This article does not talk about such trials but rather about committed research institutes and researchers who strive to conduct research following ethical norms. In such trials research protocols are reviewed and approved by ethical review committees. Issues of informed consent, disclosure of risks and benefits to participants, their rights, and so on, are addressed. It is also ensured that benefits for participating in the trial are not an undue enticement for an individual to participate and face unknown risks.

We are a non-governmental, not for profit organisation working on medical and social issues related to HIV/AIDS. As a part of our work we interact with various stakeholders of such trials. We are confronted with ethical issues involving such research as a part of our work.

The question that comes to our mind is: "Why should people participate in any research that can expose them to the unwanted effects of the drug or vaccine?"

The usual answer we get when we ask this question is: "they participate for the upgradation of science," indicating that participants' motives are mostly altruistic. When science is for the betterment of humanity it is the responsibility of all of us to contribute in it.

But when we look at the profile of the majority of participants of such trials we see that they are from economically backward strata in society. They are less educated and rarely are professionally related to the topic of the research. Is science is the sole responsibility of these people? Surely not.

We need to examine the motives behind people's participation in such trials. Are there other advantages in participating? Or do they have a sense of obligation towards the person who motivates them to participate? Do hierarchy and power structures operate in spite of the researchers' good intentions? Is it enough to take participants' 'informed consent' or do we need to do more?

Why do those involved with such research not participate in these trials? Those who are involved in conceptualising, designing as well as implementing research are in the best position to understand all the risks and benefits of the study, and its importance to build scientific knowledge. During informal discussions with such people they point to 'conflict of interest' as a reason for non-participation. Could this issue be addressed differently? If at all there is a conflict of interest, researchers working on the project should refrain from participating, but other colleagues from the institutions or their relatives/ friends can surely participate. This would actually motivate outsiders as well.

This raises many questions: Do participants receive true and complete information regarding the trial's safety? Are the benefits of participating in the study over-emphasised? Are we taking advantage of people's emotional and/or financial status to increase participation in the study? Would a detailed understanding about the issue discourage people from participation?

We must take action against blatantly unethical trials. We must also take a second look at research that may be questionable even though it seems to follow ethical guidelines.

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Problems with the availability of narcotic medicines

In December 2004, the Maharashtra State Chemists and Druggists Association issued a circular (1) telling their members to keep records of every tablet, injection, capsule and syrup of all psychotropic substances and antidepressants marked as 'Nrx'. Much has appeared in the press since then on the non-availability of life-saving medicines without prescriptions. Patients questioned pharmacists' integrity. The Food and Drug Administration (FDA) was held responsible for patient unfriendly rules. We decided to investigate the subject.

The Narcotic Drugs and Psychotropic Substances (NDPS) Act (2) was enacted in 1985 to regulate the manufacture, sale, purchase, stock and use of narcotic or potentially addictive drugs. These drugs, which are listed in a schedule (3), may be dispensed only upon prescription. They are used for chronic conditions such as depression, anxiety, tension, psychosomatic and behavioural disorders, and are used for long durations, usually life-long. Since these drugs can be misused (4) their use must be monitored stringently. The Act specifies that pharmacies selling these drugs must maintain a record of all sales. Failure to produce complete records can lead to a heavy penalty and even imprisonment.

When the Act was first enacted, doctors were expected to write triplicate prescriptions with one copy for their records, the second for the pharmacy and the third for the patient. Patients had to go back to the doctor for refill prescriptions every time. The rules were cumbersome but were followed.

Over the years, this practice fell into disuse. Prescriptions were filled by the pharmacy and handed back to the patients. Eventually many scheduled drugs started getting dispensed without a prescription to friends, known regular patients and on special requests. We can easily imagine how such sales were accounted for and where the profits from such sales went. This holds equally true for private and public sector pharmaceutical companies. If the drugs were sold without bills there was no tax paid. Pharmacists, druggists and the authorities all have tar on their hands.

It is believed that the Narcotic Bureau woke up after a big haul of illegal stock of these medicines. Subsequently, it decided to enforce existing regulations.

In December 2004 the Nagpur District Chemists and Druggists Association (NDCDA) informed its members (1, 6) that the Narcotics Bureau was harassing distributors, stockists and retailers and issued instructions to sell Schedule Nrx medicines only to regular customers whom they could identify – it did not

mention the need for a proper prescription. This instruction added to the plight of patients suffering from chronic illnesses, who had been getting these essential drugs conveniently from pharmacies. The NCDA's action was condemned in the press (5). In several instances pharmacists refused to sell narcotic drugs even on a valid prescription.

The enforcement of existing rules is for the good of everyone. But this should have been done slowly so that patients were prepared, and had proper prescriptions in hand. Pharmacists are expected to be aware of the rules but unfortunately even doctors prescribing these drugs are ignorant of the rules.

Instead, the NCDA demanded that narcotic drugs be removed from the purview of the Narcotics Drugs Act and placed under the scope of the Drugs and Cosmetics Act. The authorities gave an assurance that the list of psychotropic substances covered by the Narcotics Act would be reduced. This would mean that fewer Nrx medicines would be monitored, and therefore easily available for abuse.

On February 25, 2005 Rule 67 of the NDPS Act was amended and is no longer applicable to those who have a license to sell drugs under the Drugs and Cosmetics Act.

Effectively, pharmacists put chronically ill patients to inconvenience and then appealed for a relaxation of existing rules. This is a crooked way of getting things done. Regulatory authorities are not in the wrong here. And nor should patients be blamed for their ignorance of the rules.

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