



DRS/MtH/IEA.76

3 December 1998

Information Exchange System

Alert No. 76

Sildenafil (Viagra®) - revised labelling: serious adverse events

United States of America. The Food and Drug Administration and Pfizer Inc. are advising doctors about new warnings and information in the product labelling for sildenafil (Viagra®) in response to postmarketing reports of serious adverse events.

The FDA continues to believe that sildenafil is safe and effective if used according to the updated labelling and notes that the postmarketing reports involving sildenafil constitute only a small fraction of the more than 6 million prescriptions written for this drug.

The labelling notes that it is not possible at present to determine whether the cardiovascular events are directly related to sildenafil, to sexual activity, to the patient's underlying disease, or to a combination of these factors.

Information has been added to the labelling under the following subheadings:

- **Postmarketing cardiovascular events:** The revised labelling addresses postmarketing reports of heart attacks, sudden cardiac deaths and hypertension.
- **Risk of sexual activity:** Sexual activity in patients with pre-existing cardiovascular disease carries a potential cardiac risk. Therefore, Pfizer advises doctors that treatments for impotence, including sildenafil, generally should not be used in men for whom sexual activity is inadvisable because of their underlying cardiovascular status.
- **Vasodilatory effects:** Physicians should consider whether their patients with heart disease could be affected by transient decreases in blood pressure, especially in combination with sexual activity.
- **Patients who were not studied in clinical trials.** Several groups of patients were not studied in the clinical trials for sildenafil. The new labelling notes that if sildenafil is prescribed for these patients, it should be done with caution. These include patients who:
 - suffered a heart attack, stroke, or life-threatening arrhythmia within the previous six months;
 - had significant hypotension or hypertension;
 - had a history of cardiac failure or coronary artery disease causing unstable angina;
 - had retinitis pigmentosa.
- **Prolonged erections or priapism:** The labelling now includes a warning about the rare occurrence of painful, prolonged erections. This is a serious condition which requires immediate medical attention. The labelling advises patients to seek prompt medical attention if their erection lasts longer than four hours.

[See also Letters to information officers: *Reminder re contraindication: concomitant use of Viagra® and organic nitrates*, 4 June 1998; and *Viagra®: associated with 16 deaths but no change in safety status*, 17 June 1998]

Reference: Talk Paper T98-83, 24 November 1998.

