



DRS/MtH/IEA.63

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## Information Exchange System

### Alert No. 63

#### **Fenfluramine and dexfenfluramine - withdrawn : cardiotoxicity (USA)**

The Food and Drug Administration, acting on new evidence about significant adverse effects associated with the anti-obesity agents, fenfluramine (Pondimin®: American Home Products), and dexfenfluramine (Redux®: Wyeth-Ayerst), has asked the manufacturers to voluntarily withdraw both products from the market. Both companies have agreed. The FDA is not requesting the withdrawal of phentermine, the third widely used medication for obesity.

The action is based on new findings from doctors who have evaluated patients taking these two drugs with echocardiograms to test the functioning of heart valves, and which indicate that approximately 30% of patients who were evaluated had abnormal echocardiograms, even though they had no symptoms. This is much higher than the expected percentage of abnormal test results and the FDA considers that fenfluramine and dexfenfluramine present an unacceptable risk at this time to patients who take them.

The FDA recommends that patients using either of these products stop taking them and contact their doctors to discuss their treatment.

These new findings suggest that fenfluramine and dexfenfluramine are the likely cause of heart valve problems of the type that prompted two earlier warnings concerning a combination of fenfluramine and phentermine ("fen-phen") which has been widely used off-label in recent years for the long-term management of obesity. [*See WHO Pharmaceuticals Newsletter Nos. 9&10, September&October 1997*]

In July, researchers at the Mayo Clinic and Mayo Foundation reported 24 cases of rare valvular disease in women who took the "fen-phen" combination therapy. The FDA alerted medical doctors that it had received 9 additional reports of the same type, and requested all health care professionals to report any such cases to the agency's MedWatch programme or to the respective pharmaceutical manufacturers.

Subsequently, the FDA received 66 additional reports of heart valve disease associated mainly with "fen-phen". There were also reports of cases seen in patients taking only fenfluramine or dexfenfluramine. The FDA requested that the manufacturers of fenfluramine and dexfenfluramine stress the potential risk to the heart in the product labelling and patient package inserts. The FDA continues to receive reports of cardiac valvular disease in patients who have taken these drugs.

*Reference: HHS News P97-32 dated 15 September 1997. [<http://www.fda.gov/cder/news/fenphenpr81597.htm>]*

