



Lifestyle drugs in India: Are we ready for them?

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Editorial

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Background

'Lifestyle has moved from being an indicator of the overall well being of an individual to a cause of disease and now, "lifestyle" has itself become an object of medical attention'.¹ Alcohol has been used enormously as one of the oldest 'lifestyle' drugs, and currently sildenafil citrate (Viagra), the drug of choice for erectile dysfunction, exemplifies a turning point in the era of modern lifestyle drugs. The compound has transformed the lifestyle of millions and greatly increased the revenue of many pharmaceutical companies. With the Indian economy growing rapidly at the annual rate of 8-9%,² we have witnessed a new era of drug discovery and development coupled with an enormous increase in the marketing of new drugs. This has certainly made us vulnerable to issues related to lifestyle drugs. There is a need to study the concept and impact of these drugs on Indian society, particularly as the topic has already been discussed in other developed nations.^{3, 4, 5, 6}

How are they defined?

The term 'lifestyle drug' is difficult to define absolutely. The general consensus is that a lifestyle drug is one

which can modify or change a non-medical or non-health related goal or condition that is at the margin of health and well-being. It can be used to alter not only the appearance, but also the physical and mental capabilities of the individual (Table 1).^{3, 5, 7, 8}

Lifestyle Drugs	Lifestyle Indications
Anabolic steroids	Muscle building, physical endurance
Orlistat, sibutramine or rimonabant.	Weight loss
Height increasing pills	Height
Hormone Replacement Therapy (HRT)	Improving post-menopausal problems
Sildenafil citrate	Impotency and erectile dysfunction
Benzodiazepines, SSRIs, Marijuana	Mood-alteration, social anxiety disorders
Nicotine Replacement Therapy & Buspirone	Cessation of smoking
Norethisterone	Short menstrual cycles, postpone menstruation
Caffeine, amphetamine	Memory loss, cognitive enhancers
Minoxidil, finasteride	Baldness
Antioxidants, botulinum toxin	Wrinkles & ageing,
Melatonin	
Cyproheptadine	Sleep and jet lag remedy
NSAIDs	Appetite enhancer
Food supplements, vitamins	Work related fatigue
Levonorgestrel	General wellbeing
	Post-coital contraception

Table 1. Indications for lifestyle drugs



Why are lifestyle drugs booming?

The boom is suggested to be a result of a complex interaction of vested interests by pharmaceutical industries, surfacing of growing insecurities in the modern day individual and the round the clock availability of media sources. In today's world a lot of individuals try to solve their problems in a reductionist way and look for a solution to every simple health problem in a pill. This bent of human psyche has been exploited by pharmaceutical industry paving the way for lifestyle drugs.

Drug companies today, rather than addressing the healthcare problems of the masses are more interested in catering to the need of a handful of people with spending power. The old dictum of 'supply and demand' has been cleverly modified by them and they, in fact, generate the demand first and then proceed to meet it. They are actively involved in broadcasting the definition of diseases first and then encouraging both prescribers and consumers to purchase their products. This has been appropriately described by Moynihan et al as 'disease mongering'.⁷ 'Disease mongering includes turning ordinary ailments into medical problems, seeing mild symptoms as serious, treating personal problems as medical, seeing risks as diseases and framing prevalence estimates to maximize potential markets.'⁹ Thus we are now seeing an increase in the medicalisation of conditions i.e. conditions that can be treated with behavioral modification are now moving along the continuum toward 'medical necessity'. The latest example of medicalisation of a problem is turning female sexual dysfunction into a disease and looking for sildenafil citrate-like alternatives to treat it.⁸

On the other hand there is a school of thought that supports lifestyle drugs in the name of progress which is helping to delineate the exact definition of optimal health. They contend that conditions such as obesity and smoking which are currently outside the scope of treatment, will, in the future be treated with lifestyle drugs. Clearly there is some ambiguity about this controversial topic.

The Indian Perspective

The concept of increasing longevity with the help of drugs is not new. Our earliest records reveal that, in an attempt to live forever and to enjoy the worldly pleasures of life, deities used to drink Amrit or 'Nectar of Immortality'.⁹ This shows that even in the absence of 'lifestyle drugs', these extraordinary mythological concepts were born in the past.

The healthcare scenario in India has to face many challenges as we are lacking a system like the National Health Scheme (NHS) of the United Kingdom or its equivalent. While 14% and 4% of health care payments in India are borne by government and insurance sectors respectively, 80% of the Indian population is spending out-of-pocket money on the health sector. This could increase poverty by 2%.¹⁰ Whether the government and insurance companies should pay for lifestyle drugs, or the individual, steering the way to poverty, is still debatable.¹¹

The use of lifestyle drugs is quite common amongst the affluent class, but of late the great Indian middle class comprising of around 350 million people is increasingly adopting the use of lifestyle drugs; opening up a huge market for lifestyle drugs which has been largely untapped so far.

India is inhabited by around 600 million people below the age of 30 years. They are the building blocks of India's future. With rampant direct to consumer advertising (DTCA), young people are continually exposed to advertisements with claims of products that will improve physical, mental and sexual performances. Lifestyle drugs can have potentially devastating consequences on these vibrant and ambitious people. The online supply of free samples of drugs such as anabolic steroids, memory enhancers, emergency contraceptive pills and sildenafil is a matter of serious psycho-sociological concern.

Advertising of products with limited efficacy, such as hair restoring agents, can tempt impressionable minds and erode self esteem. The possibility of addiction liability of such drugs and the long term negative affect on the overall health of the nation cannot be denied.

These pills are widely available over the counter in India and are advertised extensively. The 'Drugs and Magic Remedies Act' of 1954, India (amended in 1992) ¹² controls advertisements which are false or misleading and objectionable. In these advertisements the law is clearly violated but no protest from anywhere has been seen to date. Of greater concern is the uncertainty of the efficacy and adverse effect profile of these pills, which opens a whole 'Pandora's Box'.

Figure 1 shows DTCA advertising in a north Indian village. Many charlatans falsely claim to treat conditions like sexual dysfunction and epilepsy with ayurvedic tablets, which in reality, may contain allopathic drugs. This became evident with an article published by Gogtay *et al*, when they noticed that ayurvedic tablets—which could successfully control patients' generalised tonic-clonic (GTC) epilepsy—when tested, were found to contain the combination of phenytoin and phenobarbitone.¹³



Figure 1. Advertisement in Indian village.

Two months after the launch, on December 26, 2005, Pfizer's Viagra exceeded its targets by capturing 1.8% of the market, estimated to be worth USD \$ 17 million (approx.). 'We are excited with the response we have received for Viagra in India,' said the Senior Director of Pfizer Pharmaceuticals Limited.¹⁴ Whether this overwhelming response to Viagra is due to marketing initiatives in the urban centers or have the multinationals managed to spread their reach to the small villages of rural India remains to be seen"

'There are moments when one becomes careless and things go out of control which leads to unwanted and unplanned pregnancy. NOT ANY MORE... "Mis-take" morning after pills helps you to tackle mistakes positively.' When these words appeared on Chennai's billboards, many socially active non-government

organizations protested. To provide Indian women control over their reproductive functions, levonorgestrel-based emergency contraceptive pills were permitted to be available over the counter, but protestors retaliated on the objectionable text put up on the hoarding / billboard; saying that it promoted 'free sex' and the name 'Mis-take' offended the general public standards. As a result of their protest, the Directorate of Drug Control of the Tamilnadu Government seized the entire stock of, 'Mis-take', worth USD \$ 0.1 million.¹⁵

The government and the editorial boards of national newspapers must recognize this problem and ensure strict enforcement of the regulations for the overall interest of society. The Indian government's initiative to ban television advertisements of alcohol, tobacco and infant milk substitutes is commendable and a step forward but a stronger political commitment will be required for the desired outcome.¹⁶

Challenges ahead

In a country like India where issues such as high maternal and infant mortality rate, malnourishment, rural health problems and communicable diseases need to be addressed, we cannot afford to deride the country's growth by misplaced priorities. India needs to be very clear about its drug policies and the pharmaceutical industry should play a significant contribution in building the country's health infrastructure. It should focus more on 'life-saving' and 'essential' medicines, rather than 'lifestyle drugs'. In a free market system, profits may be an indicator of what we want as individuals, but they may not be the best indication of what drugs we need as a society. Indian drug regulators should not be influenced by approvals in the west, where an image-conscious aging society is willing to pay high prices for such products. To do so could have a devastating effect on India's growth. Are we ready for it?



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CONFLICTS OF INTEREST

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