

Portuguese pharma firm says best practice followed in French drug trial

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Portuguese pharmaceutical company Bial insisted Friday that it had followed "international best practice" in a French drugs trial that has left one person brain-dead and five others hospitalised.

The company said in a statement it had followed "the applicable legislation" and that it would cooperate with the investigation underway to "determine in a rigorous and exhaustive manner" what happened.

The six victims, all men aged 28 to 49, had repeatedly taken the medication developed by Bial, which is intended to treat pain and [mood disorders](#) such as anxiety.

"Our principal concern, at the moment, is taking care of participants in the trial," Bial said, particularly those who have been hospitalised.

The manufacturer said the product was an "inhibitor of the enzyme FAAH", or fatty acid amide hydrolase, which was being developed with "respect since the start for international best practice, with pre-clinical trials carried out, notably with respect to toxicology".

"This trial was approved by the regulatory authorities and the French ethics committee," the company said.

It added: "108 volunteers in good health participated in the testing of this new molecule without developing any adverse reaction, either moderate or serious."

French Health Minister Marisol Touraine had earlier said 90 people had been given the substance in variable doses.

Based in northern Portugal near the town of Porto, Bial says on its website that it is the country's largest pharmaceutical company, founded in 1924 with a presence in 58 countries.

It has produced treatments for a range of ailments including problems with the nervous system and cardiovascular health, as well as antibiotics and anti-allergens.

The drug test in France has been carried out since the summer by Biotral, a medical research company approved by the [health](#) ministry, on behalf of the Portuguese [company](#).

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