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THE EVOLUTION OF GENERIC MEDICINE HOW IT CAN MARKET DIFFERENT MEDICINE FOR DIFFERENT DISEASE

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Abstract:

The main goal in introducing generic medicines into market was to decrease prices. After the expiry of patent or marketing rights of the patented drug, generic drugs are marketed. Generic drugs are available at affordable prices with maintaining quality. These 'Generic' formulations balance public interest as critical disease like cancer, AIDS etc. In situations where demand for medicines exceeds supply, criminally minded people tend to profit out of crime by manufacturing and distributing counterfeit medicines as a substitute for genuine medicines (branded and generic). India's Pharmaceutical market grew at 15.7% during December 2011.

The various aspects of generic, branded and counterfeit drugs and their impact on the Indian Pharmaceutical Industry However, in addition to this effect, such policy brought about unintended changes in the industrial structure. In this work evaluate the intentional impacts as well as the unplanned impacts from the introduction of generic medicines, particularly with respect to scale and innovation. a negative impact on price indexes, which is nonetheless attenuated by sectoral regulation. a large increase in scale in favor of domestic companies, but with just a small increase in R&D expenses and innovation within those companies. Such increase in scale should be seen as a window of opportunity for sectoral industrial policies aiming at larger scale and profitability, associated with commitment to innovative investments, which is certainly a difficult policy to make.

Keywords: *Evolution Generic Medicines, Prices Generic medicines, Economic, Process of Generic Drug*

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INTRODUCTION:

Generic drugs are copies of brand-name drugs that have exactly the same dosage, intended use, effects side effects, route of administration, risks, safety, and strength as the original drug. In other words, their pharmacological effects are exactly the same as those of their brand-name counterpart It has also been defined as a term referring to any drug marketed under its chemical name without advertising. Although they may not be associated with a particular company, generic drugs are subject to the regulations of the governments of countries where they are dispensed. Generic drugs are labeled with the name of the manufacturer and the adopted name (nonproprietary name) of the drug.

A generic drug must contain the same active ingredients as the original formulation. According to the U.S. Food and Drug Administration (FDA), generic drugs are identical or within an acceptable bioequivalent range to the brand-name counterpart with respect to pharmacokinetic and pharmacodynamic properties. By extension, therefore, generics are considered (by the FDA) identical in dose, strength, route of administration, safety, efficacy, and intended use. The FDA's use of the word "identical" is very much a legal interpretation, and is not literal. In most cases, generic products are available once the patent protections afforded to the original developer have expired. When generic products become available, the market competition often leads to substantially lower prices for both the original brand name product and the generic forms. The time it takes a generic drug to appear on the market varies. In most countries of the world, patents give 20 years of protection. However, many countries/regions, e.g. the European Union and the USA may grant up to 5 years of additional protection for drugs patent term restoration. [5]

Prescriptions may be issued for drugs specifying only the chemical name, rather than a manufacturer's name; such a prescription can be filled with a drug of any brand meeting the specification. For example, a prescription for lansoprazole can be filled with generic lansoprazole, Prevacid, Helicid, Zoton, Inhibitol, or Monolitum. A generic drug of biological type (e.g. monoclonal antibodies), is different from chemical drugs because of its biological nature and it is regulated under extended set of rules for it; see Biosimilars.Generic drug names are constructed using standardized affixes that separate the drugs between and within classes and suggest the action of the drug. Large pharmaceutical companies often spend millions of dollars protecting their patents from generic competition.[citation needed] Apart from litigation, companies use other methods, such as reformulation or licensing a subsidiary (or another company), to sell generics under the original patent. Generics sold under license from the patent holder are known as authorized generics; they are not affected by the 180-day exclusivity period, as they fall under the patent holder's original drug application. [5,7]

A prime example of how this works is simvastatin (Zocor), a popular drug created and manufactured by US-based Merck & Co., which lost its US patent protection on June 23, 2006. India-based Ranbaxy Laboratories (at the 80 mg strength) and Israel-based Teva Pharmaceutical Industries (at all other strengths) received 180-day exclusivity periods for simvastatin; due to Zocor's popularity, both companies began marketing their products immediately after the patent expired. However, Dr. Reddy's Laboratories also markets an authorized generic version of simvastatin under license from Zocor's manufacturer, Merck & Co.; some packages of Dr. Reddy's simvastatin even show Merck as the actual manufacturer and have Merck's logo on the bottom.

Brand-name drug companies have used a number of strategies to extend the period of market exclusivity on their drugs, and prevent generic competition. This may involve aggressive litigation to preserve or extend patent protection on their medicines. Patents are typically issued on novel pharmacological compounds quite early in the drug development process, at which time the as clocksto patent expiration begins ticking After the expiry of patent or marketing rights of the patented drug, generic drugs are marketed. Generic drugs are available at affordable prices with maintaining quality. These ‘Generic’ formulations balance public interest as critical disease like cancer, AIDS etc. It is widely accepted both developed and developing countries. An estimated half of all prescriptions in the USA are now filed with approved generic drugs. In order to market drugs, U.S. generic manufacturers must have a permit and approval from the Food and Drug Administration (FDA) indicating that the active ingredient is approximately the same as that of the brand name. The determination of drug approval is made according to whether it is pharmaceutically equivalent, bio-available, and bioequivalent.

World Health Organization (WHO) provided a definition for counterfeit drugs. In situations where demand for medicines exceeds supply, criminally minded people tend to profit out of crime by

manufacturing and distributing counterfeit medicines as a substitute for genuine medicines (branded and generic). The consequence of this will be infiltration of counterfeit medicines into national distribution channels. India's Pharmaceutical market grew at 15.7% during December 2011.

Globally India ranks third in terms of manufacturing pharmaceuticals product by volume.1a The Indian pharmaceutical industry is expected to grow at a rate of 9.9% till 2010 and after that 9.5% till 2015. The Indian pharmaceutical market is expected to touch US $72 billion sale by 2020 from US $11 billion. The market has the further potential to reach US $70 billion by 2020. India ranks 17th in terms of exports its product to more than 200 countries around the globe including highly regulated markets of USA, Europe, Japan, and Australia. The paradox is that despite producing huge pharmaceutical products, India has been identified as one among several developing countries that are regarded as the source of counterfeit medicines by the organisation for Economic Cooperation and Development (OECD). On the other hand, WHO says 3.2% Indians will fall bellow the poverty line will because of high of high medical bills. 39 million Indians are pushed to poverty because of ill health every year. Around 30% in rural India didn't go for any treatment for financial constrains. The world health organization (WHO) is also worried about Indians high out-of-pocket (OOP) expenses to medicines. This paper presents various aspects of generic, branded and counterfeit drugs and their impact on the Indian Pharmaceutical Industry. [11]

One of the most debated issues in health care today concerns the difference between brand name (also called branded, innovator, and pioneered) drugs and their generic versions. Evolution of every drug starts from a research laboratory and ends in a medical shop. Many new molecules are invented in research laboratories. Specific pharmacological formulations require tedious technology and procedures.

Many of such molecules never achieve final approval. After formulation of a drug, it is tested on animals and then on human volunteers. These quality controls are stringent and FDA certification is necessary for avoiding side effects and toxicity of drugs. Only after testing the drug in large number of patients in drug trials, the drug comes in market. Drug companies spend lot of money in formulating each drug. Thus every drug cost depends on the expenditure of the research and procedures of approval. Every newly launched drug is thus very expensive to begin with. Companies have drug patent of their drug for a specific time period of 10 to 12 years and cost as much as 2.0 billion dollar. Each year, world wide, only about 25-30 new chemical entities drugs enter the market1b. These figures2 indicate that pharmaceutical companies face huge difficulties during drug development. Hence their investments in research, resources, time, should be rewarded by taking patent protection. During this period, the drug cannot be copied by anybody. After the patent is over, the same drug can be copied by anybody and the costs reduce drastically. Many of the anti-diabetic, antihypertensive and antibiotic drugs are available now as generic formulations. It's important to remember that there are brand name and generic versions of medicines like high blood pressure, diabetes, etc. Today about 50% of all prescriptions are filled with generic drugs. The FDA has established standards for generic drugs that might seem complicated but are really simple. In accordance with Black's law dictionary,' the term "counterfeit drug" may be used to describe a drug made by someone other than the genuine manufacturer, by copying or imitating an original product without authority or right, with a view to deceive or defraud, and then marketing the copied or forged drug as the original. In reality, however, a counterfeit drug is defined differently in different countries.

The absence of a universally accepted definition not only makes information exchange between countries very difficult but it also limits the ability to understand the true extent of the problem at global level. In order to address this problem the following definition has been developed by the World Health Organization (WHO): "A counterfeit medicine3 is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging." According to the FDA, to substitute a generic for brand name drug must follow following criteria - It must contain the same active ingredients (the chemical substance that makes the drug work), the same dosage strength (the amount of active ingredients, for example 20 mg or 40 mg), the same dosage form that it, it needs to be available in the same form as the original – for example as liquid, pill, etc. They have same route of administration (the way the medication is introduced into the body) and It must deliver similar amounts of the drug to the bloodstream (that is, it needs to deliver a comparable amount of drug into the bloodstream within time period as brand name drug).

According to the FDA, to substitute a generic for brand name drug differences in the following criteria- They look different (different sizes, shapes, color or markings and different names), might have different inactive ingredients. Drugs are made up of both active and inactive ingredients. Some people may be sensitive to inactive ingredients. For example, some people have reactions to certain dyes used in some drugs.

The most important advantage with generic drugs are less expensive than the branded versions. They are cheaper as no R & D investments are involved as in the case of branded or new drug. Generic manufacturers are able to sell their products for lower prices because they are not required to repeat the costly clinical trials of new drugs and generally do not pay for costly advertising, marketing, and promotion. In addition multiple generic companies are often approved to market a single product; this creates competition in the market place, often resulting in lower prices. So Generics can cost between 20 and 80 percent less4. Generics vary by manufacturer (different pharmacies carry different generics). whether or not generics are always the same as brand is another question. "Different" doesn't always mean "not as good." In some cases a generic drug can be better than the branded version in more ways than just being significantly less expensive. Cheaper does not mean lower quality.The authorized generic has identical size, shape, colour, taste, smell, mouth-feel and inactive ingredients as the brand-name drug whereas the generic version is different. The authorized generic provide consumers the highest brand quality at lower prices and can be marketed during the 180-day exclusively period and even the expiry of the product.

Economics:

Generic drugs are usually sold for significantly lower prices than their branded equivalents. One reason for the relatively low price of generic medicines is that competition increases among producers when drugs no longer are protected by patents. Companies incur fewer costs in creating generic drugs (only the cost to manufacture, rather than the entire cost of development and testing) and are therefore able to maintain profitability at a lower price. The prices are low enough for users in many less-prosperous countries to afford them. For example, Thailand has imported millions of doses of a generic version of the blood-thinning drug Plavix (used to help prevent heart attacks), at a cost of 3 US cents per dose, from India, the leading manufacturer of generic drugs.

In the UK, generic drug pricing is controlled only by the reimbursement price. Beneath this, the price paid by pharmacists and doctors is determined mainly by the number of licence holders, the sales value of the originator brand and the ease of manufacture. A typical price decay graph will show a 'scalloped' curve, which usually starts out on the day of generic launch at the brand price, and then falls as competition intensifies. After some years, the graph typically flattens out at approximately 20% of the originator brand price. In about 20% of cases, the price 'bounces', which means some license holders, withdraw from the market when the selling price dips below their cost of goods. The price then rises for a while until they re-enter the market with new stock. Generic manufacturers do not incur the cost of drug discovery. Sometimes, reverse-engineering is used to develop bioequivalent versions to existing drugs. Generic manufacturers also do not bear the burden of proving the safety and efficacy of the drugs through clinical trials, since these trials have already been conducted by the brand name company. (See the Approval and regulation section, below, for more information about the approval process.) The average cost to brand-name drug companies of discovering and testing a new innovative drug (with a new chemical entity) has been estimated to be as much as $800 million.Merril Goozner estimates the true cost is closer to $100 to 200 million.

Generic drug companies may also receive the benefit of the previous marketing efforts of the brand-name drug company, including media advertising, presentations by drug representatives, and distribution of free samples. Many drugs introduced by generic manufacturers have already been on the market for a decade or more, and may already be well known to patients and providers although often under their branded name.

For as long as a drug patent lasts, a brand name company enjoys a period of marketing exclusivity or monopoly, in which the company is able to set the price of the drug at a level which maximizes profitability. The profit often greatly exceeds the development and production costs of the drug.[citation needed] (This is partially offset by research and development of other drugs which do not make a profit.) The advantage of generic drugs to consumers comes in the introduction of competition, which prevents any single company from dictating the overall market price of the drug. Competition is also seen between generic and name-brand drugs with similar therapeutic uses when physicians or health plans adopt policies of preferentially prescribing generic drugs as in step therapy. With

multiple firms producing the generic version of a drug, the profit-maximizing price generally falls to the ongoing cost of producing the drug, which is usually much lower than the monopoly price.

Pricing strategy:

The pricing strategy for each biosimilar needs to balance two competing forces. On the one hand, the price will have to reflect the high investment in development and manufacturing and marketing, as well as pharmacovigilance commitments. These high barriers mean the competitive intensity will be weak, which translates into more pricing leverage. Therefore, price differentials between originator product and biosimilar can be much less than for traditional generics. On the other hand, a small price differential reduces the incentive to switch. The consensus seems to be that a 20-25% discount is optimum. Sandoz's Omnitrope was launched at a 20% discount compared to Eli Lilly's Humatrope in Germany. However, the discount is likely to increase when BioPartners' Valtropin is launched. Biosimilar human growth hormone in Australia costs 25% less than the brand. Originator products' pricing strategies will have a huge influence on the uptake of biosimilars. Many brands have raised the price of first-generation products to encourage switching to their second-generation products. The introduction of biosimilars may increase the cost differential and increase the switch back to first generation products. Against this background, we believe that the biosimilar market will be characterised by price competition, even when there is only one or a very limited number of players for a given product. This will constrain the size of the commercial opportunity. As a result, in the short-term at least, the commercial benefits from biosimilars are likely to be small. A small price differential reduces the incentive to switch. Furthermore, physicians will be cautious about the relative safety and efficacy of biosimilars in the short term at least. Therefore, the market may develop slowly, which is one reason why the commercial rewards are likely to be limited in the short term. Biopharmaceuticals are expensive and marketers working in many branded companies can expect competition from biosimilars to emerge as health services worldwide struggle to contain Spiralling healthcare costs iii. Indeed, biosimilars are now a fact of pharmaceutical life. [21]

Price Reduction

The result of the F-test shows the significance of the regression, despite the limited number of observations. Also, the R2 coefficient suggests a good fit for the model. All the parameters presented the expected sign, despite the non-significance of the variable exchange rate, which deserves an explanation, given that the pharmaceutical sector is a strong importer of inputs and finished goods. 13 Non-stationary time series may often lead to a spurious regression, in which the similar tendencies among the series produce high significance of the regression – high R2 – without any economic significance.

We begin the discussion with the analysis of the market share of generic drugs. As expected, the influence is negative and significant, i.e. there is a bias pro-reduction of prices in which the market share of generic drugs contributes for a reduction in the price index. The variable associated with the market share of other drugs, the non-generic ones, presents a positive influence on the price level. I.e. the increase in the market share of these drugs increases the overall price level in the sector. Also, the effect of declining prices from the generic drugs is stronger than the effect of raising prices from the non-generic ones. However, it should be noticed that the group "other drugs" comprises several heterogeneous products, including similar drugs. Since the similar drugs have lower prices, just as the generic drugs, the forces acting on the variable "other drugs" may influence the overall price level in the upward direction – via reference drugs (patented or not) – and in the downward direction – via similar drugs. Thus, the smaller coefficient for this variable may be a result of these two forces and of the weight of these diverse drugs in the price index. The variable INPC Pharmaceutical (lagged in one period) shows that the price of the previous period influences negatively the current price level, like in a classic cobweb model. I.e. an increase in the price index in *t* tends to promote a decrease in the price level in *t+1*, what suggests the convergence for a stationary, or equilibrium, price level.

Although not significant, the coefficient of the exchange rate variable shows a positive impact on prices. This result is plausible given the sectoral dynamics, since this sector is a strong importer of inputs, particularly of the active principles for medicine production. According to data from the Brazilian Institute of Geography and Statistics (IBGE), through the 2005 Annual Industrial Survey, the imported products correspond to approximately 27% of the production costs in the sector, and therefore present a direct influence on production costs and on the industry *mark-up*. Thus, a rise in the exchange rate increases costs of production and implies an increase in consumer prices.

However, the exchange rate is not significant for determination of prices, despite its relevance for

production costs. This result seems to deny the impact of inputs on final costs, but we believe this result may be explained by the regulatory influence of the government.

The importance of price adjustments of CMED is undisputable. In the months when regulatory price changes occur, there is an average increase in the price index of 1.3%. This coefficient indicates that the greater influence on the determination of INPC Pharmaceuticals comes from regulation, and the results for the dummy variables of the generic drugs also point to this conclusion. The coefficients of these variables after 2002 do not show any modifications in the policy of generic drugs over time. I.e. the impact of generic drugs on the price index is negative, but steady throughout the period.

The expected intuitive relation is that an increase in the share of generic drugs would lead to a decline in the price level. The share of generic drugs on the total medicine supply changes from 4.7% in the beginning of the analysis to 19.57% in September 2009, last month when data is available. Given the negative influence on the price level and the government's indication that generic drugs should cost at least 35% less than reference drugs, it is expected that the increasing market share would cause a decline in the overall price index over time. However, this result is not observed. As mentioned before, there is not a temporal effect different than the fixed effect already observed for the total values of the variable "share generic".

The econometric exercise shows great influence of CMED regulation on price determination, pointing to a greater relevance of regulation than of generic drugs on the behavior of prices in the sector. The way prices of drugs are regulated may be taken as a reference to the market. It is potentially a price coordination mechanism for the private sector, which may minimize the effect of generic drugs on the price level. In order to corroborate this result, figure 2 shows the accumulated evolution of INPC Pharmaceutical during the period of analysis, along with the evolution of the exchange rate and of the General Market Price Index. Visually it may be verified that CMED represent the greater influence on INPC Pharmaceutical. The price increases which occur every April after 2004 and the price liberalization for over the counter drugs in early 2003 demonstrate that the regulatory mechanism is much more important in the determination of sectoral prices than any other influence, including the generic drugs.

Besides, the sectoral price level follows under the general market price index (IGP-M) throughout the period, which also points to the effect of regulation. Regarding the exchange rate, it may be noticed that it shows no correlation with the INPC Pharmaceutical. The period after 2004 is characterized by a decline in the exchange rate, whose influence does not seem to be stronger than the impact of CMED. [23]

The Choice of the Price Index and an Evaluation of the Price Evolution:

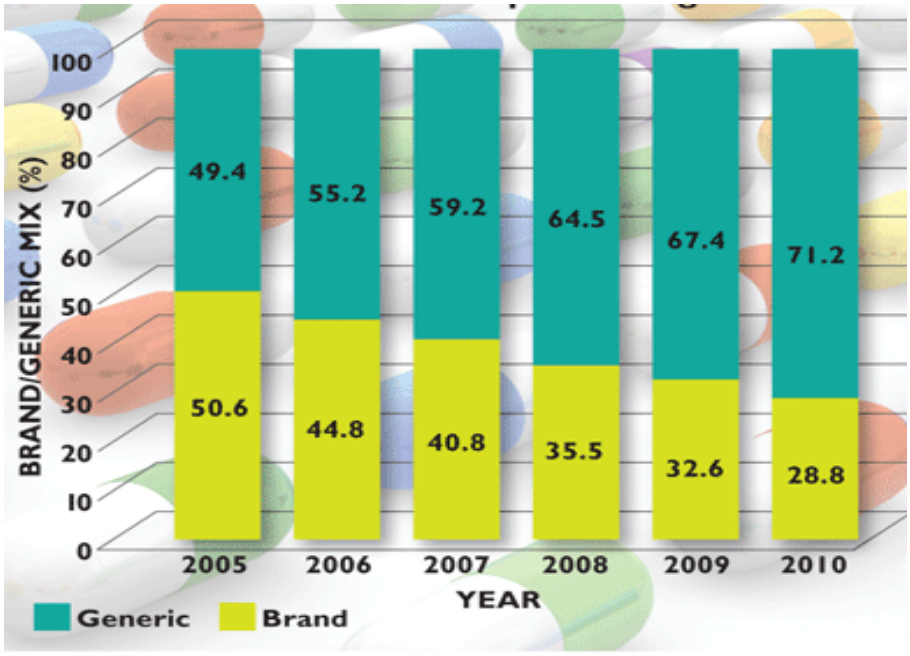
Since our main goal is to capture the effects of generic drugs on the final consumer, we chose to analyze the National Consumer Price Index – Pharmaceutical Products (INPC) . The reason is the range of household income included in calculation of this index. INPC measures the cost of living for families with monthly income from 1 to 6 times the minimum wage in Brazil,which is closer to the consumer basket of low-income populations. Given that INPC measures a narrow income range, it is more likely that the influence of generic drugs would be captured by this index. This is because there is a higher elasticity of demand and thus higher consumer substitutibility effect on the drugs in this level of income.In addition, the calculation of the price index considers the bestselling products, through a unweighted geometric average of the variations in the prices of the collected products (IBGE, 2007). Thus, the index may be composed of any combination of drugs (generic, similar, and reference drugs), in any number. The INPC Pharmaceutical was chosen given its greatest likelihood to capture the increase in the market share of generic drugs within the income range included in the index. [19]

The model used in the econometric analysis replicates an oligopoly structure with adaptive adjustment *a la* Bertrand, in which producers adjust prices according to their market share. This is a reasonable assumption for the pharmaceutical market, given that it is highly oligopolized, especially if we consider the high degree of substitution between generic and brand-name drugs, which amplifies the possibility of price wars. For a better illustration, There are basically three different price indexes in Brazil which include specific data and allow for the analysis of the pharmaceutical sector separately: the Wholesale Price Index – Pharmaceutical Products (IPA-OG Pharmaceutical), the Broad Consumer Price Index – Pharmaceutical Products (IPCA Pharmaceutical), and the National Consumer Price Index – Pharmaceutical Products (INPC Pharmaceutical).According to the website Pro-Generic(2009), income groups under four times the minimum wage present a limitation of access to

drugs of around 65% due to income constraints. It is expected that such income groups would consume lower price drugs, precisely the generic drugs. However, the consumption of similar drugs may also be high within these groups, also due to the low costs of this line of products. This may be a limitation for the use of the indexes. Nevertheless, our model is able to isolate the generic medicine in order to overcome these limitation [21], [23]

- In 2010 India's share of the generic market is about 30% out of 71.2% and reached $100 billion.
- In late 2012 40% of DMF's were filled by Indian market in USFDA for supplying API's.
- Now India's share of the generic market is about to 35%. Hence the contribution of the Indian pharmaceutical industry for the growth of generic drugs in the world is very high.

Indian generic drug market:



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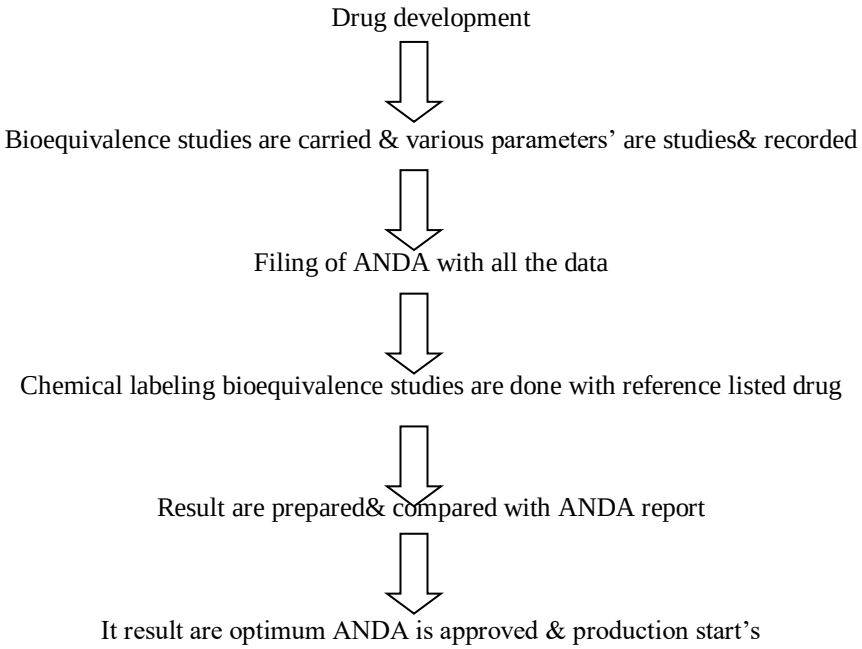
PROCESS OF INTRODUCTION OF GENERIC DRUGS:

Most nations require generic drug manufacturers to prove that their formulation exhibits bioequivalence to the innovator product. The FDA must approve generic drugs just as innovator drugs must be approved. The FDA requires the bioequivalence of the generic product to be between 80% and 125% of that of the innovator product



Milestones in generic drug development:

This value range is part of a statistical calculation and does not mean that FDA lets generic drugs differ from the brand name counterpart by up to 25 percent. These studies compare the absorption of brand name and generic drugs into a person. body. These studies are submitted to FDA to support approval of generics. The average difference in absorption into the body between the generic and the brand name are 3.5 percent and comparable to differences between two different batches of a brand drug

Approval process for generic drugs:

Enacted in 1984, the U.S. Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act, standardized U.S. procedures for recognition of generic drugs. An applicant files an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA), and seeks to demonstrate therapeutic equivalence to a specified, previously approved as reference listed drug's• . When an ANDA is approved, the FDA adds the drug to its Approved Drug Products with Therapeutic Equivalence Evaluations list, also known as the Orange Book, and annotates the list to show equivalence between the reference listed drug and the approved generic. The FDA also recognizes drugs using the same ingredients with different bioavailability, and divides them into therapeutic equivalence groups. For example, as of 2006, diltiazem hydrochloride had four equivalence groups, all using the same active ingredient, but considered equivalent only within a group.

On October 4, 2007, FDA launched the Generic Initiative for Value and Efficiency, or GIVE will use existing resources to help FDA modernize and streamline the generic drug approval process. It also aims to increase the number and variety of generic drug products available. Having more generic-drug options means more cost-savings to consumers, as generic drugs cost about 30 percent to 80 percent less than brand name drugs.In the United States, generic drug substances are named through review and recommendation of the United States Adopted Names (USAN) Council.

PHARMACEUTICAL INDUSTRY AND GENERIC PRODUCTS:

The health care products at present have been prominently provided by many pharmaceutical Industries in India. Now the pharmaceutical industry is focusing on research of new chemical entities and products and development of generic products, because of the increased export market demands and competition for survival in Indian and foreign market. Mostly the research has been going on cardiovascular agents, central nervous system, antidiabetic agents, anti-cancer agents, anti-HIV agented. The Indian companies have better option to focus more on generic drugs to raise their standards equivalent to the generic drug markets of the developed countries. Because of best chemistry skills

and low cost advantages, India is the best option for many MNCs to set up manufacturing and to spend more money in the field of research. As more and more patents expire, sales of the generic portion of the Indian pharmaceutical market are expected to increase day by day. [25]

The generic market reached 100 billion dollar in 2010. The generic growth is three times higher than the overall growth of drugs. 20 drugs will lose patent protection between 2010 and 2014 with the total market value 107 billiion dollar5b. According to expectation of pharmaceutical industry, percentage of generic drugs in the US market will rise from 14 to 21. This growth will enhance the export of pharmaceutical products from India will double every year. In future contribution from the Indian pharmaceutical companies will increase due to low cost of worker, innovation, recent success in track record in design operation of high tech manufacturing, testing, quality control, research, clinical testing and biotechnology. Most of the Indian companies have United States Food and Drug Administration (USFDA) approved plants, about 20% of all Abbreviated New Drug Applications (ANDA) to the USFDA are field by Indian companies. Now India's share of the generic market is about to 35%. Hence the contribution of the Indian pharmaceutical industry for the growth of generic drugs in the world is very high over the next few years an abnormally large number of blockbuster drugs are scheduled to lose their patent protection, opening the doors to cheaper generic drugs.[15]

MYTHS AND FACTS:

MYTH 1 --

Generics are not as safe as brand-name drugs

FACT 1--

Generics use the same ingredients, and work the same in the body have the same risk-benefit profile

MYTH 2—

Misbranded drugs

FACT 2--

Generally people think that generic drugs are misbranded because of change in the color, taste, appearance than original (ethical drug). But alterations of the color, taste, appearance is the part of the generic formulations and they are not misbranded.

MYTH 3--

Duplicate drugs

FACT 3--

Due to their change is the brand name or shape of the of dosage shape packing, some may think the drugs are duplicate.

MYTH 4—

Rejected drugs and fake drugs

FACT 4--

Due to cheap price of the generic drugs, it is generally thought that generic drugs are rejected form the company that is why they are selling for the low price.

MYTH 5--

Drugs manufactured at third party manufacturing unit

FACT 5--

This myth is in the mind of the wholesaler or the retailer that the drugs which are manufactured at some other plant which is not company.s own plant. Generally this true because generic drugs are generally manufactured at small scale industry but it is not applicable in all the cases.

MYTH 6--

Ineffective drugs:

FACT 6--

People also have a mindset that .costlier will be effective.They think that there is surely something wrong with the medicine because it is too cheap

MYTH 7--

Generics are not as potent as brand-name drugs.

FACT 7--

Generic drugs have the same quality, strength, purity and stability

MYTH 8--

Generics take longer to act in the body.

FACT 8--

The generic drug delivers the same amount of active ingredient in the same time as the original drug.

MYTH 9--

Brand-name drugs are made in modern manufacturing facilities, and generics are often made in sub-standard facilities

FACT 9--

Sub-standard facilities are not permitted by the FDA.

PRECAUTIONS WHILE USING GENERIC PRODUCTS:

- Consultation of complication with the doctor
- Avoid the use of expiry date products
- Keep them away from the reach of children
- Strictly follow the doctor.s prescription
- Read all the instruction given on the product carefully
- Store them according to the instruction given on the product
- Purchase them from the authorized medical shop.

ADVANTAGES OF GENERIC MEDICINE:

When a drug patent expires, other pharmaceutical companies can begin producing generic versions of the drugs. These products provide many economic advantages to consumers in both developed and developing countries, insurance companies, other pharmaceutical businesses and public health. The biggest benefit that generic drugs provide is economic benefits. Most of the cost of any new drug lies in the research and development of the product. A generic drug allows a company to reverse-engineer an existing product and manufactures it under a non trademarked name.

Figure shows the comparison of prices (10 tablets) of branded drugs versus generic drugs.

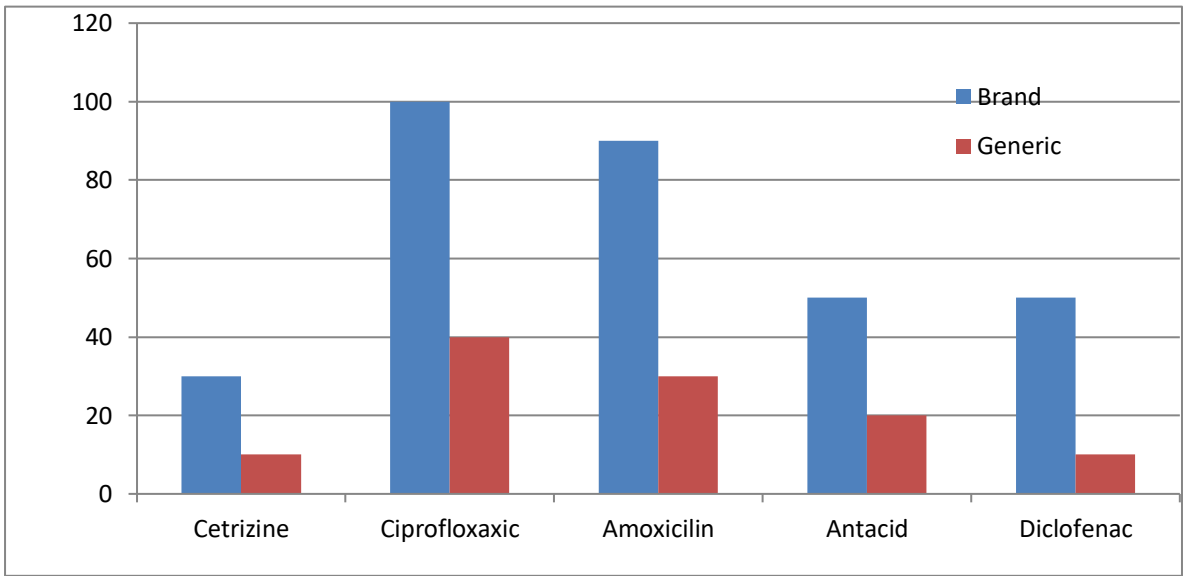


Figure : Comparison of price of various branded drugs versus generic drug (market survey on 25-03-2010)

- In addition to saving consumers money, generic brand drugs also make needed medicines widely available to populations that could not previously afford them.
- Generic drugs are just as safe as the trademarked "name brand" drugs for which they substitute. The FDA requires any generic drug to undergo clinical trials, both to prove safety and efficacy Also, generic drugs must provide patients with "bio equivalent" results to the name-brand product they replace, meaning that the generic drug must achieve the same results as the drug it copies (within a certain range of statistical tolerance) [2]

DRAWBACKS OF GENERIC DRUGS:

Drawbacks of generic drugs are much smaller than its advantages.

- Generally generic drugs may parasite the economy of the company whose patent got expired or whose molecule or formulation was unique.

- During bioequivalence studies, some error may arise which may lead to some complications More over bioequivalence studies are less accurate than bioavailability studies.
- There may be some variations during reformulations
- Some patients may be allergic to new colour, flavour etc.
- Generic drugs are not possible in all the cases. Because it takes long time to expire any patent. [2]

CONCLUSIONS:

Regarding the desired results of the policy of generic drugs, we could say the results are partially successful. The econometric exercise shows large influence of CMED's regulation on prices, which suggests that regulation may be more important for welfare than the generic drugs. The way medicine prices are regulated may be considered a reference for the market and, potentially, a price coordination mechanism for the private sector, with stronger effects than the decline caused by generic drugs. This is because the low market share of generic drugs in total supply – around 20% may not be enough to cause a strong downward in prices, which may be confirmed by non-significance of the time evolution of the influence of generic drugs. This is also confirmed by the graphical analysis of the evolution of INPC Pharmaceutical, which seems to respond more strongly to CMED changes than to any other determinant.

This is an important topic to which we add some questions: to what extent may the policy of generic drugs be seen as successful in increasing welfare given its low market share in comparison with other countries which adopt the policy? To what extent may the policy of generic drugs be seen as successful in increasing welfare considering that regulation seems to be the most important price coordinator for the sector? This is a complex issue, which needs to be further explored.

The unintended results, in turn, point to a moderate resume of development in the pharmaceutical industry, particularly in the production of drugs. However, such increase is not necessarily due to the policy of generic drugs alone. The effects of the policy seem to relate mainly to firm size, increasing the number of large domestic firms, and not as much to profitability, which are more closely related to changes in the exchange rate. Thus, there are two simultaneous effects, being the policy of generic drugs the most visible one, but not necessarily the most important one. I.e. the policy of generic drugs may not be taken as the only cause of the increasing profitability of the firms.

There is an improvement on all innovation indicators for some domestic firms, as well as an increase in the amount invested in internal R&D and in the total expenses on innovation. In comparison with foreign firms, the analysis regarding revenues shows that the situation of domestic firms is better than the situation of foreign firms, although the absolute amount spent by multinational is still higher.

Thus we can say that the gains in scale caused by the generic drugs may be able to create technological capacities for domestic firms. For that, it is also important for firms to show Lower fluctuations in profitability, which in Brazil is heavily dependent on fluctuations of production costs via the exchange rate. The reduction of external dependency will also come with innovative effort and additional gains in scale.

Therefore, the unintended effects of the policy of generic drugs may be seen as a window of opportunity for government action in the pharmaceutical sector and for some R&D intensive firms. This increase in scale and innovative capacity may be intensified with a proper guidance by public policies aiming to promote scale and profitability, along with a commitment with innovative investments; this is clearly not an easy policy to build.

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