

Diabetes drug may have killed 500 in France: authorities

November 16 2010, by Roland Lloyd Parry

French health authorities sounded an alert Tuesday to patients who took a diabetes drug believed to have killed 500 people over three decades in France before it was banned last year.

Drug safety body Afssaps urged patients who used Mediator, a drug for overweight people with diabetes that was also used as an appetite suppressant, to see their doctors if they had taken it for more than three months.

"Analyses by expert epidemiologists estimate that about 500 deaths could be attributable to benfluorex," Mediator's <u>active ingredient</u>, since its launch in France in 1976, Afssaps said in a statement.

The drug was banned in 2009 after being linked to heart valve damage. Five million patients were treated with medecines containing benfluorex, Afssaps estimated.

The company that sold it, pharmaceuticals firm Servier, rejected the estimate as "theories founded on extrapolation".

It said 2.5 percent of the population had valve trouble and age and diabetes heightened the risk.

"Simply observing a valve problem in a diabetic person does not allow it to be attributed to medicinal treatment which remains a very rare cause," it said in a statement Tuesday.



Afssaps director Jean Marimbert said at a news conference that anyone who had taken Mediator for more than three months should see a doctor.

"It is particularly important if the person took Mediator for three months or more since January 2006," he said.

Irene Frachon, a doctor who this year published a study warning about Mediator, said "Mediator is responsible for a health disaster."

She added that there was no need to panic, however, estimating that one in 2,000 people who took the drug were at risk of serious ill-effects.

"The health authorities were late in withdrawing this drug despite several alerts" about threats it posed to the <u>heart valves</u>, Frachon told AFP on Tuesday.

"I know personally some of the victims and what they have suffered. Some of them have undergone open heart surgery and they have to take lots of medication," Frachon said, estimating 80 percent of those affected were women.

A similar drug also sold by Servier, the appetite-suppressor Isomeride, was withdrawn in 1997 after tests showed it raised the risk of high blood pressure, Afssaps said.

It added that 11 cases of valve damage in patients taking that drug were reported to <u>drug safety</u> authorities in France between 1997 and 2006.

That year saw the first confirmed case of heart valve damage caused by benfluorex, in a woman who had to have a valve replaced after taking Mediator.

Newly appointed Health Minister Xavier Bertrand's office said he was



"concerned by the case" and would give a new conference later on Tuesday.

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