

'Fen-phen' derived drug responsible for thousands of hospitalizations and deaths in France

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A new study published in the journal *Pharmacoepidemiology & Drug Safety* reveals that benfluorex, a fenfluramine derivative drug used in France under the name Mediator, is likely responsible for thousands of hospitalizations and deaths over a 30 year period.

Benfluorex (<u>Mediator</u>) was used in France from 1976 to 2009. Despite its anorexic properties, the <u>drug</u> was not marketed as an appetite suppressant but as an adjunct for the treatment of hyperlipidemia and among overweight patients with type 2 diabetes.

Mahmoud Zureik, MD, PhD, of the French National Institute of Health and Medical Research, and colleagues utilized existing data on benfluorex exposure in France, the risk of actual hospitalization for valvular insufficiency, and mortality from vascular insufficiency as a basis for detailed calculations.

Results show that the use of benfluorex during the period 1976-2009 was very likely responsible for around 3,100 hospitalizations and 1,300 deaths due to valvular insufficiency.

"Despite its similarity with the two appetite suppressants fenfluramine and dexfenfluramine, benfluorex was kept on the market for more than 30 years in France," Zureik notes. "French citizens, practitioners, politicians, and public health actors were seeking to understand why the



French health products safety agency took so long to withdraw this drug which was of very limited efficacy and was dangerous." Because of this scandal, a new law has been passed that substantially modifies the regulatory system for drugs in France.

More information: Zureik and Fournier. Estimate of deaths due to valvular insufficiency attributable to the use of Benfluorex in France. *Pharmacoepidemiology & Drug Safety* 2012: <u>DOI: 10.1002/pds.3213</u>

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