

Pentavalent vaccine unsafe, say experts

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PUNE: Concerned by the deaths following administration of pentavalent vaccine, a group of academicians, professors, teachers of public health and pediatricians from different cities, including Pune, has requested the Union health secretary to withdraw it from the immunization schedule.

The pentavalent vaccine (DPT+Hib+Hep B) was introduced in Kerala and [Tamil Nadu](#) on the recommendation of the [National Technical Advisory Group](#) on Immunization (NTAGI). There were concerns about its safety and, therefore, the NTAGI mandated that it was to be introduced in immunization programme in just two states (Tamil Nadu and Kerala)- to monitor the vaccine's safety.

"Thereafter, according to the minutes of the NTAGI meeting, the data was to be reviewed after one year of the introduction, before extending its use to other states. We are concerned that well before the data from Kerala and Tamil Nadu could be analyzed, it was introduced in Haryana at the end of last year," states the letter sent to Union health secretary on January 15.

In the last three weeks, three more infants died in Kerala, while one died in Haryana this week, after being administered with the vaccine. On the face of it, there seems to be no 'alternative cause' for the deaths, the letter states.

In November, there were three deaths in [Vietnam](#) and this led to the immediate termination of programme being stopped immediately in that country. Similar deaths have occurred in Sri Lanka, Bhutan and Pakistan after the use of the vaccine. When each death is seen in isolation, it is reasonable to consider them as mere coincidences - but that is not acceptable when it happens repeatedly, states the letter.

In Pakistan, it was said to be 'sudden death'. This, unfortunately, is mistaken with the sudden infant death syndrome (diagnosed only in case of unexplained deaths), which it was clearly not, it says.

Bhutan had eight deaths and it was said that the deaths were due to encephalitis, although there was no evidence of infection. It has been noted, subsequently, that after the vaccination was stopped for a year, there were no more such 'encephalitis' deaths.

In Sri Lanka, the expert group probed the deaths following administration of the vaccine and reported that they could not find alternative cause for the deaths other than the use of the vaccine (and so had to conclude that the deaths were probably related to the vaccine). That they wrote in their report that the vaccine was unrelated to the deaths is another story, the letter states.

"It is for us as experts and the Union government to look at all these seemingly isolated instances of deaths in a comprehensive manner to see the underlying pattern and act if needed. Considering that the vaccine is given to a large number of children who are well, it is crucial that they be completely safe," the letter states.

"As doctors, we are aware that most medicines have some side effects, but repeated instances of deaths as side effect from a vaccination programme for a disease that itself can be treated with antibiotics cannot be acceptable," the letter states.

The team of doctors and professors who wrote the letter include senior paediatrician Jacob Pulliyel, [head of paediatrics](#), St Stephen's Hospital, Delhi, and also a member of NTAGI; professor B M Hegde, former vice chancellor, Manipal University; Vikas Bajpai of Centre for Social Medicine and Community Health, [Jawaharlal Nehru](#) University; professor Amitav Banerjee of D Y Patil Medical College, Pune, and paediatrician Arun Gupta, member, prime minister's council on nutritional challenges, among others.