Global Update

News in Brief

Industry

Trials and tribulations: Besides outsourcing of software jobs to India, there is great interest today in India as a destination for pharmaceutical clinical trials. A study, done by an Indian government task force on pharmaceutical research and development, found that new drugs can be developed in India at a tenth of the cost of the process in the west. Lower costs, huge pool of patients (many of them treatment naïve) and many English speaking, western educated doctors and researchers all contribute to India's attractiveness. Hence pharmaceutical companies in India are pressurizing the government to amend some of the laws which delay trials in India. To protect Indian patients from exploitation by foreign companies currently Phase I trials of drugs developed outside India are banned and Phase II and III trials of drugs allowed only after Phase II and III trials have been done outside India. But many feel that unless exclusive policies are trimmed and unless time to approval for trials is drastically cut down India will be left out of the global drug developmental segment. A review panel headed by RA Mashelkar, Director General of the Council of Scientific and Industrial Research, concluded the government needs to be aggressive, recommending that regulators expedite approval for phase II and III trials on the basis of approvals given in countries that are signatories to the International Conference on Harmonisation, an organization that standardizes drug-approval regulations between countries. The CII (Confederation of Indian Industry) has even asked for automatic approvals of trials if applications are not cleared within a stipulated time frame. The flip side of the debate is that the regulatory agency which handles drug development - the Drug Controller of India is not equipped to handle the deluge of clinical trials which may come. It also has no strong enforcement mechanism to ensure ethical trials. If we want to take advantage of global markets, we also need to streamline a system to ensure that Indian patients are not exploited (The Lancet 8 May 2004).

Law

Off label - off limits?: The freshest controversy brewing in Indian medical circles is whether "off label" prescriptions should be allowed in India. "Off label" prescriptions are those indications of a drug for which there is no formal approval but strong scientific and medical evidence exists. The issue hotted up last year when letrozole an anti-cancer drug was being promoted by a drug company for infertility. The Indian Medical Association is currently lobbying for "off label" prescriptions. Since when used on basis of good medical evidence it is sometimes the best treatment option. However many feel it is an irresponsible act and “doctors here cannot have this freedom, given the low level of patient awareness and the influence of drug companies on prescription practices”. (BMJ 24 April 2004; 328: 974)

Scandal

Healthy criticism: A study of health care facilities in rural Rajasthan has exposed some harsh truths. Forty one percent of practitioners who call themselves doctors in the private setup have no medical degree. A visit to the

clinic resulted in an injection in 68% of cases and a drip in 12%. In only four percent of cases were investigations done. The study also showed that on average 45% of medical or paramedical personnel were absent from government run sub-centers (serving a practice population of about 3600) and 36% were absent from the larger primary health centers (serving 48 000). The sub-centers were closed 56% of the time during their regular opening hours, at unpredictable times, discouraging people from walking an average of 1.4 miles from their village. The study results by Dr Abhijit Banerjee and Dr Esther Duflo from the Massachusetts Institute of Technology and Dr Angus Deaton from Princeton University do not seem specific to Udaipur but are reflections of the malaise which afflicts the entire health care system in the country.

In another editorial in the Lancet "Political neglect in India's health", there is dismay that issues related to public health barely featured in the media or election campaigns during the electoral build up of the world's largest democracy. In 2001, the Indian Government spent $4 a head on health, compared with it's smaller neighbors, $8 in Bhutan and $15 in Sri Lanka. Political will and public willingness may yet bring light in this wilderness (BMJ 24 April 2004; 328:975, www.povertyactionlab.com, The Lancet 15 May 2004).

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