

# News from here and there

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## Health ministry institutes reward scheme for whistle-blowers reporting spurious drugs

In November 2009, the Ministry of Health and Family Welfare notified a new reward scheme for whistle-blowers who help unearth cases of spurious drugs. Announced earlier by the Health Minister, Mr Ghulam Nabi Azad, as part of the government's 100-day agenda, the scheme aims to check the problem of the availability of fake drugs in the market. The scheme follows several high-profile seizures of consignments of spurious drugs, including 3 consignments from China which were confiscated at the Chennai port, by agencies such as the Central Bureau of Investigation.

The Indian pharmaceutical sector has been growing at a rate of 12%–14% per annum, and now accounts for 8% of the global production and 2% of the world pharmaceutical market. The size of the Indian pharmaceutical industry is around Rs 85 000 crore and 40% of this constitutes exports. The country has developed a global reputation for being able to produce and supply low-cost drugs, especially generics. However, in recent years, there have been cases of spurious drugs with 'Made in India' labels being seized within the country (for example at the Chennai port, where the drugs were discovered to have been sent from China) and in other countries, such as Nigeria. Currently, the Central Drugs Standards Control Organization (CDSCO) is conducting an all-India survey to evaluate the extent of the availability of spurious drugs in the country by drawing samples from different regions in the country on the basis of the statistical principles provided by the Indian Statistical Institute, Hyderabad. In addition, the Drugs and Cosmetics Act, 1940 has recently been amended by the Drugs and Cosmetics (Amendment) Act, 2008 to award more stringent penalties to those involved in the trade of spurious drugs.

The whistle-blower reward scheme has been announced with the aim of addressing this problem and protecting the health of citizens. The scheme shall be applicable to whistle-blowers in the area of drugs, cosmetics and medical devices. The rewards scheme will be applicable to informers as well as officials within the drug controller's office/government functionaries. The award will be 20% of the value of the seized consignment, up to a maximum value of Rs 25 lakh (over US\$ 50 000). However, in the case of government officials, the reward will not exceed Rs 5 lakh for one case and a maximum of Rs 30 lakh in the officer's entire service. A quarter of the reward amount will be paid at the time of filing the chargesheet to ensure that the whistle-blower does not turn hostile during legal proceedings related to the seizure of the spurious drugs. Another 25% of the reward amount will be paid only at the time of disposal of the case in favour of the government in the first court of law. The remaining 50% will be paid to the whistle-blower when the case has been finally disposed of in favour of the government and no appeal with respect to the matter is pending in any other court of law in the country.

The eligibility and quantum of the award in each case will be decided by a committee comprising government officials from various departments. The identity of the whistle-blowers will be protected and only known to a few officials in the CDSCO.

S. Srinivasan, a health activist who is also involved in the

production of low-cost generic drugs, commented on the development, saying, 'The government's decision shows how India's export market prestige is wagging its tail.'

ANANT BHAN, *Pune, Maharashtra*

## 25 years after the Bhopal gas tragedy

Twenty-five years after the Bhopal gas tragedy, the New Delhi-based Centre for Science and Environment (CSE) has released a report which states that all 11 groundwater samples collected by the CSE from areas around the Union Carbide factory in Bhopal have large quantities of mercury, chlorinated benzene compounds and organochlorine. Groundwater from these areas continues to be used for human consumption. Public meetings, processions and an all-faith prayer meet marked the 25th anniversary of the Bhopal gas tragedy. Earlier, the Union Minister of State for Environment and Forests, Jairam Ramesh, had stated the need to move on, given that 25 years had elapsed since the tragedy. Predictably, the statement met with derision and the minister subsequently apologized for any perceived insensitivity in his remarks.

The world's worst industrial disaster occurred in Bhopal on 3 December 1984. An explosion at the Union Carbide India Limited (UCIL) pesticide plant resulted in the release of 30–40 tonnes of toxic methyl isocyanate (MIC) gas. The gas spread over approximately 75 square kilometres, killing thousands and maiming hundreds of thousands of people for life.

Union Carbide had been manufacturing three kinds of pesticides in the infamous factory in Bhopal before the tragedy. Heavy metals such as chromium and mercury had been used in the manufacture of these pesticides. Toxic chemical wastes generated before the plant shut down have yet to be completely disposed of from the site.

The Bhopal Memorial Hospital and Research Centre (BMHRC), a 360-bedded superspecialty hospital, has been providing free primary and superspecialty healthcare to the victims of the gas disaster since its inauguration in the year 2000. This includes free services in the specialties of cardiology, cardiac surgery, nephrology, urology, neurology, neurosurgery, psychiatry, pulmonology, ophthalmology, radiology, microbiology and pathology. Of a total of 570 000 survivors, 377 000 gas victims are registered with the hospital and its outreach centres. Reiterating the centre's commitment to the service of the survivors of the disaster, the Director of the BMHRC, Brig. (Dr) K. K. Maudar, said, 'More than 3 400 000 visits to the hospital by registered gas victims, for both outpatient and inpatient treatment, have been recorded so far. In addition, intensive research has been done at BMHRC to determine the effects of exposure to the toxic MIC gas that had caused the tragedy in 1984, the results of which have been published in international, peer-reviewed journals.' The studies have shown that exposure to MIC *in utero* in the first trimester of pregnancy results in a persistently hyper-responsive state of the

immune system (*Occup Environ Med* 2009;**66**:279), while exposure at various ages results in significant immunotoxicity and elevated levels of circulating biomarkers of inflammation, including interleukins and cytokines. *In vitro* studies on human cultured cell lines following exposure to MIC have also demonstrated its capacity to cause genotoxicity, chromosomal and microsatellite instability, as well as mitochondrial oxidative stress (*Cell Biol Int* 2009;**33**:675–83). The pathogenic potential of such derangements is still being elucidated.

PRABHA DESIKAN, *Bhopal, Madhya Pradesh*

#### **Gates Grand Challenges grants awarded**

The Bill and Melinda Gates Foundation awarded 76 grants of US\$ 100 000 (Rs 46.5 lakh) each to public health researchers around the world in Round Three of the foundation's US\$ 100 million Grand Challenges in global health initiatives. The grants were awarded to researchers from 22 countries, including India. These grants fund innovative research with a potential to address health problems faced by the developing world.

The grants are open to anyone from any discipline and require no preliminary data. The application procedure is short and simple, and needs to be filled online. Of the 76 grants awarded, three went to research teams from India. These include one for an 'electronic nose' to diagnose tuberculosis in resource-poor settings. The team which bagged this grant, the International Centre for Genetic Engineering and Biotechnology (ICGEB) team, comprising Ranjan Nanda, K.V.S. Rao and Virander Chauhan, will focus on validating its hypothesis that a tuberculosis patient's breath contains molecules that are different from those of a healthy individual. If this is successfully established, the team will focus on detecting and depicting this information through a hand-held, easy-to-use gadget. The device, dubbed the 'electronic nose', will have layers of absorbent material that can differentiate between various chemical molecules.

Another team from the ICGEB, comprising Virander Chauhan, Deepak Gaur and Chetan Chitnis, has been awarded a Gates Foundation grant to develop a blood-stage malaria vaccine. This vaccine would use a combination of two proteins found among a wide diversity of malaria parasites to stimulate antibodies that would stop red blood cells from being infected by parasites by blocking multiple pathways of invasion.

A team of researchers comprising Abani Nag and Amiya Hati from the Kolkata-based Vivekananda International Health Centre

has been awarded a grant to test the hypothesis that ultrasound measurements of the liver and spleen, as well as functional liver enzyme tests, will help differentiate between cases of malaria relapse and re-infection, leading to more appropriate treatment and drug therapy. The duo had discovered during ultrasound investigations that the liver and spleen of patients who had malaria and were suffering from a relapse were more enlarged than those of patients with a fresh infection. With this grant, the team members plan to test 1200 patients to see if they can establish statistically significant data that will allow them to use liver enlargement as a test.

Last year, two Indian researchers (Nikita Malavia and Karthikeyan Kandavelou) had won Gates Grand Challenges grants.

ANIMESH JAIN, *Mangalore, Karnataka*

#### **Novel health insurance scheme in Tamil Nadu**

In February 2009, the Government of Tamil Nadu launched a medical insurance scheme for people of the state with an annual income of less than Rs 72 000. The scheme covered treatment for 51 categories of medical problems which were identified by a committee. People with these medical problems were on long waiting lists at government hospitals or the problems were not adequately covered. Under the plan, the beneficiaries can access treatment at non-government hospitals which have expressed their willingness to treat patients covered by the scheme. The state government pays Rs 469 per family in return for which the insurer (Star Health Insurance) provides a cover of Rs 100 000 for 4 years. The rate payable for each procedure is fixed. Approximately one crore families are estimated to be covered under the scheme and the government has paid a premium of Rs 517.307 crore to the insurer. A controversy arose when *The Times of India* (Chennai edition, 10 November 2009) reported that unnecessary hysterectomies were being done under the scheme. The report alleged that 540 women between the age of 25 and 35 years had their uterus or ovaries removed. It also quoted the CEO of Star Insurance as saying that of the 1.5 lakh women covered by the company under a general medical insurance scheme, only 7 women under the age of 35 years had had a hysterectomy. It seems, therefore, that there is need for caution and audit of procedures. The Tamil Nadu government has already initiated the process.

GEORGE THOMAS, *Chennai, Tamil Nadu*