National vaccine policy in the era of vaccines seeking diseases and governments seeking public private partnerships

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This vaccine policy is more about spending and coverage, than about protecting children. It is not designed to enhance national public capacities for public immunization programmes, but to justify spending public money on public private partnerships (PPPs) or privately produced vaccines in the name of protection from diseases, whose incidence figures and public health statistics are dubious and industry manufactured.

The Indian government announced a National Vaccine Policy through the Ministry of Health and Family Welfare (MOHFW) for the first time in mid-2011 (ref. 1). Unlike the policy drafts for National Health Policy, National Health Research Policy, National Biotechnology Policy, etc. which were kept in the public domain for discussion among stakeholders, this vaccine policy draft was not. Why was the entire drafting exercise done in such a tearing hurry and intriguing secrecy, when the government has been having its way with the national immunization programmes all these decades despite the lack of a clearly articulated policy?

During the last few years, the Indian Government came under severe criticism over its tendency to drift along an industry-friendly path in the introduction of dubious new vaccines, and in suspending public-sector vaccine production to favour private firms[2–9]. A public interest litigation (PIL) in the Supreme Court in February 2009 sought the revival of public-sector vaccine production and the formulation of a national vaccine policy based on scientific evidence and self-reliance[9]. Another PIL was admitted in the Delhi High Court in December 2009 questioning the introduction of pentavalent vaccine into the Indian universal immunization programme (UIP), without proper studies to prove its need in India[10,11]. In the meantime, a draft document for evidence-based national vaccine policy emerged in June 2009 through an interdisciplinary workshop of scientists, doctors, health professionals, lawyers and activists (ICMR–NISTADS policy document). This policy document was submitted to the government for consideration and also was published in the *Indian Journal of Medical Research*[12]. This was received well and there is no evidence of any credible critique of it so far. However, the government chose to ignore it and came up with its own policy to legitimize its spendthrift approach and pro-industry drift, regardless of its occasional lip service to public sector in the parliament and media.

The hurry for the government policy seems to have been due to an interim order of the Delhi High Court in April 2010, specifically referring to the vaccine policy draft (ICMR–NISTADS) and asking the government to make its policy on those lines[11]. The MOHFW sought help from members of the National Technical Advisory Group on Immunization (NTAGI) to formulate a vaccine policy. Mysteriously, the minutes of the NTAGI meeting that entrusted the task to two of its members were subsequently amended to drop one of them and gave the task only to N. K. Ganguly, former DG, ICMR. He produced a draft document without consulting or involving other NTAGI members and without even acknowledging the ICMR–NISTADS policy document referred by the Delhi High Court. His draft was circulated among NTAGI members for suggestions in February 2010. Even though some of them gave comments and suggestions, there was no attempt to make it a collective exercise despite protests. It was later modified and released in July (though dated April 2011) as the official government policy, without any further validation by NTAGI, civil society, Ministry, cabinet or parliament. What is inside this national vaccine policy booklet that compelled such a backdoor entry in total avoidance of public consultation? Was it meant to kill the other (ICMR–NISTADS) draft? Ironically, the same government that opposed the Jan Lokpal Bill on the grounds that only parliament can make policies, has already announced this vaccine policy prepared by one man.

A critique of National Vaccine Policy of MOHFW, 2011

The government policy pays lip service to several important issues such as criteria for new vaccine introduction into UIP, including the Grades of Recommendation Assessment, Development and Evaluation (GRADE) system, strengthening the surveillance of Vaccine Preventable Diseases (VPD) and Adverse Events Following Immunization (AEFI), operational efficiency, etc. However, by subsuming these issues into the more overarching emphasis on supply-side factors, public private partnerships (PPP), innovative (read speculative) financing, global fund (read advance market commitments to further MNC pharma businesses), etc., it seems that the government has fallen trap to the same 'global' slogans of the World Bank that has pushed the world into recession and the aid politics of Gates Foundation, WHO, Global Alliance for Vaccines and Immunization (GAVI), multinational pharma industry, etc. Such policies are not only out of tune with our national health security needs, but are also out of sync with the times we are witnessing, considering the yearning for health reforms in the US. Clearly, this vaccine policy is not designed to enhance national public capacities for public immunization 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 immunization and implies that all immunization is universal. Such policies only strengthen anti-vaccine lobbies and cynics.

Policy sans evidence, push for new vaccines

The policy does not provide an uncompromising scientific basis on which a vaccine can be introduced in Indian UIP based on its proven 'need' (actual disease burden in relation to other diseases), suitability (for local strains and variants), safety and efficacy, cost-benefit and risk-benefit analyses based on evidences from India. In other words, it does not commit itself only to need-based and evidence-based vaccination, but assumes that all new vaccines are good for the Indian

population and should be introduced in the Indian UIP. None of the evidence criteria mentioned for the inclusion of new vaccines into UIP is mandatory, which allows this policy to be used according to the whims of the people in power. Indeed, the whole idea of evidence-based policy is turned on its head with the first two statements under Section 3.2 titled 'Barrier to strengthen immunization programme': 'Weak VPD surveillance system; Lack of data on disease burden in India and resulting perception that the disease is not an important public health problem'[1]. Thus, the policy is not only putting the cart before the horse, but also taking a philosophically or ideologically different approach; it is the difference between adopting suitable vaccines to control serious diseases and finding disease burden to suit available vaccines. In other words, it is the difference between finding solutions to problems and offering solutions to imaginary or insignificant problems. This ideology also explains why a government that cannot even cover half of our children under the 'universal' immunization programme, or have enough government hospitals to treat the poor, gives ingenious arguments of 'equity' and 'access' to justify government spending on expensive new vaccines (regardless of the disease burden), saying that the poor cannot afford vaccines that are outside the UIP.

The government policy justifies the introduction of dubious, new combination vaccines (Section 5.2)[1] in terms of the number of injections reduced and savings on logistics, while conveniently ignoring the fact that the cost of the combination vaccine multiplies manifold with each vaccine added[4]. Most combination vaccines are just expensive cocktails with no net health benefit than their individual components, other than the patenting, pricing and marketing advantages they offer to the company that makes them. Indeed, many non-universal vaccines (such as the HB and HiB in the pentavalent vaccine) are gaining backdoor entry into captive UIP markets by riding piggy-back on one or more universal vaccines[4,13]. The policy plays the possum to published scientific literature on these aspects.

Pushing vaccines through PPP and dubious 'innovative financing'

It is obvious that introduction of new vaccines in UIP would demand enhanced immunization budget of the government. The policy mentions need for 'innovative financing', without elaborating it. However, a cursory glance at the current global vaccine financing system indicates that innovative financing means speculative financing through advance market commitments. The International Finance Facility for Immunization (IFFI) that funds GAVI in its speculative trade is doing so against the promise of future funding from donor countries, raising money in the meantime by issuing bonds to international capital markets, which themselves operate in ways no less speculative than the American banks that triggered off the world recession we are going through today[14].

Under this model, the government promises the vaccine manufacturer that if it makes a vaccine, the government will purchase say 25 million doses of vaccine/year at a 'front loaded' price of say US$ 10/dose – no matter how useless the vaccine is or whatever its side effects are – and the industry on its part promises that it will bring prices down to say US$ 8 after 8 years! All the money will be paid upfront by the government to a bank account, to be transferred to the company later. The government itself may source its funds by floating public bonds with assured rates of return. It may be a win-win situation for the vaccine manufacturers and the public investors, but not for the poor taxpayer, who foots the bill of both the vaccine manufacturer and the bond investor.

Moreover, advance market commitments to global financing schemes directly impinge on our sovereignty in subsequent decisions. For instance, if India signs GAVI's support for pentavalent vaccine introduction in UIP, the country can no longer procure pentavalent vaccine from domestic companies like Serum Institute of India, Panacea Biotech, etc. This is because, GAVI has already made an advance market commitment to GSK and MERCK, so India has no option but to buy vaccines from these companies, and GAVI's funding from IFFI is sustained and the price of the vaccine in USA would be reduced. Thus, this circular model would collapse if any link is broken.

The government's fanatical adherence to PPP despite the recent history of dubious PPPs highlighted in the media, parliament and courts is another area of concern. The report of CAG on the Commonwealth Games 2010 noted that Suresh Kalmadi converted the government-owned organizing committee into a body outside governmental control, despite full funding from the government. The new PPPs being envisaged for vaccines will be no different, except that now this is no longer the sleight of hand of a minister, but a matter of national policy of public spending and private profiteering!

The policy rightly recommends expansion of NTAGI to include public health researchers, academicians, epidemiologists, etc. but does not say who will select them or how and for how long, or how to ensure a composition that prevents conflicts of interest and promotes rational decision-making.

In conclusion, it is an irony that a bottom-up vaccine policy draft (ICMR-NISTADS document) lauded by its present DG (ICMR) was replaced by a top-down draft of his immediate predecessor, without the mandate of the scientific community, civil society, cabinet or parliament, and yet we are told that no single person can control government policy and only parliament can make policies.

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