TWO WRITERS

## A DRAMATIC BIRTH, AN AWAITED REBIRTH

CINEMA

16 O'CLOCK FOR WHIZKID


# Outlook

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# When A Baby Is A Business Opportunity

*Scared middle-class India buys unwanted vaccines, some 15 of them, as big pharma helps doctors rake in the moolah with 30-300% mark-ups*



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Illustration by R. PRASAD

COVER STORY

# VACCINE VENDORS' GREED GONE VIRAL

**Immunisation is a nexus controlled by big private vaccine makers, mostly foreign, that decides your baby gets 15 shots more for the doctor to make money. Even if the vaccine is useless—not to talk of the huge mark-ups.**

BY ARUSHI BEDI

**THERE is no vaccine against the venal mind. No immunisation ever invented gives us a complete coat of armour. The law is only good enough to catch the more obvious type of visible corruption. When it's raised to a more abstract and institutionalised level, where it forms the very operating logic of a system that surrounds you with good words, it simply becomes the natural order of things. But once in a while, a crack develops in the consensus and the light filters through. The evening of January 20, when the lonely dissenting voice of Dr Vipin Vashishtha was sought to be banished by the Indian Academy of Paediatrics (IAP), was one such moment. What showed through in that light was the entire unholy architecture of India's immunisation programme.**

The evening did not go well for Dr Vashishtha (*see interview on p 38*), ex-convenor of the academy. In the late hours, his fellow members had him thrown out unceremoniously from the IAP general body meeting. The reason: Dr Vashishtha had blown the whistle on the silent collusion of interests between paediatricians and vaccine manufacturing companies. It's a nexus that enables these companies—Indian and multinational—to push expensive vaccines into the market, some of them not even answering to a real need. The market is worth thousands of crores, and booming. And doctors make unwarranted profits in the process, at the cost of the unknowing public.

**The Indian Academy of Paediatricians decides which vaccines are to be introduced—all private doctors go by its charter. And the nexus begins right there.**

The IAP, the nodal private sector body, directly influences 10-15 per cent of all immunisation in India—and though that makes it seem limited in scope, this is only in terms of volumes. In value terms, the market is almost as big as the state-run immunisation programme. And the IAP's charter of immunisation, followed by all private paediatricians, exists like a quasi-official model of healthcare to be aspired to by everyone. Immunisation via the public health agencies is a more regulated territory, but still the creeping influence on it is not hard to divine—this is because the overarching coalition of global interests that pulls the strings from remote boardrooms is the same on the public as well as private sector (*see story on p 40*).

Healthcare is a transaction of trust. Immunisation is one of the first steps in that transaction in an individual's life. But the field has become so grey that vaccines are being sold for diseases not even prevalent in India! Take yellow fever vaccines. A well-known vaccine distributor in Delhi says some 2,000 units of yellow fever vaccine are sold every month in India. Yellow fever has zero incidence in India (or Asia)—while being prevalent in Africa and Latin America—and the vaccine is only needed to be administered to individuals who travel overseas. Each dose of the vaccine costs Rs 1,850 to the patient.

For Dr Vashishtha, it's been a long battle against this tacit compact; the January 20 general body meeting was the last straw. It all began in 2011, when he took over as the IAP convenor. The IAP, a national association of paediatricians, is responsible for making recommendations for new vaccines that enter the market: this

becomes the benchmark adhered to by paediatricians across India. The government too consults it to update its own national immunisation programme.

The revelations made by Dr Vashishtha have now reached Parliament. On March 17, Dausa MP Harish Meena raised a starred question in the Lok Sabha on the subject. In his reply, Union health minister J.P. Nadda admitted the government was aware of the corruption within the IAP and had also received a complaint from a doctor in Karnataka on it. The government "does not endorse the recommendations" of the IAP, Nadda added, and "all vaccines included in the Universal Immunisation Programme (UIP) are available free of cost across government health facilities." Yet, no sign there of any move to address the lack of regulations or of any inclination to introduce a structure of guidelines.

India vaccinates over 27 million newborns every year—a 10 per cent ratio means 2.7 million of them get vaccinated through the private sector. Naturally, in urban areas, the ratio is much higher. "Over 40 per cent of children immunised in cities are taken to private hospitals," says Pradeep Haldar, chairman, National Technical Advisory Group on Immunisation (NTAGI), the government body responsible for making suggestions for vaccines to be introduced into the country.

The essential issue is the structure of the industry. Most vaccines are sourced from foreign players with limitless resources. And they are willing to spread it around a bit among doctors and distributors with a single agenda: to increase sales. Not only does this bring about huge price mark-ups, it also pushes 'cash vaccines'—those that make big bucks but may not be the safest or the most needed for disease prevention. And when reputed bodies of paediatricians and other groups offer their stamp of approval, they are basically acting as lobbyists—though in the guise of arbiters acting in the name of public good.

SANJAY RAWAT


**The private sector, unlike the state-run UIP, pushes a whole bouquet of vaccines, and without any empirical data to back their need or effectiveness.**

CONSIDER this. The UIP, which is the government programme targeted at immunising all children up to age five against certain diseases, offers a range of six vaccines across India. In addition, there are three more state-specific vaccines. A private doctor, on the other hand, may offer you a range of 25 vaccines for your child! The costs involved may seem tolerable for a lot of city parents eager to ensure a healthy baby; the volumes bring in the profits, which are substantial. Dr Bakul Parekh, paediatrician and IAP secretary general, says a parent can spend anywhere up to Rs 25,000-30,000 in the full course of vaccination for their newborn. Count also the consultation fee charged by doctors for every dose, for almost one visit to the doctor every month till the child turns 12. Now compare this to the UIP, which is offered to all children free of cost.

Under the Drugs and Cosmetics Act, 1945, paediatricians are required to maintain records of every vaccine dispensed by them, to ensure only registered medical officers dispense or prescribe such vaccinations. *Outlook* asked several paediatricians for such records but they were unwilling to provide them. Moreover, there is no government or non-governmental authority where such records need to be submitted by paediatricians. This unregulated scenario has opened a huge market for non-authorised doctors to sell such vaccines.

The biggest motivating factor here is the undue mark-ups offered to every intermediary. Studies suggest mark-ups can range from 30-300 per cent. *Outlook* obtained several documents from distributors and doctors laying bare the scale involved. Take the pneumococcal conjugate vaccine, administered to prevent pneumonia. It costs the parent Rs 3,800 per dose. And the landed cost of the vaccine, meaning the amount it's imported for, is only Rs 1,200 per dose. In other words, between distributor and doctor, that's a neat mark-up of over 300 per cent.

Compared to pharmaceuticals and medical devices—which are need-based, curative aids—the vaccine market operates on a different logic, because these are by definition preventive interventions and irrational fear can be a factor. Often, the very existence and supply of a vaccine can engineer demand. "Several new vaccines are introduced in India that may or may not be required by all children. There is no objective way to prioritise new vaccine introductions. Ideally, it should be guided by our local burden of disease and needs. But companies push these vaccines just to earn higher profits and many paediatricians collaborate with them," says Yogesh Jain, founder of Jan Swasthya Sahayog and a member of the National Health Mission steering group.

The mere awareness of a disease, whether prevalent in India or not, becomes a coercive tool for doctors to prescribe costly vaccines that might not be needed. The UIP takes into account geographical variations—the prevalence of Japanese encephalitis, for instance, is limited to certain states—and most vaccines it prescribes are essential for the well-being of a child. The private sector, though, pushes through a whole bouquet of vaccines without any empirical data to back their need or effectiveness. Dr Jacob Puliyel of St Stephens Hospital, New Delhi, and a member of the NTAGI board, elucidates this with the example of the pneumococcal vaccine. "The vaccine used to eliminate pneumonia targets only 10-13 strains of the disease, which is known to have more than 100 strains," he says. "If you do the math, it means the vaccine is capable of preventing pneumonia only in four out of hundred children," he adds.

So how do such vaccines enter the Indian market to begin with? According to paediatricians, this happens through a

# NO IMMUNITY FROM GREED

The vaccine rip-off tale at a glance

**Vaccines required according to the government**

**₹9,451 cr***
Government spending under UIP in 2017

1. BCG (Bacillus Calmette Guerin) (For tuberculosis)
2. DPT (Diphtheria, Pertussis and Tetanus Toxoid)
3. OPV (Oral Polio Vaccine)
4. Measles
5. Hepatitis B
6. TT (Tetanus Toxoid) (for children in the 10-16 age group and pregnant women)
7. Pneumococcal (pneumonia)
8. Pentavalent vaccine (DPT+HepB+Hib)
9. Rotavirus (diarrhoea)
10. JE vaccination (in selected high disease burden districts)

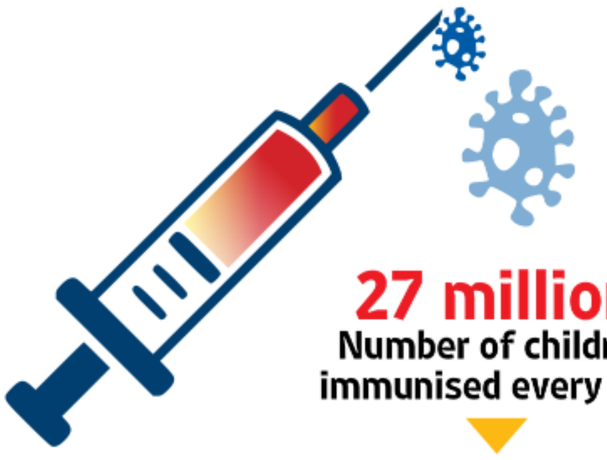
**2,000 units**
of yellow fever vaccine are sold every month in India, which has zero incidence of the disease.

**15 vaccines not essential but pushed by private practitioners**

1. IPV (Inactivated polio vaccine) (Polio) (duplication)
2. DT (diphtheria and tetanus toxoids) (duplication)
3. Tdap (Tetanus and diphtheria toxoids and acellular pertussis) (duplication of DPT)
4. Typhoid (easily curable)
5. Hib (Haemophilus influenzae type b) (meningitis) (duplicate)
6. MMR (Measles, mumps, and rubella) (duplication)
7. HPV (Human papillomavirus) (efficacy questioned)
8. Hepatitis A (easily curable)
9. Chicken Pox (easily curable)

**VACCINES UNDER SPECIAL CIRCUMSTANCES**

10. Rabies
11. Influenza
12. PPSV23 (Pneumococcal Polysaccharide Vaccine)
13. Meningococcal (meningitis)
14. Cholera
15. Yellow Fever



**27 million**
Number of children immunised every year

**2.7 million**
immunised in private sector

**₹25,000-30,000***
Total cost of immunisation per child in private sector

**₹8,100 cr***
Total private practitioners market **

## Doctors as Vendors
The Mark-Up Story

Mark-ups in vaccines in private sector
**30-300%**

Pneumococcal conjugate vaccine's landed cost
**₹1,200**

Maximum Retail Price
**₹3,800**

Mark-ups, which include commissions to distributors and doctors
**300%**

*Figures are only estimates; **Private practitioner market = Total cost of immunisation per child x no of children immunised in private sector
Source: ICMR

Graphic by SAJI C.S.

well-oiled system of quid pro quo between vaccine companies and organisations responsible for recommending vaccines. "Most doctors depend on the recommendations given by organisations such as the IAP," says Dr Vashishtha. And many IAP members, who chair discussions on what vaccine to recommend, have associations with companies who appease them through gifts and several other soft bribes, he adds.

Several doctors told *Outlook* on the condition of anonymity that once a certain vaccine is cleared by the Drug Controller General of India (DCGI) for use in the country, representatives from different multinational vaccine companies visit doctors to push their products. This is done by offering not only extremely lucrative mark-ups on vaccines but also other incentives, like covering travel expenses to exotic locations for medical conferences and free samples of vaccines the company would like to promote. The IAP itself is almost completely funded by private players, a look at their website confirms. The organisation receives hefty donations to the tune of crores from several companies, both Indian and foreign. Online records show that, in 2016, IAP earned Rs 5.5 crore and yet did not show any profits in its financial documents.

A 2012 paper published in the Indian Journal of Medical ethics—titled '*Financial incentives and the prescription of newer vaccines by doctors in India*', by Dr Rakesh Lodha and Anurag Bhargava—also records the mark-ups in newer vaccines. The common Haemophilus influenzae type b (Hib) conjugates vaccine, for instance, has an MRP of Rs 426 and is supplied to doctors at Rs 251, a discount of 69 per cent per dose for the doctor. The information for the paper was obtained through communication sent to a doctor by distributors. "The significant financial incentive being offered to doctors on dispensing newer and combination vaccines alters the nature of the re-

lationship between doctor and 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," concludes the paper.

When *Outlook* got in touch with Dr Bhargava, a professor at the Yenepoya Medical College in Mangalore, he said such mark-ups are commonplace within the industry. He attributes it to the shutting down of public sector vaccine manufacturers in 2008. "The shutting down of PSUs manufacturing vaccines has allowed private companies to take advantage of a market without regulation or a cap on prices, which enables them to further push vaccines through high mark-ups," he says.

The cold chain used in transport poses another issue. Most vaccines need to be stored under controlled temperatures of 2-8 degrees Celsius; exposure to temperatures above that can spoil it. In the private sector, the cold chain is maintained by MNC suppliers themselves and the quality standards can be dubious. Walk into Bhagirath Palace in Chandni Chowk, home to one of the biggest drugs wholesale markets in Delhi, and you see vaccines being transported from trucks to individual shops without adequate refrigeration, breaking the cold chain. Dr Davinder Gill of Hilleman Laboratories, a vaccine developer, says no real data is available on how much may have perished. "Wastage statistics are hard to get in the private sector. No manufacturer makes such records public," he says.

One way of telling whether a vaccine is spoilt or not is the labels, which change colour if the vaccine inside is spoilt, says Dr Gill. The system may have utility, especially in the cities, but smaller towns still face the threat of spoilt vaccines being administered. *Outlook* sent a detailed questionnaire to several companies in this regard but got no response. We also got in touch with a distributor who, while requesting anonymity, admits faulty vaccines could still be distributed in smaller towns and villages via non-licensed stockists unaware of proper cold storage methods. "In cities, if a vaccine gets spoilt, it's usually returned to the company but in smaller towns and villages, such vaccines slip through the systems and may be administered to patients."

**The health ministry offers no set regulations for the administration of vaccines or for controlling unneeded vaccines in the private sector.**

THE IAP and individual practitioners have been trying to grapple with the issues at some level. Several doctors who attended the IAP's annual medical conference in Bangalore last year tell of how company representatives present there distributed gold coins to doctors who bought a certain amount of a new vaccine. To combat this problem of co-dependence creating undue advantage, the IAP has put in place regulations for declaration of conflict of interest. "Each meeting for recommendation of vaccines under the IAP is first reviewed by a committee and then voted upon," says Dr Parekh.

Several high-level members attend such meetings, bringing in conflict of interest. Vashishtha says he has witnessed this network first hand—while preparing the schedule for the 2016 recommendations, two doctors, Dr Anupam Sachdeva and Dr Ajay Gambhir, did not submit their conflict of interest forms and the effect was visible. Recommendations to include a vaccine of a particular company, voted on unanimously, were taken back by the then IAP president under the influence of Dr Sachdeva, the current IAP president, Vashishtha alleges.

"A vaccine from the company Biomed was put in the schedule after deliberations. Yet, under Dr Sachdeva's influence, the recommendations carrying this vaccine were withdrawn. To make matters worse, Dr Sachdeva also did not submit his conflict of interest form," says Dr Vashishtha, adding that Sachdeva wished to promote a similar vaccine manufactured by the company Bharat Biotech instead. An Indian company, Bharat Biotech did not respond to *Outlook*'s queries despite several attempts. Bharat Biotech was also the principal sponsor of the paediatricians' conference at Bangalore and has paid over Rs 1.5 crore to the IAP. The same company allegedly distributed gold coins as freebies to doctors in the conference.

When *Outlook* got in touch with Dr Gambhir and Dr Sachdeva, they rubbished the allegations against them, stating the required declaration of conflict of interest had been duly submitted and yet they were being targeted by Dr Vashishtha. Dr Gambhir in turn alleged the IAP has several members who do take grants and bribes from foreign organisations. "The influence of the foreign lobby is immense in the IAP. Several doctors take grants and bribes from such companies, including all-expenses-paid foreign trips. This corruption has been industrialised as many of these companies use IAP as a front to recommend such vaccines to the public for consumption," he says. Dr Sachdeva too says the IAP takes several grants as well as funds from vaccine companies for the running of the organisation—a clear signal of a conflict of interest.

The lack of guidelines and credible regulation, either at the organisation's level or from the government, is clearly the core issue. The immunisation subcommittee of the IAP has issued guidelines for the use of some vaccines—these may not be required by all children and have been placed in the category of "vaccines to be administered after one-to-one discussion with the parents", as there are insufficient epidemiological grounds for their routine administration. Yet, the guidelines remain vague and open to interpretation and, given the significant financial inducements, one can fairly predict the eventual picture.

The government too has no well-evolved guidelines for vaccines or code of conduct for those administering them. According to existing guidelines, a new vaccine can enter the country simply through a study on 60 people presented to the DGCI, provided it's licensed in any other country. There is no need for firms to establish disease burden or even efficacy of the vaccine. The health ministry simply offers no set regulations for the administration of vaccines or for controlling unneeded vaccines in the private sector. The strange thing is, no such move towards an ombudsman-like role seems to be on the anvil either. This has left open a huge lacuna in a vital area of health delivery. On one side, the prices follow a kind of laissez faire. And on the other, a huge country like India remains vague and open-ended even about the list of vaccines actually required.

# 'PHARMA MONEY IS CORRUPTING PAEDIATRICS ACADEMY'

*A former member of the Indian Academy of Paediatrics (IAP),* ***Dr Vipin Vashishtha*** *was ousted from the academy for highlighting the nexus between physicians and vaccine manufacturers last year. The Bijnor-based paediatrician documented the rampant corruption and system of favours in an open letter addressed to all members of the academy. In an interview with* **Arushi Bedi**, *he lays bare the nexus and talks about how he is still under fire for raising questions. Edited excerpts:*

**What made you blow the whistle on corruption in the medical fraternity?**

I was convenor of the Committee of Immunisation in the IAP for six years. When I took over in 2011, there was no way to address the conflict of interest among the academy members. Some IAP members are on the advisory boards of big vaccine companies and many participate in CME (Continuing Medical Education) programmes organised by such companies and get honorarium.

According to WHO guidelines, members must declare such relations and also whether the physicians or any of their family members have received any cash or compensation in kind from vaccine-manufacturing companies.

**So what happened?**

The implementation of these guidelines was going quite well until 2015 but, in 2016, two members of the academy were inducted into the committee as chairman and nodal president. Taking advantage of their position in the academy, they started opposing the regulations on conflict of interest. The academy drafted its new immunisation schedule for the year on May 6, 2016. Certain recommendations on the schedule were unanimously passed by the committee and the regulatory board, and then uploaded on the official website as per protocol. Such recommendations also need to be published in the *Indian Paediatrics Journal*, which goes to all members of the academy, so they can be implemented. Yet, with no authority to do so and without giving any reasons, the president of the academy stalled the process of publication for several months and, eventually, the recommendations were not published.

Most practitioners across the country depend on these recommendations for their day-to-day vaccine-administration practices. These recommendations are also monitored by the government and NGOs to evaluate policy for the entire country.

**Who removed the recommendations from the website?**

The recommendations can only be removed on the direction of the president. The two members I mentioned had asked the then president Dr Pramod Jog to write to the board of the academy to remove the recommendations. This has been the main conflict.

**What did you do after this happened?**

I immediately opposed it and sent many e-mails to Dr Jog and other committee members. When nothing happened, I wrote an open letter to all 24,000 members in December 2016. This letter was leaked by one of the recipients and was all over the media the next day.

**What did you say in your letter?**

I had asked for a proper investigation to find out what all had been going on in the academy in the past five to ten years in certain cases. Vaccine companies have huge resources at their disposal and are trying to influence recommendations by offering favours to practitioners. They promote their own agenda through doctors and their own KOLs (key opinion leaders). The letter also mentioned that such companies were funding most academic programmes and CMEs. This raises the possibility of a nexus between the companies and the doctors making profits on a quid-pro-quo basis.

**How does this nexus work?**

It operates at various levels. One is the private sector, which is badly regularised or controlled. There are no government guidelines to control this sector even though it constitutes 10-15 per cent of all vaccine-related functions in the country. The majority of vaccines, say around 80-90 per cent, are distributed or supplied by the public health system, which is also not all clean.

The companies try to influence the recommendations by sponsoring various members of the recommending body and, in fact, directly offering them incentives in cash and kind. Before the conflict of interest guidelines came into place, they used to decide who the participants at a panel discussion on a particular vaccine would be, what should be the subject of the discussion and even which vaccines should be recommended.

**Has there been a change in practices since the new rules were put in place?**

> ***"Vaccine companies have huge resources at their disposal. They try to influence the IAP's recommendations and promote their own agenda by offering favours to doctors."***

SANJAY RAWAT

Things have improved since 2011. But vaccine companies still sponsor trips of certain members and pay for their travel. They pay for both work and leisure—and sometimes payments are made on a monthly basis. They have also been known to sponsor medical practitioners' foreign conferences. Some physicians have tried to undermine the recommendations of the body by distancing themselves from the issue. Contrary to what the IAP committee on immunisation is recommending, these physicians have floated their own recommendations and guidelines, which seem more in consonance with those of the vaccine companies. This has created even further confusion. The ethical guidelines went out of the window and such recommendations were supported by the so-called KOLs in associations, which are also funded by the companies.

**Is this happening all over the country?**

Yes. The members in question come from all parts of the country. It is funny how they have already declared they have conflict of interest with such companies, but are still allowed to participate in CMEs as faculty. They might not be part of the main committee recommending a particular vaccine, but they are still opinion leaders and influence decisions.

**What are the MCI guidelines on this?**

There are strict guidelines for medical practitioners to not accept honorarium from pharmaceutical companies. A medical practitioner can receive gifts worth upto Rs 1,000. The government has also approved these guidelines recently. Such alliances with the vaccine companies are clear grounds for suspension of medical licence.

**There was also news of you being manhandled by the academy members at the conference. What happened there?**

At the paediatrics annual conference in Bangalore held in January, while the executive board meeting was going on, the president suspended me from the academy and debarred me from participating in the general body meeting because of my letter and its media coverage. I wanted to present my findings and defend my case, but got no opportunity. How can an office-bearer facing serious allegations of violation of conflict of interest be the same person to take this decision? The suspension order was sent to me on e-mail just a few hours before the meeting. When I started to put my point forward in the meeting, they manhandled me and threatened me with more physical assaults. This was on the night of January 20. The next morning, I went to the police station and lodged an FIR against these people, which I later withdrew in good faith.

**How have other doctors reacted to this incident?**

After the incident, I received support from all over the country. Several paediatricians have boycotted the activities of the academy. The current office-bearers have also been boycotted. States such as Kerala and UP have passed resolutions to look for members with any conflict of interest and not take part in the activities of the academy until these issues are resolved. In the last two months, the activities of the academy have been stalled.

Many doctors have also called my suspension illegal. The questions I raised in the open letter sent to the association had around 16-17 issues that are yet to be addressed.

**What is your next course of action?**

The battle has to be fought on two fronts—the personal and the organisational. On the personal front, I am going to approach the Medical Council of India (MCI) on the code of ethics. There is a guideline of the MCI that says it is the duty of a medical practitioner to use all available means to expose such unethical practices. I went through all recourses to bring what was going on to the notice of the president. Only when I was pushed to the wall did I write that letter.

At the organisational level, the system needs to be overhauled completely. Persons with dubious credentials should never be in a position to dictate terms of policy that will affect the health of our children. Our organisation needs to be freed from the clutches of the vaccine mafia and its agents. It is pharmaceutical money that is corrupting our organisation. The medical council has rightly put a cap on gifts and freebies that companies can give to doctors. It is high time they looked into organisational funding through conferences and CMEs by vaccine manufacturers.

> ***Dubious persons shouldn't be in a position to dictate terms of policy that affect children's health. The IAP needs to be freed from the clutches of the vaccine mafia and its agents.***

COVER STORY

# 'FREE' VACCINES AREN'T FREE OF THE FOREIGN HAND

## The perils of India's growing dependence on vaccine imports and private manufacturers

BY ARUSHI BEDI

**HOW many vaccines does a newborn need? Does a child need vaccination regardless of how minor the ailment or rare the disease? Even doctors don't offer a clear answer. More than 85 per cent of the total vaccines sold in India are administered through state-run programmes under the central government's Universal Immunisation Programme (UIP). Aiming to immunise all newborn children, the programme started off with six essential vaccines and, over the past few years, introduced three more—rotavirus, Pentavalent and pneumococcal vaccines—while the mumps vaccine is in the process of being added. Battling overstretched resources and poor coverage, the programme has also drawn flak for yielding to the influence of international bodies, leading to certain vaccines being introduced that allegedly don't match the profile of immunisation needs on the ground. For instance, every year, five lakh children die due to vaccine-preventable diseases and another 89 lakh are at risk, because they are either unimmunised or partially immunised.**

So is public money being spent for private profit through the welfare-oriented, 'free' immunisation programme? "The UIP is funded by taxpayers' money, so when any vaccine is introduced for mass immunisation, it has to be proved that the disease burden (spread of the disease) and the vaccine's quality actually call for rolling out a state- or nation-wide programme for it," says Dr Jacob Puliyel, head of paediatrics at St Stephens Hospital in Delhi and a member of the National Technical Advisory Group on Immunisation (NTAGI).

As a huge amount of public money—Rs 9,451 crore, as per the Indian Council of Medical Research's projection for 2017—is spent to enable free immunisation, the choice of vaccines involves a balancing act between the cost of the product and its utility in keeping the country free of preventable diseases. Getting a measure of vaccine utility requires wide-ranging studies on disease burden, immunisation efficacy and the vaccine's adverse effects on individual children as well as its collective impact. It is on the basis of the profile emerging from such studies that the money spent by the government on the vaccine procured through tenders needs to be justified.

The past decade or so has seen a proliferation of new vaccines in the market, led by big multinationals seeking to widen their reach in developing countries such as India. This has encouraged a supply-push approach to immunisation rather than a demand-driven one. Queering the pitch even more is an opaque tangle of global institutions—decisions on procurement for the UIP happen within an elaborate, complex system controlled by this network. It involves conditions on expenditure attached to 'soft loans' from the International Monetary Fund (IMF), approval mechanisms of the World Health Organisation (WHO) and recommendations of the Global Alliance for Vaccine and Immunisation (GAVI), which works as a bridge of sorts between global pharma giants that make vaccines and developing countries that procure them.


**IMMUNITY DISORDER Polio vaccination kits wait for use at a rural primary health centre near Allahabad, UP**

As things stand, the National Vaccine Policy too is proving to be of little help in this regard. According to a paper published by Y. Madhavi and N. Raghuram in science journal *Current*, the old policy was amended "in a tearing hurry" by the Union ministry of health and family welfare in 2011 without any consultation with the stakeholders. "[The amended policy is] not designed to enhance national public capacities for public immunisation programmes, but to justify spending public money on privately produced vaccines in the name of protection from diseases, whose incidence figures and public health statistics are dubious and industry-manufactured. In its eagerness to push vaccines, this policy completely missed the very idea of selective immunisation and implies that all immunisation is universal," write Madhavi and Raghuram.

The changed orientation had a direct effect. "There were few studies for establishing disease burden on the ground even though it costs much less to monitor diseases than to develop and produce vaccines," Madhavi tells *Outlook*. "Vaccines are recommended by scientists who develop them or companies that make them, but bulk procurement by a sovereign national government must be guided by disease burden and efficacy, not by estimates and advance market commitments encouraged by international agencies. If a disease is prevalent in some other country, it's assumed India bears a burden as well."

Take the Pentavalent vaccine, for instance. It is a single-vial combination of vaccines to protect against five diseases—diphtheria, pertussis, tetanus (DPT), hepatitis B and haemophilus influenzae type B (Hib). A quick look at the GAVI web-


GETTY IMAGES

site shows it was recommended by the alliance to replace the DPT vaccine and increase the uptake of vaccination against hepatitis B and Hib. Introduced as part of the UIP in 2011, Pentavalent is suspected to have actually killed 276 children so far, most of them in Delhi, Tamil Nadu, Madhya Pradesh and Kerala, according to the health ministry's reply to an RTI query by Puliyel. A ground report by the Human Rights Law Network (HRLN) revealed a dozen suspected deaths in Delhi, with all the children showing similar symptoms.

"About 24 hours after the vaccine was administered, the children are reported to have cried inconsolably in pain, while their abdomen had turned black and blue," says Prakriti Sareen, a member of the HRLN team that brought out the report. But, even though, technically, deaths within 72 hours of administering a vaccine are taken to be a result of 'adverse effects following immunisation' (AEFI), the government has refused to acknowledge the connection between the vaccine and the deaths.

Pentavalent came to India piggybacking on GAVI recommendations even though it's not licensed by the US Food and Drug Administration (FDA). Moreover, according to Puliyel, no rigorous field research was done in India on its effects. When trials in 2008-09 led to the deaths of 14 children in Sri Lanka and 43 in Bhutan, both countries showed Pentavalent the door. That's when the WHO diluted the protocol used for measuring the AEFI, besides limiting Pentavalent to just two states in India to begin with. The change in protocol, according to the WHO website, was done by a 40-member committee, half of whom represented vaccine-manufacturing companies. It raised suspicion that the interests of Pentavalent's manufacturer had something to do with the change in the WHO protocol.

**Half of the 40 members**
**of the WHO committee that changed the protocol for adverse effects following immunisation represented vaccine-manufacturing firms.**

Moreover, several studies have shown that India's disease burden for hepatitis B and Hib—the two diseases that Pentavalent prevents in addition to what the DPT vaccine was already covering—is almost negligible. These include studies conducted by the Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, and the National Institute of Nutrition, Hyderabad. According to an editorial in the journal of the Indian Academy of Paediatrics, "The frequency of chronic infection for hepatitis B was similar in both unvaccinated and the vaccinated individuals—about 0.15 per cent—rendering the hepatitis B vaccine completely useless in India. The papers also observed that the immunological and epidemiological outcomes of rolling out Hib are not being monitored as the UIP has no capacity for that function."

Dr Naveen Thacker, Asia Pacific Paediatric Association president and CSO representative on the GAVI board, denies the vaccine caused the reported deaths. "A vaccine is introduced in the country only after it goes through rigorous examination by the NTAGI committee," he says. "The studies conducted to investigate deaths related to Pentavalent do not show any causal relationship with the vaccine." Gagandeep Kang, member of NTAGI and the WHO's Immunisation and Vaccine Implementation Research Advisory Committee, too brushed aside the deaths as "circumstantial" in a recent conference.

India's dependence on vaccine imports and private players has grown manifold over the past few years due to the shutting down of state-run PSUs in 2008. This is a huge change from the 1984 vaccine policy that had stressed on self-sufficiency and, in fact, enabled exports to other developing countries. The closing down of the PSUs left the UIP at the mercy of imports from foreign firms and gave donor agencies greater control over the choice of vaccines. Today, India procures its vaccines from several private companies, both Indian and foreign, including Bharat Biotech, Serum Institute, Pfizer and GSK. In 2010, two PSUs were revived for vaccine production, but the attempt was half-hearted—their contribution remains a measly 2.4 per cent of the total vaccine base. Worse, the change in the procurement policy in favour of new combination vaccines means that even the government won't purchase vaccines produced by its own PSUs.

The dependence on foreign pharma giants is such that the contracts usually include advance market commitments, which have forced many countries to bend over backwards for generating sufficient demand to meet the supply coming through GAVI. The contracts commit governments to procure a predetermined number of doses of a new vaccine. "In fact, the commitments are often made even before clinical trials for efficacy are completed by the manufacturer," says Madhavi. Moreover, the vaccines are supplied at subsidised rates through GAVI only for five years (as per the contractual obligation), after which the full price has to be paid. With only 1.17 per cent of India's GDP allotted to healthcare, this could turn out to be too big a price to pay.

This has hiked the per-dose cost paid by the government. For instance, Pentavalent costs the government Rs 60 per

# ‘NO NEED TO REGULATE THE PRIVATE SECTOR’

***Pradeep Haldar**, deputy commissioner (immunisation) at the Ministry of Health and Family Welfare and chairman of the National Technical Advisory Group on Immunisation, spearheads the universal immunisation programme (UIP) in the country. Haldar tells* **Arushi Bedi** *that the choice of vaccines is led by public health concerns, not individual needs as in the private sector. Excerpts from the interview:*

**A question was raised in the Lok Sabha recently on the influence of vaccine-manufacturing firms on doctors and the Indian Academy of Paediatrics (IAP)...**

There are no regulations for vaccination in the private sector, where only a small section of the population gets immunised. A private setup will not look at the protection of a community. They will see if an individual is protected or not. As the government, we look at vaccines from the point of view of the population at large, so our vaccination components are different.

**The private sector is reportedly recommending more vaccines compared to the public sector. Why?**

There are some vaccines the government may not have introduced in the public interest or due to lack of disease burden. The IAP, on the other hand, approves several vaccines for individual use.

**Can we do without the vaccines that are not part of the UIP?**

Such diseases are not public health concerns. They are only required for a small population and need to be given only to people who might be affected by the disease.

**But several private practitioners claim all vaccines are important...**

The parents need to decide if a child needs a medicine. If we force the private sector to follow government schedules, we would be depriving the public of other vaccines they might want to take.

**Is there no need to regulate the private immunisation sector?**

There is no need unless you want the private sector to become part of national immunisation through the public health programme. The private sector has access to several vaccines that may not be of public importance.

**The introduction of rotavirus and Hib meningitis vaccination has caused an uproar in some circles due to lack of disease burden in the country. Is this true?**

We have conducted rotavirus studies over different periods in five sites to see the burden of diarrhoea cases. There is also literature on the basis of which we have calculated that almost one lakh children die due to rotavirus every year. Chances of severe diarrhoea and death are high in early infections of rotavirus, but subsequent episodes are known to be less severe. By the time the child is a year old, we may not be able to diagnose the virus since the infection will be less severe, not conspicuous. For Hib too, we need to have proper facilities to diagnose the problem, along with samples to do culture and sensitivity tests for finding out the disease burden. There is no standard protocol to diagnose and treat pneumonia. In smaller areas, children are mostly given antibiotics without diagnosing if the pneumonia is due to Hib.

**Pentavalent vaccine has replaced the DPT, which costs far less. How is the government justifying it?**

Every dose of DPT and hepatitis B costs Rs 4. We need to use auto-disable syringes to vaccinate, which cost us Rs 2 each, making the total cost of one dose of DPT and hepatitis Rs 12. A dose of Pentavalent, which has an additional antigen, costs Rs 60. Any public health intervention through immunisation has proven to be the most cost-effective.

**How is the government dealing with vaccine shortages in the UIP?**

The government has had no shortage in the national programme since 2010, when we adopted the push-and-pull mechanism.

**What about wastage of vaccines? Is it due to lapses in the cold chain management?**

The major reason for wastage is the use of multi-dose vials under the programme. When a packet of 10 is opened and only three children come for immunisation, the rest goes waste. Most of the time, vaccine wastage is due to the programme design and requirement. Our cold chain systems have been digitised through EVIM (Electronic Vaccine Intelligence Network).

dose, according to Pradeep Haldar, deputy commissioner (immunisation) in the health ministry. It is a tenfold leap from the per-dose cost of the DPT vaccine (Rs 6). “Similarly, while the HPV vaccine costs the government around Rs 290 per child under the subsidised GAVI rates, a cost-benefit analysis done for the government by Thailand-based agency HTAP shows that the affordable price for introducing the vaccine would be no more than Rs 130,” says Puliyel.

The distribution channel too is a cause for concern. According to the Immunisation Technical Support Unit (ITSU) under the health ministry, at least 25 per cent vaccines go waste—due to gaps in the supply chain and logistics management, they lose their efficacy by the time they are administered. While this is true for most vaccinations, the wastage is higher in the case of the BCG vaccine against tuberculosis (over 50 per cent, according to ITSU). Dr Davinder Gill of Hilleman Laboratories, which works on improving quality and supply chain of vaccines in India, believes that major technological and policy interventions are needed to reduce vaccine wastage. “Apart from an improvement in the infrastructure and handling of such vaccines, the government needs to clearly lay down open-vial policies, which include the protocol on storing the remaining doses of vaccines after a vial is opened,” says Gill.

There is also a need to keep a check on how much money is spent to meet international obligations vis-à-vis vaccines. A thrust on self-sufficiency in vaccine production can only contribute to the government’s focus on ‘Make in India’. Also, if the stated emphasis on targeted delivery of subsidies were to be extended to the heavily subsidised UIP, it would demand more accurate data collection on the effects of new vaccines, besides pinpointed governmental interventions to make the programme successful not just on paper, but also on the ground.

**“Commitments to procure vaccines are often made even before clinical trials for efficacy are completed by the manufacturer,” says Y. Madhavi.**