# Vaccine Policy and Advance Market Commitments

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The new National Vaccine Policy Draft 2011 by the Union Ministry of Health and Family Welfare comes out openly in favour of public-private partnerships and suggests flexible governing and funding mechanisms to support vaccine development in the PPP mode. This article argues that our vaccine policy must look into the health of the children in the country and it should not be overly concerned solely with the viability of the vaccine industry.

The Union Ministry of Health and Family Welfare's National Vaccine Policy Draft has been posted on the website.[1] It is now open for public comments before it goes to the National Technical Advisory Group on Immunisation (NTAGI) and then has to be approved by the cabinet and ratified by Parliament. As the draft includes a number of momentous suggestions, it is important to be debated widely before it is enshrined as a policy.

## Background and Context

Judicial prompting provided the impetus for the government to formulate this policy. While hearing a public interest petition about the introduction of new vaccines in the country without sufficient evidence, the Delhi High Court asked the Union of India to state its policy on vaccines. New vaccines being introduced would be assessed in the light of that policy. The vaccine policy ideally would state how the government proposes to universalise the benefits of immunisation to the large sections who do not receive the basic vaccinations. It would also describe how new vaccines are to be selected for introduction in the programme for universal immunisation. Ideally it would lay down the process of selection of members to the NTAGI and how the procedures of this committee are to be open to the public – including the methods of estimating disease burden, vaccine efficacy and assessment of costs, benefits and adverse effects of newer vaccines.

## Critique of Policy

Unfortunately, the draft is non-committal on almost all of these issues. Instead, it brings up other matters whose serious implications are underplayed, perhaps deliberately. These momentous policy changes are buried on pages 10, 11 and 16 of the draft policy document. The vaccine policy comes out openly in favour of public-private partnership (PPP). It suggests flexible governing and funding mechanisms to support vaccine development in the PPP mode, because "the private sector has the discipline and culture for business development and marketing".

The policy draft states that industry (the private partner) will in future be allowed to influence policy. It states that "industry must be provided a channel to voice opinion to be utilised in framing policy". The fact that this would invite conflicts of interest because of the tension between the profit motives of industry and the promotion of public health is ignored. Furthermore, the policy states that if industry has a "genuine concern that a decision is made to its detriment", there must be a speedy redressal by an independent (of government) mechanism.

The funding mechanisms will ensure that costs are borne by the government and profits are reserved for the private partner for their "entrepreneurial skills and marketing abilities". The document even suggests that repositories in public sector institutes and platforms in the Indian Institute of Technology must support the vaccine industry (private partner) as they manufacture "risky vaccines".

The policy prescribes the "risk of manufacturing vaccines must be cushioned by assistance from government". The boldest suggestion is that it should be "mandatory for government to support developments with Advance Market Commitments and honour the commitments". It further says that a vaccine fund, through "innovative financing mechanisms" must be considered, for introducing new vaccines.

## Advance Market Commitments

The concepts of advance market commitment (AMC) and the implications of the term "innovative financing" as used by the Global Alliance for Vaccines and Immunisation (GAVI) – an organisation of vaccine manufacturers, the Bill and Melinda Gates Foundation and the World Health Organisation (WHO), among others need to be stated explicitly.

AMCs are aimed at providing incentives for new vaccines through guaranteeing the market for the product even before it is tested – the government promising it will buy a certain amount of vaccines at a given price. It is to be binding even if the vaccine produced has poor efficacy or

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even if the market price of the vaccine is a fraction of the AMC price. AMC was first used for pneumococcal vaccine research. The vaccine that resulted from this effort prevents just four cases of cough and cold for every 1,000 babies vaccinated and the vaccine costs Rs 1,200 per child at the United Nations International Children's Emergency Fund (UNICEF) prices. The cost of vaccinating 1,000 children to prevent four cases of pneumonia is Rs 12 lakh. Instead, on an average, treating the pneumonia in four children with the drugs recommended by the WHO would cost only Rs 40.

The money for the vaccine in the AMC must be deposited with the World Bank even before the delivery of vaccine, so the directors of the pharmaceutical do not have to lose sleep about marketing the drug or about withdrawal of orders on account of the low efficacy of the product. The policy drafters understand the government will not be able to foot the hefty bill. The draft, therefore, helpfully suggests "innovative financing" to be able to make the money available to the World Bank upfront. The term "innovative financing" is GAVI speak and must be understood as such. The Government of India is being urged to issue sovereign bonds in the capital markets so that investors and speculators can put up the money. This is a win-win situation for the pharmaceutical industry and the bond investors – for all, except perhaps the taxpayer. These innovations need careful consideration before this is accepted as a national policy.

## Moving Forward

Vaccines have eradicated small pox and it is one of the greatest successes of modern medicine. Characteristics of vaccines in the past have been their low costs and their remarkable cost-effectiveness. The diphtheria, tetanus, pertussis vaccine (DPT) costs less than Rs 15 for all the doses needed to immunise a child. According to the National Family Health Survey, we are not been able to provide this vaccine to half our population. The production of these essential vaccines, inexpensively in our public sector undertakings, was a source of security for the country, at a time when private manufacturers were dropping out of the market because of the low profitability of these products. The public sector should be what the national vaccine policy supports.

It is no one's case that more expensive vaccines sold by private manufacturers must not be introduced in the public health system in India. However, there must be a transparent evaluation of the need for the vaccine and it must have demonstrable cost-effectiveness. Vaccine policy must enunciate these guiding principles and describe how the evaluation is to be done. Our vaccine policy must look into the health of the children in the country and it should not be overly concerned solely with the viability of the vaccine industry.

This looks like a policy not to have a policy, but to utilise vaccines indiscriminatingly. If we are being asked to make long-term advance market commitments before evaluating the utility or even the market value of a vaccine, this policy needs a careful scrutiny.

NOTE

1 http://www.slideshare.net/prabirkc/national-vaccine-policy-2011