Improving generic medicines use in transition economies

INTRODUCTION

The provision of healthcare has traditionally been managed based on the philosophy that, when the patient is concerned, price should not be a hindrance. However, in a real world situation, accesses to life-saving medicines are far from perfect. It has been reported by the World Health Organization that more than a third of the world's population has no access to essential drugs and more than half of this group of people live in the poorest regions of developing world such as in Africa and Asia.[1] Several factors determine the accessibility of drugs in developing countries and definitely cost of medicines is one of it.[2,3] For chronic medication users, one of the way to combat the escalating cost of healthcare is using generic medicines. Generic drugs provide the opportunity for major savings in healthcare expenditure since they may be substantially lower in price than the innovator brands.[4,5] Providing timely access to affordable, safe and effective products should be the central purpose on every government's health agenda. Although in most developing countries, the use of generics medicines is well mandated by the government agencies in their respective national health policy statements, but majority of healthcare practitioners and consumers still remain sceptical toward its efficacy, quality, and safety.[4] This further been complicated by the lack of initiatives by the respective government and nongovernment agencies in developing countries to promote the benefit of generic medicines to the consumers.

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GENERIC MEDICINES (GENERICS)

Developing new medicines is a long and expensive process. Before being given marketing permission, medicines or more properly developed molecules have to be tested first in animals and then in humans to determine their safety and effectiveness in the condition for which they are to be used. There is the ever-present danger of medicines failing different tests during the development process, causing huge losses to the company. Hence, molecules, which make it to the market, have to cover the costs of medicines which "fell by the wayside." Considering the high costs, the commercial nature of drug companies and the need to stimulate research and development, a drug company, which develops a new molecule, is allowed a certain time period during which only it can produce and market the medicines. The innovator company can sell the molecule to another company for a "royalty" fee. During this period, due to lack of competition and to recover costs, companies usually sell the medicine at a high price. Once the patent period expires, then other companies can manufacture and sell the medicines, often at lower prices. These medicines are known as "generic medicines" or "generics." In Malaysia, branded generics are common where generic copies of medicines are manufactured and sold by different companies under their brand names. Generics must be shown to be bioequivalent – delivering about the same amount of the drug to the site of action in a similar time frame – to the originator product manufactured by the innovator company.

PROCESS AND PRODUCT PATENTS

There are two types of patents with respect to a medicine. The first is a product patent where the drug molecule is patented, and no competitors can manufacture the molecule till the patent period is over. The other type of patent is the process patent where only the process of making the molecule is patented but the molecule is not. A competitor can manufacture the same molecule using a different process. This ensures competition and keeps medicine prices low. Many developing countries used to allow only process patents for medicines.

PROMOTING FREE TRADE

After the Second World War, many organizations were set up to promote economic reconstruction and trade between nations. By the early 1990s, many of the world's countries, including India, China, and even Malaysia, had liberalized their economics. To further stimulate trade between nations, a series of negotiations were held, and World Trade Organization (WTO) established in the mid-1990s. The General Agreement on Tariff and Trade (GATT) emphasized intellectual property of the company which developed the molecule and were afforded a longer patent protection period of at least 20 years. Furthermore, process patents were no longer allowed. Different countries were allowed varying periods of time to comply with the requirements of GATT with regard to medicines. Developed nations had to compliant by 1996 while developing nations did so by year 2000.

THE NEED FOR PROMOTING GENERICS

From personal observation, many medicine regulatory bodies in developing countries do not actively involve themselves in educating and convincing consumers on the safety, efficacy and quality of registered generics. This is totally different ball game in developed country whereby the regulatory bodies such as the United States Food and Drug Administration and the European Medicines Agency play a pivotal role in educating consumers on the benefit of choosing generic medicines via various educational channels.[6,7] Besides focusing on consumers,; efforts are also needed in addressing specific issues related to generics to the healthcare professionals. Massive educational campaign is needed in order to educate this group of people especially on general concepts of bioequivalence as this topic is not well understood by many practicing healthcare professionals. To overcome this problem, educational seminar can be organized as part of compulsory continuous professional development programs by respective professional bodies. Similarly, future health care professional who will be directly involved in patient care such as doctors, nurses, and pharmacists need to be well informed on every aspect of rational prescribing since their junior years. This can be basically done by incorporating topics on rational prescribing in their standard therapeutics course or as problem-based modules in their tutorial.

In a nutshell and particularly in the present economic climate, in order to achieve optimal outcomes, consumers must not only receive appropriate treatment, but also have the knowledge and skills to use it to its best effect. Health professionals and government agencies have a vital role to play in promoting quality use of medicines through good treatment choices, good communication with consumers, and collaboration with each other However, with the global escalating healthcare cost, governments in many countries have adopted ongoing series of cost containment attempts in an effort to spend their limited financial resources efficiently so that equitable access to healthcare can be provided.

Mohamed Azmi Ahmad Hassali

Discipline of Social and Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia

Address for correspondence:
Prof. and Dr. Mohamed Azmi Ahmad Hassali, Discipline of Social and Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia, Penang, Malaysia.
E-mail: azmihassali@usm.my

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