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"Are we Indians prepared to shift to lone generic prescriptions in this COVID scenario?"

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ABSTRACT
A topic of never-ending debate among physicians, pharmacists, drug regulators and drug policy makers across the world is "Branded versus Generic drugs". Generic drugs are those, sold without a brand name as they are not protected by trademark registration whereas branded have a specific name provided by the manufacturer. Hence, generics are cheaper version of brands with a profound bioequivalence profile. Conventional medicinal prospectus in country like India, does not attend to the essential feature of rational or generic prescription writing. One of the major reasons is the escalation of branded generics, that are sold at amounts adjacent to the innovator brands. This adds to the cost of pharmaceuticals in the country year by year. Time and again the consequence of generic prescribing has been emphasized to reduce the cost of drugs and in turn enhance the availability, of at least the essential drugs in all most all health care centers. Hence, it is vital to figure out the fundamental pharmaceutical concepts about branded, branded generic and generic drugs which impart a greater effect on patients' pocket and affect stakeholders in the field of health care. This review article will help in exploring and understanding these issues in a better way to allocate conversant pronouncement making for the profit of patients and society equally. Even though the countries across the globe are fronting the COVID-19 pandemic presently, sustaining the supply of drugs and pharmaceutical products is of course ultimate to conceal the instant therapeutic rejoinder. In this regard, the role of Pharma industry in India, is highly pivotal to not only encounter its national necessity but also correspondingly be imperative for the world. This article will also highlight the plausible significances of COVID-19 on the global pharma market and the important role to be played by Indian pharma market to contribute the global retort to this pandemic.
Key words: Branded, Branded generics, Generics, Patents, Innovator drugs, Bioequivalence

INTRODUCTION

Almost 30% of the population in the world don't get access to essential medicines as figured out by World Health Organization estimates recently.[1] The expenditure of pharmaceuticals as a fraction of overall healthcare expenses have been intensifying worldwide.[2]Situations are extremely worse in most of the African and Asiatic countries. Some recent reports revealed the fact that, the handiness of essential drugs was even less than 50% in many African and Asiatic countries.[3]High charge of the drugs is the key aspect that hinders access to drugs by poor and mediocre communities in such developing and underdeveloped countries. It's sorrowful that, even the government in such countries seems to be least concerned to counter this problem. Well, the circumstances in India are also the same. Healthcare expenditures are growing year

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after year in our country, both in real terms and when Gross Domestic Product is concerned.[4]Situation become horrible, where enduring therapy needs to be provided to the patient at a lowest monetary saddle along with a nominal outskirt of fault as concerns control of disease processes.

Generic drug prescriptions may be a probable solution to this everlasting problem. Because, some economists in our country do expect that this single move can low drug prices and inflate access to inexpensive health resolutions even by the poor communities. Recently, in 2014, consistent with the latest National Sample Survey Office on healthcare, drugs arose as a most important module of entire health expenditure every day. For example, everyday health care expenditure is almost 72% and 68% in rural and urban areas respectively.[5] This report makes it clear that, for a country like India by means of one of the chief per capita disbursements on health, even a reticent fall in drug charges will free many people from the pervasive phenomenon of a "medical poverty trap". Generic drugs have established a fresh impulsion in India with the personal advocating on their wide use by the present Prime Minister, Sri Narendra Modi ji on April 17, 2017, during the inauguration function of a charitable hospital in Surat. The Prime Minister had recently proclaimed that prescription of drugs by their generic names will be compulsory in the country. This is because; the only-generics-policy will satisfy both social benefits as well as make some pecuniary sagacity. By endorsing generic drug use, the government will safe guard its generic drug industries, which is one of the prime providers of low-priced medications across the globe.

Considering the Indian pharmacy market scenario, we have here different categories of drugs such as innovator brands, branded generics, and unbranded generics or simply generics.[6,7] As far as the costs of these drugs are concerned the innovator brands are of high cost followed by branded generics and generics. Nevertheless, these drugs of different categories do vary in their price facts different of drugs are different, their efficacies are comparable.[8,9]Even though, there is not much difference in efficacy between the above categories of drugs and India being an international hub of generic drug manufacturing, the probable benefits of the cheapest drugs are not translating into real savings for ordinary people. Moreover the recent directive of MCI under code of medical ethics 1.5 which states "Every physician should as far as possible, prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of drugs" creates confusion between terms "generic drugs" and "generic names".[10] This is because of extended use of branded generics in our country. These drugs are marketed at a price point very close to the innovator brands with a brand name provided by the manufacturer, despite being generics and forbid the entry of unbranded generics into prescriptions due to issues of confidence and perception. This command now passes the responsibility of selecting the brand name of drug and manufacturer to the pharmacist. Commendable hypothetically, this guidance does not fit in the not so robust drug regulatory system of our country which is struggling to provide quality medicines from all manufacturers. Hence, it is important to understand the underlying concepts about branded, branded generics and unbranded generic medicines in Indian scenario. The present review article will investigate this subject in detail toper mitwell- versed choice making for the advantage of patients as well as the stakeholders equally.

The COVID-19 outbreak has appeared as an extraordinary worldwide health catastrophe. While the degree of its complications has not yet been recognized completely but it is obvious that it is going affect the international trade of drugs and pharmaceuticals presently as well as in future [1]. It has been predicted that the global pharmaceuticals distribution chain is to be intermittent, and further the low-and middle-income countries (LMICs) are going to experience tremendous

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consequences in terms of accessibility of essential medications. This article will also include discussions pertaining to the readiness of Indian pharma market to underwrite to the fight against COVID-19 through its enduring involvement in generics manufacturing and distribution of quality guaranteed medicines.

Naming a drug

To understand this article, one need to be very clear about the different names that a drug can be assigned with. A drug usually has three different type of names including chemical name, non-proprietary name, and proprietary name/brand name. In common verbiage, the word "generic name" is used in place of non-proprietary name. Etymologically this is not correct. This should be employed to the whole chemical or pharmacological group of compounds. Chemical name describes the compound chemically.[11] This is the name allotted when a new chemical entity (NCE) is developed. Such name is given to the drug in harmony with the rules and regulations of chemical nomenclature as recognized by IUPAC (International Union of Pure and Applied Chemistry). This name helps to understand the basic molecular information about the NCE and is mostly referred by chemists or other technical personnel associated with the study of drugs and pharmaceuticals. However, this name is not used to identify the drug in clinical prescriptions or marketing. The non-proprietary name given to a drug that is not subject to proprietary rights. This name should always be concise, attractive, and meaningful. Many a times this name is used in drug-based discussions and textbooks. Further, there are two categories of such names including approved names and official names. Approved name is given by bodies like United States Adopted Name Council (USAN) soon after the introduction of a drug. Official name is approved by the National Pharmacopeia Commission and included in the official book i.e. Pharmacopeia. This name is identical with approved name. This is the name provide by the manufacturing and marketing company of the drug. They are written with capital initial letter and are often further distinguished by superscript R in a circle. This is the name widely used by the clinician for prescribing in our country. This description can be made more richer with the following example of one of the most common drugs named PARACETAMOL. Considering Paracetamol, the chemical name is *N*-(4-hydroxyphenyl) acetamide. The non-proprietary name as per British Approved Name (BAN) is Paracetamol and United States Adopted Name (USAN) is Acetaminophen. The Official Name is Acetaminophen. We have got several brands such as Panadol, Calpol, Adol and many more for paracetamol.

Generic drugs vs Branded drugs

The evolution journey of every drug begins in a research laboratory and finally ends in are tail medical shop. The cost of each drug depends on the net expenditure made on the research and approval processes by the innovator company. Every newly launched drug is thus very expensive to begin with. The innovator company files for a patent to defend in opposition to other companies in manufacturing and marketing the same drug. At this point when the drug is newly discovered, the drug has two names: the original scientific/chemical name also known as generic name and a name provided by the manufacturer also known as brand/innovator name to make it stand out in the market. Generic drugs on the other hand have the same active ingredients as branded drugs, already approved by the Food and Drug Administration (FDA). The chief regulatory obligation for generic drug is accessible in Table 1.

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Table 1: The chief regulatory obligation for generic drug.

A Generic Drug Must have
Same active ingredients as the innovator drug
Same dosage form
Same conditions of use
Same strength
Same route of administration
Bioequivalence

According to the FDA, to substitute a generic for a brand name drug, firstly it should contain the same active ingredients. Secondly, it must have the same dosage strength (the amount of active ingredients, i.e. 20 mg or 40 mg). In addition to that, it must be available in the same dosage form (for example, as a liquid, pill, etc.). Also, it must have to be administered through the same route of administration (i.m, i.v, s.c, p.o.) as of the its branded kin. It must be bioequivalent (same rate and extent of absorption as the branded drugs.). [5, 10]There is a general misperception that generic drug concentrations can be 80% to 125% of the branded formulation.[12]In other words, the variance may be up to 45%, which is not true. This is because, one of the important parameters for bioequivalence is the area under the curve (AUC) of the plasma concentration of the drug vs time graph. The AUC of a generic formulation must be in between 80% to 125% of the branded formulation. Well, the 90% confidence interval of the AUC must also fall within the foresaid range and we all know that the confidence interval is a range within which we can be sure that the true result lies.[10,12] So, for the entire confidence interval to fall within the 80% to 125% range, the variance is generally less than 5%.[12]Still in many ways the generic and branded drugs may differ considerably from each other. Generics may contain different excipients or additives, and this might be the important reason of some patient showing allergy or sensitivity. Apart from that the generic drug product may vary in color, shape,or markings. And of course, the biggest difference lies in the cost as generics are generally less expensive than branded comparators.

How a generic version of a branded drug comes to the market?

In the 98th United States Congress, on September 24, 1984, the act termed "The Drug Price Competition and Patent Term Restoration Act" was passed. This act was established with the main objective to cheer the production of generic drugs by the pharmaceutical industry and form

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strict rules and regulations for generic prescriptions in United States.[13] As per this act, the requirement was an abbreviated new drug application (ANDA) to be projected by the drug manufacturing companies to the governing agencies for gaining the permission for making and selling a generic drug. This so called ANDA method, does not require the manufacturer to carry out repeat testing of generics in animals which is often time-consuming, as their branded versions have already been tested and approved for the safety and effectiveness. They are formulated when patent and other exclusivity rights of the innovator have expired.[14] Putting on an application for ANDA's in US, it is generally required that the application in the requisite format must be acquiesced underneath any of the specific sections and subsections of Federal act [505(j)] [15]. Well, US being one of the foremost export termini for Indian generics, it is highly significant to fulfill the US drug-regulations.[15,16]The ANDAs assessment procedure is most vital for developing generics. Figure 1 schematically represents the FDA and CDER (Center for Drug Evaluation and Research) assessments carried out for generic applicant.

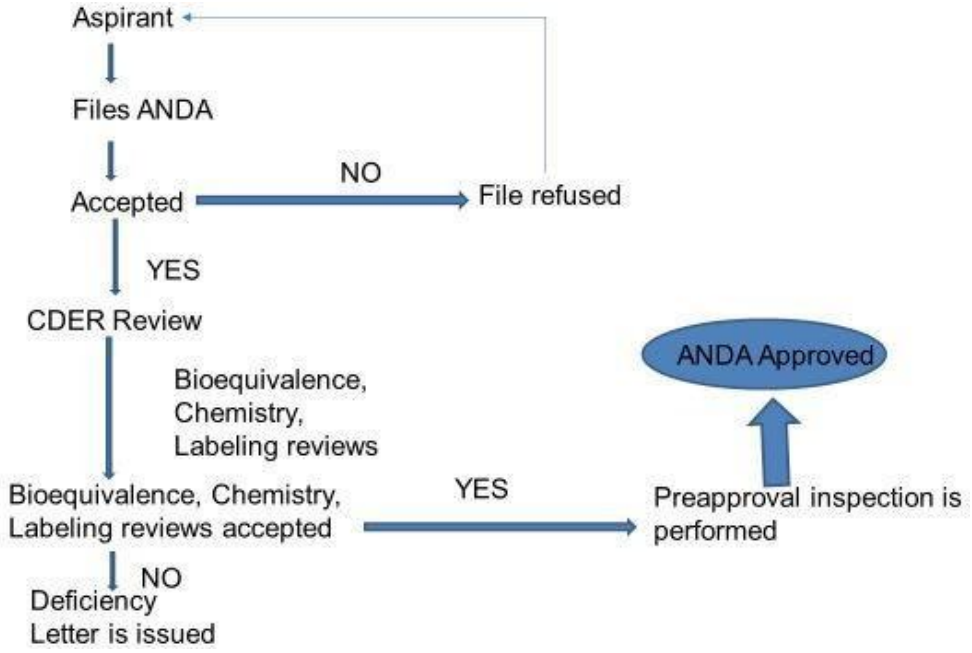

Figure 1: Assessments carried out for generic applicant

Hence, as discussed above, for generic drug manufacturers, employing additional coin age for drugdiscovery and preclinical and clinical trials is not obligatory. Hence, they are available at a lower cost and therefore, they can offer prospects for reserves in drug disbursement in a country like India to a greater extent. Some important drugs going off patent in 2021 have been tabulated in Table 2.

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Table 2: Examples of drugs losing their patent term in 2021.

Sl. No.	Official Name	Brand Name	Manufacturing Company	Indications	Patent expiry date
1	Lopinavir; Ritonavir	KALETRA	AbbVie Pharmaceuticals	HIV infection	2021
2	Ritonavir	NORVIR	Alkem Laboratories Limited	HIV infection	2021
3	Posaconazole	NOXAFIL	Activz Lifesciences India Private Limited	Fungal infections	2021
4	Varenicline Tartrate	CHANTIX	Pfizer	Stop smoking	2021
5	Formoterol Fumarate	PERFOROMIST	Mylan Inc.	Asthma, COPD, Exercise persuaded breathing difficulties	June 22, 2021
6	Sunitinib Malate	SUTENT	Pfizer	Cancer	August 16, 2021
7	Nebivolol Hydrochloride	BYSTOLIC	Allergan Sales, LLC, an AbbVie company	Hypertension	September 17, 2021

Source: https://www.corporatepharmacy.com/page/upcoming_generic_drugs

Definite dates may vary

But why branded generics rule pharmaceutical market in India?

India is one of the largest harbors of branded generics. As already discussed above, branded generics are molecular copy of an off-patent drug with a trade name. It's also true that, India didn't have any patent laws till 2005. So, generic versions of many drug molecules having patent protection in the other part of the world, were produced (by reverse engineering) and marketed in India till this year. Another fact is that, in India, the generic drug business includes the transactions value of generic drugs traded by both big pharma companies as well as Indian generic companies like Ranbaxy, Lupin and Sun Pharma and so on. The Competition Commission of India (CCI) recently pointed out that branded generics in India enjoy a price bonus due to recognized quality guarantee that comes with the brand name.[12] Hence, it can be somehow concluded that "Quality consideration" is a possible motive at the back of the prescription of branded generics by doctors. However, it is also uniformly feasible that the brand creation is to announce unnatural product distinction in the marketplace, proposing no healing difference but

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Permitting pharma companies to wrest leases.[17]The debate further continues as very often it's being argued by many companies that, even chemists and pharmacists encourage & sell, drugs which are affordable than that recommended by doctors. This very act facilitates to maintain a price edge and don't have to contribute to the incentives.

When healthcare in India is emanated, then many health care professionals do opine that it should not be a clash amid classy brands and economical generics in any way. Rather, it should be a drive for value medication for patrons deprived of bargaining on the predictable consequences and the Standard Treatment Guidelines (STG).[18]Though, at several circumstances, health policy spheres are recurrently blaming branded drugs for rising healthcare expenses, the urgings are usually measured insignificant due to in accessibility of strong proof substances. In fact, branded generics were presented with an idea for complex drugs to be accessible at reasonable prices. Although the government is encouraging the instance of nationwide use of only generics, the preparedness of our country India for this change is still questionable, because the way to unbranded generics is covered with intractable barriers.

The lack of specified worldwide standard drug monitoring mechanism discourages Indian medics from believing the efficacy of any generic drug with ease and in such situation, brands come into play. The clinician usually recommends a drug tag trusting a firm level of effectiveness and information obtained and shared within the practicing frat. Now, the question arises is that if not the physicians then will the Indian pharmacist decide a generic instead of a brand? Well, in answer to this question, most Indian pharmacists are ill-equipped to distribute and allot generics with accuracy. Need on generics without help would hand over the responsibility of choosing a drug from the medic to the chemist and could lead to undependable remedial practices where medications would be distributed with a revenue edge as the powerful force. Besides, in many chronic and critical cases (cancer, sepsis, asthma) a hasty swing from branded drugs to generics will add to both physician's and patient's predicament. If the so-called drug regulatory system of our country for quality checks is not made vigorous the idea of only generics will boomerang sooner or later. Figure 2 depicts the different drug regulatory apparatus in India. The drug samples in India are supervised both centrally and regionally, but inadequate resources lead to insufficient testing. Taking the example of Kerala, which is considered to have maximum drug consumption rate in India, in real had the lab accommodations and staff to test the quality of around 6,000 drug samples/year, the actual requirement being more than 3 lakh tests.[18]As a result of which many a times spurious low- quality medicines in the are being found in the Indian supply chain.[19] In India, we have an overabundance of companies manufacturing medications. These generally ranges from the uppermost excellence to the lowermost. Hence, on one hand, we have the apparent tags producing medications in GLP-controlled laboratories with skilled personnel. On the other hand, we have also got small industries where the production protocols of medicines are not followed properly. Without founded on the principle of eminence quality guarantee through internationally authorized strictures and bioequivalence tests, the generics-only decree remains an unsuccessful disaster.

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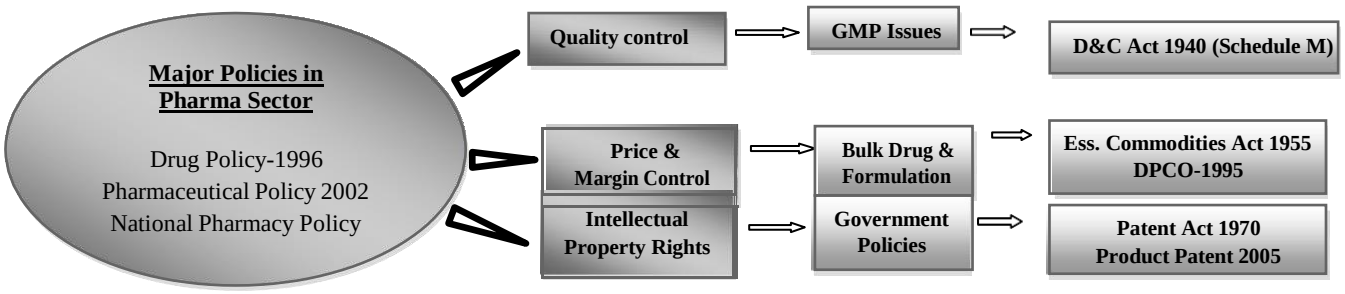

Figure 2 (A): Guidelines & controller in Pharma sector

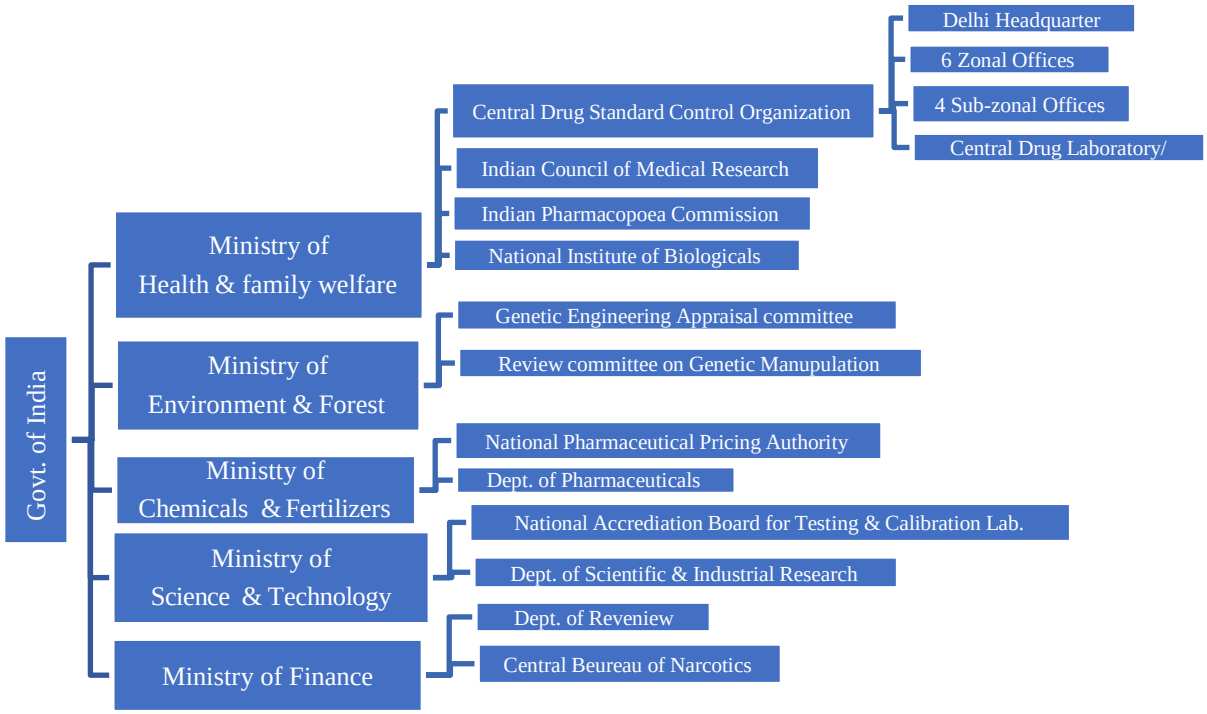

Figure 2 (B): Guidelines & controller in Pharma sector: **Genetic Engineering Appraisal Committee (GEAC) , Review Committee on Genetic Manipulation (RCGM), National Accreditation Board for Testing and Calibration Laboratories (NABL), Department of Scientific and Industrial Research (DSIR), Department of Pharmaceuticals (DoP), National Pharmaceutical Pricing Authority (NPPA), Department of Revenue (DoR), Central Bureau of Narcotics (CBN), Central Drugs Standard Control Organization(CDSCO), Indian Council of Medical Research (ICMR), Indian Pharmacopoeia Commission (IPC), National Institute of Biologicals (NIB), Central Drugs Laboratory (CDL), Central Drugs Testing Laboratory (CDTL)**

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What is the future of generic drug market in India?

The Indian pharmaceuticals market has got some unique topographies. As discussed earlier, branded generics rule the Indian pharma market, making up for 70 to 80 per cent of the trade market [20]. Even though, the country grades tenth universally in terms of value, it is graded third in terms of volumes. However, these features extant their peculiar chances and challenges. According to IBEF (Indian Brand Equity Foundation), pharmaceutical exports of India during 2012 to 2019 have gradually grownup from $10 billion to $19 billion.[20] Recently it was found that, India accounts almost 10% of world's pharmaceutical manufacture by volume and 1.5% by value. Indian drug industry is the world's chief provider of generic drugs and panelsabout18% of the internationalmarketplace.[21] The reason could be probably due to low-priced drug products that enable it to make these more inexpensive to both developing and developed countries. For example, recently according some treatment approximations for AIDS made by Doctors Without Borders a charitable organization, it was found that by means of generic Indian drugs the overall treatment expenses was 2-3 times cheaper equated to treatment by means of branded drugs.[20] Subsequently, UNICEF and UNITAID also rely to a greater extent on Indian generic drugs for their support-based agendas. Consequently, a much superior and bigger budding for India's generic drug area is there presently, to upsurge trade partners equally at regional level and worldwide. The government presently is also trying to encourage this by advancing R&D for drug and pharma research within India. Economists have predicted that, drug expenditure in India will raise 9-12 per cent over the next five years. Thus, India will become one of the top 10 countries in terms of medicine spending. Going frontward, improved progress in national rummage sale will greatly be contingent on the aptitude of drug manufacturing companies to make parallel their product range to long-lasting treatments for chronic diseases importantly including cardiovascular diseases, diabetes, depression and cancers that are on extreme intensification in the present context. The Indian government has been consistently trying to implement many steps timely to lessen costs and bring down healthcare overheads. Prompt introduction of generic drugs into the marketplace has persisted in emphasis and is anticipated to profit the Indian pharmaceutical companies. Besides, the push on rural healthcare programmee, essential/lifesaving drugs and vaccines also foretells glowing for most of the Indian pharmaceutical companies.

Indian generic market: The COVID-19 scenario

It has been already cited that generic drug manufacturing companies in India, adore a sturdy international place. However, drugs/vaccines that demonstrate to be beneficial for treatment of corona virus infections are expected to be questioned for patent arguments in India. The vital query arising in the present context is how Indian generic companies could successfully launch a drug/vaccine which proves to be effective in the treatment of COVID-19 deprived of an authorization from the patentee? Hence, in this epidemic, worldwide dependence on Indian generics is expected to turn out to be multifaceted. One of the possible reasons could be the skiving of reliable substitutes for active pharmaceutical ingredients supplies. Studies supports that 70% of their bulk drugs are imported from China by Indian pharmaceutical companies, and hence the making of active pharmaceutical ingredients and their supply chain have retained a giant knockout due to this outbreak [22]. In addition, the Govt. of India has restricted the export of 26 bulk drugs and their formulations [23], including antibiotics such as erythromycin, chloramphenicol, clindamycin, and some antiretroviral drugs such as acyclovir. This in turn account for almost 10% of all Indian exports yearly.[24] In other words the manufacturing ability,

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production volume and export latent of Indian generic market, are significantly affecting global pharmaceutical access by now. On the other hand, as this pandemic is still continuing to binge numerous countries across the globe, several collaborations, and agreements of market participants like Cipla, Merck, Gilead Sciences in pharmaceutical sooq have abetted in escalating their trade, by intensifying their product demand and up surging the forthcoming sales in nearby future. Market troupes have taken diverse ingenuities in the prevailing pandemic scenario to foster their business looking at the present customer demand and simultaneously preserving their social duties in this situation. For instance, Cipla being permitted by FDA for the manufacturing of albuterol sulfate inhalers, a drug being proved to avert the asthma-like symptoms in COVID-19 patients. It has disseminated almost 35,446 kg of albuterol to the United States during March 2020 [24]. Reports also revealed that, Mylan launched generic Remdesivir, a drug claimed to be useful in COVID-19 infection, in India during July 2020 at Rs. 4400/100 mg vial[24].These examples clarify that, growing demand and sales of generics drugs in the present context are fueling the development of generic drug market in future. The tactical pronouncements of the topmost pharma companies in India will offer noteworthy prospects for generic drug market contestants.

Conclusion

It's definite that, "Make in India" movement is routing in the exact route. It is extremely imperious to make dominance in healthcare, the benchmark in advance of any revolution. A two-cleft way can be trailed in this regard. Firstly, educating and endorsing retailer-pharmacists to a greater extent and secondly swelling the dimensions of prevailing drug testing laboratories. There is an urge for setting up well defined drug quality assurance system before hand to solve the problem of branded versus generic in India. The community segments of India, such as recently lunched "janaushadhi" scheme, multi-specialty hospitals and some NGOs should acquire drugs from pharmaceutical companies which estimate lowest price, which is no doubt the present practice. But along with this, a practice of auditing quality of each batch of medicines abounding and purchasing only quality drug products should be firmly trailed. The existing and forthcoming potential of generics in India and US is extremely optimistic as Indian government is beholding generic drugs for offering improved health care to public. Our pharmaceutical manufacturing industries grow rapidly all over the world and one of largest generic exporter in world whereas, US being the major destination for export. Thus, the proper validated regulation is required for manufacturing generic drugs in India and US which requires proper symbiotic relation between India and US. Hence, some amendments in the existing drug policies in the country and a little honest effort from the physicians, the pharmacist, the stake holders, and the consumer are warranted to switch to only generic prescriptions now.

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