Pharming Group N.V. Compassionate Use Policy

Pharming Group N.V. (Pharming) is a global biopharmaceutical company dedicated to transforming the lives of patients with rare, debilitating, and life-threatening diseases. Pharming conducts clinical trials to study investigational products in patients where the studies are designed to obtain safety and efficacy data that may be used to support regulatory approval of the product and subsequent wider access for the patients whom it serves.

An expanded access program (EAP), also known as compassionate use, provides some patients who have serious or life-threatening diseases or conditions with access to investigational treatments not approved by regulatory authorities such as the U.S. Food and Drug Administration (FDA).

Pharming understands that physicians and their patients may wish to access our investigational drugs which have not yet been approved. Pharming evaluates requests for compassionate use of investigational products outside of the clinical study setting when individuals have serious or life-threatening conditions and are not able to participate in clinical studies nor have the ability to pursue other treatment options for their condition.

Pharming is committed to supporting individuals with serious or life-threatening illnesses that are medically appropriate for consideration, to participate in the compassionate use program. However, we cannot ensure we will be able to help in every situation.

Decision Criteria for Considering a Compassionate Use Program
Due to the complexity of making decisions of medical appropriateness for compassionate use of investigational products, the following considerations apply to treatment requests (including but not limited to):

- Product requested must be in active clinical development
  - The product requested must be in an active clinical development program where Pharming holds the regulatory filing.
- Local Regulatory Authority authorization
  - The regulatory authorities where the individual seeking compassionate use lives must allow early access to investigational therapies through their applicable regulations.
  - Institutional Review Board (IRB) authorizations as required by local standards.
  - Ethics committee approval as required by local standards.
- Seriousness of condition for the request

- The patient for the request must have a condition that is potentially irreversible and disabling and/or life-threatening.

- Not eligible for a clinical study
  - Participation in a relevant clinical study is not an option due to ineligibility or geographical limitations.
- Investigational product use benefit is anticipated to outweigh possible risks
  - The candidate's clinical status suggests the possible benefits of treatment with investigational products will outweigh anticipated potential risks based on available information.
- No other appropriate treatment options are available
  - All other relevant and appropriate treatment options have been exhausted, intolerance or lack of response to other treatment options, or in the treating physician's opinion the candidate is not suitable for other treatment options.
- Supply of product
  - Supply levels of the investigational product must be sufficient to meet the request and not interfere with current and planned investigational studies.

Laws governing compassionate use at the country level apply and may impact the availability of investigational therapies in specific countries or regions. Pharming reserves the right to restrict the availability of investigational products and will determine potential availability on a country-by-country basis.

How to request Compassionate Use

Requests for compassionate use of Pharming investigational products can only be made by an individual patient's qualified and treating physician.

The patient's physician must:

- Provide adequate information to ensure the patient is medically appropriate.
- Be appropriately licensed and qualified to administer the investigational product and agrees to monitor and manage all aspects of treatment.
- Be willing and capable of following all applicable legal and regulatory requirements for the compassionate use of investigational products.
- Comply with all required reporting requirements including adverse event reporting.

Qualified physicians may submit compassionate use of investigational product requests to **medinfo@pharming.com**

Pharming will review the requests and supporting documents from the submitting physician and may ask for additional information and documentation to ensure the patient is medically appropriate for the program. We aim to respond as quickly as possible once adequate information is collected, to make a determination of appropriateness. A complete response will be available within 5 business days of a complete application.

For general medical information questions outside of the compassionate use program including our ongoing or planned clinical trials please email Pharming Medical Affairs: **medinfo@pharming.com**