Saudi Pharmaceutical Journal (2014) 22, 491–503

King Saud University

Saudi Pharmaceutical Journal

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REVIEW

The experiences of implementing generic medicine policy in eight countries: A review and recommendations for a successful promotion of generic medicine use

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Received 2 October 2013; accepted 14 December 2013
Available online 25 December 2013

KEYWORDS

Generic medicines;
Health system;
Generic policy;
Generic substitution;
Pharmacists;
Physicians

Abstract Generic medicines are clinically interchangeable with original brand medicines and have the same quality, efficacy and safety profiles. They are, nevertheless, much cheaper in price. Thus, while providing the same therapeutic outcomes, generic medicines lead to substantial savings for healthcare systems. Therefore, the quality use of generic medicines is promoted in many countries. In this paper, we reviewed the role of generic medicines in healthcare systems and the experiences of promoting the use of generic medicines in eight selected countries, namely the United States (US), the United Kingdom (UK), Sweden, Finland, Australia, Japan, Malaysia and Thailand. The review showed that there are different main policies adopted to promote generic medicines such as generic substitution in the US, generic prescribing in the UK and mandatory generic substitution in Sweden and Finland. To effectively and successfully implement the main policy, different complementary policies and initiatives were necessarily introduced. Barriers to generic medicine use varied between countries from negative perceptions about generic medicines to lack of a coherent generic medicine

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Peer review under responsibility of King Saud University.

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http://dx.doi.org/10.1016/j.jsps.2013.12.017
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policy, while facilitators included availability of information about generic medicines to both healthcare professionals and patients, brand interchangeability guidelines, regulations that support generic substitution by pharmacists, and incentives to both healthcare professionals and patients.

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1. Introduction

In recent years, many governments and third party payers have advocated utilisation of generic medicines as a means of confronting the escalation of healthcare expenditure in general and medicine expenditure in particular, by instigating various policies, initiatives and strategies (Simoens and De Coster, 2006; Sermet et al., 2010; Godman et al., 2010a; Godman et al., 2012a; Ministry of Health Labour and Welfare of Japan, 2012a; Godman et al., 2012b). A generic medicine is 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" (WHO, 2012). A generic medicine is identical to its corresponding innovator medicine in terms of safety, quality, efficacy, dosage form, strength and route of administration, and has the same intended use as the innovator medicine (The US Food and Drug Administration (FDA), 2009). The active ingredients are the same but the excipients (i.e. inactive ingredients) might differ from one product to another (US FDA, 2012) as some other aspects including shape, colour and packaging (U.S. Department of Health and Human Services, FDA/CDER, 2012).

2. Objective of the review

This paper aimed to highlight the vital roles of generic medicines in healthcare systems and the need to establish and implement generic medicine policies. In this review, the experiences of promoting the use of generic medicines were explored in eight selected countries, namely the United States (US), the United Kingdom (UK), Sweden, Finland, Australia, Japan, Malaysia and Thailand. As it will be shown later in this review, the policies adopted are different from one country to another. For example, generic substitution is encouraged in the US, while it is legally not allowed in the UK and mandatory in the Sweden. Thus, due to these significant differences, direct comparison between countries was not attempted but rather the experience of each country was presented narratively with more focus on main policies. After that, by analysing the

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