All India Peoples Science Network (AIPSN) Statement

Corbevax for 12-14 year-olds: arbitrary decision-making on Vaccines continues in India

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The Union Health Ministry announced through a press release on March 14, 2022 that vaccinations against Covid-19 for children in the age group of 12 to 14 years would start from March 16, 2022 using the Corbevax vaccine manufactured in India by Biological E. Limited, Hyderabad, with license from BCM Ventures, USA, set up by the vaccine developer Texas Children's Hospital. Corbevax is a protein subunit vaccine where the spike protein of SARS-CoV-2 is directly injected with stabilising chemicals and adjuvants in order to raise antibody levels in the recipient. This is different from Covaxin which uses full inactivated virus or Covishield which uses an adenoviral viral vector to introduce the DNA coding for the spike protein into cells. The vaccine is open-source and offered to manufacturers without patent but with a small fee for BCM. Government is being charged Rs.145 per dose whereas Rs.990 would be charged by private hospitals. While Corbevax undoubtedly expands the basket of vaccines available in India to combat the pandemic, the modalities of its approval, deployment and related decision-making processes raise many disturbing and recurring questions which have plagued India's vaccine policies and the integrity of its regulatory institutions and mechanisms.

The Government statement said the decision to initiate vaccinations for the 12-14 years cohort was taken "after due deliberations with scientific bodies." However, it is known that the National Technical Advisory Group on Immunisation (NTAGI) was not consulted, nor was any recommendation obtained from the National Expert Group on Vaccination Administration for Covid-19 (NEGVAC) either regarding vaccination for this age-group nor for deployment of Corbevax as the sole vaccine for this cohort. It appears that the Government itself does not have confidence in its own expert bodies, which calls into question the very credibility of the decisions being made. Unfortunately, it is precisely such non-transparent decision-making which contributes to vaccine hesitancy, as had happened earlier with Covaxin for similar reasons. It may be noted that, once again, approvals in India for Corbevax for this age group have been granted without peer reviewed or even pre-published data and clinical trial data pertaining to this age group is not available in the public domain, whereas approval for adults were granted based on interim trial results. The difficulties and delays faced by Covaxin in obtaining WHO approval due to inadequate data are well-known, as are the world body's statement that it could not be expected to "cut corners" in well-established approval procedures. The Government risks repetition of this international embarrassment by once again resorting to short-cuts in India's domestic scientific approvals and regulatory systems.

India's vaccine policy has been characterized by poor planning, arbitrary and non-transparent decision-making based on extraneous considerations rather than scientific evidence. The Government is arbitrarily dividing up the market amongst different vaccine manufacturers by approving only specific vaccines for different age-groups, rather than adopting a more equitable public vaccination programme. As a consequence, vaccine production and exports have not kept pace with requirement and demand despite tall claims of being the "vaccine capital of the world," and this has in turn impacted on vaccine deployment strategies and choices.

AIPSN calls upon the government to strictly follow laid-down regulatory procedures and scrutiny by scientific and expert bodies, then formulate and implement evidence-based policies with transparent decision-making rationale. Only this will restore public confidence in India's vaccination policy and obviate vaccine hesitancy.

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