

## Policy Document

# Evidence-based National Vaccine Policy\*

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**India has over a century old tradition of development and production of vaccines. The Government rightly adopted self-sufficiency in vaccine production and self-reliance in vaccine technology as its policy objectives in 1986. However, in the absence of a full-fledged vaccine policy, there have been concerns related to demand and supply, manufacture vs. import, role of public and private sectors, choice of vaccines, new and combination vaccines, universal vs. selective vaccination, routine immunization vs. special drives, cost-benefit aspects, regulatory issues, logistics etc. The need for a comprehensive and evidence based vaccine policy that enables informed decisions on all these aspects from the public health point of view brought together doctors, scientists, policy analysts, lawyers and civil society representatives to formulate this policy paper for the consideration of the Government. This paper evolved out of the first ever ICMR-NISTADS national brainstorming workshop on vaccine policy held during 4-5 June, 2009 in New Delhi, and subsequent discussions over email for several weeks, before being adopted unanimously in the present form.**

**Key words** Combination - cost-benefit - epidemiology - immunization - policy - private - public - public health - UIP - vaccine

\*Based on deliberations of a workshop on vaccine policy held during 4-5 June, 2009 in New Delhi.

## Introduction

Vaccines are very useful as preventive medicine in public health to reduce morbidity and mortality due to communicable diseases, though they are not a substitute to safe drinking water, sanitation, nutrition and environmental health in the long run.

## Preamble

Vaccine R&D and production are areas of modern scientific endeavours in which India was among the leaders in the world, well over a century ago<sup>1</sup>. Independent India continued to rely on public sector vaccine production and readily adopted the policies of World Health Organization (WHO) and United Nations Children's Fund (UNICEF) regarding mass immunization<sup>1</sup>. A policy objective of achieving self-sufficiency in vaccine production and self-reliance in vaccine technology was formally adopted in 1986, with new public sector vaccine production units established to meet the demand-supply gaps in vaccines and for export<sup>2</sup>. However, over the years, many vaccine Public Sector Units (PSUs) have either been closed down or have stopped vaccine production<sup>1,3</sup>. Even though many private sector vaccine units sprang up during this period, often drawing directly or indirectly from the public sector resources, (such as raw materials, expertise, manpower and finances) vaccine production remained erratic and demand-supply gaps continue till date<sup>3,4</sup>. This is particularly true for most of the vaccines identified as essential for the various national programmes, while the market is flooded with a host of new vaccines and combination vaccines that are not a part of any national programme<sup>5</sup>. Thus, there is a growing mismatch between the stated policy of self-reliance and self-sufficiency and the actual situation emerging on the ground that remains unaddressed.

## Vaccine types and programmes

From a policy perspective, there are many types of vaccines. Among the national programmes, the most important is the Universal Immunization Programme (UIP) for children, which includes 6 vaccines: BCG, DPT, polio, measles, DT and TT. These six vaccines are also known as the primary vaccines and universal immunization is also known as Routine Immunization (RI)<sup>6</sup>. Of these 6, polio vaccine receives a special emphasis as a part of the WHO global drive to eradicate polio<sup>7</sup>. Public sector manufacturing capacities exist for all these vaccines, though the closure of many PSUs over the last several decades and the suspension

of three major PSUs in 2008 have affected their availability and affordability<sup>8</sup>. Then, there are the so-called secondary vaccines for Selective Immunization (SI) against yellow fever, Japanese encephalitis, hepatitis B, typhoid, cholera, *etc.*, required for specific risk groups or age groups or special situations across the whole country or selected states/regions. Most of these primary and secondary vaccines, required in bulk quantities by the Government agencies are often in short supply, perhaps with the exception of hepatitis B vaccine, and public sector units are not currently manufacturing them, though it is feasible in most cases. Therefore, this requirement is currently being met by the indigenous private sector or through imports. Furthermore, many of the therapeutic vaccines and antisera required in large quantities by the Government are made in the public sector. These include the anti-tetanus serum, diphtheria toxoid, anti-snake venom, anti-rabies vaccine, animal husbandry vaccines *etc.* The public sector often maintains stocks of some of these vaccines/antisera beyond the normal usage levels to meet contingencies, a practice adding to the overall expenditure. In contrast, the vaccines abundantly available in the market are typically newer ones manufactured by the private sector/ multinational companies, against mumps, rubella, pneumococcal and meningococcal disease, rotavirus, influenza, human papilloma virus, newer typhoid vaccines, acellular pertussis vaccine, *etc.*<sup>4</sup>.

Many of the newer vaccines are quite expensive, especially since they are sold as combination vaccines. Virtually every combination vaccine combines the new vaccines (non-UIP) with at least one UIP vaccine<sup>5</sup>, such as DPT or measles, making it more difficult for public health agencies to deal with universal (RI) and non-universal vaccines (SI) as distinct categories for purchase and immunization. Several more new vaccines are being developed world over<sup>9</sup> that are entering the market every year ([www.immunize.org](http://www.immunize.org)). Even though none of the new vaccines (except hepatitis-B) is currently a part of any of the Government programmes, many of them are in widespread use, as private doctors often prescribe them and people purchase. There are frequent demands from the industry, medical associations and some international organizations and aid agencies that the newer vaccines be included into the national programmes<sup>10,11</sup>. Therefore, a major policy question for the government is: How many vaccines are to be included under any government (national/state) programme to adequately fulfill its public health

commitments to the nation? A related policy question is: Should any (and how many) vaccines be left for voluntary vaccination by individuals, even under prescription, especially considering the difficulties in regulating irrational prescriptions<sup>12</sup>? What should be the norms to determine the necessity, suitability, safety, efficacy, accessibility and affordability of a vaccine at the individual level? Similarly, how should the government maximize the coverage potential and sustainability of a vaccination programme at the national level?

### **Budget allocation for vaccines**

The Government of India currently spends over Rs. 200 crores annually on the procurement of the 6 UIP vaccines alone<sup>13</sup> (excluding the Pulse Polio Immunization Programme). However, it manages to immunize only about half of over 26 million children born every year<sup>13</sup>. The Government is committed to achieving full coverage with these vaccines, which would double the procurement costs at the current prices. In addition, inclusion of hepatitis-B alone in UIP would further enhance the total cost of procurement by at least two-fold more. Including the DPT-Hep-B-Hib pentavalent vaccine in the UIP (in place of DPT) is estimated to cost Rs. 1200 crores<sup>14</sup> (Rs. 400 crores from the Indian Government and Rs. 800 crores from Global Alliance on Vaccine Initiative[GAVI], though for a limited period of time). Special vaccination drives such as polio involve many fold additional costs<sup>15</sup> and any improvement in coverage or protection achieved through special drives only strengthens the argument for similar emphasis and budgetary allocations for other UIP vaccines. The secondary vaccines needed under various Government programmes could cost a few more hundred crores of Rupees. Inclusion of vaccines against infections such as rotavirus, mumps, measles, rubella (MMR), human papilloma virus (HPV), pneumococcal, meningococcal and others in any national programme, whether universal or selective, will push the total Government procurement budget to several thousands of crores of rupees<sup>16,17,20</sup>, even if they are purchased at bulk prices from the private sector. The cost may come down significantly if they are manufactured in the public sector, but that would demand heavy initial investment in technology transfer and capacity expansion. Such investments may only be justified if the public health needs for such vaccines is unequivocally established. Moreover, the cost of procuring vaccines is only a small fraction of the total cost of vaccination/immunization, which

includes logistics, cold-chain, syringes and other accessories, manpower related costs, *etc.* Even though some of these costs may be shared across vaccines, there will be an inevitable inflation in the overall costs of immunization with every new vaccine added to the national programme. While public health necessity can justify budgetary increase, proving such a necessity is a major challenge<sup>16-21</sup>, as explained later. Therefore, a major policy question is: how much Government expenditure on vaccines is adequate to fulfill the public health objectives of the Government and the public health needs of the people? A related policy question is: for those vaccines that are outside the Government programmes and left to individual choice, how does the Government intend to help the individuals to make rational choices on vaccination, unaffected by commercial interests and concerns of accessibility and affordability?

### **Vaccine decision support system**

One of the biggest stumbling blocks for evidence-based vaccine policy is the lack of reliable epidemiological data on disease prevalence and incidence, pathogen variations and serotypes/ strains and the level of immunity protection against them in various populations in India, with and without vaccination, or before and after vaccination<sup>22-24</sup>. The current level of disease surveillance is too inadequate to support unequivocal scientific decisions based on established principles of public health<sup>25-27</sup>. Studies that extrapolate data from small sample sizes based on a few hospitals, blood banks *etc.*, from India or from studies done abroad only confound the problem further<sup>25-27</sup>. These limitations severely affect the task of the National Technical Advisory Group on Immunization (NTAGI), on which the Union Government currently relies for all its vaccination decisions. This situation benefits interest groups that attempt to push all available vaccines into the National Programmes, regardless of their necessity, suitability, cost-efficacy, safety, sustainability and health priorities<sup>28,29</sup>. Unlike curative medicines, vaccines are typically given to a large and healthy population and this policy therefore needs a stronger justification. Once a vaccine is included in the National Programme, the manufacturers secure a huge market in a single stroke for years together, unlike in the case of other medicines<sup>10,30</sup>. Furthermore, irrational vaccine prescriptions and promotion of voluntary vaccination by private doctors and aid agencies have turned vaccines into consumer goods<sup>5,27</sup>. Therefore, a rational vaccine policy must govern not only the

Government's own vaccination programmes, but also enable rational vaccination decisions at all levels including private hospitals or individuals in general. Hence the need for establishing a rigorous decision support system within the purview of the Government setup. Since such a system can cater to many public health decisions beyond vaccines, such as diagnostics, drugs, healthcare delivery systems, outbreak control, disaster management *etc.*, it has a stand-alone value independent of vaccines, even if it demands huge resources.

### Vaccine development and production

It is evident from the literature that strain variation of the pathogen and scientific data on sero-prevalence are critical for vaccine development, the choice of seed strains and production technology<sup>29,31-34</sup>. Moreover, while vaccine development for every pathogenic organism may be a legitimate R&D objective, researchers benefit from the awareness that every vaccine that is worth developing may or may not be worth including in the national programme, when examined from the public health and policy point of view. Thus, prioritization and coordination of national vaccine development needs and expenditures are an important policy area for the Government. Today, there are at least 23 public-funded organizations and universities in the country that are engaged in R&D on at least 14 new or improved vaccines<sup>35</sup>. More than 7 candidate vaccines are being developed and evaluated in indigenous Government-funded research organizations, while private companies (Shantha Biotech, Bharat Biotech, Panacea, Serum Institute of India *etc.*) are developing generic versions of off-patented vaccines (Hepatitis B, Influenza type B and their combinations), or doing clinical research through international collaborations and market contracts. Indigenous vaccine R&D capacities (anti-rabies vaccine, typhoid, leprosy, Kaysanur forest disease vaccine, JE vaccine, new oral cholera vaccine *etc.*) lie primarily within the public funded organizations and public sector units<sup>35</sup>. Therefore, R&D and production in public funded organizations, and PSUs must be patronized to develop and produce affordable, safe and effective vaccines that are needed for the Indian markets or for exports. Prior identification of which vaccines are most suitable for the public health needs within and outside India may be helpful for the researchers in steering their research priorities accordingly. Whenever indigenous strains are used abroad for developing vaccines or other products, whether under collaboration or through independent

projects, benefit-sharing provisions under the National Biodiversity Act must be invoked to maximize the access of the fruits of that research for the Indian people and Indian manufacturers.

### Vaccine pricing and regulation

The Government remains the single largest maker and buyer of vaccines<sup>4</sup>, unlike in the case of drugs, and therefore has a major stake in determining who supplies which vaccines and at what prices for the national programmes in the interest of public health. All vaccines required for any national (or state) programme and procured in bulk by the government can be subject to price regulation or exclusively reserved for the public sector. The public sector units are most suited to ensure consistent manufacture and supply of affordable vaccines for national programmes unaffected by market vagaries provided they are ensured of remunerative prices, Government procurement, prompt payments and other advance market commitments. The private players can complement the public sector in meeting national programmes, while leveraging their price competitiveness in other vaccines to cater to markets abroad. The Government can facilitate the indigenous public and private sector firms to access technologies and overseas markets. The Government is also responsible to ensure that the PSUs obtain the necessary financial, administrative and managerial support to comply with good laboratory practices, good manufacturing practices and other regulatory norms needed for domestic and export markets.

### Distribution and utilization of vaccines

Ultimately, vaccines are useful only if they reach people who need them, in good condition, administered appropriately and on time. Massive investments have taken place over the past decades, and particularly in the last few years in strengthening infrastructure and building capacities of the healthcare staff related to vaccine delivery ([http://www.mohfw.nic.in/NRHM/Documents/Executive\\_summary\\_April\\_09.pdf](http://www.mohfw.nic.in/NRHM/Documents/Executive_summary_April_09.pdf)). Yet, large gaps remain in the planning and execution of the immunization program in many large states and rural as well as urban areas, as is evident from the low coverage of primary vaccines under the UIP (<http://www.mohfw.nic.in/NRHM/MIS/MIS%20for%20NRHM%20as%20on%2030th%20April%202009.xls>). This reduces the effectiveness of vaccines and masks the true demand for vaccines. The problems at the operational level are well documented, but attempts to correct them continue to be poorly monitored<sup>36-44</sup>. The ill-effects of the polio

eradication campaign on routine immunization have been well documented, and illustrate how national priorities can easily be diverted<sup>45-53</sup>. Immunization campaigns, particularly because of their repetitive nature are not merely technological exercises; they have significant social, economic and political dimensions. Paying adequate attention to them can ensure better acceptability, affordability and sustainability.

### National vaccine policy

In this backdrop, as a part of the broader National Health Policy, a national vaccine policy is needed, based on the principles of public health and comprehensive primary health care. This is to enable rational and evidence-based decisions for the development, entry, production, stable supply, pricing, promotion and use of appropriate vaccines on scientific grounds. Additionally, this is also needed to protect the national vaccine programmes and national health security, as well as to leverage indigenous capabilities to cater to domestic and overseas markets.

### Objectives

1. To contribute to the prevention of mortality and morbidity due to communicable diseases that afflict large populations, especially children; through the development/production and use of safe, effective and affordable vaccines, chosen rationally.
2. To ensure consistent delivery and administration of vaccines to everyone in need.
3. To achieve national self-reliance in vaccine R&D, as well as to maximize the national benefits of international sharing of indigenous biological diversity of pathogens, hosts and knowledge, to the Indian end-users of vaccines on terms that are fair and just.
4. To achieve pre-eminence in the capabilities of the indigenous public sector for self reliance and foster a leading role for them in all the aspects of vaccine development, production and immunization for national health security and biosecurity.
5. To develop and use the interdisciplinary knowledge base needed for science-based policy and evidence-based medicine in the field of vaccines.
6. To promote ethical conduct in the development, trials, adoption and administration of vaccines, especially aimed at children and pregnant women.
7. To develop a system for monitoring and compensating adverse events following vaccination where required.
8. To enable India to play a leading role in the supply of affordable vaccines to the emerging world, considering the declining interest of the multinational sector to make cost-effective vaccines for the emerging world.
9. To synergize all other relevant policies for effective implementation of the national vaccine policy to fulfill the above objectives.

### Guiding principles, context and approach:

1. A vaccine is just one among the many inputs needed for effective public health management of communicable diseases. Other measures like food security, safe drinking water, sanitation, primary education, gender sensitivity, and health education are known to be the most important factors in the control of communicable diseases<sup>7,54</sup>. Even all the known vaccines put together cannot prevent all deaths due to all communicable diseases. However, amongst medicines, rationally selected vaccines are the most cost-effective in reducing morbidity and mortality and have an important role to play as a public health measure in the control of some communicable diseases<sup>55-57</sup>.
2. Most of the indigenous capabilities and strengths in this area were pioneered or sustained by the public sector. Strengthening the role of the public sector in the area of vaccines is crucial to ensure self-reliance and to protect national health security from the uncertainties of the local and global market forces, as well as from bio-terrorism and biological warfare<sup>4</sup>.
3. Vaccination should be need-based and all vaccines are deemed non-universal, unless specified otherwise based on scientific evidence<sup>4,5,21,25-27</sup>. While therapeutic vaccines and antisera are administered only to patients diagnosed with a treatable condition<sup>58,59</sup> (e.g., Tetanus, diphtheria anti-snake and anti-rabies), preventive vaccines are generally administered to largely 'normal' populations and therefore need stronger medical and economic rationale<sup>7</sup>. Even the so-called 'Universal' vaccines are universal only for the children and pregnant women<sup>60,61</sup>. Most adult vaccines are not required for all the adults, and are often used for "selective" immunization of high-risk groups<sup>62,63</sup>.

4. The mere availability of a safe and efficacious or even affordable vaccine cannot be a good enough justification for its widespread use. Vaccines are not consumer goods and should not be given or taken, unless their necessity is proven based on the scientific principles of public health. As vaccines are given to a healthy population, their safety and efficacy should be thoroughly assessed based on various scientific parameters, before any vaccine is introduced into the National Programme.
5. Vaccines outside the UIP should not be unethically promoted through direct or surrogate advertising, advocacy by individuals, groups or aid agencies, on their own or funded directly or indirectly by the vaccine industry<sup>64,65</sup>.
6. The choice of which vaccine to give (or not to give), target population, and mode of administration (dosage, schedule, interval between doses, intramuscular or intradermal, *etc.*), are important policy decisions that must be guided by a strong scientific rationale, with rigorous inputs from multicentric field epidemiology, irrespective of whether it has been proven in populations abroad<sup>66-68</sup>. Cost-benefit as well as risk-benefit assessment should be carried out in India taking into account local serotypes and variations in indigenous host-pathogen-environment interactions<sup>17-19,28,29</sup>. These studies can be best done by one or more public sector institutions and the results be made available openly on the website of the concerned agency for wider peer review and public debate. The dosage and schedule should also be decided after wider scientific debate in the country.
7. Vaccine choice, source of procurement and the quality standards of the products as well as of the production system should be based on sound principles to achieve maximum benefit to maximum number of people and are independent decisions of the national Government guided by this national policy<sup>4</sup> (not imposed by industry and international organizations). At the same time, it should be the endeavour of this policy to develop all the requisite indigenous capabilities in line with the evolving global standards, without compromising the national health security or self-reliance<sup>3,69</sup>.
8. Technological advances in vaccines, especially for mass immunization, have to be measured in terms of their improvements in efficacy, long-term protection<sup>63</sup>, safety, and cost-competitiveness, stability during storage and transport, and method of administration<sup>4, 66-71</sup>. Technological superiority of vaccine should not be assumed solely in terms of purity, sophisticated methods of production, combinations or other incremental innovations aimed at extension of intellectual property and commercial monopoly<sup>5</sup>.
9. Combination vaccines are convenient but useful and acceptable only when universal and non-universal vaccines are not combined, whether for public or private use. In any case, the safety and efficacy of every combination vaccine has to be freshly established in the target population and cannot be extrapolated from the safety and efficacy of its individual components<sup>5</sup>. Cocktail combination vaccines and genetically engineered multivalent vaccines must be differentiated clearly. In case of cocktail combinations, the price of the combination may not exceed the sum of its individual components.
10. Clinical trials and bio-safety regulations in vaccines targeting children and pregnant women pose special ethical concerns, due to the inability of fetuses and infants to decide for themselves, even if the parents are assumed to take decisions in the best interest of their children<sup>71-74</sup>. Such issues can become more critical when foreign entities conduct clinical trials on Indian children. Phase lag is necessary in such situations<sup>74</sup>. In addition, unless absolutely necessary, vaccine trials in children should begin with grown up children and then move downwards. Suitable amendments may be introduced in the proposed National Biotechnology Authority Act to address these and other public health concerns.
11. The Government shall evolve a suitable legislation enabling Adverse Vaccine Reaction Monitoring & compensation for injuries to any person(s) arising out of vaccinations in India, including for those in the trial phase<sup>75,76</sup>. This should apply to all vaccines, whether provided by the Government, public sector or by the private manufacturers/practitioners. The legislation would be designed to fix responsibility and deliver compensation adequately and promptly in the event of injuries/adverse events due to vaccines and vaccination<sup>77</sup>.
12. Pricing of all vaccines should be brought under the Drug Price Control Order (DPCO) and subjected to regulation in accordance with the objectives of this policy<sup>78,79</sup>. Pricing of vaccines should be done

on a transparent basis and agreed principles of reasonable returns on investment, rates of royalty and costing of R&D efforts. There should be no overhead taxes imposed on vaccines such as excise duty, value added tax (VAT), customs duty *etc.* The difference between maximum retail price (MRP) and the price at which vaccines are supplied to wholesalers, retailers, hospitals or even to doctors will also be minimized to deter monetary incentives for unethical vaccine promotions<sup>80</sup>.

13. International sharing of indigenous biological diversity of pathogens, hosts<sup>81</sup> and knowledge should be governed by the legal principles of prior informed consent and benefits sharing agreements set in the National Bio-Diversity Act. The material transfer agreement should have a clause preventing the recipient from seeking or claiming intellectual property rights over any inventions derived from Indian biodiversity or indigenous knowledge. It should also have copyleft style clauses for open sharing of the research results to develop vaccines and other technologies to combat diseases. Prior informed consent to any overseas individual or entity should be subject to the condition that Indian scientists, technologists and public sector manufacturing entities will have automatic royalty-free rights to use all the further improvement in that knowledge and any technology, product or process that comes out of the shared biological resource or knowledge, or to license it further to indigenous private firms if deemed necessary. This maximizes the national benefits of international sharing to the Indian end-users of vaccines
14. Publicly funded R&D on vaccine technologies should be made available widely on a non-exclusive basis to promote manufacture of quality vaccines at competitive prices. Research papers emerging out of publicly funded R&D should also be made available freely through an open access policy. In all publicly funded vaccine research and development programmes, affordable access to vaccine technologies and the crucial role of the public sector manufacture for national programmes should be given priority over all IPR issues and other technology transfer considerations<sup>3</sup>. Further, knowledge commons approach to R&D and other measures that enhance access to vaccine technologies identified under the National Vaccine Policy should be promoted.

15. The above principles and public health concerns of the nation will have an overriding priority over any multilateral, bilateral or regional trade agreements.

### Policy measures

1. The success of vaccination or any other public health program depends heavily on the disease surveillance and monitoring system in the country<sup>4</sup>. Ideally, such a system should contain frequently collected information on the incidence and prevalence of diseases in the population, local variations in the pathogens including serotypes, resistance to drugs/antibiotics if any, host response to vaccination<sup>82</sup>, efficacy<sup>83</sup> and duration of protection<sup>63</sup>, *etc.* These data form the basis for all decisions regarding whether to adopt vaccination as a strategy and if so, whether universal or selective and for how long<sup>84,25</sup>. In order to augment the present mechanisms available for disease surveillance and monitoring as well as vaccination, the Panchayati Raj institutions should be strengthened, and training imparted to the health management information system (HMIS), integrated disease surveillance project (IDSP), Accredited social health activist (ASHA), Auxiliary Nurse Midwife (ANM) and health workers.
2. To ensure selection of appropriate vaccines on scientific grounds, for the Universal Immunization Programme, well-defined criteria of cost-efficacy and logistical feasibility<sup>37-44</sup>, appropriateness should be formed based on the science of Public Health<sup>17-19,28,29</sup>. A Committee should do this selection after a broad based debate amongst the concerned Public Health experts. No new vaccine should be introduced into the UIP unless adequate and sustained resources/efforts have been devoted to achieve universal coverage of the existing vaccines<sup>3</sup>. The lure of external aid/loan cannot be a sufficient ground for introduction of new vaccines under UIP<sup>4, 19, 28</sup>.
3. In order to ensure stable and affordable supply of vaccines to the national immunization programme and also to address national health security and biosecurity concerns, all essential vaccines covered under UIP (TT, DT, DTP, BCG, Polio, Measles) must continue to be produced by the public sector<sup>71</sup>. Further, the presence of at least two functional PSUs per vaccine (as a backup for each other) must be ensured as a protection against market uncertainties.

4. For patented vaccines and other interventions needed for public health, the Government should take all necessary law and policy measures including government use and compulsory license provisions to ensure timely availability of vaccines at an affordable cost. For off-patented vaccines, suitable law and policy measures should be taken to promote competition by providing incentives to generic manufacturers.
5. All the vaccine PSUs must be urgently revived and modernized to fill the demand-supply gaps in all essential vaccines and anti-sera, including the UIP vaccines<sup>13, 3, 85</sup>. The Government purchase orders for safe & effective vaccines available from PSUs must not be diverted to the private sector under any pretext<sup>3, 71</sup>. For example, the recent introduction of a pentavalent vaccine (that combines DTP with Hepatitis B and Influenza type B) into the UIP<sup>14</sup> effectively diverts all the DTP purchase order from PSUs to private entities, as the PSUs do not manufacture them so far. Besides, the merits of universal vaccination against Hepatitis B and Influenza type B are highly debatable<sup>11, 21, 25, 29, 86, 87</sup>.
6. Various vaccine PSUs are currently under different managerial regimes—state and central Governments, and even within the central Government, under ministry of health and family welfare (MOHFW), department of biotechnology (DBT) and national dairy development board (NDDB)<sup>3</sup>. In order to enhance functional coordination between them to meet the national vaccine needs, their governing bodies should be expanded to include public health experts, epidemiologists, microbiologists immunologists, vaccine policy experts, pharmacologists, economists, sociologists and other interdisciplinary experts and non-Governmental organizations (NGOs).
7. The current National Technical Advisory Group on Immunization (NTAGI) should be restructured into a central National Vaccine Regulatory Authority (NVRA) that allows wider representation to indigenous scientists, policy experts and indigenous public sector and civil society. Apart from invited membership, provision should also be made for voluntary participation of representatives from any non-commercial organization. This authority would be empowered to take all major decisions such as monitoring disease burden, vaccine development, adoption, production, procurement, distribution, immunization and follow-up.
8. Indigenous vaccine R&D and production capacities must be strengthened to ensure a stable and affordable supply of all essential vaccines, especially the UIP vaccines<sup>3</sup>. For this purpose, the core strengths of the vaccine PSUs must be preserved and nurtured<sup>71</sup> with higher functional autonomy (at least at par with the Navratnas), incentives to attract interdisciplinary talent for R&D and production.
9. Enhanced public funding and programme support for R&D into communicable diseases, especially neglected diseases and vaccine-preventable diseases.
10. Further strengthening the integrated disease surveillance programme. Critical appraisal of literature should be undertaken while considering new vaccine adoption in UI or SI decisions. Limited data on the actual prevalence of a disease may overestimate the actual disease burden. Large multicentre and community based studies should confirm the real burden of any particular disease in the country.
11. Improved logistics and supply chain system, including maintenance of cold-chain during periods of heavy load shedding, especially in rural areas. Emphasis on the outreach of vaccination programmes to remote areas and the marginalized populations, tribals *etc*; Promotion of awareness and trust building in communities through various measures to ensure full vaccination coverage.
12. Regulation of advertisements and other promotional marketing activities to prevent unethical means and kickbacks to doctors. Literature should not be cited selectively to base decisions. The role of the industry as the educators of the professionals, policy makers and people must be discouraged. Direct-to-consumer promotional advertisements<sup>64,65</sup> on upcoming vaccines (*e.g.*, rotavirus, HPV, Chickenpox *etc.*) with incomplete and biased information must be banned.
13. Government procurement of vaccines under UIP must be based on price and opportunity parity, and no PSU should be excluded from Government vaccine procurement, as long as the product quality and affordable price are ensured<sup>3,71</sup>. Similarly, no PSUs should be excluded from producing any vaccine, as long as it stakes a credible claim to manufacture it in compliance with all the regulatory and quality

norms at competitive prices. The Government may make advance market commitments with vaccine PSUs subject to quality parameters, but not with any other private or foreign entity to the detriment of the vaccine PSU. No private firm should be paid higher prices than their PSU counterparts supplying to UIP. The whole process should be made transparent.

14. Any private sector unit that wishes to produce new (non-UIP) or combination vaccines must produce some UIP vaccines (individually and not as combinations) to fill any shortfalls in PSU production and Government procurement<sup>5</sup>.
15. A critical review of the current UIP vaccines and new vaccines may be undertaken by the National Vaccine Regulatory Authority (NVRA). Any new vaccine introduction in UIP must be qualified before its introduction for Universal or Selective Immunization, based on epidemiological evidence, suitability and efficacy to the local pathogens and human populations, risk-benefit and cost-benefit analyses<sup>3-5, 7, 25, 29, 31, 63, 65, 73, 81-83, 87, 88</sup>.
16. Similarly, a critical review of the combination of UIP and non-UIP vaccines must be carried out in view of the stated policy objectives. Combining any UIP vaccine with any non-UIP vaccine needs rigorous scrutiny and public debate. Other combinations must be proven to be equivalent to or more effective and safer than single vaccines before adoption. In any case, cocktail combinations and multivalent vaccines must be clearly differentiated<sup>5</sup>.
17. The Government of India is solely responsible for the compliance of its PSUs for good manufacturing practice (GMP) and all other regulatory norms, as well as to prevent stoppage of production on such counts<sup>89</sup>. Therefore, the Government of India must provide all the necessary administrative and financial support for PSU compliance with GMP and all other regulations<sup>3</sup>. The governing bodies and other technical committees of PSUs must be expanded to enable expert monitoring/advice from vaccine policy and public health experts, apart from scientists/technologists of relevance. Representatives from private vaccine manufacturers and industry-funded medical associations/academies must be specifically prohibited to prevent conflicts of interest.
18. In order to make the essential vaccines more affordable to the indigenous end-consumers, measures such as tax concessions/exemptions may be considered.
19. Rejuvenation of the existing institutions of research, education and training of public health workers. The National Vaccine Regulatory Authority (NVRI) will identify such aspects relevant to India and coordinate with existing agencies like Indian Council of Medical Research (ICMR), DBT, Council of Scientific and Industrial Research (CSIR) *etc*.
20. Promotion of health systems research to formulate optimized health systems that can deliver vaccines efficiently and effectively.
21. Strengthening of basic infrastructure and manpower in primary health care centers (PHC) and ancillary programs such as ICDS and the ASHA network, with emphasis on name-based tracking of individual children and women, ensuring planned fixed-day immunization sessions, reporting based on correct denominators and frequent decentralized monitoring of coverage independent of service reports are keystones of successful coverage<sup>7,37,39,41,44</sup>. In addition, the regular audit of vaccine utilization is essential. Currently, all these are not subject to regular and independent scrutiny, and can be brought under the ambit of NVRA. A prevailing concern has been the tendency of immunization programs to operate independently of other primary health care programs<sup>7</sup>. Maintaining this balance will be critical to the success of both, the UIP and the other PHC programs.
22. Increase in budgetary allocations for investment in proven cost-effective programmes.
23. Private vaccine markets and also their use in private clinics should be regulated through a mechanism to be brought under National Vaccine Regulatory Authority (NVRA) supervision.
24. A thorough and transparent review of all public private partnerships (PPP) in vaccine development, production and delivery is needed, including the upcoming vaccine park at Chengalpattu<sup>3,13</sup>. All measures should be taken to ensure that PPPs do not amount to public spending and private profiteering. The public private partnerships for developing and manufacturing new vaccines may be beneficial only when the state of art for making

vaccines remains with public sector, while private sector is made to meet vaccines that are needed.

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