S. African company fights move to ban painkiller

November 17 2011, By DONNA BRYSON , Associated Press

(AP) -- A South African pharmaceutical manufacturer is fighting moves toward banning a painkiller that has been removed from the shelves in the U.S. and Europe because of fears it could harm the heart.

South African authorities have moved to join their counterparts in the U.S. and Europe to halt sales of dextropropoxyphene after decades of use, but a major manufacturer in South Africa, Adcock Ingram, insists it's safe.

"We always maintained that the drug is safe, and still maintain the drug is safe," Dr. Abofele Khoele, Adcock Ingram's medical executive, said in an interview Thursday. "We've got studies to prove the drug is safe."

But he acknowledged that dextropropoxyphene, which is found in such Adcock Ingram painkillers Doxyfene and Synap Forte, has raised concerns elsewhere.

Adcock Ingram is appealing an April ruling by South Africa's Medicines Control Council against the drug. This week, the company lost a court bid to allow doctors to keep prescribing dextropropoxyphene products pending a ruling on the appeal.

Health Ministry spokesman Fidel Hadebe told The Associated Press the court ruling "is a major victory for the public. Government has a duty to protect the public from any possible medical harm."

Hadebe could not say when a Health Ministry appeal body would rule on Adcock Ingram's request for a review. Adcock Ingram has requested a quick decision.

Adcock Ingram's Khoele said his company's recipe for dextropropoxyphene products differed from those in the West, including in the way it is absorbed. He also said South Africa was stricter on dosages.

Late last year, shortly after the U.S. Food and Drug Administration asked companies to voluntarily stop selling dextropropoxyphene products, Xanodyne Pharmaceuticals agreed to withdraw Darvon and Darvocet, brand name versions of the drug, from the U.S. market.

The FDA had concluded that the pain medication "can cause serious toxicity to the heart" and "puts patients at risk of potentially serious or even fatal heart rhythm abnormalities."

In 2009, the European Medicines Agency recommended that all marketing authorizations for medicines containing dextropropoxyphene be withdrawn throughout the European Union.

The FDA first considered removing dextropropoxyphene from the market in 1978, but concluded then that its benefits outweighed its risks. Adcock Ingram's Khoele said the FDA's recent reversal, based on new evidence, was surprising.

"I think our regulators should take note of the goings on around the world," Khoele said.

But he said the South African regulator should have sought information from local manufacturers before making a decision.

Khoele said that the company would abide by the decision of the appeal board.