Dear Members,

In the first week of this month, I was invited by a television channel along with a few others to talk about branded products and generics, their quality, price and so on. The public and the media interest come against the backdrop of various recent developments. Firstly, generic medicines are cheaper compared to their branded counterparts. The general perception is that generics are exactly the same as branded products, of the same quality and give the same clinical outcomes in patients. Our prime minister's Jan Aushadhi scheme is aimed at making quality medicines available, accessible and affordable to the citizens of India gives further impetus to the public interest as well as certain doubts. The Medical Council of India through a circular has directed all doctors to prescribe by generic names and not by brand names. If doctors throughout the country prescribe by generic names, and if the generic variants of a drug are not available in the pharmacy, which brands should be dispensed by the pharmacist, remains a big question. Can a pharmacist dispense a branded product against the generic prescription without being considered as doing so, due to vested interests? If in the pharmacy there is no qualified pharmacist, which is the case in many pharmacy stores or medical shops in the country, which drug will then be given to the patient by the assistant in the shop? Are there enough generics available to meet the requirement if all doctors prescribe by generic names? Quite a number of assumptions are being made and they appear in newspapers adding to the confusion.

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One such news item describes that India is the 3rd largest producer of pharmaceuticals in the world and since it exports generics to a number of countries, availability of generics would not be a problem. Firstly, it is necessary to understand the generic vs brand situation in India. What we have in the Indian market are generic medicines sold under various brand names and these are popularly termed as branded generics. While in other countries, say for example in the USA, brand refers to innovator product and there will be only one brand for a new product that is covered under a patent. As the patent expires, regulators, in this case, USFDA approves a few generic products for that drug through an approval process referred to as ANDA. Before approval, bioequivalence of the generic with the branded product is ascertained and the manufacturing facilities for the production of these generics are inspected and approved. In such cases, the generic products would be a few and all are manufactured under conditions that were approved and bioequivalence ascertained. In our country, we have in some cases 40 or more brands for the same product and a few generic versions all of which are manufactured in a variety of manufacturing units and bioequivalence among these had not been established. Can these products be switched from one to the other without having bioavailability issues? If we assume that all these are bioequivalent without actually establishing it, would these lead to similar outcomes in patients? Only clinical research geared towards evaluating outcomes in patients can establish that fact and such research is not normally performed in our country.

Another important aspect is the price differential of the branded products and their generic equivalents. For all those branded products that fall under the NLEM, prices are already tightly regulated. In such cases how would it be possible to produce generics at a much lower price without compromising on quality? Manufacturing under cGMP conditions and performing quality control tests to release the products in compliance with cGMP requirements cannot be achieved without incurring costs and without maintaining state-of-the-art facilities. Would generic manufacturers meet all these norms and yet produce medicines at a fraction of a price of the branded products? Do we have a list of approved facilities that manufacture generics versions of all NLEMs as well as other medicines? When we have answers to the above questions, then the public can safely assume that generics are cheap yet equiefficacious to branded products. It is necessary that the policy makers and the drug regulators of our country build confidence among the patients, doctors, and pharmacists by providing answers to dispel doubts and confusion.

The intent behind the proposed 'genericisation' is good and laudable but a lot of groundwork needs to be done before it can be properly implemented. There are options, however, to generate high-quality generics at affordable costs for domestic consumption. Firstly it is necessary to do away with the system that allows several different or similar sounding brand names for a single medicine. Allow only a couple of brand names for the first two or three companies that introduce a new molecule into clinical practice in our country and the rest of the companies are allowed only to introduce generic versions after demonstrating the bioequivalence. Secondly, the government must consider directing the top 100-150 pharma companies to manufacture quality generic versions of all NLEM products of value equivalent to their CSR share and supply directly to the central government for distributing under the Jan Aushadhi scheme after fixing prices that deemed appropriate.

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