IJFANS INTERNATIONAL JOURNAL OF FOOD AND NUTRITIONAL SCIENCES
ISSN PRINT 2319 1775 Online 2320 7876
 UGC CARE Listed (Group -I) Journal Volume 11, Iss 11, 2022

Generic Medicines, Cloud behind the Horizon

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Abstract: In many regions of the world, it is common practice to substitute generic prescription drugs for brand names, usually due to cost considerations. But generic replacement isn't a widely acknowledged technique in India. However, at the end of the day, the choice remains with the key stakeholders. The ultimate goal is affordable healthcare. The criteria for bioequivalence are to establish bioequivalence, the calculated 90% confidence interval for AUC and Cmax should fall within the bioequivalence range, usually 80-125%. The non-parametric 90% confidence interval of Tmax should lie within a clinically acceptable range. Chemically the generics should fall in the range of 90-110% of the brand drug. Government initiatives for promoting generic drugs prescription: MCI directives to prescribers to prescribe by generic names; Government directives regarding availability of generics at all government hospitals; Opening up of Jan Aushadi stores throughout country and Public private partnership for opening Jan Aushadi stores in remote areas with remunerations
Keywords: Clinic, Jan Aushadi, Generic, Healthcare, Medicine.

1. INTRODUCTION

Patients with chronic illnesses may find that using generic medications significantly lowers their out-of-pocket drug costs when compared to brand-name alternatives. In many regions of the world, it is common practice to substitute generic prescription drugs for brand names, usually due to cost considerations. But generic replacement isn't a widely acknowledged technique in India. This is caused by a number of things, such as the lack of generic formulations, practitioners' mistrust of generic medications because they believe them to be of lower quality, and drug counterfeiting. In institutional settings, however, where medications can be purchased in bulk and administered from the institutional inventory with the proper quality control procedures in place, the implementation of the generic prescribing policy is still ongoing. Since 2012, the Ministry of Health and Family Welfare, West Bengal, has been running a public-private partnership (PPP) "fair price medicine shop (FPMS)" program with the goal of encouraging generic prescriptions in public sector hospitals. Within the hospital grounds, the government supplies the physical space and equipment needed for the medical outlets, and on mutually agreed upon terms, the private partner handles the purchasing and dispensing of medications [1]–[5]. The products are provided at a significant savings over the suggested retail price. In addition to numerous additional things that are given under the guidance of regional FPMS monitoring committees, there is a list of items that must be kept in stock in order to provide hospital patients with them. Apart from this state-level endeavor, the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, has been operating special stores since 2008 called "Jan Aushadhi Stores" where inexpensive generic medications are offered. 157 "Jan Aushadhi Stores" have been established thus far in 12 Indian states, including West Bengal. Thanks to these activities, an increasing number of patients are becoming aware of the concept of generic drugs and are able to weigh the benefits and drawbacks of doing so against buying branded medications from the open market. Although they haven't been well studied, scientific data on consumer attitudes and experiences with generic

ISSN PRINT 2319 1775 Online 2320 7876
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pharmaceuticals are essential for maintaining a policy on their use. Unlike in India, reports on consumer views and preferences are primarily accessible from nations where substituting generic drugs in retail pharmacies is a common practice.

The two most worrying aspects of the global health care system are rising health care prices and high spending. The national sample survey organization has released its most recent data, which shows that 78% of healthcare spending comes from out-of-pocket expenses, of which 70–87 percent are related to medications. According to studies, the cost of medications varies greatly in India, and the impoverished cannot afford to buy medications. "A pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights" is the definition of a generic drug according to the World Health Organization. In economies where the goal is to reduce healthcare expenses and reallocate savings to other facilities, the promotion of generic medications is extremely advantageous. Generic medications are underutilized, despite the desire of numerous insurance companies and government organizations in both developed and developing nations to reap these advantages. Numerous studies that have been published in this area use quantitative questioner-based research designs to learn about the perspectives of stakeholders in healthcare setups, with a primary focus on patients. There aren't many qualitative studies accessible, but it's unknown how pharmacists and other experts in the pharmaceutical sector, who make up the other two stakeholders, see the situation[6]–[10]. The use of generic medications can be greatly increased if these characteristics of generic drugs are investigated and fixed in accordance with the needs of many stakeholders and healthcare practitioners. One of the top producers and suppliers of generic medications is India. Nonetheless, there is a paucity of data regarding generic drug availability, demand, and perception among various stakeholders from an Indian standpoint. Therefore, the goal of the current study is to recommend actions to improve the prescription, sale, and use of generic pharmaceuticals by the relevant stake holders. It does this by using qualitative methodologies with Indian stakeholders[1]–[5].

Generic medications have been crucial in keeping costs under control in the European Union (EU), where overburdened healthcare systems are dealing with increasing demands from an aging population. Currently, 92% of treatment volume in the area is provided by off-patent medications. Additionally, the cost of off-patent pharmaceuticals is 61% less than it was during market exclusivity due to competition from generic medications. In addition to saving payers an estimated €100 billion in 2014, this has helped patients in numerous nations and therapeutic areas have far greater access. But over the course of the next few years, there will be a significant decrease in the number of small molecule original brands losing their exclusive market position in Europe, along with the cost savings potential of generic medications and the increased competition they bring about. What part, therefore, will generic drugs play in maintaining EU health systems? The IMS Institute for Healthcare Informatics carried out study to measure the entire extent of generic medications' contributions and to comprehend current market developments in order to respond to that inquiry. The study's findings are presented below, along

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with their implications for different parties involved in the long-term health of the local healthcare system. The paper concludes by outlining a plan of action for legislators to support the potential contribution of the generic drug sector[11]–[13]. Since India has among of the highest out-of-pocket costs per person among all countries, these generics will save a significant amount of money that may be used to other medical concerns. The use of generic medications has grown dramatically in the last several years in every nation. The rules that govern the approval of generic drugs are largely the same worldwide, with very few exceptions in developing nations. In these regions, bioequivalence studies are not required in order to obtain approval for generic drugs, and the United States is the gold standard for regulation in this area. Jan Aushadhi, which translates directly to "Medicine for People" in Hindi, was a new project launched by the Indian government in 2008 under the Department of Pharmaceuticals. Under this concept, government-assisted retail stores would be set up to provide low-income citizens of the nation with high-quality, non-branded medications at a fair price. It has assumed responsibility for opening Jan Aushadhi outlets, which are pharmacies that, to the greatest extent feasible, solely sell generic name medications while also giving public sector pharmaceutical projects priority. 3200 Jan Aushadhi outlets were open and operating in over 33 states and union territories in India as of March 15, 2018. Compared to the almost 8 lakh retail pharmacies in existence, there are not nearly enough Jan Aushadhi stores—possibly 3200—and many rural areas remain neglected. In October 2016, the Medical Council of India amended the code of conduct for doctors and suggested that all doctors prescribe medications with readable generic names and make sure the prescription is logical and encourages the use of generic medications. The Indian government may eventually introduce legislation requiring physicians to write prescriptions for generic medications for their patients[14]–[17]. The generic medication market is expected to increase at a compound annual growth rate (CAGR) of 5.59 percent between 2021 and 2030, from its estimated $390.57 billion in 2020 to $574.63 billion by 2030, according to Precedence Research. The US Food and Drug Administration states that a generic medication is "created to be the same as an existing approved brand-name drug in dosage form, safety, strength, method of administration, quality, and performance characteristics." Cost reductions from using generic versions of a drug take time to materialize when the patent on the original product expires. Similar to branded drugs, generics must face competition in the market before prices can drop. Two to three years after losing exclusivity protection, generic drug prices usually drop by 60–70% in comparison to branded treatments[18]–[21]. Price stability requires ongoing market competition, even for very old, unpatented medications. In a study of more than a thousand generic drugs, price increases and a lack of competition were found to be related. Over a five-year period, pharmaceutical companies with monopolies experienced an average price increase of around fifty percent[22], [23]. In a different study, the cost of over 1400 Medicare Part D generic drugs increased by more than 100% in 300 cases between 2010 and 2015.

2. LITERATURE REVIEW

A four-pronged approach—Education, Engineering, Economics, and Enforcement—has been presented by Godman et al.[1] to encourage the use and advancement of generic drugs in Europe.

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This approach can be applied similarly in India. The four "Es" are as follows: (i) "Education": develop initiatives to change the way generic prescriptions are prescribed by providing educational resources; (ii) "Engineering": concentrate on organizational interventions to change agreements regarding the cost and supply of current medications in connection with disease management initiatives; (iii) "Economics": employ both positive and negative incentives to encourage doctors and patients to prescribe more generic drugs. (iv) "Enforcement": start enforcing laws or regulations, such as ones requiring pharmacists to abide by legislation requiring generic substitution. It is important to prepare well-designed survey research that specifically consider patients, community pharmacists, and physicians in order to derive a general picture of opinions toward the prescription of generic drugs.

Himmel et al.[2] surveyed German primary care patients regarding their opinions of using generic medications. Nearly one-third of the participants believed that the comparatively cheap generic medications were either completely different or of lower quality than branded medications. Patients who were over 60, had chronic illnesses, and/or had no formal education were more likely to hold this opinion. Patients in this study who were admitted to the public hospital had little resources both educationally and socioeconomically, but they nevertheless thought that the generic medications supplied by FPMS worked well. Patients experienced 10% or so side effects after taking both branded and generic medications, with no discernible difference. This is in contrast to the finding that, following the substitution of generic medications, 13% of German primary care patients experienced additional side effects. According to an American survey, roughly 10% of respondents thought generic medications would have more side effects than name-brand medications. In a different study, 85% of the Finnish patients said that switching to generics was not dangerous. In a recent poll done in Maharashtra, India, however, the results showed that, contrary to the worldwide picture, over 80% of participants thought that generics were relatively less safe to use than their branded equivalents. In the Brazilian study, 28.1% of participants overall thought that generic medications have more side effects than branded ones.

Idris Mohammed Idris et al.[3] said that for the purposes for which they are designed, generic medications are interchangeable and clinically identical. The use of generic medications is strongly advised everywhere due to its accessibility and affordability. Customers, however, have a bad attitude and view of generic medications since they believe they are of lower quality and are not as effective as branded medications. The purpose of this study was to evaluate the general perception of customers regarding generic medications and to evaluate paracetamol, a locally made generic medication, in vitro. Between October 26 and November 21, 2017, in Asmara, Eritrea, the National Drug Quality Control Laboratory conducted an in vitro quality control evaluation and an analytical and cross-sectional investigation in three hospitals of their choosing. A questionnaire and a check-list for documenting the quality control characteristics of paracetamol tablets were used in the systematic random sample strategy to gather data. The study comprised 403 respondents in total. Sixty-eight percent of the study participants were women. In general, nearly half of the respondents (49.1%) prefer locally produced paracetamol to that

which is imported. Sixty-five percent of the respondents did not think that more expensive medications were of higher quality. Good experience (62.1%) was the primary factor influencing consumers' preference for the local paracetamol (Azemol) pill over the imported one. Approximately 78.1 percent of the consumers also thought that medications made in other countries were of greater quality. At the multivariate level, preference for local paracetamol over brand-name versions was linked to educational backgrounds such as elementary (, 95% CI: 1.251, 14.035) and junior (, 95% CI: 1.146, 5.028). The local paracetamol's in vitro test satisfied all requirements for identification, weight variation, pharmacopeial, friability, disintegration, and dissolution tests. In conclusion, when local and brand-name paracetamol were compared, most customers thought the local product was of worse quality. The local paracetamol, however, was just as good as the brand-name equivalent, as the facts showed. Healthcare providers should inform patients about the benefits of generic medications in order to encourage their broad adoption.

Ricardo Arcaro et al.[4] said that in the US, generic medication was introduced in 1984. Since then, a large number of research on the attitudes and behaviors of consumers when buying generic medications have been carried out in numerous nations. It has been difficult to comprehend the variables that can affect attitude and purchase intention in this market. With the purpose of defining and refining promotional methods for the usage of these products, this study intends to give a mapping of the research on attitudes toward and intentions to purchase generic pharmaceuticals. We used the keywords "generic drug," "purchase intention," and "attitude" to search the Web of Science, Science Direct, Scopus, Lilacs, Pubmed Central, Springer, and Embase databases for papers pertaining to the theme with a time constraint of June 2020. The findings show that, despite publications in the top journals in the field attesting to its significance, this issue is relatively new. The research theme could be divided into three clusters, according to analysis that produced five strategic insights: (i) consumer attitude and behavior; (ii) patient and healthcare professional perspective; and (iii) assessment of the risks associated with generic medications to determine which factors can influence purchase intention. This gives decision-makers a wider perspective when it comes to guiding public policy strategies in the healthcare industry.

Praveen Kumar Aivalli et al.[5] said that a well-functioning health system must guarantee equal access to necessary pharmaceuticals, immunizations, and technologies with guaranteed quality, safety, and efficacy as well as their scientifically sound and economically viable use. India has been described as the low- and middle-income world's pharmacy. In terms of the amount of medications exported, India has the third-largest pharmaceutical sector in the world. Unfortunately, a number of necessary medications are still out of reach in India, particularly for the underprivileged, as a result of inadequate policy and implementation. In the private sector, fees for services are often paid at the time of service delivery through out-of-pocket (OOP) payments. The current insurance schemes exhibit fragmentation in terms of the population segments covered and the services offered. Similarly, conditional cash transfers and strategic purchasing are restricted to targeted services such as immunizations, maternal and child health

ISSN PRINT 2319 1775 Online 2320 7876
 UGC CARE Listed (Group -I) Journal Volume 11, Iss 11, 2022

services for underprivileged and vulnerable populations, and certain secondary and tertiary conditions. Generally speaking, prescription drug costs are not reimbursed. Pharmaceuticals are an essential component of the health system and enhance population and individual health and well-being. Unaddressed negative impressions that lack empirical support can have a detrimental impact on the use of health services, especially in the public sector.

3. METHODOLOGY

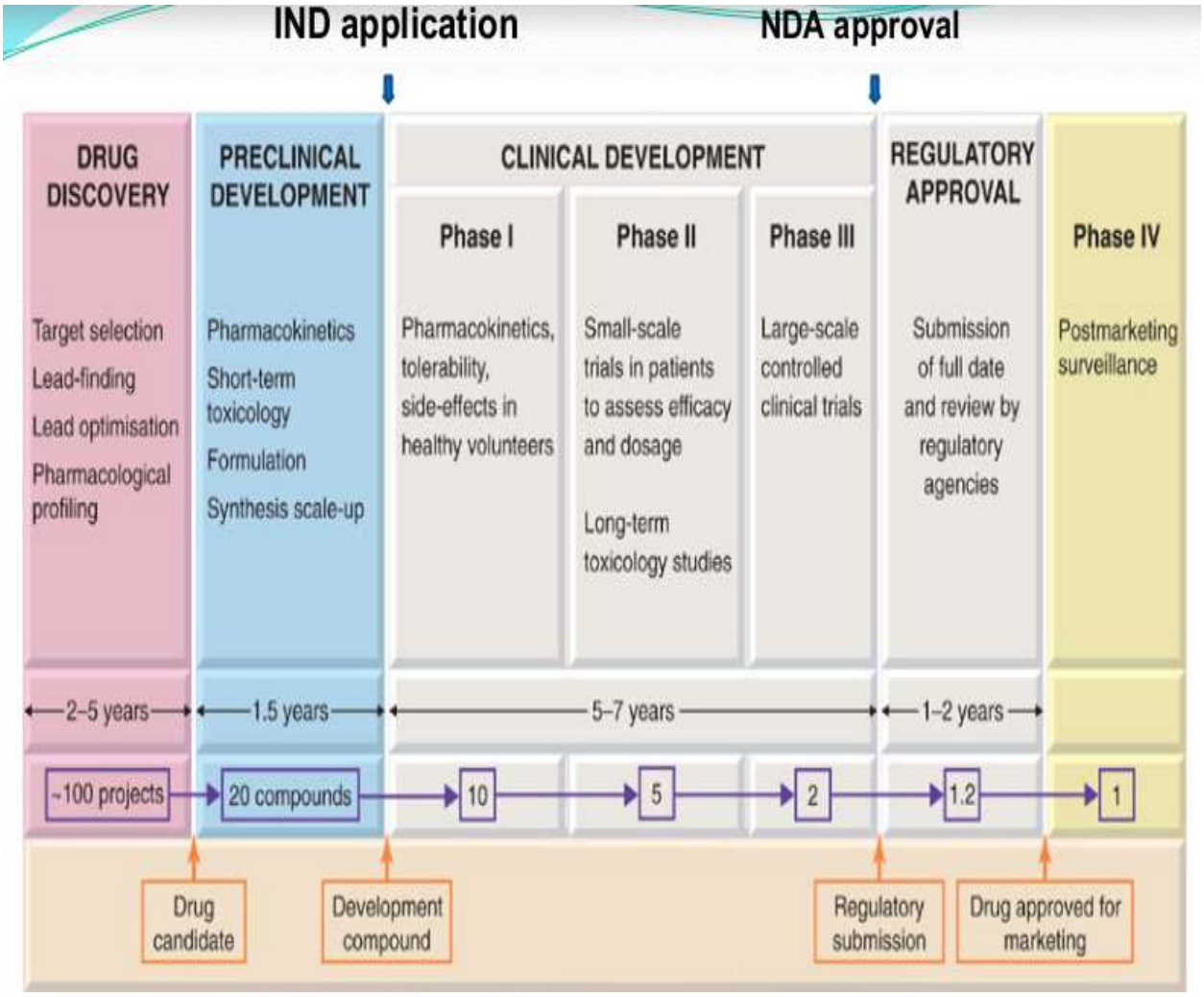

Fig 1 shows IND application and NDA approval

Reason behind the high pricing of the new drugs

- Pharmaceutical companies invest loads of money more than actual cost of the drug
- Total cost rounds up to 2.6 billion USD
- Many molecules fail the trials and can't be brought to market
- Drug enjoys exclusivity of few years for the cost recovery before generics hit the market

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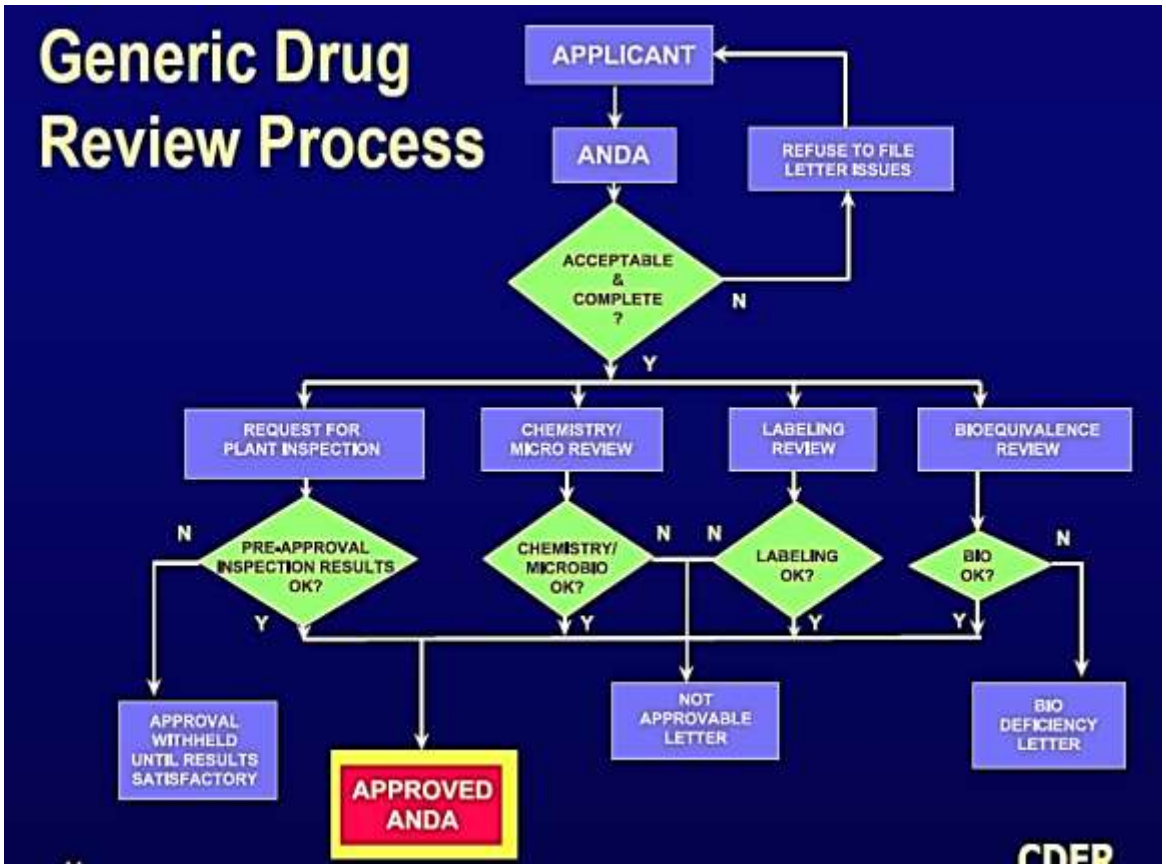

Fig 2 shows generic drug review process

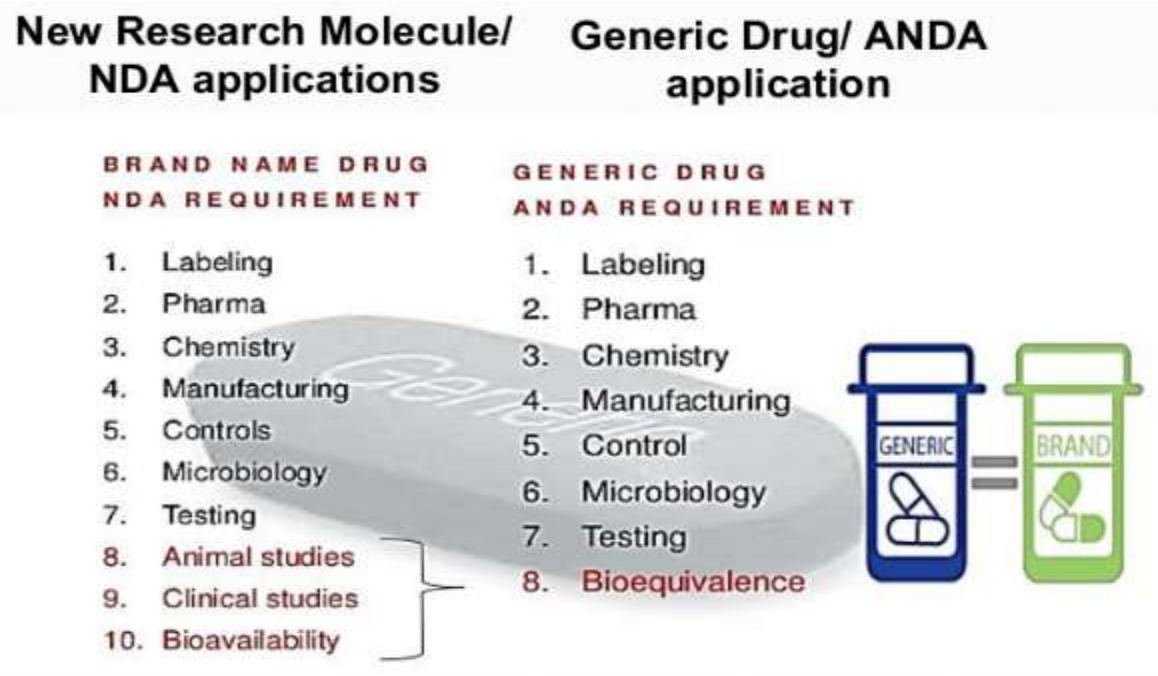

Fig 3 shows common technical document

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4. RESULTS AND DISCUSSION

Bioequivalence of a drug product is said to be achieved if its extent & rate of absorption are not statistically different from those of the reference product when administered at the same molar dose.

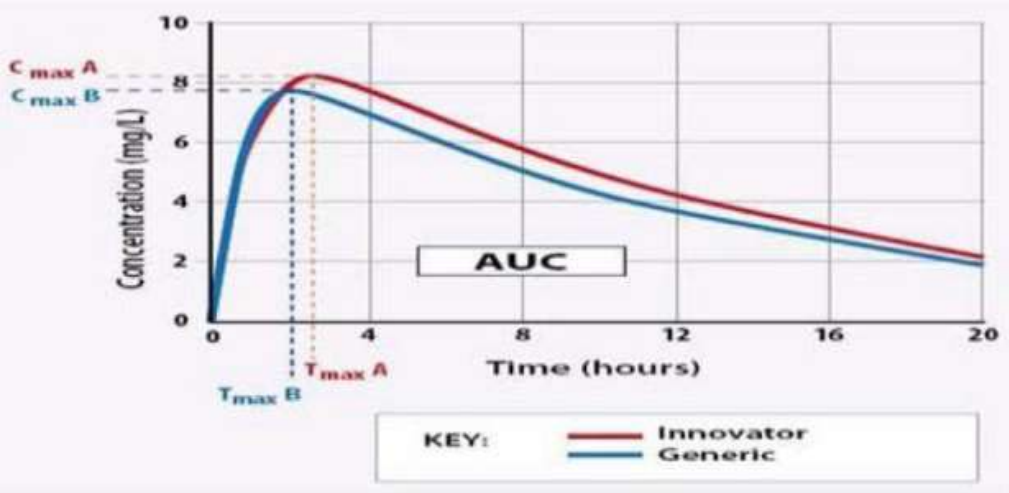

Fig 4 shows model graph of comparison between innovator and generic products

The criteria for bioequivalence is to establish bioequivalence, the calculated 90% confidence interval for AUC and Cmax should fall within the bioequivalence range, usually 80-125%. The non-parametric 90% confidence interval of Tmax should lie within a clinically acceptable range. Chemically the generics should fall in the range of 90-110% of the brand drug.

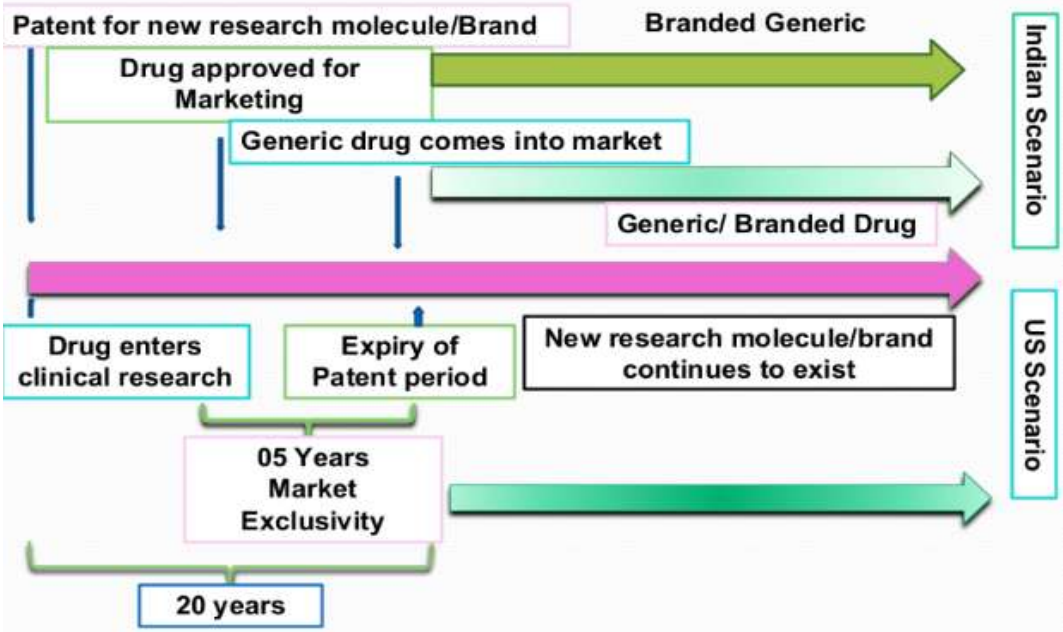

Fig 5 shows Indian drug scenario

5. CONCLUSION

Bioequivalence of a drug product is said to be achieved if its extent & rate of absorption are not statistically different from those of the reference product when administered at the same molar

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 UGC CARE Listed (Group -I) Journal Volume 11, Iss 11, 2022

dose. To establish bioequivalence, the calculated 90% confidence interval for AUC and Cmax should fall within the bioequivalence range, usually 80-125%. The non-parametric 90% confidence interval of Tmax should lie within a clinically acceptable range. Chemically the generics should fall in the range of 90-110% of the brand drug. It has been found that there have been multiple differences between branded vs branded generics as shown in Table 1 given below.

Table 1 depicts branded vs branded generics

Branded	Branded Generics
Produced by well known pharmaceutical companies in GMP certified facility	Produced by same companies in GMP certified facility
More expenditure on marketing and promotion	No expenditures on marketing and promotion
Costlier due to money spent on drug promotion	Cheap
No compromise on quality	No compromise on quality
Quality of excipients and fillers may be better	May have different excipients and fillers than original brand

Table 2 indicates the comparison of branded and branded generics

Pharmacological name, strength & dosage form	Manufacturer	Trade name	PTR (1X10)	MRP (1X10)
Cetrizine HCL 10 mg tab	Cipla	Alerid Tablet (B)	INR 27.16	INR 35.31
		Cetcip Tablet (B/G)	INR 2.24	INR 25.00
Fluoxetine HCL 20 mg/cap	Cadila	Fludac Capsules (B)	INR 29.80	INR 37.26
		Cadflo Capsules (B/G)	INR 6.00	INR 28.00
Ciprofloxacin 500 mg/ tab	Cadila	Ciprobid Tablets (B)	INR 54.84	INR 68.56
		Ciprodac Tablets (B/G)	INR 15.00	INR 68.56
Lansoprazole 30 mg/cap	Cipla	Lanzol -30 capsules (B)	INR 42.36	INR 53.77
		Lansec-30 capsules (B/G)	INR 15.68	INR 47.25

Branded medicine (B) Branded- generic medicine (B/G), Price to the retailer (PTR), Maximum Retail Price (MRP)

However, at the end of the day, the choice remains with the key stakeholders. The ultimate goal is affordable healthcare. Government initiatives for promoting generic drugs prescription: MCI directives to prescribers to prescribe by generic names; Government directives regarding availability of generics at all government hospitals; Opening up of Jan Aushadi stores throughout country and Public private partnership for opening Jan Aushadi stores in remote areas with remunerations.

References:

[1] Brian Godman, "Policies to Enhance Prescribing Efficiency in Europe: Findings and Future Implications," 2011, [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3153015/

[2] W. Himmel, "What do primary care patients think about generic drugs?," 2005, doi: 10.5414/cpp43472.

[3] I. M. Idris, "Consumers' Perception of Generic Medicines and Evaluation of In Vitro Quality Control Parameters of Locally Manufactured Paracetamol Tablets in Asmara, Eritrea: A Cross-Sectional Study," 2021, doi: https://doi.org/10.1155/2021/6642826.

[4] Ricardo Arcaro, "Attitude and Purchase Intention to Generic Drugs," 2021, doi: https://doi.org/10.3390/ijerph18094579.

[5] Praveen Kumar Aivalli, "Perceptions of the quality of generic medicines: implications for trust in public services within the local health system in Tumkur, India", [Online]. Available: https://gh.bmj.com/content/2/Suppl_3/e000644

[6] R. Shrestha *et al.*, "Generic Medicine and Generic Prescribing in Nepal: An Implication for Policymakers," *Journal of Multidisciplinary Healthcare*. 2022. doi: 10.2147/JMDH.S348282.

[7] M. A. Hassali *et al.*, "The experiences of implementing generic medicine policy in eight countries: A review and recommendations for a successful promotion of generic medicine use," *Saudi Pharmaceutical Journal*. 2014. doi: 10.1016/j.jsps.2013.12.017.

[8] J. Qu *et al.*, "A nationwide survey exploring physicians' and pharmacists' knowledge, awareness and perceptions regarding generic medicines in China," *BMC Health Serv. Res.*, 2022, doi: 10.1186/s12913-022-08438-9.

[9] A. O'Leary *et al.*, "Generic medicines and generic substitution: Contrasting perspectives of stakeholders in Ireland," *BMC Res. Notes*, 2015, doi: 10.1186/s13104-015-1764-x.

[10] N. Sammut Bartolo *et al.*, "Public perception of generic medicines in Malta," *J. Pharm. Heal. Serv. Res.*, 2020, doi: 10.1111/jphs.12366.

[11] S. S. Dunne and C. P. Dunne, "What do people really think of generic medicines? A systematic review and critical appraisal of literature on stakeholder perceptions of generic drugs," *BMC Med.*, 2015, doi: 10.1186/s12916-015-0415-3.

[12] S. Mostafa, M. A. Mohammad, and J. Ebrahim, "Policies and Practices Catalyzing the Use of Generic Medicines: A Systematic Search and Review," *Ethiopian journal of health sciences*. 2021. doi: 10.4314/ejhs.v31i1.19.

[13] D. Flood, I. Mathieu, A. Chary, P. García, and P. Rohloff, "Perceptions and utilization of generic medicines in Guatemala: a mixed-methods study with physicians and pharmacy staff," *BMC Health Serv. Res.*, 2017, doi: 10.1186/s12913-017-1991-z.

[14] P. Dylst and S. Simoens, "Generic medicine pricing policies in Europe: Current status and impact," *Pharmaceuticals*. 2010. doi: 10.3390/ph3030471.

[15] Shweta, D. Kumar, and D. Chandra, "A hybrid framework to model resilience in the generic medicine supply chain of MSMEs," *Benchmarking*, 2023, doi: 10.1108/BIJ-11-2021-0697.

[16] F. El-Dahiyat and R. Kayyali, "Evaluating patients' perceptions regarding generic medicines in Jordan," *J. Pharm. Policy Pract.*, 2013, doi: 10.1186/2052-3211-6-3.

[17] N. Y. Shraim *et al.*, "Knowledge, attitudes and practices of community pharmacists on generic medicines in Palestine: A cross-sectional study," *BMC Health Serv. Res.*, 2017, doi: 10.1186/s12913-017-2813-z.

[18] S. A. Ghosn, M. D. Ali, Z. A. Alzaher, and A. Ahmad, "Final year pharmacy students7 knowledge and perceptions towards generic medicines: A survey-based pilot study from Eastern province, Saudi Arabia," *Pharm. Educ.*, 2022, doi: 10.46542/pe.2022.221.221225.

[19] H. I. Duh and C. Diniso, "Generic medicine brand knowledge structure, relationships and purchase," *Int. J. Pharm. Healthc. Mark.*, 2020, doi: 10.1108/IJPHM-10-2018-0054.

[20] P. Rana and V. Roy, "Generic medicines: Issues and relevance for global health," *Fundamental and Clinical Pharmacology*. 2015. doi: 10.1111/fcp.12155.

[21] D. S. Kim, J. Shin, and J. Chung, "Analysis of the Korean generic medicine market: Factors affecting the market share of generic medicines," *Clin. Transl. Sci.*, 2022, doi: 10.1111/cts.13161.

[22] M. Kleinstäuber, S. Colgan, and K. J. Petrie, "Changing understanding, perceptions, pain relief of and preference for

ISSN PRINT 2319 1775 Online 2320 7876
 UGC CARE Listed (Group -I) Journal Volume 11, Iss 11, 2022

generic medicines with patient education: An experimental intervention study," *Res. Soc. Adm. Pharm.*, 2021, doi: 10.1016/j.sapharm.2020.09.014.

[23] A. Auta, E. T. Bala, and D. Shalkur, "Generic medicine substitution: A cross-sectional survey of the perception of pharmacists in north-central, Nigeria," *Med. Princ. Pract.*, 2013, doi: 10.1159/000355473.