IN THE HIGH COURT OF DELHI AT NEW DELHI

(CIVIL ORIGINAL JURISDICTION)

C.M. No. OF 2013

IN

WRIT PETITION (CIVIL) No. 13698 OF 2009

PUBLIC INTEREST LITIGATION

IN THE MATTER OF:

DR. K. B. SAXENA & ORS. …PETITIONERS

VERSUS

UNION OF INDIA & ORS. …RESPONDENTS

APPLICATION FOR AMENDMENT OF PRAYERS OF THE WRIT PETITION UNDER SECTION 151 CPC

To,

The Hon'ble Chief Justice of Delhi And
His Hon'ble Companion Justices of the Hon'ble High Court of Delhi

The humble application of the petitioners above named:

1. The Petitioners, a group of public health experts led by former health secretary, had filed the above writ petition in 2009 seeking the quashing of certain vaccines, especially Pentavalent vaccine, and also seeking the formulation of an evidence based rational vaccine policy. The Petition highlighted the Government's arbitrary policy on vaccines by using, as case studies, the proposed introduction of Hepatitis B, Haemophilus influenzae Type B (Hib), Pneumococcal and the Pentavalent vaccines which are of doubtful utility, unproven efficacy, expensive and are not required. World over, before a vaccine is introduced in the public health system, a number of studies are carried out with proper methodology and expertise, taking into account a number of factors, and also conflict of interest is strictly guarded against. In India, not only these tests are not being done, adverse studies against these new vaccines are deliberately being ignored.

2. Vaccines are vital to avoid unnecessary suffering, disability, and death. Immunization is a proven tool for controlling and even eradicating disease.

Just as essential and life saving medicines are needed for medical care, certain vaccines, based on proven utility, are considered essential and they have an important role in health care promotion. India is one of the biggest consumers of vaccines in the world. Under the EPI, six basic vaccines are provided to the children in the country: BCG, DPT, DT, TT, Measles and Polio. These vaccines cost as little as Rs. 30 per child to the exchequer. Yet they are still not made universally available and many children are denied their basic right to immunization. The survey by the Government of India has shown that 53% of the population does not receive these basic vaccines.

3. World over, about 6 factors are seriously studied and researched before a vaccine is introduced:

    a) **Incidence of the disease:** How many people are affected by the disease for a given population in the country or a particular region?

    b) **Severity of the disease:** Whether the disease causes serious discomfort, disability or death? Or is it just a minor ailment in the majority of cases and it results in complication in a very small number?

    c) **Public Health significance:** Which is the population vulnerable to the disease? How is the disease transmitted? What are the health care and economic consequences of the disease?

    d) **Treatment options:** Is the disease untreatable? Does it require expensive or prolonged medication? Is it curable with inexpensive and easily available drugs? Is it naturally curable?

    e) **Efficacy of the vaccine:** If a said number of persons are vaccinated, then what fraction/percentage of them acquire immunity from the disease?

f) **Cost of the vaccine:** How much will it cost to vaccinate the entire population as against giving medical care to the few who fall ill?

g) **Side effects:** What are the health side effects of the vaccine that is sought to being given to every child?

4. Petitioners had pointed out that these factors are being ignored and no proper epidemiological and other studies are being carried out, and Government is trying to introduce newer and newer irrational vaccines. Since vaccines, unlike medicines, are given to all, they need a clear cost-benefit rationale. It must be noted that 'costs' does not only include the cost of the vaccine but also includes the financial and administrative burden of installing the requisite infrastructure (hospitals, clinics, refrigerators, storage), hiring and maintaining staff (doctors, nurses), expenditure on consumables (vaccine containers, syringes), and administrative costs and other overheads. Cost of procuring vaccines is only a small fraction of the total cost of imminuzation. Also, these new vaccines have potential side effects.

5. A long standing demand of public health experts was fulfilled when Government in August 2001 established NTAGI, an advisory committee, for immunization policies. However, members of the NTAGI are just being hand-picked by the Government, without any transparency or system in their appointment process. Once appointed they generally toe the Government's line and merely act as a rubber-stamping authority.

6. The petitioners had stated in the petition that the above is happening because the Government has not framed any policy and ad hoc decisions are being taken. This Hon'ble Court asked the Government to frame a policy keeping in mind the principles of rational vaccine, and also consider the draft policy framed by a very large number of experts which had been filed

by the petitioners. Pursuant to this the Government framed a policy but the same does not meet the tenets of evidence based vaccine, does not incorporate the principles of the draft policy annexed to the petition and is focused on the needs of private vaccine manufacturers. Therefore, the petitioners have challenged the said policy by way of an application filed in the instant matter on which this Hon'ble Court was pleased to issue notice.

7. The vaccine policy framed by the Government is totally contrary to letter and spirit of the orders passed by this Hon'ble Court. This Hon'ble Court had vide order 07.04.2010 had stated the following: *"A vaccine policy has been framed by some experts (it appears on page 211 of the paper book). The Respondents may examine the policy for framing similar or other guidelines, whenever it becomes necessary at some stage."*

8. On 15.09.2010, this Hon'ble Court inter-alia recorded in the order: *"At this juncture, Mr. Prashant Bhushan submitted that the committee has to keep in view the four vital aspects:-*

    (i) Incidents of disease in India and its effect potentially,

    (ii) The efficacy of the vaccine to prevent the disease as prevention is better than cure,

    (iii) The side effects of the vaccine, the nature of adverse side effects and the approximate statistics of the persons who are likely to be effected by such side effects and

    (iv) The costs factor."

9. This Hon'ble Court on 08.12.2010 stated: *"Let the policy be finalized within two months from today."* Thereafter, on 23.02.2011, this Hon'ble Court stated: *"Petitioner No. 8 can file additional comments including all the objections that have been raised in the writ petition within three weeks hence, if not yet filed. It is submitted by the learned counsel for the respondent- Union of India that the policy shall be finalized within two months."* Therefore, respondents had to comply with certain directions given

from time to time by this Hon'ble Court. The same has not been done as detailed in the application 18416/2011. The petitioners have also shown that proper procedure was not followed in framing of the said policy. The NTAGI was told in the meeting of 28 May 2012 that comments from the members and public would be sought and the policy would be revised and presented to the NTAGI. No such revision has been presented to the NTAGI.

10. The Policy merely states that vaccine selection is a complex process and the following 'may be considered for informed decision'. Thereby the policy suggests that vaccines may be introduced without evaluation. It leaves huge discretionary powers to the Government to make irrational decisions as the evaluation is not made mandatorily. The policy must instead state how the disease burden would be estimated – how many are affected and how many suffer serious consequences and death. It must look at vaccine efficacy and state how many people will need to be vaccinated to prevent I case of morbidity and one death. It must explicitly state the total cost to vaccinate the population to prevent one case of morbidity and each death which cost will include cost of vaccine and cost of administering the vaccine. For comparison the cost per life saved of other already accepted interventions must be stated. These calculations must be explicitly stated on the Health Department web site and open to the public under RTI. The calculations must be made by a body with no conflicts of interests and all potential conflicts must be stated in a publically accessible website. The NTAGI must be selected by an independent body from among applicants for a fixed term. The policy that has been provided to the Court does not do this and must therefore be set-aside.

11. The Government has now stated that it wants to introduce Pentavalent in six states. The said decision has been taken without any proper evaluation of the trial study in 2 states of Kerala and Tamil Nadu. The minutes of the NTAGI meeting dated 26.08.2010, regarding the vaccine Pentavalent had

itself stated: "*As the vaccine has not been introduced there is not enough data on vaccine safety therefore the vaccine should be initially used in the states with better AEFI management and surveillance system to monitor the vaccine safety… The Core committee recommendation on Pentavalent vaccine were discussed and based on the recommendation the committee members felt that the vaccine should be introduced in selected few well performing states and further roll out should be based on the impact assessment of the vaccine including safety aspects… Pentavalent vaccine to be introduced in Immunization programme in the states of Tamil Nadu and Kerala. Thereafter data may be reviewed after 1 year of introduction before expanding the vaccine to other states.*" Hence, AEFI (Adverse Effects Following Immunization) was a serious concern for even NTAGI, and it stated explicitly that there was need was to monitor the AEFI in the above 2 states before it is considered for roll out to other states.

12. Petitioners had shown that the Pentavalent vaccine programme must quashed as the vaccine had little utility and was known to have caused deaths in 5 deaths in Sri Lanka 3 deaths in Pakistan and 8 deaths in Bhutan. The vaccine was introduced to evaluate side effects in 2 states in India. The vaccine has resulted in at least 15 deaths already. An article in the electronic British Medical Journal (BMJ) web site explains why the Government is scared of such an evaluation and why it is keen on expansion to other states without evaluation. The pattern of sudden unexplained deaths in some recipients of the vaccine in these two states follows the same pattern seen previously in Sri Lanka, Bhutan, Pakistan etc. When an evaluation is made of the partially data collected from Kerala in the first 6 months of administering Pentavalent vaccine, it is clear that it will be improper to expand the programme to other states or even continue the programme in these two states if the Government is to follow the basic medical ethical principle of *'primum non nocere'* (at first do no harm). The figures in the BMJ website suggest that 5 children died soon after

administering vaccine without an alternate explanation for their death. 4 died after their first dose of the vaccine. According to information obtained through RTI 40,000 babies had received vaccine at that point. If the same death rate following Pentavalent vaccine in Kerala in the first 6 months were extrapolated in a national immunization programme the article calculates that 3125 deaths following immunization is likely. This is 15 times more than deaths from Hib meningitis.

13. Schedule Y of the Drugs and Cosmetics Act applies to post-marketing surveillance for approved drugs. Section 12 obligates drug manufacturers to conduct post-marketing surveillance studies after getting protocols and the names of investigators approved by the Licensing Authority as defined under clause (b) of Rule 21 during the initial period of two years of marketing. Accordingly, as the manufacturer of the vaccine, Serum Institute is responsible for collecting data on all side effects that result from the drug. The Government has records of some adverse events including deaths after Pentavalent vaccine. If the vaccine manufacturers have not reported independently and in a timely manner these adverse events the Drug Controller is duty bound to take action against the manufacturers. The court must be informed of what action has been taken. Failing this the court may direct action against the DCGI for grave dereliction of duty. Pentavalent cannot be allowed to be introduced unless a through evaluation is carried out of the trial in 2 states, as was undertaken by the Government before this Hon'ble Court.

14. Therefore the petitioners pray to this Hon'ble Court, on the basis of above statement of facts and arguments, to modify the final prayers of the writ petition to be the following:

    a) Quash the proposed introduction of Pentavalent vaccine in the Universal Immunization Programme until proper trials, epidemiological studies are carried out and a clear cost-benefit analysis is done in a transparent

manner by an expert technical body and the side-effects & deaths following the use of this vaccine are adequately analyzed.

b) Set-aside the vaccine policy (Annexure A10 of C.M. 18416/2011) which has been approved by the Government.

c) Direct the Government to formulate a rule-based rational vaccine policy which would prescribe mandatory analysis and epidemiological studies which need to be carried out before a vaccine is sought to be introduced into the public health system and would do so in a transparent manner while allowing for public and scientific scrutiny.

d) Direct the Government to set up a committee to transparently select members of NTAGI for a fixed term from credible public health experts and pediatricians with no conflict of interest, to formulate new vaccine policy and then to act as per the said policy

e) Issue or pass any writ, direction or order, which this Hon'ble court may deem fit and proper under the facts and circumstances of the case.

PRAYERS

In these circumstances the Petitioners respectfully pray that your Lordships may be pleased to pass the following direction:

(i) Modify the prayers of the writ petition in terms of paragraph 14 of this application

(ii) Pass further orders as may be deemed fit and proper.

AND FOR THIS ACT OF KINDNESS THE APPLICANTS AS IN DUTY BOUND SHALL EVER PRAY

PRASHANT BHUSHAN
Counsel for the Petitioners

Filed on: April 2013
New Delhi