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Argentina investigates deaths of vaccinated kids

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BUENOS AIRES, Argentina —

Argentine authorities are exploring a possible link between the deaths of 14 children and an experimental vaccine they were taking in a clinical trial run by GlaxoSmithKline.

Argentina's food and drug administration is investigating whether the deaths are tied to the Synflorix vaccine, said an agency official who spoke on condition of anonymity because he was not authorized to discuss the case.

The drug, designed to fight pneumonia, ear infections and several other pneumococcal diseases, was manufactured by the London-based GlaxoSmithKline PLC, the world's second-largest drug maker.

A U.S. spokeswoman for Glaxo, Sarah Alspach, said the company is not attributing the deaths to the experimental vaccine, which is being tested in three Latin American countries and in other countries around the world.

An independent board monitoring participants' safety recommended that the Latin American trials be temporarily suspended - which they were in late June - but then gave its OK for tests to resume, she added.

"We rely on their safety review," Alspach said. "Safety is our primary concern, always, with the development of any new treatment."

More than 19,000 babies have received at least one dose of Synflorix, which Glaxo plans to test on a total of 24,000 infants, she said. The company is still enrolling participants.

But according to the Argentine official, who works at the country's National Medicine, Food and Medical Technology Administration, the agency "received complaints about irregularities in the recruitment of patients" for the drug trial and on July 31 asked that recruitment be suspended.

Glaxo stopped recruiting the following day, saying it had already gathered the necessary number of participants, the official said.

Ana Maria Marchesse, who heads one of two groups that notified the national food and drug administration, told The Associated Press that she'd witnessed "poor ethical management" of patient recruitment.

"They didn't explain to the parents that this was an experimental vaccine, and a lot of the parents who signed consent forms were illiterate," said Marchesse, a pediatrician who heads the Health Professionals' Labor Association in the northern Argentine province of Santiago del Estero, where she said seven of the 14 children died.

"In some cases, they first gave them the vaccine and then gave them a 13-page consent form to sign that I had to read three times to understand," she added.

Marchesse said her group and a provincial doctors' association reported what they saw to the food and drug administration.

Glaxo's trial includes thousands of babies in Argentina, where Alspach said 12 children died; in Panama, where another two died; and in Chile. The natural infant death rate in those countries from pneumonia is 4 to 5 of every 1,000 live births - more than four times the rate seen in the study, Alspach said.

Pneumonia is the world's top killer among infectious diseases, causing more than 2 million deaths a year in children under five, mostly in developing countries, she said.

The company is testing the vaccine in more than 40 clinical studies around the world, she added. Data from other studies show the vaccine is about as safe and tolerable as competitor Wyeth's blockbuster Prevnar, a vaccine widely used against pneumococcal disease, she said.

Still, the Argentine province of Santiago del Estero is conducting a separate inquiry into the deaths of the seven children there, local Health Minister Franklin Moyano told state news media.

"While legal authorities investigate, we're in an observation phase to see if everything happened as expected, or if there were deviations that caused damage, in this case the death of seven kids," he said.
