

News from here and there

Union Budget for 2008 offers tax exemption to private hospitals

The Union Government released the budget proposals for the forthcoming year on 28 February 2008. The most remarkable feature of the budget proposals is the tax exemption being offered to private players for setting up hospitals in smaller towns. This suggests that the government intends to stay away from providing universal, comprehensive medical care. The largest budgetary allocation has been for the National Rural Health Mission (NRHM) which gets Rs 12 050 crore of the total provision of Rs 16 534 crore.

This mission, aimed at revamping the primary health centres, is indeed welcome. The government had promised a 30% annual increase in allocation to the NRHM, but the increase this year works out to be 11.4%. Despite many promises by many governments to increase budgetary allocation for health to 3% of the GDP, it has never been more than 1%, and this year is no different—it is 0.99%.

Overall, the budgetary proposals on the health front show a continuation of earlier policy—the government will concentrate on some public health measures, while leaving provision of medical care largely to the private sector. Individual patients will continue to have to pay out-of-pocket for medical care.

GEORGE THOMAS, *Chennai, Tamil Nadu*

India faces possible vaccine shortage as vaccine laboratories are shut down

The production licences of 3 vaccine-manufacturing public enterprises under the Ministry of Health and Family Welfare were cancelled on 15 January 2008. These manufacturing units are the Central Research Institute, Kasauli; Pasteur Institute of India, Coonoor and the BCG Vaccine Laboratory, Chennai. The Drug Controller General of India had ordered suspension of vaccine production due to non-compliance with good manufacturing practice norms under the Indian Drugs and Cosmetics Act of 1940. These 3 public sector enterprises had met the bulk of vaccine requirements of the national immunization programme for many years now.

With 26 million births every year, the demand for vaccines had increased concomitantly. Given this scenario, other organizations had made up the shortfall in government procurement from these public sector units. These organizations include Haffkine Biopharmaceuticals, Mumbai; Serum Institute, Pune; State Vaccine Institute, Nainital; Bharat Immunologicals and Biologicals Corporation Ltd, Bulandshahar; Biomed, Ghaziabad; Radicura Pharma, New Delhi and Biological Evans Ltd, Hyderabad.

Now, with the closure of these 3 public sector enterprises, the spectre of a possible shortage of essential vaccines in India has been raised. The crunch is expected to be particularly acute with regard to BCG, given the directive to the closed units that they should not supply BCG vaccines even from the stocks held. Supply of inexpensive antirabies vaccine and yellow fever vaccine is also expected to be affected adversely.

A centralized 'vaccine park', with state-of-the-art infrastructure

for production of and research into vaccines, is proposed to be set up in Chengalpattu near Chennai to replace the 3 closed units. Hindustan Latex Ltd (HLL), a public sector undertaking, has been identified to set up this complex. However, concerns have been raised regarding this choice given the fact that HLL has little experience in vaccine production and technology.

Concerns have also been expressed by the medical fraternity regarding the possible rise in cost of essential vaccines with the sudden closure of the 3 manufacturing units.

On the other hand, there were 4 measles vaccine-related deaths reported from Thiruvallur, Tamil Nadu, on 23 April 2008. The vaccine was manufactured by Indian Immunologicals Ltd, Hyderabad. Following this, the Union Health Minister, Anbumani Ramadoss, instructed all state governments to stop further use of the measles vaccine manufactured by Indian Immunologicals Ltd, until further orders.

Samples of the vaccine have been sent to the Central Drugs Laboratory, Kasauli for further testing. The Union Health Ministry has also sent a high level team, led by the Director of the National Institute of Communicable Diseases (NICD) to Tamil Nadu, to investigate this episode. The team will examine the quality of the vaccine, the status of the cold chain, the quality of diluents and also look for any other possible human error that may have occurred during transport and administration of the vaccine.

PRABHA DESIKAN, *Bhopal, Madhya Pradesh*

Baby bottles made of plastic may be unsafe because of bisphenol A (BPA) content

Health Canada is the first regulatory body in the world to take action on bisphenol A (BPA).

On 18 April 2008, Health Canada announced that it will initiate a 60-day public comment period on whether to ban the import, sale and advertising of polycarbonate baby bottles which contain the oestrogen analogue BPA.

BPA is widely used as a component of polycarbonate, epoxy plastics, as well as in the inner plastic lining of food cans and dental sealants. Several studies have indicated that low levels of BPA can leach out of polycarbonate bottles under normal conditions of use. Ambiguous data on the *in vivo* oestrogenicity of BPA is pitting scientists and consumers against manufacturers of plastics who continue to assert that BPA is non-toxic.

In July 2007, a statement released by the Office of Food Additive Safety at the US Food and Drug Administration (FDA) stated that it had confidence that there was no safety concern for BPA in regulated food contact materials and that the use of polycarbonate-based baby bottles and BPA-based epoxy-coated cans used to hold infant formula were safe.

In January 2008, a study on BPA conducted by the Centers for Disease Control and Prevention (CDC) in the USA, found BPA in the urine of 92.6% of Americans. Disturbingly, children were found to have higher concentrations of the chemical than adolescents. This report led to a resurgence of consumer anxiety over the leaching of BPA in polycarbonate infant feeding bottles and infant formula cans.

Health Canada reacted to this report by conducting an independent screening assessment of BPA and determined that exposure to BPA of newborns and infants in Canada is below levels that may pose a risk. However, to be prudent, the Government of Canada is proposing to reduce BPA exposure in this vulnerable population by proposing a number of actions including banning polycarbonate baby bottles, developing stringent migration targets for BPA in infant formula cans, working with industry to develop alternative food packaging and develop a code of practice, and listing BPA under Schedule 1 of the Canadian Environmental Protection Act.

In response to Health Canada's announcement, The American Chemistry Council (ACC) issued a statement stating that the draft assessment released by Health Canada was consistent with the safety evaluations conducted by many other scientific and government bodies, which confirm the negligible health risks to the general population in Canada from exposure to BPA.

Nevertheless, some major Canadian retailers have reacted to Health Canada's announcement by pulling out bottles containing BPA from their shelves and replacing them with BPA-free alternatives.

MEENAKSHI KASHYAP, *Canada*

Tamil Nadu puts a ban on unethical advertising by doctors

The Tamil Nadu Medical Council (TNMC) has warned hospitals and doctors against unethical advertising and said that action will be taken to strike doctors off the medical register if they, or the hospital with which they are associated, continued with advertisements.

In the past 2 years, all kinds of procedures such as the so-called keyhole surgery for orthopaedic conditions, 'pinhole' surgery for the heart, 'high-flexion' knee replacement, 'mini day surgery' and numerous other such claims have been made not only in colour advertisements in several newspapers, but also on huge billboards all over Chennai and other towns. Following a Supreme Court ruling, most billboards in Chennai, not just the ones advertising medical procedures, have been removed in mid-April. However, advertisements in newspapers continue. The TNMC has given doctors and hospitals 3 months from April to fall in line.

In the neighbouring state of Karnataka, too, the Karnataka Medical Council has recently decreed that newspaper advertisements by doctors and hospitals are unethical.

GEORGE THOMAS, *Chennai, Tamil Nadu*

Roche and Cipla continue to spar over right to market anticancer drug

Indian generic drug-maker Cipla and Swiss-based multinational F. Hoffman La Roche are engaged in a bitter patent dispute over Erlotinib, manufactured by Cipla and a generic of Roche's patented lung cancer drug, Erlotinib (retailed as Tarceva).

Roche got a patent for Erlotinib in February 2007. Cipla announced that it would sell its version of the drug a few months later, at one-third (Rs 1600 per tablet) the price of Roche's drug. Roche took Cipla to court to stop it from selling the drug. Cipla counter-sued stressing that Roche's drug was merely a tweaked

version of a pre-1995 drug. This would make the drug ineligible for patent protection under Indian law and Cipla demanded a revocation of the patent. In a judgment delivered on 19 March 2008, the Delhi High Court allowed Cipla to continue manufacturing and selling its version of the drug. The judge cited the concern that stopping Cipla from selling the cheaper drug could lead to irreparable harm for cancer patients.

Cancer activists welcomed the judgment, lauding the fact that the concern for patients had been found more important than patents. Roche has blamed the high cost of Tarceva on steep import duties, and has since appealed to a larger bench of the High Court.

In a recent development, a Roche distributor, Taksal Pharma, has alleged that Cipla is promoting the use of its drug for 4 types of cancer: non-small cell lung cancer, pancreatic cancer, neck and head cancer as well as colorectal cancer, whereas it has been given regulatory permission to use its drug to treat only lung cancer. Roche itself has only been given approval to market its drug for lung and pancreatic cancer.

Unapproved use, if found to be true, could land Cipla in serious trouble with the Drug Controller General of India (DCGI). It would be a violation of the provisions of the Drugs and Cosmetics Act, 1940.

ANANT BHAN, *Pune, Maharashtra*

Binayak Sen awarded the Jonathan Mann award for Global Health and Human Rights

Dr Binayak Sen, community health and human rights activist, was announced as the recipient of the Jonathan Mann award for Global Health and Human Rights for 2008. He is the first recipient of this award from India.

The award is presented by The Global Health Council annually at its international conference. It was instituted in 1999 to honour the memory of Dr Jonathan Mann, a prominent figure in the twentieth century fight against global poverty, illness and social injustice. The award is given to a practitioner who has done important practical work, especially in the field of health and human rights, and has worked in developing countries with marginalized people.

Dr Sen has worked in Chhattisgarh for many years, helping establish a hospital for poor mine workers called Shaheed Hospital in Dalli-Rajhara, started a community-based non-governmental organization (NGO) called Rupantar with his wife Dr Ilina Sen, and is also an office-bearer in the People's Union for Civil Liberties (PUCL). The Global Health Council and other organizations issued a statement of support for Binayak, and urged the Indian government to find the means to release him to receive the award in person at this year's (35th annual) conference on 29 May 2008 at Washington D.C. Sen was selected from among hundreds of nominations by a distinguished jury of experts in health and human rights.

Dr Sen continues to be incarcerated in Chhattisgarh and has now completed a year in jail, including a recent spell of solitary confinement. Efforts continue to secure the release of Dr Binayak Sen.

ANANT BHAN, *Pune, Maharashtra*