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QualPharma

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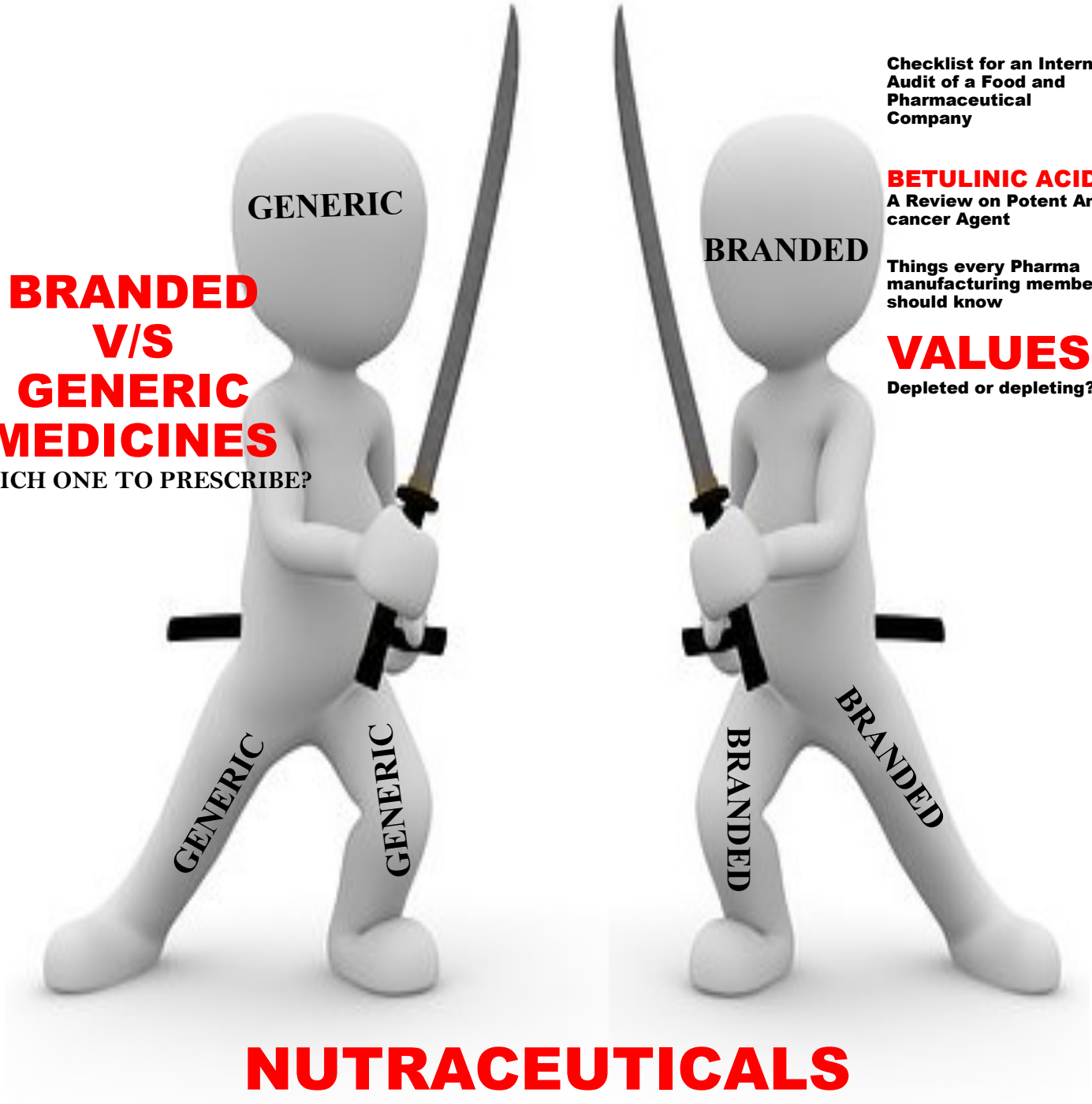

BRANDED V/S GENERIC MEDICINES

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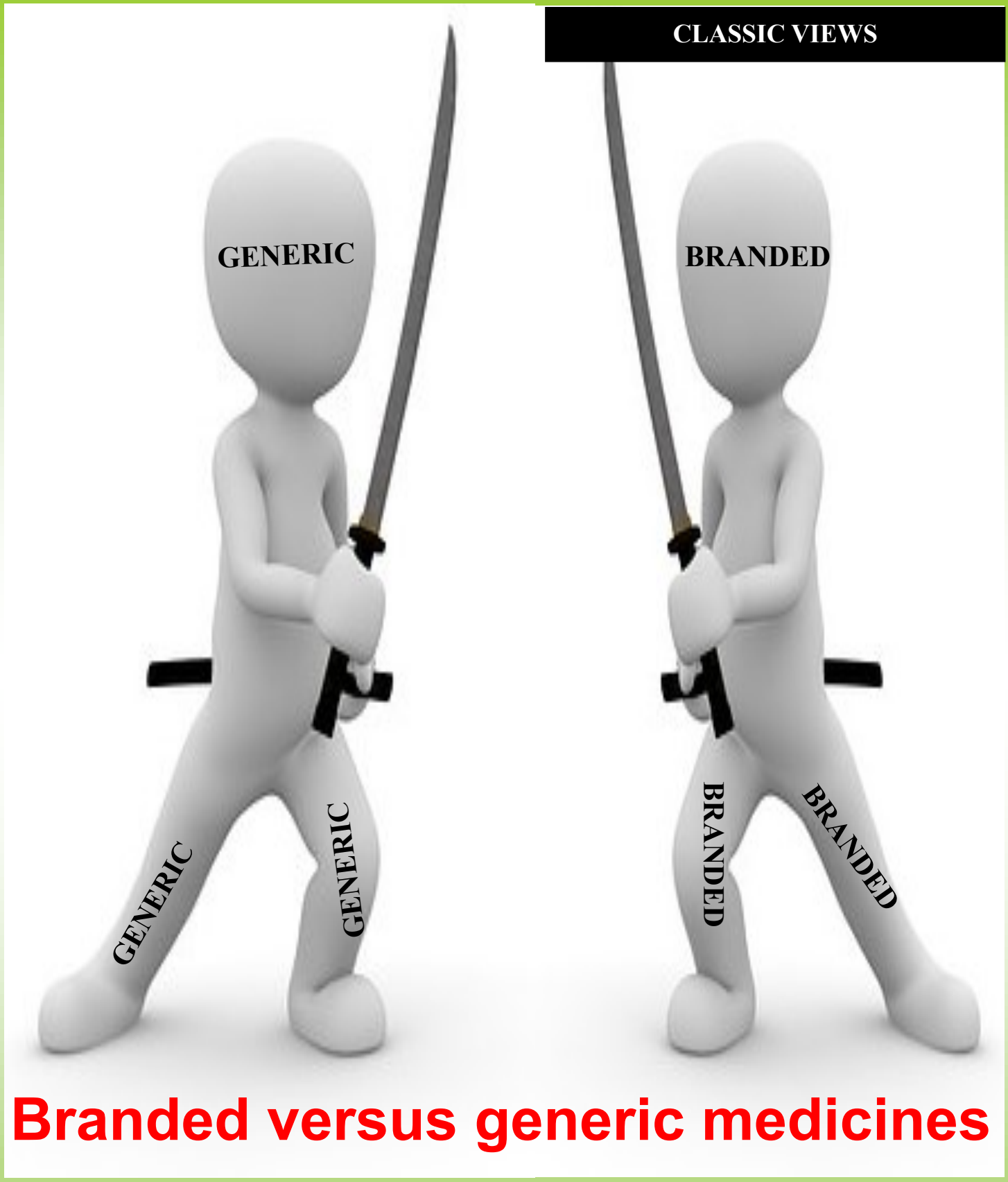

Branded versus generic medicines

Which one to prescribe?

~ Dr Sanjay Agarwal

A generic drug is a pharmaceutical drug that is equivalent to a brand-name product in dosage, strength, route of administration, quality, performance, and intended use, but does not carry the brand name. The generic drug has the same active pharmaceutical ingredient (API) as the original, but may differ in characteristics such as manufacturing process, formulation, excipients, colour, taste, and packaging.

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".

As per the 2014 National Sample Survey Office survey on healthcare, medicines emerged as a principal component of total health expenses—72% in rural areas and 68% in urban areas. For a country with one of the highest per capita out-of-pocket expenditures on health, even a modest drop in drug prices will free hundreds of households from the widespread phenomenon of a medical poverty trap. Keeping this objective in mind, the Indian government is strongly advocating prescription of generic drugs by doctors, as they cost less than branded drugs.

The Indian government is planning to put in place a legal framework to ensure that doctors must prescribe only generic medicines. The Medical Council of India (MCI) had also issued orders in 2016 to all central and state government hospitals asking them to ensure that doctors write out prescriptions with generic names of medicines.

While this push for a generics-only policy is a step in the right direction, it is important to assess and ensure that Indian generic companies are competent enough to take on the task before institutionalizing such a policy.

Following are some of the issues the Indian government and health regulatory agencies must address to make generic-only policy successful.

Inferior quality of generic medicines:

Quality, efficacy, safety, and economy are some aspects which are presumed to differ between branded and generic formulations. There is a vast difference in the quality of generics in India and elsewhere in the world. The USFDA and European regulatory agencies approve a generic drug only after it has met rigorous standards established by them with respect to identity, strength, quality, purity, and potency. In addition, all generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand name drugs. The generic drug manufacturer also has to prove that its drug is bioequivalent to the brand name drug. While in India, there is no strict monitoring of manufacturing of generic drugs and bioequivalence studies are compulsory only for drugs with low solubility. In addition, many of the reported close to 10,000 generic drug manufacturers, do not have a manufacturing facility that conforms to and is approved by the World Health Organization's Good Manufacturing Practices (WHO GMP). Periodic Inspections of Indian generic drug plants has revealed pest infestations, dilapidated infrastructure and poor personal hygiene of workers.

Dr Sanjay Agrawal

Dr Agrawal founded PHARMA CONSULTANTS and INVENTOR to fulfill his passion, capabilities and desire to assist pharmaceutical companies around the globe. He has actively worked in pharmaceutical and related industries for more than 28 years and started this firm in 2005. He is **Editor-in-Chief** of renowned IJM Today and honorable member of the editorial board of **The Antiseptic**.

The technical infrastructure in India is grossly inadequate for quality testing and certainly not comparable with the West. The loan licensing system enables fly by night operators to enter the market with their own generic, creating competing spaces at national, regional and local levels. The Indian government must make it mandatory for drug manufacturers to adhere to globally accepted standards, to ensure high quality generic medicines.

Spurious and Sub-standard medicines:

Often times, many generic drugs have been found to contain less than the required amount of active pharmaceutical ingredient (API), compromising their efficacy. This can prove disastrous in case of antibiotics, as it may lead to delayed recovery, increased risk of complications and development of bacterial resistance.

Sub-standard manufacturing practices:
Time and again, the poorly managed documentation practices of Indian generic manufacturers featured as the primary criticism flagged by foreign regulatory authorities. The lack of reliable and complete data on the test results of specific drug batches, along with poor record keeping, were some of the observations of regulatory inspectors.

Absence of Good Governance:

There is clearly a lack of good governance as is evident from the fact that the government has been unable to ensure compliance from all the stakeholders despite the presence of well-defined rules governing the manufacturing and selling pharmaceutical products in India such as the Drugs & Cosmetics Act, Voluntary UCPMP (Universal Code of Pharmaceutical Marketing Practices), MCI (Medical Council of India) etc.

India's current drug regulatory mechanism has inherent inefficiencies and inadequate infrastructure.CDSCO and state FDAs are grossly understaffed to perform its assigned duties of protecting the general population from substandard, spurious, and counterfeit medicines.In such a scenario how will the Drug Controller General of India (DCGI) ensure that the patients get the same quality of generic drug as the branded drug?

Shortage of Qualified and Trained Pharmacists in Retail Pharmacies:

Out of 7.5 lakh-odd retail pharma outlets in the country, very few are manned by qualified pharmacists.Empowering the not-so-qualified pharmacist to dispense generic drugs can do more harm than good to the patient.

Even if a doctor writes a prescription in generic names for single-ingredient drugs, pharmacists will sell the brand that maximises their commission and will in all likelihood not stock the less costlier but equivalent generic medicine that is as good. This defeats the basic intention of making medicines affordable for consumers.

Prescription by generic names merely shifts the focus of the pharmaceutical industry's unethical drug promotion to the pharmacist; away from the prescriber, and resulting in business as usual.

As things stand, pharmacists at retailer counters are ill-equipped to dispense generics accurately. A poorly qualified and ill-trained chemist will not be able to make the distinction to dispense highly differentiated products such as inhalers and products having NDDS through a generic prescription.

The government must explore ways of educating and certifying retailer-pharmacists as Community pharmacists in partnership with pharmacology departments of Pharmacy and medical colleges. The community pharmacists are the most accessible health professionals to the public. They dispense medicines and counsel patients and answer queries at the time of dispensing drugs. Community pharmacists are the necessary link between the physician and the patient to address the concerns of patients related to medicines.
Non-Availability of generic medicines:

The Government of India has championed setting up Jan Aushadhi stores, which are pharmacies selling only generic name medicines to the extent possible. There are not enough Jan Aushadhi stores in the country at the moment, possibly less than 3,000 against the more than eight lakh retail pharmacies in existence.

Majority of these stores are in urban areas with many rural areas still underserved. In addition, often many generic medicines are not available in many of the Jan Aushadhi stores.

To overcome the negative perception of generic drugs and make them acceptable by the public, following measures must be taken immediately:

- Make bio-equivalence study mandatory for every generic formulation. This will ensure the availability of not only affordable but also high quality generic drugs.
- Ensure that a qualified and trained pharmacist, who has adequate knowledge about drugs and diseases, mans all retail pharmacies in the country.
- Strengthen the Drug Administration Department with adequate manpower to ensure compliance and establish good manufacturing practices (GMP) among all manufacturing units.
- Rationalise the number of drug manufacturing units; improve their productivity and the overall quality of generic drugs.
- Introduce recognition and reward systems among physicianswho prescribe more generic drugs.

To conclude, the solution to the problem of branded versus generic lies in strengthening the existing drug regulatory and quality control structure. The government needs to strengthen regulatory frame-work and address malpractices and corruption to ensure availability of quality generic medicines to the public. The pharmaceutical industry also needs to ensure that all generic manufacturers adopt good manufacturing practices, voluntarily or through legal enforcement.

A time bound plan to make generic prescriptions mandatory will also prepare Indian pharma's vast supply chain of 800,000 wholesalers and retailers to get used to the new initiative progressively.

Finally, patients in whose interest the generics-only reform is being rolled out will be in a better position to understand the nuances of generic medicines and exploit the benefits, if they are educated over a period of time instead of a sudden switch from their regular medications of branded products, which they have been taking for many years.

Only a time-bound health policy covering all aspects of healthcare can address these issues in a holistic manner.

~ Dr Sanjay Agarwal