

# **Kyowa Kirin, Inc. Policy**

## **Requests for Expanded Access to Unapproved Drugs in the U.S.**

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Kyowa Kirin seeks to fulfill its management philosophy of striving to contribute to the health and wellbeing of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

This Kyowa Kirin Policy on Requests for Expanded Access to Unapproved Drugs describes the principles that the company follows when considering requests by physicians for use of unapproved Kyowa Kirin drugs outside of clinical trials.

### **I. Kyowa Kirin Policy for Evaluating Expanded Access to Unapproved Drugs Outside of Kyowa Kirin Clinical Trials**

In clinical trials, Kyowa Kirin tests investigational drugs that have not yet been approved by the U.S. Food and Drug Administration (FDA) for commercial sale and FDA-approved drugs used in an investigational setting for unapproved uses (these are referred to collectively as unapproved drugs in this policy). We conduct research on unapproved drugs so that we can better understand how they work, obtain evidence that they are safe and effective, and obtain approval from FDA to make these drugs available commercially. Our scientific and ethical obligations to our patients, healthcare professionals and stakeholders are to conduct this clinical research as efficiently and effectively as possible.

At the same time, Kyowa Kirin recognizes that on rare occasions, physicians may identify patients with serious or life-threatening conditions who cannot participate in our clinical trials but who may benefit from one of our unapproved drugs. In such situations, Kyowa Kirin will consider requests from physicians on a case-by-case basis and in a fair and equitable manner, for the supply of unapproved drugs to use with individual patients (excluding emergency use and other exceptions), and larger patient populations, as defined by the FDA.

Kyowa Kirin will evaluate such requests in a scientifically and ethically responsible way according to the principles set forth below and applicable U.S. federal and state regulations for expanded access.

1. Kyowa Kirin will consider provision of an unapproved drug when consistent with applicable Kyowa Kirin policies, U.S. federal and state regulations, and if the physician determines that the expected benefits outweigh any potential risks to the patient.
2. The patient must have a serious or life-threatening disease or condition.
3. There must be no suitable alternative treatments reasonably available for the patient.
4. The request for use of the unapproved drug must not interfere with the initiation, conduct, or completion of the company's clinical development program.
5. Patients must not be eligible, or it must not be feasible for patients, to join our ongoing clinical trials of the unapproved drug.
6. There must be sufficient data available to provide evidence of a potential patient benefit that justifies the potential risks of the treatment use, and those potential risks must not be unreasonable in the context of the disease or condition to be treated.
7. The physician requesting access must (i) be licensed and qualified to prescribe, and if applicable administer, the unapproved drug, (ii) agree to directly supervise treatment, (iii) agree to comply with relevant U.S. federal and state regulations for expanded access (which may include expanded access programs managed by the company or single-patient expanded access via the physician obtaining an IND), and (iv) agree to follow Kyowa Kirin policies applicable to expanded access use in general and any conditions or restrictions set by Kyowa Kirin for the particular unapproved drug and patient.
8. There must be sufficient clinical data to identify an appropriate dose (amount and frequency) of the unapproved drug provided, appropriate formulation and instructions for use by physicians and patients.
9. Kyowa Kirin must have a sufficient supply of unapproved drug and the resources to reasonably accommodate the likely duration of treatment.
10. Kyowa Kirin reserves the right to review continued access to the unapproved drug in light of future changes in drug development conditions (e.g., commercialization, discontinuation of drug investigational programs, etc.).

## **II. Process for Requesting Expanded Access**

Physicians who are interested in treating a patient with a Kyowa Kirin unapproved drug and meet the above stated criteria must do the following:

1. Submit a request to Kyowa Kirin's via email to the Access Mailbox: [access@kyowakirin.com](mailto:access@kyowakirin.com) or via any Kyowa Kirin Medical Science Liaison with whom you have contact. The company will endeavor to acknowledge receipt of the request via email within five (5) business days of submission of the request.
2. Provide additional information as may be requested by Kyowa Kirin such as:
  - Relevant medical patient information
  - A persuasive scientific rationale for the theoretical benefit that the unapproved drug could provide to the patient.
  - A statement no comparable or satisfactory alternative therapy options are available for the patient, including participation in ongoing relevant clinical trials.

Making a request does not guarantee the granting of access to an unapproved drug. Kyowa Kirin will review each request on a case-by-case basis. The decision to grant access is solely Kyowa Kirin's decision. Kyowa Kirin reserves the right to terminate the supply of drug at any time.

## **III. Contact for Further Information and Link to ClinicalTrials.Gov**

Persons with questions about Kyowa Kirin's policy for expanded access or about other issues related to expanded access to unapproved drugs may contact the company at the Access Mailbox: [access@kyowakirin.com](mailto:access@kyowakirin.com).

Further information about Kyowa Kirin's clinical trials in the U.S. is available on the [NIH's ClinicalTrials.gov website](https://www.clinicaltrials.gov).