Generics and Biosimilars; A Step Towards Sustainable and Low Cost Health Care

Puneeta Gupta¹, Mehvish Khan²

Abstract
Millions of people across the globe go without essential medicines resulting in many avoidable deaths each year. It’s no secret that the cost of prescription drugs, including the life-saving ones has been rising far faster than inflation over the last few years. If we take the example of diabetes and as India has the largest number of patients with the condition in the world; it has been shown that patients belonging to the low income group in urban India were spending 27% of their annual income and those in rural India 34% of their annual income on diabetes care; most of which was spent on purchase of medicines. This raises the question of whether current pricing of drugs is based on reasonable expectation of return on investment or whether it is based on what prices the market can bear. The price of pharmaceuticals has become an issue of great concern for people and governments around the world. Thus governments across the globe must make efforts to correct the present distortions around the concept of generic drugs.

Introduction
Access to health care is a human right, and that includes access to safe and affordable prescription drugs. Millions of people across the globe go without essential medicines resulting in many avoidable deaths each year. Any society faces a great moral contradiction when healthcare is so expensive that majority of people cannot afford it.

It’s no secret that the cost of prescription drugs, including the life-saving ones has been rising far faster than inflation over the last few years.¹ Globally, annual spending on anticancer drugs, e.g. is around US$100 billion, and is predicted to rise to $150 billion by 2020. From 1995 to 2014, in fact, there was a sharp increase in the launch price (the cost of a new drug being introduced to the market for the first time) of new cancer drugs.² Pralatrexate (Folotyn) for example, a cytotoxic antimetabolite (folate antagonist), is used for patients with aggressive form of non-Hogkins’s lymphoma; cost of which runs from $345,000 to $541,000 per year; the price of eculizumab, a monoclonal antibody; run anywhere from between $432,000 to $542,000 per patient. (approved to treat atypical hemolytic uremic syndrome (aHUS), paroxysmal nocturnal hemoglobinuria and generalized myasthenia gravis). Actimmune (interferon gamma-1b) for life-threatening osteopetrosis and chronic granulomatous disease is available in price range of $244,000 to 572,000 annually; Similarly atezolizumab (tecentriq) for the treatment of patients with metastatic urothelial carcinoma, is priced around $12,500 a month.³

Now, if we look at the prices of some novel drugs which have been introduced for other common conditions, e.g the injectable compounds for dyslipidemia, approved in 2015, PCSK9 inhibitors, alirocumab (praluent) and evolocumab (Repatha), are costing $14,000 a year. Similarly the new drugs for hepatitis C, sofosbuvir (brand name Sovaldi), was launched at a cost of $1,000 a pill, even drugs, that have long been on the market for long are not immune from this price rise, for example imatinib (gleevac), a drug for chronic myeloid leukemia, tripled in cost from $31,930 in 2005 to $118,000 per year in 2015. The cost of insulin tripled between 2002 and 2013, despite no notable changes in the formulation or manufacturing process. The cost of pyrimethamine (daraprim), a 60-year old drug, rose from $13.50 to $750 per pill (a 5455% raise) after pharmaceuticals acquired the distribution licence, sparking a public debate in North America.

The astronomical drug prices and developing world
About 40% of Indians live on income of less than 100 rupees per day and most of them pay out of pocket for healthcare. In fact out-of-pocket (OOP) spending in India is over four times higher than public spending on healthcare.³ Now if we take the example of diabetes and as India has the largest number of patients with the condition in the world; it has been shown that patients belonging to the low income group in urban India were spending 27% of their annual income and those in rural India 34% of their annual income on diabetes care; most of which was spent on purchase of medicines. The situation becomes even more grim when we take into account the World Health Organization (WHO) report which estimates that around 649 million people in India do not have regular access even to essential medicines.⁴

Drug prices; Isn’t that really just a problem for poor countries?
It is quite understandable that in majority of low- and middle-income countries, drug expenditure can be a critical public health problem with some drugs out of reach for even well-insured patients.⁵ But, this high cost is a rising concern in western developed world also; with many people not able to take the medication, their providers prescribe for them. Nearly 1 in 10 American adults don’t take their medications as prescribed by their physicians, because they can’t afford to, (U.S. Centers for Disease Control and Prevention,s National Center for Health Statistics).⁶

¹Professor, ⁵PG student, Department of Medicine, Acharya Shri Chander College of Medical Sciences Sidhra, Jammu, Jammu and Kashmir
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This raises the question of whether current pricing of drugs is based on reasonable expectation of return on investment or it is simply based on what prices the market can bear. In fact as complaints grow about exorbitant drug prices, pharmaceutical companies are coming under pressure to disclose the development costs and profits of prescription drugs and the rationale for charging what they do.

Why Does it Cost so much to Develop a New Medicine? The Economics of Drug Discovery and Development (R&D).

For patients, new medicines offer fewer side effects, fewer hospitalizations, improved quality of life and most importantly, the extended lives. But developing medicines is a long, complex process. On average, it takes at least ten to fifteen years for a new medicine to complete the journey from initial discovery to the marketplace. The average cost to research and develop each successful drug was estimated to be $2.6 billion in a study carried out in 2014.

However, does this significant research and development spending as cited by the pharmaceuticals, should lead to such high pricing so that it is neither affordable at the patient level and nor it is sustainable at payer level. Moreover, the enormous amount of money the drug companies spend on marketing and lobbying is undeniable.

Generics and biosimilars; the cheaper alternatives

The prescription drugs can be classified into traditional or chemical pharmaceuticals and biopharmaceutical or ‘biological medicines”. The traditional prescription drugs or pharmaceuticals are molecules with a small, well-defined and stable chemical structure that are typically manufactured through chemical synthesis;

Biologics or biopharmaceutical are medicines which are synthesized or extracted from a biological source often with highly complex structures. The manufacturing processes of biologics involve living systems (eg, mammalian cell lines, microbial agents, plants, fungus) and complex processes (eg, gene isolation, recombinant DNA engineering, protein purification); which require high technological expertise with precision in order to ensure consistency and quality of the final product unlike single molecules which are chemically synthesized with highly predictable structures and functions;

Starting with insulin three decades ago, about 300 biologics are now available for human use. Gene-based and cellular biologicals, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available; thus bringing hope to those with few other alternatives.

Now apart from above discussed research, development and approval steps which of course require lot of investment, the main factor which gives pharmaceutical companies almost free hand to pricing of drug is the patent on new molecule, giving them exclusive marketing right of their innovation. Thus chemical patent, pharmaceutical patent or drug patent is a patent for an invention in the chemical or pharmaceuticals industry and is usually given for 15 to 20 years An important step towards decreasing the overall cost of the drug and making them available to all including the poorest of poor is the development of generics and biosimilars.

When a pharmaceutical company introduces a costly new drug, they can do so because they have an exclusive patent on it. Once drug patents expire after a stipulated time period, other pharmaceutical companies can copy that branded drug, and sell it for significantly less price as a generic compound

By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product., has the same strength, use, indications, form (such as a tablet or an injectable), and route of administration (such as oral or topical). Because of their intrinsic complexity and because no two cell lines, developed independently, can be considered identical, biopharmaceuticals cannot be fully copied. This is recognised by the regulatory authorities and has resulted in the establishment of the term ‘biosimilar’ in recognition of the fact that, whilst biosimilar products are similar to the original product i.e biologics, they are not exactly the same.

With the make-up of the drug already approved, generics and biosimilars do not require the added expenditure of research and development, thus the final cost to the manufacturer and the consumer is much lower because the approval pathway is much shorter than branded drugs.

When multiple generic companies market a single approved product, market competition typically results in prices about 85% less than the brand-name (generic drugs were estimated to have saved the U.S. health care system approximately $1.67 trillion from 2007 to 2016.)

What is the way ahead

The price of pharmaceuticals is an issue of great concern for governments around the world. The right to access essential medicines has found its way into international treaties and national constitutions and moral claim for universal access to essential medicines has been put forth not only by faith-based organizations and civil society activists, but also by many drug developers.

Conclusion

The governments across the globe must make efforts to correct the present distortions around the concept of generic medicines by providing quality assurance of medicines and allowing the emergence of a true generics market, where different products can compete on price rather than on brand image.

References