VOL.2 NO.2 & 3 JULY-AUG & SEPT–OCT 2002

BUMPER ISSUE

HEALTH & ENVIRONMENT

CSE

NEWSLETTER FROM THE CENTRE FOR SCIENCE AND ENVIRONMENT

EDITORIAL

This Diwali, there was definitely more focus in the media on the pollution from crackers – noise and air. But paradoxically, there was also, definitely as much or even more pollution, in most cities on this night. Delhi, in most parts, the air was foul. The noise was deafening.

Why was there no change? Why, when school children have been vocal in their advocacy against noise pollution from crackers, governments have made the right noises about banning crackers? Why is there no perceptible impact of these actions?

The reason simply is that we do not consider that health is of any concern. It is still not on the public agenda. Therefore, it becomes easy, too easy, for the vested interests to ensure that any efforts to curtail pollution

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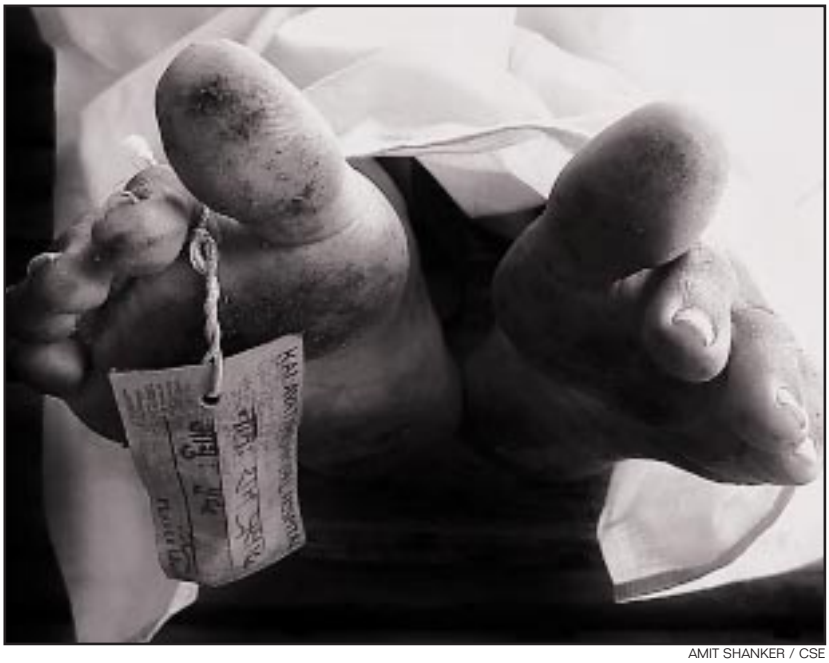
INSIDE

LEAD STORY



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HEALTH STATISTICS

Death by numbers

Statistics (or the lack of it) leads to mismatched budgets, creates inequities and skews up health priorities

Strategies can evolve only when data is presented into information to forecast scenarios

Does the number of children who die before their first birthday decrease each year? How many children don't get a square meal in India? Do malaria, dengue, cholera, leprosy and other forgettable diseases occur only in pockets sporadically every other year? Is AIDS under control or is it increasing everywhere in India uniformly? All these answers are provided by statistics.

Statistics give a snapshot of societal trends, influencing and shaping public opinion and defining to a very large extent how a government will act. But can these numbers be trusted? Are they as objective as they are thought to be or can they be manipulated to serve a particular subjective interest? How can one spot bad statistics? How often are statistics concocted in the backrooms of hospitals and shady government offices? When do statistics become unreliable?

are stymied and killed. Take the case of firecrackers. There is a huge and equally vocal lobby operating to support a dirty and noxious industry. The lobby works overtime, first to ensure that the regulations for noise levels is diluted, then to ensure that the regulations are toothless. Not worth the paper they are written on because there is no implementation.

The Central Pollution Control Board (CPCB) notified noise standards for firecrackers way back in 1999 after an expert committee, headed by M L Munjal of the Indian Institute of Science examined the issue. It commissioned the National Physical Laboratory (NPL), which on study found that people within two metres of the explosion are in danger of "definite risk hearing loss" and more susceptible populations could face the risk of hearing damage as well. NPL suggested a limit of 115 dB for firecrackers. Another study by the Defence Institute of Physiological and Allied Sciences (DIPAS), exposed children and adults to continuous – 30 minutes – noise from firecrackers at a distance of 6 metres. Each person, directly after this exposure was taken to a sound attenuated room to record the change made to the auditory thresholds. This study concluded that 30 minutes exposure to cracker noise – between 137 to 150 dB from a distance of six metres raised the auditory threshold in adults by 13.3 dB and in children by 11.3 dB. The results showed a temporary hearing loss, recovered within two hours.

On scrutiny of this information and worldwide data, the committee set regulations that the manufacture, sale or use of firecrackers generating noise levels exceeding 125 dB at four metres from the point of bursting is prohibited. The department of explosives (DoE), under the ministry of industry and commerce was made the implementing agency for the rules. This is where the matter has stopped. Literally.

Firecracker associations want the level amended. They argue that the DIPAS study only suggested "temporary" loss of hearing so it is clear that they can make louder crackers and suggest ranges of 140 dB and higher as "safe". They are lobbying furiously and using their compliant members of parliament to push and prod for modification.

In any case, with no enforcement worth its name, the law is more or less dead. CPCB says it has written to the DoE many times asking for action to ensure compliance. But with no response. In September 2000, the Delhi High Court had ordered that the manufacturers print the noise levels on the wrappers. But even this has not been done. The random checks done by CPCB in March of this year, found many brands exceeding the noise regulations. It wrote to DoE asking for action. Nothing. As yet, no testing procedures have been specified, given the manufacturers a free hand.

Then, there is the issue of monitoring noise levels in a locality to ensure that the ambient noise levels are not breached. Levels are monitored at stations, which record the levels based on the distance the crackers are burst. So, if the monitoring station is far away from the point of explosion, the noise impacts on residents will never be recorded.

This is about noise. In the case of air pollution, the regulations do not exist. Nothing has yet been done to monitor or to regulate the toxins — from metallic to gaseous -- from firecrackers. We know that this year in Delhi, much like last year, total and respirable particulate emission jumped to a dangerous high on Diwali night. In the residential colony of Ashok Vihar, RSPM emissions were over 1082 microgram per cubic metre (µg/cum), up from 421 (µg/cum) the night before. The health impact of this acute exposure could be deadly for the susceptible — children, old, asthmatic, heart patients. Perhaps even for others. But who cares?

It is nobody's case that Diwali should not be celebrated. It should. But surely, given the already high levels of exposure and contamination of our environment, we will have to ensure that Diwali nights are not deadly for some. This means paying attention to regulation and enforcement. But to do this, we will have to first decide if good health is also part of the wealth that we pray for each Diwali night.

As I have said before in this column, public health must have an important political constituency. It must have a voice. A powerful voice of reason. Otherwise, we will continue to become cracker deaf and pollution dumb. A gruesome future.

— Sunita Narain
Director

The Beginning

In America in late 1800s, immigration and health officials fed the public with imagined figures and stories of the problem of migrants who brought diseases and infections, crime, and prostitution and ate into America's prosperity. In order to counter this, analysts devised scientific methods to count births, deaths, and marriages, which tried to reflect the true health of the state. Those who conducted such numeric studies — came to be called statisticians and their "art", statistics. Over time, social research became more theoretical and more quantitative. As researchers collected and analysed their data, they began to see patterns and trends. When complexity in technique increased, the possibility of manipulation increased. Statisticians devised different methods to interpret the same data differently. Often, methods of assessment produced conflicting results. These arise because the results obtained from surveys are vastly different or the tools used to analyse the data produces different results (see box: *Divide and rule*).

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Divide and rule

The lack of standard protocols for assessment and bad measuring systems result in manipulated outcomes

Q. Does the mean incidence of cancers stay unchanged, increase or drop, using four different statistical methods?

Cancer incidence

	1995	1996
Cervical	100	200
Prostrate	200	100

■ **Using arithmetical average**

	(100+200)/2	(200+100)/2
Mean incidence	150	150

A. *Incidence of cancer remains unchanged*

■ **Arithmetical average of percentages, in the first period (or base year)= 100%**

	1995	1996
Cervical	100%	200%
Prostrate	100%	50%
Mean incidence	100%	125%

A. *There is 25 per cent increase in incidence of cancer*

■ **Arithmetical average of percentages, in the second period (second year as base year)= 100%**

Cervical	50%	100%
Prostrate	200%	100%
Mean incidence	125% —>100%	
	100%—> x = 80%	

A. *There is 20 per cent decrease in cancer incidence*

■ **Geometrical average of percentages using either period**

$\sqrt{(50\% \times 200\%)} = \sqrt{(200\% \times 50\%)} = 100\%$

A. *Incidence of cancer remains unchanged*

Deadly Deception

Poverty

Poverty data globally is extremely poor and unreliable according to a recent paper by Sanjay Reddy and Thomas Pogge, economists from University of Columbia, New York. They have criticised the World Bank's World Development Report, a respected document on poverty and other social data, because of its use of an arbitrary international poverty line unrelated to any clear conception of what poverty is. It employs a misleading and inaccurate measure of purchasing power "equivalence" that creates serious and irreparable difficulties for international and inter-temporal comparison of income poverty. It extrapolates incorrectly from limited data and creates an appearance of precision. The systematic flaws introduced by these three factors lead to a large understatement of the extent of global income poverty and to correct inference that it has decline. Says Sanjay Reddy, "Such estimates give a skewed global picture. The discrepancy of under-estimating poverty is larger for poorer countries like India, especially for poorer states within India. All reports that have shown that poverty has declined and the gap between rich and poor has decreased is based on flawed data and need to be re-examined".[1]

Eminent economist Peter Svedberg of Stockholm University and author of *Poverty and Undernutrition: Theory, Measurement and Policy* (Oxford University Press, 2002) has severely criticised the many incorrect measures and yardsticks used by influential organisations like the Food and Agriculture Organisation. Data from such organisations has influenced food, hunger and nutrition policies and programmes in countries like India.[2]

Apart from international agencies like the United Nations and the World Bank, information on poverty in India is also estimated by national agencies like National Statistical and Survey Organisation (NSSO), Central Statistical Organisation (CSO) and Ministry of Rural Development, using different parameters. But here too the numbers and data are often flawed. Poverty is defined by income earned over a period of time. Most poor people however still subsist by making a living by extracting food and other items from forests, rivers and other sources. How does one account for people who live in non-monetised economies? How many such people access daily needs from these sources? How many of them are malnourished, vulnerable to diseases, or have access to health services? This essential information is not available to policy makers because it is never recorded.

A number of projects aimed at targeting poverty rely on information provided by these agencies. However, if these numbers themselves do not project a true picture of the nature and extent of poverty, any intervention that bases its objectives on these numbers is bound to fail.

Malaria

Malaria is a classic example of how the largest disease control programme in the developing world has been executed for over 40 years in the absence of data and quality information. According to the data provided by the National Anti Malaria Programme (NAMP), two to three million cases of malaria are reported every year. The World Health Organisation's South East Asia Regional Office (WHO-SEARO) estimates that there are 15 million cases and 19,500 deaths in India annually, five times more than governmental estimates. This problem of unreliable information about malaria is not restricted to India. Globally, malaria incidence figures remain speculative. As in India, Thailand and Brazil have a fairly good surveillance system, yet only half the clinical cases are reported. A study suggests that figures from Africa represent only about 5 to 10 per cent of the total prevalence. The WHO estimates that the figures could be greater by as much as three-fold.

Depending on numbers for the control of malaria creates other problems too. The Annual Parasite Index (API) is a measure of the malarial parasite that is present in the bloodstream of a population. It is an indicator of the persistence of the malarial pathogen in the human blood across seasons. API figures reflect how many

carriers of malaria exist in a community. Once this is determined for a large population, susceptible population can be identified. However, in case of a large management unit like a city or a district, if API varies widely in different pockets, pockets with high API get averaged out with pockets with low API. Areas of potential outbreak thus remain unidentified.

A large number of malaria cases are not reported; physicians prescribe anti-malaria regimen without blood tests; and private practitioners keep no records at all. Hence a large number of cases remain unreported. Procedures to gather data for grassroots workers are too arduous (see box: *Counting conundrum*).

AIDS

Ever wondered how many AIDS sufferers are there in India? If conservative politicians are to be believed, AIDS epidemic will not spread among the morally upright people of India. If non-governmental organisations (NGOs) and international agencies are to believed then the situation is at crisis point. With both sides throwing unrealistic numbers, millions of dollars have been wasted and precious time lost because no concrete data is available. This is not unique to India. It is fashionable to invest in AIDS for donors, who often clamour to assist countries and institutions in developing countries (see box: *Questioning priorities*).

On August 8, 2000 the Ministry of Health and Family Welfare and its nodal agency for managing the AIDS programme — the National AIDS Control Organisation (NACO) — criticised the Joint United Nations Programme on HIV/AIDS (UNAIDS) — for what it says are "exaggerated" figures of HIV-infected people in the country. With increasing pressure from the parliament, the then health minister, C P Thakur accused UN agencies of mis-reporting facts and creating confusion. "I am at a loss to understand how there can be so many different estimates by different UN agencies," an anguished Thakur told reporters at a press conference. Thakur said the NACO, which is supervised by his ministry, generates epidemiological data from field studies and it would be "advisable" for UN agencies to use these figures.

The government's main objection was to the figures in the latest UNAIDS report on the global HIV/AIDS epidemic, which show that 310,000 Indians died of AIDS in India in 1999. However, the report did not explain the source of the figure. Six years earlier, NACO had officially questioned the basis on which UNAIDS calculated that India then had 1.75 million people infected with the AIDS virus. Explaining how UNAIDS arrived at the figure for the number of Indians who died of AIDS in 1999, Gordon Alexander, a senior UNAIDS official in India said. "We arrived at the number of 3.1 million using an internationally accepted model based on experience in various parts of the world." However, because there are huge differences in the assumed parameters, to begin with, the idea of extrapolating and applying different basal conditions in 'universal models' to a 'specific country' is questionable. The numbers that thus would be arrived at would be unreliable. According to Alexander, while there was room for discussion on the figures, the idea was to "emphasise the need for prevention and support and a care system for HIV patients."

Official Indian estimates for the year put the number of AIDS deaths to a modest 11,000, though some experts have questioned the reliability of this figure too. The health minister admitted that these were projections. "We have to develop a proper model for estimation of AIDS deaths based on the number of infections in the country," he said. "It is not always easy to get actual reports on deaths as the cause of death is always recorded as due to opportunistic infections like tuberculosis, meningitis, pneumonia etc."

About the number of estimated cases of AIDS, NACO said that there were as many as 3.5 million reported HIV infection cases in the country. However, NACO's former director Prasada Rao denied that figure and attributed it to a "typographical error." If India did have the hundred of thousands of HIV-infected people as estimated, there should have been many more cases of people afflicted with diseases that mark the final phase of full-blown AIDS. Rao said there was no evidence of this happening anywhere in India.

Some public health groups have an explanation for the confusion over AIDS statistics. According to Purshottaman Mullolli of the Joint Action Council (JAC), the "conflicting statistics" could be "attributed to... a deep conspiracy to inflate figures in order to justify the expending of all too readily available loans from the World Bank." An umbrella group of NGOs working in the areas of human rights and HIV, the JAC has campaigned against a NACO programme that targets so-called high-risk groups, leading to their social ostracisation.

Counting conundrum

Cumbersome reporting procedures lead to misreporting. The operational manual for the malaria action programme, published by the National Malaria Eradication Programme (NMEP), New Delhi reveals the complexity of these procedures. It provides broad guidelines for the different tiers of workers involved in malaria control for collecting data. Different forms need to be filled in by all the multipurpose workers (MPW), surveillance workers, health inspectors, technicians, zonal and district malaria officers. The forms cover the numbers of case, and examinations, family health registers, tour journal, monthly reports, positive and remedial steps taken, survey reports, spraying report, fever treatment depot forms etc. A separate set of forms is used for urban areas (which is covered under the Urban Malaria Scheme). In case of an epidemic, consequent follow-up reports are also sent in different proformas, making the entire process of reporting very tedious. Most reports are sent from the state office to the central office every six months. In case of an outbreak in a remote area such as villages in Assam or Orissa, a report takes anytime between a week to a fortnight to reach the National Anti Malaria Programme (NAMP) in Delhi. By this time, the outbreak becomes an epidemic.

Source: Directorate of National Malaria Eradication Programme 1995, *Operational Manual for Malaria Action Programme (MAP)*, Ministry of Health and Family Welfare, New Delhi

"The fact is that far from alleviating problems, a scare is being created in the country," he said. This has led to the import of expensive AIDS-related medical equipment even as basic health services in the country are starved of essential supplies, he added.

Two years after this episode, NACO, UNAIDS, and host of other programmes that run in the country still lack information on the number of people that suffer from AIDS in India. NACO has proposed to strengthen its annual National Sentinel Surveillance Survey by including sexually transmitted disease clinics, antenatal clinics, intravenous drug users sites and homosexual sites.

Earlier this year, the health ministry said there were 3.97 million people infected with the virus that could lead to AIDS. The figures, derived from a report by the ministry's Sentinel Surveillance Survey, said the spread of the virus had been contained. However a report released by the Futures Group International for USAID says the cumulative new HIV cases for 2000-2025 in India range from 30 million (mild epidemic) to 140 million (severe epidemic).[3] Health minister Shatrughan Sinha has been quick to dismiss such figures. Especially with more funds coming in from the Bill and Melinda Gates Foundation giving NGOs more reasons to rev up their strident attack.

Statistics is a weapon in political battles over social problems like AIDS. Advocates take different positions and use numbers to make their points. It is common to hear a debate with contradictory statements – "It's a big problem!," "No, it's not!". The debate continues.

Cancer

Yet another compelling evidence of how the government plays with statistics is seen in the data on cancer released by Indian Council for Medical Research (ICMR) in November 2001. The National Cancer Control Programme (NCCP) says that 700,000 new cases of cancer are detected each year and around 300,000 people die. It predicts that more than 1.4 million people will be suffering from cancer by the year 2026, listing environmental conditions as one of the most important reasons of the prevalence of cancer in the present era. In 1965, the K N Rao Cancer Assessment Committee had recommended the establishment of a National Cancer Registry Programme (NRCP), which would provide the mortality and morbidity data and help study the distribution of cancer in different parts of India. It was only in 1972, 17 years after its recommendation that NRCP was set up. There are two main types of cancer registries in the country — the Population Based Cancer Registry (PBCR) that provides information about the disease in an area and the Hospital Based Cancer Registry (HBCR) that provides information about the stage at which the patient enlists in a hospital and the treatment that is administered. It would be safe to assume that the data available on cancer would be updated, concise and precise. Unfortunately that is not the case. The last report that was released from the ICMR's stable was in 1992 and it contained 13-year-old data.

This kind of data is certainly not in a position to aid the government in devising prevention strategies.[4] The ICMR cancer registry suggests that cancer is rising in India, but the capacity of health facilities in government hospitals is sufficient to meet the increasing numbers. If this is so, then why is it that the number private cancer hospitals have increased from 11 in 1990 to 42 in 2001?[5]

Death, birth and other things

Roughly, how many people die in India every year? The Registrar General of India that documents the numbers of deaths in hospitals or those reported to municipal offices provides the only authentic record. Unreported deaths never make it to the final list. Yet figures for death and birth rates are projected and guesstimates and calculated based on decadal averages. The number of actual deaths in epidemics is not known.

Often people themselves over-report deaths and disease. An interesting anecdote has been mentioned in P Sainath's seminal book, *Everybody loves a good drought*. In a village called Bansajal, in Sarguja district of Chattisgarh, the total number of deaths from all causes was eight as against the reported figure of 25. On being questioned, the *sarpanch* (village head) responded, "Unless we have news of people dying like flies, we don't get a single hand pump". In the absence of actual data, this kind of tactics brings relief but shifts the focus from the real problem.[6]

System Error

The Ministry of Statistics and Programme Implementation (MOSPI) is responsible for gathering data from the grassroots and compiling them for

Questioning priorities

AIDS is huge political issue, both in India and globally. Donors clamour to take up AIDS programmes in politically important countries and regions. Take the case of funding the AIDS programme in the newly liberated East Timor. Initially many donors expressed interest to set up the country's AIDS programme. It has sparked a public health debate as many health specialists question whether donors are too focussed on combating HIV/AIDS while neglecting more basic needs in the impoverished country. "It makes much more sense for donors to concentrate on bread and butter issues" such as reducing infant and maternal and expanding immunisation, says one doctor in Dili. According to UN officials, so far only seven known AIDS cases within East Timor's 779,000 people has been detected. Meanwhile the US Agency for International Development (USAID) and Australian Agency for International Development Aid (AusAID) have developed comprehensive programmes, investing in US $2 million and US $590,000 respectively.

"We know it's extremely important to pay attention to the epidemic in the early stages" says a USAID spokesman. Adds a spokesman from AusAID "There's fair chance that the figure of seven is an underestimate." Yet with no reliable data, consultants are already rushing ahead to devise elaborate programmes. "The cart is very much before the horse at this stage," says the Dili doctor.

Source: Anon 2002, Timor's Health Priorities Questioned, Intelligence, *Far Eastern Economic Review*, July 25, p 8.

various ministries. The Central Statistical Organisation (CSO) coordinates and lays down norms and standards for statistics and data collection. It also provides grants to various non-governmental organisations for undertaking research and surveys. The National Statistical Survey Organisation (NSSO) conducts economic census surveys. The NSSO has a specialised Survey Design and Research Division (SDRD) and a Field Operations Division (FOD).[7]

At the national level, the Central Bureau of Health Intelligence (CBHI), under the Directorate General of Health Services (DGHS), within the Ministry of Health and Family Welfare, is the sole organisation, which deals with the collection, compilation, analysis and dissemination of the information on health conditions in the country. It covers various aspects of health including health status, health resources, utilisation of the health facilities etc. It produces the *Health Information of India*, a compilation of data from the Registrar Generals Office's, NSO, NFHS, CSO, and reproductive and child health surveys. Apart from these inputs, it compiles reports that it has received on various diseases and health infrastructure figures from the states. The main problem with the *Health Information of India* is that all it only presents is data from government hospitals. Private hospitals that cater to 60 per cent of India's urban demands and about 40 per cent of the rural needs are not covered. Though private hospitals need to report epidemics and outbreaks of at least 16 notifiable diseases under the state law, very few outbreaks are ever reported by private hospitals. These diseases include tuberculosis, cholera, diarrhoea, malaria, rabies and other infectious and communicable diseases. In Mumbai city for example, when leptospirosis broke out in 2000 and 2001, patients went first to private clinics, which had never encountered a case of the disease earlier. As a result they treated patients for malaria, which led to many deaths. Had the municipal body been notified of this, an epidemic could have been prevented.

Although every ministry and department and their specialised agencies collect data, very little meaningful data on the overall picture exists. The problem in India's statistical system is a combination of data frauds, poor statistical knowledge and lack of political will to report the true picture. The crux of the problem is that data is called for only when new programmes are being proposed and old one's renegotiated. Since most programmes like malaria, tuberculosis and AIDS have either been there for too long or are assured sustained funding, there is little or no pressure from decision-makers for acquiring good quality data that would reflect ground realities. Also statisticians have not evolved methods to correlate trends between demographic, social, health and environment variables. Paying attention to details in statistics and understanding actually what is being written could help in understanding them better (see box: *Clearing the numerical fog*).

Clearing the numerical fog

How solid is the statistical support for research reports, news items, or political assertions? Often, not. Here are a few tips on how to cut through the numerical fog. While reading statistics ask questions and look out for conscious biases.

QUESTIONS TO ASK WHILE READING STATISTICS

- Who is the author? What is the source of the report?
- What is the basis of this information?
- What's missing?
- Is there a qualitative/quantitative check done?
- Does the study present any review of regional/global data or similar studies by other organisations?

THINGS TO WATCH OUT FOR WHILE READING STATISTICS

- Are the questions being asked relevant?
- Is the source of data reliable?
- Is all the data reported?
- Is the data presented in context and interpreted correctly?
- Are accepted statistical procedures and techniques employed?

In all states, at least 24 registers are maintained by a sub-centre (the smallest health unit in a district). For the grassroots workers the rigmarole of reporting the same data to different authorities in different sections and departments takes its toll. Hence there is a lot of parallel reporting of the same data. Often these grassroots workers are not even informed of project status. In some cases reports continue to come into state offices even though the programme has ended many years ago. In Maharashtra, the state health officials noticed this problem and in the early 1990s devised a comprehensive 16 page format for the sub-centre to report to the district and state office.

Department of Corrections

The problem arises in the way in which programmes and policies are designed in the absence of good data. All health programmes (except infectious epidemics) are target driven. So without knowing how large the problem is, targets and achievement indicators are set. Often a disease may be absent locally but yet work and effort made by the sub-centre and PHC needs to be shown. Take the case of tuberculosis. Policy makers thought that there could be no cooking of data because the treatment protocol involves close monitoring and effort from the health facility. Yet, the health centres need to show a designated number of people in a population. The health workers conduct X-ray examination of lungs, which may or may not be the conclusive tests for TB. In order to meet targets, even non-TB patients are accounted for as TB patients. In the case of leprosy any pale or non-sensitive patch of skin is treated for leprosy. In many states, there is an unwritten rule of not mentioning malaria and meningitis in any report. All these are termed as "fevers". These remain ignored and could arise from any cause like malnutrition, tetanus and heat stress. Health officials can be pulled up for malaria and meningitis deaths but not fever deaths. In Orissa, Chattisgarh and Bihar it is obvious that most "fever" cases are malaria and some meningitis cases. In a recent case in Thane, 20 tribal people died due to malnourishment and the district health authorities conveniently called these deaths as "fever" deaths.[8]

States too have their limitations. At one end, structural changes and conditionalities imposed by donors like the World Bank has frozen new recruitments and is asking state governments to reduce their large workforce. At another level, programmes have failed because reduced workfroce meant job cuts of grassroots workers which in turn has reduced programme effectiveness. Take the example of the World Bank sponsored Enhanced Malaria Control Programme (EMCP).[9] It has suffered in meeting its objectives because in many critical areas, workforce was extremely limited or even absent.

Statistics and data are meaningful only if they are produced and reported, acted upon at the right time. Most data that is reported takes an extremely long time to pass from one desk to any desk, from one office to another, where files make tortuous journeys from district to state to the central offices. Time lag is often several years. How much can one rely upon this data is all a big question mark. Data is presented in the most unintelligent manner, often without any crosschecking and with absolutely no analysis. The Central Bureau of Health Intelligence depends upon the states to give them reports. Not all states send their reports on time. The CBHI seldom crosschecks with state offices, though states often questions district level data in case a certain anomaly is noticed.

All that matters in generating good meaningful data is who is collecting the data, who is using it and how well is it leading into programme strategies. If more immediate data like epidemics, especially those that are expected to occur in a region during a specific season are reported more intensively during a certain period, a better picture on the outbreaks can emerge and more prompt reporting can be made. The problem with outbreaks and epidemics is that they follow the usual course of reporting and lack absolutely any urgency in an emergency situation. In the recent Japanese encephalitis epidemic in Assam a report generated from the local Malaria Research Centre took more than 10 days before any assistance from the Centre could be sent.[10] In Bangladesh, the Matlab programme, a community-based maternity-care delivery system, has been conducting long term population based assessments on diarrhoeal diseases found that on an average 3 per thousand people suffer from cholera and in peak season 9 per thousand contract the disease. This would mean that annually at least 300,000 people would suffer from cholera in Bangladesh alone. Yet the annual incidence report for June to August by the Bangladesh health authorities to the Weekly Epidemiological Record and Disease Outbreak News published by the WHO was zero cases of cholera.[11,12]

Long-term programmes like TB, leprosy and immunisation programmes need to look at trends, while the combination of short-term and long-term assessment need to assess the overall demographic picture. Based on this health facilities and infrastructure and budget need to be designed.

Strategies can evolve only when data is presented into information to forecast scenarios, based on which decision can be taken and programmes can be committed. The real shame is that despite famed statisticians and econometricians who set up institutes and chaired committees, they have failed to inspire bureaucrats, make simple formulae and workable methods for grassroots level workers. The Planning Commission, boasting of the finest mathematical minds, today is a organisation bungling outdated data, based on which it designs programmes and policies for ministries. The National Human Development Report-2001 released earlier this year is a prime example of regurgitating old meaningless data and basing policies upon it.[13] With little or no data, funding and investment priorities get skewed.

Simply put, what cannot be measured cannot be accounted for, what cannot be accounted cannot be managed, and what is not managed cannot be controlled. Stronger collaborations across ministries can be made to do comprehensive assessments on poverty, land holding, income, food scarcity, nutrition etc., based on which vulnerable areas and populations can be mapped. Several opportunities to re-strategise the Indian health system exist with the government and civil society. The proposed Infectious Diseases Information Surveillance project by the World Bank can revamp data collection and statistics reporting with respect to infectious diseases.[14] The AIDS programme is still in its infancy can resolve methods of estimating AIDS in India. Participation from civil society and communities can improve quality of data.

So right from birth, sickness, productivity and growth to death, almost everything is a guesstimate.

How good data helps

- **Improves efficiency in planning and control**
- **Streamlines budget allocation**
- **Gives a baseline for future planning**
- **Costs only 5-7 per cent of project budget**
- **Helps prioritise vulnerable sections within the target population**
- **Assists in integrating programmes with common goals**

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AMIT SHANKER / CSE

COUNTERFEIT MEDICINES

Enough to make you sick

Fake medicines are concoctions with wrong ingredients or incorrect quantities of active ingredients or products without any active ingredients at all

It is virtually impossible to differentiate between real and counterfeit medicines, given the current institutional capacity

Nearly 10 per cent of the global pharmaceutical commerce is attributed to fake drugs

Combating this menace should be a shared responsibility

Devinder Singh of Patiala is an angry man. His 14-year old son Amarpreet, suffers from Wilson's Disease, which was diagnosed in 1997. Prior to this, Amarpreet was an active boy who loved playing football. Wilson's disease is a genetic disorder wherein the intestines absorb more copper and accumulate it in the liver. The accumulation of copper causes its release directly into the bloodstream, which poisons the whole body. This damages the kidneys, brain, and eyes and ultimately causes death.

The first symptom that occurred in Amarpreet's case was cramping of fingers. That was followed by loss in speech and problem in walking, eventually resulting into paralysis. On diagnosis, Penicillamine capsules were prescribed (that were marketed by Biochemie Austria) by Christian Medical College (CMC) Hospital in Vellore. Amarpreet recovered completely and he resumed his usual activities right from walking, normal speech and even attending school. However, a follow-up visit to the doctor turned into a nightmare for the family.

In June 1999, Amarpreet was prescribed Cilamin 250 capsule, the Indian Penicillamine capsule manufactured and marketed by M/s Panacea Biotec Ltd. The medicine was provided by the CMC pharmacy. The quality of the medicine was never questioned, nor did it occur to anybody that the medicine would cause a relapse of the disease. It was only when Amarpreet's condition started deteriorating after taking these medicines, and he was taken to CMC again, that the doctors questioned the authenticity of the medicines given (see photo: *Amarpreet Singh).*

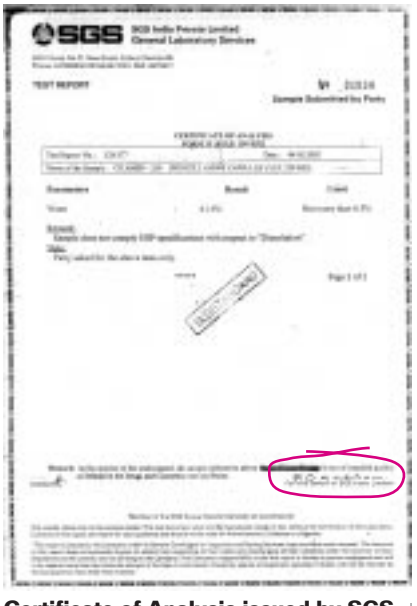
It took Devinder Singh two long years merely to get the medicine tested and prove its substandard quality. He was turned down by a number of reputed laboratories. Société Générale de Surveillance (SGS) India (part of the globally reputed chain of testing laboratory) conducted this test only after Singh contacted the SGS Geneva office. A certificate of analysis from SGS India in Chennai dated February 4, 2002 clearly indicates the substandard quality of the medicine (see: *Certificates of analysis issued by SGS*).

During this long struggle of pleading in courts and demanding justice, Amarpreet has already crossed the two-year "window period" for recovery from the disease. Devinder Singh's case has now been accepted as a public interest litigation case and hearings have commenced. In a country where human life has minimal value, Devinder's two-year struggle for justice is no surprise. The laboratories made every attempt to delay the tests and the results. Reporting of grievances to the Drug Controller and the Chief Vigilance Officer led nowhere.

Singh researched and managed to get the support of two more patients suffering from Wilson's disease, where spurious drugs caused further deterioration of their health. One was the case of S P Arora's son, Rajesh Arora, from Rajpura in Punjab, who at the age of

DEVINDER SINGH

A paralysed Amarpreet Singh



Certificate of Analysis issued by SGS to Devinder Singh showing that the drug was 'not of standard quality.'

32 years old, weighed only 30 kilogrammes and had his spinal cord curled up. He would easily slip underneath the space between the front and back seats of a Maruti 800 (see photograph: *Rajesh Arora, p10).* Rajesh died in July 2002. In Patiala, Anoop Singh's son who too suffered from Wilson's disease died in 1998 due to consumption of the Cilamin capsules.

Several such cases occur every day in India. Many go unreported and unnoticed.

Fundamentals of counterfeiting drugs

Counterfeit drugs or fake medicines are concoctions with wrong ingredients or incorrect quantities of active ingredients or products without any active ingredients at all. Products with incorrect quantities of ingredients or expired medicines may initiate allergic reactions in patients and cause harmful interactions with other administered drugs. Products with the wrong ingredients are toxic and harmful, often causing death. A review by the World Health Organisation (WHO) titled "Global trade in counterfeit drugs," found that 60 per cent of fake drugs had no active ingredients, 16 per cent had the incorrect ingredients and 17 per cent had the incorrect amount.[1]

What makes the case of counterfeit drugs so dangerous is that it is virtually impossible to differentiate between real and counterfeit medicines. J N Pande, head of medicine, All India Institute of Medical Sciences (AIIMS), New Delhi says, "The most worrying aspect is that the majority of the fake drugs are in the fast moving category. They may contain the same salts (as the original) but the purity and quantity is lower. As a result, patients consume more drugs to get results." Since doctors, patients, and other medical staff fail to recognise fake medicines, they do not doubt the authenticity of the pills and tablets, and when these medicines fail to cure, some other causes are held responsible. According to Ravi Kant, Assistant Drug Controller of Delhi, "People have begun to use good quality paper and dyes. The foils on tablets and the paper wrapping used for packaging, all look well made. All in all there is no give away on this stuff."

Licensed to kill

Today the growing fake drug market is no longer restricted to producing tablets and capsules. It has now graduated to the production of expensive and sophisticated injections, expensive tablets and inhalers. The procedure is expensive and complicated but raking in profits is easy. Legal controls and punitive measures are few, which only encourage manufacturing of spurious drugs. In February 2002, fake drugs worth Rs 1 crore were seized from Jagatpuri in East Delhi. The drugs included 10,000 vials of Netromycin, a very expensive antibiotic used for life saving purposes.[2]

In July 2001 drug inspectors along with members of the Delhi Medical Association (DMA) collected 53 samples from different locations in and around Bhagirath Place. It is a wholesale market notorious for its second hand drugs and scrap market in Delhi. Most of these samples belonged to well-known companies such as Pfizer, Novartis, Lupin, Dabur, and Glaxo. At least nine samples had no medical ingredient and four had it in negligible amounts.[3] Whereas in 1997 only 198 pharmaceutical distributors were based around Bhagirath Place, by 2001, the number had shot up to 693.[4]

Cough expectorant manufactured by a company in Gurgaon was found to be contaminated with diethylene glycol; 36 children from 2 months to 6 years of age who were admitted to two hospitals in Delhi between 1 April and 9 June 1998 developed high fever and kidney failure and 33 children died in three days.[5] A number of such stories appear in the lost corners in the city newspapers that receive nothing more than a glance.

Bihar and Uttar Pradesh are the two states where the problem of counterfeit medicines prevails in the form of a huge money-making industry. Recently in October 2002 in Patna, the alleged spurious drug racket kingpin Kumar Sahu was arrested. Yet the State Drug Control Office has not cancelled the licence of Sahu's medicine shop "Subh Laxmi Agency." The Bihar Drug Control Administration has no infrastructure to test the samples that they collected from Sahu's shop nor is there any facility available at the central government laboratory at Ghaziabad.[6] The trade thus, continues right under the very nose of the drug control authorities. In a small residential area just outside Hyderabad, there are more than 200 pharmaceutical companies. Some of these are publicly traded at the Indian Stock Exchange. The operations of these 'companies' can range from a garden shed to a warehouse. "In the next 10 years, spurious drugs will be the single biggest problem" in public health, says Ranjit

Rajesh Arora on his deathbed, July 2002 S P ARORA

Roychoudhury, president of the Delhi Society for the Promotion of the Use of Rational Drugs.

But why do counterfeit medicines persist? Is there an inherent undersupply of medicines, or is there too much demand? Are patients and buyers too ignorant to check for differences between fake and real thing? Or is the government and its agencies too weak to control the entry of counterfeit drugs? The truth lies in them all, but the government and its agencies — the Drug Controller Authority (DCA) under the Ministry of Health and Family Welfare — have certainly a more significant role to play.

Global menace

India is not the only country suffering from epidemic of counterfeit medicines. Globally, the trade of counterfeit drugs is conservatively valued at 20 billion dollars and is one of the fastest growing grey economies — after prostitution, narcotics, terrorism and arms trade.[7] Nearly 10 per cent of the global pharmaceutical commerce is attributed to fake drugs. The most recent examples of fake drugs include addition of wheat flour in the manufacturing of contraceptive pills and the adding of industrial solvent during the making of paracetamol syrup. Neomycin eye drops and meningococcal vaccine has been found to contain tap water.[8] Counterfeit drugs lead to tragedies. In 1995, in the Philippines, a multinational drug company discovered counterfeit asthma inhalers. In Nigeria, fake drugs killed 2500 people in 1995 when they were infected with meningitis. Dora Akunyili, director general of The National Agency for Food and Drug Administration (NAFDAC), the agency that safeguards food and drugs standards in Nigeria says, "The evil of fake drug is worse than malaria, HIV/AIDS and armed robbery put together. Whereas AIDS can be avoided, malaria can be prevented and armed robbers can kill a few at a time, fake drugs kill in thousands."[9]

Many people died in Cambodia in May 2000 from counterfeit drugs meant to treat malaria. The consumption of fake paracetamol that was prepared with glycerol contaminated with diethylene glycol — a toxic chemical used as anti-freeze — resulted in the death of 89 people in Haiti in 1995. Fake artesunate, widely present in South East Asia, is increasing the incidence of malaria in the region. A report published in *The Lancet* showed that fake artesunate in South East Asia ranged from 11 per cent in Thailand to 64 per cent in Vietnam.[10] In May 2001, Colombia's National Institute for the Supervision of Medications & Foods (Invima) discovered a thriving drug operation in Bosa, a poor neighbourhood of Bogotá and found that sale of fake drugs was as lucrative as the cocaine business of Latin America.[11]

In Russia, counterfeit drugs have increased ten times since 1998 and cover approximately seven per cent of the total market. Most of these drugs include antibiotics, insulin, and drugs for heart diseases. More than 60 per cent of the drugs sold are fake versions of Russian brands. An estimated loss of over $100 million occurs annually due to fake drugs.[12] The same is true for drugs for tuberculosis in east Europe, AIDS in Africa and Thailand, infectious diseases in South America and in the poorest regions of Africa.

The concerns in the USA and the richer European countries are more in the area of counterfeit lifestyle drugs. Following transcript from a hearing in Washington shows their efforts against it:

"On May 17th, 2002 seven individuals and five companies were indicted by a New York grand jury and charged with manufacturing counterfeit Viagra and selling it over the Internet. The investigation covered a 17-month period during which investigators purchased 28,000 bogus Viagra tablets from China and India. Wholesalers in Hong Kong and resellers in Florida, Nevada, and Colorado operate hand-in-glove. The wholesalers were also linked with a counterfeit product that was found in three cities in China. Another aspect of this case involved Girith Vishwanath of Benzo Chemical industry in India who sold a tablet-punching machine that weighed 1,500 pounds to undercover operators and offered a constant supply of tablets blend for his customers to manufacture his own Viagra. Those indicted bragged that they could deliver 2.5 million counterfeit Viagra tablets to New York each month. Ingenious criminals were able to import counterfeit medicine notwithstanding the current regulations and border controls. Any lessening of those regulations and controls will expose American consumers to an unacceptable level of risk."[13]

India is at the forefront of exporting spurious drugs too. In September 2000, the Delhi Police arrested four Uzbek women and an Indian for possessing 800 kilogrammes of spurious drugs valued at Rs 2 million. Supply of the spurious drugs was traced to UNISUL Private Limited, located at Sonepat in Uttar Pradesh

(UP). On reaching Delhi, these medicines were stored in different godowns in Delhi at Nangli Devat village and Aaram Bagh. The four Uzbek women had come to India to sell Chinese silk and later on tied up with the local suppliers for dealing in spurious drugs.[14]

In Vietnam and Myanmar, according to WHO more than 40 per cent of antibiotics that are imported from India and as much as 11 per cent of antibiotics in the market are fake or substandard.[15] In Africa, especially Nigeria, Kenya, Tanzania and their neighbouring countries are severely affected by the invasion of counterfeit drugs from India and the Indian subcontinent. Raid at an illegal warehouse in Nigeria, revealed alleged revalidating of fake Actifed and Menstrogen tablets with forged labels and packets containing the names of Indian firms as manufacturers of the sub-standard drugs.[16] In July 2000, Italian authorities seized two tons of raw materials for counterfeit drugs transported from India and China for packaging in Europe and sale in North and South America. In addition, about 5 to-8 per cent of bulk drugs shipped in the US either are counterfeit, unapproved, or substandard.

Flavine International, a USA based pharmaceutical firm admitted in 1996 that it had imported nine counterfeit drugs since years. One of them included gentamicin, a common antibiotic. The Food and Drugs Administration (FDA), Maryland, USA, believes that counterfeit gentamicin may have been responsible for as many as 66 deaths in the US and hundreds of severe reactions. The FDA also has admitted to having little or no information concerning about 4,600 foreign drug manufacturers that have shipped products to the US since October 1997, including 409 in India. The 1996 internal memo of the FDA states that it literally has no control over the fake drugs that enter the US. It warns, "These drugs can reach anyone including the President."[17]

What is lacking

There is a lack of public awareness about counterfeit medicines and their presence in the market. Medicines of substandard quality that do not cure a disease or that cause side effects are seldom reported It is a difficult task to track the presence of counterfeit drugs at the national and global levels. Nonetheless, regional surveys are conducted and independent information is used for reporting to the local police and other authorities. Such studies could help in raising the public awareness. This may be crucial for the pharmaceutical companies where they could utilise the information to investigate the misuse of their medicine labels and devise measures to curb fraud practices.

WHO has recognised counterfeit medicines to be an underestimated danger, especially affecting the developing countries. Lembit Rago, head of drug quality at WHO says, "There is no single country which can be called a safe haven, where there is no counterfeiting. It's a global problem and it needs global action."[18]

Multinational pharmaceutical companies are now determined to fight the counterfeiting of medicines. The companies are conducting a check of their products in the industrialised countries. They follow the path that the medicines go from the manufacturer to the pharmacist eventually to the consumers. They organise educational campaigns for medical staff and issue press releases for raising awareness about counterfeiting drugs. However, currently, the companies in developing countries do not have adequate resources to follow suit.

According to the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), most countries lack strict rules and regulations regarding counterfeiting drugs. "The risk of punishment appear more theoretical than real in many countries," says an IFPMA report," judging by the relatively small number of successful prosecutions which are reported."[19]

In 1990 Glaxo Wellcome, Bayer and Bristol-Myers Squibb established the International Counterfeiting Action Programme (ICAP). In 1999, with more members (currently there are 15) ICAP became the Pharmaceutical Security Institute (PSI), that represented member companies and conducted investigations. However, there is one serious flaw — secrecy within the industry. Companies do not disclose information that could damage their reputation. Unfortunately, that makes the struggle against counterfeiting more difficult. Counterfeiting can kill eventually damaging the sales and reputation of the company.[20]

There are many reasons for counterfeiting practices, particularly medicines. Fake drugs are easy to manufacture and easily undetectable. Good quality packaging is very important for the counterfeiters to succeed. A major hurdle is surpassed once a workroom for packaging the medicines is located, because mere visual inspection of the medicine cannot detect a problem. Packaging manufacturers and printers do not fall under the scope of medicinal legislation and associated inspection requirements; hence go scot-free. The process in which a patient buys a medicine by itself makes the patient vulnerable. The doctor prescribes the product but in most cases, never sees it. The pharmacist purchases the product from the wholesaler merely by visually inspection and commonly purchases products from more than one wholesaler. This raises the probability of aggravation of the situation.

A peculiar situation in India is that many chemists operate without a proper license. Ashwini Kumar, the Incharge Drug Controller General India, says that each chemist shop is required to be operated by a person who has a diploma in pharmacy. But who checks this? In a study sponsored by the National Pharmaceutical Pricing Authority (NPAA), a government body that helps control drugs in the country it was found that although consumers are aware of spurious drugs, they are at a total loss regarding the reporting of counterfeiting to appropriate officials and getting the medicines tested. Most of the times the medicines go undetected and unreported. "The NPAA", says L M Kaushal, the Deputy Director (Cost)," cannot regulate the spurious drugs market in any way. It is the cheap cost of these fake drugs that attract the consumers in the first place. And since they are unable to differentiate the real from the fake, it becomes easier to sell the counterfeit medicines over the counter."

Even the legal scenario is no better. Says Nasser Kabir, legal advisor to a leading newspaper in India, "The law prima facie is not well equipped to take care of defaulters most of the provisions are archaic and need urgent amendment." Sanjeev Chaswal, a Delhi based lawyer puts forth the fact that majority of the culprits are small drug manufacturers with a turnover of Rs 20-50 million, employing no more than 20 people. These small firms have licences to make generic drugs but since that does not give them much earning, they turn to manufacturing fake drugs. Most of the shanty factories are totally unregulated. In splitting up the process of manufacturing the counterfeit drug mafia is able to shroud its activities in secrecy. The tardy pace of the legal process in India, which causes cases to drag on for years, helps them in getting away with the crime. (see box: *Legal fakes*)

Bringing about change

Counterfeit drugs today form a part of an organised crime. Corruption, business interests of unscrupulous politicians and unregulated pharmaceutical companies have led to the increase in this trade. To combat the incidence of counterfeit and substandard drugs, the governments need to strengthen their drug regulatory authorities and their powers to enforce drug laws and regulations. Every step in the counterfeiting of drugs, from the manufacture, import, export, distribution, and sale of counterfeit and substandard drugs should be prohibited by law as a serious criminal offence. The government should re-work the existing law and ensure that the offence is no longer a minor offence confined to the state drug controller suspending or cancelling the licences of medicine shops selling spurious drugs.

Drug registration in India needs to be strengthened to ensure that all drugs that are, domestically produced as well as those imported are assessed for safety, efficacy, and quality before they are available to the consumers. To achieve this, drug regulatory authorities should develop significant capacity and know-how. Political pressures prevent drug inspectors from investigating counterfeit and substandard drugs and prosecuting counterfeiters. Inspectors should be given the rights to enter manufacturing or packaging premises collect samples for tests, and not conduct sale of the drugs until they check the results of the tests.

Having sophisticated tools for investigating counterfeit medicines is required if any progress is to be made in curbing the menace of spurious drugs. The use of near-infrared spectroscopy (NIRS) for rapid, on-site and non-destructive identification of counterfeit pharmaceuticals has been well documented.[21] Upgradation of testing laboratories and training of scientific personnel in these laboratories for quick analysis of drug samples and the setting up of special courts to deal with summary trials would help control the entry of spurious and substandard drugs in the supply chain.

Organisation of Pharmaceutical Producers of India (OPPI) along with the IFPMA and the Pharmaceutical Security Institute (Geneva, Switzerland) is planning to set up an intelligence network to counter the counterfeit drugs trade. Glaxo is going in for holograms, special ink, printed/locked capsules, biocodes and embossing of tablets with a logo, explains P S Khanna, resident director of OPPI in Delhi. Many are also seeking the help of private detective agencies or using marketing staff to monitor the trade.

Major Indian pharmaceutical companies — Alembic, Cipla, Dr Reddy's Labs, Lupin, Nicholas Piramal,

Legal fakes

The Drugs and Cosmetic Act 1940 does not define "spurious". Section 9B & 17 deliberate more on drugs that are passed off as original drugs and are more in line with what intellectual property law deals with rather than criminal law. Spurious as defined by the Supreme Court in Chaitanya Kumar vs Sushila (AIR 1975 SC 1718,1721) means 1) not genuine, not proceeding from true source and 2) not Legitimate. This case was on conduct of elections and concerned with representation of peoples. Law lexicon defines spurious as above.

The law, which is in force, cannot be adequately implemented for lack of staff or want of proper facilities for analysing samples of drugs taken from manufacturers and traders. An adulterated or spurious drug may cause grievous hurt or death to a person– offences which are punishable under various section of the Indian Penal code (IPC), but it will be impossible to show/prove that the same offences were due to the use of spurious drugs.

Hence punishment to does dealing with spurious or fake medicines is hardly possible under the act. Under the present law, a person could be let off with simple imprisonment of two to three years with fine. According to Ajit Dangi, director-general of the Organisation of Pharmaceutical Producers of India (OPPI), "Under the Indian Drugs Act, a spurious drugs manufacturer can face an imprisonment for not less than 3 years and Rs 5,000 (about US $100) fine. However, unless foolproof evidence is gathered in coordination with the pharmaceutical industry, the Drugs Controller, and the police, it is difficult to root out the problem. "National Capital Territory (NCT) of Delhi does not even have an act of its own to deal with spurious drugs", says health minister A K Walia. Walia is of the opinion that any person found to be manufacturing and/or selling spurious drugs should be given imprisonment for life. He also wants the punishment to be made stringent for manufacture and/or sale of "sub-standard drug" from the existing jail term for one or two years to up to three years.

An expert committee set up in 2001under the Ministry of Health as recommended the amendment of Section 27 of the Drugs and Cosmetic Act penalty for contravention so as to incorporate the provisions of Section 320 and 326 of the IPC, which would make spurious drugs manufacturing and their sale a criminal offence.

At present, the drug control administration has neither the machinery nor the intent to nab the culprits who now form a very powerful syndicate of their own.

Ranbaxy, Sun Pharmaceutical and Wockhardt have joined hands to form the Indian Pharmaceutical Alliance (IPA) to look into the counterfeit trade. Their anti-piracy task force looks especially into complaints regarding counterfeit drugs.[22] The setting up of an inter-ministerial Standing Committee would also help check this burgeoning trade (see box: *New committee*).[23]

India's reputation as the hub of counterfeit drug exports may have a serious consequence to the industry in the future. The current practice of large industries contracting with small-scale units for smaller "jobs" indicates the limited capacity of the producers resulting into poor quality of the drug. Additionally, with no recall policy in the pharmaceutical sector, the drugs with expired data of use would persist in the market until they are bought out. Small-scale units that undertake production on a contractual basis from the large scale companies are more than willing to produce large quantities of medicines especially due to the insecurity business, and thereby their income.

Internally, DCA and pharma companies should monitor the movement of every batch of every drug. A chain of command that is monitored by the pharma company and strong punitive measures by DCA will ensure that fake drug markets are stamped out. A recent Supreme Court hearing in the case of Venu Veterinary Division, has ruled that a dealer in drugs and cosmetics could be prosecuted for selling spurious or substandard goods. This important hearing sets the distributor and manufacturer apart, with the Supreme Court stating that there is no prohibition in the law which states that a dealer cannot be prosecuted for sale of spurious medicines or cosmetics below the prescribed standard of quality without the manufacturer also being made a co-accused.[24] What is needed is more stringent laws like this to deal with the burgeoning counterfeit mafia trade.

Government is contemplating tightening the law against spurious drugs flooding the market and may bring a bill to amend the provisions of the existing laws for the purpose. "Law is there but it is not adequate. We must strengthen the law as spurious drug manufacturers are the real killers and antinationals, "Health Minister Shatrughan Sinha said. However, there are certain drawbacks in the existing law. If spurious drugs are caught, the onus to prove that the medicine did not belong to them lies with the manufacturers of genuine medicines," Sinha said.

One way to track the prevalence of counterfeit drugs is to define the points of entry of drugs into the market. Rigorous inspection and surveillance should be conducted in collaboration with customs and police to prevent and control smuggling. South Asian and Indian ports are notorious for exporting spurious drugs to Africa, Russia and South East Asia. Custom officials are not trained to distinguish between drugs, and therefore are incapable to prevent smuggling of counterfeit drugs. Combating counterfeit and substandard drugs at the national level is thus a shared responsibility involving the relevant government agencies, pharmaceutical manufacturers, distributors, health professionals, and the general public. Making them realise how their interests are threatened would help focusing their attention on the issue.

New committee

With a view to achieve better integration between the health policies and the industrial policies in the Pharmaceutical sector, the Drug Controller Authority of India proposes the setting up of an inter-ministerial Standing Committee. The committee will constitute the Ministry of Industry, Department of Chemicals and Petrochemicals with the Ministry of Health and Family Welfare and officials of the other departments like Bureau of Industrial Costs and Prices, Biotechnology, and Ministries of Commerce and Revenue as members. The Committee would oversee the following:

- **implementation of new measures and other related decisions such as revision of the National Formulary which would undertake scientific scrutiny of master formulae for manufacture of formulations**
- **strengthening of the institutional and statutory arrangements for enforcing quality control**
- **dissemination of information regarding safety and efficacy of drugs to medical and paramedical personnel**
- **centralisation of drug registration, rationalisation of formulations and monitoring of adverse effects of drugs.**

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PRODUCT WATCH

CSE

Return of the devil

Dangerous drugs like thalidomide that were banned for their toxicity have been re-incarnated to treat cancer and other diseases. Labelled as a "miracle drug", thalidomide was known to be an effective tranquilliser without any side effects. The drug was first synthesised by Ciba in 1953 to treat anxiety and morning sickness in pregnant women. Marketed as Distaval, the drug was banned in 1962 after scientists confirmed that it led to birth defects such as retardation and deformed limbs. More than 12,000 children in 46 countries had been affected by then, with only 8,000 of them surviving past the first year of life. The actual mechanism of how the drug worked remains a mystery .

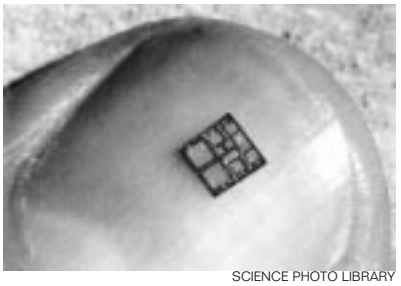
Despite its ban in 1962, thalidomide has been on restricted sales globally. It been prescribed for relief from painful lesions in leprosy, mouth and genital ulcers and cancer. Dabur India has acquired the rights to manufacture and market thalidomide to treat cancer and leprosy lesions. S Ganguly, senior clinical research scientist at Dabur India, Sahibabad office, mentions that extreme precaution is being taken to see that the drug is marketed to the right patient. It would be available only at cancer institutions and accessible for leprologists from suffering leprosy patients. The marketing is to be restricted to a few dealers who would be authorised to sell the drug and who will maintain detailed records to track the prescribing doctors and the patient alike. A 24-hour toll free help line will also be set up for patients

The marketing of thalidomide is going to be under close scrutiny by consumer watchdogs. One slip and the horror would well be repeated.

BRIEFS

Heavily chipped

A study led by Eric Williams and his team at the United Nations University in Tokyo has found that a 2 gramme microchip is equivalent to 1.6 kilogrammes of fossil fuel, 72 grammes of chemicals and 32 kilogrammes of water. Looking into all the chemicals including coal, which are involved in turning raw quartz into a 32 MB RAM microchip, the team found the chip manufacturing required more fuels and solvents because of its tiny size and the need to keep it free from dirt and dust. Making a typical car required only about twice its weight in fossil fuels. According to Eric Williams, "In order to produce one memory chip that weighs two grams, the total amount of materials and fossil fuels required to make that chip is 1,400 grams. That's 700 times the weight of the original chip." The environmental costs of manufacturing a chip thus far outweigh that of even making a car. With new advances in technology and changing of computers every two years, the environmental impact of owning a computer increases drastically.



SCIENCE PHOTO LIBRARY

The focus now has to shift from making chips that run on less power to manufacturing those that require less energy than it does at the present.

Mercurial tempers

Each mercury fever thermometer when broken or thrown away is a threat to health. The one-gram of mercury found in one thermometer is enough to pollute a 20-acre lake, says Michael Bender, Director of the Mercury Policy Project, USA.

Mercury is used in lamps, batteries and electrical equipment, as well as in thermometers and dental fillings. Concern over its presence in the atmosphere arises since mercury is known to cause permanent damage to the brain, nervous system and kidneys. Almost indestructible, mercury when put along with other waste into landfill sites, can easily seep through the groundwater and from there into rivers, lakes and the sea. It can also evaporate into the air, especially if the waste is incinerated.

Though mercury is produced naturally in rocks, soil and volcanoes, industrialisation has boosted up the production of this heavy metal almost three times. Almost 50 to 70 per cent of the 5,000 to 10,000 tonnes of mercury found in the atmosphere is due to human activities. In its evaporated form, mercury can travel for thousands of miles. Since it is know to accumulate in cold places high contamination levels of mercury are to be found in Arctic regions, and especially among fish and animals there. In water, mercury transforms naturally into methyl mercury, a highly toxic compound that gets absorbed by humans and animals. Because it then accumulates up the food chain sea fishes can accumulate large quantities of mercury in their tissue. Pregnant mothers and their fetuses are particularly sensitive to the effects of mercury. According to the Centres for Disease Control (CDC), Atlanta, USA, one-in-ten women of childbearing age have mercury levels in their bodies above what is considered protective for a developing fetus.

Threatened children

A study conducted by Joseph Laquatra, associate professor of design and environmental analysis in the New York State College of Human Ecology at Cornell, in the US, has found children belonging to lower socio-economic status more prone to threats from indoor air pollutants. Their houses have higher levels of radon, lead and mould than those occupied by higher income households. If these children then spend the rest of the day exposed to the same pollutants in a childcare facility, they are at a significantly higher risk for falling sick due to lead poisoning, cancer, asthma attacks and allergies. Studying 328 houses and 75 childcare facilities in six nonmetropolitan counties of New York State, homes of lower income residents were also found to contain

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higher levels of carbon monoxide. Lack of an effective ventilation fan further aggravates the pollutant level. These houses also had asbestos problems and presence of basement mould. Mould is a known trigger for allergies and asthma. Exposure to lead, asbestos, radon and carbon monoxide can lead to early death.

Cancer clusters

Factors like where a woman lives at birth and puberty may have an impact on her risk of developing breast cancer later. A study conducted by Jo Freudenheim, professor in the department of social and preventive medicine in the University of Buffalo's school of medicine and biomedical sciences, USA, finds that women who developed breast cancer were more likely to have lived closer together at birth and at their first menstruation than women who did not develop breast cancer. This suggests a possible linkage between breast cancer and early environmental exposure to potential carcinogens.

Identifying these places and exposures is one way of proving these linkages. In that respect, geographers and epidemiologists are working on a computerised mapping programme wherein details about residential data along with the distance between the surrounding environment comprising of steel mills, chemical factories, petrol pumps and toxic waste sites that have been in the existence between the two counties between 1918-1980 will be weighed against with the birth and menarche details of the women. This information will then be compared for women with or without cancer. Early data collected and calculated reveals the greatest clustering of cancer cases at the time of menarche. This could be because breast tissue may be more sensitive to environmental insults in childhood and that exposures early in life could increase the risk of breast cancer in adulthood.

Chernobyl's burden

CSE

On April 26 1986, the Chernobyl nuclear accident released vast amounts of radionuclides in the environment. Various studies conducted over the period of time have focussed on the increase of incidences of thyroid cancer and leukaemia in children. Evidence now suggests that rates of thyroid cancer in children have risen as a consequence of Chernobyl incident. The increase has been found to be the highest in children living close to the area of the incident, especially Belarus. For 8 days after the accident, the entire population of Belarus was exposed to Iodine 131. Iodine 131, when ingested, concentrates in the thyroid gland and can cause thyroid cancer. The level of iodine 131 surpassed permissible levels over 1,000 times. 170,000 children under 7 in the Chernobyl area received radiation doses high enough to cause thyroid cancer.

Although less than five cases of thyroid cancer in children were reported between 1986 and 1989, the number increased to 29 in 1990, 51 cases in 1991 and 62 in 1992. No such clear evidence has however been found in the case of leukaemia. A new disease in the form of **'Chernobyl AIDS'** has made its appearance wherein the radiation leads to the breakdown of the immune system, loss of hearing and the build up of fluid in children's heads.

Smoggy California

California is one of the smoggiest states of the USA. Tonnes of toxic emissions get released each year in California. These emissions include a cocktail of industrial and chemical solvents. This hazardous mixture can cause cancer, reproductive harm and neurological damage. Children are most vulnerable. With the amount of pollutants present in the air, a 18 year adolescent inhales enough contaminations to exceed the acceptable exposure level by almost hundred times.

B O O K R E V I E W

Where There Is No Data: Participatory Approaches To Veterinary Epidemiology In Pastoral Areas Of The Horn Of Africa·Andy Catley and Jeffrey Mariner·2002·IIED, London·pp 20.

An excellent issue paper published by the International Institute for Environment and Development (IIED), London. The increasing incidence of foot and mouth disease and other veterinary diseases sets the need for having hard data available so that realistic and affordable disease control strategies can be planned. The paper highlights various approaches to understanding participatory appraisal (PA) which aims to set at rest the many fears that veterinarians have about qualitative data being unreliable, invalid and difficult to incorporate into official disease information systems. The authors outline how participatory approaches and methods can be used in conducting various animal health surveys, impact assessment and evaluation studies and to develop disease control strategies. In the end, the paper also touches upon the problems encountered in using PA–the lack of sufficiently trained veterinarians. A comprehensively packaged paper on participatory approaches to veterinary epidemiology.

Children being more active inhale relatively more air than adults. Since their immune system is also yet to be developed, their cells are more vulnerable to attack by carcinogens. In Los Angeles alone, toxic air contaminants cause 720 cancer cases per million people annually. The recent report of the EPA clearly shows that diesel exhaust can cause cancer. The diesel health impact assessment report recently released recommends reduction of tailpipe emissions by requiring cleaner-burning engines and replacing diesel fuel with ultra-low sulphur content diesel. ``Overall, the evidence for a potential cancer hazard to humans resulting from chronic inhalation exposure to (diesel emissions) is persuasive," says the health impact report released by the EPA.

Heart risks

The September issue of *Circulation*: Journal of the American Heart Association reports on how polluted air is more harmful for those suffering from heart diseases. According to Juha Pekkanen, senior researcher at the National Public Health Institute, Unit of Environmental Epidemiology in Kuopio, Finland, people with heart disease are about three times more likely to have ischemia (decreased oxygen supply to heart muscle) during exercise testing after being exposed to high level air pollution. The main culprit was particulate matter having diameter less than 2.5 micrometers and even ultra-fine particulate matter, having a diameter less than 0.1 micrometers.

Monitoring the electrocardiogram (ECG) of 41 residents of Helsinki,the study found that 23 patients experienced exercise associated symptoms when air pollution was high two days before a clinic visit. Avoiding outdoor exercise on hazy days could be one way of staying off the risk of ischemia.

Plumbing matters

The corrosion of metallic plumbing materials carrying drinking water produces environmental problems. Corrosion has an effect on the water quality, it changes the taste of water and gives rise to unpleasant odour. It is the growth of microbes or leaching of contaminants from the metallic, plastic or concrete plumbing that is a cause of concern. Holes caused in water pipes due to corrosion allow the influx of contaminants into drinking water systems.

Marc Edwards, professor of civil and environmental engineering at Virginia Polytechnic Institute and State University, USA, is leading the research which focuses on the health impacts caused due to corrosion of plumbing materials. How serious the matter is can be gauged from the fact that the US will be spending about $ 325 billion in the next 20 years to replace losses due to corrosion and to upgrade water distribution systems.

Capital air

Delhi can now breathe easy. Stars can be seen in the sky. A 25 per cent reduction has been noticed in pollution levels of the capital. According to Dilip Biswas, chairman of the Central Pollution Control Board, average particulate matter in the air dropped to 347 microgrammes per cubic metre in 2001 as compared to 405 microgrammes in 2000. Sulphur dioxide levels have come down to 14 microgrammes from 18 microgrammes and nitrogen dioxide levels now stand at 34 microgrammes as against 36 microgrammes in 2000.

The phasing out of commercial vehicles older than 15 years in 1998, coupled with switching over of majority of the vehicles to compressed natural gas (CNG) and closing of thousands of chemicals and textile factories has helped Delhi breathe easy. Vehicles alone in Delhi account for nearly 70 per cent of the pollution, while power plants are responsible for 15 per cent and the remaining 10 per cent is contributed by the various industries.

Killer weed

A recent study published in Environmental Health Perspectives talks of how a cocktail of common herbicides may result in reduced fertility and cause miscarriages.

The cocktail, a mixture of 2,4-D, dicamba and mecoprop has been in the market after World War II. The mixture is generally available as over the counter product. Studies done on crop workers of Europe and Kansas

USDA

show that farmers who work with 2,4-D have a higher rate of non-Hodgkins lymphoma. The pesticide industry in the US has already spent more than 30$ million on 2,4-D toxicity trials. Studies conducted in wheat, sugar beet and potato farming regions of USA have found twice the rate of birth defects among children of crop workers who conceived the children during the months when the pesticide 2,4-D was sprayed.

Four cities study

The Chinese government and the US Environmental Protection Agency (EPA) recently conducted an epidemiologic study of children's and adults' respiratory health in relation to their exposure to both ambient as well as indoor air pollution in urban and suburban districts of China.

Called the Four Chinese Cities Study, 7,621 school going children residing in eight districts of Lanzhou, Chongqing, Wuhan and Guangzhou were covered. It measured the ambient particulate matter present in these cities and also took into consideration various risk factors like home environment, parental smoking, history of parental asthma, having been breastfed and gender.The prevalence rate for wheeze, asthma, bronchitis,hospitalisation due to respiratory diseases, persistent cough, and persistent phlegm was calculated.

Positive associations have been found between morbidity prevalence and ambient levels of coarse particulate matter (PM) which range in the size of PM10-2.5. The evidence of associa-

tion between levels of nitrogen dioxide and sulphur dioxide and children's respiratory symptoms though present, is weaker than that of PM.

Immunological exposures

The greatest risk of exposure to various petroleum derivatives is experienced by the petrol filling station workers. Long term exposure to such derivatives is known to bring out immunological changes in the workers. A two year period study was done on 89 male petrol filling workers of Hyderabad and Secunderabad, belonging to the age group of 20-45 years and working for a period of 2-18 years.

The study measured the activity of serum adenosine deaminase (ADA), which is an enzyme important for developing cell immunity. ADA activity increases during the body's imunnological responses. The research has been inspired by an earlier study on the role of serum ADA activity in tobacco factory workers who were occupationally exposed to tobacco dust and were found to have increased ADA activity as compared to control group. A marginal increase in serum ADA activity of petrol filling stations workers has been reported in this study but the research calls for further insights to substantiate the findings.

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Tylenol blues

Tylenol, the most popular non-prescription drug of the US has been found to have an important role to play in causing liver damage. Study conducted over a period of 25 years by the Food and Drug Administration (FDA) advisory panel shows that acetaminophen, the active ingredient in Tylenol causes liver disease. More than 50 million Americans use Tylenol every year. How much of it is safe and can small doses also be toxic is the question now being asked. Says Kate Trunk of the FDA, " You cannot allow more innocent men, women and children to suffer." Her own son died from liver disease after taking acetaminophen drug on injuring his wrist.

The drug manufactured by Johnson & Johnson (J & J) carries no reference about its potential side effects on its packaging. On the contrary, its campaign once boasted of "nothing's safer" but the reality now is something different.

Over dose of acetaminophen in itself is responsible for more than 56,000 emergency room visits every year in the USA, with more than 100 being fatal. According to William Lee of the university of Texas Southwestern Medical Centre, acetaminophen is the leading cause of liver failure. Treatment of tylenol related cases is rarely successful. After a while, J & J included a warning with each adult Tylenol package noting that the liver damage could be due to the mixing of the drug with alcohol and the drug by itself was safe.

For the warning to become mandatory, the FDA has to formally adopt the recommendation.

Poisoned fragrance

Lead is added to candle wicks to stiffen them and to let them burn for longer time. Burning a leaded-wick candle raises the level of particulate matter not just near the candle but also throughout the room and even the house. The study conducted by Shirley Wasson and her team and reported in the June issue of *New Scientist* suggests that just four hours of burning of one average leaded-wick candle will raise the lead levels to 6.2 microgrammes per cubic metre ($\mu g/m^3$) in the room with the candle and to 2 $\mu g/m^3$ throughout the rest of the house. The US National Air Quality Standard for lead set by the Environmental Protection Agency (EPA) is 1.5 $\mu g/m^3$. Since 1992, US import of lead candles has risen by 800 per cent. More than 3 million lead wick candles are sold every year in the US alone. A safer though expensive alternative would be that of using zinc instead of lead in wicks.

Asthma research

Concerned over the increase in the number of children with asthma, the US Environmental Protection Agency (EPA) and the American Lung Association have launched the Asthma Research Strategy, which would discuss future research efforts and address specific issues.

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The research would be used to devise appropriate strategies to control environmental factors that exacerbate asthma. According to the EPA, the year 2001 saw around 3.8 million children being affected by asthma attack. Most of these attacks were triggered by environmental contaminants like particulate matter, smoke, air pollution, and pollen.

The Asthma Research Strategy aims to set standards that would aim to protect children prone towards asthma attack. It would be discussing future research efforts and addressing issues like–factors which contribute to the induction and exacerbation of asthma (biomass smoke, air pollutants), susceptibility factors (genetics, socio-economic status, health, type of housing, and lifestyle patterns) and assessing the management of environmental pollutants which are relevant to asthma.

THE FOCUS IS ON THE MISUSE AND RESISTANCE OF ANTIBIOTICS

Putting off the threat

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The growing threat of the irrational and irregular use of antibiotics and the resultant resistance to them is a now a cause of major concern. In 1981, the *Alliance for the Prudent Use of Antibiotics (APUA)*, a non-profit organisation with headquarters in Boston, Massachusetts, USA was set up. The main objective of APUA is to promote the proper usage of antibiotics and at the same time, work towards curbing antibiotic resistance worldwide.

APUA has affiliated chapters in over 20 countries and a scientific membership represented by around 90 countries. The objectives of APUA are fulfilled through education and awareness programmes. Ongoing research and surveillance is a major activity undertaken by APUA. It is through its wide network of global chapters that APUA builds national capacity in the area of antibiotic use and resistance research and education. Experts in the field of medicine, microbiology, health education, and policy analysis form part of the professional staff of APUA. People drawn from the field of ecology, communications and international programme development are also associated with APUA.

APUA works in collaboration with the World Health Organisation (WHO), the Pan American Health Organisation (PAHO), US Agency for International Development (USAID) and the Centres for Disease Control and Prevention, (CDC) Atlanta, USA. It also networks with the local health ministry of the country.

The Indian chapter of APUA was established in 1996. Doctors from the All India Institute of Medical Sciences (AIIMS), New Delhi provide the main leadership. J S Bapna, from the Health and Pharmaceutical Management Unit of the Indian Institute of Health Management and Research (IIHMR), Jaipur, has been associated with APUA-India chapter since a long time. Through its various programmes of education and advocacy, APUA-India reaches out to the medical community, consumers, researchers and policy makers.

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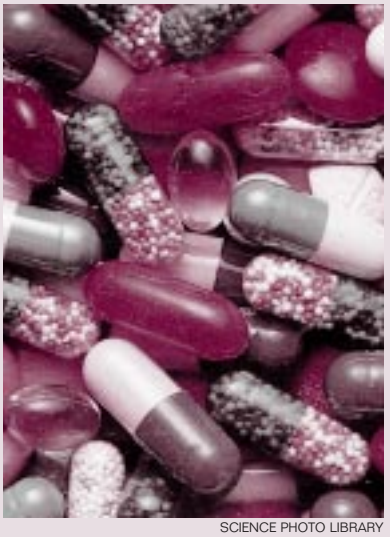
Educating people



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The Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) is a non-governmental organisation, which has been promoting rational use of drugs in India both in the public and private sectors. One way of doing this is by developing methods for improving availability and accessibility of safe and effective drugs. DSPRUD also develops methods for good quality control and assurance of drugs. Emphasis is given on improving procurement, storage and distribution of drugs.

It carries out health education programmes with particular reference to the use of medicines so that rational prescribing of drugs can be effected. In addition it also conducts research and monitoring on all aspects of drug use. Studies are carried out on the impact of educational intervention programmes on prescribing behaviour of physicians with focus on antibiotic use of acute respiratory infections (ARI) and diarrhoea at health centres. DSPRUD also helps in formulating *Standard Treatment Guidelines* in clinical practices.

In pursuance of their objectives, they have launched several activities. The India-World Health Organisation (WHO) Essential Programme works on the development of a drug policy; selection of a list of essential drugs; establishment of a pooled procurement system; development of a quality assurance system; promotion of rational prescribing; providing drug information to patients; and advising the public about proper use of medicines.

Training forms an integral part of the organisation. Training programmes focus on promoting awareness of rational use of drugs amongst medical professionals. The organisation works in tandem with the government and organises training programme for their officials to. Other activities include consultancy on drug management, supplies and publications related to drug use.

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Readers write in

With reference to the May newsletter article DOUBLE INDEMNITY DEATH BY DDT you are aware that the DDT is not totally banned in India and the Central Government owned undertaking Hindustan Insecticides Limited (HIL) manufactures DDT in our country. Hundreds of formulators make usable formulations out of this.

The HIL manufacturing capacity is 10,000 tonnes. When the issue of banning the DDT came up, our govt decided that it will be" in the restricted use category" so as not to close down HIL. Import of the DDT was not allowed, however under the WTO diktats, there cannot be ban on import of DDT as it is made in India. President Bush has allowed manufacture of DDT in the US for export. His contention was that poor countries suffered from malaria and the DDT is needed for vector control. Use of pesticides has brought about mutations in the mosquito and the new varieties are highly dangerous.

Our two Central Ministries- of Health and Agriculture- decide whether to ban, allow restricted use or unrestricted use for all pesticides. These two Ministries never jointly formulate policy So when one bans, the other allows restricted or unrestricted use. The DDT is in restricted use category of the Health Ministry. The Health officers find that DDT is the cheapest pesticide so should not be banned. Why and How? It is longest lasting so one spray remains potent for a longer period and the second is not required immediately. Effect is longer lasting so cheap.

For the health of living beings it is this long lasting impact, which is most dangerous. So living beings remain exposed for a longer period of time. It is the second, third and fourth generation pesticides that disintegrate faster. That is why, probably, pesticide spray on fruits is allowed theoretically before 14 days of the fruit brought to market. Nobody follows even this rule. Even *Ziziphus* (Hindi: *ber)* used to be infected in the ripening stage. Now producers spray heavy dose just before the fruit is sent to market. So the fruit does not rot even when it is overripe and has shrivelled.

There is absolutely no control or monitoring on switch over from the health to agriculture. We have observed DDT and BHC packets in shops marketing pesticides to farmers. There is no restriction. The Agriculture Ministry says that the Dirty Dozen are banned. We tried our level best to convince the Ministry to inform farmers through field officers and offices, placing big posters but no action. We doubt if the officers can give out the names of banned pesticides. It is not only the traces found in bodies but the impact on living organisms. The DDT has been banned in the USA in 1972. A study carried out in 1989 showed that 99 per cent of US residents had traces of DDT.

One highly objectionable practice of Mumbai Municipality is to spray pesticide in the overhead water tanks in private properties for malaria control. We have objected for over 15 years, in vain. Officers in this department will lose their job so continue the practice. You may like to check in Delhi. Best wishes.

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◆ ◆ ◆

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◆ ◆ ◆

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This newsletter is funded by the Delegation of the Commission of the European Communities, New Delhi, as part of its support for the Centre's programme on environmental health. Institutional support comes from the Swedish International Development Agency (SIDA) and the Evangelischer Entwicklungsdienst (EED), Germany.

Compiled by: Pranay Lal, Sarita, D B Manisha Designed by: Surender Singh Printed by: Excellent Printing House, New Delhi