

Why does the wind not cease?
Why does the mind not rest?
Why do the waters, seeking truth,
Never ever cease?

The freshness need not be borrowed from elsewhere.

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Financial incentives and the prescription of newer vaccines by doctors in India

RAKESH LODHA¹, ANURAG BHARGAVA²

¹Department of Paediatrics, All India Institute of Medical Sciences, Ansari Nagar, New Delhi 110 029 INDIA email: rlodha1661@gmail.com ²Jan Swasthya Sahyog, I-4, Parijat Colony, Nehru Nagar, Bilaspur, Chhattisgarh 495 001 INDIA email: anuragb17@gmail.com

The pharmaceutical industry spends a significant amount of resources on marketing its products. According to one estimate, the top 50 companies in India alone spent Rs 5,340 crore in 2004 on drug promotion, spending 290% to 1,025% more on marketing than on research and development (1). The interactions between the pharmaceutical industry and the medical profession related to promotion of medicines have been described as an entanglement; 16 forms of this entanglement have been described (2), and they range from acceptance of gifts and sponsorship of lavishly organised continuing medical education events featuring industry-sponsored speakers, to industry-sponsored research (2). While physicians claim that they are not influenced by the promotional practices of the industry, there is compelling evidence that aggressive promotional efforts lead to irrational and incautious use of more expensive, newer medicines, and escalation of healthcare costs (3,4). The primary responsibility of physicians is to promote their patients' best interests, while the primary concern of the industry is to promote profitability (4). In the past few years, there has been increasing concern over the influence of the pharmaceutical industry over the practice of medicine, medical education and research (5), and guidelines of professional bodies strongly discourage physicians from accepting costly gifts, hospitality, trips and subsidies of any type from the industry (6). The WHO's criteria for ethical medicinal promotion clearly prohibit industry from offering financial inducement and incentives (7). In India, where unethical drug promotion is a significant problem (8), the Medical Council of India's code of conduct (9) still does not address what constitutes appropriate, ethical and legal conduct

in the interactions between professionals and their associations with the pharmaceutical industry.

We report, here, a new and disturbing form of entanglement being employed as a marketing strategy by vaccine manufacturers in India, and discuss briefly its ethical, scientific and public policy implications. This strategy involves the promotion and sale to doctors of newer vaccines - including polyvalent vaccines which are not part of the Expanded Programme of Immunisation (EPI) - at a highly discounted price in relation to the maximum retail price (MRP). The prices of vaccines quoted in a communication sent to doctors are given in Table 1. As highlighted in the table, the percentage margin between the price to doctors and the MRP ranges from 30% to 69%, while in rupee terms, the discount over the MRP per vaccine dose ranges from Rs 85 to Rs 620. Many vaccines require the administration of three or even more doses, wherein the margins of profit for each vaccine could even be Rs 1,800 per child vaccinated. In addition to the private communications to physicians, companies have now started advertising the price of their vaccines to doctors in medical journals. Another company (Chiron Panacea) has placed advertisements in paediatrics journals quoting the price of the pentavalent vaccine 'Easyfive' as Rs 275 to the doctor while the MRP of the vaccines is Rs 585. While physicians will incur some costs for the storage of vaccines, the margin of profit is still huge, and could be termed as profiteering. Such high margins are difficult to find in other professions or industries or in the case of other goods. Unlike other goods, in the case of medicines, patients are unable to make an informed choice about the need and choice of medicine, and rely on the

Table 1

Difference in a vaccine's MRP and the price at which it is offered to physicians

Vaccine	Constituent vaccines	MRP, in rupees, 2008 (A)	Price offered to physicians, in rupees (B)	Discount in rupees (A-B)	Percentage Margin of profit for the physician (A-B)*100/B
Pentaxim	Diphtheria, Tetanus, acellular pertusis, inactivated poliomyelitis vaccine, Haemophilus influenzae b conjugate vaccine	2066	1446	620	42.9%
Imovax Polio	Inactivated Poliomyelitis vaccine	365	280	85	30.4%
Tripacel	Component pertusis, Diphtheria and tetanus toxoids	1211	762	449	58.9%
Okavax	Varicella vaccine	1468	986	482	48.9%
Avaxim 80	Hepatitis A Vaccine	952	665	287	43.2%
TetractHib	Diphtheria, Tetanus, pertusis, Haemophilus influenzae b conjugate vaccine	504	305	199	65.2%
ActHib	Haemophilus influenzae b conjugate vaccine	426	251	175	69.7%

Source: Letter from the manufacturing company to pediatricians

judgement of the practitioner to make a reasoned choice on their behalf. Whereas other medicines are administered in illness and have limited indications, vaccines are administered to prevent disease, and every healthy child can be considered eligible in a sense. In the case of many new and expensive vaccines, as well as the combination vaccines that are being promoted in these communications, the indications for use in the Indian context are not well established, in terms of the epidemiologic rationale or cost-benefit analysis (10). In fact the price of combined vaccines for some diseases is more than the cost of the separate vaccines. The immunisation subcommittee of the Indian Academy of Pediatrics has issued guidelines for the use of some of the vaccines that are being promoted (11). These have been placed in the category of "vaccines to be administered after one-to-one discussion with the parents", as there are insufficient epidemiologic grounds for their routine administration. The guidelines of the IAP are vague and open to interpretation and, given the significant financial inducement to prescribe, they will facilitate over-prescription of some of these vaccines (12).

The communications to doctors highlight the prices without providing drug information related to the vaccines. This violates the basic tenets of ethical drug promotion, which should involve provision of prescribing information rather than inducements to prescribe. One of the handouts to doctors even mentions the price of a vaccine for yellow fever (which does not exist in India), without making any reference to the fact that it is required only for those travelling to an area endemic for yellow fever. The significant financial incentive being offered to doctors on dispensing newer and combination vaccines alters the nature of the relationship between the doctor and the patient and opens a wide area of conflict of interest: the doctor benefits significantly by prescribing a particular vaccine whereas the benefit to the recipient may be marginal. "What would my patient think of this arrangement?" (6) is a question that can test the ethical appropriateness of our interaction with the pharmaceutical industry. In the above case, patients' knowledge of these marketing practices, and the acquiescence

by doctors, will seriously undermine patients' and the public's reliance on the trustworthiness and professional judgement of Indian doctors.

This promotional campaign raises numerous issues for public health and policy in India.

First, the aggressive marketing of vaccines of questionable public health significance in the private sector is occurring in the backdrop of shortages of essential vaccines required for the EPI (10). This is consequent to the closure of the three public sector units which were manufacturing these vaccines, on grounds which are highly questionable and have been widely criticised (13). Private sector manufacturers have been reluctant to provide low-cost essential vaccines to the government even though they are marketing the same vaccines in combination with other vaccines. A large number of children in India are at risk of suffering and dying from vaccine-preventable diseases, because of vaccine shortages. We agree with the demand that vaccine manufacturers should be made to provide vaccines for the EPI before they are allowed to promote expensive vaccines for their profits (10).

Second, the huge margins on offer clearly indicate that the retail prices being paid by parents and patients are highly inflated. The companies could have afforded to sell their vaccines for far lower prices without a loss in profitability. This indicates that there is scope for a substantial reduction in vaccine prices. These practices can be curbed only by placing all vaccines back under price control. Vaccines were under price control till 1995 when the criteria for inclusion in the list of price controlled drugs were changed. Though vaccines and antisera are essential medicines, the new criteria implemented used market-based criteria without any regard to the importance of the drug.

Third, the manner in which these vaccines are being promoted represents the nadir of drug promotional ethics. We are in need of institutional and legal mechanisms to curb aggressive, misleading and unethical promotion of medicines.

The United States Food and Drug Administration, for example, closely monitors promotional material and makes manufacturers accountable for this material by issuing letters of warning (14).

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Vaccines: for whose benefit?

YASH PAUL

Consultant paediatrician, A-D-7 Devi Marg, Bani Park, Jaipur 302 016 INDIA email : dryashpaul2003@yahoo.com

Development of vaccines is a priceless gift from humans to humankind because vaccines prevent diseases while drugs treat or control diseases. Without any research grant or government funding, in 1796 Edward Jenner developed an inoculum. It is said that when the British government asked him to license his inoculum technology for a small royalty on each dose, Dr Jenner refused, electing instead, to give all rights to his preparation technology and preparations to the public free of any royalty. Unfortunately, today's bottom-line-driven vaccine manufacturers are more interested in developing vaccines that maximise their profits.

A doctor must care for individuals. Advice regarding immunisation, like other aspects of medical care, should be given after full consideration of the financial status and circumstances of the family but in the best interest of the individual concerned. The list of essential vaccines should be decided by experts and not by the pharmaceutical industry; the industry should cater to our needs. But at present newer vaccines are being dumped in our country and experts or experts' group(s) are coerced to create a need for these vaccines.

The government should give some sort of incentives for immunisation as vaccines prevent diseases, reducing the burden of expenditure on treatment of diseases and also reducing absenteeism from work and education. The government should consider exempting vaccines from sales taxes and charges in order to reduce the price of vaccines. Similarly, there should be some mechanism to regulate the difference between the maximum retail price (MRP) and

the price to doctors or chemists. At present there is a huge difference in these rates for some of the expensive vaccines. I would like to cite the example of one such vaccine.

Currently the varicella vaccine is available in India from three manufacturers. Their price structure is given in Table 1. Even if all the three vaccines happen to be of similar efficacy, one may be tempted to recommend vaccine C because of the huge profit margin to the doctor. If the difference between the MRP and cost to the doctors is equal or nominal, doctors may consider the comparative merits of the vaccines instead.

TABLE 1 Price structure of three varicella vaccines				
	Vaccine	MRP	Cost to doctors	Difference
A.	Earlier	1430	1120	310
	Now	1599	1102	497
B.		1468	1005	463
C.		1690	1050	640

Market forces play a role in the reduction or increase in a product's price. Strangely, the increase in MRP of brand A vaccine is not related to an increase in the cost of production. On the contrary, the table shows that the price for doctors was actually reduced, though marginally.

The difference between the MRP and the price for doctors or chemists is very small for those vaccines which are part of the National Immunisation Programme. The difference between the MRP and the price for doctors is Rs 500-600 for some newer vaccines. The MRP of DPT is Rs 15.50 and the cost to doctors is about Rs 12.50 whereas the MRP of DaPT is Rs 699 and the cost