

Deaths of seven girls fuel political clampdown on vaccine work

About 72,000 Indian women die each year of cervical cancer, a disease caused by the human papillomavirus, writes Amy Kazmin in New Delhi.

Many of these deaths are preventable by vaccines already widely used in the US, Australia and Europe, and included in their recommended immunisation protocols.

In 2009, Path, a US-based health charity, launched a project funded by the Bill and Melinda Gates Foundation to study the cost and feasibility of incorporating HPV vaccines, produced by Merck and GlaxoSmithKline, into India's public sector immunisation programme.

However, the programme to vaccinate 14,000 adolescent girls from poor families ran into trouble after seven died soon after their vaccinations.

The ensuing media and political storm – highlighting sensitivities around drug trials in the developing world

– has contributed to the restrictions on such studies, affecting both Indian and global pharmaceutical companies.

The causes of the girls' deaths were never established or conclusively linked to the HPV vaccine.

But serious questions were raised over whether the participants' parents – many of whom were illiterate – had given informed consent, and whether the project adequately tracked any adverse reactions.

In August, an Indian parliamentary committee concluded the Path project was a clinical trial in all but name and that the organisation had used "subterfuge" to avoid the "arduous and

strictly regulated process" of such a trial.

The committee report said many of the girls' consent forms had apparently been signed by school principals and hostel wardens, and expressed scepticism that the girls' parents were fully briefed on the pros and cons.

The committee also found there was no rigorous process to track adverse events, leading to "gross underreporting". It came down hard on Indian

government agencies for alleged dereliction of duty.

"The safety and rights of the children in this

vaccination project were highly compromised and violated," the report said.

It also claimed that Path's "sole aim was to promote the commercial interests of HPV vaccine manufacturers, who would have reaped windfall profits had Path been successful in getting the HPV vaccine included" in India's immunisation protocols.

Path called the parliamentary report an "inaccurate characterisation of this important work" and said it disagreed with its "findings, conclusions and tone".

The organisation said the HPV project was driven by its belief that "poor and low-income girls in India should not be deprived of the right or access to this proven, life-saving and safe vaccine that wealthy and middle-class girls in India and around the world have access to through the private market and other public immunisation programmes".

Melinda Gates funded the Path project with her husband Bill

