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A COMPARATIVE OVERVIEW OF GENERIC DRUG REGULATION IN USA, UK AND INDIA

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ABSTRACT

Consumers in the US are saving a lot of money thanks to the sharp rise in the use of generic pharmaceuticals. In order to help the Department of Health and Human Services (HHS) discover strategies to encourage the use of generic drugs, Secretary Sebelius asked the Assistant Secretary for Planning and Evaluation (ASPE) to look into possible opportunities and roadblocks to doing so. This Issue Brief provides an overview of the findings from ASPE's review of the relevant literature. Let's start by briefly reviewing the trends in the use of generic medications, their legislative history in the United States, and their potential to reduce healthcare costs. Next, the literature on generic drug costs and healthcare savings is examined. We divide the data on barriers to the use of generic medications into three primary categories: state-level generic replacement regulations, generic availability characteristics, and attitudes and behaviors of physicians and customers. Overall, we found that there is currently a significant amount of use of generic medications. As we'll see in the section below, there will soon be more substitution particularly therapeutic substitution as the supply of generic drugs is expanding, which is encouraging for cost savings.

INTRODUCTION

Consumers in the US are saving a lot of money thanks to the sharp rise in the use of generic pharmaceuticals. In order to help the Department of Health and Human Services (HHS) discover strategies to encourage the use of generic drugs, Secretary Sebelius asked the Assistant Secretary for Planning and Evaluation (ASPE) to look into possible opportunities and roadblocks to doing so.

We divide the data on barriers to the use of generic medications into three primary categories:

1. State-level generic replacement regulations,
2. Generic availability characteristics, and
3. Attitudes and behaviors of physicians and customers.

Overall, we found that there is currently a significant amount of use of generic medications.

The legislative foundation of generic drugs

The Food and Drug Administration (FDA) requires innovative new drugs to file a new drug application that includes data from clinical trials that demonstrate the drug's safety and efficacy in order to approve their branded pharmaceuticals. Innovative branded pharmaceutical companies spend a lot of money and effort on drug development and regulatory approval.

According to some estimates, the time and financial resources required to bring a breakthrough drug to market can easily surpass one billion dollars. Generic versions of drugs are equally effective as name-brand ones. Every aspect of a medication, including the active ingredient, strength, dosage form, and mode of administration, must be chemically and medicinally similar in generic form to the original, branded version. The inactive ingredients in generic equivalents of name-brand drugs don't have to be the same.

The price of generic drugs

Compared to manufacturers of branded drugs, generic pharmaceutical manufacturers face far lower entrance obstacles. Compared to the anticipated cost of over one billion dollars to bring a new branded drug to market, the research and development of a new generic drug only costs one to two million dollars. Prices for generic medications have significantly decreased as a result of increased competition and low entry barriers.

The number of generic alternatives appears to have an impact on the price difference between name-brand and generic medications. The FDA examined the effect of generic drug introduction on average generic costs to ascertain how generic drug prices compared to brand-name pharmaceuticals.

Importance of regulations

Individuals and the government are willing to spend money on medications because of their ability to save lives, restore health, prevent diseases, and terminate epidemics. However, in order to accomplish this, medications must be high-quality, affordable, safe, and used appropriately.

This means that in order to ensure that they are of a quality that meets the specified requirements, regulations must be placed in place for their conception, manufacture, importation, exportation, and subsequent distribution.

Inadequate regulations controlling the manufacture and distribution of pharmaceutical products directly lead to the spread of toxic, subpar, and fake drugs on the domestic and global markets.

Methodology

Checklist

- Domestic patient legislation
- Domestic approval procedures
- Domestic pricing structures
- Domestic spending caps, and domestic reimbursement guidelines
- Pharmacy and wholesale profits
- Control over prescriptions by general practitioners In the case of pharmacists, the right to substitute others.

Plan of work

1. **Phase-I:** Deal with databases, journals, research publications, guidelines, and regulatory documents on generic drug regulation in the United States, United Kingdom and India.
2. **Phase-II:** Extracted pertinent information from the literature, analyzed it using a systematic approach, and focused on regulatory frameworks, legislations, and guidelines specific to United States, United Kingdom and India

3. **Phase-III:** Understand the generic drug registration and approval procedures in United States, United Kingdom and India.
4. **Phase-IV:** Compares the regulatory requirements in the United States, United Kingdom and India as well as identifying similarities and differences in approval processes, dossier formats, and administrative documents.
5. **Phase-V:** Understand the harmonizing generic drug regulation procedures with common formats and expanding bioequivalence requirements, highlighting the need to analyse United States, United Kingdom and India regulations' impact on emerging nations and finally thesis writing and submission for approval.

Requirement differences between USA, UK and INDIA

S.no	Requirements	US	EU	INDIA
Administration				
1	Regulatory authority	Food and drug administration	European medicine agency	Central drug standard and control organisation
2	Application	Anda	Maa	Maa
3	Debarment certification	Required	Na	Na
4	No. Of copies	3(archival, review, field)	1	1
5	Approval timeline	18months	12months	12months
6	Clinical study fees	Under $2 million –nda application	National fee (including hybrid applications): £103,059	50,000 inr
7	Presentation	Ectd & paper	Ectd	Paper
8	Pharmacovigilance	Not required	Required	Required
9	Agent authorization	Required	Not required	Not required
B. Finished product control				
1	Assay	90 - 100 %	95 - 105 %	90 - 110 %
2	Disintegration	Not required	Required	Required
3	Colour Identification	Not required	Required	Required
4	Water content	Required	Not required	Required
C. Manufacturing & control				
1	Number of Batches	1	3	1
2	Packaging	A minimum of 1,00,000 units	Not required	Not addressed
3	Process Validation	Not required at the time of submission	Required	Required
D. Labelling				
1	Prescription status	Rx	Pom	Rx

2	Labels	Vials/carton/pil	Vials/carton/pil	Proposed draft labels and cartoons provided in module i
3	Side by side comparison	Required	Required	Required
E. Stability				
1	Date and time of submission	3 months accelerate and 3 months long term	6 months accelerate and 6 months long term	6 months accelerate and 3 months long term
2	Container Orientation	Inverted & upright	Do not address	Upright and inverted
3	Qp certification	Not required	Required	Required
4	Retension of sample	5 years from the date of filing the application	No such required but usually followed	3 years from the date of filing the application

Submission differences between US, UK AND INDIA

Requirements	US	EU	INDIA
Agency	One Agency USFDA	Multiple Agencies EMEA CHMP National Health Agencies	One Agency DCGI
Registration Process	One Registration Process	Multiple Registration Process Centralized (European Community) Decentralized (At least 2 member states) Mutual Recognition (At least 2 member states) National (1 member state)	One Registration Process
Application	ANDA / NDA	MAA	MAA
Debarment classification	Required	Not Required	Not Required
Number of copies	3	1	1
Approval Timeline	~18 Months	~12 Months	12 - 18 Months
Fees	Under $2 million-NDA Application $51,520 – ANDA Application	National fee (including hybrid applications): £103,059 Decentralised procedure where UK is CMS: £99,507	50,000 INR

Country	In term of value			Volume global market
	Value of generics in 2022	Value of generics in 2023	Value of generics in 2030	
USA	USD 411.99 Billion	USD 425.99 Billion	USD 613.34 Billion	80
UK	$400 billion	$415 billion	$505 billion	81
India	$19billion	$20 billion	$25 billion	20

SUMMARY

As the patents on branded drugs are set to expire, the generic medicine production sector of the pharmaceutical business is experiencing tremendous growth. One of the most important international strategies that aims to cut the costs of medical care and increase the number of patients who have access to prescription medications is to encourage the manufacture of generic pharmaceutical companies. Those that produce generic drugs have the option of submitting a reduced version of the New Drug Application (ANDA), which only includes bioequivalency studies. It includes the information regarding the effectiveness and safety of the drug that was provided by the initial innovative medication manufacturer.

One of the procedures for dealing with complaints regarding patent infringement is outlined in paragraph. To a considerable extent, the Hatch-Waxman Act has been successful in accomplishing its two objectives, which were to reduce the cost of pharmaceuticals for consumers and to encourage innovative pharmaceutical companies to continue the development of revolutionary drugs. By offering financial incentives to well-known companies, Hatch-Waxman developed a legislative framework with the intention of preventing the introduction of generic drugs.

As part of the current research project, an attempt was made to investigate the current state of generic pharmaceuticals on the international market as well as the regulatory environment in which they operate. In spite of the ongoing efforts to harmonize, I have conducted research on three different countries: the United States of America, India, and Europe. It has been discovered that the United States of America has the most stringent drug approval laws in the entire globe. In order for a pharmaceutical business to be able to sell a medicine, they are needed to provide the proof that is legally required to demonstrate that the drug is both safe and effective.

Three different approval procedures are followed by the pharmaceutical industry in the European Union. These procedures are known as the Centralize, Decentralize, and Mutual Recognition Procedures. Despite the fact that marketing authorization applications for innovative pharmaceutical approvals are always submitted through the Centralized Procedure, generic medicinal goods are approved through the Decentralized Procedure. The European Medicines and Healthcare Association (EMEA) is rapidly becoming the gold standard in the pharmaceutical business and is gaining respect on a global scale. CDSCO stands for the Central Drugs Standard Control Organization, which is India's primary institution responsible for medical regulation.

Companies in the pharmaceutical sector in India are finding the generic pharmaceutical industry to be intriguing in recent times due to the highly qualified pool of chemists and the low-cost environment. The rules for the approval of generic pharmaceuticals are more stringent than those in the United States and the European Union, according to studies.

CONCLUSION

The current research project examined generic pharmaceuticals' international market and regulatory environment. Despite ongoing harmonization efforts, I have researched the US, India, and Europe. The US has the strictest drug approval laws in the world. Pharmaceutical companies must provide legal proof that a drug is safe and effective before selling it. Pharmaceutical companies in the EU follow three approval processes. Centralize, Decentralize, and Mutual Recognition Procedures. Although innovative pharmaceutical marketing authorization applications are always submitted through the Centralized Procedure, generic medicinal goods are approved through the Decentralized Procedure. Central Drugs Standard Control Organization is India's main medical regulator. The rules for the approval of generic pharmaceuticals in India are more stringent than those in the United States and the European Union, according to studies.

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