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SC asks Centre to produce files related to grant of cancer drug licences to GSK, Merck Sharpe

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New Delhi, Aug 12: The Supreme Court on Tuesday asked the Centre and Indian Council of Medical Research (ICMR) to produce files relating to grant of licences to pharma majors Merck Sharpe and GlaxoSmithKline for administration of two vaccines on minor girls for prevention of cervical cancer.

The bench was hearing a PIL seeking to quash licensing of two vaccines for cervical cancer treatment on the ground that approval for their use was done without adequate research on safety.

It has been alleged that the Drugs Controller issued licences for the vaccines without adequate research on safety as directed by the parliamentary standing committee on health.

A bench headed by Justice Dipak Misra also asked directed the Centre to place before it the report of the House panel which had criticised the manner in which the vaccines were introduced in India. It also wants to know what action the government has taken subsequent to the report placed before Parliament in August last year.

The two vaccines in question are Gardasil and Cervarix, manufactured by Merck Sharpe and GlaxoSmithKline, respectively

The panel had in April 2010 recommended legal action against US-based Program for Appropriate Technology in Health and accused the NGO of violating ethical standards while promoting the cervical cancer vaccination programme in the country.

"The Union of India is required to assist the court in a proper prospective on the issue," the bench ordered, while asking the competent authority to bring the files. It fixed the matter for a hearing on October 28.

The two drugs in question are Gardasil and Cervarix, manufactured by Merck Sharpe and GlaxoSmithKline, respectively.

While making Gujarat, Andhra Pradesh and Telangana as parties in the matter as some villages in these states were chosen for administering the vaccine on experimental basis, Justice Mishra asked the government to show what procedure was followed by the Drug Controller and ICMR before the drugs were introduced and what were the reasons for choosing these three states.

It also said it will examine whether proper protocol and procedure was followed for the introduction of these vaccines because it was alleged that deaths and various other ailments have occurred due to such administration of vaccines.

Clinical trials.