



June 11, 2008

**Dear Health Care Provider:**

The purpose of this letter is to advise prescribers of Caverject Impulse® Dual Chamber System (alprostadil for injection) that distribution is being held pending approval of more detailed user instructions.

In response to a request from the US Food and Drug Administration (FDA), Pfizer undertook in-vitro device testing and assessment of the Caverject Dual Chamber delivery system. It was concluded from the manufacturing perspective that the design of the device could be improved. It was further concluded that the functional performance of the current device could be enhanced by more detailed user instructions until an improved device is available.

We are currently in the process of developing and testing more detailed user instructions, in consultation with the FDA. We are also reviewing options for enhancing the design of the delivery system.

Please note that we have **not** discontinued the Caverject Impulse® Dual Chamber System and we expect to have them available in early 2009. Please also remember that Caverject® (alprostadil) Sterile Powder vials are still available and continue to be an effective treatment for erectile dysfunction.

As with all medical products, health care professionals are strongly encouraged to report any serious adverse events that are associated with the use of Caverject Impulse® Dual Chamber System either to the Med Watch program of the FDA by phone (1-800-FDA-1008) or to Pfizer Inc, by phone (1-800-438-1985).

*For more information, please contact Pfizer Medical Information at 1-800-438-1985.*

**Important Safety Information**

CAVERJECT IMPULSE is indicated for the treatment of erectile dysfunction due to neurogenic, vasculogenic, psychogenic, or mixed etiology.

The most common side effect of CAVERJECT IMPULSE was penile pain, reported by 37% of patients in clinical studies. Only 3% discontinued CAVERJECT IMPULSE for this reason.

CAVERJECT IMPULSE should not be used in men hypersensitive to alprostadil, men with conditions that may predispose them to priapism, men with anatomical deformities of the penis, men with penile implants, or men for whom sexual activity is not advisable or is contraindicated. Penile fibrosis, including Peyronie's disease, was reported in clinical trials with CAVERJECT IMPULSE.

Patients should be instructed to report any erection lasting 4 hours or longer. Treatment of priapism should not be delayed more than 6 hours.

Each patient should be titrated to the lowest effective dose.