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Short Communication

Can promotion of medicines be more humane?

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I am documenting my thoughts about my recent experience with pharmaceutical promotion of the latest high-cost biotech molecules. Having spent four decades in pharmaceutical marketing, regulatory affairs, and clinical research, I have developed my views and opinions on pharma promotion. Let us begin with a brief history.

Earlier, the Drugs Controller General of India (DCG (I)) required a small clinical study involving Indian population before granting import and marketing permission for new molecules. The intention was to identify any potential ethnic variations. While a sample size of 100 patients may not have been sufficient to draw definitive conclusions, the underlying thought was sound, and the intentions were commendable. However, recent advancements in organ-on-a-chip technology have simplified the process of detecting such variations. Indications of possible differences in metabolism and drug interactions can now be identified even before the initial regulatory submission for the drug.

Accepting this new development, and in response to strong lobbying by multinational corporations, along with a relatively weak pushback from local companies that have themselves engaged in basic research, the Drug Controller General of India (DCGI), in accordance with the New Drugs and Clinical Trials Rules of 2019, now permits the importation of products without local studies if they are approved in major Western countries. This policy has facilitated the entry of new molecules and biotech products that remain under patent protection.[1]

Let us now examine the pricing. The Maximum Retail Price of these new products is the rupee equivalent of the product's price in the originating country, typically in USD or Euro. This is because price activists in those countries are consistently seeking comparisons to drive prices down. Consequently, a molecule may cost between 8 to 10 lakhs for a year's therapy.

To make treatments more affordable for the Indian population, companies offer schemes such as 2+2 or 3+3, which means that if you purchase the first two or three cycles, the next two or three cycles will be provided at no additional cost. Key opinion leaders are incentivized to recommend these therapies to their patients. Frequently, doctors suggest these expensive products, even though similar outcomes could be achieved by using more affordable generic or biosimilar versions of earlier off-patent molecules from the same class, such as tyrosine kinase inhibitors[2-3] or with comparable mechanisms of action like etanercept[4] and infliximab.[5]

This is acceptable in the case of chronic debilitating diseases such as rheumatoid arthritis, where the patient has many more years to live, or in assisted reproduction, where the patient is essentially healthy, or for a vaccine that will guarantee long-term protection. Patients can receive value for money by utilizing these schemes, creating a win-win situation.

But what about diseases where patients' expected lifespan is short? Most anticancer medications are indicated

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in cases of metastasis and/or after failure of two to three earlier treatment cycles with different therapies. If patients agree to a 3+3 treatment scheme and must discontinue due to intolerable adverse events or succumb to their illness, they will never have access to the free portion of the package. Who benefits?

The sales and marketing teams look at the topline, the finance head at the bottom line, and between the two lines is our patient who suffers the disease, the side effects, plus emotional and financial upheavals. This is unscrupulous and borders on the unethical. You cannot worship Kubera and Yama at the same time.

Companies should be more humane and provide better schemes for such patients. With a little bit of thought some better schemes can be designed. Some out-of-the-box thinking is needed, as one size doesn't fit all.

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Conflict of Interest

None.

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