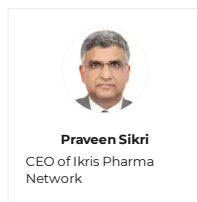


INDIA

Sourcing unregistered imported medicines? A reality check for Indian patients

August 31, 2022, 4:53 PM IST / Praveen Sikri in Voices, India, TOI



For a country which not only has a high disease burden but also a substantial number of patients with rare diseases, importing of medicines for certain health conditions and in certain circumstances perhaps becomes inevitable. And since many of these imported medicines happen to be unregistered, they tend to find their way into the country through illegal channels, unless explicit authorization is taken from the authorities under relevant rules and laws. Experts estimate that nearly 85% of unregistered imported medicines entering India make use of illicit channels or come without government approvals. From patients and their relatives' standpoint, this puts a question mark on the authenticity of the medicines imported and their relevance and utility in terms of eventual patient outcomes. So for the families, merely accessing a desired medicine from outside the country is not enough, accessing genuine medicines and through the right processes and channels is equally important.

What are unregistered medicines?

According to WHO, unregistered or unlicensed medical products are those that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority (NRR) for the market in which they are marketed/distributed or used. In fact for a patient, the risks of sourcing from illegal channels can increase manifold since an unregistered medicine can even turn out to be a substandard product, a falsified product, or worse still, a fake or a spurious product altogether.

Imported medicines represent most advanced treatment options

Nonetheless, for a patient and his relatives, imported medicines simultaneously represent the most advanced treatment options exemplifying best standard of care at a given point of time. Indeed, these medicines become the only ray of hope for patients and their families. But if there is any compromise in terms of sourcing, logistics and storage standards, the results can be disastrous for the patient's health outcome.

Huge gap between clinical trial conditions and real-life conditions

Patients would do well to remember that there is a huge gap between the way medicines and pharma products are handled and managed in clinical trial conditions and real-life situations. Typically, the results of clinical trials for a given medicine show about 5 to 15% improvement over existing alternatives and standards of care. And under clinical trial settings, the most stringent protocols have to be followed in terms of administering of a medicine, the dosage amount, the time when the medicine has to be given, and the duration over which it is given etc. In addition, the conditions for transit and storage of the medicines have to be followed to perfection leaving no room for any deviation and error. For

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instance, if a medicine needs to be stored and preserved in sub-zero temperature throughout its lifecycle, there must be suitable infrastructure and equipment available to ensure that it fulfils that condition. In contrast, the real-life conditions are very different. A patient may not take the medicine at the exact recommended time; and dosage amount may fluctuate to possibly avoid wasting of the medicine.

Unregistered medicines from unregistered suppliers don't guarantee the fulfillment of these conditions

More importantly, there is no way unregistered suppliers who supply these unregistered medicines to Indian patients can guarantee the meeting of these exacting conditions and protocols. As such, there is no way the patient consuming the medicine can establish the authenticity of the source in the distribution chain especially in light of the fact that the medicine is being brought in from outside the country. Concomitantly, it is nearly impossible for the patient to know whether the supplier or the distributor had strictly and scrupulously followed storage and transportation protocols for a given medicine as required. However, what must not be forgotten is that these are not ordinary medicines coming at usual prices. Instead these medicines are priced in lakhs and can prove to be unreasonably sky-high even for upper middle class families. Therefore, given the delicate and life-threatening condition of the patient and the excessively high cost of these medicines, that is all the more reason why there should not even be an iota of doubt over the authenticity and the genuineness of the medicine. If not, while the patient outcome suffers on the one hand, the government ends up losing revenue on the other.

Defeats the very purpose of procuring the medicine

So, even if the medicine is made available to a patient within a very short period of time and charged lower than its actual market rate, in the end it amounts to wastage of time, effort and money. For the dubious medicine serves as nothing more than a placebo for the patient and a false ray of hope for his family. And since most such cases involve an emergency health condition and the unregistered imported medicine is expected to be a treatment of last resort, any deterioration in patient's condition or even death is attributed to the gravity of the disease and not the questionable nature of the medicine itself. It is well possible that had the family sourced the unregistered imported medicine from legitimate sources and channels, the patient's condition would have shown improvement.

Developing a drug is a highly complex enterprise involving multiple processes, stages and resources. Only original manufacturers or duly authorized distributors can be expected to possess the original and genuine medicines. Today, there are authorized consultants and facilitator companies present in the country which by virtue of their excellent network with global manufacturers and distributors can make unregistered imported but truly genuine medicines available for Indian patients. So, Indian patients and their families need look no further now.



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