

ROTA VIRUS VACCINE ADVERTISEMENT PULLED OFF

Glaxo Smith Kline's advertisement about rotavirus diarrhea has been retracted after Nalini Abraham acted as whistleblower. Dr Nalini Abraham, a public health specialist in Delhi, wrote to the Advertising Standards Council of India (ASCI), a voluntary self regulatory body of the advertising industry. Her arguments were that first, vaccines are prescription drugs. In the past when the chicken pox vaccine was advertised the IMA had objected to it. Second it amounted to misrepresentation of facts when the advertisement claimed that "the vaccine is the only way to reduce the incidence of infection and steps like frequent hand-washing do not help." She also argued that there was not a single study till date that showed that the vaccine was effective in India to reduce the incidence of diarrhea or deaths due to it, as there were numerous local strains of the virus. She quotes Lodha et al's article in Indian Pediatrics June 2012 to drive home her point that Indian strains are different and may not get cross protection from the strains currently in the vaccine. It is clear that the advertisement contravened Chapters 1.1 and 1.4 of the ASCI Code. Chapter 1.1 says advertisements must be truthful and any claims should be capable of substantiation. According to Clause 1.4, advertisements shall neither distort facts nor mislead the consumer through implications or omissions. After deliberating on the complaint, the ASCI's Consumer Complaints Council concluded that the claim in the advertisement, "vaccine is the only way to reduce the incidence of infection," was inadequately substantiated. And the statement, "Rota virus vaccine is the only way to treat Rota virus," was misleading (*The Hindu 15 December 2012*).

FDA APPROVES THE FIRST DRUG FOR TB AFTER 1970

After a hiatus of 40 years the FDA has approved a new drug for tuberculosis. Bedaquiline, is a diarylquinoline developed and marketed by Janssen Pharmaceutica as Sirturo. It does not inhibit the DNA gyrase like other quinolones but affects the proton pump for ATP synthase. The FDA also granted Sirturo fast track designation, priority review and orphan-product designation since it is one of the few drugs which has been show to be effective in MDR tuberculosis. Sirturo's safety and effectiveness were established in 440 patients in two Phase 2 clinical trials. Patients in the first trial were randomly assigned to be treated with Sirturo plus other antitubercular drugs or a placebo plus other antitubercular drugs. All patients in the second trial, which

is ongoing, received Sirturo plus other TB drugs. Both studies were designed to measure the length of time it took for a patient's sputum to be free of *M. tuberculosis*. Results from the first trial showed patients treated with Sirturo combination therapy achieved SCC (sputum culture conversion) in a median time of 83 days, compared with 125 days in patients treated with placebo combination therapy. Results from the second trial showed the median time to SCC was 57 days, supporting the efficacy findings of the first trial (*www.fda.gov 31 December 2012*).

POLIO WORKERS ATTACKED IN PAKISTAN

Pakistan is one of the 3 countries still endemic for polio. It had registered a impressive 65% drop in cases this year. However the 3 day national wide immunization drive planned in mid December was sabotaged when 9 health workers were shot dead by terrorists. Then on 1st January 2013, 6 female health workers and one male doctor were shot dead. The youngest to die was a 17 year old school girl. Opposition to the campaign had grown when it was shown that a doctor had run a fake vaccination campaign to help the CIA track down Osama Bin Laden in Abbottabad. Though nobody has claimed responsibility, it is widely believed to be the Taliban. The Taliban has systemically undermined the health programs in the Swat region of Pakistan by specifically targeting the Lady Health Workers. A BMJ study on how the Taliban undermined community health care in Swat, Pakistan showed that maternal mortality has increased and 29% of the health facilities in the Khyber Pukhtunkhwa region have been damaged. This province accounts for 40% of all Pakistan's polio cases. Repercussions for neighboring countries are invariable. For example China had an outbreak in 2011 after being polio free for more than a decade. The virus had been imported from Pakistan and 18 people were paralyzed and 1 died in that outbreak. These killings could just be the 'game changer' like the 2003-2004 immunization boycott in Nigeria by religious and political leaders. That had lead to a rebound not only in Nigeria but also 15 other African countries and Indonesia. The global community has to stand up and speak out against the terrorist, an invisible enemy who destroys the carefully planted seeds of social wellbeing in a second of mindless violence (*BMJ 3 January 2013, The Lancet 5 January 2013*)

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