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Health Policy : Generic Drugs - The Ethical Dimensions

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ABSTRACT

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Recent restrictions imposed by the Government of India on prescribing 'brand medicines' have invoked stiff resistance from stakeholders, including doctors and public. The aftermath of such a restriction and making available only generic medicines and depriving the patients of their right to have the medicines of their and their doctors' choice is examined in this article under the lens of cardinal bioethics principles. Insisting on prescription of only generics with dubious standards of quality, efficacy and safety proves to be 'unethical' and 'undesired' when examined under the cardinal principles of ethics. The alleged 'conflict of interest' of practitioners is also not proved. Authority should evolve mechanisms to ensure quality of generics before enforcing their use and should ban brand medicines when such legislations are made. Suitable price regulating and quality control legislations and adequate machinery to enforce them effectively will go a long way in making available medicines of desired quality in the country. In the existing circumstances, any decision to ban 'brand medicines' violates all basic tenets of ethics and is sure to defeat the very intention of fetching quality healthcare to the community.

Keywords: Generic Medicines, Brand Medicines, NMC Regulations, MCI Regulations

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BACKGROUND

Discussions around "generic medicines" in India stirred up a Hornet's Nest in the wake of the recent directive issued by the National Medical Commission (NMC) of India forcing the registered medical practitioners of Modern Medicine to prescribe only generic drugs.[1] The NMC in its 'Regulations relating to Professional Conduct of Registered Medical Practitioners" stated that all doctors must prescribe generic drugs, failing which they will be penalized, and even their license to practice may be suspended for a period.

Following protest from various stakeholders including the Indian Medical Association (IMA) and the Indian Pharmaceutical Alliance (IPA), the regulations are kept in abeyance.[2] However, the Indian Medical Council Regulations Act of 2002 is still in vogue and there also exist clauses on prescriptions of generic drugs, though much more flexible than what are prescribed in the notification kept in abeyance.

'Generic' Vs 'Brand Medicines' in India

To understand the intricacies of this complex issue, one has to know the legal complexities related to drug research, intellectual property right related to new drugs, patenting, manufacture, quality control, distribution and the endpoint sale of medicines in this country. India was referred to as the "Pharmacy to the World"[3] and had often been the savior in situations like the epidemic of Anthrax in US[4] or during the Covid Pandemic of yester years when India became the vaccine producer and supplier to a large chunk of world population spread across 150 countries in the world.[5] Similarly, Indian pharmaceutical industry is termed 3rd in the world for producing medicines by volume.[6]

Indian pharma market is flooded with "off patent brand generics" where the registered pharma companies manufacture or "procure and distribute" medicines in patented or non-patented "brand names" assigned by such pharma manufacturers or distributors. Thus the same medicine or pharmacological entity is available in the market in innumerable number of "brand names" that often embarrass not only the patients/consumers but also the medical practitioners themselves.[7] It may even happen that a doctor may not be able to identify or recognize the content of a "pharma brand" in the market.

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On the other hand, there are several medicines that are popularly known both to the doctors as well as to the public by their brand names without even knowing the pharmacological ingredient in the "brand". This situation, in fact, is far from justifiable. At present there exists no easy way out given the fact that there are myriads of "brand products" manufactured or and marketed by tens of thousands of pharmaceutical companies spread across the length and breadth of the country. Some such firms do not manufacture at all and simply procure medicines, label them with their brand names and market them. Such firms are called C&F firms. C&F Agents (Clearing and Forwarding Agents) play a crucial role in the pharmaceutical industry. They act as intermediaries between the manufacturers and the retailers. They distribute pharma product received from company to distributors after repacking them. They work on regional, area or state level and earn fixed percentage of margin. The "high price of medicines", to a great extent, is due to the fact that a huge percentage of the price is constituted by the profit or "commissions" given to the C&F agents, distributors and retailers in addition to the expenditure on marketing strategies that may even include unethical practices of providing cuts and commissions to various links in the large pharma sale chain.

The Central Government strategy to provide medicines at affordable and low cost resorted to avoiding all such "exploitative links" in the chain and resorted to the strategy of directly procuring the medicines from the manufacturer and making it available to the retailer and to the public. In this process, the 'generic medicines' are available in the "Jan Aushadhi" outlets at a cost of less than 30% of their "brand counterparts" in the open market. So, bypassing the middle men and direct sale to the outlets and then to the patient is a very acceptable option. This will look a very feasible and perfect option for making available the medicines to a large percentage of populace who are at loss, finding it very difficult to meet the healthcare related expense.

In the larger public health policy that "something is better than nothing" and the effects of " large population level interventions with cheaper and affordable" medicines are likely to provide better dividends than making available the high price "quality medicines" to a handful of people could never be challenged also. But, given the poor and deplorable conditions of "manufacturing and quality control mechanisms of medicines in the country"[8] the matter needs to be examined under the lens of "Ethics and Scientific" temper.

Why not ban all the "Brand" medicines? A Cry in wilderness !!!

A very genuine question asked to the "Authorities" who insist on "prescribing only the generics" is "why not ban all the brand medicines, if they are not to be prescribed by the registered medical practitioners?" Why is this question "genuine"? In India, the medicines could only be prescribed by Registered Medical Practitioners 'who possess at the least the basic qualification of MBBS. If the registered medical practitioners cannot prescribe such 'brand medicines' then there's none in the country who can prescribe them. In that situation, why should the 'brand medicines' be in the market at all? To be dispensed by the pharmacists, without prescriptions? Or, to be prescribed by the unqualified or practitioners of other systems of healthcare? Neither is possible as both the referred parties are incompetent to prescribe and are ignorant about modern medicines. Then, why should the companies in India manufacture 'brand medicines' at all? So, the easy solution is to ban all pharma companies 'who manufacture or market brand medicines' in the country. Can the authorities do that? Can the pharma industry with its multimillion turnovers be prevented from manufacturing and marketing 'brand medicines"? Not at all. This is the crux of the matter and here is the Achilles' heel of insisting on the 'generic prescriptions' by the authorities.

Looking through the lens of bioethics principles

Cardinal principles of bioethics that decide and dictate ethical guidelines for medical practice need to be considered and the decision to impose ban on prescribing brand medicines need to be examined. Let's examine the 'ethical validity' of insisting on such a step by looking through the 'lens of the cardinal principles of bioethics.

Patient Autonomy and Physician's right to prescribe

Patient has the right to get the best medicines. How's it possible? We do have international standards related to manufacturing of medicines. We have the "WHO -Good manufacturing Practices (GMP)[9] and other safeguard mechanisms like "ISO Certification etc aimed at ensuring the quality of medicines. But, the 'monitoring and drug testing mechanisms are very fragile in the country.[10] The saddest part is that a pharma manufacturing firm can operate without any such certifications as well. Thus it becomes imperative for the consumer to ensure the quality of medicines that they purchase.

It's also the 'moral obligation' of the doctors to ensure that the medicines that they prescribe should be of 'desired quality', if not of 'best quality. When they prescribe 'generics' it's impossible as generics manufactured from all parts of the country will be available in the open market and the same pharmaceutical preparation made available to the patient at different occasions will be coming from different sources of varying quality whereas with a 'brand medicine' such a question doesn't arise. If a 'brand medicine' manufactured by a WHO GMP Certified, or and ISO Certified company is prescribed, it ensures uniform quality of the medicines across all places and against all times. The right to choose such a medicine for prescription is undeniable to the prescribing physician and the right to get such 'quality medicines' of the patients cannot be denied also. Thus, from the point of view of the first cardinal principle of bioethics viz "Autonomy", generic prescription could not be unilaterally imposed on the physicians. The right to prescribe the "best available medicine, in terms of prescribed standards, is the undeniable right of any medical practitioner, leave alone the professional rights and freedoms that are inherent to a profession like Medical Practice.

"Do No Harm"

The second cardinal principle of bioethics is "Non-maleficence" or "Do No Harm" In any situation confronting the practitioner regarding prescribing medicines, how do they arrive at a decision? To answer this question one has to ask some more questions. How do medical practitioners arrive at clinical diagnosis? How do they predict regarding the prognosis of any disease condition? Along with this we can ask the earlier question also. How do they choose medicines? In all the questions above, the practitioner takes a decision based on epidemiologic principles. Be it diagnosis, selection of mode of treatment or prediction of prognosis the decision is based on the practitioners' "experience that he/she has accrued over years" of his/her clinical experience. Same is true with prescribing medicines also. Though there are innumerable numbers of generics and "brand medicines" in the market (of the same pharmacological composition) each and every practitioner is comfortable in prescribing certain "brands". These brands are their choice based on their clinical experience. Though a few of such prescriptions might be alleged of having "conflict of interest" (which is being discussed later), majority of these prescriptions are based on the principle of "Not doing Harm". They are aware that the medicines that they prescribe have quality and would give positive response for their patients. When the practitioners are denied to have the liberty of prescribing the medicines of their choice, is it not violating the second cardinal principle of Bioethics viz. "Non-maleficence"?

Beneficence

The third cardinal principle of bioethics is "Beneficence" or "do always good". This endorses the basic tenet that whatever a treating doctor does should be for the "good" of the patient. From the forgoing discussion on Non-maleficence, it would be evident by now that the treating doctor always chooses a medicine that he/she thinks is the best for the patient based on their previous experience. When the doctor is pressurized to prescribe a 'generic' the doctor will be forced to prescribe something that he/she is not sure of fetching benefit to the patient. Thus, it violates the basic principle of 'Beneficence".

Justice

The fourth cardinal principle of bioethics viz justice refers to the distributive justice in resource allocation. In a health System like ours, where the resource allocations are already limited by various factors and the budgetary allocations for "Health" doesn't even amount to three percent of the GDP,[11] it's imperative that the allocated resources need to be distributed fairly and equitably. When such resources are being expended for procuring generic medicines, the quality of which is not sure,[12] the resource allocations violate the basics of distributive justice. Even in the current situation, majority of public healthcare delivery institutions are distributing only generics and often anecdotal evidences are being published from many such institutions and by many practitioners about the inefficacy of such medicines and the practitioners being forced to prescribe 'outside' brand medicines to save their patients.

Conflict of Interest

"Conflict of Interest", probably, is the most important argument raised against the practitioners who hesitate or refuse to prescribe 'generics'. What is conflict of interest? Conflict of interest is said to be committed in healthcare when the omissions or commissions of the treating physician are for their benefit and overlook the benefit to the patient. The primary interest of any practitioner need to be the betterment of the patient and here the 'financial' interest of the practitioner (for gaining cuts and commissions from pharma companies), which is of secondary nature, is said to

overtake the primary interest of betterment of the patient and conflict of interest is alleged. In fact, not adequate evidence is available with the authorities to prove this "fiduciary" misappropriation. Hence, conflict of interest of any sort could not be alleged on the practitioners who hesitate or refuse to prescribe generics.

Way ahead

Genuineness of Authorities in their intention of fetching quality healthcare to the patients could never be challenged. Their far fetching and long term strategies are also not questionable. But, insisting on 'prescribing only generics' is totally unfair in the current scenario in India where the Authorities do not have adequate mechanisms to ensure quality of such drugs.

Instead of such measures, they should come out with proper regulatory mechanisms to control the price of medicines. At present, except on a very few medicines, the Government have no role in deciding the price. The existing "liberty" to the pharma companies and C&Fs result in the wide variation in the prices of different brands of the same pharmacological entity.

Government may think of taking over the authority of deciding the 'price of medicines', which need to be worked out taking all the stake holders in to confidence. Similarly, the huge expenses related to 'drug research' in developing any 'new medicine' needs to be borne in mind and necessary compensatory provisions provided to the 'original developers' of the medicine during it's patency period.

It's absurd that the market is permitted to be flooded with all 'brand medicines' and 'off patent branded generics' and the practitioners are prohibited from prescribing them. One another paradox is that the restrictions are being imposed only on 'qualified medical practitioners' who hold valid registration with the Authority and all those 'unqualified practitioners' who even prescribe antibiotics (remember the menace of 'antimicrobial resistance) and steroids are outside the net. If brand medicines are intended for export let them be restricted and their sales need to be banned in the country. This may be done after ensuring 'quality and efficacy of generics' including their bio-availability details and quality of contents like "excipients" (substance other than the active pharmacological ingredient in any tablet, syrup or pharmaceutical preparation). Till that time, any restriction imposed on qualified medical practitioners against prescribing brand medicines in the country, is totally unethical and against the larger interest of the public.

END NOTE

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