

Jan Swasthya Abhiyan

Health for All - Now!

Health is a Basic Human Right!

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All India People's Science Network (AIPSN)
All India Drug Action Network (AIDAN)
Asian Community Health Action Network (ACHAN)
All India Democratic Women's Association (AIDWA)
Bharat Gyan Vigyan Samiti (BGVS)
Breast Feeding Promotion Network in India (BPNI)
Catholic Health Association of India (CHAI)
Centre for Community Health and Social Medicine, JNU
Christian Medical Association of India (CMAI)
Community Health Cell (CHC)
Forum for Creche and Child Care Services (FORCES)
Fed. of Medical Representative Assns. of India (FMRAI)
Joint Women's Programme (JWP)
Medico Friends Circle (MFC)
National Alliance of People's Movements (NAPM)
National Federation of Indian Women (NFIW)
National Association of Women's Organisations (NAWO)
SAMA – Resource Group on Women's Health
SATHI – CEHAT
Voluntary Health Association of India (VHAI)

Participating Organisations:

Over 1000 organisations concerned with health care and health policy from both within and outside the above networks.

14/06/2012

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To,

Sri P. K. Pradhan, Additional Secretary & Mission
Director, NRHM
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi

Dear Sri P.K.Pradhan

Subject: Comments by Jan Swasthya Abhiyan on
Draft National Vaccine Policy

On behalf of **Jan Swasthya Abhiyan**, we welcome the opportunity to provide comments on the draft **National Vaccine Policy**. The Jan Swasthya Abhiyan is a national network of over 20 national and a large number of state networks and organisations, that are working in the area of health and pharmaceuticals.

We are attaching our comments and shall be happy to present the same in person if such an opportunity can be provided. We look forward to further dialogue on this issue.

Thanking You,

Yours Sincerely,



(Dr. Amit Sengupta)
for Jan Swasthya Abhiyan

cc. **Dr. Ajay Khara**,
Member secretary,
National Technical Advisory Group on Immunization

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Comments by Jan Swasthya Abhiyan on 'Draft National Vaccine Policy'

Summary

The new Draft National Vaccine Policy of MOHFW 2011, is an outcome of the ongoing PIL in the Delhi Court against introduction of penta-vaccine in the Universal Immunization Programme (UIP).

- It lays great emphasis on production of quality vaccines, expediting approval of new vaccines and introduction of new vaccines in the UIP.
- However, it is not geared to take rational decisions on introduction of a new vaccine in the Universal Immunization Programme based on its 'need' (actual disease prevalence, and its burden in relation to other prevailing diseases), suitability (strain specificity, variation etc.), safety and efficacy based on scientific evidences from India and based on cost-benefit and cost-effective analyses.
- It assumes that all new vaccines are good for Indian population too and all new vaccines should be introduced in Indian UIP.
- It doesn't make distinction between Universal and non-universal vaccines (vaccines for selective immunization).
- Its argument about equitable access to new vaccines is misleading when immunization coverage for existing universal vaccines is only 50% and when cost-efficacy of the new vaccines has not been established in India conditions.
- Overall, this policy is meant to justify an agenda that seeks to push all new vaccines in Indian UIP.

Background

National Vaccine Policy (April 2011), available as a booklet with Ministry of Health and Family Welfare (MOHFW) came to public notice only in mid July when it was released in a five star hotel in presence of a few members of WHO, National Technical Advisory Group on Immunization.(NTAGI) and government officials. This policy booklet emerged in response to a petition filed by civil society and Public Health Academicians against union Health Ministry on Pentavalent vaccine introduction in Indian UIP in Dec 2009 in the Delhi High court, alleging that this vaccine is being introduced without proper studies done in India and that they are being introduced under pressure from WHO, GAVI and the pharma industry. This PIL sought stay order on the introduction of pentavalent vaccine till its justification is established. An interim order of Delhi High court in April 2010 (referring to policy draft prepared during the workshop co-organised by NISTADS and ICMR) states that the respondents may examine the policy draft prepared by some experts to prepare guidelines whenever it becomes necessary at later stage. This policy draft (authored by 36 experts) subsequently published in the Indian Journal of Medical Research (IJMR), argues for an evidence-based national vaccine policy for decisions regarding introduction of new vaccines in UIP. The current new draft national vaccine policy of MOHFW is quite at variance with the scientific approach adopted in this paper.

It is claimed that this Draft Policy, seeks to streamline the decision-making process on new and underutilised vaccine introduction, besides addressing issues of vaccine security, management, regulatory guidelines, vaccine research and development, and product development. These aspects relate to the production of quality vaccines. They are welcome. However it is a matter of concern that the Draft Policy does not emphasize safety or cost-efficacy of vaccines which is of paramount importance from the Public Health point of view. There are no recommendations about strengthening or improving or restructuring our disease surveillance system. This lacunae is important because in India lack of actual prevalence data and lack of cost-benefit evaluation studies helps the pharma industry to push new vaccines, whether they are needed or not or whether they are cost-effective or not in Indian conditions.

Its pro-industry tilt is obvious when it fosters rapid introduction of new vaccines, through "speedy regulatory clearances". It recommends mechanisms "where the risk of the manufacturers is cushioned by appropriate assistance from the Government;" and says that it should be mandatory for the Government to support such developments

with Advance Market Commitments and honour the commitments.” Why national governments are under pressure to commit advance market commitments? It is to be noted that GAVI gets funding from IFFI, whose funding commitments are based on donors or speculative loans from capital markets. Speculative bonds to GAVI are based on advance market commitments from national governments. (Oxfam-MSF report). Therefore, it is a circular model, where even one break in the link in the chain would collapse the system.

Policy agenda to push new vaccines lacks scientific evidence

The Draft Policy says “In a situation where there is abundance of new and expensive vaccines on one hand and limitations of resources on the other, it becomes imperative that use of vaccines through induction in the Universal Immunization Programme (UIP) as well as in the free market is done through a framework of decision-making that confers positive health and economic benefits to the society”. Specifically, the policy appears to be clearly an agenda to introduce vaccines like Pneumococcal, Rotavirus, Hib vaccines etc, rather than a guide that justifies the need for above vaccines. (section 3.1, 3rd para) (section 4 last 5 lines in first para).

For instance, the second para, 4th line of executive summary states, *‘Most of the new vaccines are used by one segment of the population, which can afford them, while the most vulnerable segment of the population, which is serviced through the UIP misses out on the opportunity.’* It is ironical that a government that cannot even cover half of our children under the UIP or does not have enough government hospitals to treat the poor, gives ingenious arguments of “equity” and “access” to justify government spending on bringing expensive new vaccines into UIP (regardless of their disease burden), saying that the poor can’t afford vaccines that are outside the UIP.

The Draft Policy assumes that all new vaccines are good for Indian population. Secondly it doesn’t make any distinction between universal and selective vaccines.

The section 3.1 on burden of Vaccine Preventable Diseases (VPDs) and Surveillance only talks about impact studies of vaccines or monitoring of vaccine preventable disease surveillance. While this surveillance is an important tool to judge the effectiveness of the vaccine, the absence of the strategies to find out the relative disease burden only reflects the eagerness of the policy makers to introduce more new vaccines rather than first establishing their need, suitability, safety, efficacy in Indian population.

Introduction of new vaccines in UIP

Section 5 appears to have considered some principles before their introduction in UIP such as disease burden, disease prevalence etc. However the whole purpose of having an evidence based policy gets defeated by statements such as '*modeling studies and data from countries with either geographical proximity or similar demography may also be used for these decision making*' (section 5.1.1, last 3 lines of the first para). This implies that based on recommendation elsewhere, vaccine can be introduced in Indian UIP. This may not suit Indian population as genetic susceptibility and treatment to various diseases of the populations with similar geographical proximity may not be the same. Therefore, suitability of a vaccine should be considered based on strains prevalent in India rather than on imported vaccines or imported strains to make vaccines for Indians. In fact, if India can make its vaccines from Indian strains for its populations would be more suitable criteria to identify local relevance of vaccines.

It is strange that while the draft Policy recommends that NTAGI should be constituted with social scientists, public health researchers besides medical experts, this recommendation was not implemented while preparing this Draft Policy! The entire exercise of policy making confined to one technocrat and medical experts.

Policy for the growth of Private sector through PPP model

"This policy document deals with issues critical to strengthening of the vaccine enterprise to ensure long term supply of affordable vaccines to the people who need the most." (2nd Para, executive summary, 10th line).

Above statement refers to strengthening of only private sector, as all the vaccine-producing public sector units were closed down except for 3 in the current policy environment that is conducive only to privatization and to Public Private Partnerships (PPs). Indian vaccine experience reveals that PPP means transfer of experienced manpower, seed virus and other resources to the private sector from public sector. Private sector is interested in new profit making vaccines in combinations rather than filling the gap of universal vaccines (ex; DTP-HB instead of DTP).

The Draft National Vaccine Policy says - "*There is limited production capacity of UIP vaccines in PSUs and the involvement of private sector manufacturers is required to ensure that supply of UIP vaccines is not threatened.*". This is in contradiction to the

fact that in 2009, Indian government had to purchase the universal vaccines at higher price from private sector and to meet acute shortages. It also had to procure vaccines from the very same public sector units through back door that were closed down. It is not true that PSUs have limited production capacity. Well functioning PSUs were reliable affordable stable suppliers of universal vaccines (despite the institutional inadequacies/problems) till 2008, when they were deliberately closed down. This was to favour private sector that led to the imbalance in UIP. Private sector was interested in supplying DTP-HB instead of DPT. PSUs were closed down to promote private vaccine sector and UIP has suffered with the resultant UIP vaccine shortages and increased AEFI leading to child health crisis in the last 3 years. ((Down to Erath 2009, Madhavi 2009, news on AEFI).

It may be noted that Shanta biotech Ltd., which developed an indigenous hepatitis-B vaccine and was once touted as a model for home-grown and government-supported private enterprise, has now been bought by the French multinational, Institut Merieux (now Sanofi-aventis) and may yet be sold to another, GlaxoSmithKline. This has made vaccine availability more uncertain.

Policy Agenda for creating global fund for newer vaccines

Section 4 on vaccine R&D highlights the need for the prioritization of vaccine R&D for locally prevalent diseases in India. It only talks about global funding in this context once again, rather than strengthening disease surveillance system to generate authentic data that would enable prioritization of research. This section proposes linkages with international agencies such as GAVI, PATH, Gates foundation etc. While nothing is wrong with the linkages with these agencies, they need to be harnessed and negotiated for the benefit of the health of the people of India, rather than subservient to their policies and agendas.

The recent debate on the introduction of pentavalent vaccine is a test case and a very good example that demonstrates the danger of serving the MNC interests. Since vaccine price is dependent on economies of scale, introducing pentavalent vaccine in India would reduce the price of the vaccine in US. If India opts for GAVI's support, India has to buy vaccines from GSK and MERCK, but not from Indian companies, because GAVI has already made a commitment to these companies to get funding from IFFI. Neither domestic industry benefits, nor the people with controversial unproven vaccine and governments will have to spend more on immunization.

The Draft Policy justifies the introduction of combination vaccines (Section 5.2) in terms of number of injections reduced and savings on logistics, while conveniently ignoring the fact that most combination vaccines are a mechanism to gain backdoor entry into captive UIP market by riding piggy-back on one or more universal vaccines.

IPR and Technology transfer:

It recommends (4.2.4, 3rd para) technology transfer from MNCs to gain access to technologies and know-how. There is no evidence that MNCs have ever transferred latest technologies to developing countries. Unless developing countries buy a technology, they do not have access to new technology.

Operational Efficiency of UIP (section 6)

The Draft Policy proposed much more dissemination of vaccines and vaccine coverage and towards this end, suggests capacity building and improving reporting of Adverse Events Following Immunization (AEFI) surveillance system. The latter is welcome but there is no mention of any vaccine injury compensation to the affected nor does it makes principle investigators responsible, if there are any ethical violations during the clinical trials or post-vaccine surveillance.

The Draft Policy reminds us at several places that the new vaccine introduction is 'the priority' while ignoring evidence for its need safety and efficacy. The policy justifies new vaccine introduction by claiming that the affordable (middle and upper middle class) can get it, but poor and needy can't get (section 6.7 on ethics and equity fist para). Why equity is talked only when it comes to vaccines and why not for basic enmities such as food, shelter, safe water and clean living conditions to the majority of poor and needy in this country?

Conclusion

This policy doesn't appear as a policy for people of India, but a policy to facilitate vaccine business for the benefit of vaccine makers and drivers that benefit from vaccine promotion.