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HPV vaccine gets immunisation nod

The National Technical Advisory Group on Immunization (NTAGI), an advisory body that recommends vaccines for India's Universal Immunization Programme (UIP), has given the green signal to the introduction of the Human papillomavirus (HPV) vaccine in the UIP.

However, the decision of who will make the HPV vaccines will depend on the outcome of a 2012 Supreme Court case. This is reported in the minutes from a December 19, 2017 meeting of the NTAGI, published on the website of the Ministry of Health and Family Welfare (MoHFW) on Wednesday.

A spokesperson from the Ministry also told *The Hindu* that media reports published earlier this month alleging that the Ministry had dropped the vaccine from the UIP after a letter from the Swadeshi Jagaran Manch protested its inclusion, were incorrect.

The Swadeshi Jagaran Manch is an affiliate of the Rashtriya Swayamsewak Sangh which deals with economic issues.

As on today, two HPV vaccines are available in India, developed by Merck Sharp & Dohme (MSD) and GlaxoSmithkline (GSK), while one vaccine developed by an Indian firm is in clinical trials. But a 2012 writ petition in the Supreme Court of India asks for the licences of the MSD and GSK vaccines to be revoked, because they were allegedly approved by the Drug Controller General of India (DCGI) without adequate clinical trials. This is why the inclusion of these vaccines in the UIP will wait till the Supreme Court decides on the case, the Ministry spokesperson said.

HPV vaccines have been at the centre of a controversy in India since 2009, when a clinical trial conducted by the American non-profit PATH, in partnership with the Andhra Pradesh and Gujarat governments, went wrong. Around 24,000 pre-adolescent girls were given MSD and GSK vaccines in the trial, overseen by the Indian Council of Medical Research (ICMR) and DCGI. When eight of these girls died, health activists said PATH and others had violated research-ethics by giving the girls the vaccine without informed consent from their parents.

They also pointed out that trial-researchers had not set up a system to track the vaccine's side-effects. These allegations led to a 2012 writ petition in the Supreme Court by the activists, demanding action against the DCGI, ICMR, PATH, MSD, GSK and the two State governments. The case is still continuing.

India has one of the world's highest burdens of HPV-related cancer. Around 67,000 women die from this disease each year, more than India's maternal mortality burden of 45,000. But opponents of the HPV vaccine say it is unnecessary, because screening for cervical cancer alone can prevent many deaths.

Proponents say that while screening is important, it is difficult to implement this in Indian healthcare settings. The NTAGI meeting minutes acknowledged this difficulty in mass-screening programmes in Tamil Nadu.

Vaccine opponents have also raised the issue of rare side-effects. Since the introduction of HPV vaccines worldwide, Japan and Denmark have reported some cases of autoimmune illnesses in vaccine recipients. But no study, so far, has demonstrated a link between the vaccines and these illnesses.

As a result, the World Health Organization and Global Advisory Committee, among others, have

declared the vaccine safe.

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Astronauts on extended space travel missions would have significant bone and muscle complications.

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