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POLICY PERSPECTIVES

Need for Multicriteria Evaluation of Generic Drug Policies

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ABSTRACT

Policymakers tend to focus on improving patented drug policies because they are under pressure from patients, physicians, and manufacturers to increase access to novel therapies. The success of pharmaceutical innovation over the last few decades has led to the availability of many off-patent drugs to treat disease areas with the greatest public health need. Therefore, the success of public health programs in improving the health status of the total population is highly dependent on the efficiency of generic drug policies. The objective of this article was to explore factors influencing the true efficiency of generic prescription drug policies in supporting public health initiatives in the developed world. Health care decision makers often assess the efficiency of generic drug policies by the level of price erosion and market share of generics. Drug quality, bioequivalence, in some cases drug formulations, supply reliability, medical adherence and persistence, health outcomes, and nondrug costs, however, are also attributes of success for generic drug policies. Further methodological research is needed to measure and improve the efficiency of generic drug policies. This also requires extension of the evidence base of the impact of generic drugs, partly based on real-world evidence. Multicriteria decision analysis may assist policymakers and researchers to evaluate the true value of generic drugs.

Keywords: adherence, drug policies, generic drug, multicriteria decision analysis, price erosion, real-world evidence.

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Introduction

In December 2011, an international group of health outcomes and policy researchers from 21 countries have participated in a series of workshops concerning the current practice around generic drug policies. The objective of these meetings was to understand how the success of generic drug policies is measured and interpreted, to expand the evidence base around generic drug policies, and to explore the health care and methodological challenges related to different drug policy initiatives.

The steering committee formed as a consequence of the workshops has met several times over the last 2 years. Research teams of the international expert group conducted several literature reviews in related areas, for example, on definition and classification of off-patent drugs in emerging markets [1], on physicians' and pharmacists' perspectives on generic drugs and generic substitution [2], and on the impact of generic substitution on health and economic outcomes [3]. Several health policy workshops have been conducted at different scientific events, including the HTAi conference in Seoul, the Latin American ISPOR meeting in Buenos Aires, the European ISPOR meeting in Dublin, the European Health Policy Forum in Gastein, and the Asian ISPOR meeting in Beijing as well as dedicated roundtable discussions of the subject in Latin America and Asia with a broad range of health care decision makers and payer representatives throughout 2012 to 2014.

The objective of this article was to introduce the topic of variance in generic drug purchasing policies, and their potential impact on the efficiency of generic prescription drug policies to support public health initiatives in the developed world. This article will be followed by several articles that go into greater depth in specific areas.

Definition of Generic Drugs

In any evaluation of generic drugs and policies, definition is a key issue. There is significant disparity around the definition of both a branded, innovator, original drug and its bioequivalent,

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interchangeable generic version meeting the bioavailability threshold. For this article, we use the term generic drug in concordance with the definition from the World Health Organization: A generic drug is a pharmaceutical product usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights [4]. We will consistently refer to the innovator drug as the original drug and assume the generic drug to be considered interchangeable within currently described generic drug policies.

Importance of Generic Drugs

In health care systems of developed countries, pharmaceuticals play a central role in the practice of medicine and patients are increasingly treated with off-patent drugs [5,6].

Once the patent of a commercially successful, original pharmaceutical has expired and exclusivity rights are lost, several generic manufacturers proceed with the production and commercialization of the drug. The market authorization process is simplified because of substantial scientific evidence behind the original drugs from clinical trials and real-world evidence from many patient-years demonstrating the effectiveness and safety of the compound.

The most important policy objective of health care systems is to improve the health status of the population [7]. The success of pharmaceutical innovation over the last few decades has improved the health status of patients for most major diseases, reducing the unmet medical need for new pharmaceutical therapies. In disease areas with the greatest public health burden (e.g., cardiovascular diseases, mental health, and diabetes mellitus [8]) first-line therapy is usually off-patent medicines [9–11]. Therefore, the success of public health programs in improving the health status of the total population—in addition to preventive health care services and accessibility to primary health care services—is highly dependent on the availability and appropriate utilization of off-patent drugs.

The price differential between original and generic pharmaceuticals is usually significant, but often extremely variable, and, to some degree, depends on the strength of price regulation [12]. Because of scarcity of health care resources, original patented drugs are increasingly used only for those patients who cannot benefit from existing low-priced generic drugs. The number of patients on original drug therapies is limited; thus, improvement in health status based on these small groups may not apply to the total population. Therefore, the major societal benefit of original drugs is the improved equity in access to effective therapies for those patients with relatively greater unmet medical need.

Components of Generic Drug Policies

Market authorization criteria for generic drugs are simplified compared with those for original pharmaceuticals. After market entry, generic substitution, international nonproprietary name prescribing, price control for generics, generic reference pricing, and tenders are widely used measures to promote the uptake of generic drugs at the lowest drug acquisition cost [13,14]. Policymakers have several options to incentivize stakeholders to abide by generic drug policies [15–17]. These tools appear to influence each other; thus, generic drug policies commonly include mixed approaches applied by decision makers and health policy experts with the ultimate aim to accelerate price erosion and penetration of generics. In Table 1, a nonexclusive list of different policy options for generic prescription drugs is presented, with their expected societal benefits related to different stakeholders.

Table 1 – Common generic drug policy interventions and their expected societal benefits

Policy interventions	Expected societal benefit related to different stakeholders			
	Pharmaceutical manufacturers	Prescribers (physicians and health care providers)	Pharmacies	Patients
Registration based on proof of bioequivalence to originals or reference	Reduced development cost for generics; increased competition by more generic drugs	Increased therapeutic alternatives	Opportunity for drug substitution	Increased accessibility to lower-priced drugs
Mandatory price reduction of new generics compared with reference product	Continuous generic price erosion with new generic entries	Increased therapeutic alternatives according to socio-economic status of patients	Opportunity for drug substitution by considering the socioeconomic status of patients	Reduced financial burden on patients
International reference pricing	Domino effect of generic price erosion in other countries	NA	NA	Reduced financial burden on patients
Central tendering in public reimbursement	Maximized price erosion by delisting higher-priced off-patent competitors	Reduced variability in drug prescribing	Reduced variability in drug dispensing	Minimized co-payment for patients
International nonproprietary name prescribing and generic substitution by pharmacists	Reduced investment into continued medical education (CME) and marketing activities	Reduced impact of marketing and CME activities on prescribers	Incentives to dispense the cheapest generic alternative	Increased utilization of nonbranded generics

NA, not applicable.

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