GENERIC MEDICINES: THE BIG PICTURE

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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

Utilization of Generic Medicines

<table>
<thead>
<tr>
<th>Country</th>
<th>% Volume of Generic Market Share</th>
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</thead>
<tbody>
<tr>
<td>Japan</td>
<td>24%</td>
</tr>
<tr>
<td>Italy</td>
<td>40%</td>
</tr>
<tr>
<td>Spain</td>
<td>41%</td>
</tr>
<tr>
<td>Hungary</td>
<td>46%</td>
</tr>
<tr>
<td>Australia</td>
<td>50%</td>
</tr>
<tr>
<td>Turkey</td>
<td>51%</td>
</tr>
<tr>
<td>France</td>
<td>52%</td>
</tr>
<tr>
<td>Czech</td>
<td>59%</td>
</tr>
<tr>
<td>Brazil</td>
<td>65%</td>
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<tr>
<td>UK</td>
<td>71%</td>
</tr>
<tr>
<td>Poland</td>
<td>73%</td>
</tr>
<tr>
<td>Germany</td>
<td>75%</td>
</tr>
<tr>
<td>Canada</td>
<td>81%</td>
</tr>
<tr>
<td>USA</td>
<td>89%</td>
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</table>

Ref: IMS Health Dec 2016
Promotion of access to essential medicines for non-communicable diseases: practical implications of the UN political declaration


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 currently 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. 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.
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.

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

# Initiatives to Reduce Prescription Cost: The European Experience

## Table 1: Definition and examples of the 4Es

<table>
<thead>
<tr>
<th>Measure (4Es)</th>
<th>Explanation and initiatives</th>
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</table>
| **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

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<td>Lipitor®</td>
<td>Atorvastatin</td>
<td>Pfizer</td>
<td>7.9</td>
<td>8.6</td>
<td>9.23</td>
<td>10.3</td>
<td>10.86</td>
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<td>Zocor®</td>
<td>Simvastatin</td>
<td>Merck</td>
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<td>6.2</td>
<td>5.01</td>
<td>6.1</td>
<td>5.2</td>
<td>5.9</td>
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<td>Celebrex®</td>
<td>Celecoxib</td>
<td>Pfizer</td>
<td>3</td>
<td>NA</td>
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<td>2.5</td>
<td>3.3</td>
<td>NA</td>
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<td>Zoloft®</td>
<td>Sertraline</td>
<td>Pfizer</td>
<td>2.74</td>
<td>NA</td>
<td>3.1</td>
<td>3.4</td>
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<td>Olanzapine</td>
<td>Eli-Lilly</td>
<td>3.6</td>
<td>4</td>
<td>4.27</td>
<td>4.8</td>
<td>4.42</td>
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<tr>
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<td>Risperidone</td>
<td>Johnson &amp; Johnson</td>
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<td>2.5</td>
<td>NA</td>
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<td>NA</td>
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<td>Venlafaxine</td>
<td>Wyeth</td>
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<td>2.7</td>
<td>NA</td>
<td>3.3</td>
<td>3.7</td>
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<tr>
<td>Norvasc®</td>
<td>Amlodipine</td>
<td>Pfizer</td>
<td>3.8</td>
<td>4</td>
<td>4.33</td>
<td>4.5</td>
<td>4.46</td>
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<tr>
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<td>Clopidrogrel</td>
<td>Sanofi-Aventis</td>
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<td>NA</td>
<td>4.2</td>
<td>3.7</td>
<td>5</td>
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<tr>
<td>Prevacid®</td>
<td>Lansoprazole</td>
<td>Takeda</td>
<td>3.7</td>
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<td>3.3</td>
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<td>3.1</td>
<td>3.8</td>
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<td>Advair®</td>
<td>Fluticasone; Salmetrol</td>
<td>GSK</td>
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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.

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

Ref: Ping, Bahari & Hassali, 2008

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

GNI by 2020 (mil) \(13,853.7\)  
Projected jobs by 2020 \(12,440\)

This EFP 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 Organization of the Islamic Cooperation and the East Asian Forum to promote Malaysia’s manufacturing capabilities overseas.
- Utilize the Government’s support schemes to upgrade plant facilities, technology and the workforce.
- Conclude international partnerships to ensure a steady demand for the products.
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.
Welcome to the PIC/S Website!

The 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.

PIC/S mission is "to lead the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products."

This is to be achieved by developing and promoting harmonised GMP standards and guidance documents, training competent authorities, in particular inspectors; assessing (and reassessing) inspectorates, and facilitating the co-operation and networking for competent authorities and international organisations.

There are currently 48 Participating Authorities in PIC/S (Convention and Scheme taken together).

The current website provides an overview on PIC/S' history, its role, Members, publications and activities. For any enquiries, please contact the PIC/S Secretariat.
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

<table>
<thead>
<tr>
<th>No.</th>
<th>Country</th>
<th>Agency Name</th>
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<tbody>
<tr>
<td>37</td>
<td>Slovenia</td>
<td>Agency for Medicinal Products and Medical Devices</td>
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<tr>
<td>38</td>
<td>South Africa</td>
<td>Medicines Control Council</td>
</tr>
<tr>
<td>39</td>
<td>Spain</td>
<td>Agencia Española del Medicamento y Productos Sanitarios (Spanish Agency of Drugs and Health Products)</td>
</tr>
<tr>
<td>40</td>
<td>Sweden</td>
<td>Medical Products Agency</td>
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<td>Switzerland</td>
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<td>42</td>
<td>Ukraine</td>
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<td>43</td>
<td>United Kingdom</td>
<td>Medicines and Healthcare Products Regulatory Agency</td>
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<tr>
<td>44</td>
<td>United States of America</td>
<td>United States Food and Drug Administration</td>
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### Members of PIC/S

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<tr>
<th></th>
<th>Country</th>
<th>Regulatory Body</th>
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<tbody>
<tr>
<td>24</td>
<td>Latvia</td>
<td>Zāļu Valsts Aģentūra (State Agency of Medicines)</td>
</tr>
<tr>
<td>25</td>
<td>Liechtenstein</td>
<td>Amt für Gesundheit (Office of Healthcare)</td>
</tr>
<tr>
<td>26</td>
<td>Lithuania</td>
<td>State Medicines Control Agency</td>
</tr>
<tr>
<td>27</td>
<td>Malaysia</td>
<td>National Pharmaceutical Control Bureau</td>
</tr>
<tr>
<td>28</td>
<td>Malta</td>
<td>Medicines Authority Malta</td>
</tr>
<tr>
<td>29</td>
<td>Netherlands</td>
<td>Inspectie voor de Gezondheidszorg (Inspectorate of Health Care)</td>
</tr>
<tr>
<td>30</td>
<td>Norway</td>
<td>Norwegian Medicines Agency</td>
</tr>
<tr>
<td>31</td>
<td>Poland</td>
<td>Main Pharmaceutical Inspectorate</td>
</tr>
<tr>
<td>32</td>
<td>Portugal</td>
<td>Autoridade Nacional do Medicamento e Produtos de Saúde (National Authority of Medicines and Health Products)</td>
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<td>33</td>
<td>Romania</td>
<td>National Agency for Medicines and Medical Devices</td>
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<td>34</td>
<td>Singapore</td>
<td>Health Sciences Authority</td>
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<td>35</td>
<td>Slovak Republic</td>
<td>State Institute for Drug Control</td>
</tr>
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- **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

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.

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!!!

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.


Prescribers Awareness On Issues Surrounding Generic Medicines

- 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.

Educational Impact among Prescribers on Generic Medicine Use

- 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

- 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.

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; Izbal Ramzan, Professor of Pharmacoeconomics, 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, pharmacoeconomics.


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.

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. When using new drugs, prescribing should be more limited and should target patients, indications, and situations for which benefit has been demonstrated.

Ref: Schiff & Galanther, JAMA 2009
Issues Related to Generic Medicines Use: Generic Manufacturers

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
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
with some adaptation for ASEAN application.
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

• 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 Research - A Fitch Group Company

Q1 2018
www.bmiresearch.com

QATAR
PHARMACEUTICALS & HEALTHCARE REPORT
INCLUDES 10-YEAR FORECASTS TO 2026

- 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

- 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% 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.

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

Qatari National Health Strategy 2011–2016 Targets
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)

• 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)
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.

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.
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 Liaison Officer.
Know Your Medicine Campaign
Publication of Educational Booklet on Generic Medicine for Healthcare Professionals
Educational Booklet on Generic Medicine for Patients/Consumers

What You Should Know About Generic Medicines

Mohamed Azmi Ahmad Hassali
Jayabal Thambyappa
Asrul Akmal Shafie
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 (GMP)

**Differences**
- Generic medicines may be composed of different inactive ingredients (excipients) compared to branded medicines. The inactive ingredients include colouring, flavourings, preservatives, and special tablet coatings.

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**WHAT YOU SHOULD KNOW ABOUT GENERIC MEDICINES**

<table>
<thead>
<tr>
<th>Aspects</th>
<th>Generic Medicines</th>
<th>Counterfeit Medicines</th>
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<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Legislation</strong></td>
<td>Must conform to national regulatory standards.</td>
<td>Do not conform to national regulatory standards.</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td>Have the same safety profile as the innovator product.</td>
<td>Harmful and unsafe due to presence of toxic/inactive ingredients that are not effective.</td>
</tr>
<tr>
<td><strong>Packaging and labelling</strong></td>
<td>Good-quality packaging. Label is written properly with accurate drug details and spelling.</td>
<td>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.</td>
</tr>
</tbody>
</table>
Educational Posters on Generic Medicine for Patients/Consumers

Apa itu Ubat Generik?
Ubat generik adalah senia dengan ubat inovator

- Senia asli
- Ubat asli dekapan
- Ubat yang mempunyai kandungan yang sama dengan ubat inovator

Apa itu Ubat Inovator?
Ubat inovator ialah ubat yang mula diproduksi dan dijual oleh syarikat yang menghasilkan ubat tersebut sebelum mereka mendapat paten.

Apa kelebihan Ubat Generik lebih baik daripada Ubat Generik?

- Harga lebih rendah
- Ketersediaan lebih mudah
- Lebih ramah kewangan

Adakah Ubat Generik lebih manjur berbanding Ubat Inovator?

- Harga lebih sederhana
- Ketersediaan lebih mudah

Mengapa Ubat Generik lebih manjur berbanding Ubat Inovator?

- Lebih ramah kewangan
- Ketersediaan lebih mudah

Yakinlah dengan ubat generik, ia sama sahaja...
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