LETTERS

Universal Immunisation Programme

This refers to a very thought-provoking article by Jayakrishnan (1). I fully agree with the statement, "Immunisation matters are left to manufacturers and international organisations, to "guide" and decide what is to be introduced in our market."(1).

There is an acute need to protect adolescents and young adults from the economically poor sections against pertussis and diphtheria. In 2008, the Indian Academy of Pediatrics Committee on Immunisation (IAPCOI), in the consensus recommendations on immunisation, stated: "There is no reason to believe that the disease burden of pertussis is low in adolescents in India. A safe and efficacious vaccine is available. The IAPCOI , therefore, recommends offering Tdap vaccine instead of Td/TT vaccine in all children/adolescents who can afford to use the vaccine" (2). Tdap contains acellular pertussis antigen, and is very expensive (MRP Rs 699) while Td costs Rs 10.08 only. In 2006, the author and a colleague had suggested the use of a reduced quantity of the whole cell pertussis component" (3).

Adolescents and young adults belonging to the weaker economic groups are more prone to infections, but they would not be able to afford such a costly vaccine. On November 5, 2008, this author had written to the Serum Institute of India, a leading vaccine manufacturer, with copies to the convener, IAPCOI and other functionaries of the IAP, "to take the initiative and come out with a combination vaccine of tetanus with reduced quantity of diphtheria and whole cell pertussis components. This is needed for the masses that also need protection against pertussis but cannot afford the current Tdap vaccine." There was no response from any one.

However, the drug manufacturers alone are not at fault. Under the existing system, tetanus toxoid with reduced quantities of diphtheria antigen and whole cell pertussis antigen is considered as a new molecule, and needs to be studied afresh for safety and efficacy before even applying for a licence. All this would require heavy investment, while the permitted price cannot exceed that of the DTP vaccine. This "will discourage any manufacturer to go for a vaccine which may be the need of the hour but is bound to act as a loss incurring venture. The solution to bail out industry should come from the authorities and the medical profession."(4) Regarding the administration of hepatitis B vaccine, I quote from a 2007 publication of Jan Swasthya Abhiyan which maintains "Considering the low prevalence of hepatitis B, and the resource constraints, this vaccine should be limited to babies born to hepatitis B+ mothers. For this purpose, all pregnant women should undergo testing for Hepatitis B as part of other tests for anaemia and blood grouping. This does not require any additional effort or equipment and the test kit can be bought in bulk by the government for, say Rs 15-20." (5).

In 2000, I had stated, "Checking of HBs Ag status is not a very expensive or difficult procedure. If it is checked for the prospective marriage partners, the problem of horizontal and later vertical transmission of the virus to the new born can be eradicated" (6).

I had emphasised the importance of blood testing by stating: "If a person is already infected, administration of the vaccine (by routine schedule) will not alter the course of the disease. The infected person may act as a source of infection, while having the false assurance that he or she has been immunised against hepatitis B disease"(6). This point was raised since, sometimes, hepatitis B vaccination is carried out as a campaign, providing vaccine free or at subsidised cost.

I fully agree with Dr Jayakrishnan's views that the national vaccination policy should be disease-oriented. In addition, it needs to be stressed that tuberculosis, measles, polio, diphtheria, tetanus, pertussis, and typhoid should be given priority before including hepatitis B, haemophilus b influenzae, pneumucoccal and varicella diseases in the National Immunisation Programme.

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Saving lives, or styling them?

The past few years have witnessed the rise of highly publicised "lifestyle" drugs. They are used to alter our appearance, physical and mental capabilities, the effects of aging, and so on. As the

availability of a treatment can convert a lifestyle wish into a health need, the pharmaceutical industry becomes a key player in the process of medicalisation, where normal conditions get pathologised.

It appears that when drug therapy is available, physicians are less willing to consider non drug treatments, even when there is no evidence that the former is superior (1). One reason is the pressure from the pharmaceutical industry. One example is the use of Orlistat for treating obesity. Although people taking Orlistat lose a little more weight than those controlling their dietary intake (about 8.9% with pharmaceutical aids vs. 5.6 % with placebo over 1 year), there is no evidence that the drug is any more effective than diet in reducing the morbidity and mortality due to obesity(2). Orlistat is available in India and the prices range from Rs 95 to 390 for 10 tablets. Its reported adverse drug reaction (ADR) varies from mild to severe like oily spotting, increased bowel movements, abdominal pain, headache, rashes and severe liver damage (3).

A number of anti-aging drugs are now available in the market. One of them is Botulinum toxin type A, used for ironing the wrinkles on the face and neck. It can produce paralysis of the small muscles of the face by blocking cholinergic transmission (4).

While there is doubt about the benefits of many modern "lifestyle drugs", there are also concerns about how the pharmaceutical market operates. Drug development is often driven by potential profitability rather than by public health needs. Once a drug is available, industry campaigns may seek to redefine the illness in the minds of doctors and potential patients, converting wishes into healthcare problems that require treatment.

In India where preventable and treatable diseases like malaria and tuberculosis thrive and kill millions of people and many new diseases emerge without any known treatment, the drug development is skewed towards unimportant "lifestyle drugs".

The increasing use of "lifestyle drugs" raises, among several others, one pertinent question: are we trying to homogenise society? There is a need to study the concept and impact of these drugs on society particularly in India. India needs to focus more on life saving and essential medicines rather than "lifestyle drugs". In a free market system, profits may not be the best indication of what drugs we need as a society.

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Ethics in animal experiments

Ethics is very important to any research. Authors are expected to report if the research was done in an ethical manner. Various studies have highlighted the fact that reports of research involving human participants do not always give adequate information on ethical aspects of the study, such as how informed consent was obtained, and details of the ethics review (1-3). This has been reiterated in studies on articles published in Indian medical journals (4-6).

While reporting of ethical parameters in clinical studies is discussed widely, the issue of ethical reporting in animal studies seems to have been ignored.

The present study was designed with the primary aim of analysing the reporting of ethical parameters in animal studies published in Indian journals. The secondary aim was to compare the reporting of ethical parameters between Indian and international journals. Most animal studies are published in pharmacology journals. Studies published in two leading indexed pharmacology journals, *Indian Journal of Pharmacology* (IJP) and *Indian Journal of Physiology and Pharmacology* (IJPP), were selected for the study. *The British Journal of Pharmacology* (BJP) was selected as a comparator international journal.

All the articles published in *IJP* and *IJPP* between 2002 and Jan – March issue of 2010 were downloaded from the journals' websites (www.ijp-online.com, www.ijpp.com). Animal studies published in *BJP* from 2002 to September 2009 were downloaded from the journal's website (http://onlinelibrary.wiley.com/journal/10.1111/%28ISSN%291476-5381). In the case of *BJP*, articles published after September 2009 were not available for open access. As for *IJPP*, articles published since 2002 were available on the website. So, to maintain uniformity, all articles published in or after 2002 were downloaded. Only original animal studies were considered for the study. Short communications, research letters and letters to the editor were not taken into account. Of the studies downloaded, 50 animal studies each from *IJP* and *IJPP* were selected randomly (by computer-generated random numbers) and 100 animal studies were selected randomly from *BJP* by the first author. For equal comparison, animal studies only related to pharmacology were downloaded from *IJPP*. Each author evaluated these animal studies on the basis of reporting of animal ethics committee approval and reporting of ethical guidelines. Discrepancies in evaluation were resolved by consensus.

Values were shown in the form of frequencies, and comparison between various ethical parameters between the Indian