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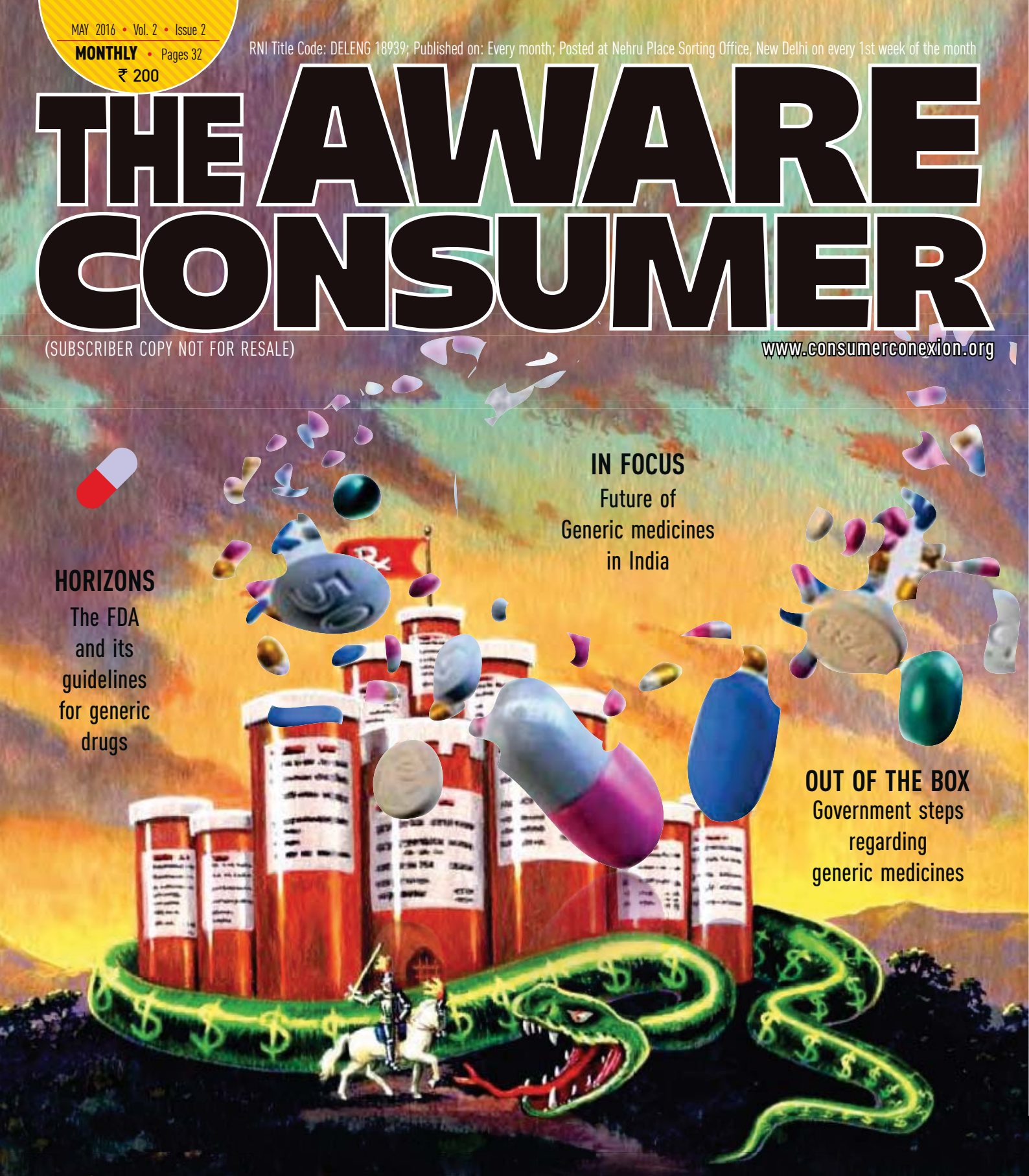


IN FOCUS
Future of Generic medicines in India

HORIZONS
The FDA and its guidelines for generic drugs

OUT OF THE BOX
Government steps regarding generic medicines

Can people trust Generic drugs

PLUS ROUND UP • MY MARKET • THE PRESCRIPTION

OUR BUSINESS is PATIENT SAFETY.

Partnership for

SAFE MEDICINES INDIA

SAFEMEDICINESINDIA.*in*

VIEW  POINT

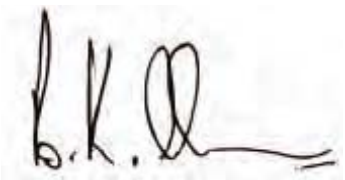
BEJON KUMAR MISRA | bejonmisra@consumerconexion.org

Generic drugs – need of the hour

IN A COUNTRY like ours, where millions of people are dying due to lack of proper healthcare and medicines, the launch of generic medicines could be a blessing for all. Generic drugs or medicine contain the same ingredients, in the very same amount, as brand-name drugs. When a medicine is first developed, the company that discovers and markets it receives a patent for this new drug. This patent usually lasts for 20 years and after, a generic version of the medicine may become available at cheaper rates by other companies. The government of most countries follows strict guidelines while launching these cheaper generic versions of the medicines so that all the people can take advantage of these cheap drugs and get the same benefit as the original brands.

Most people are happy with the availability of such drugs at such affordable rates, but many have complained about their effectiveness. Although a generic drug is identical to a brand-name drug in dosage, safety, strength, way of administration, quality, performance characteristics and intended use yet many are skeptical about its actual use. Generic drugs are chemically alike to their branded counterparts and are always sold at much lower rates than the branded price. Drug companies today have to submit an abbreviated new drug application (ANDA) for approval to market a generic product. Although the government is trying it's best to help the people get cost effective medicine, yet strict quality guidelines and reaction from some users have made the path for generic medicine tough if not difficult.

So, to help the nation and the people get their share of cheap and quality medicine, it is necessary for the development of Generic medicines or drugs, whose branded counterpart is often out of reach of the common man.



Generic drugs are chemically alike to their branded counterparts and are always sold at much lower rates than the branded price.

“Consumer Rights Are Our Fundamental Rights, IT is our Duty to ensure we are not shortchanged”

INSIDE

THE AWARE CONSUMER QUARTERLY | MAY 2016

RESEARCH FEATURE

11 | Things being done for the development of generic drugs in India

India is the main supplier of essential medicines for developing countries, and UNICEF procured millions worth of services and supplies from India.

HORIZONS

14 | FDA AND ITS GUIDELINES FOR GENERIC DRUGS

In a developing country like India, it is essential to have cheaper drugs where millions of people are already below the poverty line. Thus, by making essential generic drugs available to the common man at affordable rates is the main motive of the government of our country.

IN FOCUS

16 | FUTURE OF GENERIC MEDICINES IN INDIA

India is a huge country with a huge population of which millions live below the poverty level. These people are most of the times unable to get their hands on essential lifesaving drugs because of their high costs.

AFTERWORD

MY MARKET

THE LAST MILE

THE PRESCRIPTION

OUT OF THE BOX

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PROFESSOR AND HEAD, DEPARTMENT OF PHARMACEUTICAL CARE AND HEALTH SYSTEM

THEY SAID IT

Effective drugs have been developed and approved, and pharmaceutical companies are putting a price tag on them that puts them out of reach of more and more people. That has to change.

ROUNDUP

GLIVEC, AN ANTI-CANCER drug, costs Rs.1,30,000 per month for 1 person. The unbranded generic version of this drug comes at Rs.10,000 per month. Medicines make up for more than half of the healthcare costs in India, and many a times they are unaffordable. A huge population of our country falls below the poverty line and many among these perish due to the lack of proper and affordable healthcare and medicines. This has led to the development and existence of generic drug manufacturing units which supply cheap and affordable drugs to the people of the country who are in need of such help.

Besides making available essential drugs at affordable rates to the common man and the poor, these companies have also been active at advocating pharmaceutical policies for the needy section of the society at all levels. Since most of these generic drugs manufacturing companies have their own units and do not need to spend money on researching or marketing them, they can sell these essential drugs at really cheap rates which allow common man to get a hand on these lifesaving generic drugs at really affordable rates.

These generic drug companies combine drug production with a non-profit idea and large scale decision to help the weaker section of the society with cheaper drugs. Medicines in India are expensive and overpriced. In the last few years a strip of Crocin has increased from Rs.6 to Rs.20 per strip, meaning triple the amount. By introduction of generic medicines such price disparity can be controlled and more people will learn to trust the generic drugs which are effective, cheaper and affordable. Thus, generic drugs can be used to provide quality and affordable medicine to the common man of our country. These cheap drugs help the common man to get proper lifesaving drugs at really affordable rates.

DATA BRIEFING

About 80% LESS

Average cost of a generic drug vs. its brand-name counterpart

Why are generic drugs cheaper than branded ones?

A GENERIC DRUG is identical to a brand name drug in dosage, safety, strength, way of administration, quality, performance characteristics and intended use. The brand-name maker often invented the drug, a process that can cost a company thousands and thousands of dollars. This is the logic behind drug patents as they give pharmaceutical companies a period of years when only they can make money on that drug in which they have made a large investment. That investment also includes advertising in the form of TV commercials and by putting billboards at bus stops. Generic drug makers don't face the same costs as manufacturers of brand-name drugs. Generic manufacturers are able to sell their drugs

for cheaper rates because they do not have spend again on the research and development for the new drugs and do not have to pay for costly advertising, marketing, and promotion. Along with this many generic companies are often given approval to market a single drug which creates competition in the market place leading to a lowering in prices.

When a pharmaceutical company develops a new drug and markets it, it receives a copyright on this new drug which no other can produce or copy for the next 17 – 20 years, to give the discovering company a chance to recover its research and development investment. After the patent expires, a generic version of the drug becomes available. The original developer company that makes the brand name drug or a different company may produce the generic version of the medicine and offer it to the market at cheaper rates. Since this time round, there is no requirement for investment in research and development or in marketing of the drug, it is priced much lower than the branded drugs. This makes generic drugs affordable for common man and makes them easily available for the people who are unable to pay for the highly priced essential branded drugs. Thus, the lack of research and development costs and marketing costs makes generic drugs much cheaper than the branded drugs.

What do doctors say about these drugs?

ALTHOUGH GENERIC medicines are equivalent to the brand name drugs in strength, quality, dosage, performance and characteristics, yet many people are afraid to use them due to lack of proper information in our country and all around the world. Most people suffer from this misconception that, the higher the drug is priced the better or more effective it is. But, actually this concept is a myth. Doctors say that they have many patients who want brand named drugs only. Only after convincing them about the generic drugs equivalence to the brand name drug and their own usage of such drugs, are they able to convince people about the usage of generic drugs.

Doctors say name brand drugs are suitable in certain circumstances, like when there are no equivalent generics

The generic manufacturer
must prove
its drug is the same (bioequivalent)
as the brand-name drug.

for such drugs, when patients have side effects or if they are really sensitive to slight changes in a drug's composition etc. Doctors say that a lot of elderly patients have learnt to recognize medications by their colour and shape, rather than by their names. So, the fact that generics can come from different manufacturers and they can be of different shapes and colour every month confuses them and makes them more disagreeable towards these drugs.

At first the people need to be educated about the uniformity and benefits of these drugs. Generic drugs are not only good for the patients but for their pockets too, as they can get the right medicare for affordable rates. Most doctors feel that doctors whose prescription rate of generic medicines is low should be punished.

Are generic drugs really good?

GENERIC DRUGS ARE equivalent to the brand-name drugs that have exactly the same dosage, usage, effects, side effects, characteristics, risks, safety, and strength as the original drug. In other words, they provide the same result as those of their brand-name counterparts. Many people are unwilling to use generic drugs as they are often much cheaper than the brand-name versions. They are doubtful about the quality and effectiveness of these generic drugs which appear to be much less expensive. Generic and brand-name drugs have been provided with strict guidelines to meet the same standards for effectiveness, safety and quality. The Food and Drug Administration (FDA) requires these drugs to have the same standard quality and result as their brand-name versions. Thus, Generic drugs are well tested to make sure their performance and ingredients meet the FDA's standards for quality and good results.

When a company develops a new drug and submits it for FDA approval, a 20-year patent is given to them, barring other companies from selling the drug during this period. As a drug patent expires, any drug manufacturer company can apply to the FDA to sell its generic version. Now since these manufacturers don't have the same development and research costs, they can sell the drug at a cheaper rate. Once generic drugs are allowed, the competition in the market keeps the price down. Today, most doctors prescribe generic version of the drugs to their patients. Although many are still of the opinion that the generic version of the drugs are not as good as the brand name ones but it's all a myth. Generic drugs have the same quality, strength, purity, and effectiveness as brand-name drugs. So, they are as good as the brand name drugs and people should have absolutely no reason to complain. There is no difference between these drugs excepting that the generic drugs may differ in shape and colour. Thus, yes generic drugs are as good as brand name drugs.

THE LOWER PRICE DOESN'T MEAN INFERIOR

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 apply to FDA to approve a generic for the same brand name drugs. Multiple generic companies are often approved to market a single product. Competition in the market place, often results in lower prices.

Can people trust generic drugs?

ALTHOUGH MOST of the prescriptions filled by doctors today are for generic drugs yet, there is still a lot of scepticism about the quality of these less expensive medications among the patients and their family members. Even though most people recognize that they can save money on generic drugs, many prefer brand name drugs. In many surveys it has been seen that, nearly a quarter of the women questioned believed that brand name drugs were more effective than the generic version of it. Due to such a high difference between the two's price many cannot believe that such a drug can be got that cheap.

But, it can be and people must learn to trust these generic drugs. Generic drugs are nothing drugs equivalent to the brand name drugs which have the same quality, effectiveness, strength and dosage but are cheap and affordable as they do not have to incur the marketing and development cost which the original brand name drug had to in order to gain access to the market. Thus, generic version of these drugs come cheap but in no way are of weak quality. The FDA approves of their quality and effectiveness before they can be launched into the market and this makes them really safe and good for usage.

Therefore for sceptics, it is must that they have faith in generic drugs and learn to accept them as equal to the brand name drugs. Although they come cheap, it does not mean that these generic drugs are in any way inferior in quality or strength or effectiveness to the brand name drugs. In fact these cheaper version drugs have made medications much more affordable and within reach for the weaker sections of the society and have helped them to get good healthcare at cheap rates. So, there is no need to distrust these generic drugs when they produce the same results at really cheap rates. They are cheap as they do not require to invest in their development or marketing, other than that they are equal to brand name drugs and can be trusted easily.

Is India ready for cheap generic drugs?

INDIA HAS HELPED in the development of cheap generic drugs and has been providing these cheap lifesaving drugs to millions of people all around the world. Branded versus generic medicines is a topic of debate among physicians, drug regulators, and policy makers across the whole world. A generic drug is a product, which can be used in place of the brand name drug without a license from the original company and marketed after the patent expires or other rights of the developer company.

In India however the regulation of manufacture, sale and distribution of drugs is mainly the concern of state authorities while the authorities at the centre are responsible for approval of new drugs and trials, laying down the standards for drugs, control over the quality of imported drugs, coordination of the activities of State Drug Control Organizations and providing advice to bring around equality in the Drugs and Cosmetics Act. The Central Drugs Standard Control Organization which is under the Ministry of Health and Family Welfare plays an important role in these issues. They deal with all new drug approvals, review of new safety information regarding approved drugs, approval and safety review of fixed-dose combinations, medical devices, and implants.

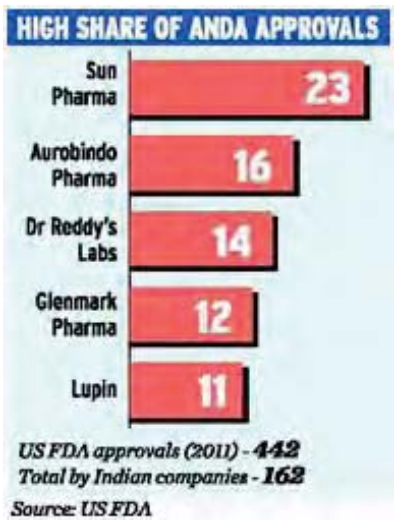
Drug regulatory apparatus in India

Law/regulatory body	Remark
CDSCO	Body under Ministry of Health and Family Welfare, Government of India provides general information about drug regulatory requirements in India
NPPA	Drugs (Price Control) Order 1995 and other orders enforced by NPPA
The Drugs and Cosmetics Act, 1940	Regulates the import, manufacture, distribution, and sale of drugs in India
The Pharmacy Act, 1948	Regulates the profession of Pharmacy

CDSCO: Central Drugs Standard Control Organization
NPPA: National Pharmaceutical Pricing Authority

In India, drug testing laboratories are located at central and regional levels to ensure the production and availability of quality medicines at affordable rates. The solution to the feud between branded versus generic drugs lies in strengthening the existing quality control structure of the country. India has been producing cheap generic version of many lifesaving drugs through the past few years and it's market and people are slowly opening up to the use of these drugs. India is a nation where millions of people lie below the poverty line and if these generic medicines can be made affordable for them, then there is nothing better than that. India is ready for these cheap drugs and will welcome them with open arms.

Things being done for the development of generic drugs in India

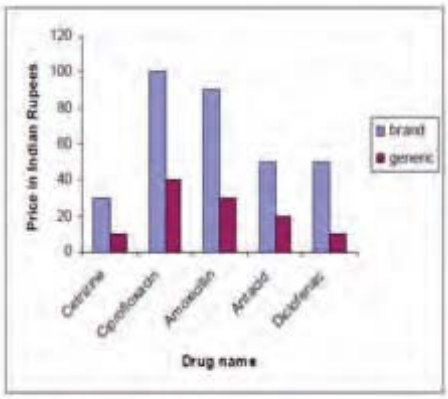


India is the main supplier of essential medicines for developing countries, and UNICEF procured millions worth of services and supplies from India.

DRUG COMPANIES HAVE contributed a lot to the improved health and prolonged life of man, today. Research and development of drugs today can be costly and there are strict regulations and guidelines that these developer companies must follow in most countries. Poorer countries encourage their drug companies to make cheaper generic versions of brand name drugs or use other ways available at their disposal to help bring the price of medicines down to more affordable levels through competition. But these companies face tough conditions and scrutiny from international institutions and other pharmaceutical companies, even when they try to develop these generic drugs in a legitimate way following all the strict rules and regulations.

In comparison to a number of other countries, India has done a great job of producing cheap enough medicines so that its citizens can afford to buy whatever it is that they need. Most importantly, it does not provide patents for drugs unless they're fully new or have some sort of advantage over already-available treatments, which means that a big portion of life-saving medicines are free to be manufactured and sold by any other company that wishes to do so.

India is one of the developing nations of today and has helped to develop the generic versions of many lifesaving drugs like HIV. This has brought down the price of HIV drugs to 100$ and has been helpful in saving many lives all across the world by providing the patients with good quality cheap generic drugs. As per global market trend, it is estimated that billions of worth of patent on drugs will expire during the period 2010 to 2017, and this will attract various pharmaceutical companies to develop generic drugs of these big brand name drugs. The pharmaceutical industry in India has shown good and rapid growth which has helped to boost the economy of India. Today Indian drug companies are entering new markets with greater ambitions, mergers and acquisitions and to capture newer markets.



(market survey on 25-03-2010)

The Indian Patent rules and guidelines have been the key factor for the development of the Indian Generic drugs industry, which makes the production and availability of essential drugs at affordable prices. The growth of generic drugs industry due to the favorable patent regime has not only helped India but also impacted positively many of the other developing countries. India is the main supplier of essential medicines for developing countries, and UNICEF procured millions worth of services and supplies from India. According to the reports of Campaign for Access to Essential Medicines, around 67 % of medicines are consigned from India to developing countries and more than half of all medicines distributed by the International Dispensary Association (IDA) to developing countries are formed in India. The following chart shows the price of generic and brand name drugs in some fields. One can clearly see how the generic version of the drugs cost much less than the brand-name drugs although both are equivalent to each other.

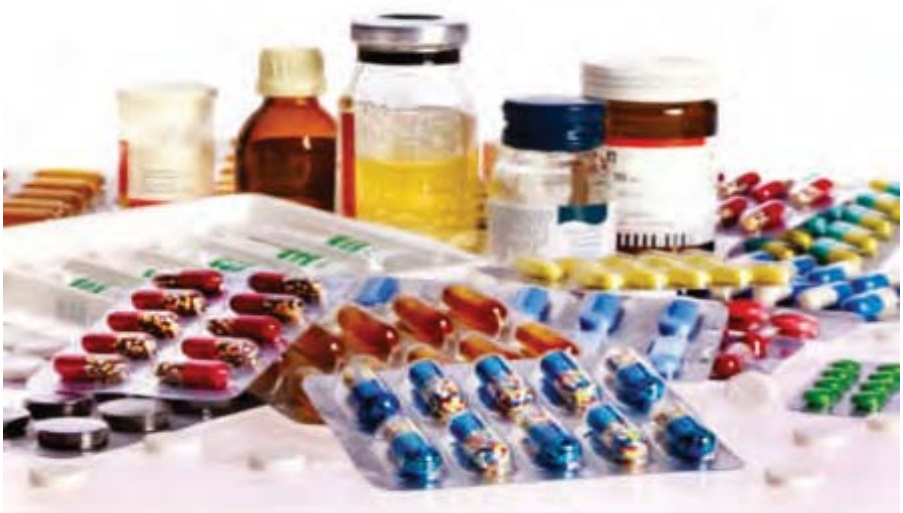
The Patents Amendment Act, 2005, launched Product Patent in India. The product patent was granted for the new product for a duration of twenty years. Previously due to lack of product patent, only process patents are allowed for a new process of production of an already known product or for manufacturing a new product. This has helped Indian pharmaceutical industry to develop generic versions of the new medical drugs without having the fear of infringement of patent. This has also helped in achieving the main objective of rule makers in the developing world to assure the availability of new medical treatments to save millions of lives by production of cheap generic versions of on-patent drugs. The introduction of product patents is deemed as a major incentive for developing new medicines, but this has put the Indian generic medicine industry in a little bit of trouble.

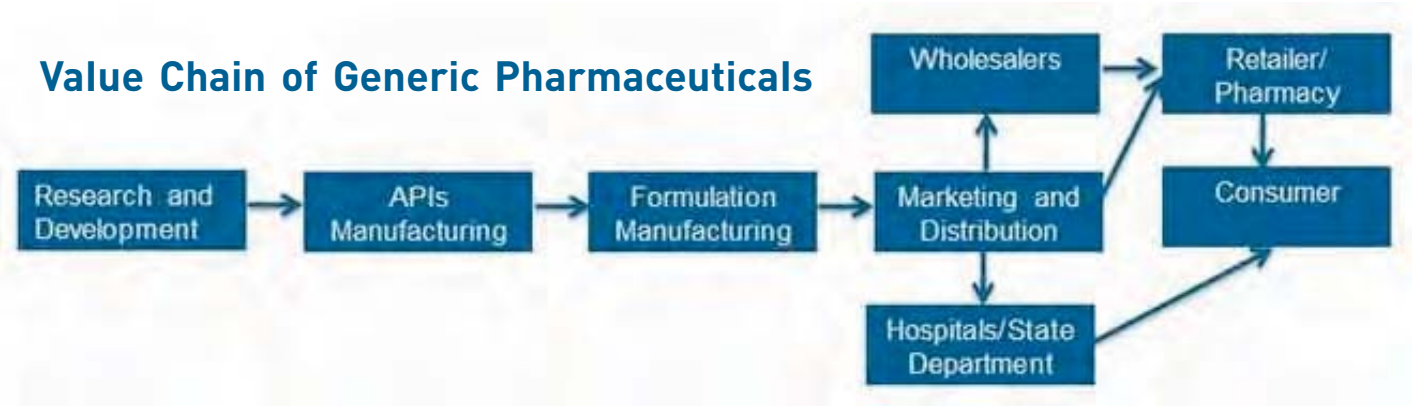
Government's role in the generic medicine industry

Today, India is one of the key players in the global generic drug market with Indian pharmaceutical companies ranked third in the terms of volume of drugs sold globally. Though Indian Generic drug market has a small share in global pharmaceutical market, the industry is growing at a remarkable rate of 10% annually. The Indian Patent Act of 2005 has provided a favourable climate to Indian drug manufacturing companies which used their reverse-engineering skills to make generic drugs equivalent of their expensive brand name drugs at cheaper costs. The government of India has also helped this subsector by giving them benefits in tax, and grants to beginners and existing companies for growth.

The higher authorities and courts have helped indirectly by taking back patents of multinational companies in India who sold their patented drugs at steep prices. It has granted compulsory license to Indian generic makers for manufacturing life-saving drugs at cheaper costs which were exorbitantly priced by the patented multi-national companies. This historical decision by the judiciary has helped Indian pharmaceutical industry to earn higher revenues from their business and thus provide cheap essential medicines to all.

One of the main reasons to popularize generic drug by the Government of India is to make drugs and medicines affordable for people, who cannot otherwise afford the high-priced branded medications and the private hospitals. As more than half of India's population lives in the rural areas, out of which around 35% is either under the poverty line or close to it is another reason for the use of generic drugs and their development here. These drugs have been developed also to reduce the unethical practices of doctors who deliberately prescribe branded drugs over generic drugs. Many private doctors still prescribe branded drugs because they get good incentives or attractive benefits from the branded pharma companies. The use of generic drugs, which are no distinct from the branded ones, will reduce the rising cost of healthcare and the poor people of the country can benefit.





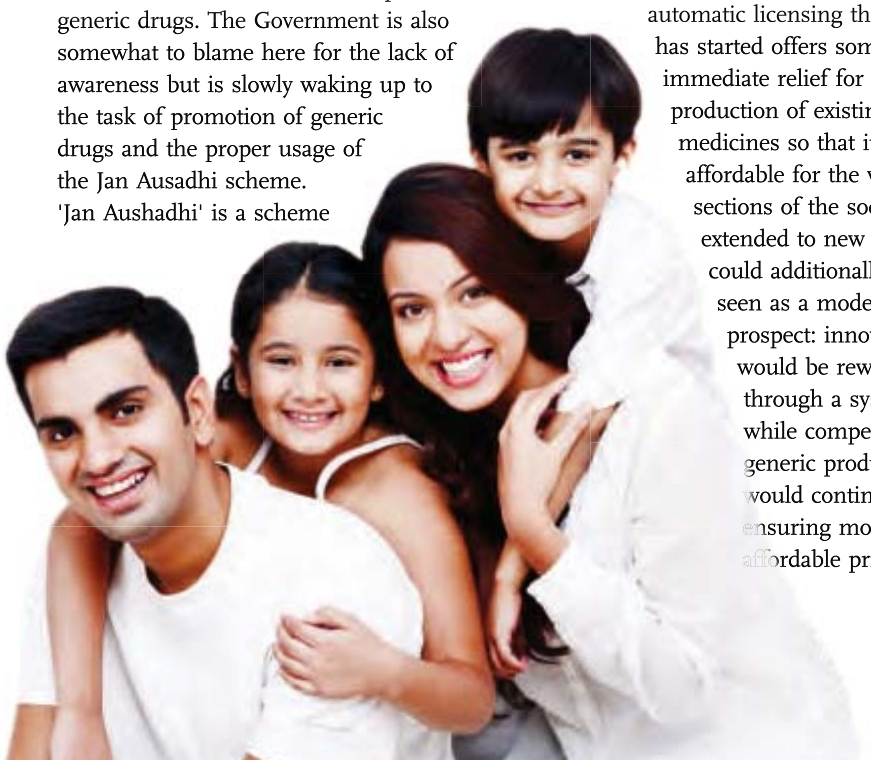
India's love for Branded goods and medicines

Indian people are very easily influenced by the brand name of a product, be it in clothes, cosmetics, accessories, grocery, durables or medicines. Same thing happens with the medicines market, where the brand names are more popular than the generic version of drugs even though they are cheaper. For the over-the-counter (OTC) drugs, the majority of people are aware of the brand names rather than their chemical or generic names. Also, in India, there is a particular section of the population who feel that since these generic drugs are comparatively cheaper, they may be of inferior quality and may not be as effective. Chemists too provide medicines that are written on the prescription and in most cases, the doctors don't prescribe generic drugs. The Government is also somewhat to blame here for the lack of awareness but is slowly waking up to the task of promotion of generic drugs and the proper usage of the Jan Ausadhi scheme.

'Jan Aushadhi' is a scheme started by the Department of Pharmaceuticals in association with a portion of the government in India, to provide quality medicines at affordable prices to the masses. These stores have been set up to provide generic drugs, which are available at cheap prices but are equivalent in quality and efficiency as expensive branded drugs.

The future of Indian generic drugs

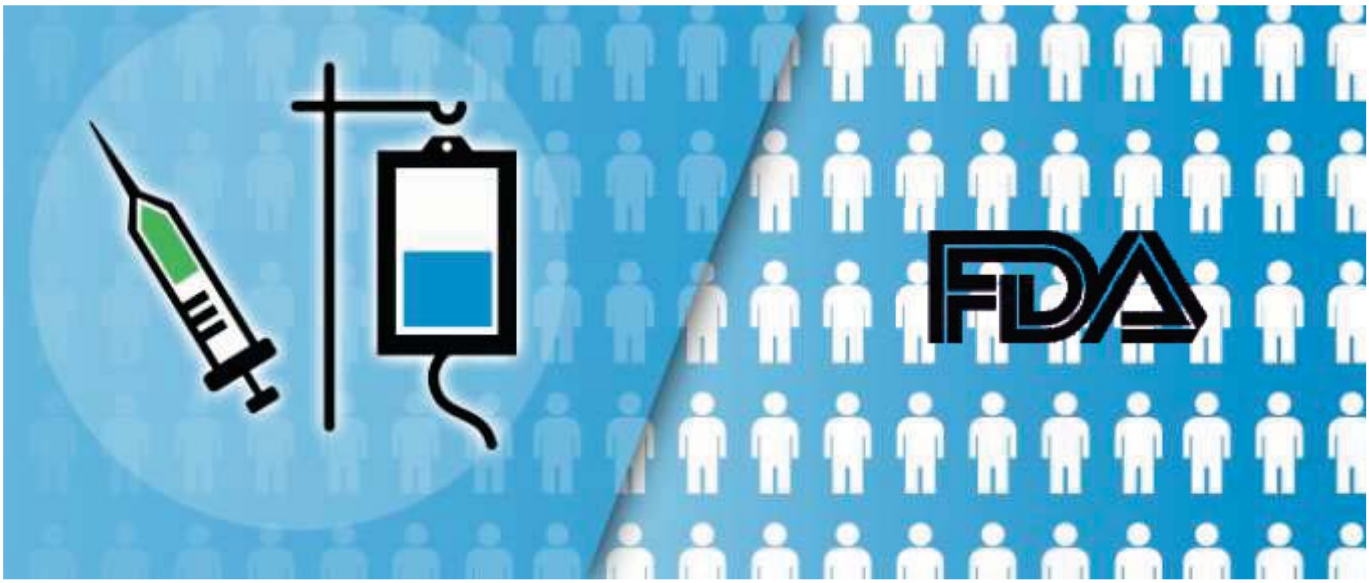
The share of Indian drug companies in the total pie of approvals for generic drugs called the abbreviated new drug applications (ANDA) in U.S.A has grown quite well. In 2011, nearly half of the ANDA approvals were by Indian firms. As a result, exports of generic drugs from India, have grown by 21 percent between 2005-06 to 2010-11. The system of automatic licensing that India has started offers some immediate relief for generic production of existing medicines so that it can be affordable for the weaker sections of the society. If extended to new drugs, it could additionally be seen as a model for the prospect: innovators would be rewarded through a system while competition by generic producers would continue ensuring more affordable prices.



The Indian government has to play a balanced role between Branded and Generic Drugs. The government also has the obligation of providing affordable healthcare to poor, therefore through various ways, the government is promoting generics to poor people. So, if people of India want to get hold of cheap and affordable drugs, then the government has to take steps for the growth of generic medicines in India. Even the people of the country are not aware of such medicines in India which can help to save many lives in this country. So, it is the duty of the government to educate people regarding such generic medicines and their effectiveness at such low rates. They are taking steps for the development of generic medicines in India, but doctors have to prescribe them more often. The government is taking steps in their development by providing cheap medicines through the Jan Ausadhi schemes; only people need to be more aware of it. Thus, if you want cheap and affordable medicines in India, it is the time you start using generic medicines and not go for brand name drugs only which are much costlier and out of reach of the common people.

Indian pharmaceutical companies ranked third in the terms of volume of drugs sold globally.

FDA and its guidelines for generic drugs



A GENERIC DRUG is identical or equivalent to a brand name drug in dosage, safety, strength, way of administration, quality, performance, properties and intended use although many people all over the world are still unaware of its effectiveness and go for the costlier branded version of the drugs. In a developing country like India, it is essential to have cheaper drugs where millions of people are already below the poverty line. Thus, by making essential generic drugs available to the common man at affordable rates is the main motive of the government of our country.

Drug products sold in the United States are generally first passed by the FDA whether they are brand name or generic drugs. Despite the strict guidelines imposed by the FDA for approval of generic drugs, and the various companies following these standards, a number of misconceptions about generic drugs persist still in the country and our society making these drugs still unpopular among the general public. Even though most of these generic drugs have been passed and approved by the FDA yet people believe that cheaper drugs may be of inferior quality. Although this is not true, yet the doctor's don't help much to spread the word of equality between generic and brand name drugs. Thus, it is their duty of educate the general public regarding this.

Generic drugs have been developed once the patent period of the original developer expires and new companies can make the equivalent drug under its generic name.

Although it all looks very simple and easy, it is actually not so. It requires a lot of hard work and approval from the FDA to get any generic drug to the market. FDA lays down some really strict rules to be followed for generic drug manufacturing units and wishes they adhere by the guidelines so that standard quality, strength and effective drugs reach the common man at affordable rates. They make sure that no guidelines are compromised and all the manufacturing unite to fulfill the required conditions.

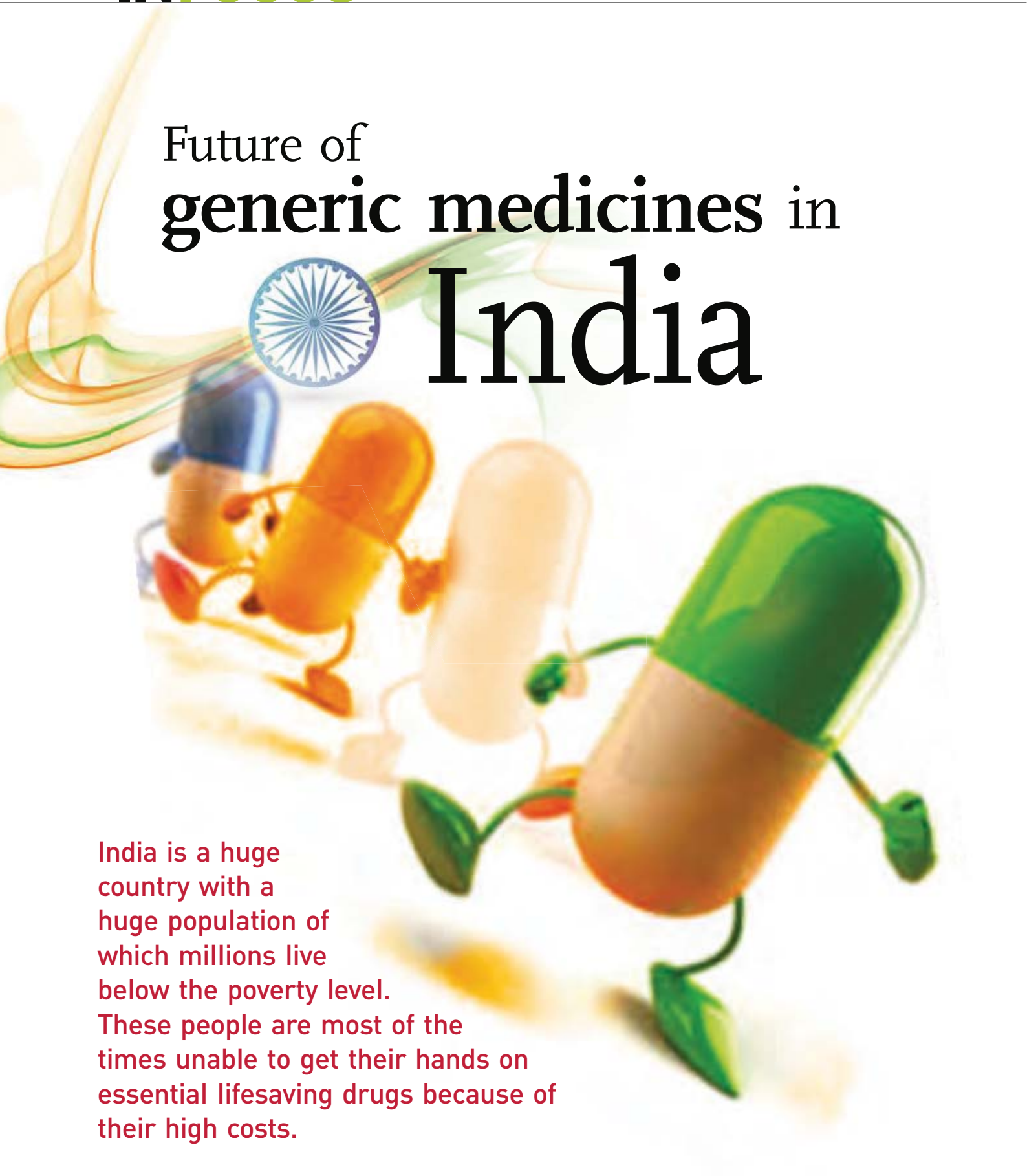
Healthcare professionals and consumers should find solace in the fact that FDA approved generic drug products have met the same strict guidelines as the developer of the drug. All generic drugs passed by the FDA have the same high quality, dosage, and characteristics as brand-name drugs. And, the generic drug manufacturing unit, packaging, and testing sites will have to pass the same quality standards like that of the brand name drugs. So, for any generic drugs to pass FDA scrutiny they have to follow certain strict guidelines and they are as follows:

- For any generic drug there has to be an FDA-approved brand-name drug. The generic drug must also have the same ingredient and the same labeled strength as this brand name drug or product. The generic drug should also have the same dosage form whether as tablets, patches or liquids. Lastly, it must be given in the same way, like swallowed as a pill or used as an injection.
- The developer of the generic drug must show the generic drug is equivalent to the brand-name drug.
- The generic drug's labeling must be similar to the brand name drug.
- The manufacturing firm of generic drugs have to document fully the generic drug's composition, steps to manufacture, and quality control measures. Each step of this manufacturing process must be written in details for proper FDA review.
- The manufacturers of generic drugs have to make sure that the materials used, and the product thus made meet the specifications of the FDA and all the guidelines have been followed. It also has to meet the standards set by the US agencies.
- The generic drug manufacturing company also has to that its generic drug is stable as labeled before being put to the market. The firm has to continue to monitor the drug's stability even when it has been put on the market. It also has to show that the casing of the drug and its packaging won't interact with the drug. Companies making sterile drugs must submit sterility assurance data showing biological integrity of these drugs.
- These manufacturing firms also have to give a full description to the FDA of the methods it uses to manufacture, make, check, package, label, and control the drug. It must certify that it abides by the federal rules and regulations about good manufacturing practices and has to allow FDA inspection of its unit to assure compliance.
- Lastly, FDA approves a generic drug only if after inspection of the proposed manufacturing site to make sure the firm is competent of adhering its commitments and to make sure that the firm can manufacture the drug repeatedly without any failure.

Generic drugs which have been approved by FDA are equivalent to their brand-name counterparts and often people can use them with total confidence. Even though they are available at low rates it does not mean that they are of inferior quality. The stringent guidelines laid down by the FDA makes sure that quality and effectiveness of these drugs is maintained and in no ways they are compromised with.

So, today if a generic drug wants to succeed in the market, first of all it must be an equivalent of the brand name drug in all departments and it should also pass all the criteria that have been put by the FDA so that these drugs can be launched smoothly in any market. Since these generic drugs are made for better availability of cheap medicine for common man, the rules to be followed are also quite strict. Thus FDA ensures that only drugs which are superior in quality, character and result are approved by them and they provide maximum benefit to the users. These drugs are similar to the brand name drugs but are available at much cheaper rates and help common man to get the best healthcare facilities.

Future of generic medicines in India



India is a huge country with a huge population of which millions live below the poverty level. These people are most of the times unable to get their hands on essential lifesaving drugs because of their high costs.

Keeping this in mind, generic medicines were developed in India so that the common man could get these essential drugs at affordable and cheap rates without any trouble. India is one of the developing nations of today and has helped to develop the generic versions of many lifesaving drugs like HIV and other drugs. So much so that this has brought down the price of HIV drugs to 100$ and has been helpful in saving many lives all across the world by providing the patients with good quality cheap generic drugs. Although on one hand India manufactures cheap generic drugs yet its people are very easily influenced by the brand name of a product, clothes, or drugs.

Also, a certain section of the population feels that since these generic drugs are comparatively cheaper, they may be of inferior quality and may not be as effective. Chemists too provide medicines that are written on the prescription and in most cases, the doctors don't prescribe generic drugs. The Government is responsible here for the lack of awareness but is slowly waking up to the task of promotion of generic drugs and the proper usage of the Jan Aushadhi scheme. 'Jan Aushadhi' is a scheme started by the Department of Pharmaceuticals in association with a portion of the government in India, to provide quality medicines at affordable prices to the masses. Now, the future of generic medicines in India looks bright and people are more educated about equivalency between the generic and brand name drugs. The Indian Patent Act of 2005 has also helped to boost Generic drug manufacture here and has been good for the country.

Generic drugs and their effectiveness

Despite the common belief that anything cheap may not be as effective, generic drugs are as effective as brand name drugs. No matter how cheap they are, they have the same quality, strength, purity and effectiveness as the original drug and since have been manufactured after the patent expiry period they need no investment for research or marketing. Thus they can keep their costs low and make these essential generic medicines available to common man for cheaper rates. So, there is no need to question the effectiveness of these generic drugs.

The generic drug must contain the same amount of medicinal ingredient as the brand name drug or product. Though, non-medicinal ingredients, like fillers and ingredients that color the drug, may be different from those of the brand name product. The generic manufacturer as a rule must furnish instances showing that the different non-medicinal ingredients have not changed the quality, purity or effectiveness of the generic drug. To prove that their products are safe and effective, generic drug manufacturers must show that the generic drug works likewise to the brand name drug.

The inactive ingredients in generic drug compared with branded drugs are not the same and can be different but the active ingredients have to be the same. So, sometimes there may be allergies to these fillers or inactive compounds which may cause people to doubt their effectiveness. Thus, special consideration should be taken when changing from a branded drug to a generic drug, or when changing between generics, if it has a smaller therapeutic index. Thus, the generic drugs are cheap and effective unless someone has some allergy to the non-medicinal part of the drug which can be different from the brand name drug, but otherwise both of them are equivalent. Today generic drugs are being prescribed more by doctors so that common man can get cheap and affordable essential drugs easily.

Manufacturers of generic drugs

Generic drugs can be produced by any company after the expiry of the stipulated patent period but will have to follow the strict guidelines provided by the local law bodies. These manufacturers are able to produce these generic drugs cheaply as they do not have to invest in research and development or market the drug to anyone. This makes the cost of such drugs really low and the competition among other such manufacturers also brings down the price of the drugs. Thus, the manufacturers of these generic drugs can sell their products for cheap in comparison to brand name drugs.

Generic drugs have the same quality, strength, pureness, and effectiveness as brand-name drugs. So, they are as good as the brand name drugs and people should have absolutely no reason to complain when different manufacturers supply them at really cheap rates. For any generic drug to be launched into the market, FDA first has to approve of it and only then can it be launched across all the markets. India is one of the key players in the global generic drug market and has helped to provide millions of people with cheap generic versions of essential lifesaving drugs like that of HIV etc.

Today, even branded drug makers have been diversifying to make up for the falling sales of their patent expired brand name drugs. It means that means that they are joining hands with their generic drugs manufacturing rivals, to take advantage of their low-cost production and greater access to markets in the developing world. Top Indian generic drugs manufacturers of today are:

- Sun Pharmaceutical Industries
- Dr. Reddy's Laboratories
- Lupin
- Ranbaxy
- Aurobindo
- Glenmark

Branded drugs Vs. Generic drugs

Brand name drugs and generic drugs are similar or equivalent to each other in strength, purity, dosage and characteristics. They both contain the same amount of medicinal ingredients but may have different non medicinal ingredients. This is the only main difference between the two drugs. Generic drugs may also come in different shape, size, and colour but the effectiveness is same as the brand name drugs. Brand implies any drug which is marketed by a company specific name. Brand name drugs thus have a specific name but generic drugs are known by their generic names and have no specific brand names.

Brand name drugs are usually quite costly as they are patented to recover their years of research and development cost along with the marketing cost of the drug, whereas generic drugs come cheap, as they do not have to incur these investments and can save on these costs. Both these drugs can be launched only after the approval of the FDA, but with generic drugs, the guidelines are stricter so that there is no compromise on the quality of the drugs while keeping them cheap. Brand name drugs are more popular and more prescribed by doctors, whereas generic drugs are prescribed less and many people are still unaware of their effectiveness and affordability.

Both generic and brand-name drugs produce the same results, although the generic drugs may have some side effects for some due to the different non medicinal ingredients present in these drugs. The market for brand name drugs is huge but slowly the generic are also getting a good market for the products. The brand name drugs may require time to be recognized in the market but once it is done it sells well but generic drugs can reach the markets immediately and only need to be prescribed more for popularity.

So, if you still confused about which to buy, then the best factor is the price. The cost of generic drugs is much lower and makes medical facility more affordable and within reach for the people of the country. Thus, now it is up to you to decide whether you want the brand name drugs or the generic ones both of which are equivalent in quality, strength and effectiveness but differ in prices.

Brand Drugs

- Protected by a patent
- Supplied by a single company
- Marketed under a brand name
- Brand drugs are priced by pharmaceutical company and regulated by the federal Patented Medicine Prices Review Board.

Generic Drugs

- Low-cost version of brand drugs
- Produced by generic companies once patents expire on brand name drug
- Are as safe and effective as brand drugs
- No national price regulation for generic drugs
- Price includes manufacturing cost and a rebate paid to pharmacies to stock their drug.

AFTERWORD

Generic drugs taking the place of prescription drugs

DOCTORS TODAY PRESCRIBE drugs for different types of diseases but due to certain benefits and extra incentives they often prescribe brand name drugs to the patients which are far costly and out of reach for many. Prescription drugs can often be very costly for a common man, especially if they have several prescriptions to fulfill. Buying generic drugs can be the best way to save money. Generics drugs have the same active ingredients as the brand-name drugs they're based on and come much cheaper than them. They cost sometimes 20 percent to 70 percent less than the brand-name drugs, as found by the FDA. If you want to use the generic drugs when possible, you can ask your doctor to prescribe it and get it from the pharmacist. Thus, now you can easily ask your doctors to prescribe these generic drugs.

Brand-name drug manufacturers have often gone to great lengths to misguide doctors, pharmacists, and the public into believing that their drugs are of higher standards, and hence are safer and more efficient than the same drugs manufactured by generic companies. They have used strategies like setting up false patient groups to force government agencies to protect their brand-name drugs, and try to show that their brand name drugs are much superior in quality and effectiveness than most generic drugs. The quality of prescription drugs, brand-name or generic, does not depend entirely on the producer but also on a sound and alert FDA. Both brand-name and generic drug companies are controlled by the FDA using uniform standards for manufacturing facilities, quality and pureness, and content of prescription drugs.

Generic drugs are safe, effective and FDA-approved. As generics employ the same active ingredients and are known to work the same way in the body, they have the same effects and characteristics as the brand-name drugs. In the case of brand name drugs when the patent expires, other drug companies can introduce competitive generic versions of these drugs, but only after they have been thoroughly tested by the manufacturer and approved by the FDA can they be prescribed by doctors and physicians for regular use. Since, these are cheap compared to the brand name drugs many patients are reluctant to buy them as they doubt their quality but with better education of patients by doctors such fears can be eradicated.

Today, eight out of ten prescription drugs today are of generic nature and are being welcomed by common man due to their affordable prices and the safe effect as the brand name drugs. Therefore, if you are searching for cheap and affordable drugs you can ask your medical practitioner to prescribe you with the generic version drugs instead of the brand name drugs. Their quality, purity, and strength are as good as the brand name drugs, and slowly they are taking their place in the prescriptions.

The market for **generic drugs** in today's world

A GENERIC DRUG is a product, that can be interchanged with a brand name drug, that is manufactured without a license from the original company and marketed after the patent on these drugs expire. This concept has become quite prevalent in the U.S., Europe and many other countries of the developing world and these generic drugs are now finding their way into other markets like Japan which has been trying very hard to reduce its healthcare and medical costs. There have been various studies and surveys going on to find out the market for generic drugs and its future. Here are some main points from those reports which will show how market is for generic drugs today and what does the future hold for it:

1. Generic drugs will account for nearly $350 Billion of revenue by the end of 2015. The market is expected to grow at a compound annual growth rate of 12% in the future 5 years.
2. To make up for the low price margins, some generic drug manufacturers are getting into the super generics opportunity. These will be sold for a relatively higher price than their pure generic counterparts, and super generics account for 18% of all spending on generic drugs.
3. In order to control costs and increase their global reach, generic drug manufacturers are using their existing manufacturing and Research and Development locations with

Can generic drugs totally out do

branded drugs?

There has been a lot of debate about the brand name drugs and the generic drugs all over the world. People from different planes have different opinion about these drugs. Many believe that generic drugs may not be as effective as the brand name drugs as they are cheap and thus may be of inferior quality. People need to be convinced more about the effectiveness of these generic drugs. Even the doctors are prescribing more of these cheap and affordable versions of drugs for the common man. No matter how costly a brand name drug is, its generic version is bound to cost 20-70% lesser than the original drug.

But whether generic drugs can totally out do branded drug is a question which is difficult to answer. This is so because even though generic drugs are bio equivalent to brand name drugs yet people are often sceptical about using them. According to them, any drug which is cheap may be of inferior quality and this leads them to choose brand name over cheap generic drugs. Even doctors sometimes stress on the brand name drugs as they get special incentives for doing so. Thus, it will be very difficult for generic drugs to totally out do brand name drugs.

In certain countries and markets there have been instances where generic drugs are doing very well and are being prescribed by doctors too for the welfare of the common man. In countries like India where millions of people live below the poverty line, such generic drugs have helped many needy people to get their hands on cheap and affordable lifesaving drugs. But still many people are influenced by brand names and they still opt for brand name drugs rather than generic ones. Generic drugs also sometimes face problems due to the non-active ingredients in the product. People sometimes are allergic to these ingredients and may have more problems from these generic drugs than good.

Thus, it is difficult to say that generic drugs can totally out do brand name drugs from the market. There are users who still feel that the generic versions of these drugs are not as effective as the brand name drugs and instead of curing their diseases they cause further damage. This may be correct in some cases but for most this is not true as both brand name and generic drugs have bioequivalent characteristics. Meaning both of them have same strength, purity, dosage, characteristics and effects but may be different is shape, size and colour. Thus, if you want to use the generic version of these brand name drugs then it is totally up to you and they are as effective as them. But in some places due to lack of competition in the markets, generic medicine prices are also sky rocketing. This means that there will remain no difference between these two drugs then and people will find it difficult to choose between the two. Thus, we cannot convincingly say that generic drugs can out do the market of brand name drugs.

such sites in countries such as India, China and Russia which have low costs for these things.

4. In order to save cost on bio-similar drugs, many countries have established regulatory pathways for their approval. It is estimated that approved generic drugs will account for more than $20 Billion in revenue by the end of 2020.

5. As the market increases, larger players expand their market share through acquisitions and mergers. Many such well-known companies are particularly keen to make use of these joint ventures in new markets like Japan.

Thus, slowly but surely markets for such generic drugs is opening up and people are becoming more welcome towards these drugs. They are cheap and affordable for most people and are equivalent to brand name drugs in quality and effectiveness. Over the years, the generics market grew stronger due to encouragement from the government as most

Generic drugs will account for nearly $350 Billion of revenue by the end of 2015. The market is expected to grow at a compound annual growth rate of 12% in the future 5 years.

governments are trying to reduce their healthcare cost. The expiration of branded drugs patent has fuelled the rapid growth of the generic drugs market as well. So, if any drug manufacturing wants to enter the market then this is the right time for it, as many big brand name drugs patents are expiring and this is providing opportunity to the generic companies to launch their products for the betterment of the general public. This has made cheap and affordable medicines available for the people all over the world.

“CLAIM YOUR
Consumer Rights Now
An Aware
CONSUMER
is a Protected Consumer”

Future for **generic** drugs

IT TAKES LITTLE to realize that the future prospects are bright and welcoming for the generic drug industry. A combination of factors like numerous branded-drug patent expirations, the prospect of generic biotechnology drugs and a favourable environment is increasing the value and opening up different opportunities for investors during the next three to five years. Patents on as many as twenty major branded drugs are about to expire in the next three years, so generic drug companies are lining up at the U.S. Food and Drug Administration to file applications to bring the generic version of each of these branded drugs to market. So the companies who are able to file such applications early get a six-month window to sell these generic drug with almost no competition and earn heavy revenues.

The continuous efforts by governments and private payers to cut cost is also boosting the growth in generic drugs, as these people almost force providers and consumers to use cheaper medications. After a recent spate of judicial and regulatory decisions, generic drug makers face higher legal, regulatory and insurance costs. Generic drugs which have been approved and passed by FDA are equivalent to their brand-name counterparts and often people can use them with total confidence. Even though they are available at low rates it does not mean that they are of inferior quality. The strict norms laid down by the FDA makes sure that quality and effectiveness of these drugs is maintained and in no ways they are compromised with.

Generic medicines are not only going to be more dominant in the future but may even be as big as the brand name drugs. The more generic drugs are developed the more will be the competition and the lesser they will cost the customers. Thus, generic drugs are good for customers who want cheap and good quality drugs of brand name quality. In both the near and long time, branded-drug patent terminations will be a boon to the bottom lines of generic drug companies. Major brand name drugs like as Pfizer's cholesterol drug Lipitor, Eli Lilly's antipsychotic Zyprexa and the sanofi-aventis/Bristol-Myers Squibb medication Plavix are all whose patent expires soon. Billions and billions of dollars of branded pharmaceuticals are losing exclusivity over the next four year and this gives chance to the hundreds of generic drugs manufacturers to introduce their drugs into the market. Many countries are trying to cut down their healthcare costs and what better way than by introduction of cheap and affordable lifesaving drugs for common man.

With many manufacturing facilities for generics located in less-developed nations, safety is a major issue for any generic drugs. In the United States, the FDA is understaffed as applications for traditional generics drugs manufacture keeps piling up. Even after legislation is passed and approved by the president, rules and regulations must be developed to provide a framework for approval of these generic drugs. Now with greater rules and regulations these generic companies producing these medications might have to undergo a limited clinical trials of generic biologics to prove they're similar enough to the brand name drugs they're trying to copy.

The Developments for the generic pharmaceutical industry are encouraging as more brand-name drugs come off patent and users push for cost cuts in health care. In addition, an increase in FDA budget and staffing should begin to rectify the backlog of branded and generic drug applications and enhance the ability of the FDA to examine all the facilities here and overseas as generic biologics get to market in the subsequent few years. Their better rules and guidelines may help to bring to the forefront some really good and great generic drug manufacturing industries, which will actually help to cut healthcare costs and provide safe and quality medicines to the people at affordable rates. Thus, although the future of the generic drugs look really bright, yet they have to be careful and adhere to all the rules and regulations of the FDA to be able to start producing these cheap drugs for markets all over the world.

Are generic drugs fit to be prescribed?

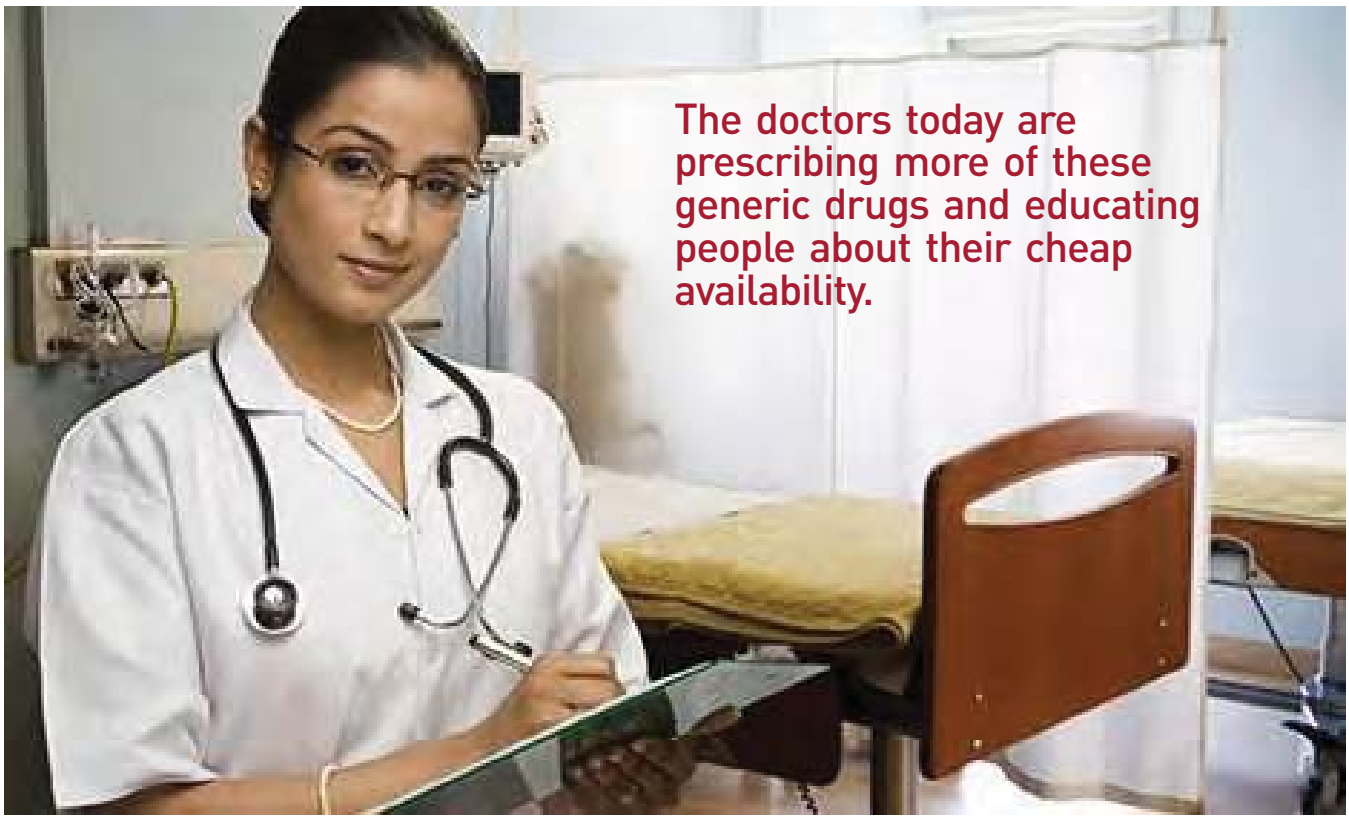
POOJA KHAITAN

Both the brand name and generic drugs are the same excepting the non-medicinal ingredients which may differ.

A BRAND-NAME drug is originally invented and developed by a drug manufacturing company after a lot of research and development. But before the company can market and sell their product they must first be passed by the Food and Drug Administration (FDA) by submitting the Application for such a drug to them. In this documentation the company provides a proof regarding a drug's safety and efficiency. Other ways show the characteristics of the drugs like its dosage form, including the manufacturing process, its stability, quality, strength, and the way it dissolves. Once the drug receives FDA approval, the developer company can then market and sell this drug for as long as the company has patent protection and no one else can do so. When this patent expires other manufacturing companies can make similar drugs and sell them according to their generic names and these are called generic drugs. Both the brand name and generic drugs are the same excepting the non-medicinal ingredients which may differ.

A generic drug is similar to a brand name drug in every way and provides affordable medicines to the customers, which is where brand name drugs lag behind. Generic drugs are of the same quality, purity and strength as that of the brand name drugs and are today being prescribed by the doctors all over the world. Although there have been instances of their not working efficiently yet mostly they do and they are fit to be prescribed. So, doctors and government stress on these generic drugs to provide cheap and affordable healthcare to all.

Do all prescription drugs have a generic version of them



A GENERIC DRUG is identical in most ways to a brand name drug in dosage, safety, strength, way of administration, quality, performance characteristics and intended use whereas the brand-name drug maker often invented the drug, a process that can cost a company thousands and thousands of dollars for development and marketing, for which they get a patent for a stipulated period of time. After the expiry of that time period manufacturers make identical drugs like those of the original ones and launch them after the FDA approval at really low rates and these are called their generic versions.

Yes, most big shot brand name drugs do have a generic version of them made available for the common man although many people are ignorant about this fact. They often don't bother about generic drugs as they think they are inferior quality drugs or they are simply unaware of their presence. The doctors today are prescribing more of these generic drugs and educating people about their cheap availability. So, the nest time you go to a chemists shop to fill your prescription, make sure to ask for the generic version of the drug and see how cost effective it is. Many country's government are providing extra incentives to these generic drug manufacturers to provide the people with cheap and affordable drugs. Therefore, if you are in the lookout for cheap and effective drugs then you can try the generic drugs and see how they are.

Government steps regarding generic medicines

In mid-1970s and late 1980s, the scientists and organic chemists from these institutes formed productive, cost-effective methods to boost active pharmaceutical ingredients manufacturing. This helped generic manufacturers to develop low-cost generic new medicines.

JAN AUSHADHI YOJANA

The innovative policy and legal reforms over long periods of time has resulted in India becoming one of the key elements among developing countries in promoting indigenous manufacturing and great development in pharma products. This has benefited millions of patients in developing countries by providing them with a source of affordable generic medicines. To increase the production of medicines domestically, the government set up the public sector units to produce new drugs with the purpose to develop and strengthen domestic capacity in medicinal drugs.

The Government then set up public research and development laboratories in various parts of India like the National Chemical Laboratory, Pune; the Central Drug Research Institute, Lucknow; and Regional Research Laboratory, Hyderabad. In mid-1970s and late 1980s, the scientists and organic chemists from these institutes formed productive, cost-effective methods to boost active pharmaceutical ingredients manufacturing. This helped generic manufacturers to develop low-cost generic new medicines. By early 1990s with more technical advancement not only generic drugs were being produced from the beginning but were far more affordable.

Unlike many other countries, India has done a great job of producing cheap enough medicines so that its citizens can afford to purchase whatever it is that they require. Most importantly, it does not provide patents for drugs unless they're fully new or have some sort of advantage over already-available treatments, which means that a big portion of life-saving medicines are free to be manufactured and sold by any other company that wishes to do so. The Indian Patent rules and guidelines have been an important factor for the development of the Indian Generic drugs industry, which makes the production and availability of essential drugs at affordable prices.

In 2005, patent law not only put some serious bars on generic competition but also had some important features such as strict patent criteria to prevent the right for anyone to object to a patent before it is allowed; and compulsory licensing. But the positive thing is that this has benefited Indian pharmaceutical industry to produce generic versions of the new medical drugs without having fear of infringement of patent. This has also assisted in accomplishing the main objective of rule makers in the developing world to assure the availability of new medical procedures to save millions of lives by generation of cheap generic versions of on-patent drugs.

One of the main reasons to popularize generic drug by the Government of India is to make drugs and medicines affordable for people, who cannot otherwise afford the pricey branded medicines and the private hospitals. As more than half of India's population lives in the rural areas, out of which around 35% is either under the poverty line or close to it is another reason for the use of generic drugs and their development here and distributed through the Jan Aushadhi scheme. This scheme helps to provide quality and affordable medicine to people all over the country.

“Let's Not Fall Victims to Fraud Be Aware”

New ways to replace older, costlier branded drugs

BRANDED DRUGS and their exorbitantly high prices have forced people to look for alternative medicines and one such not so new and welcome change is in the form of generic drugs. Generic drugs are nothing but equivalent to the brand name drugs in purity, strength and dosage but are available at a much lesser price due to no investment and marketing cost. Such generic drugs have helped to provide good healthcare to many people all across the world at really affordable rates. These drugs are cheap but in no way there is a compromise in their quality. FDA approval is a must before these generic drugs can be launched into the market and thus one can say it is safe to use these drugs.

The new Generic drugs which have been approved by FDA are equivalent to their brand-name counterparts and people can use them without any fear or discomfort. If a product is not approved by the FDA, the company can get a New Drug Application from the manufacturer, which is then looked into to determine if the drug meets FDA standards. Drugs that pass this review then become exclusive products that meet FDA standards, giving drug producers the exclusive power to sell the drugs for a period of time, just as with any latest drug. The severe guidelines laid down by the FDA makes sure that quality and effectiveness of these drugs is maintained and in no ways they are compromised with. Doctors today are prescribing more of these generic drugs than the old branded drugs to help the people to get quality healthcare at affordable rates.

FDA approval is a must before these generic drugs can be launched into the market and thus one can say it is safe to use these drugs.

Today with the advancement in the field of medicine and technology countries are coming up with newer and better methods to cater to the requirements of the people and providing them with high quality and cheap drugs which are in every way similar to the famous and costly brand name drugs. Thus, people have now become more aware of the existence of such drugs and are buying them over the counter from pharmacies or are asking their doctors to prescribe them to get cheap and affordable drugs. So, there have been many new drugs and generic drugs which are slowly replacing the older costlier drugs and proving the common man with really cheap substitutes which are in no way different from the actual brand drug.

So, today people are opting for these new generic drugs instead of the old brand name drugs for affordable healthcare and to get cheap medicines. The government of all countries are trying to provide boost to such new generation drugs which provide cheap and quality healthcare to all its citizens. Therefore, with the cooperation of the government and other institutions drug production companies today are making new and inexpensive drugs to provide reliable and affordable healthcare to the people of their country.

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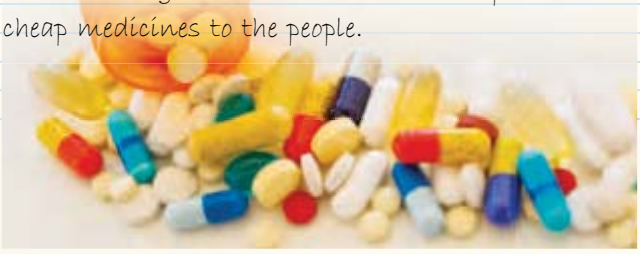
A consumer's right to good and cheap medicine

Every consumer all over the world has the right to good and cheap medicine and healthcare. Brand name drugs are often too costly for a common man in a place like India where a great chunk of the population lies below the poverty level. Thus, it is the responsibility of the government to provide people with cheap and affordable healthcare facilities. India has been a hub of cheap and affordable generic medicines for years, but the people of the country have been ignorant to such facts. Even if they knew this, they have been influenced by brand names in all departments.

Even doctors are provided with incentives and benefits to promote brand name drugs which leaves out the cheap generic drugs out in the cold. But with the turn of century and with more education about use of generic drugs, people have started using more of these cheap and affordable generic drugs which are in no way less than the brand name drugs. Their right to affordable healthcare has prompted the government to take steps and boost the growth of generic drugs to provide all common people with quality and cheap medicare facilities. Thus, in India the government is trying to provide the citizens with cheap and affordable medicines in the way of generic drugs, which has helped to save the lives of many. The use of safe and effective generic medicines has changed the healthcare facilities in our country and name have benefitted from the different schemes the government has started to provide cheap medicines to the people.



Consumer's view on generic medicines

A significant proportion of doctors, pharmacists and common people reserve no too high opinion of generic medicines. It is because of these attitudes which present barriers to the wider use of generics. Most people of our country are unaware or skeptical about the use of such generic drugs and most believe that these are inferior quality drugs and thus they are priced cheaply. But the fact is not so. Lack of awareness and help from the doctors has negatively impacted the growth of generic medicines in many parts of India and around the world. People believe that they are cheap and thus must be of poor quality.

Some people even have complained about the aggravation of their medical symptoms when on usage of these generic drugs rather than the brand name ones they used before. This may be due to the non-active ingredients present in the drugs, which vary between the branded drugs and generic drugs. A number of surveys have also shown that a large portions of patients had negative views about generic drugs, believing them to be less effective, of lower quality and not fit for the treatment of major diseases, as compared to their branded counterparts. Thus, consumer's view vary on this subject although most think these drugs are of inferior quality. Doctor's too often hold such views and refrain from prescribing these drugs which hampers the chances of patients getting good quality medicines at cheap rates. This means that consumer's still need to be educated on the effectiveness of these affordable variety of drugs and this can be done with the help of physicians and other bodies only.

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