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Editorial

Comparison of Generic and Branded Medicine

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The so called comfortable, sweat less living by having changing life styles is bringing complimentary diseases and this leads to dependence on medicines for instantaneous relief. Medicines have now become a pivotal part of an individuals' life creating a sense of satisfaction and reliability considering one's health. Considering the fact that medicines being related to one's health, a judicious selection is desired while keeping in view a fact that the market is flooded with different categories of medicines such as generics and branded medicines. A branded medicine also known by the name proprietary or innovator medicine is marketed by the innovator and get market exclusivity for the same till the patent get expired. They are usually more expensive due to the huge amount of investments made in research and development. Further, to gain maximum profit for the innovation, the innovator of the branded medicine extensively promote its product to the physicians and pharmacies which additionally increase the cost of branded medicines. In addition to this, the innovator during the period of market exclusivity rights, enjoy monopoly during which the company maximizes profitability by setting undue prices. On the other hand generic medicines or non-proprietary medicines get marketing rights once the patent period of branded medicine has expired. Generic medicines are considered to be fundamentally similar or bioequivalent in terms of quality, safety and efficacy to an innovator (brand name) product and are cheaper than branded medicines due to less investment in their development. Thus, generics can be considered as equivalent alternative or substitute to branded drugs which can reduce economic burden for developing countries without sacrificing the safety and efficacy. Nevertheless, the generics are good options for branded drugs, it does not means that we do not need innovations in the field of drug delivery. There are still certain diseases such as orphan diseases for which there is no treatment available and also some of the existing drugs have severe side-effects that needs to be subsided. The regulation governing the medicines are stringently placed in every country, as the drugs are directly related to patient's life. However, the regulation issued by USFDA and EMEA are considered to be most stringent and needs to be followed if one wants to market the product in US or European countries. For branded drugs, as per USFDA, if an innovator wants to market its brand, a New Drug Application (NDA) has to be filed after Phase-3 of Clinical trials. For approval, the drug is evaluated for medical, statistical, biopharmaceutical, chemistry, pharmacological and microbiological parameters. On approval, the innovator get market exclusivity for 20 years once patent is filed for the innovation in the respective country. On the other hand, an Abbreviated New Drug Application (ANDA) has to be filed for the approval of generic drugs on expiration of patent of branded products on establishment of therapeutic equivalence. Establishment of therapeutic Equivalence identifies that the drug products has same level of safety and effectiveness as branded drug. A publication of USFDA, commonly known as the Orange Book includes approved drug products with therapeutic equivalence evaluations. Every year, numbers of drugs goes off patent which provide opportunity to generic manufacturers to produce generic substitutes. Approximately 100 drugs having market value of $50bn are listed whose patent will expire till 2022. Thus, ANDA requires the applicant to demonstrate only therapeutic equivalence with respect to innovator product. Hence, the generic approval process is less cumbersome as compared to the branded, involving only establishment of bioequivalence and thus cheaper than branded medicines.

Though generics are considered equivalent to branded medicines, they are still not commonly prescribed in developing countries due to lack of stringent regulation and awareness. In developing countries like India, the regulation of medicines is not as stringent as in developed countries. Despite being the highest exporting nation of generic medicines which accounts for 20% of the global generics, the Indian generic prescription market is still in a creeping state. The CDSCO and MCI, the regulatory authority in

India, has not established stringent measures to control the unethical prescription and sales of branded medicines, even when their generic counterparts are available. In India, the branded drugs are promoted with the misleading claim that they are more efficacious than generic drugs. The government initiatives like opening of Jan Aushadhi stores to ensure the availability of generic medicines to the masses seems to be unsuccessful due to lack of awareness, poor availability, less prescription habit of physicians. Though, government under provision compulsory licensing (CL), issue licenses to domestic drug manufacturers to produce and market affordable generic versions, however such a provision is limited to only life-saving medicines in case of extreme urgency. A stringent regulation regarding the prescription and sale of generic medicine is the necessary to reduce economic burden for health care in developing countries in India. However, in developing countries like India, the lack of compliance to good manufacturing practices (GMPs), by generic drug manufacturers leads to impression that generic medicines vary by manufacturer, which means you could receive different versions based on manufacturer. Thus, a strict manufacturing regulation is required to ensure the quality of medicines produced is of same standard, then only a generic substitution is meaningful. An economical alternative to branded medicine, generics, could significantly reduce economic burden of developing countries and they can be consumed with confidence for being of same standard as of branded drugs. However, there is a need to place stringent regulation governing the prescription writing, sales and manufacturing of generic medicines. Creating awareness to overcome misconception that generics are of substandard quality and to build up reputation and perception of generic medicines in the eyes of healthcare professionals and patients is required to boost the generic market. Nevertheless, the generics are good options for branded medicines, it does not mean that we do not need innovations in the field of drug delivery. There are still certain areas to be conquered such as orphan diseases for which there is no suitable treatment available and also some of the existing drugs have severe side-effects that needs to be subsided.

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