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IN HASTE: THE HINDU EDITORIAL ON VACCINATING CHILDREN AGAINST COVID-19

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The emergency use authorisation (EUA) granted on April 26 to two COVID-19 vaccines — Corbevax for children 5-11 years, and Covaxin for children 6-11 years — is one more instance where the Indian drug regulator has acted in haste. Even if the EUA granted to Covaxin in January 2021 despite no safety and efficacy data of the phase-3 trial is condoned as a desperate measure in ensuring greater vaccine availability, the regulator clearly has no fig leaf to defend the greenlighting of the vaccines for children at this stage. Evidence from across the world after the deadly Delta variant and the extremely transmissive Omicron variant has shown that unlike adults, children in general, and little children in particular, do not suffer from severe disease. The ICMR's fourth seroprevalence survey (June-July 2021) soon after the second wave peaked nationally found that 57.2% of children (6-9 years) and 61.6% of children (10-17 years) were infected by SARS-CoV-2 virus; seroprevalence among adults was 66.7%. Since vaccination of adolescents began only in early January 2022, the antibodies detected in children in mid-2021 were only from infection by the virus. The extremely infectious Omicron variant would have infected an even larger percentage of children. Yet, the number of severe cases and deaths in children 5-11 years has been very low. True, with schools reopening, children could be at greater risk of contracting infection. But with natural infection found to offer protection across age groups, India could have waited for validation of the available evidence on the vaccines for children.

Unlike in January 2021 when approving vaccines for adults as soon as possible was the highest priority, and hence the EUA based on fewer cases and short follow-ups was seen as a necessity, the situation is not the same now, especially in the case of children as young as five. Hence, the regulator's urgency to greenlight vaccines for children under the EUA route is highly questionable. Clinical trial data of Corbevax for children 5-12 years were posted as a preprint, which is yet to be peer-reviewed, on the day approval was granted; trial data of Covaxin for children 2-18 years were posted as a preprint in December 2021. The Health Ministry had already set a precedent last month by clearing Corbevax for children 12-14 years without first seeking the approval of the National Technical Advisory Group on Immunisation (NTAGI), which clears vaccines for the national immunisation programme. With NTAGI clearly against approving vaccines for children, there is every likelihood of the expert body being ignored again. Also, Prime Minister Narendra Modi's message on April 27, a day after the EUA, that every eligible child should be vaccinated at the earliest might prompt the Health Ministry to sidestep the NTAGI once more, thus departing even more from evidence-based policy making.

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