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A BRIEF STUDY BETWEEN INNOVATOR DRUGS AND BRANDED DRUGS: A REVIEW

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ABSTRACT:

While a new drug is located, the company that discovered it would practice for patency to save you different companies from generating and promoting the drug. This patency may additionally soak up to twenty years and for the duration of this period, the company will produce and sell the drug below a logo call to get better its funding and make some earnings. But after the patency expires, other companies are allowed to produce a similar drug. It is what gave rise to brand and generic name in drugs. This articles gives a brief explanation on innovator and Generic drugs and steps involved during Generic drug development process.

KEY WORDS: Innovator drugs, Generic drugs, Branded drugs, BMR

Innovator/Branded Drugs

An innovator drug is the first tablets created containing its precise lively element to get hold of acclaim for use. It is usually the product for which efficacy, protection and quality were absolutely hooked up. Whilst a new drug is first made, drug patent typically might be obtained by the founding corporation. Maximum drug patents are protected up to 20 years. In the course of the patent duration, other groups can't make or sell the equal drug until the patent expires.

Generic Drugs

A well-known drug is made of the identical energetic factor as its innovator drug. An energetic component is the chemical contained inside a drug that makes it work. In different phrases, the pharmacological effect of a normal drug is precisely similar to those of its innovator counterpart. Other companies can manufacture the generic drugs when patent expires [2].

Examples of brand name and generic drugs can be cited with following diabetes and hypertension drugs. Metformin is a generic drug for diabetes, but its brand name is Glucophage. Similarly,

Metoprolol is a generic drug for hypertension but its brand name is Lopressor. These drugs will be known by different names in different countries, but the generic name remain constant [1].

DIFFERENCE

The difference among brand call and common tablets is inside the situations of manufacturing the medication. While logo name drug refers to the call giving through the manufacturing organization, established drug refers to a drug produced after the energetic factor of the emblem call drug.

INNOVATOR/BRANDED DRUG	GENERIC DRUG
Same Active Ingredient	Same Active Ingredient
High price compared to Generic	Low price compared to Branded drug
Inactive ingredients are approved by FDA	Inactive ingredients may differ but proven to be approved by FDA
No difference in Strength and Dosage	No difference in Strength and Dosage
The appearance of Drug size, color, shape and packing are same any where	Packing and the Drug itself may look different
Marketed under Brand name of company	Produce by Generic companies
Protected by a Patent	After Patent rights they are produced at low cost

Table 1: Differences between Branded and Generics

Myths of Generic Drugs

Some myths that are often associated with generic drugs:

- ✓ Generic drugs are not as safe as innovators.
- ✓ Generics drugs are not as effectives as innovator
- ✓ Generics drugs take longer time to act in the body.

Generic drugs use the same active ingredients as innovator drugs and work the same way. So they have the same risks and benefits as the innovator drugs. Generic drugs may look different because of certain inactive ingredients, such as colors and flavorings agents, may be different. These ingredients do not affect the safety, effectiveness or performance of the generic drug.

So, there's no truth in the myths that generic drugs are inferior in quality as compared to innovator drugs.

Generic Drug Issues

Innovator pills are greater pricey due to the fact the business enterprise who first manufactures the drug spends massive quantity of cash in lookup to increase the new drug which consists

of medical trials, advertising and merchandising of the drugs. Generics tablets are less expensive as their manufactures are no longer required to reveal their efficacy and protection via scientific trials as these have additionally been installed via the innovators. However, generics pills nonetheless want to conform to equal preferred of quality, protection and efficacy required of the innovators. In addition, when the patent of a drug expired, there will be extra business enterprise produce widely wide-spread tablets which create opposition and might also decrease the fee of a drug.

CONCEPT OF GENERICS

- ✓ Time and again the importance of generic prescribing has been emphasized, primarily to reduce the cost of drugs.
- ✓ There are two concepts to be under- stood here, one is generic vs. patented drugs and the other is a drug's "brand name" vs. "non-proprietary name" or "generic name."
- ✓ Non-proprietary name is the name for the active ingredient in the medicine that is decided by an expert committee and is understood internationally. Thus, paracetamol/acetaminophen is the non- proprietary name (generic name) while Crocin/Metacin/Meftal/Tylenol etc. are brand names [3].
- ✓ It is a well-known fact that generic drugs are "drugs that are 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" [4].
- ✓ Bioequivalence is a sine qua non to generic drugs. Good quality bioequivalence studies will help to ensure safety, efficacy, and potency of a generic drug.
- ✓ When it is said that doctors should prescribe generic drugs, it means that they should prescribe drugs manufactured by other companies after expiry of patent of parent drug of the innovator company.
- ✓ Very often, generic prescribing is misconceived as prescribing by a drug's generic name or non-proprietary name.
- ✓ All generic drugs have a brand name as well as a non- proprietary name but all drugs having a non-proprietary name (generic name) may not be generic drugs.

GENERIC DRUG PRODUCT DEVELOPMENT

Generic products are the pharmaceutical equivalent of innovator product where active ingredients are present in same proportion, in the same dosage form and given in the same route of administration.

- ✓ Generic product is identical regarding biological activity where potential bio-involution problems are not present.
- ✓ They are approved as safe, effective and have enough labels [5].
- ✓ They meet the same requirements for identity, strength, purity, and quality.
- ✓ They are made to the same exacting quality as innovator products, as defined by the FDA's good manufacturing practice rules [6].

A) DEVELOPMENT STRATERGIES:

Generic medication makers, on the other hand, must show that their formulation is bioequivalent to the brand-name equivalent in terms of quality and performance [7].

B) REFER THE PATENTS:

Before selecting the generic product to be developed the industries should consider the patent status and market share for sure [8].

C) REFERENCE LISTED DRUG (RLD):

After having the RLD in pharmaceutical industries, the lab carries all the in-vitro tests, especially assay, dissolution of related substance [9].

D) TARGET MARKET SELECTION:

Target market selection determines and decides the way the company will develop the generic product, how to analyze the reference and generic product, the way stability test will be conducted, the way of selection of the batch size and so many variables [10].

E) MANUFACTURING FACILITY:

To register a generic product for US, EU or other countries, the manufacturer must have GMP or MHRA approved facility to manufacture the drug, to proceed stability test and for bulk manufacturing as well. Then the auditor will visit the plant as well before shipment and prior to dossier and other paper submission [11].

F) PRE-FORMULATION STUDY:

In preformulation study, drug-excipient compatibility has to be determined because it affect the final dosage form and stability of the drug and can modify the pharmacological effect as well "Pre-formulation" work must be reviewed prior to preparing actual trial formulations to achieve as much information related to the drug substance & reference product as possible [12].

G) SELECTION OF EXCIPIENT: There are some basic requirements of pharmaceutical excipients:

- ✓ Chemically inert
- ✓ Cheap and available
- ✓ Exert the desired response for which they are used

H) SELECTION OF MANUFACTURING METHOD:

The scale-up plan must take into account the manufacturing technique used in smaller batch manufacturing, and the equipment employed in the development process frequently imposes many limits during scale-up operations.

For example, in the production of solid dosage forms, the following pharmaceutical unit procedures are used:

- ✓ Wet granulation

- ✓ Compression
- ✓ Extrusion
- ✓ Drying
- ✓ Dry blending
- ✓ Roller compaction
- ✓ Encapsulation
- ✓ Coating [13].

I) ANALYTICAL METHOD DEVELOPMENT:

Quality of the procedure itself

- ✓ Accuracy
- ✓ Precision
- ✓ Specificity
- ✓ Limit of Detection
- ✓ Quantitation Limit
- ✓ Robustness

J) SUBMISSION BATCHES:

Batch manufacturing record, Batch size, Process validation batches, Validation master plan will be the key for manufacturing process.

The following should be included in a validation master plan:

- ✓ Sampling plan
- ✓ Critical process steps
- ✓ The study purposes
- ✓ Responsibilities of personnel
- ✓ Critical parameters of process and product
- ✓ Testing plan
- ✓ Criteria of acceptance

K) ANDA:

Firstly, applicant submits an ANDA to the "Office Generic Drugs" or "Centre for Drug Evaluation and Research". The document room staff then processes the ANDA by giving it an ANDA number and stamping a received date on the cover letter of the ANDA. Then ANDA then sent to a consumer safety technician who is responsible for reviewing the preliminary sections of the ANDA checklist. During ANDA filing, the drug's bioequivalence, microbiology and chemistry, as well as the labeling, are all taken into account. The filing review is completed within 60 days. When proposal inspection is reviewed and other documents are reviewed and found satisfactory, then ANDA is approved [14].

REFERENCES

1) https://www.rosemedicalgroups.org/blog/difference-between-brand-name-and-generic-drugs.
2) http://www.myhealth.gov.my/en/generic-vs-innovator-drugs.
3) WHO. (2013a). *Guidance on INN[Internet]*.
   Available from: http://www.who.int/medicines/services/ inn/inn guidance/en/index.html.
4) WHO. (2013b). *Generic Drugs[Internet]*.
   Available online at: http://www.who.int/trade/glossary/ story034/en/.
5) Nikam, N.R., Vakhariya, R.R. and Magdum, C.S. (2019) Generic vs. Brand Medicines: An Overview. Asian Journal of Pharmaceutical Research, 9, 109-115. https://doi.org/10.5958/2231-5691.2019.00018.2
6) Barei, F., Pen, C.L. and Simoens, P.S. (2013) The Generic Pharmaceutical Industry: Moving beyond Incremental Innovation towards Re-Innovation. Generics and Biosimilar Initiative Journal, 2, 13-19. https://doi.org/10.5639/gabij.2013.0201.011
7) Terblanche, N.S. (2008) New Pharmaceutical Product Development: Barriers to Overcome and Opportunities to Exploit. Journal of Commercial Biotechnology, 14, 201-212.
8) Chawla, K., Tofighi, T., Agarwal, A., Thomas, J. and Mondald, T. (2014) A Global Comparison between Brand-Name and Generic drugs. Indian Journal of Pharmacy Practice, 7, 23-28.
9) Chow, S.C. (2015) Bioavailability and Bioequivalence in Drug Development. WIREs Computational Molecular Science, 6, 304-312.
10) Handoo, S., Arora, V., Khera, D., Nandi, P.K. and Sahu, S.K. (2012) A Comprehensive Study on Regulatory Requirements for Development and Filing of Generic Drugs Globally. International Journal of Pharmaceutical Investigation, 2, 99-105. https://doi.org/10.4103/2230-973x.104392
11) Rahi, S. and Rana, A. (2019) Role of ICH Guideline in Registration of Pharmaceutical Products. International Journal of Drug Regulatory Affairs, 7, 14-27. https://doi.org/10.22270/ijdra.v7i4.365
12) Bachhav, A.A., Ahire, S.A. and Jadhav, A.G. (2019) Preformulation Study of Piroxicam. International Journal of Pharmaceutical Sciences and Research, 10, 811-818.
13) Pramod, K., Tahir, M.A., Charoo, N.A., Shahid, H., Ansari, S.H. and Ali, J. (2016) Pharmaceutical Product Development: A Quality by Design Approach. International Journal of Pharmaceutical Investigation, 6, 129-138. https://doi.org/10.4103/2230-973X.187350
14) Rafi, N., Sandeep, D.S. and Narayanan, A. (2018) Regulatory Requirements and Registration Procedure for Generic Drugs in USA. Indian Journal of Pharmaceutical Education and Research, 52, 544-549.