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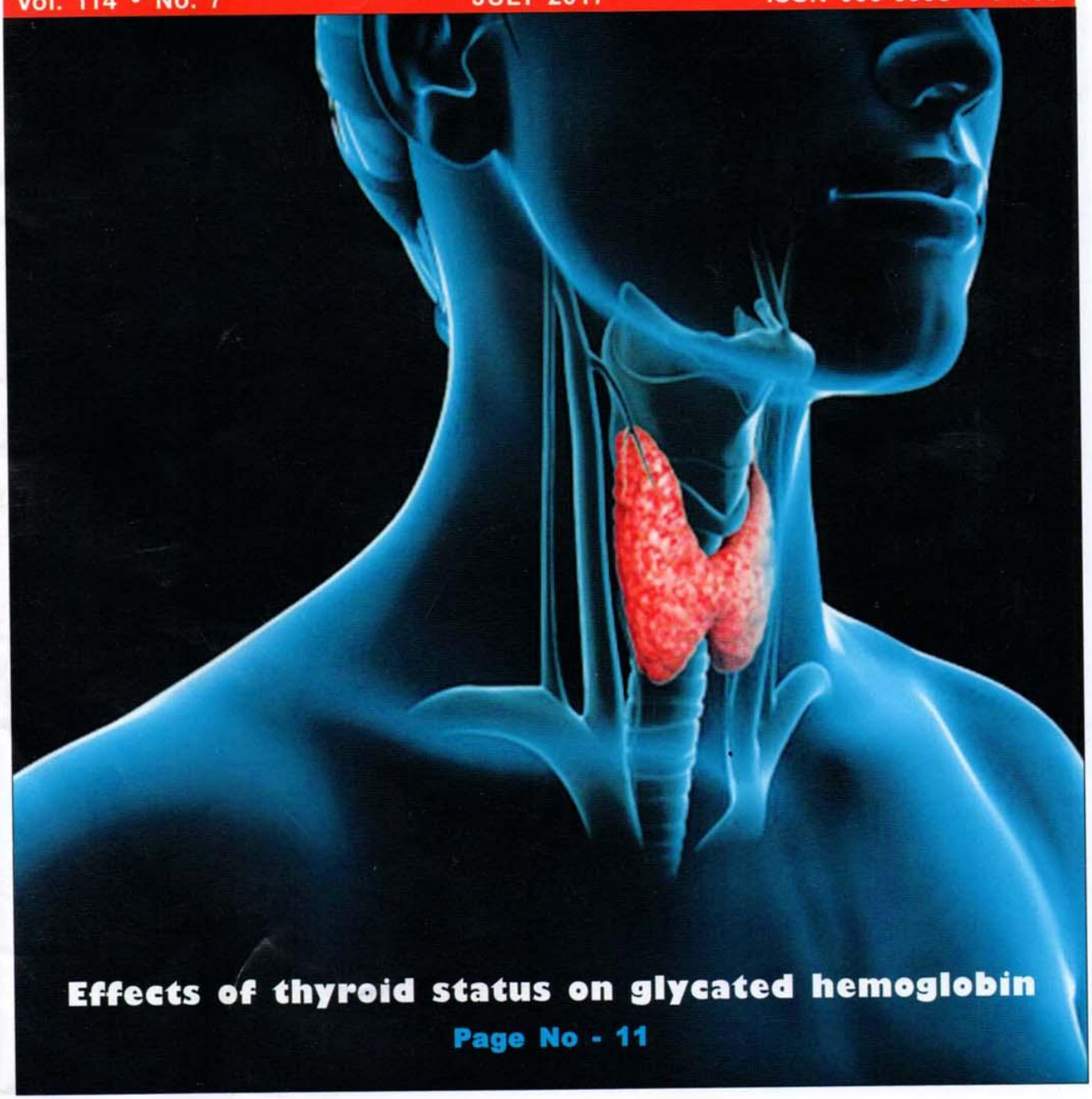

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GENERAL

Only generics (drugs/names): Is India ready?

SANJAY AGRAWAL

Introduction

Branded versus generic medicines is a topic of debate and discussions among physicians, drug regulators, and policy makers across the world. Endocrinologists face a situation where chronic therapy is to be provided at a minimum financial burden to the patient with a minimum margin of error as far as control of disease process is concerned.

It is important to understand the underlying pharmaceutical concepts about branded and generic medicines which may affect all stakeholders in the field of health-care. This article will explore this issue so as to allow informed decision making for the benefit of patients and society alike. Conventional medical curriculum does not address this important aspect of rational prescription writing. This is especially relevant for endocrinology as chronic disease require long-term use of drugs some of which have narrow therapeutic index like levothyroxine and peptides like insulin and hormones which come under the heading of biologicals for which entirely separate set of regulations exist.

The English dictionary defines the word generic as: "Not protected by trademark registration; Nonproprietary or any product, as a food, drug, or cosmetic that can be sold without a brand name".[1]

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Briefly, it pertains to the salt name or active ingredient of a drug delivery form, e. g., tablet "obimet" has active ingredient "metformin", the chemical name of which is 1,1-dimethylbiguanide monohydrochloride. Chemicals are given nonproprietary name by World Health Organization (WHO) which is the unique name of drug.

The concept of generic drugs

According to WHO, "A generic drug is 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".[2] To understand this definition a brief review of drug development process is required.[3]

Whenever a new potential pharmaceutical product is identified, the inventor (individual or company) files for protection of their intellectual property. This pharmaceutical product is now patent protected and no one can produce it without permission (or license) from a patent holder. Patents are transferable following a legal process involving payment of royalty. Innovator Company is the first one to identify or develop and market the pharmaceutical product. Once the duration of patent protection expires (usually 20 years unless specified),[4,5] the product can be manufactured and marketed by anyone without permission from the innovator provided it shows bioequivalence with the innovator's product. These products are called generics and manufacturers called generic manufacturers while those from innovator companies are called "branded". The term "biosimilar" is distinct from "generic" and applies to medications obtained from living organisms which can be humans, animals or bacteria.

Branded Vs Generic

The branded versus generic debate is an ongoing one, with various stakeholders actively involved in it. The relative merits of branded and generic drugs have been discussed, with varying opinions. Quality, efficacy, safety, and economy are some aspects which are presumed to differ between branded and generic formulations.[6,7] Table 2 summarizes the contrast between these classes of drugs.

Approval process of generic drugs

As discussed above, following expiry of patent of drug for innovator, it can be manufactured and marketed by any pharmaceutical company. Before marketing the drug, generic manufacturers need to obtain permission from relevant drug regulatory authorities. First, any drug manufactured should follow good manufacturing practices guidelines, the enforcement of which is the responsibility of drug regulators. The manufacturing units should obtain certification in this regard from drug regulators of the respective state.[8]

Second, there is a requirement for in-vitro dissolution and in-vivo bio-availability and

bio-equivalence (BA-BE) testing of new brand (from generic manufacturer) which compares the release of active pharmaceutical ingredient (API) on certain dissolution and liberation characteristics and pharmacokinetic parameters (Cmax, Tmax, and area-under-the-curve) with those from reference standard.[9] If dissolution and BA-BE of API are within acceptable range only then, the new brand is approved for marketing. This ensures that the quality of drugs marketed by generic manufacturers is as good as the one marketed by the innovators. In-vivo BA-BE studies are required only at the time of seeking approval for marketing and not after that while in-vitro studies can be performed anytime.

Economy

An innovator company needs to invest money into new drug development and initial marketing of concept and molecule. Patent protection is primarily intended to provide financial security and assure decent financial returns to innovators so that research and development needs in future can be taken care of. The average cost of developing a new drug is calculated to be US $ 2.6 billion. This estimate includes opportunity cost and price of failure.[10] The clinical development phase of a drug is the most expensive. Also with stricter regulatory requirements, the number of clinical trials required for generating evidence of efficacy and safety has increased with consequential increase in cost of development of the new drug. All these considerations (and many more) decide the cost of a drug from an innovator, which sets the benchmark. On the other hand, generic manufacturers need not replicate most of the experiments and clinical trials thus saving a lot of money and reducing their cost. Once off-patent competition brings down the cost of drug marketed by the innovator in many cases.

Governments usually do not invest in drug development as aggressively as corporate sector. As far as India is concerned, centchroman is the only new drug identified and marketed by an Indian public sector undertaking.[11] Hamycin, an antifungal drug, is another Indian discovery, which was earlier produced by Hindustan Antibiotics Limited.

Indian Scenario

The regulation of manufacture, sale and distribution of drugs is primarily the concern of state authorities while central authorities are responsible for approval of new drugs and clinical trials, laying down the standards for drugs, control over the quality of imported drugs, coordination of the activities of State Drug Control Organizations providing expert advice with a view to bring about the uniformity in the enforcement of the Drugs and Cosmetics Act. Central Drugs Standard Control Organization (CDSCO) under Ministry of Health and Family Welfare is the pivotal agency dealing with all drug related issues. This organization deals with all new drug approvals, review of new safety information regarding approved drugs, approval and safety review of fixed-dose combinations, medical devices, and implants. All endocrine and metabolic drugs are covered by these organizations and acts. Food supplements (including many herbal products) are regulated by separate laws since they are legally not considered drugs.[14]

In India, drug testing laboratories are located at central and regional levels which are entrusted with the job of ensuring production and availability of quality medicines. During the years 2011-2014, the regional laboratories tested samples at 91% of the installed capacity but their overall detection rate of sub-standard drugs was only 3.6%.[15]

The total number of samples tested was 43,387 over a period of 3 years. This number though impressive still lags significantly in terms of detection rate and especially when corrected for growth in the number of pharmaceutical companies over this period. In addition, with its manpower of 327 employees in 2012, CDSCO is grossly understaffed to perform its assigned duties of protecting the general population from sub-standard, spurious, and counterfeit medicines.[16] The 2014 episode of death of 13 women and illness of 138 following tubectomy and prescription of poor quality ciprofloxacin is a clear indicator of the deficiencies in our system which makes available poor quality medicines.[17,18]

Generic Drugs Versus Generic Names

The recent directive of Medical Council of India 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."[19] By default, most drugs sold in India are generic. However, they are marketed under a brand name given by the manufacturer. This directive passes the onus of selecting the brand name of drug and manufacturer to the pharmacist. This guidance puts the health of patients in the hands