Generics Drugs — Are They Really Equivalent to Brands

Generic drugs by definition are "the drug products which are comparable to a brand/reference listed drug product in dosage form, strength, quality and performance characteristics, and intended use" [1]. Government of India and several of its States are promoting the use and prescription of generic drugs in public-sector hospitals with the vision of "ensuring availability of quality medicines at affordable prices to all" [2]. Generic drugs, being cheaper, have the potential to reduce the country's healthcare expenditure and ensure affordable healthcare to millions of people.

Even though generic drugs are being promoted, certain issues need to be highlighted. According to the definition and recommendations by WHO and FDA, only those generic drugs which are bioequivalent to the branded counterparts can be approved for marketing [1,3]. They also recommend that a generic drug should have an effectiveness range of between 80-125 percent of the original drug, which, however may be dangerous especially for drugs with narrow therapeutic index. Moreover, the quality control of generic drugs may not be as stringent as that of the brands. The issues related to lack of control over constituents and uncontrolled price of branded products during non-availability of generic drugs have been highlighted in this journal earlier [4].

Recently we encountered another problem while prescribing generic drugs. While treating a child with severe acute malnutrition, we prescribed ''multivitamin tablet'' presuming that it would contain all the vitamins (A, B, C, D, E) in at least the recommended daily allowance. When we checked the constituents of the product being given to the child, it contained only vitamins belonging to B-complex group, yet carried the name 'Multivitamin Tablets' (***Fig.* 1**). Therefore it may not serve the exact purpose which it is supposed to do. As per the definition of generic drugs, their pharmacological effects should exactly be the same as those of their brand-name counterparts [1]. But this problem of quality control over generic drugs remains unchecked due to lack of strict guidelines. The drug should provide what it intends to deliver; the labelling and nomenclature should adhere to ethical standards and not confuse and compromise the recovery of sick patients. Generic drugs need to maintain the quality and not merely serve as a measure of cost-cutting on health care expenses.

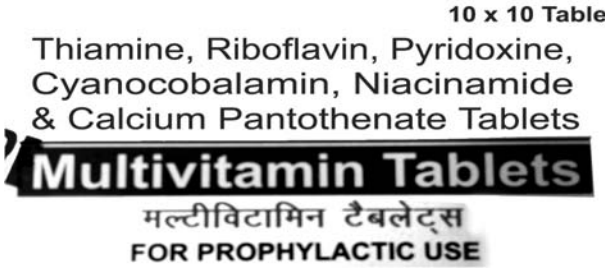

FIG. 1 *Label of a generic drug by the name of 'Multivitamin Tablets'.*

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