The "spurious drugs" gene and its pervasiveness

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The reports of a racket in spurious and expired drugs operating in Tamil Nadu (1, 2) have thrown up several issues akin to the Indian Premier League. In the latter case, suddenly, after the one wrong tweet, skeletons tumbled out from nowhere and people who would have known about it, and who were probably accomplices just by their silence and inaction, were heard crying "Thief!"

The scenario with respect to Tamil Nadu, and at the time of writing Gujarat too, is no different. It is my belief that none of the usual crimes in society is beyond the ken of administrators and police persons. Just as no instance of tax evasion is outside the purview of tax administrators of India. It is just that we choose to turn a blind eye when it suits us.

The expired and the spurious

Now, what is the evil in this case that makes everybody jittery? It is that expired drugs belonging to a leading Bangalore-based drug company were found in a Chennai dumpyard by ragpickers. These "expired drugs" – that is, drugs past their expiry date – were being recycled. Among the articles seized from the suspects were "drug labels, injections, syringes, antibiotics, anti-hypertension pills, anti-inflammatory drugs, ointments for burns and cut injuries, protein supplements and cough syrups." (3) This is nothing new. Some years ago (circa 1993), Glaxo was accused of the same violations. The Glaxo factory was even shut down and its licence was suspended. This only resulted in the transfer of the then commissioner of the Maharashtra Food and Drug Adminstration (4, 5, 6).

Recycling expired drugs is clearly a violation of the spirit of the law. The recent amendments to the Drugs and Cosmetics Act (7) allow the authorities to levy a heavy fine and a prison sentence of 10 years that can even be extended to life imprisonment. Since nobody enjoys paying fines or going to jail, let alone for a life term, why do some people recycle expired drugs?

This is like asking: If you know that getting caught for murder will most probably, even in India, get you to jail or the scaffold, why do people do it? The law in both cases is obviously not a sufficient deterrent; this is all the more so with respect to medicines.

One difference may be that while murder is often, but not always, committed in the heat of passion, recycling drugs past their expiry date requires a little longer term planning – to fix partners in the industry and trade, obtain paraphernalia such as lookalike labels, deal with people in power, and so on.

There is also the question of proof. If, like the Indian Premier League commissioner, the perpetrators have managed to destroy key evidence in time, or obfuscate it over the long period that India's legal system takes, then there is no hope for justice, and many in this parallel industry will get away literally with murder.

Incidentally, the burden of proof in the Drugs and Cosmetics Act, except in West Bengal, is not on the accused. In a sense, thank God for it – imagine the scale of horse-trading that would take place between drug department functionaries and the accused, a scene envisaged and feared by the drug industry post-2008 amendments where the possibility of a life term is very real.

However, recycling expired drugs does not appear to be the only crime in the present case. It is the news in the grapevine of "spurious drugs": claiming that a tablet is paracetamol when it is actually chalk powder, or palming off distilled water as a critical injection. It is also news that these spurious drugs have entered the much lauded (in a sense rightly so) procurement system of the Tamil Nadu government. For this writer, circulating spurious drugs is a worse crime than recycling drugs past their expiry date. It is a greater breach of trust. Spurious and adulterated drugs have greater chances of causing death or serious adverse reactions.

So, is recycling drugs past their expiry date a lesser crime? In a sense the answer is "Yes", especially if the drug still works. (Indeed, how can a drug "expiring" at midnight on Dec 31 cease to be legal and medical tender at 12.01 am January 1?) It is highly improbable, with due exceptions, that anybody will die of taking an "expired" drug.

The law on spurious drugs

The law in India does not talk of "fake" drugs. As per the law (Section 17 of the Drugs and Cosmetics Act) a drug in India can be spurious, adulterated, or misbranded, and the manufacture and sale of such drugs is prohibited and attracts penalties (Sections

18 and 27 read together).* Recycling a drug past its expiry date may be seen as coming under the scope of a "misbranded" drug** or a drug not of "standard quality" defined as per Section 16 the Act. Rule 65(17) of the Act specifically prohibits selling drugs past their expiry date.

Nevertheless, one needs to understand that it is silly to equate selling genuinely potent drugs past their expiry date with selling spurious or even substandard drugs. But the law has no room for nuances - only case law can highlight these finer problems.

But the law being what it is, and especially the amended 2008 law being what it is, we still need to understand why people trade, or, should we say, traffick, in spurious drugs, or why they even recycle drugs past their expiry date. Our guess is that it is partly because of the prices of these drugs. Many of the popular brands are overpriced in the market. Even a person hell bent on fraud will not take the risk of making aspirin or paracetamol, both of which sell under Rs 10 per strip of 10, compared to, say, a drug like atoravastatin, the top brand of which sells at Rs 100 per 10. So drug pricing and, indeed, lack of drug price regulation is certainly one cause – but not the only one – of the prevalence of spurious drugs. This is certainly one strong reason for a strong regulation of prices.

Other spurious behaviours

Having said this, many irrational drugs and unscientific fixed dose combinations (FDCs) are "fake" or spurious as well – and probably "misbranded" too. Indeed, both licensing authorities and drug companies are responsible for the widespread sale of such drugs. One study (8) reported that more than 60% of the top-selling 300 drugs in the ORG-IMS-Nielsen list are irrational. That's so much good money belonging to ordinary people going down the drain. The other reason that some genuinely well-made drugs, especially of relatively lesser known companies, are considered "fake" or spurious is that prescribers mis-diagnose and mis-prescribe, under-prescribe or, as is often the case, over-prescribe. No thought is given to drug-drug interactions which inhibit, exacerbate or confound response. Indeed, very little literature is available regarding these irrational FDCs. In the absence of prescription audits, medical audits and death reviews, a lot of incompetent and irrational practice does not get the serious attention that it deserves.

Part of the problem is also with the nature of medical reasoning and logic. A good deal of it is empirical, based on probabilities, and only with difficulty can one establish causality even if one can see association. Second, the science of pharmacology itself is suspect beyond a certain point. Not all drugs are approved at dream efficacy levels. So it can happen that you take a drug and you just happen to be in that subsection of humanity for which the drug will not work. You are likely to jump to the conclusion that the drug is "spurious" or "fake". And even drugs made by so-called big pharmaceutical companies misbehave. This is often discovered during Phase 4 studies, much to the discomfort of the blockbuster manufacturers. And then comes the dissimulation, first by the marketing department and then by the lawyers, from both sides. And this is sometimes aided and abetted by "research and development": the withdrawal of rofecoxib is a case in point.

The prevalence of spurious or misbranded or adulterated drugs, and the desire of some elements wanting to make a buck or two, is a reflection of general lax standards in the medical community in India, the pharmaceutical fraternity and the related licensing and supervising authorities. These lax standards start from "fake" medical, dental or pharmacy colleges – those that do not meet specifications, or where approvals and degrees are purchased. These are colleges that churn out clear-eyed graduates with the primary goal of recovering their "investments".

Then we have adverse clinical trials that are not published, the irrational production, licensing and prescription of drugs, their overpricing, policies that lead to unjustified universalisation (of, say, certain vaccines); cut practices, commissions by doctors to doctors, pharmacists to doctors, pathologists and CT scan centres to prescribers and, of course, a percentage from every professional to the fixers, graspers and turners in the government, the administrators, the tax collectors and the supposed custodians of the law. These transactions appear to the ordinary citizen facilitation fees and sweat equity in perpetuity. I am even beginning to feel sympathetic to Lalit Modi and the IPL scamsters for their healthy, honest avarice.

We cannot even begin to scratch the surface of the content of medical and surgical practice with unnecessary surgeries, and, increasingly, the deals of everybody, including patients, with health insurance companies.

So we need a bit of perspective with regard to crimes related to the production and propagation of behaviours that are deemed criminal in law and in popular perception. Society at several levels and multiple hierarchies reproduces desirable and undesirable behaviours. If making a quick buck by hook or by crook is okay for match fixers, politicians, administrators, judiciary, police, film stars, lawyers, doctors and those in business and industry, avenues of wealth accumulation also beckon to the have-nots who wannabe. If we are not clear how we are going to treat these rock stars of (mostly) unaccountable greed and gratification, then why strike hard, with an invidious Drugs and Cosmetics Act, at someone trying to enter the club of crooks?

What can we do?

One suggestion that is often thrown up in this kind of discourse is that we do not have sufficient numbers of drug inspectors. That may be true. We also have too many types of medicines circulating. This needs to be drastically cut to only essential drugs as per the WHO List of Essential Drugs or the National List of Essential Medicines. That will pare the problem to some manageable level of diversity. The other response of those in power is to increase the barriers for entry – for retailers, traders and manufacturers – by asking for more paraphernalia before licensing. Apart from being out of tune with the spirit of a market economy, this does not make sense in a large country where access has to be improved through regulation that improves access to medicines, rather than making it more difficult. In a sense this is also being played out internationally under the guise of harmonisation, IMPACT, ACTA, TRIPS Plus, FTAs, etc. – devices that make the poor even more dependent on the better-off countries.

The public at large – even the medical fraternity for that matter - has no quick and affordable way to check on the quality of medicines. There is large-scale illiteracy about what constitutes a quality drug. This situation needs to be remedied. The judicial process for drug related offences needs to be reasonably quick and the punishment must be commensurate with the offence. Price regulation is necessary – there is tremendous asymmetry of information between medicine end-users, prescribers and sellers, and these are conditions ripe for failure of market competition. As we observed earlier, high prices are an inducement for duplicate and "fake" drugs to be made. Unethical behaviours at all levels of medical, pharmacy and dental education and medical practice need to be spelt out and made culpable crimes. These include inducements for irrational prescription in return for gifts in cash, kind and exotic holidays. Drug company sponsorship of annual meetings of medical associations should be banned. No doctor, in the guise of a "key opinion leader" or otherwise, nor any medical association, should be allowed to get away with endorsing medical and non-medical products. We need to understand and act on the political economy of sleaze and unethical behaviour of which spurious drugs are only a part of the scenario.

Ethical behaviour needs to be applauded and our systems need to be designed so that not only is good rewarded but it is seen to be rewarded.

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Endnotes

*** According to the website of the Central Drugs Standard Control Organisation**, possible crimes and misdemeanors related to medicine, manufacture and marketing of drugs are of three categories:

Category A: Spurious or imitation drug products are formulations made to resemble another drug, especially a popular brand, in order to cash in on the popularity of the original product. The product may or may not contain the active ingredients. Spurious drugs may be manufactured by unlicensed or licensed manufacturers. This category includes "adulterated drugs", or those found to contain an adulterant or substituted product or contaminant, rendering them dangerous.

Category B: Grossly substandard drugs are manufactured by licensed manufacturers but have serious defects that affect the quality of the drug. Such defects may arise out of the manufacturer's gross negligence or because good manufacturing practices were not followed. These defects may be under the following categories: (i) active ingredient contents are below 70% for thermo labile products and below 5 % of the permitted limits for thermo stable products; (ii) tablets or capsules fail in disintegration tests wherever prescribed; (iii) tablets or capsules fail in dissolution tests and the active contents are found to be less than 70% for thermo labile products and below 5% of the prescribed limits for thermo stable products; (iv) liquid preparations show the presence of fungus; (v) parenteral preparations fail in sterility, pyrogen or endotoxin tests or have undue toxicity; (vi) vaccines fail in tests of potency, sterility, toxicity or moisture content; (vii) an adulterant is found present which renders the product injurious to health.

Category C: Drugs with minor defects are manufactured by licensed manufacturers but are found not to be of standard quality because of defects arising from minor variations in quality. Such defects may occur because pre-formulation development studies were inadequate, in-process controls were not exercised by the manufacturer, or the drugs were stored or transported in unsuitable conditions. Examples of such defects are: (i) broken or chipped tablets; (ii) the presence of spots, discolouration or uneven coating; (iii) cracking of emulsions; (iv) clear liquid preparations showing sedimentation; (v) change in the colour of the formulation; (vi) slight variations in net content; (vii) formulations failing in weight variation; (viii) formulations failing to

respond to the colour test; (ix) isolated cases of presence of foreign matter; (x) labelling errors including nomenclature mistakes such as Rx, NRx, XRx, Red Line, Schedule H caution, colour, etc.

Summarised from: Website of the Central Drugs Standard Control Organisation, government of India: Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008. http://cdsco.nic.in/Guidelines%20under%20new%20penal%20provisions.pdf

**** According to Section 17 of the Act:**

"A drug shall be deemed to be misbranded (a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or (b) if it is not labelled in the prescribed manner; or (c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular."

One wishes that recycling expired drugs were mentioned as a misdemeanor less opaquely and more explicitly. Top selling products such as "Fair and Lovely" and its clones would certainly be misbranded cosmetics, defined likewise in the Act, under Section 17-C.

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Supreme Court judgment on medical interrogation: on the just use of science and the ethics of doctors' participation in criminal investigation

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In early May 2010, a three-member bench of the Supreme Court of India, headed by the outgoing chief justice, delivered a path-breaking judgment (1). It declared illegal, and a violation of human rights, the use of medical techniques such as narcoanalysis and various methods of "lie detection" (hereafter known as medical tests) in the investigation of individuals suspected of a crime, without their consent as well as other extensive safeguards.

Over the years, the *Indian Journal of Medical Ethics* has consistently criticised and opposed the participation of health professionals in carrying out the death penalty; in torture and in the police interrogation of people accused of a crime. *IJME* has opposed the use of scientifically questionable medical tests as methods of criminal investigation. The court's judgement is a welcome response to a worrisome practice.

In no time in the country's history have the use of medical tests, and the participation of doctors in police investigation, ever been as extensive (at the drop of a hat, tests such as polygraph, narcoanalysis and brain mapping have been ordered on thousands of individuals suspected of crimes including terrorism), as prominent (newspapers have carried front page reports, and the electronic media have run clips of people getting interrogated inside operation theatres) and as universally acceptable (even politicians have demanded that their rivals be put under narcoanalysis), as in the last few years. In a time of jingoism and political-ideological hype on terrorism, the irrationality of public opinion and swaying from professional commitment by individual health professionals, though highly reprehensible, can still be explained. However, what was more disgraceful and shameful was the fact that, barring a few who stuck their necks out, the community of health professionals in general maintained a stoic silence. The same was true for medical journals (barring a few) and medical associations that are supposed to provide leadership to the profession.

We hope the Supreme Court's judgment will make the profession do some introspection. Indeed, not only do we all need to introspect on where we are failing as a profession, we also need to prepare ourselves for the next phase of our campaign to uphold professional ethics. This is because while this is a very good judgment to protect the human rights of those accused of crimes, it falls short on protecting the professional ethics of doctors, and in providing good guidance on the future use of medical techniques in interrogation.

But before we look at the judgment's shortcomings let us first celebrate the areas in which it has strengthened human rights in the country.