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Prescribing generics: All in a name

In September 2016, the Medical Council of India (MCI) brought an amendment in the Indian Medical Council Regulations (Professional Conduct, Etiquette and Ethics) in clause 1.5[1]. This is related to the use of generic names of drugs by doctors. It stated that 'every physician should, as far as possible, prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs'[1]. This was followed by a statement made by the honourable Prime minister of India on 17th April, 2017 regarding the framing of a law to make it mandatory for doctors to prescribe medicines by their generic names[2]. Another circular dated 22nd April, 2017 was released by the MCI to the medical community, asking them to follow the amended clause 1.5 and stated provision for disciplinary action against defaulters[1].

All this created apprehension, anxiety and uncertainty among the medical fraternity. There were queries as to how could the Government ensure the quality of generic medicines? Who would be responsible if a patient did not respond to the prescribed generic medicines? All these statements and confusion arose without either the policymakers or the prescribers realizing that in the majority of cases generic medicines were already being prescribed, only the name being used was 'non-generic'. A medicine that goes off-patent becomes a generic medicine. It could be available under an official International non-proprietary name (INPN) or a brand name. The official name or INPN is the generic name of a medicine that is accepted worldwide. Generic medicines in India are mostly available in brand names, *i.e.* branded generics. The confusion is due to the lack of awareness about what generic medicines are.

More specifically, generic medicine is a pharmaceutical product which is bioequivalent to the patent product regarding dosage form, strength, route of administration, quality, safety, performance characteristics and intended use. The World Health Organization defines a generic medicine as 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[3].

A drug patent is granted to the innovator company for a duration of up to 20 years to allow recovery of its research expenditure. After the expiry of a drug patent, their generic version may appear in the market and is sold under an internationally agreed name called INPN. A generic medicine contains the same active substance(s) as the innovator medicine; however, it may have different incipients, colour, shape or taste. The generic medicine may be manufactured by different pharmaceutical companies and may be marketed as their brand as branded or commodity generics. These generic medicines marketed by different companies as branded or unbranded generics have variable prices[4].

Generic medicines play a key role in providing cost-effective health care, and their use is increasing worldwide. Prescription audits have shown that generic medicines account for over 80 per cent of medicines prescribed in countries such as USA, UK, China and Australia. In India, however, lesser than 50 per cent of medicines are prescribed by their generic (INPN) names, this despite the fact that India is one of the largest exporters of generic medicines worldwide[4].

In 2008, the *Jan Aushadhi* scheme was launched by the Government of India, to provide cost-effective generic medicines through exclusive outlets named '*Jan Aushadhi* Medical Store' in various districts of India[5]. The initial plan was to establish at least one *Jan Aushadhi* store in each of the 630 districts of the country, to be extended to sub-divisional levels and major towns and villages by 2012. However, only 157

such stores could be opened by December 2012, and the number was reduced to 99 subsequently. Moreover, these stores were providing only 130 of the 319 selected medicines, and only 50 per cent of these medicines were physically available for dispensing[5].

The scheme was renamed as '*Pradhan Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP)' in September 2015. The government prepared a strategic action plan to increase the number of PMBJ *Kendra* numbers as well as increase the number of medicine available. Although the number of PMBJP stores has increased to over 800, but the numbers of medicines available are only around 200 out of the planned list of 600. The number is far from being adequate to ensure availability of unbranded generics to patients across India[5].

The advantage of unbranded generics is their lower cost in comparison to the branded counterparts[4]. Various regulatory agencies worldwide, such as the United States Food and Drug Administration ensure that the generic medicines are at least 80-85 per cent cheaper than their branded version. In India, the National Pharmaceutical Pricing Authority regulates prices of medicines[6]. This, however, is restricted only to the medicines in the National List of Essential Medicines included in the First Schedule of the Drugs (Prices Control) Order, 2013. The manufacturers are free to fix the marketing costs for the non-schedule medicines[6].

The major reason why doctors may not prescribe unbranded generic medicine is the lack of confidence of physician and patients in their quality[4]. Aggressive promotion of branded generic medicines by the pharmaceutical companies further aggravates the problem. Lack of Good Manufacturing Practices (GMPs) by pharmaceutical companies has been a major concern and raised doubts regarding the efficacy and safety of generic medicines. One such instance of disregard of GMP by an Indian manufacturer, forced the European Medicines Agency's Committee for Medicinal Product for Human Use to recall all the batches of generic clopidogrel[7]. A generic medicine should be bioequivalent to the innovator drug. Two medical preparations are considered to be bioequivalent when the rate and extent of bioavailability of the active drug in such preparations are not significantly different under standard test conditions[8].

Before April 2017, companies manufacturing generic versions of medicines did not have to prove their bioequivalence to their branded/innovator congeners. Thus, thousands of both branded and non-branded medicines are available in the Indian market, which have not been tested for bioequivalence. This is set to change with the Government of India's new amendment in the Drugs and Cosmetics Rules, through a notification on April 3, 2017, which makes bioequivalence testing mandatory for the manufacture of a generic medicine in India[9].

Another challenge with prescribing generics is faced while prescribing medicines with a narrow therapeutic index (NTI) (*e.g*. digoxin, warfarin, phenytoin and carbamazepine) in their generic (INPN) names. The bioavailability of such medicines may vary between two different manufacturers and lead to clinically significant implications ranging from therapeutic failure to drug toxicity. In the absence of information about bioequivalence of generic medicines in the market for medicines with NTI, it needs to be ensured that the patient is dispensed with correct medicines of the same brand manufacturer and any switch to other brands needs to be immediately brought to the notice of the physician[4].

The emergence of biological products as a new armamentarium to treat critical illnesses has added another dimension to the existing problem with regard to generic pharmaceuticals. In the case of biological products, there is no clear consensus regarding the substitution with the off-patent 'generic' version. This is because in the case of biological products even minor changes in the manufacturing process could result in major changes in the off-patent version. Therefore in case of biologicals, the term generic is not used. Instead, these are referred to as biosimilars, *i.e.* the product is similar but not same to the innovator's product[10].

There is no doubt that generic medicines offer cost savings, a big advantage in a country like India, where out-of-pocket expenditure accounts for the major source (69%) of healthcare spending, and nearly 70 per cent of it is spent on medicines[11]. Many patients and their families lose their lifetime savings due to exorbitant healthcare costs[11]. However, merely enforcing legislation on doctors to prescribe only by generic (INPN) names, without addressing the concerns raised by the prescribers is certainly not a wise approach and may not work. Instead, a step-wise approach is warranted to promote the use of non-branded generics.

To begin with, the drug regulator's office, the Central Drug Standard Control Organization (CDSCO) should list all the medicines available in the Indian market along with their available generic versions and costs on a public portal, accessible to everyone. Thereafter, CDSCO should ensure that all the available generic versions are bioequivalent and can be used interchangeably. All the pharmaceutical companies manufacturing generic medicines should be made GMP compliant. Furthermore, the confusion between branded and non-branded generics should be resolved, and the price variation between these be minimized. This would bring transparency and accountability to the healthcare system. The concerns regarding the generic substitution of medicines which have a NTI and biosimilars need to be addressed.

All these steps need to be initiated and the information made freely accessible and publicized among both the healthcare providers and the general public. These initiatives by the regulatory agencies will boost the confidence of both the prescribers and patients regarding the use of non-branded generic medicines and will ensure compliance with the new regulation requiring mandatory prescribing of medicines by their generic (INPN) names. Otherwise, the motive behind the amendment in the clause 1.5 of the Indian Medical Council regulations may fail to achieve its target of providing patients with affordable and quality medicines.

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