3. BRANDED/GENERIC MEDICINE-DEFINITIONS

3.1 DEFINITION OF BRANDED/GENERIC DRUG IN US/EU ETC

3.1.1 DEFINITION OF GENERIC DRUG IN USA

According to FDA, a generic drug is the same as a reference-listed (i.e., brand name) drug with respect to conditions of use, active ingredient(s), route of administration, dosage form, strength, quality, safety, performance characteristics and labeling [21 CFR314.92 and 314.105(c) (www.fda.gov/cder/ regulatory/applications/ anda.htm)]. In addition, the generic drug must be bioequivalent to (i.e., perform in the same manner as) the brand name drug. The generic drug must have the same intended use as the pioneer product that serves as its prototype.

A generic drug that is therapeutically equivalent is expected to have the same clinical effect and safety profile as the brand name drug when administered under the conditions specified in the labeling. If generic drugs are determined to be therapeutically equivalent, physicians and pharmacists can substitute them for brand name drugs. The generic drugs must be manufactured according to the same Good Manufacturing Practices (GMP) regulations of the FDA (www.fda.gov/cder/ogd/ # 2006; 166:332-337).

Generics also go through a rigorous scientific review to ensure both safety and efficacy (www.fda.gov/oc/initiatives/advance/generics.htm). Sometimes generic version of a drug has different colors, flavors or inactive ingredients and also does not look alike the branded one because of trade mark laws (www.fda.gov/cder/ord.). In most cases, generics are available once the patent protection available to the original developer expires. Introduction of generic in the market leads to lowering of the prices of both innovator as well as the generic one. The time it takes a generic drug to appear on the marker varies. In U.S., drug patents give twenty years of protection, but they are applied for before clinical trials begin, so effective life of a drug patent tends to be between seven to twelve years.

3.1.2 DEFINITION OF ‘BRANDED/INNOVATOR DRUG’ IN USA

The term branded drug has not been defined in the US drug regulations anywhere. However, a branded drug is the original/innovator/pioneer product that has undergone and passed the rigorous tests and evaluations involved in developing the drug product. The
innovator company has sole rights to manufacture and market this product for a specified
time. The branded/innovator drug is costly as compared to the generic drug.

3.1.3 DEFINITION OF ‘DRUG’ AS PER US FDA

Section 201 (g) (I) of the Federal Food Drug and Cosmetic Act (21 U.S.C.#
321[G][I]) provides for the definition of drug. It does not differentiate between
prescription and non-prescription drug.

The term “drug” means (A) article recognized in the official United States
Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official
National Formulary, or any supplement to any of them; and (B) articles intended for use in
the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other
animals; (C) articles (other than food) intended to affect the structure or any function of
the body of man or other animals; and (D) articles intended for use as a component of any
article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim
subject to sections 403 (r) (B) and 403 (r) (3) or sections 403 (r) (I) (B) and 403 (r) (5) (D),
is made in accordance with the requirement of section 404 (r) is not a drug solely because
the label or the labeling contains such a claim. A food, dietary ingredient or dietary
supplement for which a truthful and not misleading statement is made in accordance with
section 403 (r) (6) is not a drug under clause (C) solely because the label or labeling
contains such a statement.

3.1.4 CLASSIFICATION OF MEDICINAL PRODUCTS IN BRAZIL

There are three kinds of medicines in Brazil (Valente, 2006):

1. New Medicines/Originator Medicines: Innovative product has the patent
   protection and identified by its brand.

2. Similar Products: It is produced after expiry of the patent under a brand name with
   similar composition as of innovator but permitted to differ in shape, size, labeling,
   excipients and its contents. It is not a pharmaceutical alternative to the innovator.

3. Generic Medicines: Medication similar to the innovator produced after patent
   expiry with proven efficacy, safety and quality. It is named in accordance with the
   Common Brazilian Name Listing. It is a similar medicine which is a
   pharmaceutical alternative (therapeutically equivalent) to the originator product.
3.1.5 GENERIC MEDICINES IN AUSTRALIA

The term ‘generic medicine’ is used in different ways. It can mean a product marketed under the drug’s approved international non-proprietary name (INN), or it can, as is usual in Australia, mean a product marketed under a different brand (proprietary) name (Birkett, 2003). The Therapeutic Goods Administration (TGA), which is the regulatory body for registering and licensing medicinal products in Australia, defines ‘generic medicine’ as follows:

i) It has the same qualitative and quantitative composition in terms of active principles;

ii) The pharmaceutical form is the same; and

iii) Where necessary, appropriate bio-availability studies have been carried out.

Under the PBS, a generic equivalent product is defined as a product with similar dosage form and containing identical amount of active drug ingredients (Nation et al., 1994). In addition, the product must also be demonstrated to be bioequivalent or therapeutically equivalent to the comparator, usually innovator product. In the Scheme of Pharmaceutical Benefits, these products are rated with a superscript ‘a’ before their brand names, which indicates that the sponsors of these brands have submitted evidence that they have been demonstrated to be bioequivalent or therapeutically equivalent, or that justification for not needing bioequivalence data has been provided to and accepted by the TGA. Thus, these brands may be interchanged without differences in clinical effects. The pharmacist is free to supply a ‘generic equivalent’ product with the consent of the patient in place of the one prescribed under the Brand Substitution Policy (BSP) introduced in Australia in 1994 (Brand et al., 1995).

3.1.6 GENERIC MEDICINE IN EUROPEAN UNION

According to the European Generic Medicines Association (EGA) a generic medicine is defined as: a medicine that contains the same active substance as, is essentially similar to, and is therefore, interchangeable with, an original brand name medicinal product. It is of the same quality, efficacy and safety as the original product and undergoes strict scrutiny before licensed and market approval. It is marketed as per patent
laws and is identified either by its own brand name or by its INN name (Donovan, 2003). Often a key element for a generic drug is establishing bio-equivalency.

3.1.7 GENERIC MEDICINE IN CHINA

Generic pharmaceuticals refer to pharmaceuticals for which the regulatory authorities has already established a technical standard, i.e., ‘drugs with existing state standard’, generally requiring no clinical trials. The procedure for approval and registration of both new as well as generic drugs is similar. Application for drug registration is received by the Provincial Drug Administration Authority (PDAAs) who after reviewing the application and onsite inspection send the qualified application to State Drugs & Food Administration (SDFA).

3.1.8. GENERIC MEDICINE IN CANADA

In Canada, a ‘new drug’ has been defined in section C.08.001 of the Food & Drug Regulations as a drug which contains a substance which has not been sold in Canada for a sufficient time and in sufficient quantity to establish its safety and efficacy. Thus, ‘new drug’ includes both novel products as well as drugs that are not novel but are ‘new’ in the sense that the particular version of the drug has not been previously marketed (as in case of a competing or a generic version of a drug that has the same properties). Under Canada’s Food & Drugs Act, the Therapeutic Products Program (TPP) of the Federal Department of Health (Health Canada) is responsible to ensure that “new drug” meet health and safety requirements.

Both generic as well as patented products are treated as ‘new drugs’ by the Food and Drug Regulations because generic is equivalent, and not identical, to the patented product it replicates. The major difference between submission for a patented and a generic product is the data required to establish the safety of new drug and its clinical efficacy. For a generic drug comparative studies to establish pharmaceutical and bio-equivalence with another, usually innovator’s product, i.e., “Canadian Reference Product” identified in section C.08.001.1 of the Regulations is required while extensive pre-clinical, toxicity studies in animals, clinical studies and pharmacokinetic studies to establish safety and efficacy of new drug is must. The generic drug must be demonstrated to deliver the same amount of active ingredient at the same rate as the original.
3.2. DEFINITION OF GENERIC / BRANDED DRUG IN INDIA

3.2.1 GENERIC DRUG IN INDIA

The Indian drug laws do not provide any definition for the terms ‘generic drug’ however, the term ‘drug’ has been defined under section 3(b) of the Drugs and Cosmetics Act 1940 which also includes the generic drug. It means a drug product manufactured and sold in the market under its pharmacopoeial/chemical/generic name.

Drug includes:

- all medicines for internal or external use of human being or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human being or animals, including preparations applied on human body for the purposes of repelling insects like mosquitoes

- such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which causes disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the official gazette.

- all substances intended for use as components of a drug including empty gelatin capsules; and

- such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the official gazette after consultation with the Board.

3.2.2 BRANDED DRUG IN INDIA

The term ‘branded drug’ has also not been defined anywhere under the Indian drug regulations however, it means a drug product which is produced and marketed by the manufacturer under its brand name. Although, this term does not find mention in any statute worldwide but literally it means, a drug which is manufactured and marketed under a particular brand name of the company in addition to the chemical name of the
compound. In US it is also known as innovator drug manufactured and marketed by the innovator. The term ‘branded drug’ in India means, a drug formulation manufactured and/or sold by the company under a popular brand name which is promoted by the company as per its sale promotion strategies. It does not correspond to innovator drug of US.

3.2.3 BRANDED-GENERIC DRUG IN INDIA:

In addition to generic and branded drugs, a third category of drug manufactured and marketed in India is branded-generic drugs. Branded-generic drug is basically a generic drug manufactured and marketed by the pharmaceutical company under a brand name which is not much popular and known among the trade. This term is also not defined under any statute worldwide, but is popular in the pharmaceutical market. The manufacturing company does not promote its sales in contrast to the branded drugs; rather retailer/dispensing chemist is the key promoter. To the pharmaceutical trade and institutions these are sold at low prices (as in case of generics), but to the consumers, they are made to appear as branded drugs, and usually sold at the prices of branded drug. Therefore, they are generics as far as trade is concerned, but branded as far as patient is concerned. The profit margin to the retailers varies from 300-1000% in case of branded generics (Bhargava et al., 2004). Presently generic drugs have virtually vanished from the Indian market and been replaced by branded generics by and large.

In India, almost all the drugs are sold under a brand name which may or may not be registered trade mark under the Trade Marks Act, 1999 (earlier known as the Trade and Merchandise Act 1958) and medicines are called as branded medicines or branded-generic (Gopakumar et al., 2007). In real sense, Indian market does not have branded medicines (a name commonly given to an innovator product) because till January, 2005, product patent was not applicable in India. This category closely resembles formulations referred to as ‘generics’ worldwide.

Pharmaceutical companies in India manufacture two types of formulations for the same molecule, i.e., branded product which they advertise and push through doctors and branded-generic which they expect retailers to push in the market (Bhargava et al., 2004). The branded medicines are manufactured and promoted by multinationals companies or by reputed Indian manufacturers. These pharmaceutical companies spend a lot on the
promotion of their branded products by inducing physicians, retailers and wholesalers. These are costlier because of high profit margins of the companies and expenses on drug promotions. About 90% of the medicines available in India fall under this category.

The different variants of medicine *i.e.* innovator/branded, generics, branded generic *etc.* manufactured and marketed by the pharmaceutical companies over the world are alike in most of the parameters with respect to the quality, safety, manufacturing facility requirement, labeling requirements as given in Table 3.2.3.1.

Both the generics as well as branded drugs are produced in the similar facilities following the mandatory guidelines in conformity with the drug regulations of respective country. Compliance to good manufacturing practices (GMP) is essential for every drug manufacturing unit engaged in production and marketing of drugs in most of countries including India. All prescription drug manufacturers must meet rigid FDA regulations, WHO and GMP approvals, as and where applicable.

**CONCLUSION:**

The term ‘generic drug’ has been defined in most of the statutes governing medicines globally including US, Australia, Canada, Brazil *etc.* However, the Indian Drugs and Cosmetics Act and Rules 1945, provide definition of term ‘drug’ under section 3(b) of the 1940 Act which includes the term ‘generic drug’. It does not provide exclusive definition for generic drug. Multiple brand medicines, if are bio-equivalent to the innovator are included in the definition of ‘generic medicine’ in Australia. In India, although multiple brand name medicines of the same medicine are allowed yet their being bioequivalent to the innovator is not mandatory for manufacturing and marketing approval. There is immediate necessity of definition of term generic drug under the Indian drug laws to promote and popularize generic medicines in the country.