

A DELHI COMMISSION FOR PROTECTION OF CHILD RIGHTS

v.

UNION OF INDIA AND ANOTHER

(Writ Petition (Civil) No 572 of 2021)

B JANUARY 25, 2022

**[DR. DHANANJAYA Y CHANDRACHUD AND
SANJIV KHANNA, JJ.]**

- Covid-19 vaccination: Vaccination of Pregnant Women and*
- C *Lactating Mothers – Petitioner seeking categorization of pregnant women and lactating mothers as belonging to the high risk category for the purposes of vaccination – Certain suggestions made by petitioner raised issues of policy – The same required the government to take decision, bearing in mind welfare, safety and dignity of such class of women – The suggestions made by the petitioner involved application of domain knowledge by experts in the area – Court not in a position to take the decision unaided by an expert determination – Union Government to place the matter before duly constituted expert group to evaluate the suggestions – Writ petition disposed of.*
- D *involved application of domain knowledge by experts in the area – Court not in a position to take the decision unaided by an expert determination – Union Government to place the matter before duly constituted expert group to evaluate the suggestions – Writ petition disposed of.*
- E CIVIL ORIGINAL JURISDICTION: Writ Petition (Civil) No. 572 of 2021.

(UNDER ARTICLE 32 OF THE CONSTITUTION OF INDIA)

- F Ms. Vrinda Grover, Kumar Shanu, Soutik Banerjee, Ms. Ayushi Rajput, Ms. Rangoli Seth, Prateek K Chadha, Advs. for the Petitioner.
- F Ms. Aishwarya Bhati, ASG, Gurmeet Singh Makker, Rajat Nair, Kanu Agrawal, Ms. Deepabali Dutta, Ketan Paul, Advs. for the Respondents.

- G Nilesh C. Ojha, Prem Sunder Jha, Ishwarlal S. Agarwal, Ms. Dipali N. Ojha, Pratik Jain Saklecha, Shivam Mehra, Abhishek Mishra, Ms. Sidhi A. Dhamnaskar, Ms. Snehal S. Surve, Ms. Poonam S. Rajbhar, Ms. Deepika G. Jaiswal, Mangesh B. Dongre, Pritam Bishwas, Anant Misra, Advs. for the Intervener.

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The Judgment of the Court was delivered by A

DR. DHANANJAYA Y CHANDRACHUD, J.

1. These proceedings under Article 32 of the Constitution have been instituted by the Delhi Commission for Protection of Child Rights¹. The specific reliefs which have been sought concern the need to provide effective access to vaccination to pregnant women and lactating mothers. These reliefs can broadly be summarized as follows:

(i) Categorization of pregnant women and lactating mothers as belonging to the high risk category to be given priority in vaccination; B

(ii) Their inclusion in the vaccination drives and setting up of a task force to operationalize a standard operating procedure² for monitoring of their health post vaccination; C

(iii) Developing educational materials and SOPs for women belonging to this group to understand the effects of vaccination and ensure informed consent; D

(iv) Creation of a registry for vaccinated pregnant women and lactating mothers to allow effective and constant monitoring of their health; E

(v) Setting up of separate vaccination centers to protect this class of persons from untoward infection; F

(vi) Engaging Anganwadi centres and ASHA workers for vaccination drives as a method of outreach particularly for women belonging to underprivileged socio economic backgrounds; and F

(vii) Providing an option on the Co-WIN portal so as to allow pregnant women and lactating mothers to classify and identify themselves such that they can be given priority while providing slots for vaccination. G

2. Initially, a preliminary affidavit was filed on 2 October 2021 by the Additional Commissioner in the Union Ministry of Health and Family Welfare³. The affidavit has detailed out steps taken for (i) constituting

¹ “DCPCR”

² “SOP”

³ “MoHFW” H

- A the National Technical Advisory Group on Immunization⁴ and National Expert Group on Vaccination Administration for Covid-19⁵; (ii) steps taken for supporting the vaccination of pregnant women; (iii) steps taken for tracking Adverse Events Following Immunization⁶; and (iv) support provided through vaccination centres and ASHA and Anganwadi workers.
- B The affidavit states that:
- (i) Initially, pregnant women and lactating mothers were not eligible for the COVID-19 vaccination as there was no sufficient evidence regarding its safety and efficacy. Subsequently, the World Health Organization and other experts recommended that the benefits of the vaccine for this group outweigh its potential risks;
- C
- (ii) Based on the recommendations of experts, a national consultation was held on the subject with representatives of State Governments, medical colleges, Federation of Obstetric and Gynecological Societies of India (FOGSI), NGOs, among others, to gain consensus on the subject of vaccinating pregnant women and lactating mothers and spreading awareness regarding the vaccination drive;
- D
- (iii) The MoHFW approved the vaccination of pregnant women on 2 July 2021 and vaccination for lactating mothers was approved on 19 May 2021. Operational guidelines for vaccination of pregnant women were released on 2 July 2021, which recommended that all pregnant women visiting for antenatal care should be informed of the risks and benefits of COVID-19 vaccines and their likely side effects;
- E
- (iv) The MoHFW has directed all States and Union Territories to engage with professional bodies such as FOGSI, Indian Medical Association, Indian Academy of Paediatrics, National Neonatology Forum;
- F
- (v) Since the full impact of the vaccines on pregnancy outcomes for the woman and the fetus are unclear, all AEFIs are monitored through a well-structured and robust surveillance

⁴ “NTAGI”

⁵ “NEGVAC”

⁶ “AEFI”

- system. For this purpose, National AEFI Surveillance Operational Guidelines and COVID-19 Operational Guidelines have been formulated; A
- (vi) A causality assessment is conducted by the designated AEFI committee and AEFI amongst the beneficiaries of vaccination are reported by the vaccinator or District Immunization Officer through the Co-WIN portal; B
- (vii) A multi-centric project to study and document the adverse events occurring in pregnant women vaccinated with the COVID-19 vaccine is being initiated across the country; C
- (viii) All pregnant women who are vaccinated are line-listed on the Co-WIN portal with their demographic details and any AEFI reported is also entered on the portal to ensure that a tracking mechanism is maintained; D
- (ix) As regards the vaccination drive for pregnant women and lactating mothers, States/UTs have been advised that they may prioritize vaccination through strategies like dedicated time period for vaccination of pregnant women and lactating mothers, designate special days for their vaccination, and identify centres for vaccination of this group; E
- (x) ASHA and Anganwadi workers form a critical support system as frontline workers by linking the vaccine beneficiaries and the service providers. Thus, dedicated Information Education Communication material has been developed for frontline workers (including ASHA and Anganwadi workers and vaccinators); and F
- (xi) An option has been provided on the Co-WIN portal to identify a woman as pregnant to ensure the woman can get vaccinated at the nearest centre. G
3. On 3 December 2021, this Court directed the petitioner to formulate concrete suggestions to strengthen the existing framework of vaccination of pregnant women and lactating mothers and share it with the Union Government. The petitioner shared these suggestions and thereafter, a further affidavit dated 13 January 2022 has been filed by the Union Government which has particularly dealt with AEFIs and the mechanism for identification of pregnant women and lactating mothers, in response to the petitioner's suggestions. The affidavit states that: H

- A (i) Regarding the declaration and identification of pregnant women and lactating mothers at the time of vaccination, only a verbal declaration, on a purely voluntary basis, is required regarding the status of pregnancy/lactation, which can be verified at the time of vaccination. Once the declaration is made, the vaccinator provides the beneficiary with information about risks of COVID-19 infection in pregnancy, the benefits and side-effects of vaccination;
- B (ii) The guidelines issued by MoHFW require reporting of any suspected AEFI irrespective of the time interval between the day of vaccination and the day of onset of symptoms. Thus, there is no time limitation for reporting AEFRs;
- C (iii) The current AEFI surveillance system collects data of all adverse events related to COVID-19 vaccine beneficiaries, including pregnant women or lactating mothers. Under this system, (a) the District Immunization Officers have been instructed to set up a network with private hospitals to report AEFRs; (b) training has been given to State officers, medical officers, private practitioners and frontline health workers on their role in AEFI surveillance; (c) Auxiliary Nurse Midwives at block/planning unit have been instructed to notify all AEFRs and medical officers have been instructed to look for any patterns; (d) pregnant women are being given antenatal care services through government or private health care facilities;
- D (iv) Medical treatment is being provided free of cost to beneficiaries who suffer AEFRs in all government health institutions. States/UTs have been asked to identify at least one AEFI management centre in each block. Additionally, MoHFW has established a patient to doctor telemedicine platform;
- E (v) Regarding the publication of data, the affidavit states that once the causality assessment is done, the data regarding AEFRs is made available in public domain on the website of MoHFW. Since all AEFRs following vaccination may not be causally linked to the vaccination, publication of data without causality assessment is inappropriate as it may increase vaccination hesitancy; and

(vi) Regarding the creation of the specific filter on the Co-WIN portal for pregnant women and lactating mothers, the affidavit states that this group has to be identified and counselled before the vaccination and there is no method of verification at the time of booking of slots. A

4. We have heard Ms Vrinda Grover, learned counsel appearing on behalf of the petitioner and Ms Aishwarya Bhati, learned Additional Solicitor General. An intervention application has been filed by Mr Ambar H Koiri, who is represented by Mr Nilesh Ojha. B

5. During the course of her submissions, Ms Vrinda Grover, learned counsel has submitted that the affidavits which have been filed by the Union of India would substantially resolve the concerns which have been raised in the petition. Learned counsel submitted that DCPCR instituted these proceedings with the object of ensuring that vaccination for pregnant women and lactating mothers is taken up on a priority. C

6. The decision to enable vaccination for lactating mothers was taken on 19 May 2021 while the decision to permit vaccination for pregnant women was announced on 2 July 2021. The Court has been apprised of the fact that in taking these decisions, the Government has been guided by its own expert groups as well as by a consensus which has evolved at the international level through the World Health Organization. D E

7. Learned counsel appearing on behalf of the petitioners has highlighted three concerns which, according to the petitioners, remain and which may be addressed at a suitable level by the government. We shall outline the concerns which have been presented during the course of the oral submissions by Ms Vrinda Grover, seriatim: F

Firstly, it has been submitted that the framework for vaccination of pregnant women and lactating mothers envisages a voluntary verbal declaration by the person who seeks vaccination, at the time of registration. In this context, it has been submitted that the woman who visits a vaccination centre may not necessarily be aware of the need to make such a declaration and in the event that she is not informed by the personnel at the vaccination centre, the recording of her status either as a pregnant woman or lactating mother may remain to be incorporated in the data set. Hence, it has been submitted that if the Co-WIN portal is suitably modified so as to incorporate a declaration at the time of G H

- A registration, this would facilitate the monitoring of the health of the vaccinated woman or mother, as the case may be.

Secondly, it has been suggested that in order to further support the surveillance measures which have been instituted by the government for monitoring AEFIs, targeted tracking of pregnant women and lactating mothers can be considered so as to bolster the process of monitoring.

Thirdly, it has been emphasized that when adequate data sets become available, the publication of data will enhance the confidence in the process of vaccination.

- C 8. Ms Aishwarya Bhati, learned Additional Solicitor General while responding to the above suggestions submitted that each of the three suggestions has been carefully evaluated by experts within the Union Government. The Additional Solicitor General submits that in the ongoing process where decisions are being continuously evolved, the government has certain concerns over implementing the suggestions at the present stage but, is open to further deliberation with the expert bodies.

- E 9. On the first aspect in particular, it has been submitted that with the process of walk-in-registration, the registration on the Co-WIN portal has become subsidiary. However, it has been submitted that the reason why it was believed that a verbal declaration at the time of vaccination would suffice was to ensure that no person is dissuaded from seeking vaccination by introducing an additional column at the time of registration. On targeted tracking, it has been submitted that a robust mechanism has already been put into place by the Union Government. As regards the publication of data, it has been submitted that at this stage, such a proposal may be premature, but the Union Government is seized of the issue.
- F Moreover, it has been submitted that the publication of raw data may not be appropriate and the data is published after due scrutiny and assessment by experts.

- G 10. This Court is cognizant that the suggestions which have been made on behalf of the petitioners do raise issues of policy. For instance, any mandate for disclosure at the stage of registration has to factor in and balance concerns over the privacy of the person. There may well not be one answer or a single acceptable solution particularly because pregnant women and lactating mothers belong to different social and economic strata. The government has to take a decision bearing mind their welfare, safety and dignity. Likewise, the need to further enhance
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the existing protocols for monitoring AEFIs can be carefully evaluated by the expert groups. The Additional Solicitor General has already stated that data is placed in the public domain after being scrutinized at an expert level within the government. The suggestions made before the Court have emanated from a statutory body. They can be considered with the same sense of cooperation which has pervaded the judicial process during the hearing of the present petition.

11. The three suggestions which have been made by the petitioners would undoubtedly involve an application of domain knowledge by experts in the area. The Court may not be in the best position to take a decision unaided by an expert determination. Hence, we are of the view that having regard to the inclination which has been shown by the Union Government, it would be appropriate if the three suggestions which have been outlined earlier are duly placed before the concerned expert groups as set out in the affidavit of the Union Government so that the suggestions can be deliberated upon at a policy level at an appropriate stage. This Court has constituted a National task Force previously comprised of eminent experts from across the country and the Union Government may engage with them as well to seek suggestions for eliciting its views and suggestions in the area. We appreciate the steps which have been taken by DCPCR in moving these proceedings and equally, the sense of responsibility with which suggestions have been made and discussed both by Ms Vrinda Grover appearing for DCPCR and by Ms Aishwarya Bhati, Additional Solicitor General appearing for the Union Government in the course of these proceedings.

12. Leaving it open to the Union of India to take a considered view after evaluating the suggestions, we dispose of the petition.

13. We further note that Mr Nilesh Ojha, counsel appearing on behalf of the intervenor, has urged before this Court that the intervenor has conducted studies which reflect that COVID-19 vaccines pose a risk to pregnant women or the fetus. On this basis, the intervenor has sought a direction from this Court to stop the administration of vaccination to pregnant women. The issues raised by the intervenor clearly lie in the policy domain and this Court cannot take medical decisions regarding the safety of COVID-19 vaccination among pregnant and lactating persons. The affidavits of the Union of India indicate that NTAGI and NEGVAC have taken great care in recommending vaccination for these groups only after receiving guidance from the World Health Organization

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A and other domain experts. Thus, we do not find it necessary to issue any directions to the Union Government as regards this intervention application.

14. Pending applications, if any, stand disposed of.

Devika Gujral
(Assisted by : Mahendra Yadav, LCRA)

Petition disposed of.