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Comparative Review On Innovator And Genericpharmaceuticals

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ABSTRACT
Genericdrugdevelopmentinthepharmaceuticaltradeisascientificandtechnological approach that is completely different from the development of reference orbreakthrough products. Breakthrough medicines are the first medicines with specific activeingredients approved for use. These are generally products whose efficacy, safety and dosagehave been completely recognized. A generic medicines are those whose novel patent has diedand may be produced by a manufacturer exceptmain innovator (patent holder). Since theinnovationanddevelopmentofreferenceproductsrequiressignificantinvestment,mostdevelopingcountriesfocusonthedevelopmentofgenericdrugs.Currently,thepharmaceuticalindustry focuses on developing generic products because it requires less time and money thaninnovators.(1)
Generic drugs are just as effective as brand-name drugs. The Indian Government andMedical Council's initiative to require clinicians to suggest generic drugs has raised manyconcernsabouttheavailabilityandqualityofgenericdrugs.Indiaisamajorsupplierofgenericdrugs to the United States. Pharmaceutical companies should stop promoting their own brandnamedrugsasishappeningintheUS.Governmentsshouldmakegenericdrugsmoreaccessible, strengthen quality control and educate doctors about the benefits of using genericdrugs.(2) In these review we tried to differentiate Innovator and Generics products with allaspects.
KEYWORDS-
Innovator,NDAApprovalprocess,Generics,,Generic drugs,Difference, Generics onpositiveside

I. INTRODUCTION

India is the world's 4th largest pharmaceutical company and 10th largest exporter.Despite the government's health care budget, a large part of India's population does not haveaccess to the most essential medicines. The production and use of generic drugs has increasedfrom49% ofthe global pharmaceutical market in2000 to 78% in 2010.(3)

Timely and effective usage of medications can provide effective treatment for manydiseases and can prevent or delay patients' need for expensive hospitalization. Generics caneffectively treat many diseases today, and their use can significantly reduce healthcare andpatient costs. Analogues are considered safe and economical. (4)
Generic Drug: In AccordancewithFDA, a generic medication is “a medication that is similar to a brand-name product indosage form, direction of use, standards and performance, characteristics and purpose.
Thegenericmedicinesaresimilartothebrandedmedicines.Brand-namedrug:Anoriginalproductmade by a pharmaceutical company. It has exclusive rights for production and distribution(patent) for a certain period of time. Branded drugs are small drugs developed and marketedbypharmaceutical companies.(5)

Innovator

Innovatormedicines are the first medicines with specific active ingredients approved for use.Thesearegenerallyproductswhoseefficacy,safety anddosagehavebeencompletelyrecognized. When a innovative drug is first developed, the patent for the drug is usuallyobtainedbythestart-upcompany.Manypharmaceuticalpatentsareprotecteddupandabout20years. During the patent period, only the Innovator company can manufacture or sell the drug.However,othercompaniescannot sellthe drug tillthepatent expires.(6)

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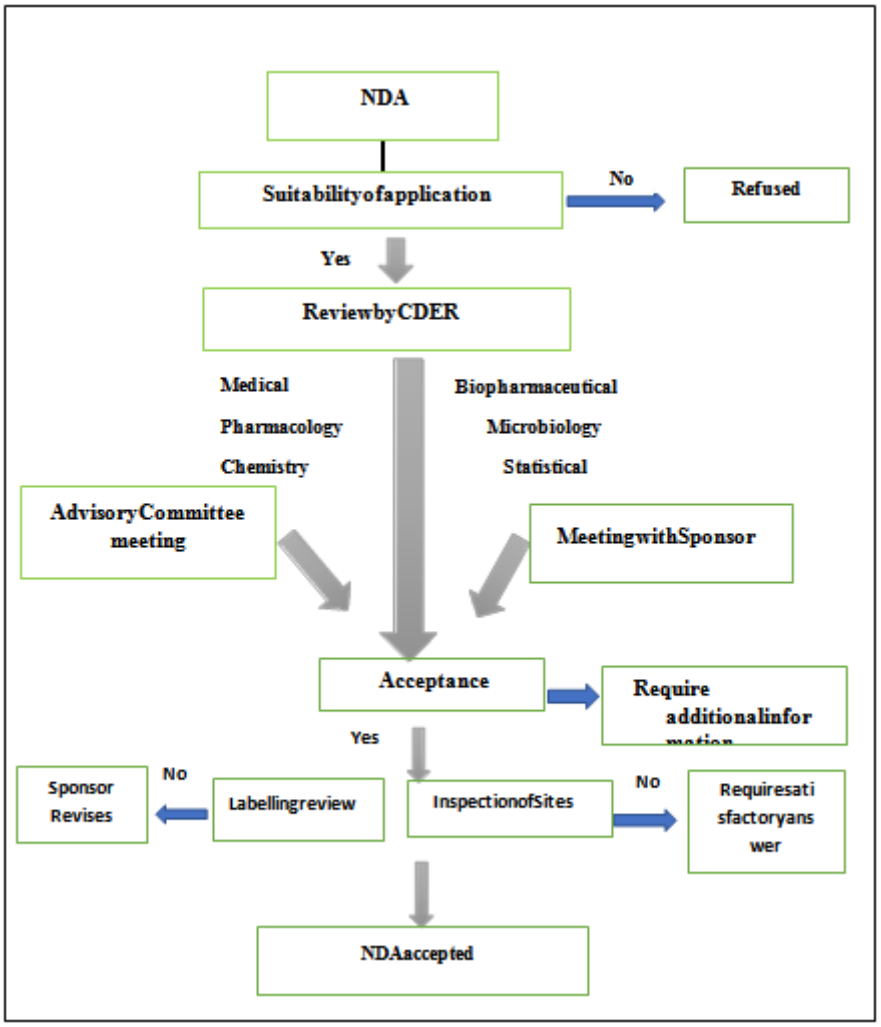
NDAApprovalProcess(7)



Concept of Generics

Agenericmedicinesarethemedicineswhichareproducedbythemanufactureraftherpatenton the Innovator medicines has been expired other than the patent holder .WHO defines theGenericmedicines:

- Generallyintendedtobereplacedbyinnovativeproducts.

- issuedwithoutthelicensefromthe innovative company.(8)

Most covered drugs are offered as off-patent generics, often at a lower price than theinnovator's brand-name products. The superiority of medications available on the market ispoorinmanydevelopingcountries.Therearenoclear andspecificrequirementsformedicinesgenericvaried in medicine .(9)

GenericDrugs–

WhatareGenericMedicines?

A Generic medicinescontainssameactivepharmaceutical ingredient as its innovator drug.An active ingredient is the chemical contained inside a drug that makes it work it work. TheGeneric drug is having same pharmacological effect as its innovator drugs. Whenthe patentisexpiredontheinnovatordrugsthentheothercompaniescanmanufacturesthegenericdrugs. (6)

Statusofgenericmedications inAseancountries:

A. SoutheastAsia,whichisgrowingrapidly,has alargeyoungpopulationandislargelyuninsured,prese

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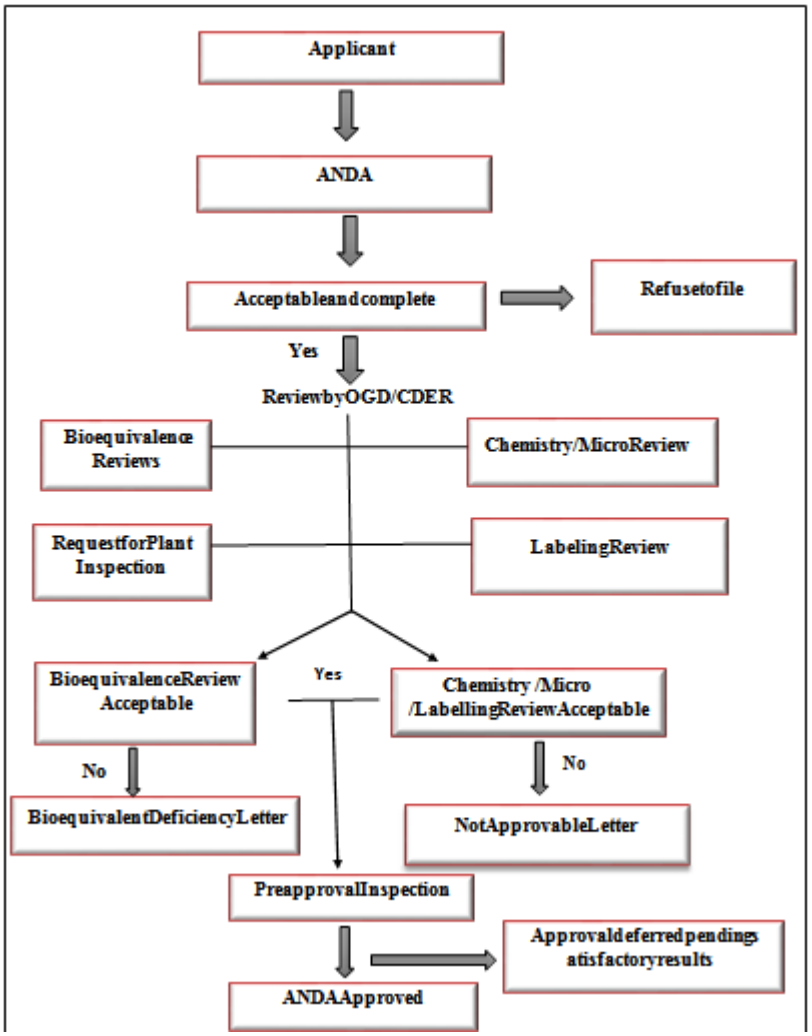
ntsgreatopportunitiesforgenericdrugsinthepharmaceuticalmanufacturing.

B. Thisfactisexpectedtoincreasecompetitionandattractmultinationalpharmaceuticalcompaniestotheregion..[10]

Genericdrugreviewprocess[11]



DifferenceBetweenGenericNamesMedicinesandBrandNameMedicines

The generic termis the official medical name of the drug's active ingredient. Genericdrugsare20%to80%cheaperthanoriginalbrand-namedrugs.Genericmedicinesareauthorizedbynationaldrugauthoritiesandmustundergorigoroustestingbeforebeingmarketed.Genericmedicine is good forpatients.[12]

SrNo	Parameters	InnovatorDrug	GenericDrug
1.	Activeingredients	Same	Same
2.	Safetyandefficacy	Same	Same

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3.	QualityandStrength	Same	Same
4.	Performanceandstandards	Same	Same
5.	Costs	Highcost	Lowcost
6.	Inspectionofmanufacturingfacilities	Yes	Yes
7.	Reviewreportsof adversereactions	Yes	Yes
8.	Reviewondruglabelling	Yes	Yes

Genericsonpositiveside:

- **Safetyandefficacy**
- **Cost**:Generic drugs are 30-60% cheaper than brand-name drugs, and the widespreaduse of generic drugs can create competition, which can lower the price of other brand-namedrugs. Patientstaking a genericdrugare readyto remaintreatment than patients taking a brand-name drug. Low co-payments is a major factor. In a recentstudy of people with hypocholesterolemia or diabetes, people who took the genericdrughad betteradherencethan thosewhotook the brand-namedrug.

- **Quality**:

MostofGenericDrugsareproducedunderthe licensefromtheInnovatordrugmanufacturers, and cheaper alternatives often become available after the drug's patentexpires. Different manufacturers produce brand-name and generic drugs, but there arestrictstandards to ensure thequality of genericdrugs.[13]

II. CONCLUSION

The review looked at comparisons between brand name drugswithgeneric medications.Prescriptiondrugsaremostlybrand-namedrugsbecauseoftheirquality,safety,andeffectiveness, but generic drugs are just as safe and effective as brand-name drugs. And theyarecheaper than brand name drugs.

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