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The Mediator° scandal in France: key dates, key issues

The scandal hit the headlines in **October 2010**, when French daily *Le Figaro* published the results of an official study estimating between 500 and 1000 deaths due to Mediator°, which causes pulmonary adverse effects and heart valve damage. In **June 2010**, a book by pneumologist Irène Frachon had begun to reveal the extent of the damage caused by the drug, despite a lawsuit by Servier that forced the subtitle "*How many deaths*?" to be censored.

Mediator° (*benfluorex*) is an appetite suppressant of the amphetamine family. It went on sale in France in **1976**. Officially marketed for use in diabetes and hypertriglyceridaemia, the drug was also widely prescribed as an appetite suppressant.

In a **1997** review, *Prescrire* pointed to the poor level of evidence and the dubious harm-benefit balance for *benfluorex*. *Prescrire* continued to caution against the use of the drug, including texts published in **2003, 2005, 2006, 2008** and **2009**.

Spain withdrew the marketing authorisation for *benfluorex* in **2003**.

France did not withdraw *benfluorex* from sale until **November 2009**.

The European Commission ruled in **June 2010** that no pharmaceutical products containing *benfluorex* could be sold in the countries of the European Union.

In **2011**, in the wake of the grave regulatory deficiencies revealed by the Mediator° scandal, several official audits and a national medicines conference "Les Assises du Médicament" were set in motion. In **August 2011** a draft law on medicines was published by the health ministry, and the French parliament is expected to act on it by the end of the year.

Prescrire has played an important role in these events, but declines to act in any kind of "official" capacity. Prescrire will maintain its wholly independent evaluation of medicines' harm-benefit balances, and continue to monitor decisions by agencies and political authorities, into **2012** and beyond.

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