

BRANDED, GENERIC AND THE MISSING INGREDIENT OF QUALITY

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'There has to be periodic lifting of samples for testing' | Photo Credit: Getty Images/iStockphoto

Many patients seek or solicit a second opinion in a medical shop — that of the seller. Any school finalist or school drop-out who can read a doctor's prescription in English or mysterious scribbling will do. It need not be a qualified pharmacist. Queries range from, "Is this medicine too strong?" "What is this medicine for?" to "Does it have any serious side-effects?" The replies are supposed to be pro bono or free under the guarantee that the prescribed medicines will be bought from the same medical shop. The prescription may have been written out by the most famous cardiologist, neurologist or gastroenterologist, but it is the verdict in the medical shop that is accepted without any doubt. The same person will not ask any questions at a bar counter or liquor shop on whether alcohol is injurious to health, or what the chances are of developing fatty liver, cirrhosis and liver failure. Nor will he ask the person at a shop selling cigarettes whether cigarettes will affect his lungs or cause cancer. In a supermarket, customers ignore the insecticide coating on vegetables and fruits and will never ask a question about safer alternatives.

This is the reality of over-the-counter sales in India, where a salesperson can decide which brand of generic medicine (pharmacological compound) can be given to a patient. The prescribing doctor has no freedom to mention his favourite brand in which he has invested his faith in terms of quality. On August 3, 2023, the National Medical Council (NMC) directed all doctors to prescribe only generic names and not brand names which led to protests.

Brand names are shunned because many brands are costly. Generic names are much cheaper. In 1975, the Hathi Committee demanded that all brand names should be weeded out gradually. That only certain renowned and branded companies have quality is a myth propagated by the big pharma companies, with their expensive propaganda and unethical marketing techniques at work.

There is an alleged nexus between pharmaceutical companies and doctors who can be influenced to give in to unethical marketing and promotional offers or kick-backs. But the Indian Medical Association and allied professional organisations of specialists believe that improving access to affordable medicines is part of their ethical commitment to patients. A doctor's reputation on successful treatment depends on the reliability of the quantity and quality of the active pharmaceutical ingredient in a tablet, syrup or injection available in a pharmacy. But who

will guarantee compliance with those quality parameters? Individual manufacturers? The networks of pharmaceutical industries, Indian standards and quality control? Price control authorities?

The prevalence rate of spurious and “not standard quality” medicines (NSQs), stands at 4.5% and 3.4 %, respectively, as shown by two national drug surveys in the last 10 years using thousands of samples from retail chemists across India. In safeguarding a patient and enabling complete healing, drugs must be 100% quality test-passed. Having even 5% of medicines failing to pass quality tests is simply unacceptable.

The government must ensure the quality of medicines produced, procured, and supplied through its Universal Health Coverage system as well as the private health-care network. For this, there has to be periodic lifting of samples for testing. Batches of medicines that fail the quality test must be banned, with punitive action taken against manufacturers. This will eliminate repeat defaulters from the supply chain. The mechanism and systems are in place but are not implemented in earnest.

The Tamil Nadu Medical Services Corporation Limited’s practice, where all supplied medicines are kept under quarantine stock till double blinded samples are cleared in quality testing by government and private sector laboratories, is worth replicating. It is only on receipt of a pass quality test report that stock entry is done.

Till such time as the government is able to make the assurance (with concrete evidence) that all medicines in the market are of standard quality, doctors should be allowed to use in their generic prescription, the name of the company (in brackets), in which the prescribing doctor has confidence in in terms of the quality of the medicine.

Without such a reliable assurance from the government, it does not have the moral right to enforce prescription only by generic name. Moreover, control over choosing the brand will pass on to the chemist, or, even worse, the half-knowledgeable sales boy who, it is feared, will decide the brand primarily on the basis of profits to be gained.

The availability rate of all essential medicines must be above 90%. In a study of the availability of 50 essential paediatric medicines in Chhattisgarh, in 2010 — the first of its kind in India — my team calculated it to be only 17%. Non-essential vitamin tonics and cough syrups line the shelves in a pharmacy but there is no trace of the low profit-margin essential medicines. There must also be a ban on unscientific combinations of medicines — currently around 40% of the retail market in India.

To ensure affordable medicines for all under Universal Health Care, free medicines and free diagnostics are acceptable policy, but implementation needs to be monitored. The network of Janaushadhi kendras needs to be expanded. Approved norms of the profit margin for wholesale agents must be limited to 15%. For retailers it must be 35% over the ex-factory or manufacturer’s selling prices (MSP) excluding transportation cost and VAT. Without these comprehensive measures, accessibility to cheaper medicines in India will be a mirage.

Following the Indian Medical Association’s protest, the NMC has withdrawn the order on ‘generic prescribing’ since August 23, 2023. But this is only a case of one step forward but two steps back in moving to the goal of universal access to affordable generic medicines for all without brand names.

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