# Purpose

SUN PHARMA development resources are focused on conducting clinical studies required by regulatory authorities to fully answer important scientific questions about the potential risks and benefits of our investigational products, and to obtain regulatory approval.

SUN PHARMA is committed to making investigational products available to a patient or patients who have a serious or immediately life-threatening disease or condition who have exhausted other treatment options. A treating physician, who is able to comply with the requirements that are stated in this document, may request information about how to apply for access to SUN PHARMA investigational products by contacting us.

The purpose of this policy is to describe the requirements for Expanded Access to SUN PHARMA investigational products to patients outside of a clinical study.

# Scope

This policy applies to provision of access to a SUN PHARMA investigational product that is not approved for any purpose in the country from which the request is intended to be used. This also includes the time period between regulatory approval of an investigational product and its commercial availability in a country.

# Policy Statements

Any use of a SUN PHARMA investigational product outside a clinical study in a country must be in accordance with local laws and regulations governing such programs, including SUN PHARMA policies and procedures. In general, where permitted by local regulation, the investigational product supplied via Expanded Access may no longer be provided by SUN PHARMA when it becomes available via the local healthcare system. SUN PHARMA may decide not to provide an investigational product under this policy if the Company does not intend to market the product in the country.

A. Review and Approval Criteria

- All requests for Expanded Access will be acknowledged and evaluated promptly in a fair and unbiased manner. SUN PHARMA or its vendors must never promise the availability of or access to investigational product through Expanded Access programs and must refer Expanded Access inquiries to the SUN PHARMA Medical Information Department (med.infoUSA@sunpharma.com or 1-833-SUN-INFO (1-833-7864636)). The decision to provide investigational product is made by the Chief Medical Officer (CMO) or his/her approved designee, who must have the requisite skills and experience to make a clinical decision as anticipated by applicable laws and/or regulations. An approved list of CMO designees shall be maintained by Medical Affairs. Decisions shall be based on bona fide medical criteria, and shall not be intended to provide financial assistance to a patient where drug is commercially available or to induce, influence, or reward usage or prescribing of the investigational product or other SUN PHARMA products. Decisions and corresponding rationale, including assessment against Patient Eligibility Requirements, must be documented by the CMO or his/her approved designee. This documentation shall be maintained by Medical Affairs.

B. Patient Eligibility Criteria

To be eligible for access to an investigational product, patients must meet the following criteria:

- Suffer from a serious or immediately life-threatening disease or condition.
- Have undergone appropriate standard treatments without success and no comparable or satisfactory alternative treatment is available or exists to treat the disease or condition.
- Are ineligible for participation in any ongoing SUN PHARMA clinical study of the investigational product, which includes lack of access due to geographic limitations.
- The patient has a disease for which there is sufficient evidence of a projected benefit from the use of the investigational product and the benefit outweighs the known or anticipated risks.
- There is adequate information to support appropriate dosing for special population patients such as pediatric, elderly, renal or hepatic disease, etc.
- Any other pertinent medical criteria for access to the investigational product, as established by the SUN PHARMA clinically or medically responsible individual.

C. Investigational Product Criteria

In addition to the patient eligibility requirements, the investigational product must meet the following criteria:

- The product is under investigation in one or more clinical studies.
- There is sufficient evidence to expect that the investigational product will have an acceptable safety profile for the intended patient population.
- The provision of the investigational product will not interfere with or compromise the clinical development of the product.

D. Treating Physician Criteria and Responsibilities

The physician(s) attending to the patient(s) who is/are receiving an investigational product through compassionate use access is (are) properly licensed and fully qualified to administer the product. The physician must agree in writing to comply with:

- Any applicable country-specific legal and regulatory requirements related to providing an investigational product under Expanded Access.
- Any SUN PHARMA requirements in terms of medical criteria, safety reporting, drug supply/use and protection of intellectual property. A treating physician may submit questions or requests regarding expanded access to med.infoUSA@sunpharma.com or 1-833-SUN-INFO (1-833-7864636).