

Drug samples are meant for advertising

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A recent Supreme Court judgement (1) ruled that drug samples provided free to physicians, marked “physician sample, not for sale”, are in fact advertisements meant to promote sales. Hence expenditure incurred on them cannot be exempted from tax liability. This ruling by Justices SP Bharucha and Ruma Pal dismissed the appeal filed by drug giant Eskayef, claiming exemption under Section 37 of the Income Tax Act which relates to any expenses incurred in business.

Medical professionals might do well to reflect on the consequences of their accepting such samples. Do they become party to the drug company’s marketing efforts? Are there other ethical implications in their relationship with their patients?

Medical professionals concerned with ethics, as well as activists advocating rational drug therapies, have long tried to dissuade doctors from falling prey to offers of drug samples. Not only general practitioners but even specialists and consultants, who otherwise do not dispense drugs to their patients, accept such samples and in turn pass them on to their patients. The question is whether free samples are free of all costs; after all, nothing in this world is free.

Pharmaceutical companies driven by market forces reap rich profits at the cost of people’s poor health. Their sole aim is to earn, and to earn as much as possible. Their pricing policies, which put essential drugs out of the reach of the common man, indicate that they are not in the business for philanthropic reasons. Why should they waste resources on these samples if not to get something in return?

In the Supreme Court appeal, the petitioner argued that free samples were handed out as part of its post-marketing surveillance programme; in order to seek physician’s feedback on the drug’s efficacy. How many practitioners or consultants are aware of this expectation? How many doctors have the time and inclination to supply such feedback? No company in India supplies a questionnaire or drug evaluation form along with drug samples.

Even if all practising doctors were trained to do drug evaluation scientifically for its efficacy and safety, to monitor adverse drug reactions, calculate the cost benefit ratio and so on, as claimed by the drug manufacturer, will the company take its product off the market if doctors find it unsuitable? All of us know of ineffective, toxic drugs and irrational formulations, which are banned in other countries but manufactured in India.

If indeed the company was getting doctors’ feedback on their drugs, did the doctors know that accepting the drugs on this condition amounts to conducting a drug trial? Do they get their patients’ informed consent to participate in this trial? Were patients given an opportunity to refuse to participate?

Studies have highlighted the problems of ‘sample practice’

— practising on the basis of the samples at one’s disposal. Patients get unnecessary drugs, in unwanted combinations and inappropriate concentrations —just because these drugs happen to be on the practitioner’s table. This raises ethical questions about whether it amounts to misuse of one’s license to practice and prescribe drugs.

Further, since newly-introduced drugs have been tested on a relatively small sample of human beings, all their side-effects and contraindications may not yet be evident. Since drug trials for FDA approval are normally not tested on children, pregnant and lactating women and the elderly, data about their possible human toxicity in these groups are generally not available. It is a safe bet not to try any new drug sample in these groups till the drug has been widely used by other adult populations for at least five years. Further, not all drugs are revolutionary or have significant benefits over existing alternatives. However, drug information accompanying the sample is selected to suit the supplier, and is not always in the patient’s interest. The medical representative’s glib and biased talk is often the doctor’s only source of drug information about drugs.

It is time that medical professionals as well as patients stopped accepting samples and showed that they are vertebrates.

Reference

1. Bhatnagar R. ‘Sample drug provided to a doctor, is an advertisement and taxable, rules SC.’ *The Times of India*, Mumbai, August 16, 2000, page 8.

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