

## 'Anti-alcoholism' drug cleared for use in France

## April 25 2012

French health authorities have approved the use of a drug, originally designed to treat nervous spasms, for the treatment of alcoholism on a "case by case" basis.

AFSSAPS, the regulator that authorises drugs, said that while the <u>drug</u> Baclofen had not been definitively shown to be efficient in the treatment of alcoholism, it had shown "clinical benefits in some patients".

It recommended in a statement that Baclofen -- the lab name for a medication branded as Kemstro, Lioresal and Gablofen -- should be considered on a "case by case" basis.

The history of the drug goes back 50 years. It was originally designed for epilepsy before becoming licensed to treat spasticity, but researchers are now interested in using it to ease alcoholic craving.

Interest was sparked in 2008 by a book, "Le Dernier Verre" (The Last Drink), by cardiologist Olivier Ameisen, who self-treated his alcoholism with high doses of Baclofen.

The AFSSAPS statement came after French doctors said last month that the drug had cleared an important early test. The trial entailed enrolling 132 <u>heavy drinkers</u> who were given Baclofen at high doses over a year.

Eighty percent either became abstinent or turned into <u>moderate drinkers</u>. By comparison, two drugs that are commonly used to treat alcoholics,



naltrexon and acamprosate, yield a success rate of 20-25 percent.

Side effects included fatigue, drowsiness, insomnia, dizziness and digestive troubles.

Lead researcher Philippe Jaury of the University of Paris-Descartes said the outcome opened the door to one-year clinical trials, expected to start in May, in which 320 alcoholics would be divided into two groups.

One batch will receive Baclofen, progressively building in dosage until the craving symptoms subside, while the others will receive an inactive look-a-like pill, or placebo.

France's health system is paying 750,000 euros (\$469,000) of the 1.2-million-euro (\$1.45-million) cost of the trial, and an unidentified donor is paying the rest, Jaury told AFP.

The pre-trial study was published in a specialist journal, <u>Alcohol</u> and Alcoholism.

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