

Soviet-era pill from Bulgaria helps smokers quit

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(AP) -- A pill developed in Bulgaria during the Soviet era shows promise for helping millions of smokers cheaply and safely kick the habit, the first big study of it shows.

It could become a new weapon to combat smoking in poor countries, but it is unclear whether it will ever reach the market in the U.S. or Western Europe.

The drug, cytisine, is now used just in Eastern Europe, where smokers usually take the pill for three or four weeks. [Generic versions](#) cost as little as \$5 to \$17 a month, compared with about \$100 for an eight-week supply of [nicotine patches](#) or about \$300 for a 12-week supply of [Pfizer Inc.](#)'s Chantix pill - common treatments in rich countries to help smokers quit.

Cytisine "is so cheap that even in developing countries, if you can afford to smoke, you can afford to stop," said Dr. Robert West of University College London. He led the study, published in Thursday's [New England Journal of Medicine](#).

Cytisine, sold as Tabex by Sopharma AD, a Bulgaria-based company, is derived from laburnum seeds, which contain a natural nicotine substitute. West said it was discovered when much of the Soviet Union's drug research was farmed out to Bulgaria. Russian soldiers referred to it as "fake tobacco," West said.

New research suggests the drug can triple smokers' chances of being off cigarettes after one year compared with those taking a [dummy pill](#).

It has been sold in Eastern Europe for about 40 years but has not been approved in Western Europe or the United States. Extab, a Sopharma subsidiary, has bought worldwide rights to sell it and plans to market it cheaply in developing countries like China and India.

Some experts are unsure it will ever make it to Western markets without larger trials - and without a big pharmaceutical stepping in to pay for them.

"It is possible that extensive bureaucracy and overcautious regulations will prevent its use in the U.S. and Europe," said Peter Hajek, director of the [Tobacco Dependence](#) Research Unit at Queen Mary University Hospital in London. Hajek said if a big drugmaker got involved, the price would probably jump.

About 95 percent of smokers who try to quit without help fail within six months, and more than two-thirds of the world's 1 billion smokers live in [developing countries](#). Smoking is the world's leading cause of preventable death.

The new study was the first major test of cytisine's safety and effectiveness. It involved 740 [smokers](#) in Poland. For 25 days, half were given cytisine and half received dummy pills. Neither they nor their doctors knew which treatment they were getting. After one year, 2.4 percent of those on dummy pills had stopped smoking versus 8.4 percent of the people on cytisine (often pronounced like "citizen").

The study did not compare cytisine to other smoking-cessation treatments, but experts said the results were on par with those of many alternatives. It had a lower success rate than the 15 to 30 percent seen in

studies with Chantix, but that drug carries warnings about possible psychiatric risks.

Nearly 14 percent of people taking cytisine reported stomach problems such as nausea, versus 8 percent of the people on dummy pills. There were two deaths in the group taking cytisine, from lung cancer and cardiac arrest, and three deaths in the placebo group, from lung cancer, stroke and respiratory problems. Dizziness and sleep problems were a little more common among cytisine users.

There have been no signs of any serious side effects in the more than 7 million people who have taken cytisine in the past 40 years, according to records from regulatory agencies in countries where the drug is licensed.

Patients are given the pills to satisfy their nicotine cravings, then are slowly weaned off the drug. They start with six pills a day, cutting down to just two by the end of the treatment.

The study was paid for by Britain's Medical Research Council, while the cytisine and the placebo pills were provided by Sopharma AD. West and one other study author reported having consulted for drugmakers, including several that make kick-the-habit products. West also has a patent pending on a nicotine delivery device.

Cytisine "looks promising, but the jury is still out," said Dr. Michael Fiore, director of the Center for Tobacco Research and Interventions at the University of Wisconsin, Madison, who had no role in the study. Fiore said that more studies are needed to confirm the findings, but that an inexpensive anti-smoking drug would be useful anywhere.

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