

## **Statement of Concern by the Alliance Against Conflicts of interests (AACI)**

September 2011

### **AACI questions the Government of India's draft National Vaccine Policy<sup>1</sup> and the resolve of Indian Academy of Pediatrics (IAP) Committee on Immunization.**

This is a statement of concern by the Alliance Against Conflicts of interests (AACI), which is an alliance of organisations and individuals working in various sectors – doctors, lawyers, women's and children's health groups, activists and media. AACI takes up cases with clear conflict of interest and brings them to the notice of the parties involved, the government and media. AACI aims at having a legal protection from conflicts of interests in all sectors in public policy.

AACI is concerned about the stated position of the Government of India in its draft National Vaccine Policy to go the PPP way, having conflicts of interests; an approach that promotes the profits of private manufactures at the expense public sector and inimical to the interests of public health and safety. AACI supports vaccines for prevention of disease and welcomes all vaccines that are cost effective in India. However, AACI is concerned that irrational vaccines are being introduced in the public health system by the Government of India, under the influence of vaccine manufacturers and international agencies like World Health Organization (WHO), without proper epidemiological and medical studies in the absence of a rational policy. At the same time AACI is also concerned about the similar push being generated by the IAP through its new schedule and the resolve of the IAP committee on immunization.

#### ***National vaccine Policy and Advance Market Commitments (AMC)***

AACI deplores the National Vaccine Policy projected to push newer vaccines. The stated position of Government of India, "...mandatory for Government to support developments with Advance Market Commitments and honor the commitments.....and setting up a Vaccine Fund through 'innovative financing mechanisms'....., for introducing new vaccines...", clearly makes the tilt towards benefiting the vaccine manufacturers without having any mechanism what so ever to identify or manage conflicts of interests or showing the will to build a credible public sector. At the same time, basic vaccines that are the right of every child are not being made available under the Universal Immunization Programme (UIP) to 53% of the population – mostly poor living in rural areas that should be the priority for any immunization program as the poor cannot afford the consequences of disease. It is highly inequitable that half of India's kids do not receive what has been agreed in delivery of child health.

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

AACI believes that introduction of new vaccine like pneumococcal, petavalent and rotavirus vaccines in national public programmes would siphon off huge health finance (which is already so meager) and that too when there is little evidence to show effectiveness of the new vaccines in terms of absolute risk reduction of diarrhea or pneumonia for child survival.

AACI supports India to have an overarching legal framework to identify, manage and end conflicts of interests from public policy in all sectors. AACI believes that conflicts of interest need to be addressed at every level.

### ***Indian Academy of Pediatrics Committee on Immunization position on new vaccines***

AACI is also concerned about the “far reaching decisions” of the ‘IAP Committee on Immunization’<sup>2</sup> as this will institutionalize conflicts of interests because this Committee has expressed its intention to be a partner with the vaccine industry. It is the very body that is to evaluate the products marketed by the vaccine manufacturers, and collaborating with the organization they are meant to evaluate, the IAP will forfeit its credibility. Such an earlier conflict of interest once featured in the BMJ.<sup>3</sup>

AACI questions the decision of the IAP Committee to partner with manufacturers, without having in place a mechanism to identify or manage conflicts of interest and going ahead with a schedule of immunization that includes all new vaccines. AACI also questions the membership of IAP in NTAGI, because of the sponsorship of IAP conferences as well as vaccine advertisements in the official journal of IAP by vaccine industry. While AACI supports IAP’s efforts to communicate with people on need of immunization, it strongly condemns institutionalization of conflict of interests.

AACI takes note of the IAP Committee on Immunization plans to make explicit the evidence base of its recommendation and to issue 'best evidence based recommendation'. AACI would like to understand the underlying implication of such recommendations made on the 'best evidence' and what it actually means. Best evidence available may be so inadequate that new evidence needs to be sought. As there has been recommendations on new vaccines without taking into consideration absolute risk reduction, the local context, or cost effectiveness studies; AACI would like to be reassured that such recommendations will not be made in the future under the guise of evidence based medicine, as merely classifying evidence does not improve the evidence.

AACI believes that it is not enough to declare interests; transparency, although an essential first step, is not a sufficient safeguard against negative impacts of

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<sup>2</sup> <http://www.iapindia.org/files/AT%20JULY%20-%20SEPT%202011.pdf>

<sup>3</sup> [http://www.bmj.com/content/319/7203/188.2/reply#bmj\\_el\\_4398?sid=9dbec9bf-9be6-4f97-aae2-bc8ade513eb3](http://www.bmj.com/content/319/7203/188.2/reply#bmj_el_4398?sid=9dbec9bf-9be6-4f97-aae2-bc8ade513eb3)

conflict of interest. 'Partnerships' have been proposed with no clarification of what this actually means. It can have a profound influence of the national policy and practice. This is because the IAP is part of the Government of India's National Technical Advisory Group on Immunization (NTAGI) whose recommendations are taken seriously at the national level to develop the policy. This kind of conflicts of interests could have led to draft National Vaccine Policy taking the same route to satisfy the needs of vaccine manufactures.

**With the above background, AACI makes following demands and recommendations.**

1. AACI recommends amending the Draft National Vaccine Policy of the Government of India to take into consideration the principles of conflicts of interests and not to enter into any advance marketing commitment to the vaccine manufacturers for the vaccines whose efficacy and cost effectiveness in the Indian context has not been proven yet. AACI demands that vaccine policy must enunciate how conflicts of interests will be identified and managed.
2. AACI recommends that Government of India should come out with a plan to transparently evaluate the need for any vaccine, which must have demonstrable cost-effectiveness and that benefits of vaccines must be reported in terms of absolute risk reduction.
3. AACI demands that Government of India should present a time bound plan to achieve 100% coverage of agreed routine vaccines with a priority to cover rural and poor children first.
4. AACI recommends to IAP that a strong and clear policy on conflicts of interest be established in the IAP functions, including the committee on immunization as its decisions concern health of India's children. IAP should set out a clear framework for those engaging the vaccine manufacturers and for managing conflicts of interest.
5. AACI recommends that the IAP issue a position paper on Absolute risk reduction by the newly to be introduced vaccines, and base its decisions on these figures when it recommends newer vaccines to include in its schedule.
6. AACI requests the Supreme Court of India to take cognizance of potential conflicts of interests in the national vaccine policy of Government of India and the IAP Committee on immunization for both pushing new vaccines for the children of India.

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