Received
by
10/12/12

IN THE HIGH COURT OF DELHI AT NEW DELHI

W.P. (C) NO.13698 OF 2009

IN THE MATTER OF:

DR. K.B. SAXENA .....**PETITIONER**

VERSUS

UNION OF INDIA AND OTHERS ....**RESPONDENTS**

INDEX

SL.NO.	PARTICULARS	PAGE NO.
1.	REPLY AFFIDAVIT ON BEHALF OF RESPONDENTS NOS. 1 AND 2 TO THE SUPPLEMENTARY AFFIDAVIT ON BEHALF OF THE PETITIONERS	1 – 7
2.	**ANNEXURE – A (COLLY.)** COPY OF SOP OF AEFI GUIDELINES, 2005	8 – 115
3.	**ANNEXURE – B (COLLY.)** COPY OF SOP OF AEFI GUIDELINES, 2010	116 – 288

THROUGH:

[MANEESHA DHIR]
SENIOR PANEL COUNSEL
D-55, DEFENCE COLONY
NEW DELHI-110024
PH: 42410000
FAX: 42410091

NEW DELHI
DATED: 07.12.2012

IN THE HIGH COURT OF DELHI AT NEW DELHI

W.P. (C) NO.13698 OF 2009

IN THE MATTER OF:

DR. K.B. SAXENA .....**PETITIONER**

VERSUS

UNION OF INDIA AND OTHERS ....**RESPONDENTS**

REPLY AFFIDAVIT ON BEHALF OF RESPONDENTS NOS. 1 AND 2 TO THE SUPPLEMENTARY AFFIDAVIT ON BEHALF OF THE PETITIONERS

I, Prem Narain S/o Late Shri Panch Deo Jaiswal aged about 45 years, working as Under Secretary with Ministry of Health and Family Welfare having office at Nirman Bhawan, New Delhi do hereby solemnly state and affirm as under: -

1. That I am fully conversant with the facts and circumstances of the case based on the record and I am thus competent to swear and affirm this affidavit.

The Seal of Oath Commissioner Sl. No. 72/2012 MANJEET KAUR App. by Delhi High Court Period 14-09-2012 to 13-09-2014 Delhi High Court, New Delhi

2. That the Respondent No. 1 and 2 crave leave of this Hon'ble Court to rely upon the short affidavit already filed before this Hon'ble Court, as the contents of the same are not repeated herein for the sake of brevity.

3. That all the averments made in the supplementary affidavit are wrong and denied, except where the Answering Respondents have specifically admitted any averments to be true or being a matter of record. The Answering Respondents also reserve their right to file any other and/or additional affidavit.

PARA-WISE REPLY

1. – 3. That the contents of paras 1 to 3 are wrong and denied except what is matter of record. In reply to the contentions raised in the preset paras, the Answering Respondents seek liberty to rely on the short reply already filed, as the same are not repeated for the sake of brevity;

4. That the contents of para 4 are wrong and denied except what is matter of record. It is submitted that the investigation conducted by WHO Expert Team in Countries stated in the present para, did not indicate vaccine as the cause of death.

5. That in reply to contents of para 5 it submitted that as a standard process for introduction of any new vaccine, Government of India closely monitors all activities including training, sensitization of ANMs, Doctors and Supervisors, awareness generation and adverse event following Immunization (AEFI) etc. Therefore, the interpretation of Petitioners that the Core Committee and NTAGI had serious concerns regarding AEFI with Pentavalent Vaccine are baseless.

6. That the contents of para 6 are wrong and denied except what is matter of record. The quoted comments in the present para were not in relation to any 'study' but refers to 'Government of India's decision to implement NTAGI's recommendation to rollout Pentavalent Vaccine in Tamil Nadu and Kerala to build up a system of scalability and also to dispel the fear of increased AEFI due to Pentavalent vaccine'. Further, as stated above the investigation conducted by WHO Expert Team in Countries stated in the present para, did not indicate vaccine as the cause of death.

7. That the contents of para 7 are wrong and denied. The Petitioners are misleading the Hon'ble Court by claiming that the Standard Operating Procedure ('SOP') for AEFI was developed after filing of the captioned petition. The fact of the matter is SOP for AEFI was published in 2005 and it was revised in 2010. The SOP for AEFI follows the original WHO categories and nowhere mentions 'Must' use of Brighton Classification. Infact, the Annexure 6 of the book which is a WHO-Aide Memoire refers to Brighton Classification encouraging its use in serious AEFI. The SOP (2010) indicates a range for frequency and nature of adverse event and nowhere states that there 'would be' 570 cases of seizure, 570 cases of HHE and 20 cases of Encephalopathy per 1 million of DPT. Rather the booklet provides a range of 30-990 cases of HHE per million doses of DPT, 600 cases of seizure which mostly are febrile in nature with a much lower risk in infants under the age of 4 months age and does not mentions about encephalopathy. It is important to

mention that all the adverse events which the Petitioners are trying to highlight are associated with DPT Vaccine, which was a part of the immunization programme since the inception of the public health endeavour in 1978. Government of India and State Governments are well aware about the possibility of such side effects and have managed most of such adverse events during the years. It is also pertinent to mention that the follow up and close monitoring of every child whether vaccinated or provided any other health related intervention is closely followed up by ASHA. These ASHAs know each and every child in the village and meet them and other Community Member on nearly a daily basis. Therefore, any adverse event is immediately reported to ASHA as well as to the ANM and Medical Officer of the nearby health facility. Copy of SOP of AEFI Guidelines of 2005 and 2010 are annexed as **ANNEXURE – A** (Colly.) and **ANNEXURE – B** (Colly.) respectively.

8. That the contents of para 8 are wrong and denied. It may be stated that the Petitioners are repeatedly trying to quote incomplete and false statements and link them to reach a hypothetical conclusion. It is a matter of fact that there was an overwhelming welcome response to Pentavalent vaccine both in Kerala and Tamil Nadu with parents of more than 27 thousand children in Kerala and 47 thousand children in Tamil Nadu came forward to get their child vaccinated within 15 days of launch of vaccine. It was the fear and agitation created by the group of people including the Petitioners who wanted to prevent the rollout of Pentavalent vaccine which would directly affect their

business of administering Pentavalent vaccine in private and thus charging hefty amount from the general public. The Report submitted by the Noel Committee in its conclusion clearly documents that "Since a safe and effective Hib vaccine is now available, prevention of invasive Hib disease with vaccine is certainly the correct choice. At present the benefit is enjoyed only by the rich and affluent who can afford this expensive vaccine and the poor children who in need of it most, are denied this vaccine. Inclusion of Hib vaccine in UIP will benefit millions of children in India".

9. That the contents of para 9 are wrong and denied. It may be noted that at paragraph 5 of the affidavit under rely it is mentioned that one of the reason why NTAGI choose Tamil Nadu and Kerala for introduction of Pentavalent vaccine was the strong AEFI surveillance mechanism in the state and further the Petitioner No. 8 was one of the Member of the recommending Committee. With regard to safety of vaccine, Government of India keeps vaccine safety at paramount importance and separate mechanism to document serious and non-serious AEFI exist under the immunization programme. While any form of serious AEFI needs to be immediately reported to District/State and Central Government in predefined format and timelines, non-serious AEFI are reported on a monthly basis through the computerized HMIS (Heath Management Information System).

10. That in reply to contents of para 10 it is submitted that the Standard Operating Procedure in case of AEFI already exist

under the Immunization Programme and are being followed in the Country including Pentavalent Vaccination.

11. That the contents of para 11 are wrong and denied. It is submitted that the Petitioners projecting false claims. The Pentavalent Vaccine was introduced in the states of Kerala and Tamil Nadu in December, 2011 and the current expansion into six more States is based on respective State's request and will be nearly an year after the introduction in 2 states.

12. That the contents of para 12 are wrong and denied except what is matter of record. The Vaccine Policy was formulated to provide a broad guiding framework for action and was duly approved after verification by experts. It may be noted that the Answering Respondents have filed reply to the application mentioned in the present para, the contents of which be read in reply to the present para, which are not repeated herein. The Answering Respondents have questioned the maintainable of the prayers sought in the aid application as the same are beyond the scope of the captioned writ petition.

13. That in reply to contents of para 13, it is submitted that the comments from various Respondents have been compiled and will be reviewed by experts for any revision, if needed.

Ram Narain

DEPONENT

7

VERIFICATION:

I, the above deponent, do hereby verity that the contents of my above affidavit are true and correct to the best of my knowledge, based on the official record maintained in the normal course of business and nothing material has been concealed therefrom.

07 DEC 2012

Verified and signed on this 7th day of December, 2012 at New Delhi.

I identified the deponent who signed in my presence.

The Seal of Oath Commissioner ... Delhi High Court

DEPONENT

CERTIFIED THAT THE DEPONENT
Shri/Smt/Km.............................Aged.........
S/o, W/o, D/o...
....
...ified by Shri/Smt.....................................
...solemnly affirmed before me at Delhi
.......................at Sl. No...........
...affidavit which have
...to him are true and
...knowledge.

MANJEET KAUR
Oath Commissioner
Delhi High Court, NEw Delhi

07 DEC 2012