

## What Should I Do? What Should My Patients Do?

A very attractive cardboard carton is shown to me. It has high-quality printing. It has a brand name and a generic name. It also has a batch number, manufacturing date, and expiry date. It has name of the company too. It has barcode and hologram. Inside is a high-quality sealed plastic container. The label says that it is a new drug for the treatment of the serious disease I have. And it is being sold for a price affordable to me.

Sounds like an offer too good to be true? Well, it is!

So, what's inside the sealed plastic container? We don't know – in spite of our best efforts, we really don't know.

Holograms are available for a few paisa each – from more than 10,000 suppliers in Asia. The barcode does not comply with international regulations. The batch number is just a series of numbers whose authenticity cannot be verified – even from the manufacturer's website. The company manufacturing, or supposed to be manufacturing, the medicines is outside the country. It does not have any license to market the drug in the country of manufacturer or in India. In fact, there is no license or approval from any of the Government of India agencies concerned with health and medication. In fact, in some instances, the address, phone number, and E-mail provided on the company website are fake. There is a school at that postal address, the phone is answered by a bank, and the E-mail remains unanswered. The drug is not sold or available in the country of manufacturer. The drug is manufactured for export only – but to which country/countries is not available anywhere. There is no published data on this molecule. No clinical trials in cancer patients. No pharmacokinetic/pharmacodynamic studies in normal human subjects. No *in vitro* testing regarding composition, active ingredient, preservatives, stabilizers, and impurities. No evidence to show it is safe. No evidence to show it is beneficial. It is made available at your house magically within 1 day, but only after cash payment in advance. It is provided without any prescription, invoice, bill, transport receipt, or any document that it actually existed.

And I'm to trust my life to it? I'm to take it on good faith that the sealed plastic container contains the thing that is promises to contain!

This is not a generic medicine (defined as legal copy of medicine made of chemical material identical to the original drug).<sup>[1]</sup> I do not know its content (active ingredient, formulation, appearance, and shelf life). I don't know it is fit to be taken by animals, leave alone by human beings or by me.<sup>[2]</sup> If I get some side effect or failure of intended benefit, I will not know if it is due to some medication or something else. I don't know if I am spending hard-earned

money on drug or placebo or worse still, some ingredient that can harm me or even cost me my life.

What should I do (as patients or their doctors) when unauthorized, unaccounted for, unapproved, and illegally imported fake “generic medicines” are offered without a proof, paper trail, or documentation for cash only?<sup>[3]</sup>

We have described elsewhere in details the above situation for high-end oral new anticancer medications which are currently under patent protection and yet being purchased by about 125 new patients with advanced lung cancer in India every month.<sup>[4]</sup> Each of these Indians falling prey to is giving away money to procure fake generic “drugs” are risking death either due to toxicity or due to the underlying disease growing in the absence of real medicines. In fact, China sees up to three lakh of their citizens die every year to fake or substandard drugs.<sup>[5]</sup>

When 31 legal and licensed generics of the anticancer drug docetaxel (from 14 countries in Asia, Africa, the Middle East, and Latin America) were tested,<sup>[6]</sup> 23 were substandard and contained 33 varieties of impurities. This occurred when branded generics were being marketed after testing and approval by drug authorities. And here, we are talking about unauthorized, unapproved, and illegally imported fake “generic medicines.”

Under these circumstances, what should I do? What should my patients do? And what should the authorities do? With the estimated loss to our economy being Rs. 500 crores every month, could this be a deliberate economic cum health-care war being waged from across our borders?

### Purvish M Parikh, Padmaj Kulkarni<sup>1</sup>

*Department of Oncology, Shalby Cancer and Research Institute, Mumbai,*

*<sup>1</sup>Department of Medical Oncology, Deenanath Mangeshkar Hospital, Pune, Maharashtra, India*

**Address for correspondence:**

*Dr. Purvish M Parikh,*

*Department of Oncology, Shalby Cancer and Research Institute,*

*Mumbai, Maharashtra, India.*

*E-mail: purvish1@gmail.com*

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