Generic Prescribing of Medicines: Diktats are Not a Substitute for Sound Public Policy

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"Every physician should 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."

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In a recent public meeting Prime Minister Narendra Modi announced that the government would take steps to reduce costs incurred on purchase of medicines by making it mandatory for doctors to prescribe medicines in generic name. In itself such a step by the government would be welcome. Unfortunately past experience shows that such pronouncements are mere empty promises that have no relation to the situation on the ground. The government, through the Medical Council of India (MCI), had in a Gazette notification dated September 28, 2016, notified that "*every physician should 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*." Till date not a single prescription audit has been conducted to either check or ensure that doctors are following this government order passed six months back. Experience on the ground indicates that an overwhelming majority of doctors continue to flout the directive. Given this it is not unreasonable to conclude that the recent pronouncement is just another empty promise.

COMPANIES MANIPULATE MEDICINE PRICES

It is important to first examine all the issues involved that determine the burden on patients incurred through purchase of medicines. Expenditure on medicines is the single largest contribution to out-of-pocket expenses (expenses directly incurred by patients) while receiving treatment for illnesses. The primary reason for this is that patients are forced to access healthcare from private providers in the absence of public facilities. Currently only 20 percent of hospital care and 40 percent of out-patient care is provided in government facilities. Patients also need to purchase medicines while receiving care in government facilities as in large parts of the country a bulk of medicines are not available in public facilities. As a result 50-70 percent of out-of-pocket expenses incurred on healthcare is accounted for by expenses on medicines. Healthcare costs are a major

source of indebtedness in India and various studies show that 5-7 crore Indians are pushed below the poverty line every year because of unaffordable healthcare costs.

The pharmaceutical industry plays a very important role in keeping medicine prices high in order to maximize profits. The final price of medicines in the market that patients pay for has no relation to the actual manufacturing and distribution costs of medicines. There is a large volume of evidence which shows that the selling price of a medicine can be 10 to 20 times (or even more in some cases) that of the actual manufacturing cost. Further, there is a large variation in the cost of the same medicine when marketed by different companies. Typically the top selling brand of a medicine is more expensive than brands that have lower market shares. The obvious question is, if a cheaper brand is available why do people buy the more expensive brand? They do so because patients do not make a choice about the brand to be bought – they are led by the advice of doctors or chemists. Pharmaceutical companies ensure a market for their drugs by promoting their brand of medicines with doctors and chemists. The larger the company the higher is its ability to promote its medicines by providing incentives to doctors and chemists. The net result is that the products of larger companies tend to be more expensive and yet sell more in the market.

Companies have been known to use a number of strategies to promote their medicines to doctors. Incentives provided include gifts, sponsored trips to exotic locations, sponsorships to doctors' associations to organise conferences, etc. In the past few years there have some attempts to curb this practice and the Medical Council of India now bars doctors from accepting gifts and sponsorships from drug companies. However this measure has not been followed up by punitive punishments to those who continue with this grossly unethical practice. Further loopholes in the MCI's directive are being used with impunity by both drug companies and a section of doctors. Thus, for example, companies show doctors they wish to favour as 'consultants' and continue to pay them large sums of money in exchange for the loyalty of such doctors towards the company's brands.

Drug companies also provide incentives to chemists in the form of discounts that they offer. Thus, for example, a pack with an MRP (maximum retail price) of Rs100 may be offered to a chemist for Rs 50. While the patient ends up paying Rs 100, the chemist is able to retain Rs 50 of that amount. This practice is rampant and drug companies

continue to lobby that they be allowed to pay large discounts to chemists, so they are able to manipulate the market.

GENERIC PRESCRIBING IS SCIENTIFIC AND RATIONAL

The logic of lowering cost to patients by insisting on generic prescriptions is related to the above. Every drug that is sold has an International Non-proprietary Name (INN) that is decided upon by a global authority. The INN of a drug is also called its generic name. In addition, in India, most companies also have a brand name for the drug. For example, the INN for a common drug used to treat fever and pain is Paracetamol. Different companies sell the same drug (Paracetamol) under their chosen brand names – Crocin, Calpol, Paracip, etc. In the case of some popular drugs in India, the same drug may be marketed by hundreds of companies, each with a different brand name. The brand identity of a drug is crucial for a company as it is this identity which allows it to differentiate its product from that of other companies. If drugs were only allowed to be sold by its INN, ie, generic name, companies would not be able to induce a larger number of prescriptions for its own product. This in turn would curb the ability of large companies to overprice their products by bribing doctors and chemists. The Drugs and Cosmetics Act was amended a few years back and it now specifies that the generic name of a drug should be displayed more prominently than the brand name. While this is being followed, companies have found innovative solutions to get around this stipulation. Almost invariably the generic name is shown in faint, almost invisible colours, while the brand name is always displayed in bold bright colours.

There is another very key reason why prescription in generic names should be encouraged. Medical students are taught about drugs only through their generic names and even experienced doctors often find the large number of brand names used for the same drug extremely confusing. Prescription in generic names is more scientific and rational.

WHY AN ADMINISTRATIVE FIAT CANNOT WORK

However, an administrative fiat to prescribe drugs in generic names just will not work unless various measures are put in place. We have mentioned about the nexus between doctors, chemists and the drug industry earlier and unless this nexus is broken by clear laws and punitive actions against violations, the practice of prescriptions by brand names will continue. Further, there is no mechanism of systematic prescription audit that can

track compliance with a system of mandated generic prescription. As past experience shows, in the absence of such a mechanism, directives will continue to be flouted.

Prescribing doctors are also likely to encounter practical issues if asked to strictly comply with the directive to prescribe only in generic names. Most drugs sold at retail outlets in India have brand names and very few are sold only in generic names. So when a doctor prescribes in a generic name the discretion moves to the chemists, who will be required to sell one out of several brands that he stocks of the same medicines. In such a situation, unless there is cap on discounts that companies are allowed to provide to chemists, the chemist would be likely to choose the more expensive brand for which he receives a higher discount from the company. Currently, in fact, under Indian law, chemists cannot substitute a drug written by a doctor. So if the prescribed drug is not available in its generic name (which is usually the case) he is not legally allowed to sell another drug that has a brand name specified. Further compounding the problem is the fact that there is a huge shortage of trained pharmacists in India, and most chemists work without the services of a full time pharmacist. So not only is substitution not legally tenable, most outlets do not have the technical ability to make such substitutions.

MEASURES THAT GOVT IS LOATHE TO CONSIDER

Mere diktats do not make good public policy unless accompanied by enabling mechanisms that allow a new policy, however good it may be, to be implemented. The hallmark of the current government has been a penchant for making grandiose announcements, without a modicum of seriousness in actual implementation. The prime minister’s statement on prescription in generic names is likely to end up as one more such instance.

If the government is really serious about curbing expenditures on medicines, there are some obvious steps it can initiate. First would be a concerted effort to make available all essential drugs free of cost in public facilities. Wherever this has been done, for example in Tamil Nadu and Rajasthan, the benefits to patients have been remarkable. Interestingly the free drug scheme in Rajasthan predates the installation of the current BJP government in the state and the BJP during the assembly elections had campaigned saying that the incumbent (Congress) government was feeding poison to patients in the name of generic medicines! The government also has the choice to overturn the Drug Price Control order of 2012, where drug prices were delinked from their manufacturing costs and pegged to existing market rates. A reversal to the earlier manufacturing cost

based pricing, where drug prices in the controlled category were determined by providing a 100 percent mark-up over manufacturing costs, would automatically bring down drug prices, in many cases by an order of magnitude. We, of course, understand why the current government would not be inclined to institute such policy changes. These desirable changes involve increased public investment on healthcare and clear intent at curbing profiteering by industry. Both are anathema to a government that puts corporate interest above public health.