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PM Modi must rescue vaccine programme from vested interests

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Representational image.

To ensure that the public is kept in the dark on formation of public health policy on vaccines the new secretariat has introduced confidentiality clauses.

The Bill and Melinda Gates Foundation's (BMGF's) prescription of foreign drugs for India's poor and the way in which it has become a major influence within key ministries in Government of India was mentioned in this newspaper recently (The Sunday Guardian, 7 February 2016). The links with the Global Alliance for Vaccine and Immunisation (GAVI) and Public Health Foundation of India (PHFI) were described. The article also highlighted the investments of the foundation and the board members in US-EU Big Pharma stocks and the resulting possible conflict of interests.

The vaccine market in India is potentially one of the largest in the world. The government is advised on what vaccines to include in the national immunisation programme by a committee of experts called the National Technical Advisory Group on Immunisation (NTAGI).

This body is expected to evaluate the vaccines, their costs and benefits for the country. Vaccines whose cost far exceeds the benefits are not to be recommended. But the entire secretariat of the NTAGI has now been outsourced to the BMGE Called the

This body is expected to evaluate the vaccines, their costs and benefits for the country. Vaccines whose cost far exceeds the benefits are not to be recommended. But the entire secretariat of the NTAGI has now been outsourced to the BMGF. Called the Immunisation Technical Support Unit (ITSU), the secretariat is funded by the Gates Foundation and has been moved out of the Nirman Bhawan, where the Ministry of Health is located, into the PHFI.

It is as if the resources of the Indian government machinery cannot stretch to pay the salaries of the 32 people in this secretariat. ITSU now puts together the papers supporting vaccines and it decides the agenda of the NTAGI and also controls what is recorded as minutes of the meetings.

To ensure that the public is kept in the dark about how the public health policy on vaccines is formulated, the new secretariat has introduced draconian confidentiality clauses. This is in sharp contrast to what happens in the United States, where anyone from the public can attend the technical advisory meetings and can question the experts on the committee. Also in sharp contrast to the US, where members to the immunisation technical advisory body are selected from among applicants by an independent body, the NTAGI in India is merely nominated by the ministry.

As the committee composition is based on the ministry, decisions cannot be based on a majority of votes, but on the strength of the arguments for or against a vaccine.

This is why the minutes of the meeting are a crucial public record. Recording the arguments of those who dissented against the “majority”, would be a powerful deterrent to reckless and irrational decision making by the “majority”.

To prevent such embarrassing come-backs, the ITSU now records the decisions based on the vote, but not the arguments presented against a vaccine.

The confidentiality clause and the new regime came onto being during the UPA rule in 2013. Prior to that, the minutes recorded the proceedings and the records have come to haunt a majority decisions. Prime Minister Narendra Modi needs to bring back transparency in its functioning.

The NTAGI introduced Hep B and Hib vaccines in the Universal Immunisation Programme (UIP) when there was evidence presented that they were not needed.

This was compounded by the decision to introduce it as a combined vaccine in the same injection vial with the DPT vaccine—making it a five-in-one Pentavalent vaccine. Each of the three decisions will be discussed individually.

HEPATITIS B VACCINE

Hepatitis B infection is usually a very mild viral infection that goes undetected by the majority of those who contract it. However, some who acquired the infection around the time of birth develop chronic liver disease and a fatal form of liver cancer. Evidence from India from the Indian Council of Medical Research (ICMR) indicates that the incidence of this problem is vanishingly small.

To make it appear that it was worthwhile to introduce the vaccine, it was made out in 2000 that 250,000 were dying each year because of this cancer, when the real figure was 5,000.

The records show how a fictitious study was quoted saying liver biopsies were performed in all Hepatitis B carriers in AIIMS, to push for the use of the vaccine.

Ten years after the vaccine was introduced in Andhra Pradesh, a study in 2014 was done by the ICMR to look for benefits.

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The data proved what was to be anticipated—that the vaccination programme has been completely useless and children who received the vaccine were no better than the controls studied who had not received the vaccine.

Admittedly, it is embarrassing to have a paper trail showing that these facts were obvious before India launched this expensive programme. The vaccination programme however continues unhindered by these facts

Hib VACCINE

The story with Hib vaccine is similar. Hib is a bacterial infection that can result in pneumonia or meningitis. But the incidence of this is so low as to make the vaccine redundant.

An editorial in the Bulletin of the WHO suggested that this vaccine was not needed in Asia. Studies in Bangladesh demonstrated the vaccine was not useful in reducing meningitis or pneumonia.

Immediately after the results of the Bangladesh study were known in 2006, a misleading press release was issued by a number of organisations including the WHO GAVI, USAID and the “Hib Initiative”, stating that the “Bangladesh study showed Hib vaccine protects children from life-threatening pneumonia and meningitis!”

The WHO, in 2006, followed this with a recommendation that Hib vaccines should be included in all routine infant immunisation programmes. The involvement of international organisations was exposed in the British Medical Journal.

In 2007, in a self-congratulatory article, GAVI and the “Hib initiative” described how they turned the tide in favour of the Hib vaccine by getting the WHO to call for universal vaccine introduction in all countries in spite of controversies about the low burden of disease in some countries.

PENTAVALENT VACCINE

The Hepatitis B and the Hib vaccines, although next to useless in India given the low burden of disease, at least were relatively safe. However, it was introduced in 2011 as a combination vaccine along with the triple vaccine against diphtheria, whooping cough and tetanus (DPT vaccine), making the new vaccine a five-in-one vaccine, or Pentavalent vaccine. This was recommended by the NTAGI in spite of concerns about the safety of the combined vaccine. Prior to its use in India, it had been used in Sri Lanka. Here, three deaths were probably caused by the vaccine and there was no other plausible reason found on detailed investigation of the deaths. The experts, however, seem to have violated the standard protocol for classification of adverse events and reported the deaths were unlikely to be caused by the vaccine. This was exposed in the British Medical Journal in 2010. When it was introduced in India, the NTAGI had noted these safety issues and stipulated that the vaccine be introduced only in Tamil Nadu and Kerala for a year. After the yearlong study was over, the safety of the vaccine was to be evaluated before it was introduced in other states.

There was a death on the first day of the use of the vaccine in Kerala on 15 December 2011. There were at least 12 deaths in Kerala before the year was over. Rather than evaluate the safety of the vaccine, the government introduced the vaccine in other states before 2012 was over, in clear violation of the explicit conditions laid down the NTAGI. This matter was raised in the NTAGI and an NTAGI sub-committee was set up to evaluate all the deaths from the Pentavalent vaccine. This committee met for one preliminary meeting on 22.4. 2013, but in spite of repeated requests the committee never met again. The fact that these decisions of the NTAGI were recorded in the minutes caused more than a little awkwardness for the people who were responsible. There have now been over 100 deaths soon after this vaccine was administered, but the NTAGI sub-committee has not been allowed to evaluate the deaths. A study done by the German government, called the TOKEN study, has shown that the Pentavalent

There have now been over 100 deaths seen after this vaccine was administered, but the NTAGI sub-committee has not been allowed to evaluate the deaths. A study done by the German government, called the TOKEN study, has shown that the Pentavalent vaccine results in sudden unexplained deaths in children within 48 hours of vaccination.

But Government of India under UPA ignored this. Hopefully the NDA will make amends.

CONSEQUENCES

In spite of the stance of denial by the government, the public are getting wary. As a result, people are losing faith in vaccines itself. The NFHS data from Tamil Nadu, which had 90% immunisation a few years ago, has come down to a mere 56%. The result is that essential vaccines like DPT are not being received by children. These are a basic right to the health of babies in India. As a consequence, diphtheria is on the upsurge in these areas. We cannot allow this to happen in the country.

This is happening because the emphasis is on introducing new and expensive vaccines against minor ailments, while ignoring serious diseases against which affordable vaccines are easily available.

THE WAY FORWARD

In 2013, a decision was taken by the UPA to outsource the secretariat of vaccine policymaking to the BMGF without any public discussion. That will have to be reversed and the secretariat will have to be made part of the Ministry of Health. The selection of members to this advisory body must be made on merit by an independent body and they must be held responsible for their advice. When Facebook tried to dilute net neutrality with their offering of free basics, a public outcry and a nationalist regulatory authority stopped them on their tracks. A similar reaction is crucial if we are to eliminate vested interests from controlling public health policy and its horrendous consequences for the country. The nation looks to PM Modi to ensure that truth prevails in this critical field of national endeavour.

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