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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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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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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.

Contents

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

experiences of all studied countries, the lesson learned during promotion and implementation of generic medicines including main facilitators that helped to increase the use of medicines and also barriers that hindered generic substitution were presented in the form of general recommendations that would be valuable to policy makers to consider when implementing or improving the current generic medicine.

3. Methodology

The country experience of promoting generic medicines was reviewed in eight selected countries. The selection was based on several factors. The US was selected because generic substitution is a very common practice while the UK was selected because generic prescribing is a standard practice. Two European countries, namely Finland and Sweden were also selected because they have successfully implemented mandatory generic substitution policy. In the Asia Pacific region, Australia, Japan, Malaysia and Thailand were selected. In Australia and Japan, several policies related to generic medicines are applied, thus their experiences would be useful. The situation in Malaysia and Thailand where no coherent generic medicines policy are in place was also explored. This narrative review was based on an extensive literature search using several electronic databases and search engines including PubMed, Medline, ISI Web of Knowledge, Scopus, Science Direct, Springer Link, Proquest, Ebsco Host, Google Scholar and Google. Additional articles and sources were identified by reviewing the bibliography of the retrieved articles. In addition, websites of several organisations and agencies including drug regulatory authorities in the reviewed countries were visited for relevant information and reports. The search strategy involved using Boolean operators for combinations of several key words including generic medicine, brand medicine, innovator medicine, generic dispensing, generic prescribing, generic substitution, generic medicine policy, medicine expenditure, medicine pricing, names of the reviewed countries (e.g. Japan), pharmacists, physicians, practitioners, prescribers and patients. Equivalent terms in thesauruses or Medical Subject Heading (MeSH) browsers were used whenever possible.

4. Role of generic medicines in healthcare system

4.1. Affordability and Access to medicines

The WHO estimated that at least 30% of the world's population lacks regular access to essential medicines, and the figure increases to 50% in the poorest countries of Africa and Asia (WHO, 2011). One of the most important barriers to access to medicines is their high cost (Cameron et al., 2009; Huskamp et al., 2003). Medicine prices are often unaffordable not only for large sectors of the population in low- and middle-income countries, but also for sizeable segments of the population without adequate social protection or insurance in high income nations (Organisation for Economic Co-operation and Development (OECD), 2008; Cameron et al., 2009). Given that generic medicines are 20–90% cheaper than their counterpart innovator brands (Matin, 1999; Shafie and Hassali, 2008) and "gold standard" and "first-line therapy" for many acute and chronic diseases (Sheppard, 2011), promoting generic medicines is important to improve medicine access both for governments and individuals who have to pay out of pocket for medicines (Cameron et al., 2009). Furthermore, generic medicines are not only cheaper substitutes for innovator medicines, they also play a role in lowering the prices of off-patent innovator medicines and other generic equivalents. A study in the US found that while the price of a first entry generic medicine was only marginally lower than the innovator brand price, the entry of a second generic medicine dropped the average generic price to about 50% of the innovator brand price. When a large number of generic medicines entered the market, the average generic price fell to 20% or even lower (US FDA, 2010). The introduction of mandatory generic substitution policy in Sweden resulted in a 15% reduction in overall medicine prices and more than 40% decrease in prices of off-patent medicines within 4 years of the policy implementation (Pharmaceutical Benefits Board (LFN), 2007). Similar results were found in Finland, with a 10.6% reduction in substitutable medicine prices and up to 80% price decrease for some medicines during the first year of mandatory generic substitution policy implementation (Aalto-Setälä, 2008).

4.2. Effective cost containment strategy

Given the limited resources, increasing health expenditure due to growing healthcare demand is a challenge faced by most countries around the world. Medicine spending often accounts for a large part of the total health expenditure, ranging from 20% to 60% in middle- and low-income countries (WHO, 2004). Moreover, it has been steadily rising as one of the most rapidly growing components of healthcare expenditures (Henriksson et al., 1999; Schneeweiss et al., 2002; Ess et al., 2003; Zuvekas and Cohen, 2007; Wettermark et al., 2008; Saudi Ministry of Health (MOH), 2008; Godman et al., 2009; Coma et al., 2009; Sermet et al., 2010; Godman et al., 2010a; Godman et al., 2010b; Leng et al., 2011; Hoffman et al., 2012). Therefore, containing medicine expenditure is necessary prior to overall health expenditure containment.

Generic medicines offer a great opportunity for substantial savings, being 20–90% cheaper than their counterpart innovator medicines (Matin, 1999; Shafie and Hassali, 2008). In the US, generic medicines saved the healthcare system about one trillion dollars over 10 years from 2002 to 2011 (Generic Pharmaceutical Association, 2012). Switching procurement from innovator brands to the lowest priced generic equivalents in the private sector in 17 developing countries could result in an average of 60% cost savings (Cameron et al., 2012). Making this switch for only four medicines in the public sector in China could potentially save US $ 370 million (Cameron et al., 2012). In Europe, generic medicines accounted for more than 50% of market share in volume but only 18% in value (Sheppard, 2011). Therefore, generic prescribing and generic substitution are often promoted as strategies for containing the escalating cost of the medicines.

4.3. Generic medicine policy as part of the national medicine policy

According to the WHO, the national medicine policy is "a commitment to a goal and a guide for action" with an objective of

promoting equity and sustainability of both public and private pharmaceutical sectors. In addition, it should ensure not only the availability and accessibility to high quality, safe and effective medicines, but also promote cost effective use of medicines to healthcare professionals and consumers (WHO, 2003). Promotion of generic medicines is recommended to be included as part of the national medicine policy (Cameron et al., 2012) as it helped to achieve a comprehensive and sustainable healthcare system in Europe (Godman et al., 2010a). This is needed to improve the affordability, and thus accessibility of medicines in developing countries (Cameron et al., 2009).

5. Country experiences with generic medicines

5.1. The United States of America

In the US, total medicine expenditure has steadily increased and reached $ 326 billion in 2012. Nevertheless, widespread use of generic medicines in recent years helped to slow the growth of medicine expenditure (Hoffman et al., 2012, 2013). It is estimated that about 80% of prescriptions filled are generic medicines (US FDA, 2012). Generic substitution (GS) is a common practice in the US, and pharmacists play an essential role in promoting generic medicines as they substituted 83.8% of prescriptions that allowed substitution (Mott and Cline, 2002). Several factors have led to this phenomenon, one being that GS is addressed and regulated by all states. However, GS regulations may differ from one state to another in many respects (Assistant Secretary for Planning and Evaluation (ASPE), 2013, U.S. Department of Health and Human Services; Bobinmyer-Hornecker, 2011; Vivian, 2008). The first issue to be addressed is which medicines to substitute. Some states adopt positive formulary concept (i.e. a list of substitutable generic medicines), while others adopt negative formulary (i.e. generic medicines that should not be substituted). Moreover, the issue of Narrow Therapeutic Index (NTI) medicines is considered (ASPE, U.S. Department of Health and Human Services; Bobinmyer-Hornecker, 2011; Vivian, 2008). The second to be addressed is generic substitution by pharmacists. According to some state laws, pharmacists are required to substitute brand medicine with its therapeutic equivalent generic version unless prohibited by the prescriber (i.e. mandatory GS), while in some states GS is just allowed (indicative/permissive GS) (ASPE, U.S. Department of Health and Human Services; Anonymous (epilepsy.com), 2007), and some others require pharmacists to obtain patients' consent before GS (ASPE, U.S. Department of Health and Human Services). However, while it seems there is no apparent impact of the status of GS (i.e. mandatory vs. indicative) on the rate of GS, obtaining consent from patients was associated with a lower GS rate (lower by 25%) in states that impose obtaining consent compared with those that do not require it (Shrank et al., 2010). This could be explained in part by the fact that many patients prefer to use branded medicines over generic medicines (Keenum et al., 2012; Shrank et al., 2009). Thus, GS laws have an impact on GS (ASPE, U.S. Department of Health and Human Services; Shrank et al., 2010).

Another factor is that patients are encouraged to use generic medicines by making them pay significantly less co-payment when selecting generic medicines as most pharmacy plans and designs and insurers adopted formularies with three tier co-payment. In this system or plan, patients pay the lowest co-payment for generic medicines (first tier), a middle co-payment for preferred brand name medicine (second tier) and the highest co-payment for the expensive non-preferred brand name medicine (third tier) (Huskamp et al., 2003; Kohl and Shrank, 2007; Shrank et al., 2006, 2007; Congressional Budget Office (CBO) Congress Of The United States, 2010). For example, in 2009, in Stand-alone prescription-drug plan, average co-payment for generic medicines was USD $ 7, while for preferred brand medicines and non-preferred brand medicines, it was USD $ 37 and $ 75 respectively (Neuman and Cubanski, 2009). Another approach to encourage generic medicines is the step therapy concept, which is use of a cheaper generic medicine or preferred brand medicine before using a more expensive brand medicine. In addition, to prescribe some expensive medicines when an equivalent generic version is available, pre authorisation is required (Congressional Budget Office (CBO) Congress Of The United States, 2010).

At the federal level, the approved drug products and therapeutically equivalent generic medicines are listed in the orange book, which is a useful guide for pharmacists and other healthcare professionals as regards therapeutic equivalence and approved generic medicines in the US (U.S. Department of Health and Human Services-FDA/CDER, 2012). However, as pharmacy practice law regarding generic substitution varies between states, pharmacists are required to be familiar with and perform product substitution in accordance with the individual state's Pharmacy Practice Act (Bobinmyer-Hornecker, 2011; Vivian, 2008). Pharmacists are playing an essential role, therefore, any policy should make sure their incentives to dispense generic medicines are maintained (Coster, 2010, 2012). On the other hand, generic prescribing is still not common practice in the US (Steinman et al., 2007). Furthermore, many physicians have negative perceptions about generic medicines and lack in-depth knowledge about the bioequivalence concept applied in the US (Shrank et al., 2011). Also, the US FDA, besides ensuring quality, safety and efficacy of generic medicines via a rigorous registration process, makes efforts to promote generic medicines by educating both consumers and healthcare professionals to increase their confidence in generic medicines (US FDA, 2009; US FDA, 2012). Promotion of generic medicines in the US resulted in substantial savings (about one trillion US dollars) over one decade (Generic Pharmaceutical Association, 2012).

5.2. The United Kingdom

Unlike the US, generic prescribing is a more common practice in the United Kingdom (UK). In 2008, more than 83% of prescriptions in general practices were written for generic names (Department of Health, 2009b). In addition, generic substitution is a common practice in NHS hospitals (Duerden and Hughes, 2010; Ferner et al., 2010). However, as generic prescribing is a standard practice, GS is not allowed in the primary care setting and community pharmacists are required to dispense the prescribed brand (Department of Health, 2009a). Several factors have led to this practice. In fact, INN prescribing is encouraged at early stages as medical schools in the UK are teaching medical students generic prescribing (Simoens and Coster, 2006; Simoens and De Coster, 2006; Duerden and Hughes, 2010). Another factor is that physicians

are encouraged in various ways, using both financial and non-financial incentives, to prescribe generically. Financial incentives include, for example, physicians' budgets and budgetary incentives, generic prescribing targets with incentives. In budgetary incentives, savings achieved by the physicians beyond the indicative budget can be used for other purposes such as training. Other factors include empowering physicians with technology and decision support systems to help them prescribe generically (such as generic prescribing programmes), and providing them with information via national and local cost effective prescribing guidelines (e.g. NICE guidelines). In addition, prescribing monitoring and feedback to improve physicians' prescribing and awareness of medicines costs is also used to encourage generic prescribing (The association of the British Pharmaceutical Industry (ABPI), 2013; Simoens and Coster, 2006; Simoens and De Coster, 2006; Habl et al., 2006; Sturm et al., 2007; Bongers and Carradinha, 2009; Vogler and Schmickl, 2010).

For prescriptions written by INN, pharmacists dispense generic medicines because the Drug Tariff Price (i.e. reimbursement level price) is usually set well below the price of the brand medicine (Simoens and Coster, 2006). Therefore, to make pharmacists dispense their generic product, generic medicine manufacturers and wholesalers offer substantial discounts on the reimbursement price, which exceed 60% – or even 80% – for some medicines (Kanavos, 2007). However, the practice or competition which arises by providing discounts while the reimbursement price is fixed (i.e. the retail price is not reduced), means the payers (i.e. NIH) do not receive the benefit of substantial savings that could be achieved by generic medicines as they are paying more than the actual price of the generic medicines (Dylst and Simoens, 2010; Kanavos, 2007; Simoens, 2012). To address this issue, therefore, Manufacturers "M" and Wholesalers "W" schemes were introduced in 2005. In these voluntary schemes, net discounts need to be disclosed so that the reimbursed level reflects the prices after discounts (Department of Health, 2005a,b, 2010). As a result, the prices of generic medicines were reduced by 32.4% in 2005 (Office of Fair Trading (OFT), 2007) and overall prices of medicines by 2% one year after the schemes' introduction (Godman et al., 2012c). It is also noted that although patients are given information about generic medicines, there are no incentives for them to accept generic medicines (Simoens and Coster, 2006).

Thus, physicians play an essential role especially in general practices in the UK by prescribing generically as community pharmacists are not allowed to perform GS. Therefore, adoption of cost effective prescribing (i.e. prescribing cheaper generic medicines) by GPs in England resulted in cost saving of around US $ 600 million in 2008 (Coombes, 2009). In the UK, British National Formulary (BNF) recommendations are a useful source for healthcare professionals when GS is not suitable for some medicines (Duerden and Hughes, 2010; Ferner et al., 2010; Joint Formulary Committee, 2011).

5.3. Finland

Generic substitution was introduced for the first time in Finland in 1993, then it was stopped in 1996 and replaced by generic prescribing (Martikainen and Rajaniemi, 2002). Since 2003, generic substitution has been mandatory. In this policy, the pharmacist has to substitute the prescribed medicine with the cheapest interchangeable product or close to the cheapest product (i.e. the product to be offered should be within a specific price range, also known as the price corridor/band). However, consumers can refuse GS and physicians also can forbid its use (Aalto-Setälä, 2008; Heikkilä et al., 2007). When asked their opinions about generic substitution during the first year of mandatory GS, consumers spoke of different reasons for accepting GS, including saving money and encouragement from pharmacists through their advice and recommendations. Some consumers refused GS because they were comfortable with the medicines they were using or confused and uncertain about GS (Heikkilä et al., 2007). Physicians generally accepted GS policy, but some believed that certain interchangeable generic products are not of the same effectiveness and safety profile (Heikkilä et al., 2007). To facilitate properly GS, the Finnish Medicines Agency (Fimea) quarterly issues a list of interchangeable products that can be substituted (Heikkilä et al., 2007; The Finnish Medicines Agency (Fimea), 2013). GS substitution leads to cost saving directly by substituting the expensive brands and reducing the price of medicines due to competition. This is because drug companies have to reduce their price to be in the price corridor/band if their products are to be substituted by pharmacists (Aalto-Setälä, 2008; The Social Insurance Institution of Finland (KELA), 2009).

5.4. Sweden

Sweden has introduced mandatory generic substitution since 2002. In this system, community pharmacies are obliged to dispense the least expensive generic medicine or parallel imported medicine available in the pharmacy. However, prescribers can disallow GS. Patients can also refuse GS but they are required to pay the price difference between the generic and the more expensive brand medicine (Pharmaceutical Benefits Board (LFN), 2007). Andersson et al. (Andersson et al., 2005) evaluated the barriers to implementation of GS and the cost saving achieved during the first year. The study concluded that the majority of prescribers and patients accepted GS. However, patients declined GS when the price difference was not significant. The actual saving resulting from substituting six medicines was SEK 15.6 million, which represented 60% of the total possible savings. Additional savings, therefore, can be achieved by GS and probably by introducing generic prescribing (Andersson et al., 2005). GS introduction also led to a drop in medicine prices (LFN, 2007) and decreased the growth of the medicine expenditure (Andersson et al., 2007). In Sweden, the Swedish Medical Products Agency (MPA) produces a list of therapeutically interchangeable products to guide the process of GS (Andersson et al., 2005; The Swedish Medical Products Agency (MPA), 2010).

5.5. Australia

The pharmaceutical benefit scheme (PBS), as an essential component of the Australian healthcare system, which has been in operation since 1948, aims to ensure 'timely access to the medicines that Australians need, at a cost individuals and the community can afford'. Under this scheme, the cost of PBS listed prescription medicines is subsidised by the government (Department of Health and Aging). However, the patients

are required to contribute a co-payment when getting their prescriptions (Department of Health and Aging; Department of Health and Aging, 2013). In 1 year (July 2011 to June 2012), the total volume of PBS prescriptions was 194.9 million and the total expenditure was AUD 9, 193.7 million. The government expenditure represented 83.4% of PBS prescriptions' total cost and the rest was paid by patients' contributions (PBS Information Management Section, 2012).

Reference pricing (RP) system is a key feature of the PBS, which opens up space for generic medicines (Beecroft, 2007; Lofgren, 2004; Lofgren, 2009). In 1990, the Brand Premium Policy was introduced. This policy, using reference pricing principle, is applied when there is more than one brand of the identical medicines listed, and these are off-patent medicines and generic equivalents. In this system, the government subsidises all equivalent medicines by a fixed reimbursement/subsidy level, which is equivalent to the lowest priced brand (known as benchmark price). The companies can set their price higher than the benchmark, but the patients have to pay the brand premium, which is the difference between the actual price of the medicine and the benchmark (Department of Health and Aging; Beecroft, 2007; Department of Health and Aging, 2013; Lofgren, 2004, 2009). In 1994, pharmacists were allowed to perform GS for products listed on the PBS schedule if they had patient consent and no objection from the prescriber (Beecroft, 2007). In 1998, the Therapeutic Group Premium (TGP) Policy was introduced. In this policy, government subsidises all medicines in a specific therapeutic group, which are deemed to have similar safety, efficacy profiles and health and therapeutic outcomes to the level of the lowest priced medicine. The companies can set the price of their medicines higher than that of the lowest priced medicines, but the patients have to pay the therapeutic group premium, which is the difference between the actual price and the subsidised price (Department of Health and Aging; Beecroft, 2007; Department of Health and Aging, 2013; Lofgren, 2004, 2009).

However, as the medicine suppliers can set their prices, they usually price them close to the original medicines (Lofgren, 2004). At the same time, they offer substantial discounts (up to 50% in some cases) to community pharmacies to dispense their products preferentially (Beecroft, 2007; Lofgren, 2004, 2009). Moreover, some physicians especially in the private sector did not support GS, which they disallowed in their prescriptions probably due to lack of incentives when prescribing generic medicines (Lofgren, 2004). Therefore, this not only raised the prices of generic medicines (Bulfone, 2009) and lowered utilisation (Lofgren, 2004; Organisation for Economic Co-operation and Development (OECD), 2008), it also meant that the government did not get the value of generic medicines as the reimbursement level was much higher than the actual price of the generic medicines. Thus, despite the introduction of these policies, the escalating cost of the PBS is challenging the sustainability of this scheme. For example, for over 10 years (1995/96 – 2004/05), the cost of PBS was annually increasing by around 13%. In addition, the prices of generic medicines are high compared with those in other OECD countries (Bulfone, 2009; OECD, 2008).

Therefore, in 2005, a mandatory 12.5% price reduction policy was introduced. According to this policy, to be listed on the PBS, the first new generic version of a medicine already on the PBS must be priced at least 12.5% below the current lowest priced brand. Under the reference pricing, the presence of a new, cheaper generic brand in the group would reduce the group price benchmark and the price cut would affect all the medicine brands (Beecroft, 2007; Lofgren, 2009). Furthermore, comprehensive changes to the pricing system and mechanism of pricing, which included mandatory price reduction and price disclosure, were introduced in late 2006 (Department of Health and Aging, 2007; Lofgren, 2009). As a result of these changes, for the purpose of pricing, the PBS medicines were separated into two formularies. Formulary 1 (F1) contains single brand medicines (almost all medicines in this formulary are patented medicines). Formulary 2 (F2) includes multiple brand medicines and single brand medicines in a therapeutic group with a medicine or medicines that have multiple brands. The medicines in the therapeutic group should be of similar safety and efficacy profiles and therapeutically interchangeable. ACE inhibitors and Proton Pump Inhibitors are examples for such therapeutic groups (Department of Health and Aging, 2007). In this system, there are no price links between medicines listed on F1 and medicines listed on F2. However, the reference pricing system is applied in each formulary. For F1 medicines, Therapeutic Group Premium (TGP) policy is applied to medicines that are linked within a specific therapeutic group. For medicines listed on F2, Therapeutic Group Premium (TGP) policy and brand premium policy are applied whenever relevant (Department of Health and Aging, 2007; Lofgren, 2009). Medicine prices are required to be disclosed to ensure that government payments reflect the actual price of the medicine. In addition, mandatory price reductions are applied on all medicines listed on F2. For price cut, F2 was divided into two sub-formularies (F2A and F2T) depending on trading terms (i.e. discounts that community pharmacies get from drug companies and suppliers when purchasing their medicines). F2A contains medicines that have less than 25% discount and F2T contains medicines that have 25% discounts or more. Prices were cut by 2% per year for 3 years (2008, 2009 and 2010) for medicines listed on F2A and a one off 25% cut (in 2008) for medicines listed on F2T. The 12.5% price reduction policy is ongoing and will come into force whenever it is applicable (Department of Health and Aging, 2007; Lofgren, 2009). Moreover, since August 2008, to encourage pharmacists to dispense cheaper brands, they are paid, as an incentive, when they dispense a substitutable, premium-free PBS medicine. This incentive payment is known as premium free dispensing incentive and equal to AUD 1.50 as of August 2010 (Department of Health and Aging, 2007; Department of Human services, 2012).

It was estimated that around 34.7% of PBS prescriptions were filled with generic medicines in 2008, representing around 17.6% of the PBS prescription costs (in 2001, this was estimated at around 19.2%). The Centre for Strategic Economic Studies (CSES) estimated that over 10 years, 2008/09 – 2017/18, as a result of the comprehensive reforms introduced in 2006, the Australian system will save $6.4 billion (The Centre for Strategic Economic Studies (CSES), 2009). In Australia, the schedule of pharmaceutical benefit is a very useful guidance for healthcare professionals and consumers as regards therapeutic equivalence between medicines, prices of medicines, brands subjects to brand premium and Therapeutic group premiums (Department of Health and Aging, 2013). In addition, National Prescribing Service limited (NPS), an independent not-for-profit organisation, plays a pivotal role in educating consumers about generic medicines and brand choices, as well

as organising educational campaigns and educational materials. NPS is also a good source for healthcare professionals (National Prescribing Service Limited (NPS), 2012).

5.6. Japan

The Japanese national health expenditure increased from about 30.1 trillion Yen in 2000 to 36 trillion Yen in 2009. The medicine component represented approximately 22.2% of the total health expenditure (Ministry of Health Labour and Welfare of Japan (MHLW), 2012b). Generic medicine utilisation in the Japanese healthcare system is low. In 2005, the volume of generic medicines was 16.8% and increased to 22.8% of the market volume in September 2011 (MHLW, 2012a). Currently, the government aims to achieve a generic market share of more than 30% by early 2013 (MHLW, 2012a). Therefore, to promote generic medicine utilisation, generic medicine policies have been introduced since 2002. Different policies were introduced including those to speed up registration on the reimbursement list, to provide financial incentives to encourage physicians to prescribe and pharmacists to dispense generic medicines and generic substitution policy (Iizuka, 2009; Simoens, 2009).

Prior to being reimbursed from health insurance, prescription medicines must be registered to the Ministry of Health, Labour and Welfare (MHLW) to be on the official list of prescription medicines with an assigned reimbursement price (Iizuka, 2009). Since 2007, to speed up the registration of generic medicines on the reimbursement list, generic medicines can be registered twice a year rather than once a year as previously (Simoens, 2009; Kobayashi et al., 2011b). In addition, since 2004, the prices of generic medicines on the reimbursement list have to be at least 30% cheaper than the originator medicines (Simoens, 2009; et al., 2011b).

Generic substitution policy was introduced for the first time in 2006. Consequently, pharmacists were only able to substitute with permission from prescribers (Simoens, 2009). However, since 2008, GS policy has been changed. Pharmacists can perform GS unless the physicians prohibit it (Iizuka, 2009; Kobayashi et al., 2011a; Simoens, 2009). GS is encouraged because it is estimated that successful implementation of GS policy would result in a saving of about Japanese Yen (JPY) 1.3 trillion of the total annual medicine expenditure (Ministry of Finance of Japan). To enhance further generic medicine utilisation, financial incentives for physicians, pharmacists and hospitals were also introduced. Physicians are incentivised by JPY 20 when they prescribe a generic medicine or prescribe a medicine by generic (INN) name. Pharmacists are also given JPY 170 if the share of generic medicines in their pharmacies is over 30% in a three-month period. In addition, to encourage pharmacists to educate consumers and patients about generic medicines, they are entitled to JPY 100 when they provide patients with information about generic medicines (Kobayashi et al., 2011b; Simoens, 2009).

Despite all these policies and initiatives, generic medicine utilisation is still low. The barriers identified include unstable supply of generic medicines to the market and factors related to healthcare professionals (i.e. physicians and pharmacists) (Iizuka, 2009; Kobayashi et al., 2011b; MHLW, 2012a). The former was addressed in 2007, when the Japanese Ministry of Health, Labour and Welfare requested from generic medicine manufacturers that they ensure a stable, nationwide supply for price-listed medicines for at least five years (Simoens, 2009). The latter was more entrenched due to a number of reasons. The low acceptance from prescribers was because of negative perceptions about generic medicines (Iizuka, 2009; MHLW, 2012a). Many pharmacists "seldom or never recommend" GS to patients as a result of the unavailability of generic medicines in the pharmacy stock, patients' objection due to insignificant cost saving, objection by physicians, doubts about the quality of generic medicines and insufficient information about generic medicines (Kobayashi et al., 2011b). Furthermore, patients lack knowledge about the availability of generic medicines and are not aware of generic substitution at community pharmacies (Kobayashi et al., 2011a). Implementation of a more comprehensive educational campaign to improve further public perception about generic medicines is therefore needed (Kobayashi et al., 2011a).

5.7. Malaysia

In 1999, the Drug Control Authority (DCA) of the Malaysian Ministry of Health reviewed the registration process of generic medicines to ensure the best international standards and practices were applied. Consequently, bioequivalence studies have become an essential requirement in registering generic medicines, except for a few generic products which have bioequivalence studies waived when scientifically appropriate (Centre For Product Registration, 2013; National Pharmaceutical Control Bureau (NPCB), 2013; Ministry of Health Malaysia; NPCB, Ministry of Health Malaysia; NPCB, Ministry of Health Malaysia, 2013). Notwithstanding the efforts of national authorities, there are still misconceptions and negative perceptions about generic medicines in terms of quality, efficacy, safety and bioequivalence among physicians, pharmacists and patients (Al Gedadi et al., 2008; Chua et al., 2010; Chong et al., 2011a; Hassali et al., 2012; Thomas and Vitry, 2009). The reasons might be a lack of a comprehensive generic medicine policy as well as guidelines that govern GS in Malaysia (Chong et al., 2011b). As a result, originator medicines are actively dispensed by community pharmacists even for chronic diseases when equivalent cheaper generic medicines are available (Babar and Awaisu, 2008).

To address the problem, a GS policy is being considered for future implementation (Ministry of Health Malaysia, 2009), which is supported by community pharmacists (Chong et al., 2010), although the majority prefer a voluntary GS to compulsory GS (Babar and Awaisu, 2008). The feasibility of policy implementation further increases as patients generally accept the offer of GS by community pharmacists (Chong et al., 2011b). However, to improve acceptance and utilisation of generic medicines consumers need to be educated about generic medicines to gain sufficient knowledge and eliminate negative perceptions (Al Gedadi et al., 2008; Thomas and Vitry, 2009). Generic medicines passing bioequivalence tests are currently listed on the "generic product list for bioequivalence studies", which is disseminated and published online for easy access to healthcare professionals (National Pharmaceutical Control Bureau (NPCB). Ministry of Health Malaysia). However, a formulary of therapeutically interchangeable products is still needed to guide generic substitution (Chong et al., 2010; Chua et al., 2010).

Currently, there is no medicine pricing policy and medicine prices in the private sector are not regulated by government (Hassali et al., 2010; Shafie and Hassali, 2008). Therefore, medicine prices are determined by the market force (Babar et al., 2007). Nevertheless, the generic medicines in Malaysia are much cheaper than original brand medicines as it is estimated that original brand medicines are 27–90% more expensive than generic medicines (Shafie and Hassali, 2008). Thus, GS can lead to substantial cost savings for both community pharmacies and medicine consumers. It is estimated that GS can save around 70% of the cost in stock purchasing for community pharmacists and approximately 60% of patients' spending on medicines (Chong et al., 2011b; Ping et al., 2008).

5.8. Thailand

In Thailand, around 97.4 % of the population was covered by insurance in 2009. Currently, there are three major insurance schemes, namely, Universal Coverage of Healthcare (UC) Scheme (introduced in 2002 and currently approximately 74% of the population are covered by this scheme), Civil Servant Medical Benefit Scheme (CSMBS) and the Social Security scheme (SSS) (Bureau of Policy and Strategy. Ministry of Public Health of Thailand). In Thailand, total Healthcare expenditure was approximately baht 588,154 million in 2008 (1 US$ = 33 baht in 2008). The total pharmaceutical expenditure represented approximately 34.16% in 2000 and steadily increased to 46.4% of the total health expenditure in 2008. Government expenditure on health represented 42.23% of the total health expenditure in 2008. (Bureau of Policy and Strategy Ministry of Public Health of Thailand, 2008–2010). In Thailand, out of pocket payment represented approximately 57.6% of private health expenditure in 2008 (Bureau of Policy and Strategy Ministry of Public Health of Thailand, 2008–2010).

At present, there is no policy that regulates the prices of medicines in the private and public sectors in Thailand. Moreover, similar to many other developing and middle income countries (Cameron et al., 2009), both brand medicines and generic medicines are sold at higher prices compared with international reference prices. This could be in part explained by lack of price control and high mark-ups. In the public sector, for example, mark-up ranges for original medicines and generic medicines were 28–41% and 20–285% respectively. However, generic medicines are much cheaper than original brand medicines. For example, in the private sector, original medicines are more expensive than generic medicines by about 3.9 times (World Health Organization/Health Action International (WHO/HAI), 2006; Cha-oncin et al., 2009). Therefore, it is necessary to consider a pricing system implementation and to review medicine prices.

In Thailand, GS policy is adopted in some insurance programmes (WHO/HAI, 2011). In addition, some hospitals have recently introduced mandatory generic substitution in inpatient settings. The evaluation of this policy reported that it would yield a significant cost saving if extended to include other settings (i.e. outpatient settings) (Kaojarern and Pattanaprateep, 2012). In addition, nationwide promotion of GS could yield a substantial cost saving to the healthcare system. For example, average potential savings for seven medicines that could be achieved from using lowest generic medicines instead of original brand medicines were 76 ± 13% equivalent to USD 3,997,118 (Cameron et al., 2012).

In Thailand, it seems that generic prescribing in primary care practice is common. However, there is still scope for improvement in this regard (Plianbangchang et al., 2010). Moreover, most surveyed pharmacists in the study conducted by Sukontharat et al. (Sukontharat et al. 2012) showed that pharmacists are supportive of GS policy implementation. However, they stated that before implementation of generic policy, arrangement and agreement between other healthcare professionals are important.

6. Lessons learned and recommendations to improve generic medicine use

In general, to effectively promote generic medicines, it is evident that any main policy to promote generic medicines needs to be supported by some complementary policies to facilitate its implementation or to overcome the barriers that may hinder its effective implementation. This is consistent with the findings that have been reported by Simoens (2010) in Europe (Simoens, 2010). From reviewing the generic medicine experiences in the eight countries, the following recommendations can be made.

6.1. National drug authorities

Generic medicines should be registered via a rigorous scientific based registration system to ensure the quality, safety, efficacy and bioequivalence of generic medicines. In addition, a post-marketing follow-up and monitoring system should be in place to detect any safety or quality issues that may arise after registration. Furthermore, it is of great importance that medicine registration authorities communicate with healthcare professionals and consumers to make them aware of the registration system requirements and the standards that medicines must pass through before being granted approval. This will make them confident in the generic medicines as essentially the same as the original brand medicines and that all medicines go through the same registration process. Moreover, drug regulatory authorities should ensure that only quality products are available in the market, because availability of low quality or counterfeit medicines not only makes prescribers reluctant to prescribe generic medicines (Al-Tamimi et al., 2013; Sharrad et al., 2009) but also lose confidence in the whole healthcare system (Editorial-Lancet, 2012).

6.2. Generic medicine promotion programmes

As the healthcare systems are different from one country to another and challenges and barriers to generic medicines might also be different, it is important to have a comprehensive plan and well-designed promotion programme that address, from various perspectives, all aspects related to generic medicines. This should include a plan for overcoming obstacles to improving utilisation. The Japanese "Action Programme for Promotion of the Safe Use of Generic Drugs" is a good example of promotion programmes (MHLW, 2012a). Moreover, poorly managed programmes are in fact a barrier to implementation of generic medicine policy (Kaplan et al., 2012). In addition, it is evident that less comprehensive educational campaigns may not fulfil the mission and short programmes have minimal impact (Kobayashi et al., 2011a; Simoens and De Coster, 2006).

6.3. Healthcare professionals: communication and co-operation

Quality use of generic medicines and successful implementation of generic substitution and generic prescribing require communication and co-operation of all involved parties in this process. There should be co-operation between healthcare professionals (pharmacists, physicians and other prescribers and dispensers). For example, when prescribers oppose GS by community pharmacists, it is an obstacle to successful implementation of GS. Communication between the national regulatory authorities, healthcare professionals and consumers and providing them with information about the requirements to register medicines in general and generic medicines in particular is important. For example, in the US, the FDA, via the office of generic drugs, provides valuable data about approved generic medicines in the US with frequent updates on its website so it can help healthcare professionals and consumers to get the latest information about medicines registered in the country. A further example, the National Prescribing Service (NPS) in Australia plays a role in educating consumers about generic medicines via educational campaigns and materials about medicine brand choices.

6.4. Healthcare professionals: acceptance of generic medicines

Health care professionals play a pivotal role in the promotion of cost effective use of medicines in general and generic medicine in particular. Therefore, it is essential to address any concerns that they have regarding the generic medicines such as negative perceptions about quality, efficacy and safety.

6.5. Patients: acceptance of generic medicines

Patients and drug consumers should be encouraged by healthcare professionals (pharmacists and physicians) to use generic medicines. They should also be educated about generic medicines by, for example, media and educational campaigns, because any concerns that patients have might make them refuse GS, lead to confusion or affect their adherence to the medicines. Moreover, it is evident in the literature that counselling, advice and recommendations by healthcare professionals encourage patients to accept generic medicines and GS.

6.6. Evidence based references of therapeutically substitutable medicines

To implement generic substitution and generic prescribing successfully, it is important to have a guide on therapeutically interchangeable drug products to help healthcare professionals to perform GS appropriately and to avoid any pitfalls or errors that may arise from inappropriate GS (Alrasheedy et al., 2013). The orange book in the US, BNF in the UK, the Schedule of PBS in Australia and the lists of interchangeable products in Finland and Sweden are examples of such references.

6.7. Medicine prices and pricing systems

It is important not only to promote generic medicines but also to evaluate prices of medicines and reasonability of their prices and to find mechanisms to reduce the prices of medicines. This is due to the fact that some medicines are priced more than expected in some countries (Cameron et al., 2009; WHO/HAI, 2006) and some generic medicines are even more expensive than original brand medicines (Shafie and Hassali, 2008). In Australia, for example, mandatory price reduction and price disclosure were intended to reduce the prices of medicines and make sure the reimbursement reflects the actual prices. Furthermore, the price difference was a determinant factor for patients to accept generic medicines, because they refuse GS when cost saving or price difference is minimal.

6.8. Reimbursement system and financial incentives

The efforts to promote generic medicines should also consider a reimbursement system and financial incentives for pharmacists and physicians. For instance, the mandatory generic substitution policies in some European countries require pharmacists to reimburse only for dispensing the cheaper or close to the cheaper therapeutic equivalent generic medicines. In addition, the patients who refuse GS or choose a more expensive brand should pay the price difference. Moreover, as in Japan, financial incentives could be considered to encourage physicians and pharmacists to recommend generic medicines to their patients.

7. Conclusion

Generic medicines can provide substantial savings to healthcare systems. However, there are many challenges in implementing fully generic medicine policies to get the maximum benefits. As the challenges are different from one healthcare system to another, a well-designed programme to promote generic medicines should address first the challenges based on the local settings. Furthermore, it seems that any main policy to promote generic medicines needs to be supported by some complementary policies to facilitate its implementation or to overcome the barriers that may hinder its effective implementation.

Conflict of interest

The authors declare that they have no conflict of interests. No funding was received for this study.

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