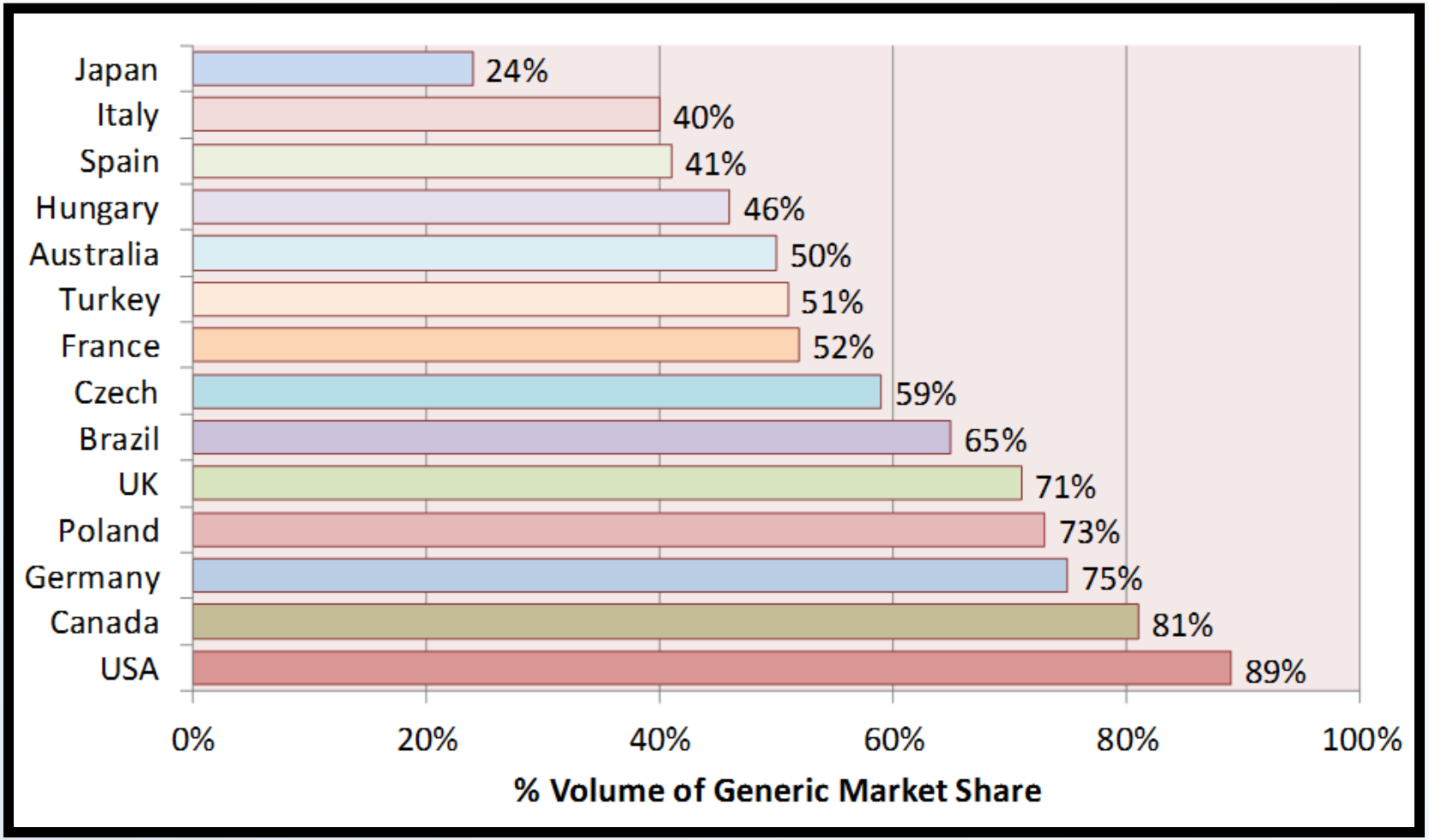
Abstract

The advantages of generic pharmaceuticals are acknowledged by policy makers worldwide, provided efficient national policies are in place, generics are available at reduced prices, drive competition and innovation, enhance access to essential medicines, ensure supply continuity, stimulate economic development, and generate savings for healthcare systems.

This paper reviews the world market of generic pharmaceuticals, with special emphasis on the current situation and expected future development. Besides providing a global picture, different regions are separately examined by both assessing recent market analyses data, and by including recent literature on generics and their role in enhancing access to essential medicines. In view of the challenges in developing countries, the Republic of South Africa is dealt with in more detail. The analysis stresses the importance of this highly dynamic and competitive market, expected to continue to grow in the future, thus remaining an attractive business for new entrants, for mergers and for acquisitions.

Ref: Brems et al, Journal of Generic Medicines, 2011

Utilization of Generic Medicines



Ref: IMS Health Dec 2016

Promotion of access to essential medicines for non-communicable diseases: practical implications of the UN political declaration

Hans V Hogerzeil, Jonathan Liberman, Veronika J Wirtz, Sandeep P Kishore, Sakthi Selvaraj, Rachel Kiddell-Monroe, Faith N Mwangi-Powell, Tido von Schoen-Angerer, on behalf of The Lancet NCD Action Group

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See Comment page 602
See Comment *Lancet* 2013; 381: 509
This is the fifth in a Series of five papers about non-communicable diseases

Department of Global Health, University of Groningen, University Medical Centre, Groningen, Netherlands (Prof HV Hogerzeil FRCP Edin); McCabe Centre for Law and

Access to medicines and vaccines to prevent and treat non-communicable diseases (NCDs) is unacceptably low worldwide. In the 2011 UN political declaration on the prevention and control of NCDs, heads of government made several commitments related to access to essential medicines, technologies, and vaccines for such diseases. 30 years of experience with policies for essential medicines and 10 years of scaling up of HIV treatment have provided the knowledge needed to address barriers to long-term effective treatment and prevention of NCDs. More medicines can be acquired within existing budgets with efficient selection, procurement, and use of generic medicines. Furthermore, low-income and middle-income countries need to increase mobilisation of domestic resources to cater for the many patients with NCDs who do not have access to treatment. Existing initiatives for HIV treatment offer useful lessons that can enhance access to pharmaceutical management of NCDs and improve adherence to long-term treatment of chronic illness; policy makers should also address unacceptable inequities in access to controlled opioid analgesics. In addition to off-patent medicines, governments can promote access to new and future on-patent medicinal products through coherent and equitable health and trade policies, particularly those for intellectual property. Frequent conflicts of interest need to be identified and managed, and indicators and targets for access to NCD medicines should be used to monitor progress. Only with these approaches can a difference be made to the lives of hundreds of millions of current and future patients with NCDs

Increase efficiency in selection, procurement, supply, and use to promote access to medicines within the existing health budget

Generic policies

Data from several countries show that access to medicines for NCDs can be substantially improved within existing budgets for pharmaceutical medicines by optimisation of the selection, procurement, supply, and use of medicines. For example, legislation can promote generic market entry and substitution, which are further facilitated by quality assurance systems to reassure prescribers and the public, price information promoting the financial advantages of generics, and reimbursement schemes promoting generic substitution and reduced patient copayments for generic products. Policies that promote generic medicines can generate large savings; in France, implementation of a general generic substitution strategy saved nearly US$2 billion in 2008 alone.[29] Policies promoting the use of safe, affordable, effective, and quality generic medicines should address the effect of mark-ups and of poor purchasing practice, and any perception that low price equals low quality.[33,34]

Ref: Hogerzeil, H. V., Liberman, J., Wirtz, V. J., Kishore, S. P., Selvaraj, S., Kiddell-Monroe, R., ... & Lancet NCD Action Group. (2013).. The Lancet,

Appl Health Econ Health Policy
DOI 10.1007/s40258-013-0043-z

CURRENT OPINION

Generic Medicines: Solutions for a Sustainable Drug Market?

Pieter Dylst · Arnold Vulto · Brian Godman · Steven Simoens

Abstract Generic medicines offer equally high-quality treatment as originator medicines do at much lower prices. As such, they represent a considerable opportunity for authorities to obtain substantial savings. At the moment, the pharmaceutical landscape is changing and many pharmaceutical companies have altered their development and commercial strategies, combining both originator and generic divisions. In spite of this, the generic medicines industry is currently facing a number of challenges: delayed market access; the limited price differential with originator medicines; the continuous downwards pressure on prices; and the negative perception regarding generic medicines held by some key stakeholder groups. This could jeopardize the long-term sustainability of the generic manufacturing industry. Therefore, governments must focus on demand-side policies, alongside policies to accelerate market access, as the generic medicines industry will only be able to deliver competitive and sustainable prices if they are ensured a high volume. In the future, the generic medicines industry will increasingly look to biosimilars and generic versions of orphan drugs to expand their business.

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Published online: 12 July 2013

Key Points for Decision Makers

- Generic medicines offer substantial savings and contribute to the long-term sustainability of health care.
- The clear division between Big Pharma and generic companies will disappear over time.
- Governments' continuous downwards pressure on generic medicine prices could threaten their long-term sustainability.
- Governments should focus on demand-side policies, alongside policies to accelerate market access, to address the various challenges the generic industry is currently facing.

1 Introduction

The development of new medicines is a costly process with a high risk of failure [1, 2]. For instance, the chance of successful market launch for a medicine entering phase I trials decreased from approximately 10 % in 2002 to 5 % in 2008 [2]. Innovator companies incur a great risk in the development of new medicines and are rewarded

Ref: Dylst,P et al. Appl Health Econ Health Policy. 2013 Jul 12.

Initiatives to Reduce Prescription Cost: The European

Table 1: Definition and examples of the 4Es

Measure (4Es)	Explanation and initiatives
Education	• Activities range from simple distribution of printed material to more intensive strategies including academic detailing and monitoring of prescribing habits. • Examples include: ⇨Education of trainee doctors in medical schools to prescribe by INN, e.g. UK. ⇨Information and other campaigns among patients to address any fears about the effectiveness and/or safety of generics including speaking with patients to address any fears, e.g. France. ⇨Physicians and pharmacists developing a list of potentially non-substitutable products where there are concerns with bioequivalence as well as the therapeutic equivalence of generics, e.g. Sweden and UK.
Engineering	• This refers to organisational or managerial interventions. • Examples include substitution targets for certain drugs in community pharmacies if physicians are still prescribing the originator, e.g. France.
Economics	This includes financial incentives for physicians, patients and pharmacists, e.g.: • Higher co-payments for patients if they wish to receive a more expensive product than the current referenced price molecule, e.g. Finland, Sweden. • Devolution of drug budgets to physicians with sanctions for over-budget situations, e.g. Germany, Sweden and UK.
Enforcement	This includes regulations by law such as mandatory INN prescribing or mandatory generic substitution at pharmacies apart from a limited number of agreed situations, e.g. Lithuania and Sweden.

Based on references [1-3, 8, 14, 16, 18, 19]; INN: international non-proprietary name.

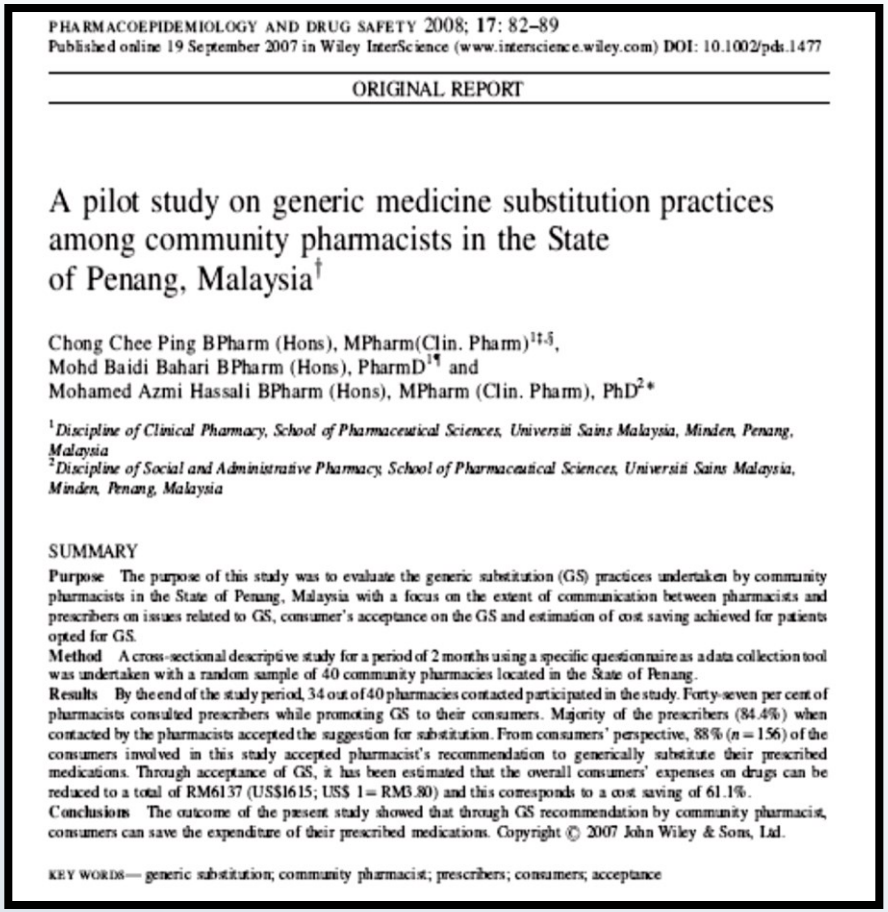
Opportunities for Generic Use

Product Trade name	Generic name	Company	Sales figures for 2002		Sales figures for 2003		Sales figures for 2004		Sales figures for 2006	Patent Expiry	Patent Extension
			(US$ billion)		(US$ billion)		(US$ billion)		(US$ billion)		
			Company	IMS	Company	IMS	Company	IMS	Company Projection		
Lipitor®	Atorvastatin	Pfizer	7.9	8.6	9.23	10.3	10.86	12	8.32	30/05/06	24/09/09
Zocor®	Simvastatin	Merck	5.6	6.2	5.01	6.1	5.2	5.9	3.06	24/04/01	23/12/05
Celebrex®	Celecoxib	Pfizer	3	NA	1.9	2.5	3.3	NA	1.61	30/11/13	
Fosamax®	Alendronate	Merck	2.2	NA	2.5	NA	3.1	NA	1.89	4/11/2003	6/8/2007
Zoloft®	Sertraline	Pfizer	2.74	NA	3.1	3.4	3.36	NA	2.04	20/08/02	30/12/05
Zyprexa®	Olanzapine	Eli-Lilly	3.6	4	4.27	4.8	4.42	4.8	2.32	23/04/11	
Risperdal®	Risperidone	Johnson & Johnson	2.1	NA	2.5	NA	3	NA	2.44	14/02/06	29/12/07
Effexor®	Venlafaxine	Wyeth	2	NA	2.7	NA	3.3	3.7	2.54	13/12/02	13/12/07
Norvasc®	Amlodipine	Pfizer	3.8	4	4.33	4.5	4.46	4.8	2.59	25/02/03	31/07/06
Plavix®	Clopidrogrel	Sanofi-Aventis	3.1	NA	4.2	3.7	5.2	5	2.83	12/2/2008	17/11/11
Prevacid®	Lansoprazole	Takeda	3.7	3.6	3.3	4	3.1	3.8	3.45	29/07/05	10/5/2009
Advair®	Fluticasone; Salmetrol	GSK	2	NA	3.6	NA	4.5	4.7	3.8	12/2/2008	
Nexium®	Esomeprazole	AstraZeneca	1.97	NA	3.3	3.8	3.88	4.8	4.94	1/9/2007	1/9/2007

Ref : Journal of Generic Medicines 2008; 5(3): 201-208.
Ref: Drug Discovery Today 2005; 10(1): 739-742.

Savings Via Generics Use: Malaysian Local Data

In Malaysia, generic medicines are much less expensive than innovator brands and generally costing between 30 to 90 per cent less



PHARMACOEPIDEMIOLOGY AND DRUG SAFETY 2008; 17: 82–89
Published online 19 September 2007 in Wiley InterScience (www.interscience.wiley.com) DOI: 10.1002/pds.1477

ORIGINAL REPORT

A pilot study on generic medicine substitution practices among community pharmacists in the State of Penang, Malaysia†

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SUMMARY

Purpose The purpose of this study was to evaluate the generic substitution (GS) practices undertaken by community pharmacists in the State of Penang, Malaysia with a focus on the extent of communication between pharmacists and prescribers on issues related to GS, consumer's acceptance on the GS and estimation of cost saving achieved for patients opted for GS.

Method A cross-sectional descriptive study for a period of 2 months using a specific questionnaire as a data collection tool was undertaken with a random sample of 40 community pharmacies located in the State of Penang.

Results By the end of the study period, 34 out of 40 pharmacies contacted participated in the study. Forty-seven per cent of pharmacists consulted prescribers while promoting GS to their consumers. Majority of the prescribers (84.4%) when contacted by the pharmacists accepted the suggestion for substitution. From consumers' perspective, 88% ($n = 156$) of the consumers involved in this study accepted pharmacist's recommendation to generically substitute their prescribed medications. Through acceptance of GS, it has been estimated that the overall consumers' expenses on drugs can be reduced to a total of RM6137 (US$1615; US$ 1 = RM3.80) and this corresponds to a cost saving of 61.1%.

Conclusions The outcome of the present study showed that through GS recommendation by community pharmacist, consumers can save the expenditure of their prescribed medications. Copyright © 2007 John Wiley & Sons, Ltd.

KEY WORDS— generic substitution; community pharmacist; prescribers; consumers; acceptance

Ref: Ping, Bahari & Hassali ,2008

Price comparison between innovator and generic medicines sold by community pharmacies in the state of Penang, Malaysia

Received (in revised form): 2nd September, 2008

Asrul Akmal Shafie
graduated with a pharmacy degree from the University of Science, Malaysia in 2001 and was registered as a professional pharmacist in Malaysia in 2002. He was awarded USM fellowship in 2003 to pursue a doctorate degree in pharmacoeconomics which he successfully completed at Cardiff University, UK in 2007. During this time, he also undertook a postgraduate diploma in Health Economics at the University of Glamorgan. His current research interests are in the area of health economics, and social and administrative pharmacy. Currently, Dr Shafie is attached to the Discipline of Social & Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia.

Mohamed Azmi Hassali
graduated with a pharmacy degree from the University of Science, Malaysia in 1998. Following his pharmacy pre-registration training at Hospital Teluk Intan, Perak, he undertook his Master's studies in the field of clinical pharmacy at USM and graduated in 2000. In 2006, he was successfully awarded a PhD degree from the Victorian College of Pharmacy, Monash University, Melbourne in the field of pharmacy practice. His current research interests are in the areas of clinical pharmacoeconomics, social pharmacy and the pharmacists' role in public health. Currently, Dr Azmi is attached to the Discipline of Social & Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia.

Abstract Generic medicines play a key role in the affordability of pharmaceuticals. This study aims to compare price and to document the actual savings that can be achieved if generics are used by consumers in the state of Penang, Malaysia. This is a cross-sectional pilot study on the price of innovator and generic medicines for the 20 most-used medications in Malaysia. Upon consent, 20 retail pharmacies were conveniently selected. A pre-validated data collection form was used to collect their selling price from the community pharmacist. The analysis was limited to medicines in the same dosage form and dose. Those still under patent protection or combined with other active ingredients were excluded from the study. This study found that most innovator drugs are 27–90 per cent more expensive than generics. Some generic drugs are, however, more expensive than their innovator counterparts (40 per cent higher). Some locally produced generics are also more expensive than foreign products. The current findings suggest that consumers can save up to 90 per cent of the cost of their medication by using generic products. Further investigation is needed to explore the causality of the observed differences in price of products in order to increase their accessibility to the general population.

Journal of Generic Medicines advance online publication, 21 October 2008; doi:10.1057/jgm.2008.25

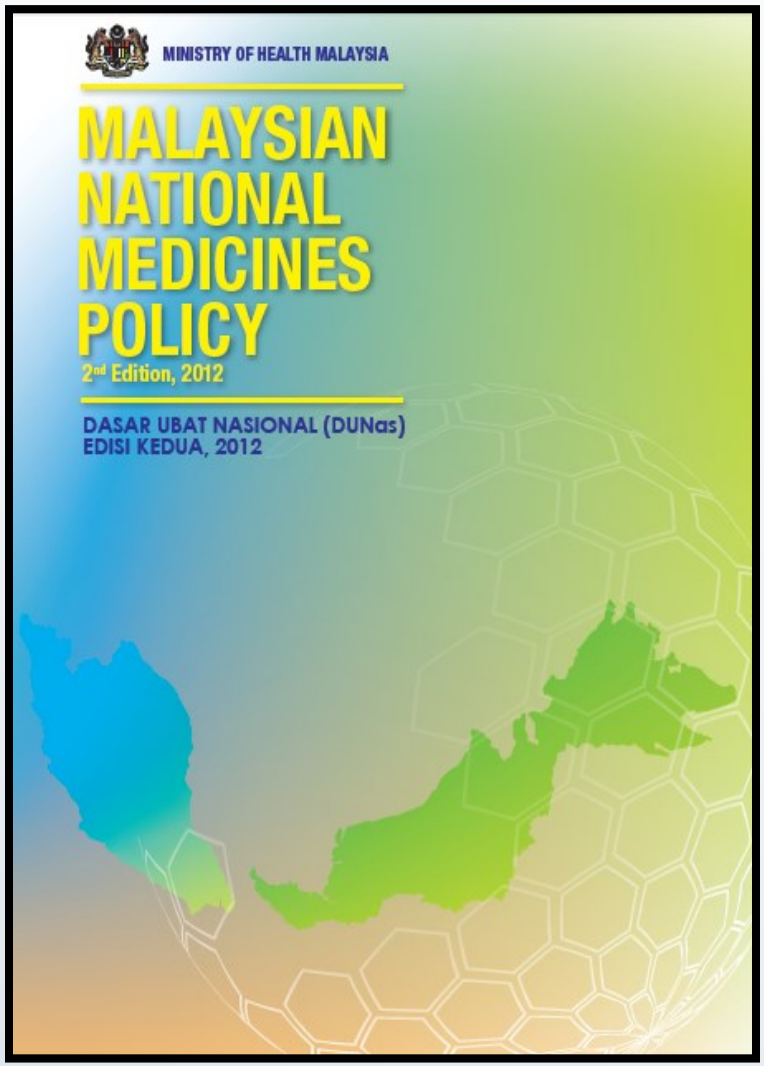
Keywords: generic medicines, pricing, saving, cost, Malaysia

Ref: Shafie & Hassali, 2008.

Generic Pricing: Experience From Malaysia

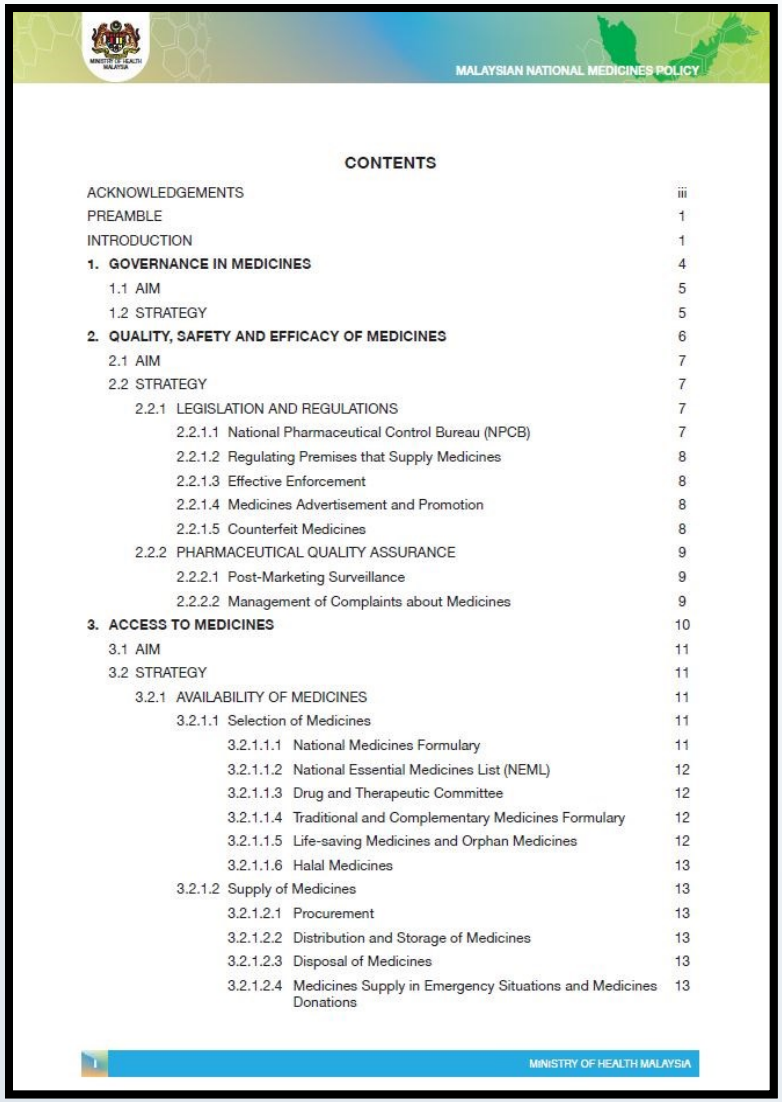
- **Subjected to similar regulatory control**
- **Much cheaper**
  - *Clopidogrel 75mg* ***RM 6.80 (USD 1.80)*** *vs* ***RM 2.10 (USD 0.60)*** *per tablet*
  - *Atorvastatin 20mg* ***RM 4.00 (USD 1.05)*** *vs* ***RM 1.20 (USD 0.32)*** *per tablet*
  - *Simvastatin 20mg* ***RM 2.10 (USD 0.60)*** *vs* ***RM 0.60 (USD 0.15)*** *per tablet*

Generic Medicines Policy in Malaysia



- **Prescribing** in generic International Non-proprietary Name (**INN**) shall be practised at all channels
- **Procurement** of all medicines by generic **INN** shall be promoted
- In selection for **procurement, priority** shall be given to **domestically manufactured medicines**
- All dispensed medicines shall be **labelled** prominently with the **generic INN** of the medicine with or without the brand name
- A **list of interchangeable** and non-interchangeable medicines shall be available
- **Generic substitution** shall be permitted and legislated for all interchangeable medicines
- **Appropriate incentives** to promote the **use** of generic medicines and their **production**

Generic Medicines Policy in Malaysia



MALAYSIAN NATIONAL MEDICINES POLICY

CONTENTS

1. **Procurement** of multi-source products by **generic names** shall be promoted to foster healthy competition in drug pricing.

2. **Appropriate incentives** to promote the **use** of generic drugs and their **production** in the country shall be introduced.

3. A **formulary of interchangeable** generic drugs and the list of products that cannot be substituted shall be made available.

4. All dispensed drugs shall be **labelled with the generic (INN)** name of the medicine with or without the brand name.

5. **Generic prescribing** and **labelling** should be encouraged, and generic substitution permitted and eventually legislated, in order to improve affordability of medicines.

Malaysian Economic Transformation Program (ETP)

- Launched on 25 September, 2010, the ETP was formulated as part of Malaysia's National Transformation Programme.
- **Aim**: to elevate the country to developed-nation status by 2020, targeting GNI per capita of US$15,000.
- The ETP's targets for 2020 will be achieved through the implementation of 12 National Key Economic Areas (NKEA).
- These areas representing economic sectors which account for significant contributions to GNI.
- The ETP represents the catalyst for economic growth and investments needed for Malaysia to achieve high-income status by 2020.

National Key Economic Areas (NKEA)

Oil, Gas and Energy

Palm Oil & Rubber

Financial Services

Tourism

Business Services

Electronics & Electrical

Wholesale & Retail

Education

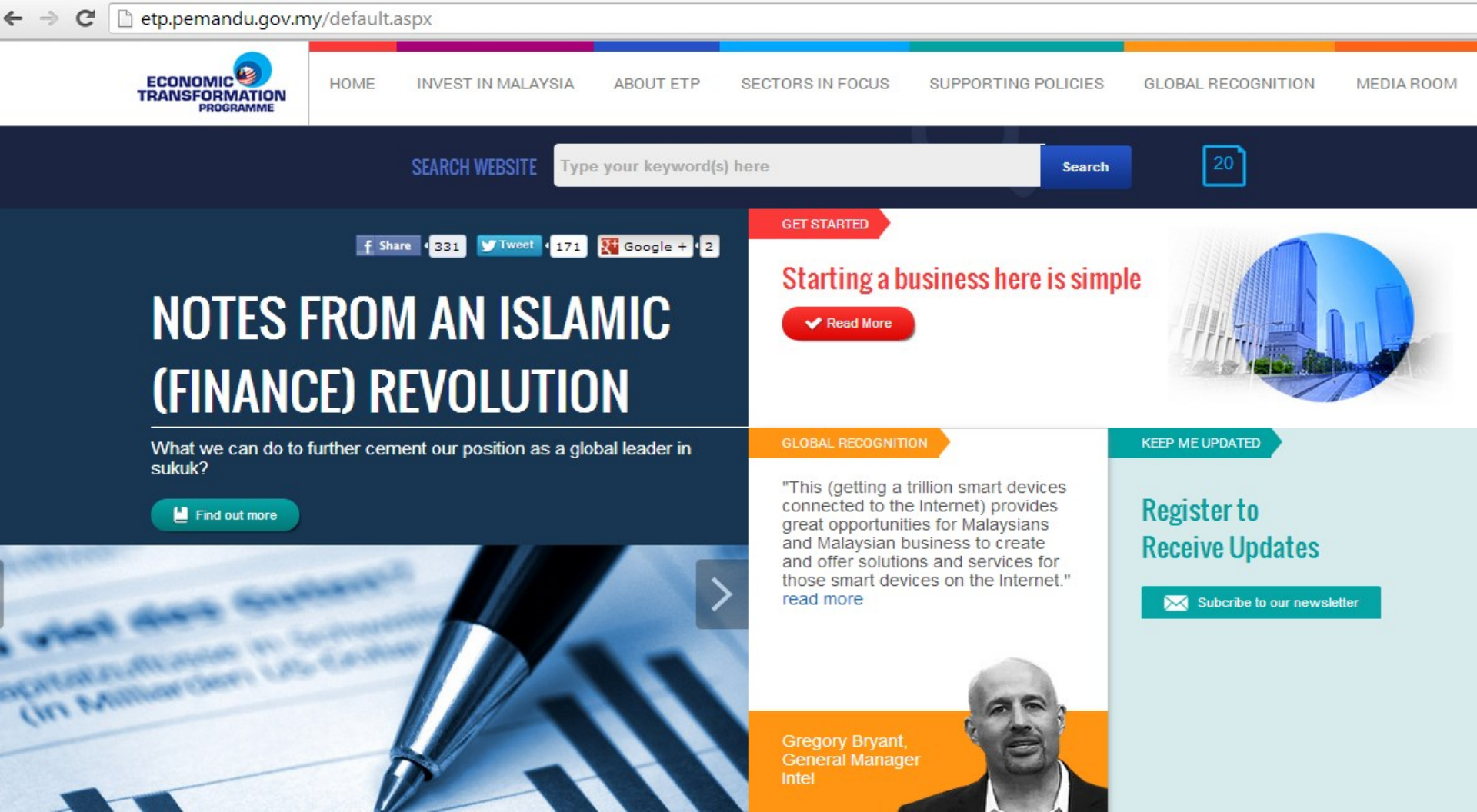
Healthcare

Communications Content and Infrastructure

Agriculture

Greater Kuala Lumpur/ Klang Valley

ETP Official Website



List of Entry Point Projects (EPP)

EPP 1: Mandating Private Insurance for Foreign Workers

EPP 2: Creating Supportive Ecosystem to Grow Clinical Research

EPP 3: Malaysian Pharmaceuticals – Increasing Local Generic Manufacturing for Exports

EPP 4: Reinvigorating Healthcare Travel

EPP 5: Creating a Diagnostic Services Nexus

EPP 6: Developing a Health Metropolis: A World-Class Campus for Healthcare and Bioscience

EPP 7: Upscale Malaysia's In-Vitro Diagnostic (IVD) Industry

EPP 8: Build Malaysian Showcase on Next Generation of Core Single Use Device (SUD) Products

EPP 9: Become the Hub for High-Value Medical Devices Contract Manufacturing

EPP 10: Malaysian Clinical Device Champions

EPP 11: Medical Equipment Supply Chain Orchestration

EPP 12: Medical Refurbishment Hub

EPP 13: Build Medical Hardware and Furniture Cluster

ETP: Health Care EPP3

ECONOMIC TRANSFORMATION PROGRAMME

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- Wholesale & Retail
- Education
- Healthcare
- Communications Content & Infrastructure

EPP 3: Malaysian Pharmaceuticals - Increasing Local Generic Manufacturing for Exports

GNI by 2020 (mil) RM 13,853.7

Projected jobs by 2020 12,440

This EPP seeks to capitalise on the impending expiry of patents on major drugs to increase Malaysia's generic drug manufacturing capacity. In order for the country to reap the benefits from this market, estimated to be worth US$132 billion, the Malaysian industry must take the following measures:

- Leverage the country's membership in The Organisation of the Islamic Cooperation and the

NKEA's Key Players

- University of Malaya
- Medical Devices Corporation
- KPJ Healthcare Berhad

GET STARTED

Whether you're an individual or a corporation, the process of starting a business here is simple.

EPP 3: Malaysian Pharmaceuticals – Increasing Local Generic Manufacturing for Exports

A few of the strategies under EPP were to:

a) Promote Malaysia as a **member** in the Organisation of the Islamic Cooperation and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme **(PIC/S)** to widen the export opportunities

b) Upgrade the **domestic manufacturing plants**

c) Have **good relationships** between **multinational corporations** and **domestic manufacturers**

d) Ministry of Health (MOH) off-take procurement agreement with new local manufactured pharmaceuticals.

MOH Off-take Agreement (3+2)

The MOH: **main buyer** of the manufacturer's future production **for 3 years** with the condition that the product must be manufactured in Malaysia. The agreement could be **extended for another 2 years** if the manufacturer demonstrates that the product can be registered and marketed in other countries

Pharmaceutical Inspections Cooperation Scheme

Pharmaceutical Inspections Cooperation Scheme

- Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP.
- Malaysia's participation as a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) since 2002.
- PIC/S is an international instrument between countries and pharmaceutical inspection authorities, which together provide an active and constructive cooperation in the field of GMP.
- Pharmaceutical products from members of PIC/S are of high quality because PIC/S ensures that all members comply with PIC/S standards at all times (i.e. assessment of new applicants and reassessment of existing member inspectorates).

Members of PIC/S

37	Slovenia	Agency for Medicinal Products and Medical Devices
38	South Africa	Medicines Control Council
39	Spain	Agencia Española del Medicamento y Productos Sanitarios *(Spanish Agency of Drugs and Health Products)*
40	Sweden	Medical Products Agency
41	Switzerland	Swiss Agency for Therapeutic Products
42	Ukraine	State Administration of Ukraine on Medicinal Products
43	United Kingdom	Medicines and Healthcare Products Regulatory Agency
44	United States of America	United States Food and Drug Administration

Ref: Pharmaceutical Inspection Co-operation Scheme (PIC/S). Members and partners. 2013 [updated 2013 December 12; cited 2013 December 20]; Available from: http://www.picscheme.org/members.php.

Members of PIC/S

24	Latvia	Zāļu Valsts Aģentūra *(State Agency of Medicines)*
25	Liechtenstein	Amt für Gesundheit *(Office of Healthcare)*
26	Lithuania	State Medicines Control Agency
27	Malaysia	National Pharmaceutical Control Bureau
28	Malta	Medicines Authority Malta
29	Netherlands	Inspectie voor de Gezondheidszorg *(Inspectorate of Health Care)*
34	Romania	National Agency for Medicines and Medical Devices
35	Singapore	Health Sciences Authority
36	Slovak Republic	State Institute for Drug Control

- **Malaysia become member of PIC/S at 1st January 2002.**
- **Malaysia is the second country Asian country to gain accession after Singapore.**

Current Situation in Malaysia

- Despite the availability of some pro-generic policies, there is a lack of implementation and enforcement through legislations
- In comparison with developed countries (e.g. USA, Australia) where pro-generic medicine policies and initiatives are in place including:
  - generic substitution policy
  - interchangeable medicines formulary
  - differential copayment system that encourage patients to accept generic medicines
  - incentives/profit margin to encourage pharmacists to recommend generic medicines
  - extensive educational campaigns targeting both healthcare professionals and patients
- However, the situation in Malaysia is relatively comparable with south-east Asian countries such as Thailand.
- Moreover, the situation in Malaysia is relatively comparable with Japan in terms of the challenges related to negative perceptions and misconceptions about safety, quality and efficacy of generic medicines among healthcare professionals and medicine consumers.

Issues Related To Generic Medicine Use

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Review Article

Consumers' views on generic medicines: a review of the literature

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Abstract

Objectives To review the literature on consumers' knowledge, attitudes and opinions of the use of generic medicines.

Method A narrative review of studies conducted from 1970 to 2008 on consumers' perceptions and views towards generic medicines was performed. An extensive literature search was undertaken using indexing services available at the authors' institution library. The following keywords were used for the search: brand, generic, multisource, medications, medicines, drugs, pharmaceuticals and consumers, customers, and patients. Electronic databases searched were Medline, Inside Web, ISI Web of Knowledge, Science Direct, Springer Link, JSTOR, Proquest, Ebsco Host and Google Scholar. These electronic databases were searched for full text papers published in English from 1970 to October 2008.

Key findings Twenty studies were identified. Eleven were from the USA, four were from Europe, two were from Canada and one each was from Australia, Brazil and Malaysia. In general, consumers showed mixed reactions towards the use of generic medicines. This was evident from the divergence of views observed by country development level, consumers' socioeconomic characteristics, drug product characteristics, pharmaceutical reimbursement system, policy environment, contact with health care professionals, past experience with medications, and knowledge of the seriousness of a medical condition.

Conclusions Patient confidence and knowledge pertaining to generic medicines use have increased over the past four decades, especially in developed countries. Mass educational efforts, financial incentives, and greater communication among patients and health care professionals were seen as major drivers to the uptake of generic medicines among consumers.

Keywords consumer; generic medicines; knowledge; perceptions; policy

Consumers: Major barriers to acceptance includes:

- *Preference for GP's prescribed brand of medicine,*
- *Concern over safety and efficacy of generic medicines,*
- *Concern about adverse effects from generic brands, and confusion that may arise from using different brands of the same medicine.*

Ref: Hassali MA et al. Int J Pharm Pract. 2009 Apr;17(2):79-88

People Assume Expensive Drugs Work Better!!!

- A study published in JAMA March 2008 evaluated the influence of drug price on the efficacy of medical therapies.
- A total of 82 healthy paid volunteers were recruited into an established pain study (using electrical shocks administered to the wrist area).
- Subjects were told that they would receive an FDA-approved opioid preparation, although in reality they were given a placebo.
- Subjects were randomized into 2 groups: those that were told the drug was a standard price and those that were told the drug had been discounted (no reason given for the discount).

People Assume Expensive Drugs Work Better!!!

RESEARCH LETTER

Commercial Features of Placebo and Therapeutic Efficacy

To the Editor: It is possible that the therapeutic efficacy of medications is affected by commercial features such as lower prices. Because such features influence patients' expectations,[1] they may play an unrecognized therapeutic role by influencing the efficacy of medical therapies, especially in conditions associated with strong placebo responses.[2,3] To investigate this possibility, we studied the effect of price on analgesic response to placebo pills.

Methods. In 2006 we recruited 82 healthy paid volunteers in Boston, Massachusetts, using an online advertisement. Each participant was informed by brochure about a (purported) new opioid analgesic approved by the Food and Drug Administration; it was described as similar to codeine with faster onset time, but it was actually a placebo pill. After randomization, half of the participants were informed that the drug had a regular price of $2.50 per pill and half that the price had been discounted to $0.10 per pill (no reason for the discount was mentioned). All participants received identical placebo pills and were paid $30. Participants were blinded to the study purpose, and researchers were blinded to group assignment. The study was approved by the Massachusetts Institute of Technology institutional review board, and all participants provided written informed consent and were debriefed after the study.

The protocol followed an established approach for studying pain.[4] Electrical shocks to the wrist were calibrated to each participant's pain tolerance. After calibration, participants received the test shocks, rating the pain on a computerized visual analog scale anchored by the labels "no pain at all" and "the worst pain imaginable." Participants received all possible shocks in 2.5-V increments between 0 V and their calibrated tolerance. Stimulation at each intensity level was carried out twice for each participant (before and after taking the pill), and the change in reaction to the stimulation was assessed. Visual analog scale ratings were converted to a 100-point scale, the postpill score for each voltage was subtracted from the prepill score, and the mean of these differences was calculated for each participant.

The percentage of participants experiencing a mean score reduction vs increase was compared between the 2 groups using a 2-tailed χ^2 test. Because stronger pain may be associated with stronger placebo responses,[3] we also compared results for the 50% most painful shocks for each participant. In addition, mean differences at each voltage between the 2 groups were compared overall with a sign test and individually with F tests. A P value of .05 was considered statistically significant. Analyses were performed using SPSS version 15 (SPSS Inc, Chicago, Illinois).

Results. Patient characteristics are shown in the TABLE. In the regular-price group, 85.4% (95% confidence interval [CI], 74.6%-96.2%) of the participants experienced a mean pain reduction after taking the pill, vs 61.0% (95% CI, 46.1%-75.9%) in the low-price (discounted) group (P=.02). Similar results occurred when analyzing only the 50% most painful shocks for each participant (80.5% [95% CI, 68.3%-92.6%] vs 56.1% [95% CI, 40.9%-71.3%], respectively; P=.03).

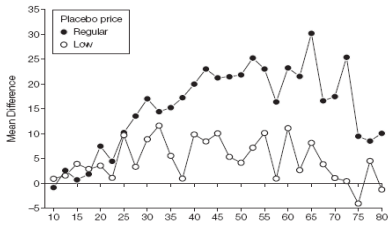
Considering all voltages tested, pain reduction was greater for the regular-price pill (P<.001). In addition, for 26 of 29 intensities (from 10 to 80 V), mean pain reduction was greater for the regular-price pill (FIGURE).

Table. Comparison of Participants Assigned to Regular-Price Placebo vs Low-Price (Discounted) Placebo

	Regular Price (n = 41)	Low Price (n = 41)	P Value
Women, No. (%)	27 (65.9)	24 (58.5)	.50
Age, mean (SD), y	30.9 (12.4)	30.0 (11.4)	.74
Calibrated maximum tolerance, mean (SD), V	51.8 (18.7)	54.9 (23.3)	.50
Shocks received, No. (SD)	18.2 (7.2)	18.6 (9.1)	.80
Change in pain scores[a]			
All shocks, No. (%) [95% CI]			
Pain reduction	35 (85.4) [74.6-96.2]	25 (61.0) [46.1-75.9]	.02[b]
Pain increase	6 (14.6) [3.8-25.5]	16 (39.0) [24.1-54.0]	
Highest-intensity shocks only, No. (%) [95% CI][c]			
Pain reduction	33 (80.5) [68.3-92.6]	23 (56.1) [40.9-71.3]	.03[b]
Pain increase	8 (19.5) [7.4-31.6]	18 (43.9) [28.7-59.1]	

Abbreviation: CI, confidence interval.
[a] Comparison of participants experiencing a mean reduction in pain after vs before the placebo pill was administered (visual analog scale point reduction between 0.01 and 48.4) and those experiencing a mean increase in pain (visual analog scale point increase between 0 and 29.2).
[b] Two-tailed χ^2 test.
[c] Highest 50% of shocks by intensity.

Figure. Pain Ratings by Voltage Intensity



No.														
Regular price	41	41	41	40	37	31	27	23	21	20	18	14	12	9	8
Low price	41	41	41	40	38	31	29	27	24	19	17	11	7	5	4

Mean difference in pain ratings, after vs before placebo, by voltage intensity. Higher value indicates greater pain reduction. The table depicts the intensity of the shocks and the number of observations in the regular-price and low-price conditions. P value is less than .05 for the shock intensities 27.5 V through 30.0 V, 35.0 V through 75.0 V, and 80.0 V.

Comment. These results are consistent with described phenomena of commercial variables affecting quality expectations[1] and expectations influencing therapeutic efficacy.[4] Placebo responses to commercial features have many potential clinical implications. For example, they may help explain the popularity of high-cost medical therapies (eg, cyclooxygenase 2 inhibitors) over inexpensive, widely available alternatives (eg, over-the-counter nonsteroidal anti-inflammatory drugs) and why patients switching from branded medications may report that their generic equivalents are less effective. Studies of real-world effectiveness may be more generalizable if they reflect how medications are sold in addition to how they are formulated. Furthermore, clinicians may be able to harness quality cues in beneficial ways,[5] for example, by de-emphasizing potentially deleterious commercial factors (eg, low-priced, generic).

These findings need to be replicated in broader populations and clinical settings to better understand how communicating quality cues with patient populations can maximize treatment benefits and patient satisfaction.

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Author Contributions: Dr Ariely had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Waber, Shiv, Carmon, Ariely.
Acquisition of data: Waber.
Analysis and interpretation of data: Waber, Ariely.
Drafting of the manuscript: Waber, Shiv, Ariely.
Critical revision of the manuscript for important intellectual content: Waber, Shiv, Carmon, Ariely.
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Ref: Waber, R. L., Shiv, B., Carmon, Z., & Ariely, D. (2008). Jama, 299(9), 1016-7.

Issues Related To Generic Medicine Use

Prescribers/Pharmacists: Major barriers to acceptance includes:

- Possibility of patient confusion and a low level of confidence with generic medicines.
- Loyalty to companies involved in research and development.
- Lack of knowledge on issues surrounding bioequivalence testing for generic medicines.


Contents lists available at ScienceDirect

Health Policy

journal homepage: www.elsevier.com/locate/healthpol

Perspectives of physicians practicing in low and middle income countries towards generic medicines: A narrative review

Mohamed Azmi Hassali, Zhi Yen Wong, Alian A. Alrasheedy, Fahad Saleem, Abdul Haniff Mohamad Yahaya, Hisham Aljadhey

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ABSTRACT


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Health Policy

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Evaluating community pharmacists' perceptions of future generic substitution policy implementation: A national survey from Malaysia

Chee Ping Chong, Mohamed Azmi Hassali, Mohd Baidi Bahari, Asrul Akmal Shafie

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ABSTRACT

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Prescribers Awareness On Issues Surrounding Generic Medicines

Health Policy 95 (2010) 229–235

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A survey exploring knowledge and perceptions of general practitioners towards the use of generic medicines in the northern state of Malaysia

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ABSTRACT

Objectives: The objective of this study was to evaluate the general practitioners' (GPs') knowledge and perceptions towards generic medicines in a northern state of Malaysia.
Method: A postal cross-sectional survey involving registered GPs in Penang, Malaysia was undertaken. A 23-item questionnaire was developed, validated and administered on the GPs. Eighty-seven GPs responded to the survey (response rate 26.8%).
Results: The majority of the respondents (85.1%) claimed that they actively prescribed generic medicines in their practice. On the other hand, only 4.6% of the respondents correctly identified the Malaysia's National Pharmaceutical Control Bureau's bioequivalence standard for generic products. There were misconceptions among the respondents about the concepts of "bioequivalence", "efficacy", "safety", and "manufacturing standards" of generic medicines. GPs in this survey believed that a standard guideline on brand substitution process, collaboration with pharmacists, patient education and information on safety and efficacy of generic medicines were necessary to ensure quality use of generics. Furthermore, advertisements and product bonuses offered by pharmaceutical companies, patient's socio-economic factors as well as credibility of manufacturers were factors reported to influence their choice of medicine.
Conclusion: Although it appeared that GPs have largely accepted the use of generic medicines, they still have concerns regarding the reliability and quality of such products. GPs need to be educated and reassured about generic products approval system in Malaysia concerning bioequivalence, quality, and safety. The current findings have important implications in establishing generic medicines policy in Malaysia.

- The majority of the respondents (85 %) claimed that they actively prescribed generic medicines in their practice.
- Only 5% of the respondents correctly identified the Malaysia's National Pharmaceutical Control Bureau's bioequivalence standard for generic products
- As many as 52% of the respondents thought that manufacturing standards for generic medicines were not as stringent as for branded products.

Ref: Chua, G. N., Hassali, M. A., Shafie, A. A., & Awaisu, A. (2010).. Health policy, 95(2), 229-235.

Educational Impact among Prescribers on Generic Medicine Use

Original Article

SAGE Open Medicine

Does educational intervention improve doctors' knowledge and perceptions of generic medicines and their generic prescribing rate? A study from Malaysia

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SAGE

Mohamed Azmi Hassali[1], Zhi Yen Wong[2], Alian A. Alrasheedy[1], Fahad Saleem[1], Abdul Haniff Mohamad Yahaya[2] and Hisham Aljadhey[3]

Abstract

Objectives: To investigate the impact of an educational intervention on doctors' knowledge and perceptions towards generic medicines and their generic (international non-proprietary name) prescribing practice.

Methods: This is a single-cohort pre-/post-intervention pilot study. The study was conducted in a tertiary care hospital in Perak, Malaysia. All doctors from the internal medicine department were invited to participate in the educational intervention. The intervention consisted of an interactive lecture, an educational booklet and a drug list. Doctors' knowledge and perceptions were assessed by using a validated questionnaire, while the international non-proprietary name prescribing practice was assessed by screening the prescription before and after the intervention.

Results: The intervention was effective in improving doctors' knowledge towards bioequivalence, similarity of generic medicines and safety standards required for generic medicine registration ($p = 0.034$, $p = 0.034$ and $p = 0.022$, respectively). In terms of perceptions towards generic medicines, no significant changes were noted ($p > 0.05$). Similarly, no impact on international non-proprietary name prescribing practice was observed after the intervention ($p > 0.05$).

Conclusion: Doctors had inadequate knowledge and misconceptions about generic medicines before the intervention. Moreover, international non-proprietary name prescribing was not a common practice. However, the educational intervention was only effective in improving doctors' knowledge of generic medicines.

Keywords

Education, generic medicine, generic prescribing, doctor, Malaysia

Date received: 26 June 2014; accepted: 18 September 2014

Introduction

Healthcare expenditure was escalating throughout the years.[1,2] Moreover, pharmaceutical expenditure had been reported as the second main driver for healthcare cost escalation after healthcare professional wages.[3] A similar scenario was observed in Malaysian healthcare system.[4] In this ever challenging scenario of healthcare provision, utilization of generic medicines is identified as one of the effective mechanisms to curb the escalating pharmaceutical cost.[5–8] Indeed, wide use of generic medicines led to substantial cost savings.[8–10] In fact, in Malaysia, generic medicines are approximately 30%–90% cheaper than original brand medicines.[11]

In view of the cost-saving benefits of generic medicines, various policies were formulated to improve the use of

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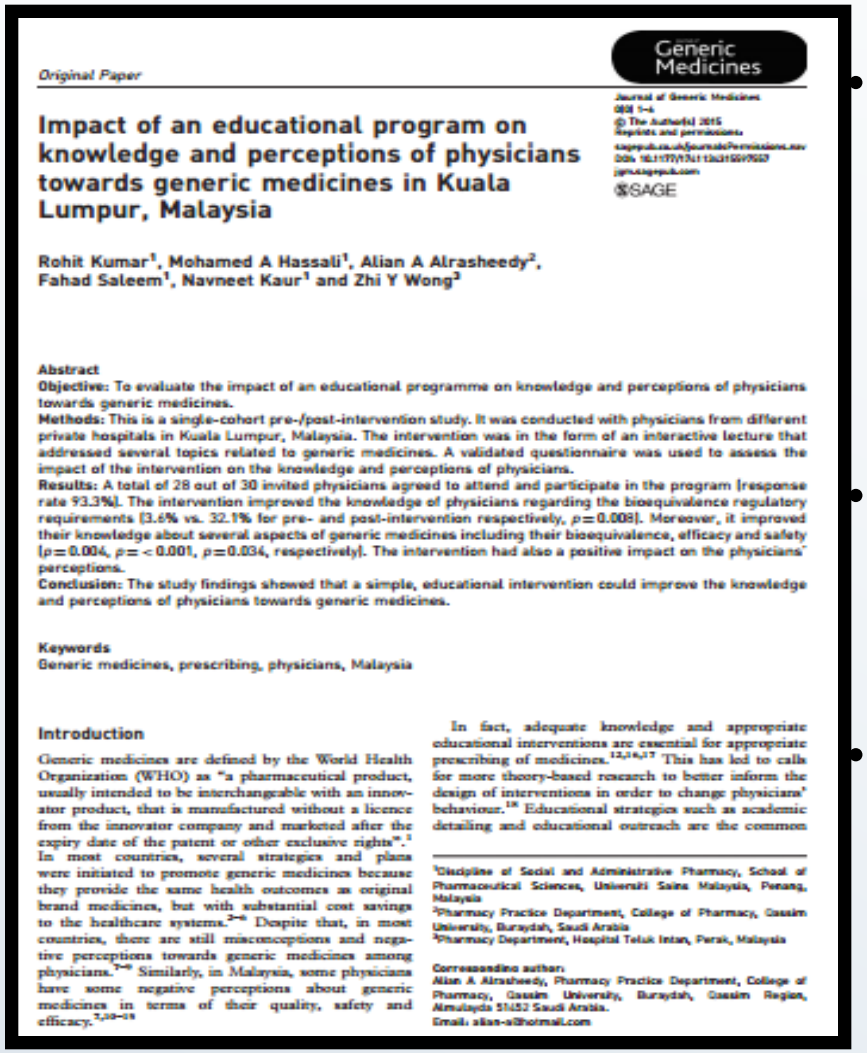
Ref: Hassali, M. A., Wong, Z. Y., Alrasheedy, A. A., Saleem, F., Mohamad Yahaya, A. H., & Aljadhey, H. (2014).. SAGE Open Medicine.

- Education increases the doctor's knowledge of the biochemical standards of the National Pharmaceutical Control Bureau of Malaysia (33% vs 86.7% for before and after intervention).
- It also enhances doctors' knowledge of safety, bioequivalence, efficacy of generic drugs.
- However, education does not have a positive impact on the doctor's perspective on how to write a prescription using a generic drug name.

Educational Impact among Prescribers on Generic Medicine Use



Original Paper

Generic Medicines

Impact of an educational program on knowledge and perceptions of physicians towards generic medicines in Kuala Lumpur, Malaysia

Rohit Kumar[1], Mohamed A Hassali[1], Alian A Alrasheedy[2], Fahad Saleem[1], Navneet Kaur[1] and Zhi Y Wong[3]

Abstract

Objective: To evaluate the impact of an educational programme on knowledge and perceptions of physicians towards generic medicines.

Methods: This is a single-cohort pre-/post-intervention study. It was conducted with physicians from different private hospitals in Kuala Lumpur, Malaysia. The intervention was in the form of an interactive lecture that addressed several topics related to generic medicines. A validated questionnaire was used to assess the impact of the intervention on the knowledge and perceptions of physicians.

Results: A total of 28 out of 30 invited physicians agreed to attend and participate in the program (response rate 93.3%). The intervention improved the knowledge of physicians regarding the bioequivalence regulatory requirements (3.6% vs. 32.1% for pre- and post-intervention respectively, $p = 0.008$). Moreover, it improved their knowledge about several aspects of generic medicines including their bioequivalence, efficacy and safety ($p = 0.004$, $p = < 0.001$, $p = 0.034$, respectively). The intervention had also a positive impact on the physicians' perceptions.

Conclusion: The study findings showed that a simple, educational intervention could improve the knowledge and perceptions of physicians towards generic medicines.

Keywords

Generic medicines, prescribing, physicians, Malaysia

Introduction

Generic medicines are defined by the World Health Organization (WHO) as "a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a licence from the innovator company and marketed after the expiry date of the patent or other exclusive rights".[1] In most countries, several strategies and plans were initiated to promote generic medicines because they provide the same health outcomes as original brand medicines, but with substantial cost savings to the healthcare systems.[2–6] Despite that, in most countries, there are still misconceptions and negative perceptions towards generic medicines among physicians.[7–9] Similarly, in Malaysia, some physicians have some negative perceptions about generic medicines in terms of their quality, safety and efficacy.[7,10–13]

In fact, adequate knowledge and appropriate educational interventions are essential for appropriate prescribing of medicines.[12,14,15] This has led to calls for more theory-based research to better inform the design of interventions in order to change physicians' behaviour.[16] Educational strategies such as academic detailing and educational outreach are the common

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- Education increased the doctor's knowledge of the biochemical standard of the National Pharmaceutical Control Bureau of Malaysia (3.6% vs. 32.1% for pre- and post-intervention)
- It also increased the doctor's knowledge of safety, biochemistry, efficacy of generic drugs
- Education has a positive impact on the doctor's perspective on generic drugs.

Ref: Kumar, R., Hassali, M. A., Alrasheedy, A. A., Saleem, F., Kaur, N., & Wong, Z. Y. (2015. Journal of Generic Medicines, 12(1), 4-10.

Good References For Busy Practitioners

Frequently asked questions about generic medicines

Andrew J McLachlan, Professor of Pharmacy (Aged Care), Centre for Education and Research on Ageing, Concord Repatriation General Hospital and Faculty of Pharmacy, University of Sydney; Iqbal Ramzan, Professor of Pharmaceutics, Faculty of Pharmacy, University of Sydney; and Robert W Milne, Associate Professor, Sansom Institute, School of Pharmacy and Medical Sciences, University of South Australia, Adelaide

Summary

In Australia, generic products must be bioequivalent to the innovator brand name product, or the market leader, before they are approved. Australia has rigorous scientifically-based evaluation procedures for generic medicines based on the internationally accepted principle of bioequivalence. Under the Pharmaceutical Benefits Scheme, generic substitution is only permitted if two products are bioequivalent. Consumers should be encouraged to know and record the name of the active ingredient in the medicines they are receiving to avoid confusion between different brands of medicines. Healthcare professionals have a key role in helping consumers understand any real or perceived differences (or lack thereof) between different brands of medicines. Prescribing generics helps to contain health costs.

Key words: bioequivalence, pharmacokinetics.

(Aust Prescr 2007;30:41–3)

Bioequivalence is then determined by comparing the peak plasma concentration (C_{max}), time to achieve a maximal concentration (T_{max}) and the extent of absorption (area under the concentration-time curve, AUC) of the products (Fig. 1).

These studies are well suited to identifying potentially significant differences in the delivery characteristics of the active substance of different products. The same bioequivalence principles apply to new drugs when different formulations of an active ingredient are compared.

Bioequivalent products are marked with a superscript a or b in the Schedule of Pharmaceutical Benefits.[5]

Is bioequivalence clinically important?

Yes, only those products that have been **proven to be bioequivalent** should be used interchangeably. On **scientific** grounds there is no reason to be concerned about substituting a generic product for a branded product that is flagged as being bioequivalent.[5]

Fig. 1

Bioequivalence analysis – a hypothetical bioequivalence study

Mean concentration–time curves for two brands of a drug after single oral doses

Ref: McLachlan, A. J., Ramzan, I., & Milne, R. W. (2007).. Australian Prescriber, 30(2), 41-3.

Generics – equal or not?

Donald J. Birkett, Professor, Department of Clinical Pharmacology, Flinders University and Flinders Medical Centre, Adelaide

SYNOPSIS

Generic products must be bioequivalent to the innovator brand before they can be marketed in Australia. There are no generic formulations of drugs with a narrow therapeutic index as it would be difficult for them to meet the required standard of bioequivalence. In Australia most generic drugs are marketed with a brand name. Some generic brands are manufactured by the same company that produces the innovator brand of the drug. Although generic brands are usually cheaper the proliferation of brands may cause confusion.

Index words: bioequivalence, pharmaceutical industry, drug regulation.

(Aust Prescr 2003;26:85–7)

Introduction

From time to time, controversies and claims arise regarding generic prescribing and generic substitution. For example, a support group for people with epilepsy issued a news release that stated:

- (generic) substitution may impair safety and efficacy of treatment
- (generic) substitution may be dangerous for patients with life-threatening diseases (like epilepsy)
- patients for whom a medication has been substituted should be carefully monitored.

These concerns make it worthwhile to revisit the issues and to try and sort fact from opinion and fiction.

Generic prescribing

In Australia writing the non-proprietary (generic) name on a prescription allows the pharmacist to dispense any brand of the drug. The pharmacist does not have to dispense the cheapest brand.

Generic substitution

This policy enables the pharmacist, without reference back to the prescriber, to dispense a different brand of the drug even though the doctor has written a prescription for a particular brand. In Australia, doctors can endorse the prescription to prevent substitution.

Bioequivalence

Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and their bioavailabilities (rate and extent of availability) after administration in the same molar dose are similar to such a degree that their effects, with respect to both efficacy and safety, can be expected to be essentially the same. Pharmaceutical equivalence implies the same amount of the same active substance(s), in the same dosage form, for the same route of administration and meeting the same or comparable standards.

Product quality and bioequivalence data are required before a generic product can be registered in Australia or listed on the Pharmaceutical Benefits Scheme (PBS). The quality data required include purity, stability, good manufacturing practice and quality control. These data are the same as those required for innovator products. It has sometimes been suggested that

Ref: Birkett, D. J. (2003). Australian Prescriber, 26(4), 85-7.

Promoting Quality Prescribing

Caution and Skepticism Regarding New Drugs. New drugs often appear to be safer—a deceptive impression resulting from more limited experience with their use. Only when more adequate types and numbers of patients are studied for sufficiently long periods can a more accurate profile of their risks and benefits emerge. Although many payers stress prescribing generic medications for cost savings, another important value of generics is the greater safety knowledge inherent in their longer track record compared with more newly marketed brand name products.[7] When using new drugs, prescribing should be more limited and should target patients, indications, and situations for which benefit has been demonstrated.

inform their thinking about pharmacotherapy to help them become more careful, cautious, evidence-based

drug therapy.

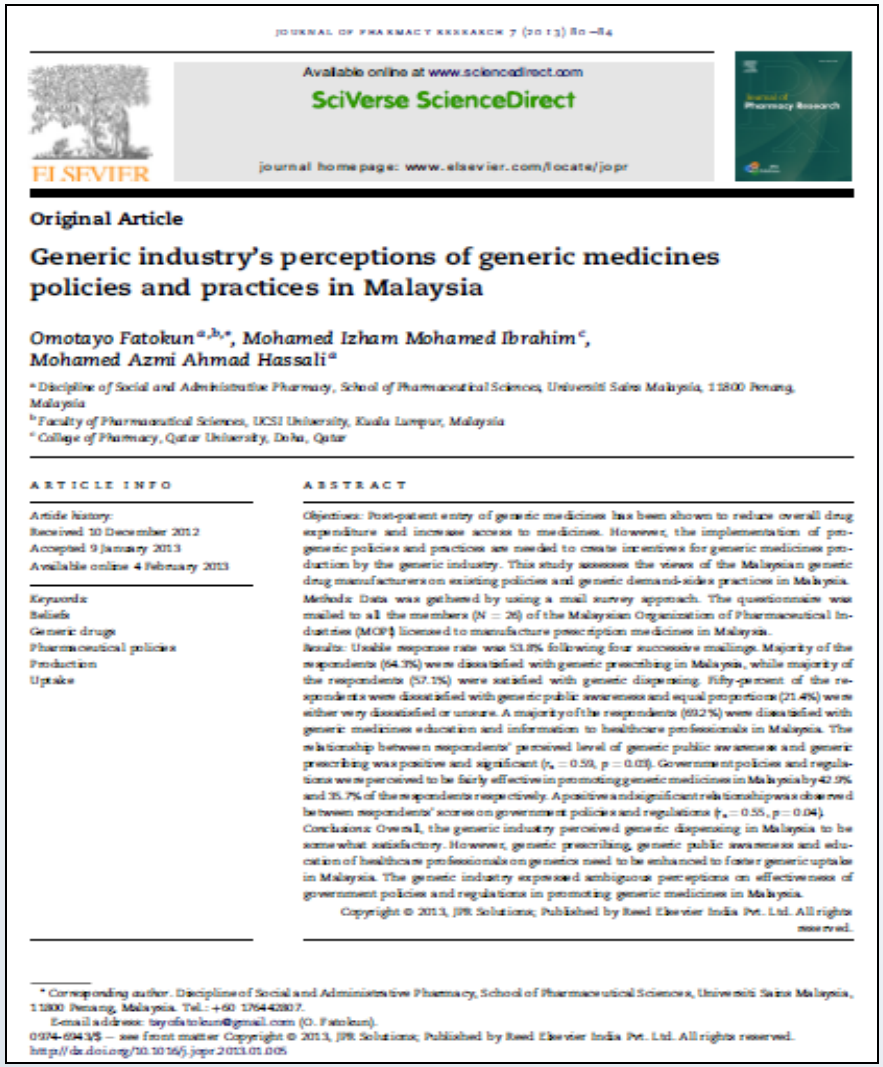
Principles for More Conservative Prescribing

sources and from colleagues with reputations for conservative prescribing

der entry, reliable laboratory monitoring) rather than just new drugs as ways to improve pharmacotherapy

Ref: Schiff & Galanther, JAMA 2009

Issues Related to Generic Medicines Use: Generic Manufacturers



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Original Article

Generic industry's perceptions of generic medicines policies and practices in Malaysia

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ABSTRACT

Objectives: Post-patent entry of generic medicines has been shown to reduce overall drug expenditure and increase access to medicines. However, the implementation of pro-generic policies and practices are needed to create incentives for generic medicines production by the generic industry. This study assesses the views of the Malaysian generic drug manufacturers on existing policies and generic demand-sides practices in Malaysia.
Methods: Data was gathered by using a mail survey approach. The questionnaire was mailed to all the members (N = 26) of the Malaysian Organization of Pharmaceutical Industries (MOPI) licensed to manufacture prescription medicines in Malaysia.
Results: Usable response rate was 53.8% following four successive mailings. Majority of the respondents (64.3%) were dissatisfied with generic prescribing in Malaysia, while majority of the respondents (57.1%) were satisfied with generic dispensing. Fifty-percent of the respondents were dissatisfied with generic public awareness and equal proportions (21.4%) were either very dissatisfied or unsure. A majority of the respondents (69.2%) were dissatisfied with generic medicines education and information to healthcare professionals in Malaysia. The relationship between respondents' perceived level of generic public awareness and generic prescribing was positive and significant ($r_s = 0.59$, $p = 0.03$). Government policies and regulations were perceived to be fairly effective in promoting generic medicines in Malaysia by 42.9% and 35.7% of the respondents respectively. A positive and significant relationship was observed between respondents' scores on government policies and regulations ($r_s = 0.55$, $p = 0.04$).
Conclusions: Overall, the generic industry perceived generic dispensing in Malaysia to be somewhat satisfactory. However, generic prescribing, generic public awareness and education of healthcare professionals on generics need to be enhanced to foster generic uptake in Malaysia. The generic industry expressed ambiguous perceptions on effectiveness of government policies and regulations in promoting generic medicines in Malaysia.

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E-mail addresses: tayofatokun@gmail.com (O. Fatokun).

0974-6943/$ – see front matter
http://dx.doi.org/10.1016/j.jopr.2013.01.005

Generic Manufacturers: Major barriers to local production includes:

- Patent clustering (i.e. acquisition of multiple patents surrounding the basic patents of the drug products) by innovator companies

- Market competition from imported generics

  - **Earlier entry of imported** generic medicines into the Malaysia drug market was due **to trade policy initiatives** and the **difficulty** of local generic drug manufacturers in conducting bioequivalence **(BE) studies**.

  - BE centres are mostly university based and non-profit orientated

  - As of 28.4.2016, there are only **5** local accredited BE centres.

Role of Universities In Establishing BE Studies Centres

- The Working Committee for BE Studies which was formed in September 1999, comprising of representatives from Universiti Sains Malaysia (USM), University of Malaya (UM), National University of Malaysia (UKM), International Medical University (IMU), National Pharmaceutical Regulatory Agency (NPRA) and the pharmaceutical industry. The members were officially appointed to undertake the task of formulating an action plan for the conduct of BE studies in Malaysia through collaborative efforts.

- Publication of the 'Malaysian Guidelines for the Conduct of Bioavailability and Bioequivalence Studies' marked the first outcome of this committee's objectives.

Lab Photos : Thanks to Prof Yuen Kah Hay, PhD

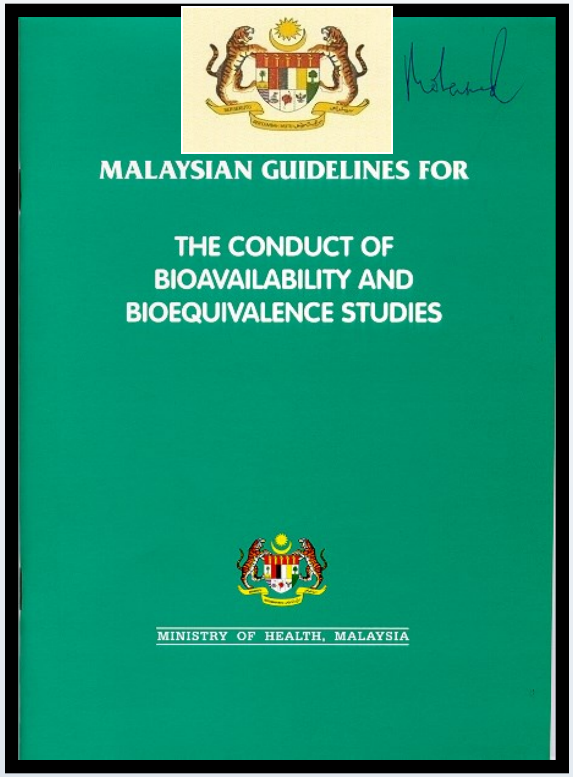
HPLC with UV-Fluorescence Detection at USM BE Lab

LC-MS/MS at USM BE Lab

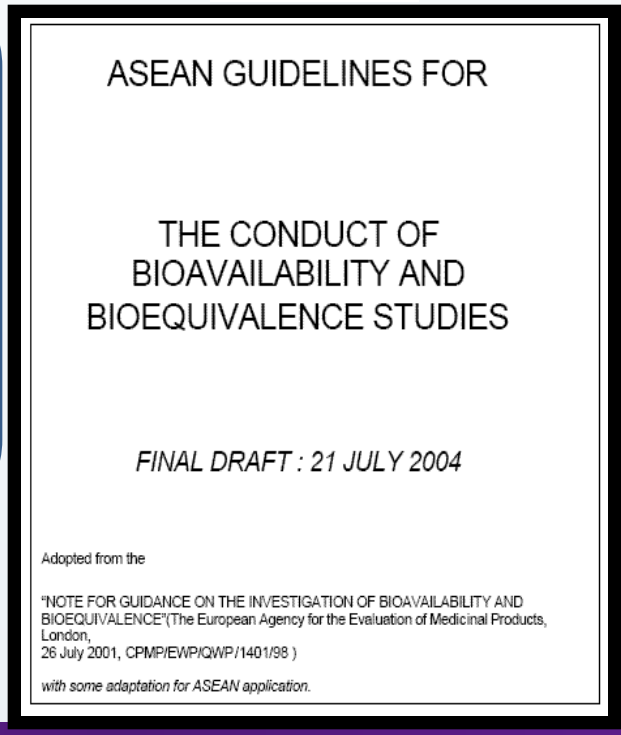
Plasma sample preparative room at USM BE Lab

Bioequivalence in Malaysia

- The Malaysia Drug Control Authority (MDCA) at its 92nd meeting in 1999 decided to include BE studies requirements for the registration of generic products of certain categories of oral, immediate-release products to ensure interchangeability between innovator and generic medicines



Adopted from the 'Note for Guidance on the Investigation of Bioavailability and Bioequivalence , **The European Agency for the Evaluation of Medicinal Products**, *..with some adaptation for Malaysian and ASEAN*


ASEAN GUIDELINES FOR

THE CONDUCT OF BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES

FINAL DRAFT : 21 JULY 2004

Adopted from the

"NOTE FOR GUIDANCE ON THE INVESTIGATION OF BIOAVAILABILITY AND BIOEQUIVALENCE"(The European Agency for the Evaluation of Medicinal Products, London,
26 July 2001, CPMP/EWP/QWP/1401/98)

with some adaptation for ASEAN application.

Press Release

PRESS RELEASE BY THE MINISTER OF HEALTH MALAYSIA IN CONJUNCTION WITH THE "PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME (PIC/S) SEMINAR 2010" ON THE 10TH NOVEMBER 2010 AT THE LE MERIDIEN HOTEL, KUALA LUMPUR.

REQUIREMENT OF BIOEQUIVALENCE STUDY (BE) FOR ALL GENERIC PRODUCTS

The Ministry of Health (MOH), Malaysia started registration of pharmaceutical products and licensing of manufacturers of pharmaceuticals in 1985, with the enforcement of the Control of Drugs and Cosmetics Regulations 1984 to ensure products marketed in the country are safe, efficacious and of quality. Since then, the local pharmaceutical industry has undergone huge transformation to upgrade their manufacturing facilities in accordance with Good Manufacturing Practice (GMP) requirements. Recognising that Malaysia has a licensing and a GMP inspection system well in place, the Pharmaceutical Inspection Co-operation Scheme (PIC/S) accepted the country as its 26th member in January 2002.

Within the last decade, the pharmaceutical product market has charted an average growth of 10-15% yearly. Presently, the pharmaceutical product manufacturers in Malaysia export their products to about 70 countries throughout the world. The export numbers are increasing by the year. Due to our strict regulatory surveillance system that complies with international standards and the industry's willingness to comply to these requirements, Malaysian pharmaceuticals are widely accepted and recognised for their quality by the importing countries.

Holistic Approach for GS

1. Agreement, cooperation and communication between pharmacists and medical practitioners are important for the successful substitution.

2. Physicians should be able to disallow generic substitution for the cases in which generic substitution is not appropriate

3. Patients should be given the opportunity to make an informed choice to consume either branded original medicines or generic medicines.

4. Need of guide on therapeutically interchangeable drug products to help healthcare professionals to perform generic substitution appropriately and to avoid any pitfalls or errors that may arise from inappropriate generic substitution

E.g. British National Formulary (BNF) in the United Kingdom (UK), the Schedule of Pharmaceutical Benefit Scheme (PBS) in Australia and the lists of interchangeable products in Finland and Sweden

Generics Medicine Policy in Qatar

1/15/2018 Generic medicines policy in Qatar - GaBI Journal

GaBi Journal
Generics and Biosimilars Initiative

GENERICS AND BIOSIMILARS INITIATIVE JOURNAL
Building trust in cost-effective treatments

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Generic medicines policy in Qatar

Generics and Biosimilars Initiative Journal (GaBI Journal). 2015;4(1):8.
DOI: 10.5639/gabij.2015.0401.003

Published in: Volume 4 / Year 2015 / Issue 1
Category: Letters to the Editor
Page: 8
Author(s): Professor Mohamed Izham Mohamed Ibrahim, PhD
Visits: 2972 total, 3 today

Keywords: generic medicines, pharmaceutical policy, Qatar

Abstract:
Qatar's pharmaceutical market is likely to remain highly dependent on imports. The use of generic medicines remains a great challenge to the country.

***Submitted:** 18 December 2014; **Revised:** 28 January 2015; **Accepted:** 1 February 2015; **Published online first:** 13 February 2015*

Qatar is the world's richest country per capita. The country established its National Health Strategy 2011–2016 in line with the Qatar National Vision 2030, which aims to advance Qatar's Healthcare Vision of creating a world-class, patient-centred healthcare system [1, 2]. There has been a huge increase in public spending on health care in Qatar, giving it the highest per capita health expenditure in the Middle East. The National Health Insurance Scheme is a strong platform to ensure a healthy population with access to affordable health care.

Public sector drug procurement is carried out through closed international tenders, Gulf Cooperation Council (GCC) bulk procurement and direct purchasing. The Qatari pharmaceutical market reached a value of Qatari Rial 1.43 billion (US$392.6 million) in 2010. Spending on medicines and pharmaceuticals in 2009 and 2010, as a percentage of total public sector spending, was US$138 million (9%) and US$143 million (8%), respectively [3]. Medicines dispensed at the Hamad Medical Corporation (HMC) health institutions are priced differently for Qataris and non-Qataris. The development of the pharmaceutical market is shaped by the decision of the Supreme Council of Health (SCH) to abolish government controls over the pricing of medicines and to allow more imported goods and suppliers in the country. Qatar has adopted an open market system. The retail prices of medicines remain among the highest in the Middle East.

There is no official policy on the bioequivalence of generic medicines, although the government is promoting their use [3]. Nevertheless, Business Monitor International (BMI) has reported that there is extensive use of branded medicines in Qatar's healthcare facilities [3]. HMC is using brands mainly because of prescriber's preference, patient trust and unavailability of a bioequivalence centre in Qatar, where bioequivalence could be studied and tested.

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- The Qatari pharmaceutical market reached a value of Qatari Rial 1.43 billion (US$392.6 million) in 2010.
- Spending on medicines and pharmaceuticals in 2009 and 2010, as a percentage of total public-sector spending, was US$138 million (9%) and US$143 million (8%), respectively.
- The retail prices of medicines remain among the highest in the Middle East.

Ref: Ibrahim MI (2015), GaBI Journal

Generics Use in Qatar

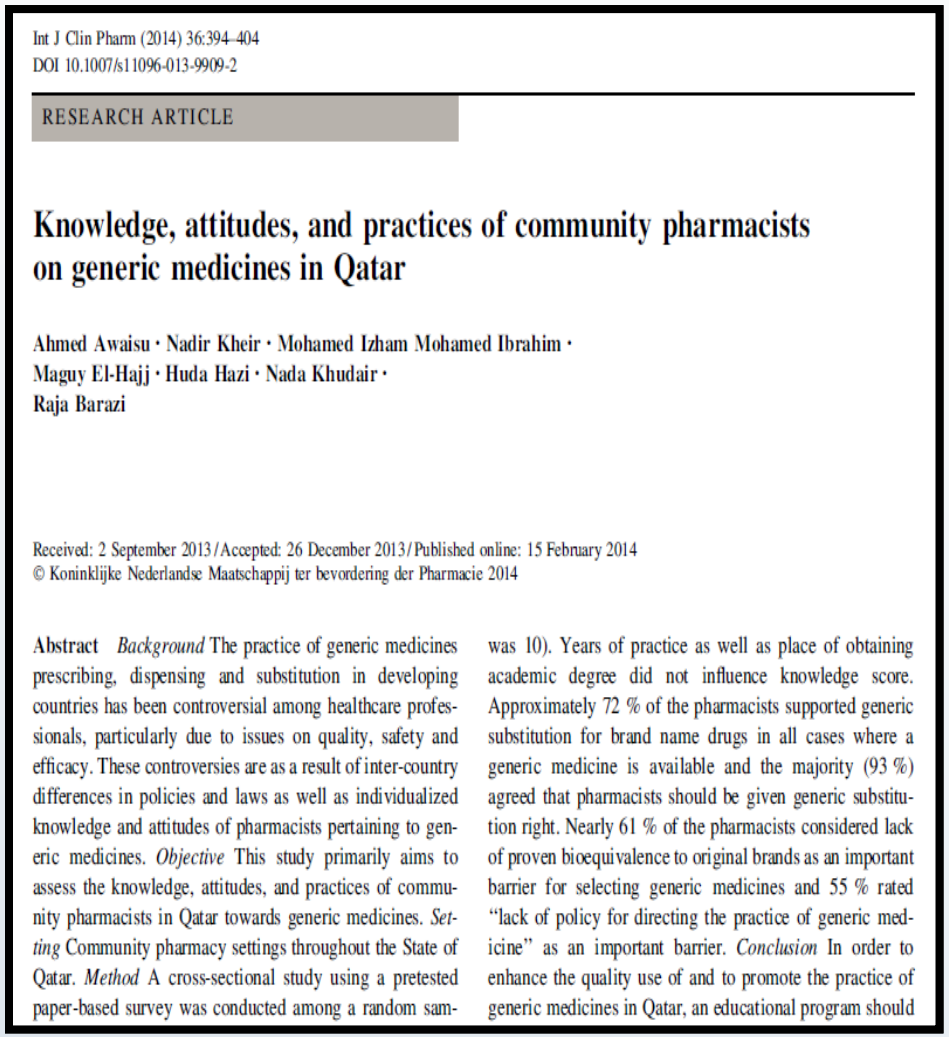
- Currently, there are no national generic medicine prescribing and dispensing policies in Qatar, and the obligation of prescribing and dispensing brand-name or generic products, especially in community practices, lies with the general practitioner and the pharmacist, respectively

- There is no official policy on the bioequivalence of generic medicines, although the government is promoting their use. Business Monitor International (BMI) has reported that there is extensive use of branded medicines in Qatar's healthcare facilities

Qatari Generic Drug Market Forecast

- BMI View: Despite their relatively small market share, generic drug sales in Qatar will experience significant growth over the forecast period.
- Pro-generic policies, as well as the effects of patent protection loss, will contribute to generic medicines market expansion.
- The gradual development of drug manufacturing facilities in the country, albeit still insignificant, will also contribute to support generic medicines sales over the long term

Community Pharmacist Study On Generic Medicines in Qatar



Int J Clin Pharm (2014) 36:394–404
DOI 10.1007/s11096-013-9909-2

RESEARCH ARTICLE

Knowledge, attitudes, and practices of community pharmacists on generic medicines in Qatar

Ahmed Awaisu · Nadir Kheir · Mohamed Izham Mohamed Ibrahim · Maguy El-Hajj · Huda Hazi · Nada Khudair · Raja Barazi

Received: 2 September 2013 / Accepted: 26 December 2013 / Published online: 15 February 2014

Abstract *Background* The practice of generic medicines prescribing, dispensing and substitution in developing countries has been controversial among healthcare professionals, particularly due to issues on quality, safety and efficacy. These controversies are as a result of inter-country differences in policies and laws as well as individualized knowledge and attitudes of pharmacists pertaining to generic medicines. *Objective* This study primarily aims to assess the knowledge, attitudes, and practices of community pharmacists in Qatar towards generic medicines. *Setting* Community pharmacy settings throughout the State of Qatar. *Method* A cross-sectional study using a pretested paper-based survey was conducted among a random sam- was 10). Years of practice as well as place of obtaining academic degree did not influence knowledge score. Approximately 72 % of the pharmacists supported generic substitution for brand name drugs in all cases where a generic medicine is available and the majority (93 %) agreed that pharmacists should be given generic substitution right. Nearly 61 % of the pharmacists considered lack of proven bioequivalence to original brands as an important barrier for selecting generic medicines and 55 % rated "lack of policy for directing the practice of generic medicine" as an important barrier. *Conclusion* In order to enhance the quality use of and to promote the practice of generic medicines in Qatar, an educational program should

- 72 % of the pharmacists supported generic substitution for brand name drugs in all cases
- Majority (93 %) agreed that pharmacists should be given generic substitution right
- 61 % o considered lack of proven bioequivalence to original brands as an important barrier for selecting generic medicines
- 55 % rated ‘‘lack of policy for directing the practice of generic medicine’’ as an important barrier

Ref: Awaisu, A., Kheir, N., Ibrahim, M. I. M., El-Hajj, M., Hazi, H., Khudair, N., & Barazi, R. (2014). International journal of clinical pharmacy, 36(2), 394-404.

Qatari National Health Strategy 2011–2016 Targets

Goal	Projects	Outcomes/ Objectives	Outputs	Outputs Baseline and Targets to 2016
National health policy	Healthcare products	To ensure effective use, safety, and quality of healthcare products by enhancing healthcare products regulation	Education program for health professionals on narcotics and generic use	Target: Establishment of national formulary (milestone)

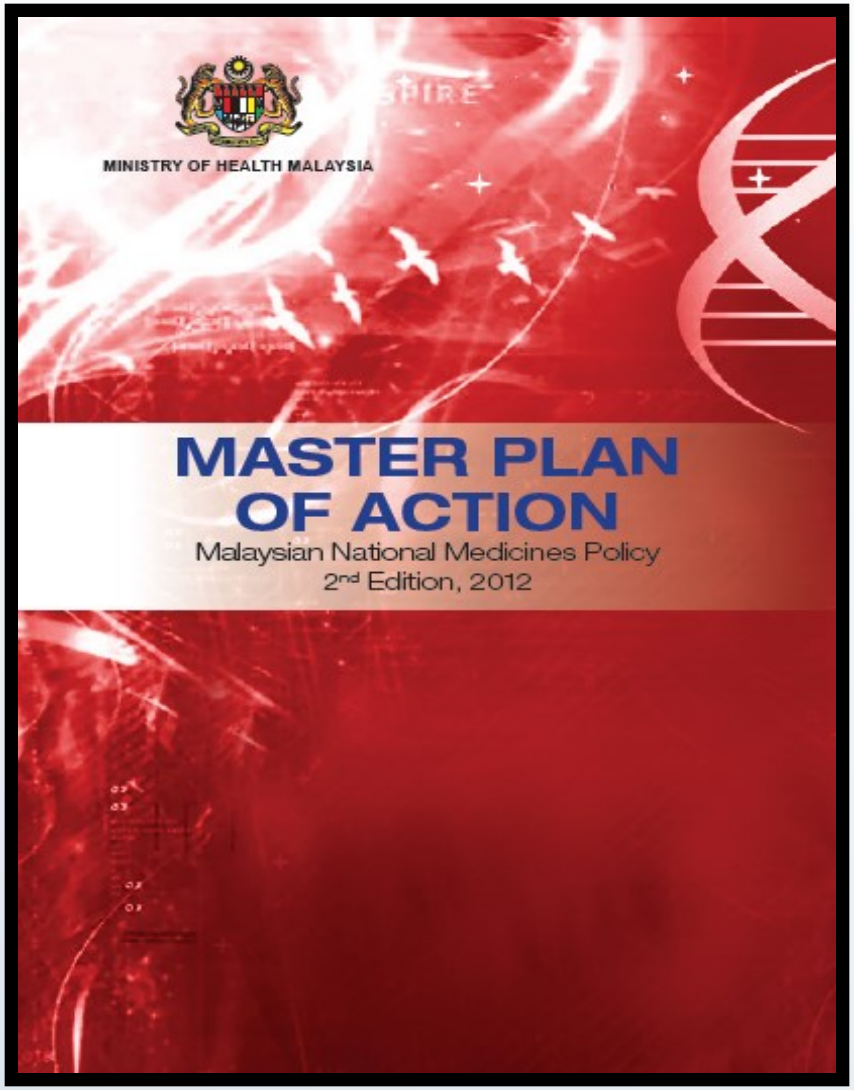
Recommendations to Encourage Generics Use in Qatar: A Personal View

- Policymakers should establish a sound generic medicine policy and guidelines for the State of Qatar
- There is a need to assess the knowledge, attitudes, and practices on generic substitution, and the need for educational interventions of physicians and other healthcare professionals in Qatar
- There is a need to build consumer confidence with generics
- There is a need to educate the final year pharmacy and medical students regarding generic medicines where they will be the future drug dispensers and prescribers

Current Malaysian MOH Effort in Promoting Use of Generic Medicines

- **Review of current policy - Master Plan of Action**
- **Nationwide educational road show**
  - Generic Medicines Awareness Program (GMAP)
  - Know Your Medicine Campaign
- **Development of educational booklet for**
  - Healthcare Providers
  - Consumers
- **Addressing The Missing Part**

Master Plan of Action



- In September 2013, a workshop involving relevant stakeholders from the government agencies and private institutions was conducted towards preparation of Master Plan of Action for second term of MNMP.
- Alongside the formation of the revised edition of MNMP, an appropriate and practical Plan of Action was developed based on the newly-organized components and the strategies outlined in the policy.
- With the reconciliation of efforts from all the stakeholders, it is very much anticipated that the implementation of the Plan of Action will bring a remarkable impact to the health of the nation.

Generic Medicines Awareness Program (GMAP)

PENGENALAN

Kos penjagaan kesihatan semakin meningkat setiap tahun dan ini merupakan satu cabaran kepada kerajaan untuk memastikan pengguna mampu mendapat ubat untuk rawatan.

Penggunaan ubat generik merupakan satu alternatif untuk mengurangkan perbelanjaan ubat. Namun, secara umumnya, penggunaan ubat generik di Malaysia masih berada pada tahap rendah.

Saiz pasaran ubat di Malaysia adalah sebanyak RM3.84 billion meliputi sektor awam dan swasta. Sebanyak RM1.15 billion (30%) merupakan nilai pasaran ubat generik dan sebanyak RM2.69bil (70%) merupakan produk *inovator*.

Oleh itu, langkah yang lebih agresif perlu diambil untuk meningkatkan penggunaan ubat generik sekaligus membantu mengurangkan perbelanjaan ubat-ubatan.

Justeru Bahagian Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia (KKM) mengambil inisiatif untuk melaksanakan satu program berbentuk siri jelajah seluruh negara atau jerayawara *(roadshow)* untuk mempromosi penggunaan ubat generik.

Peningkatan penggunaan ubat generik yang berkualiti adalah satu strategi utama untuk memberikan ubat diperoleh pada harga yang berpatutan dan mampu dimiliki oleh seluruh rakyat Malaysia.

Diharapkan seminar ini dapat meyakinkan preskriber terhadap kualiti ubat generik dan seterusnya mampu meningkatkan penggunaannya ke arah penjimatan perbelanjaan ubat pada masa akan datang.

Objektif Program

Objektif Am

- Untuk meningkatkan keyakinan preskriber terhadap kualiti, keselamatan dan keberkesanan ubat generik agar penggunaannya dapat dipertingkatkan.

Objektif Khusus

- Menyebarkan maklumat berkaitan penggunaan ubat secara rasional dan ubat-ubatan generik di Malaysia dalam kalangan preskriber.
- Memberi pendedahan kepada preskriber berkaitan ubat-ubatan generik iaitu kesetaraan bio *(bioequivalence)*, keberkesanan dan keselamatan produk, pendaftaran produk dan kawalan kualiti produk farmaseutikal di Malaysia.
- Memberi penerangan berkaitan faedah dan manfaat penggunaan ubat-ubatan generik berdasarkan kajian farmakoekonomik dalam penjimatan kos perbelanjaan ubat-ubatan.

ATUR CARA SEMINAR

Masa	Perkara
0730-0830	Pendaftaran & Kaji selidik Pra-seminar
0830-0840	Ketibaan Penceramah dan Jemputan Kehormat (VIP)
0840-0845	Bacaan Doa
0845-0900	Ucapan Alu-aluan & Perasmian Pengarah Kesihatan Negeri **YBhg. Dato' Dr. Hjh Zailan Binti Dato' Hj. Adnan**
0900-0930	Minum Pagi
0930-1015	**Topik 1 : *"GENERIC MEDICINES: THE BIG PICTURE"*** *Profesor Madya Dr. Mohamed Azmi Bin Ahmad Hassali* *Timbalan Dekan,Pusat Pengajian Sains Farmasi, Universiti Sains Malaysia*
1015-1025	Sesi soal jawab
1025-1110	**Topik 2 : *"ENSURING QUALITY, SAFETY AND EFFICACY OF GENERIC MEDICINES : MANUFACTURER'S PERSPECTIVE"*** *Encik Jimmy Piong Teck Onn* *Executive Council, Malaysian Organisation of Pharmaceutical Industries*
1110-1120	Sesi soal jawab
1120-1220	**Topik 3a : *"ENSURING QUALITY, SAFETY AND EFFICACY OF GENERIC MEDICINES : REGISTRATION PROCESS REQUIREMENT"*** *Puan Mazuwin Binti Zainal Abidin* *Ketua Penolong Pengarah Kanan US4,* *Biro Pengawalan Farmaseutikal Kebangsaan,* *Kementerian Kesihatan Malaysia* **Topik 3b : *"ENSURING QUALITY, SAFETY AND EFFICACY OF GENERIC MEDICINES : POST MARKET ACTIVITIES"*** *Puan Rokiah Binti Isahak* *Ketua Penolong Pengarah Kanan US4,* *Biro Pengawalan Farmaseutikal Kebangsaan,* *Kementerian Kesihatan Malaysia*
1220-1230	Sesi soal jawab
1230-1300	Kaji selidik Post-seminar & Makan Tengahari

Laman sesawang Kenali Ubat Anda
www.knowyourmedicine.gov.my

Talian Pusat Panggilan Farmasi Kebangsaan
1 800 88 6722 (NPCC-Bebas tol 24jam)

- Nationwide road show to improve prescribers' understanding about generic medicines.
- Involves different stakeholders including NPCB, policy maker, generic manufacturers, doctors, pharmacists and etc.

Generic Medicines Awareness Program (GMAP)

knowyourmedicine.gov.my/en/content/what-you-should-know-about-generic-medicines

The "Know Your Medicine" campaign is a project jointly organized by the Ministry of Health (MOH) and the Consumers Association of Malaysia (FOMCA). It was initiated in 2007.

Official Website of Pharmaceutical Services Division
Ministry of Health for Consumers

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Home > What You Should Know About Generic Medicines

section
ABOUT US

Enquiries on medication may be directed to National Call Centre Toll Free Line
1 800-88-6722(NPCC)

What you should know about generic medicines

Thu, 2009-08-20

The public can rest assured that all medicines, branded or generics, registered by the Drug Control Authority are safe, efficacious and of good quality. Generics medicines do offer patients with accessible and affordable medicines. Although generics bypass the expense and time required to demonstrate the drugs efficacy and safety through clinical trials, generics still need to conform to same standard of quality, efficacy and safety required of branded medicines. Therefore, it is important for Malaysians to be aware that 'Cheap Price is not an indicator or a perception of 'Low Quality' medicines.

Read more

Know Your Medicine Campaign

Objectives

The objective of this campaign is to:

- increase consumer awareness of the rational use of medicines
- provide consumers with information on different issues related to health and medicine
- ensure that consumers know their medicine, what they should and should not be taken, and why
- increased adverse drug reporting through patient education
- improve knowledge in the use of medicine by pregnant women, nursing mothers and children
- assist senior citizens in the use of medicine

Target Group

To all consumers who are concerned about their health and the health of their loved ones.

Activities

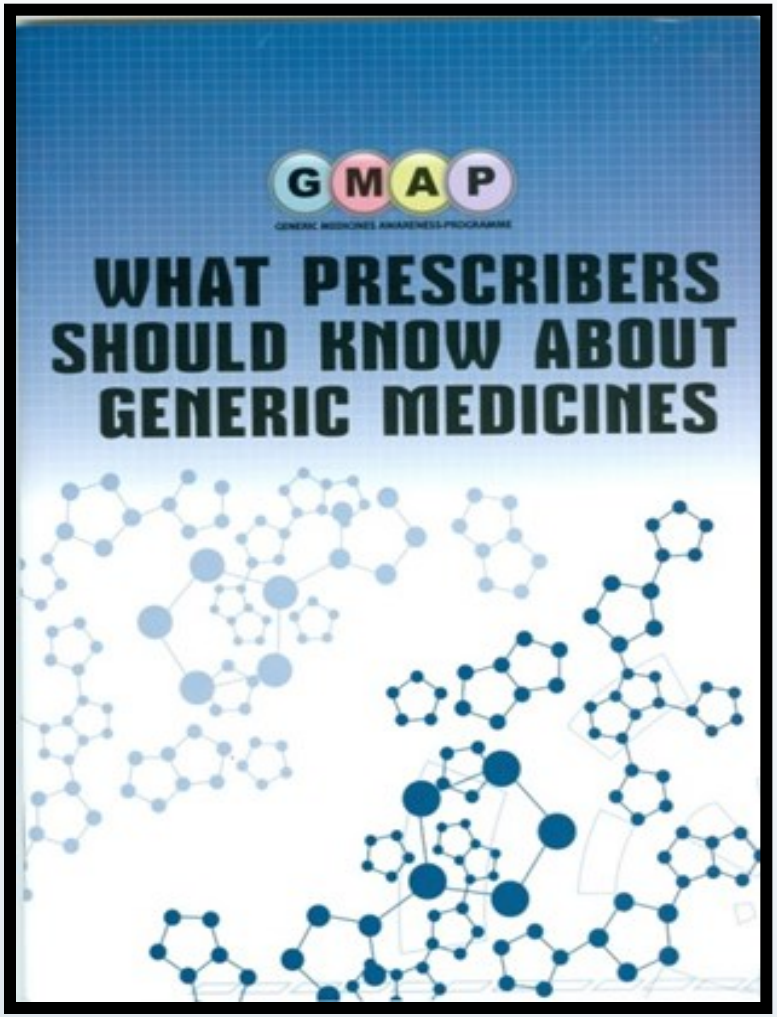
The campaign is conducted by a pharmacist from both public and private sectors, through the following activities:

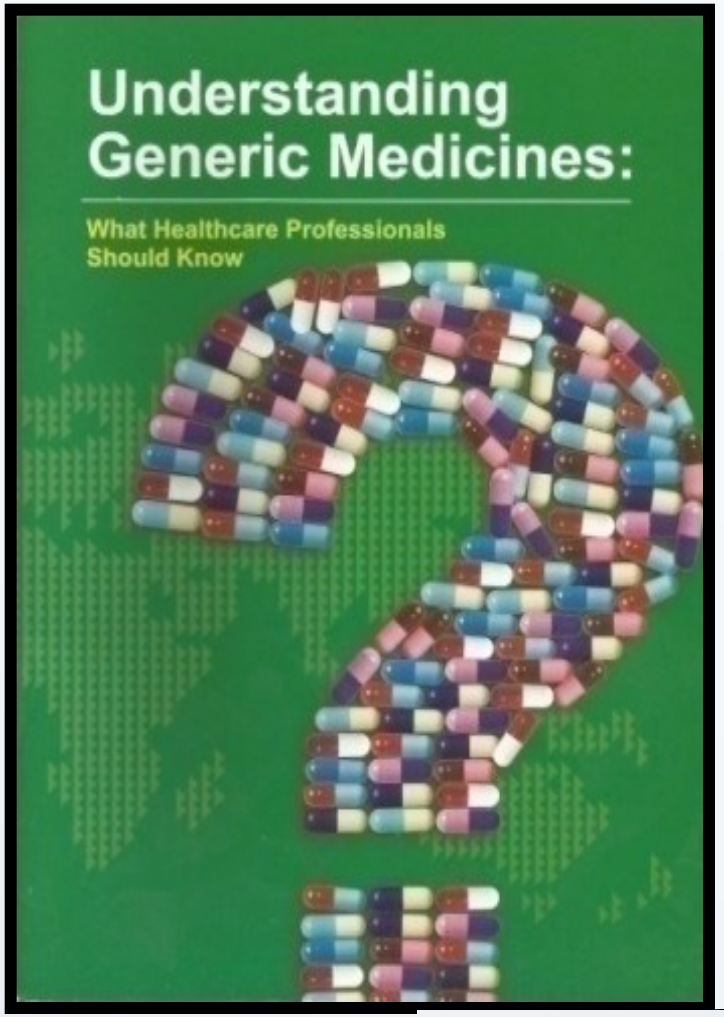
- Workshops for consumers in all countries that target both rural and urban areas
- Activities exhibitions and lectures 'Know Your Medicines'
- Reviews and research on consumer perceptions and knowledge of medicine
- continuous promotion in the media

For organizing campaign activities in your area, kindly contact the respective State Laison Officer

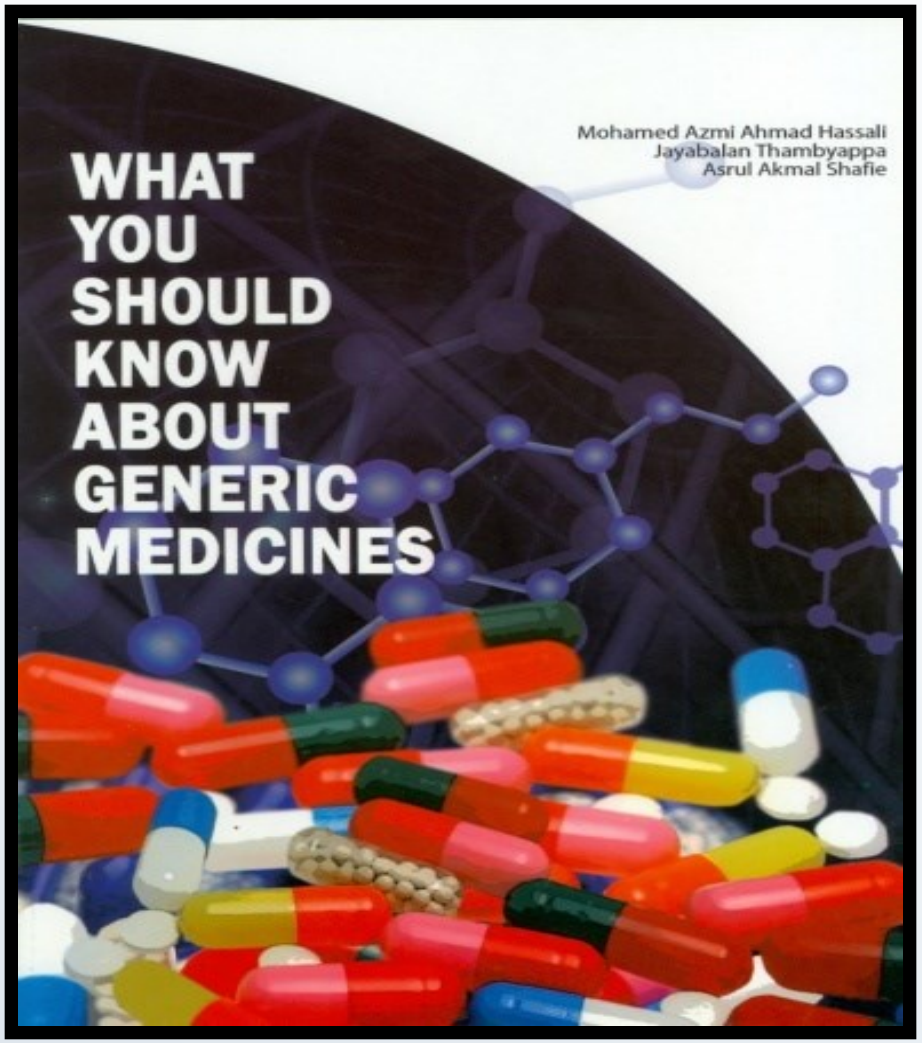
Know Your Medicine Campaign

Publication of Educational Booklet on Generic Medicine for Healthcare Professionals





Educational Booklet on Generic Medicine for Patients/Consumers



Snapshot of Educational Booklet on Generic Medicine

5. Similarities and differences between generic and branded medicines

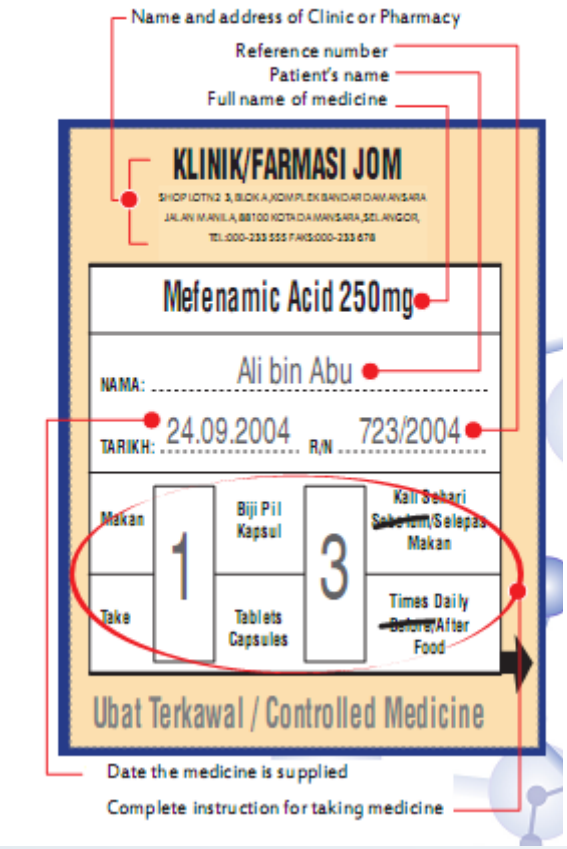
Similarities

- Active ingredients
- Labelled strength
- Dosage forms
- Mode of administration
- Time of action
- Therapeutic effects
- Bioequivalence
- Side effects
- Label
- Both brand-name drugs and generics facilities meet the same standards of good manufacturing practices (GM

Differences

- Generic medicines may be composed of different inactiv ingredients (excipients) comp to branded medicines. The ina ingredients* include colourin flavourings, preservatives, an special tablet coatings.

A SAMPLE LABEL THAT MEETS THE MALAYSIAN LEGAL REQUIREMENTS



WHAT YOU SHOULD KNOW ABOUT GENERIC MEDICINES

Aspects	Generic Medicines	Counterfeit Medicines
Definition	Pharmaceutical product usually intended to be interchangeable with an innovator product, that is manufactured following the expiry of the patent and other exclusivity rights. Generic medicines should provide the same dose as branded medicines.	Medicine that is deliberately and fraudulently mislabelled with respect to identity and/ or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.
Legislation	Must conform to national regulatory standards.	Do not conform to national regulatory standards.
Safety	Have the same safety profile as the innovator product.	Harmful and unsafe due to presence of toxic/inactive ingredients that are not effective.
Packaging and labelling	Good-quality packaging. Label is written properly with accurate drug details and spelling.	Fake packaging – product packaged and labelled to look like branded or generic drugs. Usually do not bear the name and address of the manufacturer and are of poor quality.

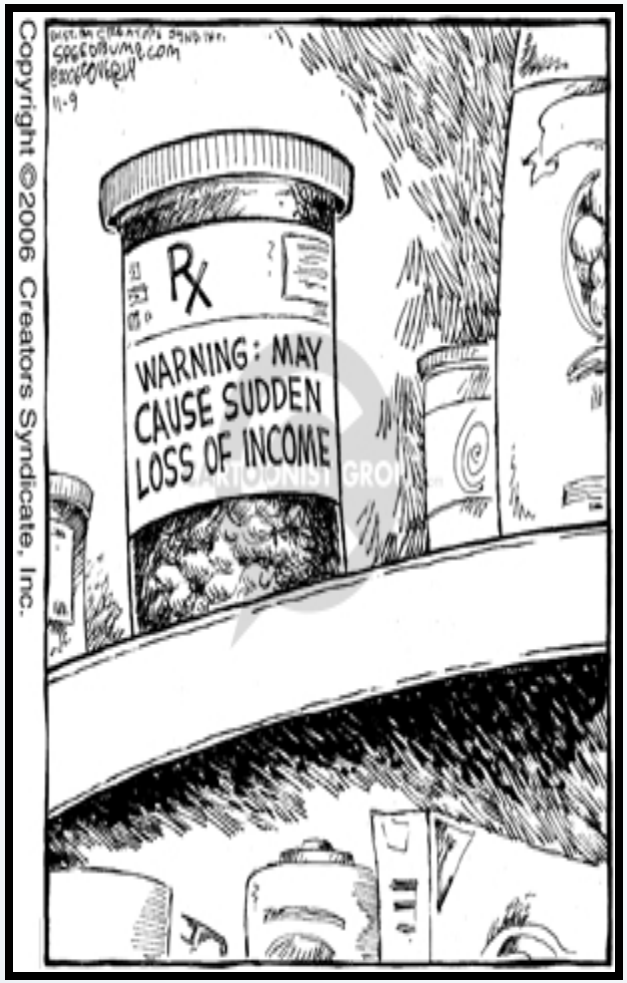
Educational Posters on Generic Medicine for Patients/Consumers

Take Home Messages

- Generic medicines provide the same quality, safety & efficacy as original branded product.

- Allowing effective competition between generic and innovator medicines is crucial for lowering pharmaceutical cost and stimulating innovation.

- Economically priced generic medicines provide a cost-effective means of controlling the fastest growing budget item in the healthcare industry: The pharmaceuticals!



THANK YOU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KAMI MEMIMPIN
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