Position on Expanded Access to Investigational Drugs

Background

Patients seeking preapproval access to investigational drugs often suffer from serious or immediately life-threatening diseases or conditions. These patients may be willing to try an experimental drug, via an expanded access program, for which robust clinical information about efficacy and safety is not yet available. The process for requesting expanded access to an investigational drug requires several steps. Typically, the treating physician will make a request of the sponsor developing the drug. If the sponsor agrees to supply the investigational drug, the physician will initiate a request with the appropriate regulatory agency to approve the request. The process varies depending on the country of the request.

Pharmaceutical companies participate voluntarily in these expanded access programs and carefully consider each request. Considerations at Pfizer include: whether the disease or condition is serious or life-threatening; whether all other approved treatment options have been exhausted; if enrollment in a clinical trial is possible; whether there is a scientific rationale to support that the requested experimental drug may provide benefit and that the potential benefits outweigh the potential risks; and if there is sufficient supply to make the investigational drug available to a patient outside the clinical trial setting.

Pfizer's Position

Clinical trials follow strict scientific standards designed to produce reliable data and results. Where possible, use of an investigational drug within a clinical trial is preferable because clinical trials follow protocols designed to monitor and safeguard patient experiences with a drug, and because trials generate data that may lead to the approval of therapies so that they may be available for wider use. At the same time, Pfizer supports efforts to provide expanded access outside a clinical trial to investigational drugs for patients diagnosed with a serious or life-threatening disease or condition, who have exhausted approved treatment options, and who are not eligible for clinical trials.

- Pfizer supports policies that ensure transparency to patients and their physicians about how to make such requests so that every request is considered equitably.
- Pfizer supports efforts to streamlined and standardized request processes to lessen physician and patient burden.

Treating physicians can submit requests on PfizerCares.com for access to Pfizer investigational drugs or unlicensed products on behalf of patients in their care. Patients and others may also use PfizerCares.com to submit questions about expanded access. Requests are reviewed by Pfizer medical experts dedicated to ensuring that requests are handled according to Pfizer policy in a timely manner. Pfizer strives to respond within five business days of receipt of the request and documentation required to evaluate the request. Requests are handled according to regulatory requirements and laws of the country where the request originates.