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INDIA

Mushrooming of unverified operators of imported medicines in India

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Even as Covid-19 has fast-tracked India's pivot to a more self-reliant drug manufacturing regime, the importance of imported medicines for certain rare medical conditions as also for other high-risk diseases for a large number of Indians remains undiminished. Equally true it is for those medicines which have been newly approved by regulators in the developed markets of the US and Europe but are yet unavailable within the country due to obvious licensing and marketing restrictions. On a positive note, in recent years, the time-to-India market for these newly approved as well as innovator drugs has drastically come down from an average of nearly 5-7 years earlier to about two years today.

Yet, because of the direness of a patient's condition which might necessitate instant availability of a drug and the desperateness of the family, a number of unverified and unscrupulous agencies and middle men have cropped up in the country capitalizing on the sheer helplessness of the situation for the family.

What does law say?

Legally speaking, an individual patient can legitimately source a drug or a medicine not registered and available within the country from outside in small quantity and for personal use. Under the rules laid down by the Central Drugs Standard Control Organisation, a formal form 12A under the Rule 36 has to be submitted by the patient along with an authorization letter by the concerned doctor to the CDSCO. What this means is that so long as a doctor certifies that a given condition of a patient needs a new drug from outside the country with all existing options within having been exhausted, a patient and his family can procure the medicine from outside. In a similar vein, a medical officer of a Government hospital or a Government medical institution, may import new drug, which has not been permitted in the country under Chapter X of New Drugs & Clinical Trial Rules 2019, but approved for marketing in the country of origin for treatment of a patient suffering from life threatening disease or disease causing serious permanent disability or disease requiring therapies for unmet medical needs. The application for import must be made to the Central Licensing Authority and needs to be certified by the Medical Superintendent of the Government hospital or Head of the Government medical institution, as the case may be.

The reality on the ground

However the reality is that today, a considerable number of so-called agencies, middle men and fixers have surfaced who neither have any respect for law nor fear of it while engaging in the most dubious and unethical practices. As a result, the desperate and the unsuspecting family of the patient readily fall prey to their designs and in most cases end up procuring either substandard drugs, or counterfeit/fake medicines which would have no therapeutic value for that given condition and may even turn out to be counter-productive. Crucially enough, the patient and the family have no means to authenticate the source of the medicine and the real manufacturer partly also due to the sensitivity of the situation when time is of utmost essence and indeed turns out to be that line of difference between life and death. And as the medicine fails, which would be the most likely outcome given the questionable nature of its origin, the family in all probability would attribute it to the severity or the ‘last stage’ of the patient’s condition and not to the dubious nature of the medicine itself. Moreover, even if the medicine has been procured from the right source and is fundamentally original and not fake, we must remember that most of these medicines require fail-proof and errorless storage and transportation conditions with some particularly demanding very precise temperature environment. In view of the long distance transport, it is nearly impossible for an unauthorized person or agency to observe and follow through with these

conditions. That they often operate under the authorities' radar without getting necessary approvals and authorizations makes them only further suspect.

Reports of illicit drug import on the rise

And without doubt, there has been a spate of media reports highlighting the gravity of the problem afflicting India in recent years. Several cancer drugs such as Afanix 40 and Crizoncent along with illegally diverted and counterfeit medicines such as Osimertinib, Ibrutinib, and Crizotinib have been reported to have come from neighbouring countries such as Bangladesh. In fact, it has been estimated that nearly 12% of total anti-cancer capsules and tablets prescribed in India are fake. Some of the other neighbouring countries that serve as conduits for the supply of these illicit imports are Nepal, Bhutan and Sri Lanka.

Authorized consultants can make it easy

Therefore, it is important for the lay people to know that instead of falling for the shady traders and middle men, there are authorized players in the country who can make those same seemingly elusive medicines available to them, and legitimately so. These consultants and facilitators are well-networked with global pharma companies, rigorously and painstakingly follow government's rules and regulations and above all, ensure that a patient gets the most authentic and genuine medicines in his time of need. Some of them even run well-designed and niche services such as Managed Access Programme, Early Access Programme, Compassionate User Programme and Named Patient Service in order to ensure that the non-availability of a medicine within the country in an emergency does not shape or determine the patient outcome in the end.

The bottomline is that there are legitimate facilitators present in the country who could procure those much-wanted medicines from outside in an emergency. At the same time, the unverified and the illegitimate operators must be reined in.

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