

Controversial HPV vaccine case lingers on

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The 2012 case pertaining to the clinical trials of human papillomavirus (HPV) vaccines, Gardasil and Cervarix, conducted on estimated 1200 tribal girls in the far off areas of Gujarat, Andhra Pradesh, and Telengana, has been deferred to January 13, 2015 for the hearing.

The ongoing case in the Supreme Court of India was supposed to be heard on October 30, 2014 but has been moved to next date due to unavailability of the government lawyers representing the states. As per a source present in the court, since the representation was not adequate from the respondents side, the SC panel decided to hear the case later.

The petition number 558/2012, filed by Ms Kalpana Mehta, Ms Nalini Bhanot and Ms V. Rukmini Rao against the multinational companies, MSD Pharmaceuticals and Glaxo Smithkline, was earlier heard on August 12, 2014. The court in its order has directed the companies to present their arguments in the next hearing. The court has sought to know what actually caused the deaths of some participants in the clinical trials. It has also asked the respondents to file their reply on whether proper consent was obtained from the girls and/or their families prior to their participation in the experiment.

It is worthwhile to recall that about 5 percent of the participants in the demo trials suffered from auto-immune diseases and other health problems. The petitioners who had requested the court to suspend the licenses for marketing and administration of HPV vaccines, received the shot in arm when the Parliamentary standing committee in 2013, strongly condemned the way these demonstrative trials were done. It had also called for a deep enquiry in the matter.

However, the the Program for Appropriate Technology in Health (PATH) which has been involved in the trials has been refuting the allegations. Similarly, the Merck and GSK too has denied any wrongdoing.

The much publicized case has generated lot of interest in India and abroad and is being closely watched over for its

implications on the industry. Now, all eyes are on the first month of the new year to know what decision SC panel takes on the issue. Given the lack of enough response from the regulatory bodies and the government lawyers in the past, it certainly is not going to be the amusing one for them.