

## Editorial

### Vaccines: Policy for public good or private profit?

A quantum leap in science and technology in the mid 1970s brought in its wake a new genre of highly profitable vaccines in the mid 1980s. A slew of new vaccines has come to the market and numerous others are in the pipeline. Not all of these meet the actual needs of the majority.

The methods used by economically well-off nations to gain control over economically poor countries by accessing their markets and creating demand for medical technologies/vaccines, irrespective of local needs, have been documented extensively<sup>1-5</sup>. As a new product is being readied, research is published to highlight the number of deaths in the country caused due to the absence of that vaccine. The estimates are often outright exaggerations or reflect poor research design. The limitations of such models have been pointed out previously<sup>6</sup>. The recent announcement by the National AIDS Control Organization (NACO) that the prevalence of HIV/AIDS is only half of the earlier estimates is the first official admission of methodological fallacies<sup>7</sup>. This comes close on the heels of an admission by authors based in Centres for Disease Control (CDC) Atlanta (authors who use a World Health Organization (WHO) Geneva address, alternatively), that the model used to calculate hepatitis B mortality in India (which enabled them to inflate the figure 50-fold) was missing<sup>8</sup>.

Public-private partnerships disguise the role of the pharmaceutical company in such research. Pharmaceutical companies can drive the agenda but be hidden within agencies like GAVI. A recent study from Bangladesh on *Hemophilus influenzae* type b (Hib)<sup>9</sup>, acknowledges funding from the Asian Development Bank and USAID, technical help from WHO, and Hib vaccine costing millions from Sanofi Pasteur. The role that the manufacturer, Sanofi Pasteur, had in the study design is not explicitly stated. Overseas international agencies are more than willing to help. This role of

international agencies and their nexus with multinational companies in influencing the public health priorities of developing countries has already received some critical analysis<sup>10,11</sup>. The general principal, that 'the one who pays the piper calls the tune,' applies to vaccine research as well.

International agencies have obliged vaccine manufacturers in other ways also. The WHO used to advise mass vaccination only for diseases like hepatitis B when the prevalence exceeds 2 per cent<sup>12</sup> but they have dropped this condition in recent years to favour the introduction of new vaccines like hepatitis B in the mass vaccination programmes of developing countries. Cost-benefit studies used to be performed in developed countries, before introduction of a vaccine. Comeau in the *Canadian Medical Association Journal* notes that with the arrival of Gardasil, a vaccine against human Papillomavirus, (the most expensive childhood vaccine proposed for mass use - it currently costs \$404 for the 3 required doses) - there have not been any cost-effectiveness analyses to determine whether the proposed vaccination programmes will result in fewer cancer deaths<sup>13</sup>.

The assistance to vaccine manufacturers has not always been subtle. A protest was recently published against the WHO and its organ the National Polio Surveillance Project (NPSP), for experimenting on human subjects without their consent, a new monovalent oral polio vaccine (mOPV1) that was 5 times stronger than the earlier licensed mOPV<sup>14,15</sup>. No mechanism was put in place, to monitor adverse effects beside routine 'acute flaccid paralysis' (AFP) surveillance. Interestingly, Dr J. Wenger the NPSP author of the article<sup>14,15</sup>, moved from the NPSP to CDC in Alaska and the new NPSP chief has said no new vaccine was used. The Lancet paper<sup>14</sup> on the 'new vaccine' has however not been retracted. No matter what the gloss that is put on the matter, it erodes confidence in this organization.

The WHO position paper published in November 2006 on Hib vaccine is revealing<sup>16</sup>. It states that “in view of the demonstrated efficacy and safety, conjugated Hib vaccine must be included in *all* routine infant immunization programs. Lack of local surveillance data should not delay introduction of the vaccine”. It can be taken to mean that if a vaccine is effective, it must be used everywhere, even in places where the disease is non-existent. Thus India (where WHO-conducted local surveillance data have repeatedly shown that there is no need for the vaccine) must now use the vaccine based on data in Indonesia and Africa. (The position paper predates the Probe Study from Bangladesh). Strangely, the paper<sup>16</sup> recommends that surveillance for Hib disease must be carried out *after introduction of the vaccine* to document impact of the vaccine. Given that the position paper was prompted by the need to propagate vaccine use in places where vaccine need could not be demonstrated in spite of repeated attempts at surveillance, favourable comparisons of post-vaccine data will presumably be made against pre-vaccination prevalence in other countries. The paper of WHO advocating universal vaccination with Hib, irrespective of an individual country’s disease burden, irrespective of natural immunity attained within the country against the disease, and not taking into account the rights of sovereign states to decide how to prioritize use of their limited health resources, is an example of top down approach of global organizations like the WHO. Individual countries must decide if they will permit this erosion of their rights especially given that Hib disease has little potential of becoming an international public health problem.

In the face of burgeoning and aggressive marketing of vaccines of doubtful utility, we have a widening demands-supply gap in Expanded Programme on Immunization (EPI) vaccines<sup>17</sup>. Over the last few decades, due to the decline of the public sector and the growing disinterest of the private sector, the number of firms supplying EPI vaccines has declined drastically both in India and abroad, prompting the UNICEF to express its serious concerns about the short supply of EPI vaccines<sup>18,19</sup>. Private manufacturers prefer to sell them as ‘value-added cocktail vaccines’ at exorbitant prices in the open market, rather than supply to EPI. The universal tendency to combine EPI vaccines with non-EPI vaccines not only creates an artificial scarcity for affordable EPI vaccines, but also creates a backdoor method for the entry of expensive and perhaps

unnecessary non-EPI vaccines into the universal immunization programme, riding piggyback on the EPI vaccines<sup>20</sup>. The combination of DPT with hepatitis B raises the price of DPT immunization 17 fold. Moreover, the relative safety and efficacy of these cocktail combinations are much lower than their individual counterparts<sup>21-24</sup>. Yet, we have many cocktail vaccines flooding the market including DTP-IPV, DTP-HB, DTP-Hib, DTP-HB-Hib, DT-Hib, DTP-Hib-IPV, and DTP-HB-Hib-IPV. Only a ban against combinations of EPI and non-EPI vaccines, and a stipulation that only those private manufacturers who supply EPI vaccines to the government will be allowed to sell them in any form in the open market will save the EPI as well as the consumers. Dire situations call for drastic action.

There are lessons from this, both for the public and Governments of developing countries. Developing countries cannot expect international agencies like WHO to be an honest broker between themselves and private for-profit vaccine manufacturers.

- The public need to maintain a healthy skepticism of the ‘facts and figures’ provided by vested interests and of the international agencies that are influenced by such vested interests.
- The Government must develop methods and means so it can derive its own data through well-planned epidemiological surveillance and it must rely more on such data.
- It must develop strong governance mechanisms to regulate private manufacturers notwithstanding the bogey of ‘license raj’ that will inevitably be orchestrated.
- It must resuscitate the ability to manufacture EPI vaccines within the public sector so public health is not held to ransom by agencies overseas.

Within the emerging scenario where expensive vaccines swallow up the less expensive options<sup>25</sup>, India could emerge as the ethical EPI vaccine supplier to the world.

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